Escuela de Medicina y Ciencias de la Salud

Del Tecnológico de Monterrey

Programa Doctorado en Ciencias Clínicas

Tesis Doctoral

Biomaterials and Abdominal Wall

José Antonio Díaz Elizondo

Directora de Tesis: Dra. Mirna Alejandra González González

Co-Director de Tesis: Dr. Marco Antonio Rito Palomares

Abril 2019, Monterrey, Nuevo León, México

Tecnológico de Monterrey

Mirna Alejandra González González, Doctorado en Ciencias de Ingeniería con Especialidad en Biotecnología, como Directora y Marco Antonio Rito Palomares, Doctorado en Ingeniería Química con Especialidad en Biotecnología, como Co-Director

CERTIFICAN que la Memoria presentada por José Antonio Díaz Elizondo con el Título: **Biomaterials and Abdominal Wall** reúne los requisitos requeridos para ser presentada y juzgada por la Comisión Sinodal correspondiente para optar al Grado de Doctor.

Mirna A. González González

Dra. Mirna Alejandra González González

Dr. Marco Antonio Rito Palomares

En Monterrey, Nuevo León, a 30 de Abril de 2019

Tecnológico de Monterrey

School of Medicine and Health Sciences

The committee members hereby recommend the dissertation proposal presented
by José Antonio Díaz Elizondo to be accepted
as a partial fulfillment of the requirements for the degree of

Doctor of Philosophy in Clinical Sciences

Dissertation Committee:

Mirna Alejandra González González, PhD
DIRECTOR

Marco Antonio Rito Palomares, PhD
CO-DIRECTOR

Jorge Eugenio Valdez García, MD, PhD
MEMBER

Julieta Rodríguez de Ita, MD, PhD
MEMBER

Alex Elías Zúñiga, PhD
MEMBER

April 30, 2019

DEDICATION

To Laura, Sofía and Rosamary. Thanks for all the patience and support given along this journey and endeavor. I am sure all of us enjoyed, suffered, and learned a lot; not only science but about each other. Thanks!!!

To my parents Carlos and Rosa María, as well as my siblings. The example set throughout these last 51 years kept the eagerness to accomplish what was started.

To God for enlightening the path to follow and always putting good friends and people around me.

ACKNOWLEDGEMENTS

Special thanks go to all who made the earning of this possible. All contributed in a special and particular way. For all of those contributions and support, I thank you.

María Teresa González Garza y Barrón PhD – beacon, mentor, and guide through the initial part of this journey.

Ciro Ángel Rodríguez González PhD – friend and mentor who has always supported my different endeavors.

Eduardo Alejandro Flores Villaba MD, MSc – friend, colleague, associate, mentor, and Devil´s advocate for almost everything including patient care.

Alex Elías Zúñiga PhD – eager, inquisitive, mentor willing to support in every possible way research and entrepreneurial activities related to technology and research.

Montserrat Guraieb Trueba MD – former student, then resident, now colleague and friend; always willing to learn, help, and assist in all projects related to surgical research and patient care.

Julieta Rodríguez de Ita MD, PhD – supporting, cheerful, inspiring, and trustworthy

Mirna González González PhD – instrumental, confident, and reassuring all the time in the last and toughest part

Marco Antonio Rito Palomares PhD – insightful and solution proposer as well as comforter

To my School of Medicine & Healthcare Sciences and its Directors here at Tecnológico de Monterrey. Thanks for giving me the opportunity of this personal achievement and allowing the use of the facilities.

To the School of Engineering & Sciences and its Directors at Tecnológico de Monterrey. Always allowing the use of all facilities at the Main Campus and PITT.

To the Department of Biology and Clinical Laboratory Sciences and the Department of Mechanical Engineering at The University of Texas Rio Grande Valley for the collaboration; particularly Karen Lozano PhD.

To the School of Materials & Engineering at Purdue for the collaboration; particularly Ernesto Marinero PhD.

ABSTRACT

Becoming a surgeon does not only require skills, but also scientific knowledge regarding the different areas in which interaction takes place.

Performing a midline laparotomy incision and the subsequent abdominal wall closure are part of the skills and knowledge that a surgery resident needs to begin mastering at an early stage. All elements that lead to a faulty wound healing process will contribute to an incisional hernia formation.

Understanding and knowing the behavior of suture and abdominal wall reconstruction biomaterials, especially after manipulation, is fundamental for selecting the adequate material for the particular tissue and surgical technique.

Several suture biomaterials were tested and studied to find changes in biomechanical properties. This study was performed after having the biomaterial undergo a cyclic tension test. A tensile strength test and mathematical models were developed and used.

Posteriorly, the study of biomechanical properties of commonly used sutures for abdominal wall fascial closure was made. A swine mode was used to simulate the human abdominal wall. The biomechanical analysis was med in used sutures by general surgery residents with different levels of experience. No statistical difference was found comparing the material or the level of experience. Polydioxanone was identified as the most suitable suture for abdominal wall closure.

Several factors have been identified related to the difficulties of surgical skill acquisition. Among them economical and patient safety lead the list. Simulation has become a major element in the active learning process and skill development area. The advantages foreseen by including simulation in a surgical training program are dependent on the validation as a learning instrument of the simulator been used. A high-fidelity simulator validation study was performed confirming that the available learning tool at our Institution complies with construction, programming and measuring capabilities of a valid simulator.

Conclusions and perspectives regarding mesh used in abdominal wall reconstruction are presented. Sutures biomaterials and skill development by general surgery specialists are also included.

RESUMEN

La formación de especialistas en cirugía general demanda que no solo sean operadores; requiere que el personal en entrenamiento tenga un conocimiento científico, y lo aplique, en las diferentes áreas que le generan impacto en su desempeño.

Realizar incisiones de la línea media y la consecuente sutura, al tiempo de una laparotomía, forma parte de las habilidades y destrezas que debe dominar desde temprano un cirujano general en formación. Todos aquellos factores que conducen a una cicatrización inadecuada de la herida tendrán como consecuencia la aparición de una hernia incisional.

Estudiar y conocer el comportamiento de los biomateriales de sutura utilizados en el cierre de la pared abdominal, particularmente posterior a su manipulación, es fundamental para la adecuada selección del biomaterial a utilizar; así mismo, es importante elegir la técnica de sutura más apropiada para cada tipo de tejido.

Se realizó un estudio para determinar los cambios biomecánicos que sufren diversos materiales de sutura, posterior a ser sometidos a una prueba de tensión cíclica. Se llevaron a cabo mediciones y modelos matemáticos que permitieron predecir las modificaciones en las propiedades de los biomateriales utilizados, incluyendo la fuerza tensil.

Posteriormente, surge la inquietud de estudiar los cambios en las características biomecánicas de las suturas más comúnmente utilizados para el cierre de fascia de la pared abdominal. Se llevó a cabo un estudio en el que se simuló en modelos porcinos el cierre de la pared abdominal. Se realizó el análisis biomecánico de las suturas utilizadas de acuerdo con el grado de experiencia de los residentes de Cirugía General que participaron en el estudio; obteniendo resultados no estadísticamente significativos, posterior al análisis comparativo de acuerdo con el tipo de biomaterial y el grado de experiencia. Sin embargo, se observó que si existen cambios en las propiedades de los biomateriales utilizados cuando se comparan con los controles. Así mismo, se identificó un material que, por su comportamiento, probablemente sea el mejor para el cierre de la fascia de la pared abdominal.

Se han propuesto diversos factores que dificultan la adquisición de habilidades en cirugía. Dentro de los principales, se encuentran los económicos y de seguridad para los pacientes; dejando un lugar importante a la simulación para lograr la adquisición de las destrezas y habilidades necesarias. Esta ventaja de los simuladores es dependiente de que el equipo a utilizar cuente con una validación como instrumento didáctico. Se realizó la validación de un simulador de alta fidelidad disponible en la Institución; comprobando que es un instrumento didáctico.

Por último, se presentan las conclusiones y perspectivas a futuro relacionadas a las mallas para la reparación de hernias de la pared abdominal. Lo mismo sucede para los biomateriales de sutura y la adquisición de habilidades por especialistas en Cirugía General.

TABLE OF CONTENTS Page

LIST OF FIGURES

LIST OF TABLES

I. INTRODUCTION

I.1. INTRODUCTION

The protrusion of a tissue or an organ through a “hole” or defect and surroundings, is known as a hernia. Usually this is referred to the described situation compromising the abdominal wall, especially at the inguinal area. These sites most commonly include the inguinal, femoral, and umbilical areas, linea alba, lower portion of the semilunar line, and sites of prior incisions. Primary hernias are classified according to the site in where they arise (Figure 1).

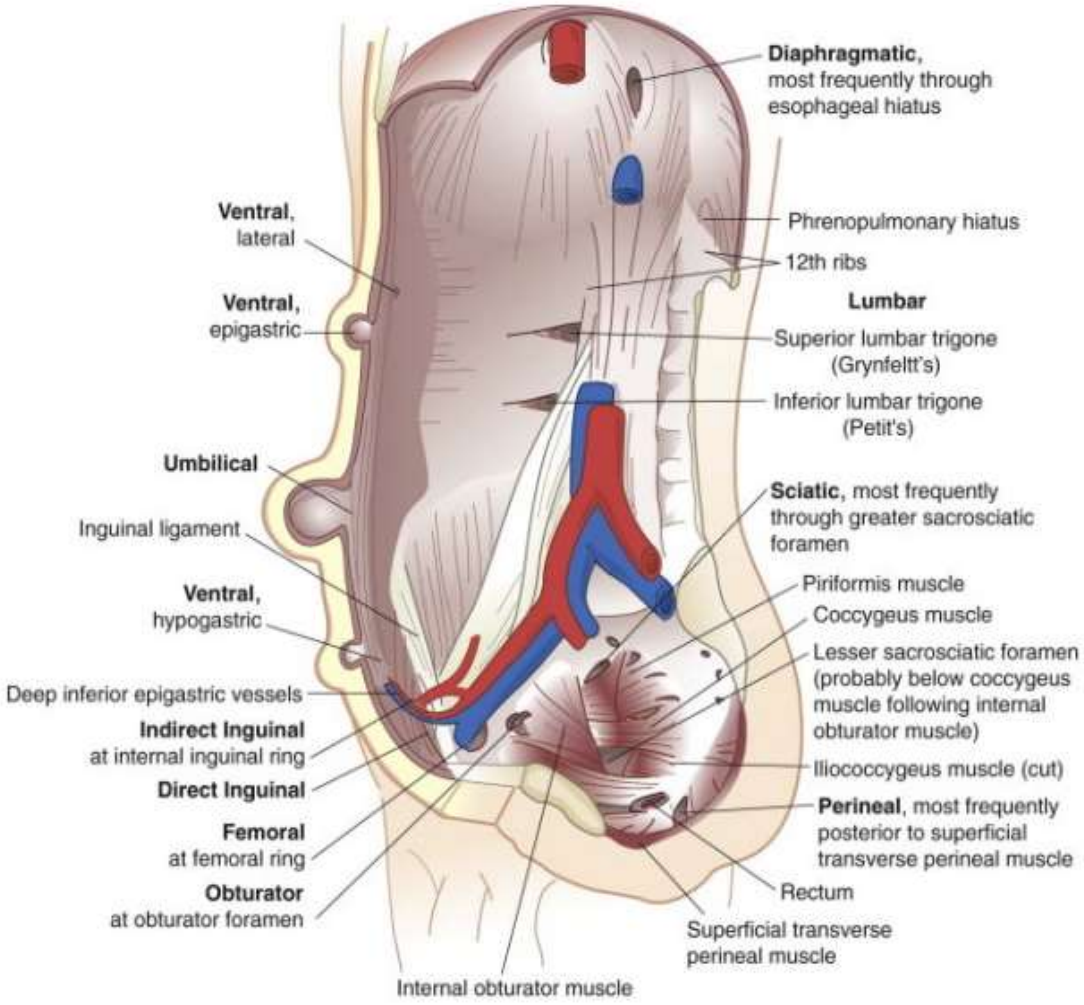


Figure 1. Types of abdominal wall hernias.
(From Dorland's illustrated medical dictionary, ed 31, Philadelphia, 2007, WB Saunders, Plate 21.)

The innermost musculoaponeurotic layer has the orifice of the hernia, while the sac has peritoneal lining and protrudes from the orifice. A large variability exists in the relationship between the hernia defect and the hernia sac.

In the United States of America, abdominal wall hernias were associated with 4.7 million ambulatory care visits in 2004. Inguinal hernia repair accounted for 600,000 surgical procedures in 2004. Abdominal wall hernias represented 372,000 hospitalizations (more than a 24-hour period hospital stay) in 2004. They also generated more than 3.7 million prescriptions in 2004 [1-4]. More than 1600 deaths were related to abdominal wall hernias in 2007 [4, 5].

In the 2015 census in Mexico, the overall reported hospital hernia-related discharge diagnosis can be appreciated in Table 1. Patients treated for complaints related to Inguinal hernias were the most common; probably, the other hernia types, including incisional hernias, were either misclassified or underreported.

Table 1. *Hospital Discharge Registry 2015*

ICD-10	Hernia Type	Year 2015
K40 – K40.9	Inguinal	294962
K41 – K41.9	Femoral	12009
K42 – K42.9	Umbilical	141957
K43 – K43.9	Ventral	47387
K44 – K44.9	Diaphragmatic	9572
K45 – K45.9	Other abdominal hernias	2135
K46 – K46.9	Other non-specified	13463
	Total	**521485**

http://www.dgis.salud.gob.mx/contenidos/basesdedatos/da_egresoshosp_gobmx.html

Midline incision for a laparotomy is the most commonly performed surgical incision, as it provides adequate exposure. It is simple and quick to perform and presents with low risk of bleeding. The main challenge of performing this type of surgical incision is the correct identification of surgical technique and suture material to perform fascial closure [6].

In an incisional hernia, a prior abdominal incision has been made and sutured. Usually, a Surgical Site Infection (SSI) or a seroma will be involved in incisional hernia development. The healing process is compromised and eventually, the strength of the abdominal wall diminished, and a hernia will develop.

Adequate closure and wound edges stabilization by sutures, are critical events that can influence the success in any surgical procedure. However, the presence of foreign materials in the surgical wound, enhances significantly the susceptibility of the host tissue to infection [7, 8]. Therefore, the final consequence of placing a suture can be postoperative infection resulting in wound healing compromise [9].

Incisional hernia continuous to be the most common long-term complication after a midline laparotomy. The incidence varies between 10 and 13% of all laparotomies and 3 and 8% of laparoscopy port incisions. Its incidence increases up to 23 to 40% when SSI is present during the healing process. Usually, incisional hernias develop during the first 3 years after the surgical intervention, even though 50% are clinically evident during the first year after surgery. Mortality rate of 0.24% has been reported when an incisional hernia develops [10].

Complications related with incisional hernia occurrence are: pain, diminished quality of life and other complications that can put life at risk, including incarceration (6 – 15%) or bowel strangulation (2%) [11].

Wound failure risk factors can be classified as patient or surgeon related. Diabetes mellitus, vascular disease, and smoking; cause a decrease in blood supply to the wound, hence, are factors that predispose the development of incisional

hernias [12]. Male sex, advanced age, emergency operation, past medical history (e.g. prior abdominal surgery), comorbidities (e.g. connective tissue disorders), and health related habits such as smoking or overweight, are included among the patient related factors and most of the time cannot be standardized or modified. Meanwhile surgeon related factors can be modified or standardized with relative ease. These include: suturing technique, suture material selection, and surgeon expertise; therefore, providing an opportunity to decrease the risk of surgical site occurrences [6, 11].

As it would be expected, after a surgical incision is made, tissue requires approximation. The main function of suture materials is surgical wound closure. Suture failure after a surgical procedure, entails serious complications with the subsequent increase on surgical morbidity and mortality [13].

The word “suture” describes any type of filamentous biomaterial used to ligate a blood vessel or a conduit, as well as the materials used for tissue approximation [14, 15]. A suture acts by creating a loop and the fixation of a safety perimeter along its geometry with the help of a surgical knot. This loop can approximate adjacent structures through suture transfixion within the loop *Suture security* is the ability of the knot and the material to hold tissue approximation along the healing process without sliding of the knot or rupture of the suture [16].

A surgical suture consists of a fiber or fibrous structure with a metallic needle attached to one end. They can be classified as: 1) absorbable or non-absorbable, 2) monofilament or braided (multifilament), and 3) natural or biosynthetic polymers (Table 2). The main property requirements of suture materials include mechanical, physical, handling, biocompatibility and antimicrobial nature. Suture material selection is of great impact in wound healing process [15]. In the modern age, technical advances have led to a unique position where we can choose specific suture materials for each type of tissue or situation [14].

Table 2. *Suture Material Classification*

Suture Material Classification	
Natural Absorbable • **Catgut (simple // chromic)** • **Collagen (simple // chromic)**	**Natural Non-Absorbable** • Silk • Linen • Cotton
Syntethic Absorbable • **Polyglecaprone 25 (Monocryl)** • **Polydioxanone (PDS)** • **Polyglycolic Acid (Dexon)** • **Polyglactin 910 (Vicryl)**	**Syntethic Non-Absorbable** • Polyamide • Stainless Steel • Polipropilene • Polyester (mono or multifilament)

The ideal suture characteristics probably should include:

1. Must not present any allergic, carcinogenic, capillary or electrostatic reaction.
2. Should be easy to sterilize.
3. Must not produce any magnetic field around it, like a wire cable.
4. Should be easy to handle.
5. Ideally should cause the least possible tissue reaction during the healing process and after fulfilling its purpose.
6. Must not favor bacterial growth around it.
7. Should hold tissue in a secure fashion throughout the wound healing process.
8. Must retain adequate tensile strength according to its transverse diameter.

None of the suture materials available today possess every one of the ideal suture characteristics. It is the surgeon´s job to calculate and measure the advantages and disadvantages of every available suture material and to choose the better fit for the surgical procedure [14, 17].

It is extremely important that the surgical strain does not break during its use; once the suture line is created and the knot is tied, suture tensile strength is of less importance. However, the suture has to have enough force to keep the tissue together along the healing process [18].

Due to the diverse amount of tissues, surgeons require suture materials with different and specific physical and mechanical properties in order to achieve better outcomes [19]. Surgeons have multiple ways to assess the biomechanical properties of suture materials [20]. The *mechanical security* of a suture material is defined as its ability of function without presenting significant variation on its performance [16].

Surgical sutures possess multiple biomechanical characteristics. Some of them are:

- *Tensile force:* amount of weight required to break the suture material, divided by the transverse diameter of the suture. The transverse area of the suture is measure by the size of the braids.
- *Smoothness:* depend on the molecular characteristics of the suture or due to a specific treatment on its surface; which helps to reduce trauma to the tissue while the suture goes thru the tissue. Its relationship with the force of the knot is expressed as *friction coefficient.*
- *Memory and elasticity:* both related; the first one, is defined as the capacity of the suture to return to its original shape after manipulation. The latter is defined as the property of the suture to lengthen when the tissue is inflamed and after a while return to its original length when tensile force disappears.
- *Inert and biocompatible:* this means that the suture does not react chemically with the environment and lacks pyrogenic and antigenic properties and possibly is capable of counteract bacterial colonization [21].

In material science, the mechanical fatigue, is a term used to refer to the failure of a material that happens in structures that are put under fluctuant and recurrent stress [22].

The work to break of a suture material is defined as the amount of energy that is required to break it. It is represented by the area under the tension-deformity curve. It measures the capacity of a material to resist sudden impacts of a determined amount of energy. The material will break if the amount of sudden energy applied exceeds the work to rupture [19].

When a suture material is stretched and then released with a new length, the tension drops in a gradual fashion; this phenomenon is known as stress – relaxation. Similarly, when equal forces are repeatedly applied to the material, this will immediately increase its length and will continue to elongate until a point of equilibrium is reached. This phenomenon is known as approximation. Part of this elongation, irreversible elongation, persists even when the stimulus is withdrawn [23].

Klink, et al., identified three phases in the process of suture relaxation. The initial phase where rapid loss of tension lasts only a minute and it can be secondary to the damage due to the cut of the tissue. The percentage of the tension lost is intimately related with the content of collagen in the tissue. The second phase, is characterized by the slow decrease in suture tension, reflecting a plastic deformation specific for the tissue. Phase three, is characterized by a plateau, which represents structural stability left in the tissue. The ratio of the residual tension and the initial tension during the first phase is strongly related with the content of collagen in the tissue [13].

The final solution for the selection of suture materials with the appropriate mechanical characteristics for the tissue where it’s going to be used, must be choosing the suture which tension-deformation curve is equivalent, or the closest one, to the tension-deformation curve of the tissue that will be sutured. As previously mentioned, other properties such as the reaction of the tissue to the suture material,

the condition and characteristics of the wound, knot security, the degree of suture absorption, and the biomechanical properties of the material, must been taken into consideration for the final selection of the material that will be used [19].

Hernia repair is one of the most common operations performed by general surgeons. Despite the frequency of this procedure, no surgeon has ideal results. One of the most important aspects for an adequate hernia repair is to have a tension free repair. To achieve such goal, the use of a mesh is crucial [24-26]. Mesh is being used to replace or reinforce the abdominal wall. To understand which properties are desirable in suture and mesh, it is important to understand some of the characteristics of the tissue the suture is holding and the mesh is replacing or reinforcing [27-29].

Mathematical models have been developed to determine the different strengths and forces of the abdominal. Some groups have also determined elasticity. Accordingly, the force of the anterior abdominal wall has been calculated in 16 N/cm. The average male abdominal wall elasticity at 16 N/cm was 23 (±7%) in the vertical axis and 15 (±5%) in the horizontal axis. The average elasticity of the female anterior abdominal wall at 16 N/cm was 32 (±7%) in the vertical axis and 17 (±5%) in the horizontal axis [27, 28]. Intra-abdominal pressure has been measured in different activities. Documentation up to 252 mm Hg occurs while lifting, coughing, or jumping. Correlation to forces of 27 N/cm has been made [29].

Basic principles in hernia repair include hernia sac reduction and removal when possible and tissue reinforcement and/or replacement. The latter is achieved by incorporating a mesh serving as a scaffold for tissue ingrowth and fibrosis.

Biocompatibility degree of host-tissue response is one of the most important issues regarding success of an implant. Grafts suffer incorporation (neovascularization and collagen remodeling throughout the implant), encapsulation (fibrotic material being deposited at the edges and around the implant), and degradation/reabsorption not leaving a trace or evidence of the mesh or implant [30].

Once aware of the arising problems due to initial mesh placement (1905 – 1955) in hernia repair, a next generation of mesh products ("second generation mesh") began to develop. These second-generation products have a barrier. The barrier is aimed to prevent adhesion formation, hence avoiding complications related to mesh use. Barriers are made of collagen, methylcellulose, omega-fatty acids, or some have a combination of materials or a dual surface (polypropylene in the parietal side and expanded polytetrafluoroethylene in the visceral side). The principle is to have less inflammation in the visceral side and an adequate tissue in growth in the parietal side of the mesh. The barrier is a retardant and helps in trying to avoid different structures to adhere to the implanted mesh.

Use of synthetic mesh products is thought to be contraindicated in contaminated or infected operative fields. An infection resistant mesh implant, which also supports repairs in contaminated fields, is needed. Ideally a biological mesh that resists infection and reinforces at the same time of a hernia repair, would probably be the best option in all hernia repairs [5, 31-34].

Third generations of mesh products have also appeared. This third generation of products is referred as biological meshes. These are being used in contaminated operative fields. Experience has been gained but yet to be compared to the outcome of a first- or second-generation mesh [35-41]. Performance and comparison among the three generations is important.

Prosthetic material in excess can be associated with a higher rate of complications. Some of these complications might include adhesion formation, intense scarring and inflammation, less mesh flexibility, decreased or loss of abdominal wall compliance, increased mesh contraction, hence hernia recurrence. Chronic inflammation may lead to increased pain and mesh degradation through oxidation changing the material´s properties [42-46].

The same principles behind intestinal adhesions (inflammation, foreign body reaction, infection, host rejection to foreign material), are some of the same issues associated with problems seen with the use of mesh in hernia repair [47-52].

Sensations of the implanted mesh, movement limitation, pain and/or neuropraxia are some of the other common issues arising concern while using synthetic or biological mesh for reinforcement or replacement.

Surgical experience consists in surgical skills as well as in an adequate judgement clinical/surgical [53]. Ericsson has contributed to elucidate surgical skills acquisition. The performance of an expert represents the maximum level of an ability acquisition and resulting in a gradual improvement in performance thru a wide experience on a determined area. In accordance to Ericsson, most of the professionals manage to achieve a stable level in performance in certain skill and keep this status for the rest of their careers. In surgery, experts have been described as experienced surgeons with consistently better outcomes than those not considered experts. Case volume by itself is not the only element that dictates the level of surgical skills among surgeons, since variations in performance have been proven among surgeons with high case volume of patients. Intentional practice is a critical process in the development of an expert. Ericsson points out that intentional practice hours are a heavier factor when compared only with surgical time [54, 55].

Surgical expertise and experience, along with scientific knowledge regarding suture and mesh biomaterial properties are fundamental aspects related to abdominal wall hernia prevention and repair. The aim of this work is to approache some of these issues and to:

1) Analyze the existent commercial surgical meshes, their properties, manufacturing procedures, and observed biological responses and the requirements for an ideal surgical mesh and potential manufacturing procedures.
2) Understand the stress-softening and residual strain effects in suture materials such as polyglycolic acid, polydioxanone, nylon, and polypropylene commonly used in surgical procedures when subjected to loading and unloading cycles by developing a phenomenological non-

monotonous stress-softening hyperelastic material model that depends on the amount of strain and permanent set effects.

3) Validate of a minimally invasive surgery (Surgical SIM® - METI, Sarasota, Fl) for skill acquisition.
4) Determine the impact of surgical trainee experience level on changes in biomechanical properties of different suture materials used for abdominal wall fascial closure in a porcine model.

In the upcoming chapters, research papers approaching these particular issues are presented. The structure of the upcoming chapters is as follows:

Chapter 2: ***Past, Present, and Future of Surgical Meshes: A Review*** (Published 2017)

Chapter 3: ***Stress-Softening and Residual Strain Effects in Suture Materials*** (Published 2013)

Chapter 4: ***Evaluation of a Surgery Simulator While Being Used by Residents with Different Levels of Experience*** (Published 2012)

Chapter 5: ***Effect of Surgical Expertise Level on Biomechanical Properties of Commonly Used Suture Materials After Abdominal Wall Fascial Closure*** (Submitted 2019)

Chapter 6: ***Conclusions and Perspectives***

Appendix 1: ***Other Published Articles and Patents***

Appendix 2: ***Conference and Meeting Participations***

I.2 REFERENCES

1. Everhart JE, Ruhl CE. Burden of digestive diseases in the United States part I: overall and upper gastrointestinal diseases. Gastroenterology. 2009;136(2):376-86. doi: 10.1053/j.gastro.2008.12.015. PubMed PMID: 19124023.

2. Everhart JE, Ruhl CE. Burden of digestive diseases in the United States part II: lower gastrointestinal diseases. Gastroenterology. 2009;136(3):741-54. doi: 10.1053/j.gastro.2009.01.015. PubMed PMID: 19166855.

3. Everhart JE, Ruhl CE. Burden of digestive diseases in the United States Part III: Liver, biliary tract, and pancreas. Gastroenterology. 2009;136(4):1134-44. doi: 10.1053/j.gastro.2009.02.038. PubMed PMID: 19245868.

4. [cited 2013 October 02, 2013]. Available from: http://digestive.niddk.nih.gov/statistics/statistics.aspx#2.

5. Sandor M, Xu H, Connor J, Lombardi J, Harper JR, Silverman RP, et al. Host response to implanted porcine-derived biologic materials in a primate model of abdominal wall repair. Tissue Eng Part A. 2008;14(12):2021-31. doi: 10.1089/ten.tea.2007.0317. PubMed PMID: 18657025.

6. H. Knaebel MK, S. Sauerland, M. Diener, M. Buchler, C. Seiler, and the INSECT Study Group of the Study Centre of the German Surgical Society. Interrupted or continuous slowly absorbable sutures - Design of a multi-centre randomised trial to evaluate abdominal closure techniques INSECT - Trial [ISRCTN24023541]. BMC Surgery. 2005;5(3).

7. B. Blomstedt BO, A. Bergstrand. Suture material and bacterial transport. An experimental study. Acta Chirurgica Scandinavica. 1977;143:71 - 3.

8. B. Osterberg BB. Effect of suture materials on bacterial survival in infected wounds. An experimental study. Acta Chirurgica Scandinavica. 1979;145:431 - 4.

9. K.N. Leknes KAS, O.E. Boe, U.M.E. Wikesjo. Tissue reactions to sutures in the presence and absence of anti-infective therapy. Journal of Clinical Periodontology. 2005;32:130-8.

10. Guías de Práctica Clínica para Hernias de la Pared Abdominal [Internet]. AMH. 2009.

11. C. Seiler TB, M. Diener, A. Papyan, H. Golcher, C. Seidlemayer, A. Franck, M. Kieser, M. Buchler, H. Knaebel. Interrupted or Continuous Slowly Absorbable Sutures For Closure of Primary Elective Midline Abdominal Incisions. A

Multicenter Randomized Trial (INSECT: ISRCTN24023541). Annals of Surgery. 2009;249(4):576-82.

12. Hesselink VJ, Luijendijk RW, de Wilt JH, Heide R, Jeekel J. An evaluation of risk factors in incisional hernia recurrence. Surg Gynecol Obstet. 1993;176(3):228-34. PubMed PMID: 8438193.

13. C. D. Klink MB, H. P. Alizai, A. Lambertz, K. T. Vontrotha, E. Junker, et al. Tension of knotted surgical sutures shows tissue specific rapid loss in a rodent model. BMC Surgery. 2011;11(36).

14. S. Jain DS. Basic Surgical Skills and Techniques. Tunbridge Wells, U.K.: Anshan Ltd; 2009. 108 p.

15. S. Saxena AR, A. Kapil, G. Pavon-Djavid, D. Letourneur, B. Gupta, A. Meddahi-Pellé. Development of a New Polypropylene-Based Suture: Plasma Grafting, Surface Treatment, Characterization, and Biocompatibility Studies. Macromolecular Bioscience. 2011;11:373-82.

16. J. Thacker GR, J. Moore, J. Kauzlarich, L. Kurtz, M. Edgerton, R. Edlich. Mechanical Performance of Surgical Sutures. The American Journal of Surgery. 1975;130:374-80.

17. J. C. Kim YKL, B. S. Lim, S. H. Rhee, H. C. Yang. Comparison of tensile and knot security properties of surgical sutures. Journal of Materials Science. 2007;18:2363 - 9.

18. S. Freudenberg SR, M. Kaess, C. Weiss, A. Dorn-Beinecke, S. Post. Biodegradation of Absorbable Sutures in Body Fluids and pH Buffers. European Surgical Research. 2004;36:376-85.

19. Chu CC. Mechanical Properties of Suture Materials. Annals of Surgery. 1981;193(3).

20. D. Greenwald SS, P. Albear, L. Gottlieb. Mechanical Comparison of 10 Suture Materials before and after in Vivo Incubation. Journal of Surgical Research. 1994;56:372 - 7.

21. Farid Saleh BP, Danielle Lodi, Khalid Al-Sebeih. An innovative method to evaluate the suture compliance in sealing the surgical wound lips. International Journal of Medical Sciences 2008;5(6):354-60.

22. C. Wangsgard DC, L. Griffin. Fatigue testing of three peristernal median sternotomy closure techniques. Journal of Cardiothoracic Surgery. 2008;3(52).

23. Holmlund DE. Physical Properties of Surgical Suture Materials: Stress - Strain Relationship, Stress - Relaxation and Irreversible Elongation. Annals of Surgery.184(2).

24. USHER FC, OCHSNER J, TUTTLE LL. Use of marlex mesh in the repair of incisional hernias. Am Surg. 1958;24(12):969-74. PubMed PMID: 13606360.

25. Burger JW, Luijendijk RW, Hop WC, Halm JA, Verdaasdonk EG, Jeekel J. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg. 2004;240(4):578-83; discussion 83-5. PubMed PMID: 15383785; PubMed Central PMCID: PMCPMC1356459.

26. Luijendijk RW, Hop WC, van den Tol MP, de Lange DC, Braaksma MM, IJzermans JN, et al. A comparison of suture repair with mesh repair for incisional hernia. N Engl J Med. 2000;343(6):392-8. doi: 10.1056/NEJM200008103430603. PubMed PMID: 10933738.

27. Klinge U, Klosterhalfen B, Conze J, Limberg W, Obolenski B, Ottinger AP, et al. Modified mesh for hernia repair that is adapted to the physiology of the abdominal wall. Eur J Surg. 1998;164(12):951-60. doi: 10.1080/11024159875000513 8. PubMed PMID: 10029391.

28. Junge K, Klinge U, Prescher A, Giboni P, Niewiera M, Schumpelick V. Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants. Hernia. 2001;5(3):113-8. PubMed PMID: 11759794.

29. Cobb WS, Burns JM, Kercher KW, Matthews BD, James Norton H, Todd Heniford B. Normal intraabdominal pressure in healthy adults. J Surg Res. 2005;129(2):231-5. doi: 10.1016/j.jss.2005.06.015. PubMed PMID: 16140336.

30. Novitsky YW. Biology of biological meshes used in hernia repair. Surg Clin North Am. 2013;93(5):1211-5. doi: 10.1016/j.suc.2013.06.014. PubMed PMID: 24035083.

31. Jansen PL, Mertens Pr P, Klinge U, Schumpelick V. The biology of hernia formation. Surgery. 2004;136(1):1-4. doi: 10.1016/j.surg.2004.01.004. PubMed PMID: 15232531.

32. Jin J, Rosen MJ, Blatnik J, McGee MF, Williams CP, Marks J, et al. Use of acellular dermal matrix for complicated ventral hernia repair: does technique affect outcomes? J Am Coll Surg. 2007;205(5):654-60. doi: 10.1016/j.jamcollsurg.2007.06.012. PubMed PMID: 17964441.

33. Marreco PR, da Luz Moreira P, Genari SC, Moraes AM. Effects of different sterilization methods on the morphology, mechanical properties, and cytotoxicity of chitosan membranes used as wound dressings. J Biomed Mater Res B Appl

Biomater. 2004;71(2):268-77. doi: 10.1002/jbm.b.30081. PubMed PMID: 15455369.

34. Rueter A, Schleicher JB. Elimination of toxicity from polyvinyl trays after sterilization with ethylene oxide. Appl Microbiol. 1969;18(6):1057-9. PubMed PMID: 5392607; PubMed Central PMCID: PMCPMC378192.

35. Franklin ME, Gonzalez JJ, Glass JL. Use of porcine small intestinal submucosa as a prosthetic device for laparoscopic repair of hernias in contaminated fields: 2-year follow-up. Hernia. 2004;8(3):186-9. doi: 10.1007/s10029-004-0208-7. PubMed PMID: 14991410.

36. Franklin ME, Gonzalez JJ, Michaelson RP, Glass JL, Chock DA. Preliminary experience with new bioactive prosthetic material for repair of hernias in infected fields. Hernia. 2002;6(4):171-4. doi: 10.1007/s10029-002-0078-9. PubMed PMID: 12424595.

37. Helton WS, Fisichella PM, Berger R, Horgan S, Espat NJ, Abcarian H. Short-term outcomes with small intestinal submucosa for ventral abdominal hernia. Arch Surg. 2005;140(6):549-60; discussion 60-2. doi: 10.1001/archsurg.140.6.549. PubMed PMID: 15967902.

38. Ueno T, Pickett LC, de la Fuente SG, Lawson DC, Pappas TN. Clinical application of porcine small intestinal submucosa in the management of infected or potentially contaminated abdominal defects. J Gastrointest Surg. 2004;8(1):109-12. PubMed PMID: 14746842.

39. Catena F, Ansaloni L, Gazzotti F, Gagliardi S, Di Saverio S, D'Alessandro L, et al. Use of porcine dermal collagen graft (Permacol) for hernia repair in contaminated fields. Hernia. 2007;11(1):57-60. doi: 10.1007/s10029-006-0171-6. PubMed PMID: 17119853.

40. Schuster R, Singh J, Safadi BY, Wren SM. The use of acellular dermal matrix for contaminated abdominal wall defects: wound status predicts success. Am J Surg. 2006;192(5):594-7. doi: 10.1016/j.amjsurg.2006.08.017. PubMed PMID: 17071190.

41. Diaz JJ, Conquest AM, Ferzoco SJ, Vargo D, Miller P, Wu YC, et al. Multi-institutional experience using human acellular dermal matrix for ventral hernia repair in a compromised surgical field. Arch Surg. 2009;144(3):209-15. doi: 10.1001/archsurg.2009.12. PubMed PMID: 19289658.

42. Klinge U, Klosterhalfen B, Müller M, Schumpelick V. Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999;165(7):665-73. doi: 10.1080/11024159950189726. PubMed PMID: 10452261.

43. LeBlanc KA, Whitaker JM. Management of chronic postoperative pain following incisional hernia repair with Composix mesh: a report of two cases. Hernia. 2002;6(4):194-7. doi: 10.1007/s10029-002-0075-z. PubMed PMID: 12424601.

44. Klosterhalfen B, Klinge U, Hermanns B, Schumpelick V. [Pathology of traditional surgical nets for hernia repair after long-term implantation in humans]. Chirurg. 2000;71(1):43-51. PubMed PMID: 10663001.

45. Coda A, Bendavid R, Botto-Micca F, Bossotti M, Bona A. Structural alterations of prosthetic meshes in humans. Hernia. 2003;7(1):29-34. doi: 10.1007/s10029-002-0089-6. PubMed PMID: 12612795.

46. Costello CR, Bachman SL, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene hernia meshes. J Biomed Mater Res B Appl Biomater. 2007;83(1):44-9. doi: 10.1002/jbm.b.30764. PubMed PMID: 17285608.

47. Amid PK, Shulman AG, Lichtenstein IL, Hakakha M. Biomaterials for abdominal wall hernia surgery and principles of their applications. Langenbecks Arch Chir. 1994;379(3):168-71. PubMed PMID: 8052058.

48. Costa D, Tomás A, Lacueva J, de Asís Pérez F, Oliver I, Arroyo A, et al. Late enterocutaneous fistula as a complication after umbilical hernioplasty. Hernia. 2004;8(3):271-2. doi: 10.1007/s10029-004-0205-x. PubMed PMID: 14986173.

49. DeGuzman LJ, Nyhus LM, Yared G, Schlesinger PK. Colocutaneous fistula formation following polypropylene mesh placement for repair of a ventral hernia: diagnosis by colonoscopy. Endoscopy. 1995;27(6):459-61. doi: 10.1055/s-2007-1005743. PubMed PMID: 8549447.

50. Fernández Lobato R, Martínez Santos C, Ortega Deballon P, Fradejas López JM, Marín Lucas FJ, Moreno Azcoita M. Colocutaneous fistula due to polypropylene mesh. Hernia. 2001;5(2):107-9. PubMed PMID: 11505647.

51. Losanoff JE, Richman BW, Jones JW. Entero-colocutaneous fistula: a late consequence of polypropylene mesh abdominal wall repair: case report and review of the literature. Hernia. 2002;6(3):144-7. doi: 10.1007/s10029-002-0067-z. PubMed PMID: 12209305.

52. Ott V, Groebli Y, Schneider R. Late intestinal fistula formation after incisional hernia using intraperitoneal mesh. Hernia. 2005;9(1):103-4. doi: 10.1007/s10029-004-0271-0. PubMed PMID: 15616763.

53. V. Palter TG, A. Harvey, H. M. MacRae. Ex Vivo Technical Skills Training Transfers to the Operating Room and Enhances Cognitive Learning: A Randomized Controlled Trial. Annals of Surgery. 2011;253(5):886 - 9.

54. R. K. Reznick HM. Teaching Surgical Skills - Changes in the Wind. The New England Journal of Medicine. 2006;355(25):2664 - 9.

55. Ericsson KA. The acquisition of expert performance: an introduction to some of the issues. Associates LE, editor. Mahwah, N.J.1996.

II. PAST, PRESENT AND FUTURE OF SURGICAL MESHES:

A REVIEW

PUBLISHED AS: Baylon, K.; Rodriguez-Camarillo, P; Elías-Zúñiga A; Díaz-Elizondo, J. A.; Gilkerson, R; Lozano, K., “Past, Present and Future of Surgical Meshes: A Review”, Membranes, vol. 7, no. 47, 2017

II.1. ABSTRACT

Surgical meshes, in particular those used to repair hernias, have been in use since 1891. Since then, research in the area has expanded, given the vast number of post-surgery complications such as infection, fibrosis, adhesions, mesh rejection, and hernia recurrence. Researchers have focused on the analysis and implementation of a wide range of materials: meshes with different fiber size and porosity, a variety of manufacturing methods, and certainly a variety of surgical and implantation procedures. Currently, surface modification methods and development of nanofiber based systems are actively being explored as areas of opportunity to retain material strength and increase biocompatibility of available meshes. This review summarizes the history of surgical meshes and presents an overview of commercial surgical meshes, their properties, manufacturing methods, and observed biological response, as well as the requirements for an ideal surgical mesh and potential manufacturing methods.

Keywords: surgical mesh; hernia repair; abdominal wall reconstruction; biocompatibility

II.2. INTRODUCTION

A hernia is defined as a protrusion or projection (prolapse) of an organ through the wall of the cavity where it is normally contained [1]. There are many types of hernia, mostly classified according to the physical location, with the abdominal wall being the most susceptible site. Specifically, reports show that the most frequently seen hernia is the inguinal hernia (70–75% of cases), followed by femoral (6–17%) and umbilical (3–8.5%) hernias [2]. Hernias are also found in other sites such as the ventral or epigastric hernia, located between the chest cavity and the umbilicus.

Hernias can be uncomfortable and are sometimes accompanied by severe pain, which worsens during bowel movements, urination, heavy lifting, or straining [3]. Occasionally, a hernia can become strangulated, which occurs when the protruding tissue swells and becomes incarcerated. Strangulation will interrupt blood supply and can lead to infection, necrosis, and potentially life-threatening conditions [4].

Hernia repair is one of the most common surgical procedures performed globally. It is estimated that there are over 20 million hernia repair procedures per year worldwide [5]. The number of procedures has been increasing and is predicted to further increase due to several risk factors such as obesity and prior abdominal surgeries [6]. Hernia repairs provide an important revenue stream for hospitals, estimated at $48 billion/year in the United States [7].

The use of hernia mesh products to surgically repair or reconstruct anatomical defects has been widely adopted: in fact, more than 80% of hernia repairs performed in United Sates use mesh products [8]. The surgical mesh firmly reinforces the weakened area and provides tension-free repair that facilitates the incorporation of fibrocollagenous tissue [9]. However, there are many types of meshes and there is a strong controversy regarding optimum performance and success of surgical procedures. Researchers have investigated metals, composites, polymers and biodegradable biomaterials in their quest to attain the ideal surgical

mesh and implantation procedure [10]. The sought-after characteristics are inertness, resistance to infection, the ability to maintain adequate long-term tensile strength to prevent early recurrence, rapid incorporation into the host tissue, adequate flexibility to avoid fragmentation, non-carcinogenic response and the capability to maintain or restore the natural respiratory movements of the abdominal wall [9].

Currently, utilized surgical meshes exhibit many but not all of the desired characteristics [8]. Therefore, current research efforts focus on providing potential solutions that range from the utilization of novel materials to new designs that could ameliorate existent shortcomings [11]. The aim of this review is to illustrate the current research in surgical meshes used for hernia repair. This review provides a perspective of existent commercial surgical meshes, their properties, manufacturing procedures, and observed biological responses. Furthermore, the article seeks to establish the requirements for an ideal surgical mesh and potential manufacturing procedures.

II.3. HISTORY

In 1890, Theodor Billroth suggested that the ideal way to repair hernias was to use a prosthetic material to close the hernia defect [12]. Many materials were used, but all failed due to infections, rejections, and recurrences [13]. Surgeons concluded that the main problem was built upon the multifilament suture material, which has been proven unsuitable in many other surgical procedures [14]. Surgeons became disenchanted with the popular cotton and silk sutures because of the frequently observed rejection syndrome and resultant endless recurring infections. The use of such sutures to secure mesh in place undoubtedly contributed to aggravate the existing bias against the surgical meshes [15].

In 1955, Dr. Francis Usher focused his attention on the materials that could solve existing problems. Nylon, Orlon, Dacron and Teflon were studied and were observed to have a variety of shortcomings such as: foreign body reaction, sepsis, rigidity, fragmentation, loss of tensile strength and encapsulation [16]. All of these precluded the acceptance of polymeric materials. After reading an article about a new polyolefin material (Marlex), which demonstrated remarkable properties, Usher started to develop a woven mesh [17]. Two years later, the Marlex prostheses were implemented. These were made of large pores, which facilitated incorporation despite infections. The growth of tissue through its interstices was the main difference when compared to previous materials. After a few days of surgical incorporation, fibroblast activity was noticed to increase, more collagen was induced without giant cells, and the whole system gained strength [18]. Despite the numerous advantages of the woven and knitted polyethylene mesh, Usher continued the search for better systems. He soon found that knitted polypropylene had many more advantages: it could be autoclaved, had firm borders coupled with two-way stretching, and could be rapidly incorporated. Finally, in 1958, Usher published his surgical technique using a polypropylene mesh, and 30 years later the Lichtenstein repair (known today as “tension-free” mesh technique) was popularized for hernia repair [18]. Even when the benefits of meshes were accepted, the recollection of evidence-based cases was required to statistically quantify their advantages. In

2002, the European Union Hernia Trialists Collaboration, a group of surgical trialists who have participated in randomized trials of open mesh or laparoscopic groin hernia repair, analyzed 58 randomized controlled trials and concluded that the use of surgical meshes was superior to other techniques [19]. In particular, they noted fewer recurrences and less postoperative pain with mesh repair. These results were supported by other studies that demonstrated that hernia repair using surgical meshes reduced the risk of hernia recurrence compared to hernia reconstruction through other methods, in 2.7% vs. 8.2% in ventral hernia repair cases and by 50–75% of improvement through surgical meshes in inguinal repair [8].

Today, many surgeons agree that use of a prosthetic mesh is the preferred way to repair hernias. It should be emphasized that in the past, the success of repair was evaluated based on the strength and permanency of the mesh itself, not on the degree of scar tissue or other factors, which subsequently develop in and around the mesh [20]. The biocompatibility of the material has proven to be a strong contributor in the rejection of the prosthesis due to scar tissue developed by the immunological system. When a surgical mesh is implanted and lacks appropriate biocompatibility (either due to the material that it is made of or its structural design), the body responds by encapsulating the foreign system leading to the formation of a stiff scar which consequently results in poor tissue incorporation, causing hernia recurrence or infection of the mesh. A large percentage of meshes then have to be removed: approximately 69% of the explanted meshes are due to prosthesis infection [21].

Although the only treatment is surgery, there are new surgical procedures that ameliorate postoperative side effects such as the laparoscopic approach. Open surgery repair is performed by making an incision in the abdomen to identify and dissect the hernia sac through the subcutaneous tissues and fascia. Once the hernia sac is dissected away from any adjacent structures and examined for contents (intestine or any other tissues), these are inserted back into the peritoneal space, and hernia repair is carried out. Repair can be executed in two ways: (1) primary repair and (2) patch or mesh. The first involves sewing the tissue of the abdominal wall using sutures, while the second technique relies in the placement of a mesh to

cover the hernia defect and reinforce surrounding tissue, fixing it with fibrin glue, staples or sutures.

In the case of a laparoscopic procedure, the surgeon starts by making several small incisions in the abdominal wall surrounding the hernia sac, in order to introduce surgical instruments and a laparoscope. In one of the incisions, carbon dioxide gas is introduced into the abdomen. The mesh or patch is then introduced, unrolled and fixed with staples or tacks. The procedure then continues with the release of the gas from the abdomen and closure of cutaneous incisions with sutures [22].

II.4. CURRENT RESEARCH ON SURGICAL MESHES

Most surgical meshes used currently are chemically and physically inert, nontoxic, stable and non-immunogenic. However, none of them are biologically inert, a property related to the mesh physiology and its role into the hernia repair process [23]. Implantation of any prosthetic material is quickly followed by an extraordinarily complex series of events that mark the initiation of the healing process [14]. As for the physiology of abdominal mesh implantation, perhaps the greatest concern, and hence the area that most research focuses on, is inflammation and wound healing [24]. The passive substrate of the biomaterials in conjunction with devitalized tissues can actively contribute to bacterial growth, resulting in infection, which delays the wound healing process [25].

The introduction of a foreign material into the body triggers a healing response characterized by one of three stereotypical reactions: (1) destruction or lysis, (2) inclusion or tolerance, and (3) rejection or removal. When an implant is introduced into the body, the immune system recognizes it as a foreign material and therefore attempts to destroy it [26]; immunosuppressive drugs must be administered to prevent the body from attacking it [27]. The rejection of an implant is primarily driven by the immune response of the T lymphocytes (T cells). The T cells are stimulated by the presence of an antigenic determinant on the foreign material. T cells are reproduced faster than the time required for immunosuppressants to interfere with its proliferation, therefore resulting in rejection of the implant given the large number of T cells attacking the foreign material [28].

Inflammation is the reaction of vascularized living tissue to injury and is the primary biological reaction to implanted medical devices. In the case of implanted meshes, the inflammatory response is presented in four stages that are related both temporally and hierarchically [29]. Immediately after implantation, prosthetics adsorb proteins, which create a coagulum around it [30]. Coagula are composed of albumin, fibrinogen, plasminogen, complement factors and immunoglobulins [31]. Platelets adhere to the proteins releasing a host of chemoattractants that invite other cells

such as polymorphonucleocytes (PMNs), fibroblasts, smooth muscle cells and macrophages to the area in a different sequence [32]. The chemotaxis process is defined as the movement of cells towards a preferred migration site triggered by a chemical stimulus [33]. The attraction of PMNs, also known as neutrophils, to the wound site is attributed to chemotaxis, and is observed as the first stage of biological response to the injured site. During the first stage or acute phase of inflammation, neutrophils phagocytize microorganisms. The neutrophil may also degenerate and die during this process, releasing its cytoplasmic and granular components near or over the surface of the prosthesis, which may also mediate the subsequent inflammatory response [34].

When the acute inflammatory response is unable to eliminate the injurious agent or restore injured tissue to its normal physiological state, the condition could progress into a state of chronic inflammation, known as second stage of inflammation. In this stage, monocytes that have migrated to the wound site during the acute inflammatory response rapidly differentiate into macrophages. In addition to macrophages, other primary cellular components such as plasma cells and lymphocytes actively contribute to the inflammatory process. Macrophages increasingly populate the area to consume foreign bodies as well as dead organisms and tissue [14].

In most of the cases where chronic inflammation is related to a medical device or biomaterial, the inflammation process will lead to an immune response or foreign body reaction, corresponding to the third stage of inflammation, where chronic inflammation macrophages fuse into a foreign body giant cell as a response to the presence of large foreign bodies [35]. Foreign body reaction is a complex defense reaction involving: foreign body giant cells, macrophages, fibroblast, and capillaries in varying amounts depending upon the form and topography of the implanted material [36].

The fourth stage of inflammation occurs in the wound healing phase and is characterized by the replacement of damaged tissue with various cells that

specialize in secreting extracellular matrix materials to form a scar [14]. Wound healing and scar formation follow the initiation of inflammation, but their progression and the magnitude of scarring can be affected by the degree of persistent inflammatory activity as well as the severity of the primary injury [37].

Fibroblasts are cells that mediate the wound healing phase. These cells enter the wound site two to five days after the injury occurs, typically once the inflammatory phase has ended. Fibroblasts proliferate at the wound site, reaching peak levels after one to two weeks. The main function of fibroblasts is to synthesize extracellular matrix and collagen to maintain the structural integrity of connective tissues; at the end of the first week, these are the only cells in charge of collagen deposition. Cells involved in the regulation of inflammation, angiogenesis (formation of new blood vessels from preexisting vasculature) and further connective tissue reconstruction attach to, proliferate, and differentiate on the collagen matrix laid down by fibroblasts [26].

From a histological standpoint, the interaction between prosthesis and organism is characterized by three main aspects: size of tissue reaction; cell density; and fibroblastic activity. As mentioned, fibroblastic activity peaks one to two weeks post-wounding, usually on the 8th day for the intraperitoneal plane and on the 10th day for the extraperitoneal plane. The optimum quantity of fibroblasts needed for a successful integration of the mesh is achieved approximately two weeks after wounding. Further accumulation of fibroblasts will cause an inflammatory phase with increased fibrosis and faster prosthesis integration associated with paresthesia and pain. Furthermore, the inflammatory process could cause contraction and shrinkage of the mesh, resulting in adhesions and fistulas, leading to prosthesis rejection and eventually explantation [25].

The wound repair process described above creates a mesh integration due to the conformational changes of the proteins. This integration is progressive, starting from the prosthesis implantation that is accompanied by the foreign body reaction followed by the inclusion of the prosthesis, which occurs within the first two

weeks. The process is finalized as the overall strength increases gradually, which last about 12 weeks and results in a relatively less elastic tissue that has only 70–80% of the strength of the native connective tissue [32].

Although integration and collagen deposition that result from the inflammatory response provide long-term strength, as pointed out, an aggressive integration could also be harmful to the tissue that surrounds the wound site causing a severe body reaction, inflammation, fibrosis, infection, and mesh rejection [23]. The fibrotic reaction generated by the body when a prosthetic material is introduced, such as in the case of surgical meshes for a hernia repair, is governed by the chemical nature of the material implanted and its physical characteristics. The integration and overall healing process of implantable surgical meshes is highly dependent upon the intrinsic mesh characteristics such as, the primary material, filament structure, tailored coatings, and pore size.

Research in abdominal wall repair has provided valuable information on the parameters, properties, and design of the meshes that influence the immune reaction of the body to the prosthesis as well as the optimal parameters to reduce fibrosis [38 ,39]. These factors are discussed below.

II.4.1. Elasticity and Tensile Strength

A deterioration of the tensile strength of the mesh or a strained mesh could potentially lead to hernia recurrence or a poor functional result. Hence, materials employed in surgical meshes must possess the minimum mechanical properties necessary to withstand the stresses placed on the abdominal wall. The maximum intra-abdominal pressure generated in a healthy adult occurs when coughing or jumping and is estimated to be approximately 170 mmHg. Given this information, the mesh used to repair abdominal hernias must withstand at least 180 mmHg (20 kPa) before failing [38].

The tension placed on the abdominal wall can be calculated using Laplace’s law relating the tension, pressure, thickness, and diameter of the abdominal wall.

According to the thin-walled cylinder model, the total tensile strength is independent of the thickness of the layer. Hence, a physiological tensile strength of 16 N/cm is defined, using a pressure of 20 kPa (2 N/cm2 as the maximum pressure to be experienced in the intra-abdominal wall), and 32 cm as the longitudinal diameter of the abdominal wall [39].

Studies over human abdominal walls have demonstrated that at the maximum tensile strength of 16 N/cm, the abdominal wall in males presents a natural mean distension of 23% ± 7% and 15% ± 5% when tissue is stretched in vertical and horizontal direction, respectively. In females, a distension of 32% ± 17% and 17% ± 5% in vertical and horizontal stretching has been observed [40].

II.4.2. Pore Size

Porosity plays a key role in the reaction of the tissue to the prostheses. Bacterial growth and cell proliferation are highly dependent upon porosity and pore size. Bacterial colonies are established principally in the spaces between pores and fibers. Macroporous meshes that have large pores have shown to facilitate entry of macrophages, fibroblasts and collagen fibers that will constitute the new connective tissue, integrate the prosthesis to the organism and prevent colonization of bacteria. Large pores have shown easy infiltration of immunocompetent cells, providing protection from infection [25]. Microporous meshes, with pores of <10 m, have shown a higher rejection rate given that scar tissue rapidly bridges small pores resulting in minimum integration, these meshes are associated with chronic inflammation.

Although it would be helpful to classify pore size in a standard form, currently, there is not a formal classification. Earl and Mark proposed the following: very large pore: >2000 μm; large pore: 1000–2000 μm; medium pore: 600–1000 μm; small pore: 100–600 μm and microporous (solid) <100 μm [32 ,41].

II.4.3. Weight (Density)

Prostheses can be classified as: heavy-weight (HW), when they are above 80 g/m^2; medium-weight (MW), between 50 and 80 g/m^2; light-weight (LW), between 35 and 50 g/m^2; and ultra-lightweight, below 35 g/m^2 [25]. While a heavy-weight mesh is produced with heavy materials, small pore size and high tensile strength, a light-weight is composed of thin filaments with large pores, generally larger than 1 mm. Given that light-weight meshes contain less material, results have shown that less pronounced foreign body reaction is to be expected. A decreased inflammatory response results in better tissue incorporation [42].

II.4.4. Constitution

Surgical meshes could be fabricated using monofilament or multifilament (twisted) systems. A surgical mesh formed of monofilament yarns provides satisfactory reinforcement ability, but with stiffness and limited pliability. In contrast, a surgical mesh formed of multifilament yarns is soft and pliable. However, multifilament yarn meshes tend to harbor infectious matter such as bacteria, increasing erosion rates by 20–30% [43]. Particularly, the small void areas or interstitial spaces between the multifilament yarns may promote the replication and breeding of such bacteria, which measures approximately 10 μm.

II.4.5. Material Absorption

Surgical meshes could be made from an absorbable or non-absorbable material. Non-absorbable meshes can withstand the mechanical requirements, are easy to shape intraoperative and have long-term stability. However, complications such as mesh stiffness over time, hernia recurrence, mesh erosion, and adhesions have been documented. On the other hand, absorbable meshes were developed to reduce these long-term complications. These meshes favor postoperative fibroblast activity. Nevertheless, after prosthesis absorption, the resulting scar tissue is not as strong as it was, and alone is insufficient to provide the needed strength and could result in hernia recurrence.

II.4.6. Commercially Available Surgical Meshes

The ideal mesh should be able to be held in situ by peripheral sutures, resist the possibility of loading under biaxial tension (coughing or lifting actions) without failure especially during the early postoperative period, and should promote a fast and organized response from fibrous tissue with minimal inflammation [3].

Given the difficulty to find a single surgical mesh that fulfills all of the “ideal” characteristics, there are more than 70 meshes for hernia repair available in the market. These are classified according to the composition or type of material as: (1) first generation (synthetic non-absorbable prosthesis), (2) second generation (mixed or composite prosthesis), and (3) third generation (biological prosthesis).

II.4.6.1. First Generation Meshes

First generation surgical meshes are predominantly based on polypropylene (PP) systems. In 1958, the first polypropylene mesh was used to repair an abdominal wall; it was a heavyweight mesh with small pores. Due to intense fibrotic reactions, the search for an “ideal” mesh continued. In 1998, a lightweight first generation mesh was introduced: this system had larger pores and smaller surface area [38,43]. First generation meshes are mostly classified into three categories: (1) macroporous meshes, (2) microporous meshes, and (3) macroporous meshes with multifilament or microporous components.

Macroporous prostheses are characterized by a pore size larger than 75 m. Polypropylene has been the material of choice with several brand names such as: Marlex, Prolene®, Prolite®, Atrium® and Trelex®.

Microporous meshes have smaller pores, commonly less than 10 m and commonly made from expanded polytetrafluoroethylene (e-PTFE) under the brand name Gore-Tex® (AZ, USA).

Macroporous meshes with multifilament or microporous components contain plaited multifilamentary threads in their composition, the space between the threads is less than 10 μm and their pores are larger than 75 μm. Several systems are in the market such as: plaited polyester (PL) meshes (Mersilene® and Parietex®); plaited polypropylene (SurgiPro®, Minneapolis, MN, USA), and perforated polytetrafluoroethylene (PTFE) (Mycromesh® and MotifMesh®) [25]. Table 3 shows the classification of commercially available first generation surgical meshes.

II.4.6.2. Second Generation Meshes

Despite the improvements made within the first generation meshes (Table 3), which include high tensile strength in order to support intra-abdominal pressure, several complications such as hernia recurrence, infection, and adhesions still prevailed. Therefore, second generation meshes were developed combining more than one synthetic material into their composition. Nearly all of these kinds of meshes continued to use PP, PL or e-PTFE but now in combination with each other and/or with other materials such as titanium (Ti), omega 3, poliglecaprone 25 (PGC-25) and polyvinylidene fluoride (PVDF) as composite systems.

Table 3. Classification of commercially available first generation surgical meshes [38].

Product (Manufacturer)	Material	Pore Size (mm)	Absorbable	Weight (g/m^2)	Filament	Mechanical Properties	Advantages and Disadvantages
Vicryl (Ethicon)	Polyglactin	0.4	Yes, fully (60–90 days)	56	Multifilament	Tensile strength of 78.2±10.5 N/cm in longitudinal direction and 45.5±13.5 N/cm in transverse direction.	Eliminates the risk of infectious disease transmission. Usually results in hernia recurrence after complete absorption
Dexon (Syneture)	Polyglycolic acid	0.75	Yes, fully (60–90 days)	56	Multifilament	N.A.	Adhesions fade as the mesh is absorbed. It is controversial whether the fibrous ingrowth into the prosthesis is sufficient to accomplish a permanent repair.
Sefil (B-Baun)	Polyglycolic acid	0.75	Yes, fully (60–90 days)	56	Multifilament	N.A.	High anatomic adaptability and low risk of late secondary infection. Retain 50% of its strength for 20 days.
Marlex (BARD)	PP	0.8	No	80–100	Monofilament	Tensile strength of 58.8 N/cm	High tensile strength. Evokes a chronic inflammatory reaction.
3D Max (BARD)	PP	0.8	No	80–100	Monofilament	Tensile strength of 124.7 N/cm	Anatomically designed. Reduced patient pain. Adhesions risk.
Polysoft (BARD)	PP	0.8	No	80–100	Multifilament	Burst strength of 558 N and a stiffness of 52.9 N/cm	Low infection risk. Not used in extraperitoneal spaces as produce dense adhesions *.
Prolene (Ethicon)	PP	0.8	No	80–100	Monofilament	Tensile strength of 156.5 N/cm	Facilitates fibrovascular ingrowth, infection resistance and improve compliance. Adhesions risk.
Surgipro (Autosuture)	PP	0.8	No	80–100	Multifilament	Tensile strength of 41.8 N/cm in longitudinal direction and 52.9 N/cm in transverse direction	High tensile strength, ease of handling and position and retains properties in vivo. Difficult complete wound healing caused by mesh structure.
Prolite (Atrium)	PP	0.8	No	80–100	Monofilament	Tensile strength of 138 N/cm	Monofilaments aligned in parallel spaced angles to maximizing material flexibility in two dimensions and a smooth and very uniform open architecture. Adhesions risk.
Trelex (Meadox)	PP	0.8	No	80–100	Multifilament	N.A.	*
Atrium (Atrium)	PP	0.8	No	80–100	Monofilament	Tensile strength of 56.2 N/cm	High tolerance to infection. Adhesions risk.

Table 3. Classification of commercially available first generation surgical meshes (cont.) [38].

Product Manufacturer)	**Material**	**Pore Size (mm)**	**Absorbable**	**Weight (g/m^2)**	**Filament**	**Mechanical Properties**	**Advantages and Disadvantages**
Premilene (B-Braun)	PP	0.8	No	80–100	Monofilament	Tensile strength of 41.4 N/cm in longitudinal direction and 36.5 N/cm in transverse direction	Mesh adaptation to the longitudinal and latitudinal axes of the connective tissue where is used for the reinforcement, rapid healing and tissue penetration. Adhesions risk.
Serapren (smooth)	PP	0.8	No	80–100	Multifilament	N.A.	*
Parietene (Covidien)	PP	0.8	No	80–100	Multifilament	Tensile strength of 38.9±5.2 N/cm in longitudinal direction and 26.6±4.2 N/cm in transverse direction	*
Prolene Light (Covidien)	PP	1.0-3.6	No	36–48	Monofilament	Tensile strength of 20 N/cm	Greater flexibility. Not used in intraperitoneal spaces as produce dense adhesions
Optilene (B-Baun)	PP	1.0-3.6	No	36–48	Monofilament	Tensile strength of 58 N/cm	Soft, thin and pliable. Ideal for inguinal hernia repair o reduce chronic pain. Not used in extraperitoneal spaces as produce dense adhesions
Mersilene (Ethicon)	PP	1.0-2.0	No	40	Multifilament	Tensile strength of 19 N/cm	Low infection risk. Evokes an aggressive macrophage and giant cell rich inflammatory reaction, followed by a dense fibrous ingrowth.
Goretex (Gore)	e-PTFE	0.003	No	Heavyweight	Multifilament	Minimum tensile strength of 16 N/cm	Smooth and strong. Evokes a chronic inflammatory reaction.

The main advantage of these composite meshes relied in the fact that these could be employed in intraperitoneal spaces causing minimal adhesion formation to neighboring surfaces given that each side of the mesh is tailored to specific needs. These meshes therefore require a specific orientation during implantation; the visceral side has a microporous surface to prevent visceral adhesion, whereas the non-visceral side is often macroporous to allow parietal tissue ingrowth. There are two categories of composite meshes: absorbable and permanent (non-absorbable). Absorbable composite meshes require hydration prior to usage, are not amenable to modification, mitigate viscera-mesh related complications, and can aid in tissue ingrowth. Parietex® is the first composite mesh to offer a resorbable collagen barrier on one side to limit visceral attachments combined with a three-dimensional polyester knit structure on the other side, to promote tissue ingrowth. Permanent composite meshes can be modified to fit specific applications and present less visceral adhesions and complications, taking advantage of the properties of both macro and micro porous meshes. Dual Mesh® (W.L. Gore & Associates, Inc., AZ, USA), Dulex® and Composix® (both manufactured by Bard Davol Inc., Providence, RI, USA) are some of the brand name meshes included in this category [42]. Table 4 lists some of the commercially available second generation surgical meshes.

Table 4. Classification of commercially available second generation surgical meshes [38].

Product (Manufacturer)	Material	Pore Size (mm)	Absorbable	Weight (g/m^2)	Filament	Mechanical Properties	Advantages and Disadvantages
Vypro, Vypro II (Ethicon)	PP/polyglactin 910	>3	Partially (42 days)	25 & 30	Multifilament	Tensile strength of 16 N/cm	Significantly decreased rates of chronic pain. Higher rate of hernia recurrence.
Gore-Tex Dual Mesh Dual Mesh Plus (Gore)	e-PTFE	0.003–0.022	No	Heavyweight	Multifilament	Minimum tensile strength of 16 N/cm (Gore-Tex Dual Mesh) and 157.7 N/cm (Dual Mesh Plus)	Promotes host tissue growth and reduces tissue attachment. Infection risk.
Parietex (Covidien)	POL/collagen	>3	Partially (20 days)	75	Multifilament	Elasticity of 3.5 at 16 N	Short-term benefit for anti-adhesion property. Greater infection rate (57%).
Composix EX Dulex (BARD)	PP/e-PTFE	0.8	No	Lightweight	Monofilament	N.A.	Minimizes adhesions and provides optimal tissue ingrowth. Infection risk.
Proceed (Ethicon)	PP/cellulose	Large	Partially (<30 days)	45	Monofilament	Tensile strength of 56.6 N/cm	Low rates of hernia recurrence (3.7%). Risk of formation of visceral adhesions.
DynaMesh IPOM (FEG Textiltechnik)	PP/PVDF	1-2	Partially	60	Monofilament	Tensile strength of 11.1±6.4 N/cm in longitudinal direction and 46.9±9.7 N/cm in transverse direction	Minimal foreign body reaction. Adhesions risk.
Sepramesh (Genzyme)	PP/sodium	1-2	Partially (<30 days)	102	Monofilament	N.A.	Reduces adhesions and the optimal tissue ingrowth is promoted. Sticky consistency difficult the surgeon manipulation.
Ultrapro (Ethicon)	PP/PGC-25	>3	Partially (<140 days)	28	Monofilament	Tensile strength of 55 N/cm	Reduced inflammatory response. Adhesions risk.
Ti-Mesh (GfE)	PP/titanium	>1	No	16 & 35	Monofilament	Tensile strength of 12 N/cm (mesh of 16 g/m^2) and 47 N/cm (mesh of 35 g/m^2)	Reduced inflammatory response. Low tensile strength.
C-Qur (Atrium)	PP/omega 3	>1	Partially (120 days)	50	Monofilament	Ball burst strength of 170±20.1 N	Short-term benefit for anti-adhesion property. No significant difference for adhesion grade or amount relative to other meshes.

II.4.6.3. Third Generation Meshes

Even with the improvements made on the second generation meshes (Table 4) where composite systems were designed to maintain the mechanical stability of first generation meshes (Table 3) and reduce inflammation and infection risk by mesh surface modification, the problems encountered with second generation meshes, such as the prevalence of adhesions, led to the development of biologic prostheses. Biologic mesh materials are based on collagen scaffolds derived from donor sources and they represent the so-called third generation meshes. Dermis from human, porcine, and fetal bovine sources are decellularized to leave only the highly organized collagen sources in addition to the dermal products included in porcine small intestine submucosa and bovine pericardium. The concept of these surgical meshes is that they provide a matrix for native cells to populate and generate connective tissue that could replace the tissue in the hernia defect [25]. Table 3 lists some of the commercially available third generation surgical meshes.

Third generation surgical meshes (Table 5) serve as biological scaffolds for repopulation and revascularization of host cells, showing a superior biocompatibility than first and second generations. These meshes do not trigger an inflammatory response from the body, though their high cost has hampered their wide acceptance.

Table 5. Classification of commercially available third generation surgical meshes [38].

Product (Manufacturer)	Material	Tensile Strength (MPa)	Advantages	Disadvantages
Surgisis (Cook)	Porcine (small intestine submucosa)	4	No refrigeration is required. Long history of safety data.	Requires hydration. Susceptible to collagenases.
FlexHD (J&J)	Human (acellular dermis)	10	No refrigeration or rehydration is required.	N.A.
AlloMax (Davol)	Human (acellular dermis)	23	No refrigeration or rehydration is required. Available in large sizes.	Hydration required.
CollaMend (Davol)	Porcine/Bovine (xenogenic acellular dermis)	11	No refrigeration or rehydration is required. Available in large sizes.	N.A.
Strattice (LifeCell)	Porcine/Bovine (xenogenic acellular dermis)	18	Available in large sheets.	Limited long-term follow up.
Permacol (Covidien)	Porcine/Bovine (xenogenic acellular dermis)	39	No refrigeration or rehydration is required. Available in large sizes.	N.A.
XenMatrix (Davol)	Porcine/Bovine (xenogenic acellular dermis)	14	Available in large sheets.	Limited long-term follow up.

N.A. Information not available in literature

II.4.7. Manufacturing Processes for Surgical Meshes

Surgical meshes are produced from different synthetic materials and in different mesh structures, the knitted structure being the most common [44]. Surgical filaments are mainly manufactured by extrusion processes and then knitted accordingly. As mentioned, meshes are typically manufactured from PL, PP, PTFE, e-PTFE, PVDF and composite materials (e-PTFE/PP) [45]. The knitting pattern can be significantly altered resulting in a broad range of properties. Thickness, pore size, tensile strength, flexural rigidity, and surface texture are highly dependent upon the knitting pattern; the resultant interplay among these characteristics imparts different performance [44]. These characteristics, besides altering the biocompatibility of the mesh given its affinity to cells, also dictate the mechanical properties of the mesh such as rigidity and deformation. Knitted meshes are a subset of the non-woven mesh configuration. However, there is much more order and consistency with pore size using a knitted design [46]. Knitting, by definition, is the construction of a fabric or cloth from the interlocking of threads through the formation of loops. Recent studies have been focused on treating the surgical mesh as a high-tech textile rather than as a prosthesis [44].

II.4.7.1. The Extrusion Process

Melt extrusion is the least expensive and simplest form of fiber extrusion [47]. This process consists of melting the polymer pellets through a combination of applied heat and friction. The molten polymer is then forced under high pressure through a small orifice or a “shower head” spinneret. The molten polymer flows out of the spinneret and freezes into a solid fiber, which is then typically reheated and drawn numerous times to further align the molecules and hence strengthen the fiber [48].

Most of the surgical meshes are made from filaments initially developed to be used for surgical sutures. Surgical sutures are made from polymers like PP [49], PL [50], e-PTFE [51] or PVDF [52] monofilaments and have been successfully used by

the medical profession for decades. Filaments used for surgical sutures have to possess several characteristics such as [53]:

1. Ability to attach to needles by the usual procedure.

2. Capability to be sterilized using ethylene oxide or ultraviolet radiation.

3. Ability to pass easily through tissue.

4. Ability to resist breakdown without developing an infection.

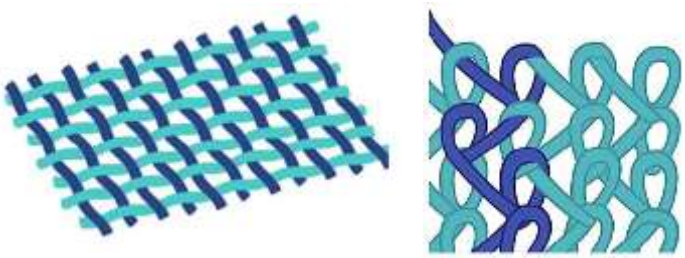
5. Possess minimal reaction with tissue.

6. Maintain its in vivo tensile strength over extended periods.

Commonly, the monofilaments used for surgical meshes have diameters in the range of 100–300 microns [54]. Multifilaments have also gained attention and have been used to fabricate surgical meshes. Lubricants are commonly applied to these filaments before the yarns are knitted. Suitable lubricants can be either hydrophobic lubricants [55] or hydrophilic lubricants such as polyalky glycol [56].

II.4.7.2. The Knitting Process

During the knitting process, fibers or yarns are curved to follow a meandering path and not oriented unilaterally as in weaving; therefore, the resulting fabric tends to be much more flexible and elastic than woven fabrics. The basic structure of a knitted fabric consists of courses and wales. Courses are rows running across the width of the fabric, while wales are columns running across the length of the fabric. When the wales are perpendicular to the course of the fiber/yarn, this is called weft knitting. When the courses and wales are approximately parallel to the direction of the fiber/yarn, the process is known as warp knitting [57]. Figure 2 shows a warp structure.



(**a**) (**b**)

Figure 2. *Schematic of: (**a**) woven; and (**b**) warp knitted structures.*

Warp knits and weft knits have been generated for use as implantable meshes to repair specific tissue sites and organs, such as those needed in hernia repair. Because of the looped stitches, the knitted structure is soft, flexible, and stretchable. It easily adapts to the movement of the human body [58], and has high elasticity, tensile strength, bursting strength and excellent porosity, which are key requirements for any implantable device that needs to mimic the biomechanical characteristics of the abdominal wall: tension of 16 N/cm with a 38% elasticity [38]. Given the interweaving, warp-knitted materials have a fixed structure that neither loosens nor peels off during cutting, regardless of the direction [55]. These material systems have been successfully commercialized and currently used worldwide. Table 5 lists some commercially available meshes classified according to the knitted technique, material, and type of filament.

Table 6. Classification of commercially available surgical meshes [59].

Mesh	Structural Textile Technique	Polymer	Fiber
Marlex	Woven	PP	Mono
Prolene®	Warp	PP	Mono
Atrium®	Warp	PP	Mono
Vypro®	Warp	PP/PG-910	Multi
UltraPro®	Warp	PP/PG-910	Mono
TiMesh®	Warp	PP/Ti	Mono
DualMesh®	Warp	e-PTFE	Foil *
Mersilene®	Warp	Polyethylene Terephthalate (PET)	Multi
Dynamesh®	Warp	PVDF	Moni
Vycril®	Woven	Resorbable undyed Polyglactin	Multi
Gore-Tex®	Woven	e-PTFE	Multi

* Membrane/patch.

The most commonly used systems in the knitting manufacturing process are the Tricot [60] and Raschel knitting machines [61], which are used to create warp or weft knitting structures [62]. Warp knitted meshes are the most popular system used to repair hernia defects, and are manufactured using the Raschel machine with a basic configuration consisting of two bars where latch-type needles are collectively mounted (running the full knitting width of the machine) and guide bars to hold yarn beams individually. The needle bars follow up and down movements, while the guide bars move back and forth across the needles of each bar to form continuous loops. The warp knit fabric design and lapping sequence is controlled by the shagging or traverse motion of the guide bars [63].

In principle, the Tricot knitting machine is very similar to the Raschel knitting; the only difference is the use of spring beard or compound needles instead of the latch needles used in the Raschel knitting machine. In addition, Tricot sinkers not only performed the function of holding down the loops whilst the needles rise as Raschel sinkers, but also support the fabric loops. The small angle of fabric take-away and the type of knitting action in Tricots creates a gentle and lower tension on the knitted fabric, ideal for high-speed production of fine gauge [64].

A double Raschel warp knitting machine (DR 16 EEC/EAC) has 16 guide bars and enables the production of textiles with different yarn materials and counts. The machine is equipped with two different gauges, E18 and E30. This system allows the design of a mesh configuration that could be adjusted to match given design parameters such as size, shape, Young modulus, and porosity [65]. The ultimate mechanical properties of the meshes are determined by the intrinsic properties of the filaments and the final configuration of the knitted fabrics.

II.5. FUTURE PERSPECTIVES

Despite the clinical success and vast body of knowledge that has been gained regarding manufacturing of surgical meshes, material properties, and surgical procedures, it is obvious that the ideal mesh has not been developed. It is well known that meshes still suffer from contraction and/or infection after implantation [66]. Furthermore, adhesions between the visceral side of the mesh and adjacent organs still occur. These complications may have serious consequences, such as chronic pain, intestinal obstruction, bowel erosion, or hernia recurrence. All of these problems have opened a great number of opportunities to create a new generation of surgical meshes [67]. This new generation will have to show a better integration with the tissue of the abdominal wall, but no adhesions on the visceral side. Based on the ideas of van't Riet [68], Ebersole [69] and Xu [70], new alternatives rely broadly on surface mesh modification by novel coatings to existent meshes and/or integration of nanofiber based systems.

II.5.1. Coatings

A variety of biocompatible and biodegradable natural and synthetic polymers are being investigated. Extensive research focuses in the development of a bi-layer composite hernia mesh in order to minimize the risk of infections and reduce adhesions on the visceral side [71, 72]. Materials that had been studied are: Polylactic acid (PLLA) [20], oxygenated regenerated cellulose (ORC) [67], n-vinyl pyrrolydone (NVP) and n-butylmethacrylate (BMA) [67], polyglycolic acid (PGA) [73], carboxymethylcellulose (SCMC) [74], omega-3 fatty acid [75], messenchymal stem cells (RMSC) [76], human dermal (HDF) and rat kidney fibroblasts (RKF) [76], collagen [77–79], chitosan [80], nanocrystalline silver particles (NCSP) [81] and titanium [82, 83]. Table 5 shows some of the properties that have made these materials attractive as active ingredients in surgical meshes [71, 80, 84–86].

Most of the recently published literature still presents PP surgical meshes as the "gold standard" though with surface modifications made with materials

mentioned in Table 5. Studies have primarily concentrated on: thickness and concentration of the materials used in the coating to be in contact with the visceral and/or abdominal side (Ex: 95% of oxidized collagen and 5% of chitosan) [26] and surface density (measured in g/m^2). The following Table 6 presents a summary of the obtained results based on the inflammatory response and percentage of adhesion.

In general, the new composite meshes show highly improved performance regarding peritoneal regeneration and visceral adhesion [84]. These studies have developed composite surgical meshes with high potential for adoption. Further studies with a focus on long-term adhesion and structural performance will complement obtained results.

II.5.2. Nanofibers

Nanofiber systems made from a large variety of materials have been explored extensively in the last decade. Scaffolds for tissue regeneration are strongly deemed as a potential application of these systems [87]. Mimicking the extracellular matrix (ECM) is vital to control cell behavior, such as adhesion, proliferation, migration, and differentiation. Tissue Engineering (TE) has been extensively explored to provide answers associated with current problems encountered in the interaction of the surgical meshes with the human body. One of the challenges of TE is to mimic the natural extracellular matrix (ECM) of the abdominal wall to promote an efficient integration. Researchers are actively exploring the implementation of nanofiber systems to effectively mimic the ECM [88–90].

Table 7. Material properties of surgical mesh coatings.

PLLA/PGA	ORC/SCMC	NVP/BMA	Omega-3 Fatty Acid	RMSC/HDF/RKF	Collagen/Chitosan	NCSP	Titanium
Variable degradation rate	Reduce mesh adhesions	Reduce mesh adhesions	Minimal risk of mesh contraction	Affinity towards fibroblasts	Weak tensile properties	Anti-inflammatory	Provides mechanical integrity
Hydrophilicity	Absorbable	Hydrophilicity	Absorbable	Favourable cell adhesion	Negligible effect on biomechanical properties	Antimicrobial	Non-absorbable

PLLA: Polylactic acid. PGA: Polyglycolic acid. ORC: Oxygenated regenerated cellulose. SCMC: Carboxymethylcellulose. NVP: N-vinyl pyrrolydone. BMA: N-butylmethacrylate. RMSC: Messenchymal stem cells. HDF: Human dermal. RKF: Rat kidney fibroblasts. NCSP: Nanocrystalline silver particles.

Table 8. Examples of surgical mesh coating parameters.

Reference	Analyzed Parameter	
	Material	**Surface Density**
Pascual et al. [86]	Oxidized collagen Chitosan	Oxidized collagen 95%/ Chitosan 5%
Ciechanska et al. [71]	MBC	6.7 g/m^2 (one side) 5.31 g/m^2 (two sides)
Cohen et al. [81]	NCSP	310 g/m^2 640 g/m^2 1130 g/m^2
Niekraszewics et al. [85]	Chitosan	20 g/m^2 (one side) 20 g/m^2 (two sides)

MBC: Modified bacterial cellulose. NCSP: Nanocrystalline silver particles.

Nanofibrous structures present several advantages, such as high specific surface area for cell attachment, higher microporous structure and a 3D micro environment for cell–cell and cell–biomaterial contact, these being associated with unique physical and mechanical properties. These structures when compared with commercial surgical meshes possess higher porosity and smaller pore size. These properties make nanofiber systems suitable for biomaterials used in wound care, drug delivery, and scaffolds for tissue regeneration [20, 44, 91].

Scaffolds for tissue engineering must possess a porous structure able to facilitate cell migration, a balance between surface hydrophilicity and hydrophobicity for cell attachment, mechanical properties comparable to natural tissue, and biocompatibility. Studies have shown that the abovementioned characteristics are also highly influenced by average diameter of the fibers and pore size. Effective cell attachment and proliferation has been observed in fiber systems with average diameters smaller than 1 m and average pore size of 14 m [92]. In commercially available meshes, even when it has been shown that cells are able to proliferate in micrometer/macrometer regimes, the cells in fact have difficulty attaching and proliferating. Cells are seen around the fibers whereas, on nanofiber based meshes, the cells attach to the fibers and quickly proliferate while making strong contact with underlying nanofibers, therefore promoting interlayer growth.

The application of nanofiber systems has been hampered due to its poor mechanical properties and nanofiber availability. Most of the available studies have

focused on nanofibers prepared through solution processes. The properties of the developed fibers can be controlled by different parameters such as utilized solvent, concentration of polymer, processing methods, and ambient conditions. For example, in the case of nanofibers made of polypropylene (one of the highly used polymers for commercially available surgical meshes), decahydronaphthalene (decalin) and cyclohexane have been used as preferred solvents. Polypropylene nanofibers prepared with cyclohexane exhibited a rougher surface when compared to the fibers prepared with decalin, suggesting that the surface morphology of the nanofibers depend on the boiling point of each solvent [93]. When stress–strain behaviors of the nanofibers are investigated, a tensile strength of 61.4 $\pm$ 1.5 MPa with 35.2% $\pm$ 1.7% of strain, and a Young modulus of 174.6 $\pm$ 1.7 MPa was obtained for the decalin based nanofibers, whilst the cyclohexane nanofibers exhibit a tensile strength of 18.2 $\pm$ 1.1 MPa with 46.7% $\pm$ 1.2% of elongation and a Young modulus of 39.1 $\pm$ 1.4 MPa [94]. The abovementioned results were obtained from bundles of nanofibers rather than individual fibers, these properties are strongly dependent on fiber orientation within the tested sample, bonding between fibers, and slip of one fiber over another [94].

Regarding nanofiber availability, there are several methods to prepare nanofiber systems. These methods include wet chemistry, Electrospinning (ES) [95] and Forcespinning® (FS) [96] techniques. Most of the available literature has used ES processes; these studies have proven the potential of these nanofiber systems towards solving many of the challenges encountered in TE. ES processes have been limited to laboratory-based research given the challenges associated with increasing yield and opportunity to work with melt based systems. FS, a technique that has been recently introduced is based on developing nanofibers through the application of centrifugal forces. The method has been proven effective to produce yields that could satisfy industry requirements (i.e., several hundred meters per minute) as well as to produce nanofibers from melt based systems therefore removing the requirement of a solvent and subsequently the potential contamination of the materials with toxic organic solvents, and cost associated with the solvent itself and

solvent recovery procedures. Other scaffolds had been produced by 3D printing procedures. Such biomimetic scaffolds are promising techniques as they could allow precise control over the geometry and microstructure [46,97].

Table 9 presents a summary of recently published work regarding the manufacture of nanofiber based surgical meshes.

Table 9. Nanofiber based surgical meshes.

Nanofiber Material	Manufacturing Process	Diameter (mm)	Tensile Strength (MPa)	Advantages and Disadvantages	Reference
Poly-ε-caprolactone (PCL)	Electrospinning	1280 ± 330	3.11 ± 1.09	Better adhesion, growth, metabolic activity, proliferation and viability of 3T3 Fibroblasts. Lack of in vivo testing.	[87,98]
Polydioxanone (PDO)	Electrospinning	860 ± 420	3.76 ± 0.49	Bioresorbable polymer. Reduction of long-term foreign body response (LTFBR). No fulfill the mechanical requirements.	[99]
Polylactide-Co-Glycolide (PLGA 8218)	Electrospinning	3280 ± 570	6.47 ± 0.41	Exceed the minimum mechanical requirements for hernia repair applications. Bioresorbable polymer. Reduction of LTFBR. Lack of in vivo testing.	
PLLA	Electrospinning	1480 ± 670	3.59 ± 0.25	In vivo advantages. Exceed the minimum mechanical requirements for hernia repair applications. Lack of in vivo testing.	
Polyurethane (PU)	Electrospinning	890 ± 330	18.9 ± 5.9	Elastic deformation.	
PET	Electrospinning	710 ± 280	3.17± 0.23	Adequate mechanical attributes. No evidence of intestinal adhesions. Trigger of a large foreign body reaction.	[100]
PET/Chitosan	Electrospinning	3010 ± 720	2.89 ± 0.27	Adequate mechanical attributes. No evidence of intestinal adhesions. Trigger of a large foreign body reaction.	
PCL/Collagen	Electrospinning	1000	2.13 ± 0.36	Biological and biomechanical stable, support skeletal muscle cell ingrowth and neo-tissue formation	[101]

PCL: Poly-ε-caprolactone. PDO: Polydioxanone. PLGA 8218: Polylactide-Co-Glycolide. PU: Polyurethane. PET: Polyethylene terephthalate.

Nanofiber systems are certainly showing a strong potential to be used in the next generation of surgical meshes, the increased availability (FS process) will certainly promote the development of practical applications. Nanofiber developed through the FS system have shown promising results regarding adhesion, growth, metabolic activity, proliferation, and viability of 3T3 cells [70,102]. It is expected that these systems will be used in combination with existent commercial meshes to

satisfy other requirements such as mechanical strength needed to bear the intra-abdominal pressure exerted by human body and implantation requirements to mention some. Future studies in this area will include the effect of nanofiber morphology, mesh design (i.e., uniaxial aligned, radially aligned, orthogonally patterned) needed to improve structural properties, and in vivo testing.

In summary, this review synergistically complements recent reviews made in this important area. Table 10 presents a comparative table with recent published reviews [38 ,103 –106]. Besides having in common the history and present scenario, this review also presents information regarding manufacturing methods (manufacturing of these meshes has a strong influence in the medical results, therefore the ultimate functionality will be strongly dependent upon the manufacturing method) and future perspectives.

Table 10. Aspects related to hernia meshes compared in recently published reviews.

	Baylon et al. (This Review)	Brown et al. [38]	Sanbhal et al. [103]	Guillaume et al. [104]	Todros et al. [105]	Todros et al. [106]
Introduction	✓	✓	✓	✓	✓	✓
History	✓	✓	–	–	–	–
Present Scenario	✓	✓	✓	✓	✓	✓
Properties Discussed	Elasticity/tensile strength Pore Size Weight (density) Constitution Material absorption	Tensile strength Pore Size Weight Reactivity/ Biocompatibility Elasticity Constitution Shrinkage Complications	Weight Pore Shape, size/porosity Mesh elasticity/strength	Properties discussed for particular meshes, varies from the type of mesh being discussed.	Pore size Density thickness	Biomechanical properties Uniaxial tensile testing Biaxial tensile testing Ball burst testing
Surgical Mesh	✓	✓	✓	✓	✓	✓
Manufacturing Processes	> 2 processes considered	–	–	–	–	–
Future Perspectives	2 perspectives considered	–	✓	✓	–	–
Comments	Comparison of meshes divided by generations: First generation (18 meshes), second generation, (10 meshes), third generation (7 meshes)	Comparison of meshes divided by constitution, Multi (3 meshes), multifilament and monofilament (13 meshes), and foil (1 mesh). Biomaterial meshes (10 meshes)	Comparison between synthetic meshes (15 meshes) Comparison between composite meshes (12 meshes)	Meshes divided by Biologically Derived Matrices, Biodegradable synthetic structures, Anti-inflammatory mesh, Meshes with enhanced cytocompatibility, Anti-adhesive Mesh, Antibacterial meshes. Review also discusses mesh fixation, self-expanding systems, post-implantation visible mesh, cell coated meshes, and growth factor loaded meshes.	Comparison between synthetic surgical meshes: HWPP (5 meshes), LWPP (6 meshes), PET (1 mesh), Eptfe (1 mesh), PVDF (1 mesh) Comparison between Multilayered meshes (10 meshes)	Comparison between synthetic surgical meshes: HWPP (5 meshes), LWPP (3 meshes), PET (1 mesh), ePTFE (1 mesh), PVDF (1 mesh). Comparison between Multilayered Meshes (10 meshes)
Total meshes compared	35	27	27	–	24	21

II.6. CONCLUSIONS

Surgical meshes have become the system of choice for hernia repair. Even though it is not the optimum method, so far it is the one that has shown a lower rate of recurrence. Currently, there are more than 70 types of meshes commercially available. These are constructed from synthetic materials (absorbable, non-absorbable, or a combination of both) and animal tissue. Despite reducing rates of recurrence, hernia repair with surgical meshes still faces adverse effects such as infection, adhesion, and bowel obstruction. Most of these drawbacks are related to the chemical and structural nature of the mesh itself.

An optimum integration with the abdominal wall and negligible adhesion on the visceral side are the most important after sought features for the “ideal” mesh. A surgical mesh will trigger one of three different responses from the body: it may be integrated, encapsulated or degraded. In order to have a minimal inflammatory response to better integrate it to the body, it is highly important to improve biocompatibility.

To overcome this obstacle, researchers are actively exploring methods to improve biocompatibility, with the goal of developing a mesh that can be effectively incorporated with minimal inflammation and/or infection. Nanofibers have been recently considered as a strong potential intermediary structure to be used as a coating, given their ultralight-weight quality, which could contribute to minimize the inflammatory response from the body and given its functional porosity, which could promote cell adhesion and proliferation.

II.6.1 Acknowledgements

The authors gratefully acknowledge support received by the National Science Foundation Partnership for Research and Education in Materials (PREM) award under Grant No. DMR-1523577: The University of Texas Rio Grande Valley–University of Minnesota Partnership for Fostering Innovation by Bridging Excellence in Research and Student Success. This work was also funded by Tecnológico de

Monterrey—Campus Monterrey, through the Research group of Nanotechnology and Devices Design. Additional support was provided by Consejo Nacional de Ciencia y Tecnología (CONACYT), Project Number 242269, Mexico.

II.6.2 Author Contributions

As a review article, all authors contributed to the writing, editing and revision of the manuscript. All authors contributed equally to the development of this review article.

II.6.3 Conflicts of Interest

The authors declare no conflict of interest.

II.7. REFERENCES

1. Williams, L.S.; Hopper, P.D. Understanding Medical-Surgical Nursing, 5th ed.; F.A. Davis: Philadelphia, PA, USA, 2015; p. 770.

2. Dabbas, N.; Adams, K.; Pearson, K.; Royle, G.T. Frequency of abdominal wall hernias: Is classical teaching out of date? J. R Soc. Med. Short Rep. 2011, 2, 1–6. [CrossRef] [PubMed]

3. Bendavid, R.; Abrahamson, J.; Arregui, M.E.; Flament, J.B.; Phillips, E.H. Abdominal Wall Hernias: Principles and Management, 1st ed.; Springer: New York, NY, USA, 2001.

4. Heniford, B.T. Hernia Handbook, 1st ed.; Carolinas HealthCare System: Charlotte, NC, USA, 2015.

5. Kingsnorth, A. Treating inguinal hernias: Open mesh Lichtenstein operation is preferred over laparoscopy. BMJ 2004, 328, 59–60. [CrossRef] [PubMed]

6. Li, X.; Kruger, J.A.; Jor, J.W.; Wong, V.; Dietz, H.P.; Nash, M.P.; Nielsen, P.M. Characterizing the ex vivo mechanical properties of synthetic polypropylene surgical mesh. J. Mech. Behav. Biomed. Mater. 2014, 37, 48–55. [CrossRef] [PubMed]

7. CORDIS: Community Research and Development Information Service. Available online: http://cordis.europa.eu/result/rcn/178015_en.html (accessed on 9 June 2017).

8. Bard Davol Inc. Available online: https://www.davol.com/index.cfm/_api/render/file/?method=inline&fileID=90027245-5056-9046-9529B0C67424C711 (accessed on 9 June 2017).

9. Pandit, A.S.; Henry, J.A. Design of surgical meshes—An engineering perspective. Technol. Heal. Care 2004, 12, 51–65.

10. Melero Correas, H. Caracterización Mecánica de Mallas Quirúrgicas Para la Reparación de Hernias Abdominales. Master Thesis, Universitat Politècnica de Catalunya, Barcelona, Spain, November 2008.

11. Zhu, L.-M.; Schuster, P.; Klinge, U. Mesh implants: An overview of crucial mesh parameters. World J. Gastrointest. Surg. 2015, 10, 226–236. [CrossRef] [PubMed]

12. Billroth, T. The Medical Sciences in the German Universities: A Study in the History of Civilization;Welch,W.H., Ed.; Macmillan: New York, NY, USA, 1924.

13. Chowbey, P. Endoscopic Repair of Abdominal Wall Hernias, 2nd ed.; Byword Books: Delhi, India, 2012.

14. Greenberg, J.A.; Clark, R.M. Advances in suture material for obstetric and gynecologic surgery. Rev. Obstet. Gynecol. 2009, 2, 146–158. [CrossRef] [PubMed]

15. LeBlanc, K.A. Laparoscopic Hernia Surgery an Operative Guide, 1st ed.; CRC Press: New Orleans, LA, USA, 2003.

16. Usher, F.C.; Fries, J.G.; Ochsner, J.L.; Tuttle, L.L. Marlex mesh, a new plastic mesh for replacing tissue defects. II. A new plastic mesh for replacing tissue defects. AMA Arch. Surg. 1959, 78, 138–145. [CrossRef] [PubMed]

17. Usher, F.C.; Hill, J.R.; Ochsner, J.L. Hernia repair with Marlex mesh. A comparison of techniques. Surgery 1959, 46, 718–728. [PubMed]

18. Klinge, U.; Klosterhalfen, B.; Birkenhauer, V.; Junge, K.; Conze, J.; Schumpelick, V.J. Impact of polymer pore size on the interface scar formation in a rat model. Surg. Res. 2002, 103, 208–214. [CrossRef] [PubMed]

19. EU Hernia Trialists Collaboration. Repair of groin hernia with synthetic mesh: Meta-analysis of randomized. Ann. Surg. 2002, 235, 322–332. [CrossRef]

20. Stowe, J.A. Development and Fabrication of Novel Woven Meshes as Bone Graft Substitutes for Critical Sized Defects. Ph.D. Thesis, Clemson University, Clemson, SC, USA, May 2015.

21. Hawn, M.T.; Gray, S.H.; Snyder, C.W.; Graham, L.A.; Finan, K.R.; Vick, C.C. Predictors of mesh explantation after incisional hernia repair. Am. J. Surg. 2011, 202, 28–33. [CrossRef] [PubMed]

22. Carbajo, M.A.; Martín del Olmo, J.C.; Blanco, J.I.; De la Cuesta, C.; Toledano, M.; Martín, F.; Vaquero, C.; Inglada, L. Laparoscopic treatment vs open surgery in the solution of major incisional and abdominal wall hernias with mesh. Surg. Endosc. 1999, 13, 250–252. [CrossRef] [PubMed]

23. Schumpelick, V.; Fitzgibbons, R.J. Hernia Repair Sequelae, 1st ed.; Springer: Berlin/Heidelberg, Germany, 2010.

24. Bendavid, R. Prostheses and Abdominal Wall Hernias, 1st ed.; R.G. Landes Co.: Austin, TX, USA, 1994.

25. Zogbi, L. The Use of Biomaterials to Treat Abdominal Hernias. In Biomaterials Applications for Nanomedicine, 1st ed.; Pignatello, R., Ed.; InTech: Rijeka, Croatia, 2008; Volume 18, pp. 359–382.

26. Anderson, J.M. Biological Response to Materials. Annu. Rev. Mater. Res. 2001, 31, 81–110. [CrossRef]

27. Batchelor, A.W.; Chandrasekaran, M. Service Characteristics of Biomedical Materials and Implants, 1st ed.; Imperial College Press: London, UK, 2004.

28. Santambrogio, L. Biomaterials in Regenerative Medicine and the Immune System, 1st ed.; Springer Internatinal Publishing Switzeerland: Cham, Switzerland, 2015.

29. Acevedo, A. Mallas sintéticas Irreabsorbibles su desarrollo en la cirugía de las hernias abdominals. Revista Chilena Cirugía 2008, 60, 457–464. [CrossRef]

30. Tang, L.; Ugarova, T.P.; Plow, E.F.; Eaton, J.W. Molecular determinates of acute inflammatory response to biomaterials. J. Clin. Investig. 1996, 97, 1329–13234. [CrossRef] [PubMed]

31. Busuttil, S.J.; Ploplis, V.A.; Castellino, F.J.; Tang, L.; Eaton, J.W.; Plow, E.F. A central role for plasminogen in the inflammatory response to biomaterials. J. Thromb. Haemost. 2004, 2, 1798–1805. [CrossRef] [PubMed]

32. Earle, D.B.; Mark, L.A. Prosthetic Material in Inguinal Hernia Repair: How Do I Choose? Surg. Clin. N. Am. 2008, 88, 179–201. [CrossRef] [PubMed]

33. Schaechter, M. Encyclopedia of Microbiology, 3rd ed.; Academic Press: Cambridge, MA, USA, 2009.

34. Jacob, B.P.; Ramshaw, B. The SAGES Manual of Hernia Repair, 1st ed.; Springer: New York, NY, USA, 2013.

35. Ramshaw, B.; Bachman, S. Surgical materials for ventral hernia repair. Gen. Surg. News 2007, 34, 1–15.

36. Anderson, J.M.; Rodriguez, A.; Chang, D.T. Foreign Body Reaction to Biomaterials. Semin. Immunol. 2008, 20, 86–100. [CrossRef] [PubMed]

37. Chu, C.-C.; von Fraunhofer, J.A.; Greisler, H.P. Wound Closure Biomaterials and Devices, 1st ed.; CRC Press LLC: Boca Raton, FL, USA, 1997.

38. Brown, C.N.; Finch, J.G. Which mesh for hernia repair? Ann. R. Coll. Surg. Engl. 2010, 92, 272–278. [CrossRef] [PubMed]

39. Klinge, U.; Klosterhalfen, B.; Schumpelick, V. Foreign Body Reaction to Meshes of Used for the Repair of AbdominalWall Hernias. Eur. J. Surg. 1999, 165, 665–673. [PubMed]

40. Junge, K.; Klinge, U.; Prescher, A.; Giboni, P.; Niewiera, M.; Schumpelick, V. Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants. Hernia 2001, 5, 113–118. [CrossRef] [PubMed]

41. Pourdeyhimi, B.J. Porosity of surgical mesh fabrics: New technology. Biomed. Mater. Res. 1989, 23 (Suppl. A1), 145–152. [CrossRef]

42. Bilsel, Y.; Abci, I. The search for ideal hernia repair; mesh materials and types. Int. J. Surg. 2012, 10, 317–321. [CrossRef] [PubMed]

43. Winters, J.C.; Fitzgerald, M.P.; Barber, M.D. The use of systhetic mesh in female pelvic reconstructive surgery. BJU Int. 2006, 98, 70–76. [CrossRef] [PubMed]

44. Halm, J.A. Experimental and Clinical Approaches to Hernia Treatment and Prevention. Ph.D. Thesis, Erasmus University Rotterdam, Rotterdam, The Netherlands, October 2005.

45. Cortes, R.A.; Miranda, E.; Lee, H.; Gertner, M.E. Biomaterials and the evolution of hernia repair II: Composite meshes. In Surgery, 2nd ed.; Norton, J., Barie, P.S., Bollinger, R.R., Chang, A.E., Lowry, S., Mulvihill, S.J., Pass, H.I., Thompson, R.W., Eds.; Springer: New York, NY, USA, 2008; Volume 11, pp. 2305–2315.

46. Tamayol, A.; Akbari, M.; Annabi, N.; Paul, A.; Khademhosseini, A.; Juncker, D. Fiber-based tissue engineering: Progress, challenges, and opportunities. Biotechnol. Adv. 2013, 31, 669–687. [CrossRef] [PubMed]

47. Blair, T. Biomedical Textiles for Orthopaedic and Surgical Applications: Fundamentals, Applications and Tissue Engineering, 1st ed.;Woodhead Publishing: Cambridge, UK, 2015.

48. King, M.W.; Gupta, B.S.; Guidoin, R. Biotextiles as Medical Implants, 1st ed.;Woodhead Publishing: Cambridge, UK, 2013.

49. Listner, G. Polypropylene Monofilament Sutures. U.S. Patent 3630205 A, 28 December 1971.

50. Hutton, J.D.; Dumican, B.L. Braided Polyester Suture and Implantable Medical Device. U.S. Patent 6203564 B1, 20 March 2001.

51. Gore, R.W. Process for Producing Porous Products. U.S. Patent 3953566 A, 27 April 1976.

52. Pott, P.P.; Schwarz, M.L.R.; Gundling, R.; Nowak, K.; Hohenberger, P.; Roessner, E.D. Mechanical properties of mesh materials used for hernia repair and soft tissue augmentation. PLoS ONE 2012, 7. [CrossRef] [PubMed]

53. Lennard, D.J.; Menezes, E.V.; Lilenfeld, R. Pliabilized Polypropylene Surgical Filaments. U.S. Patent 4,911,165 A, 27 March 1990.

54. Laurencin, C.T.; Nair, L.S.; Bhattacharyya, S.; Allcock, H.R.; Bender, J.D.; Brown, P.W.; Greish, Y.E. Polymeric Nanofibers for Tissue Engineering and Drug Delivery. U.S. Patent 7235295 B2, 26 June 2007.

55. Zhukovsky, V.; Rovinskaya, L.; Vinokurova, T.; Zhukovskaya, I. The Development and Manufacture of Polymeric Endoprosthetic Meshes for the Surgery of Soft Tissues. Autex Res. J. 2002, 2, 204–209.

56. Rousseau, R.A.; Dougherty, R. Knitted Surgical Mesh. U.S. Patent 6638284 B1, 28 October 2003.

57. Schumpelick, V.; Nyhus, L. Meshes: Benefits and Risks, 1st ed.; Springer: Berling/Heidelberg, Germany, 2004.

58. Cobb, W.S.; Peindl, R.M.; Zerey, M.; Carbonell, A.M.; Heniford, B.T. Mesh terminology 101. Hernia 2009, 13, 1–6. [CrossRef] [PubMed]

59. Klosterhalfen, B.; Junge, K.; Klinge, U. The lightweight and large porous mesh concept for hernia repair. Expert Rev. Med. Devices 2005, 2, 1–15. [CrossRef] [PubMed]

60. Wang, X.; Han, C.; Hu, X.; Sun, H.; You, C.; Gao, C.; Haiyang, Y. Applications of knitted mesh fabrication techniques to scaffolds for tissue engineering and regenerative medicine. J. Mech. Behav. Biomed. Mater. 2011, 4, 922–932. [CrossRef] [PubMed]

61. Camp Tibbals, E., Jr.; Leinsing, K.R.; DeMarco, P.B. Flat-Bed Knitting Machine and Method of Knitting. U.S. Patent 6158250 A, 12 December 2000.

62. Dougherty, R.; Vishvaroop, A. Surgical Tricot. U.S. Patent DE60020350 T2, 11 May 2006.

63. Ting, H. A Study of Three DimensionalWarp Knits for Novel Applications as Tissue Engineering Scaffolds. Master Thesis, North Caroline State University, Raleigh, NC, USA, August 2011.

64. Spencer, D.J. Knitting Technology: A Comprehensive Handbook and Practical Guide to Modern Day Principles and Practices, 2nd ed.; Pergamon Press: Oxford, UK, 1983.

65. Deichmann, T.; Michaelis, I.; Junge, K.; Tur, M.; Michaeli, W.; Gries, T. Textile Composite Materials for Small Intestine Replacement. Autex Res. J. 2009, 9, 105–108.

66. Raz, S. Warp Knitting Production, 1st ed.; Melliand Textilberichte: Heidelberg, Germany, 1987.

67. Emans, P.J.; Schreinemacher, M.H.; Gijbels, M.J.; Beets, G.L.; Greve, J.W.; Koole, L.H.; Bouvy, N.D. Polypropylene Meshes to Prevent Abdominal Herniation: Can Stable Coatings Prevent Adhesions in the Long Term? Ann. Biomed. Eng. 2009, 37, 410–418. [CrossRef] [PubMed]

68. Van't Riet, M.; de Vos van Steenwijk, P.J.; Bonthuis, F.; Marquet, R.L.; Steyerberg, E.W.; Jeekel, J.; Bonjer, H.J. Prevention of Adhesion to Prosthetic Mesh: Comparison of Different Barriers Using an Incisional Hernia Model. Ann. Surg. 2003, 237, 123–128. [CrossRef]

69. Ebersole, G.C.; Buettmann, E.G.; MacEwan, M.R.; Tang, M.E.; Frisella, M.M.; Matthews, B.D.; Deeken, C.R. Development of novel electrospun absorbable polycaprolactone (PCL) scaffolds for hernia repair applications. Surg. Endosc. Other Interv. Tech. 2012, 26, 2717–2728. [CrossRef] [PubMed]

70. Xu, F.;Weng, B.; Gilkerson, R.; Materon, L.A.; Lozano, K. Development of tannic acid/chitosan/pullulan composite nanofibers from aqueous solution for potential applications as wound dressing. Carbohydr. Polym. 2015, 115, 16–24. [CrossRef] [PubMed]

71. Ciecha ´ nska, D.; Kazimierczak, J.; Wietecha, J.; Rom, M. Surface Biomodification of Surgical Meshes Intended for Hernia Repair. Fibres Text. East. Eur. 2012, 96, 107–114.

72. Karamuk, Z.E. Embroidered Textiles forMedical Applications: New Design Criteria with Respect to Structural Biocompatibility. Ph.D. Thesis, Swiss Federal Institute of Technology Zurich, Zurich, Switzerland, 2001.

73. Norton, J.A.; Barie, P.S.; Bollinger, R.R.; Chang, A.E.; Lowry, S.F.; Mulvihill, S.J.; Pass, H.I.; Thompson, R.W. Surgery, 2nd ed.; Springer: New York, NY, USA, 2008.

74. Yelimlie¸s, B.; Alponat, A.; Cubukçu, A.; Kuru, M.; Oz, S.; Erçin, C.; G.nüllü, N. Carboxymethylcellulose coated on visceral face of polypropylene mesh prevents adhesion without impairing wound healing in incisional hernia model in rats. Hernia 2003, 7, 130–133. [CrossRef] [PubMed]

75. Franklin, M.E.; Voeller, G.; Matthews, B.D.; Earle, D.B. The Benefits of Omega-3 Fatty Acid-Coated Mesh in Ventral Hernia Repair. Spec. Rep. 2010, 37, 1–8.

76. Gao, Y.; Liu, L.J.; Blatnik, J.A.; Krpata, D.M.; Anderson, J.M.; Criss, C.N.; Posielski, N.; Novitsky, Y.W. Methodology of fibroblast and mesenchymal stem cell coating of surgical meshes: A pilot analysis. J. Biomed. Mater. Res. B. Appl. Biomater. 2014, 10, 797–805. [CrossRef] [PubMed]

77. Kidoaki, S.; Kwon, I.K.; Matsuda, T. Mesoscopic spatial designs of nano- and microfiber meshes for tissue-engineering matrix and scaffold based on newly devised multilayering and mixing electrospinning techniques. Biomaterials 2005, 26, 37–46. [CrossRef] [PubMed]

78. Lamber, B.; Grossi, J.V.; Manna, B.B.; Montes, J.H.; Bigolin, A.V.; Cavazzola, L.T. May polyester with collagen coating mesh decrease the rate of intraperitoneal adhesions in incisional hernia repair? Arq. Bras. Cir. Dig. 2013, 26, 13–17. [CrossRef] [PubMed]

79. Van't Riet, M.; Burger, J.W.; Bonthuis, F.; Jeekel, J.; Bonjer, H.J. Prevention of adhesion formation to polypropylene mesh by collagen coating: A randomized controlled study in a rat model of ventral hernia repair. Surg. Endosc. 2004, 18, 681–685. [CrossRef] [PubMed]

80. Niekraszewicz, A.; Kucharska, M.;Wawro, D.; Struszczyk, M.H.; Kopias, K.; Rogaczewska, A. Development of aManufacturingMethod for SurgicalMeshesModified by Chitosan. Fibres Text. East. Eur. 2007, 15, 105–109.

81. Cohen, M.S.; Stern, J.M.; Vanni, A.J.; Kelley, R.S.; Baumgart, E.; Field, D.; Libertino, J.A.; Summerhayes, I.C. In Vitro Analysis of a Nanocrystalline Silver-Coated Surgical Mesh. Surg. Infect. (Larchmt) 2007, 8, 397–404. [CrossRef] [PubMed]

82. Junge, K.; Rosch, R.; Klinge, U.; Saklak, M.; Klosterhalfen, B.; Peiper, C.; Schumpelick, V. Titanium coating of a polypropylene mesh for hernia repair: Effect on biocompatibility. Hernia 2005, 9, 115–119. [CrossRef] [PubMed]

83. Scheidbach, H.; Tannapfel, A.; Schmidt, U.; Lippert, H.; Köckerling, F. Influence of Titanium Coating on the Biocompatibility of a Heavyweight PolypropyleneMesh. Eur. Surg. Res. 2004, 36, 313–317. [CrossRef] [PubMed]

84. Niekraszewicz, A.; Kucharska, M.; Wawro, D.; Struszczyk, M.H.; Rogaczewska, A. Partially Resorbable Hernia Meshes. Prog. Chem. Appl. Chitin Its Deriv. 2007, 12, 109–114.

85. Niekraszewicz, A.; Kucharska, M.; Struszczyk, M.H.; Rogaczewska, A.; Struszczyk, K. Investigation into Biological, Composite Surgical Meshes. Fibres Text. East. Eur. 2008, 16, 117–121.

86. Pascual, G.; Sotomayor, S.; Rodríguez, M.; Bayon, Y.; Bellón, J.M. Behaviour of a New Composite Mesh for the Repair of Full-Thickness Abdominal Wall Defects in a Rabbit Model. PLoS ONE 2013, 8, 1–16. [CrossRef] [PubMed]

87. Plencner, M.; East, B.; Tonar, Z.; Otáhal, M.; Prosecká, E.; Rampichová, M.; Krejˇcí, T.; Litvinec, A.; Buzgo, M.; Míˇcková, A.; Neˇcas, A.; et al. Abdominal

closure reinforcement by using polypropylene mesh functionalized with poly-ε-caprolactone nanofibers and growth factors for prevention of incisional hernia formation. Int. J. Nanomed. 2014, 9, 3263–3277. [CrossRef] [PubMed]

88. Alves da Silva, M.L.; Martins, A.; Costa-Pinto, A.R.; Costa, P.; Faria, S.; Gomes, M.; Reis, R.L.; Neves, N.M. Cartilage Tissue Engineering using electrospun PCL nanofiber meshes and MSCs. Biomacromolecules 2010, 11, 3228–3236. [CrossRef] [PubMed]

89. Popat, K. Nanotechnology in Tissue Engineering and Regenerative Medicine, 1st ed.; CRC Press: Boca Raton, FL, USA, 2010.

90. Vasita, R.; Katti, D.S. Nanofibers and their applications in tissue engineering. Int. J. Nanomedicine 2006, 1, 15–30. [CrossRef] [PubMed]

91. Dorband, G.C.; Liland, A.; Menezes, E.; Steinheuser, P.; Popadiuk, N.M.; Failla, S.J. Surgical Fastening Device and Method for Manufacture. U.S. Patent 4,671,280 A, 9 June 1987.

92. Brown, P.; Stevens, K. Nanofibers and Nanotechnology in Textiles, 1st ed.; CRC Press: Boca Raton, FL, USA, 2007.

93. Watanabe, K.; Kim, B.S.; Kim, I.S. Development of Polypropylene Nanofiber Production System. Polym. Rev. 2011, 51, 288–308. [CrossRef]

94. Watanabe, K.; Nakamura, T.; Kim, B.S.; Kim, I.S. Effect of organic solvent on morphology and mechanical properties of electrospun syndiotactic polypropylene nanofibers. Polym. Bull 2011, 67, 2025–2033. [CrossRef]

95. Huang, Z.-M.; Zhang, Y.Z.; Kotaki, M.; Ramakrishna, S. A review on polymer nanofibers by electrospinning and their applications in nanocomposites. Compos. Sci. Technol. 2003, 63, 2223–2253. [CrossRef]

96. Padron, S.; Fuentes, A.; Caruntu, D.; Lozano, K. Experimental study of nanofiber production through forcespinning. J. Appl. Phys. 2013, 113. [CrossRef]

97. Yarlagadda, P.; Chandrasekharan, M.; Shyan, J.Y. Recent Advances and Current Developments in Tissue Scaffolding. Biomed. Mater. 2005, 15, 159–177.

98. Plencner, M.; Prosecká, E.; Rampichová, M.; East, B.; Buzgo, M.; Vysloužilová, L.; Hoch, J.; Amler, E. Significant improvement of biocompatibility of polypropylene mesh for incisional hernia repair by using poly-ε-caprolactone nanofibers functionalized with thrombocyte-rich solution. Int. J. Nanomedicine 2015, 10, 2635–2646. [CrossRef] [PubMed]

99. Chakroff, J.; Kayuha, D.; Henderson, M.; Johnson, J. Development and Characterization of Novel Electrospun Meshes for Hernia Repair. Int. J. Nanomedicine 2015, 2, 1–9. [CrossRef]

100. Veleirinho, B.; Coelho, D.S.; Dias, P.F.; Maraschin, M.; Pinto, R.; Cargnin-Ferreira, E.; Peixoto, A.; Souza, J.A.; Ribeiro-do-Valle, R.M.; Lopes-da-Silva, J.A. Foreign Body Reaction Associated with PET and PET/Chitosan Electrospun Nanofibrous Abdominal Meshes. PLoS ONE 2014, 9, 1–10. [CrossRef] [PubMed]

101. Zhao, W.; Ju, Y.M.; Christ, G.; Atala, A.; Yoo, J.J.; Lee, S.J. Diaphragmatic muscle reconstruction with an aligned electrospun poly("-caprolactone)/collagen hybrid scaffold. Biomaterials 2013, 34, 8235–8240. [CrossRef] [PubMed]

102. Xu, F.; Weng, B.; Materon, L.A.; Gilkerson, R.; Lozano, K. Large-scale production of ternary composite nanofiber membrane for wound dressing applications. J. Bioact. Compat. Polym. Biomed. Appl. 2014, 29, 646–660. [CrossRef]

103. Sanbhal, N.; Miao, L.; Xu, R.; Khatri, A.;Wang, L. Physical structure and mechanical properties of knitted hernia mesh materials: A review. J. Ind. Text. 2017. [CrossRef]

104. Guillaume, O.; Teuschl, A.H.; Gruber-Blum, S.; Fortelny, R.H.; Redl, H.; Petter-Puchner, A. Emerging trends in abdominal wall reinforcement: Bringing bio-functionality to meshes. Adv. Healthc. Mater. 2015, 4, 1763–1789. [CrossRef] [PubMed]

105. Todros, S.; Pavan, P.G.; Natali, A.N. Synthetic surgical meshes used in abdominal wall surgery: Part I—Materials and structural conformation. J. Biomed. Mater. Res. Part B: Appl. Biomater. 2017, 105, 689–699. [CrossRef] [PubMed]

106. Todros, S.; Pavan, P.G.; Pachera, P.; Natali, A.N. Synthetic surgical meshes used in abdominal wall surgery: Part II—Biomechanical aspects. J. Biomed. Mater. Res. Part B: Appl. Biomater. 2017, 105, 892–903. [CrossRef] [PubMed]

III. STRESS-SOFTENING AND RESIDUAL STRAIN EFFECTS IN SUTURE MATERIALS

PUBLISHED AS: Elías-Zúñiga, A.; Montoya, B.; Ortega-Lara, W.; Flores-Villalba, E.; Rodriguez, C.A.; Siller, H. R.; Díaz-Elizondo, J. A.; Martinez-Romero, O., “Stress-Softening and Residual Strain Effects in Suture Materials” Advances in Materials Science and Engineering, vol 2013

III.1. ABSTRACT

This work focuses on the experimental characterization of suture material samples of MonoPlus, Monosyn, polyglycolic acid, polydioxanone 2–0, polydioxanone 4–0, poly(glycolide-co-epsilon-caprolactone), nylon, and polypropylene when subjected to cyclic loading and unloading conditions. It is found that all tested suture materials exhibit stress-softening and residual strain effects related to the microstructural material damage upon deformation from the natural, undistorted state of the virgin suture material. To predict experimental observations, a new constitutive material model that takes into account stress-softening and residual strain effects is developed. The basis of this model is the inclusion of a phenomenological nonmonotonous softening function that depends on the strain intensity between loading and unloading cycles. The theory is illustrated by modifying the non-Gaussian average-stretch, full-network model to capture stress-softening and residual strains by using pseudoelasticity concepts. It is shown that results obtained from theoretical simulations compare well with suture material experimental data.

III.2. INTRODUCTION

Technical advances in the field of surgery have exponentially grown during the last few years. Progressive research, better understanding of the physiopathological processes behind every procedure, more experienced surgeons, and the increasing interest of biomedical companies in developing new products have made possible the excellent results seen in surgery nowadays.

Sutures have remained for many decades a cornerstone for most surgical procedures. Wound closure, vascular and intestinal anastomosis, structures fixation, bleeding control, and tissue approximation are only a few examples from the many uses sutures are given; however, there is no perfect suture for all purposes, and the enormous variables involved in the cicatrization process make this task a difficult one to achieve.

The ideal suture should have certain characteristics that will abet the therapeutic course; it is supposed to have an adequate tensile strength in each phase of the healing process, should be surgeon friendly, induce minimal or no tissue reaction, and must not stimulate infection. Also it should be biologically inert and should be able to have a suitable response to edema and tolerate the different environments within the human body. Since there is no such a product available at present, it is essential to comprehend not only the biological responses to the materials but also understand the precise behavior of each suture in order to decide on the best and most efficient way to take advantage of each particular property of any given suture [1]. Nichols et al. cautioned surgeons about the handling of sutures by surgical instruments since this could result in premature suture failure [2].They indicated that their rough handling and the usage of clamps and forceps could damage and weaken these.

Therefore, learning the biomechanical performance of sutures will help surgeons not only to determine the appropriate clinical applicationfor each type but alsotoimprove surgical techniques to take advantage of each suture properties [3].

Some of the most important characteristics of a suture regarding its mechanical material properties are related to softening and permanent set effects which appear when sutures are subjected to cyclic load, and, thus, the normal stress versus stretch curve shows a reduction on the stress magnitude during the unloading process [4–13]. This stress-softening effect known as the Mullins effect becomes clinically relevant because initial characteristics exhibited by a suture material immediately after it has been manufactured could change dramatically when stress is applied during the suturing and healing processes [2]. Understanding the material response behavior of suturematerials could help surgeons in the selection of the most appropriate suture material.

The aim of this work is to characterize the stress-softening and residual strain effects in suture materials such as polyglycolic acid, polydioxanone, nylon, and polypropylene commonly used in surgical procedures when subjected to loading and unloading cycles by developing a phenomenological nonmonotonous stress-softening hyperelastic material model that depends on the amount of strain [14] and permanent set effects [15].

We have organized this chapter as follows. In Section III.3, we provide detail of the uniaxial experimental tests performed on suture materials. A brief review of the required equations to describe finite deformations of an incompressible elastic material is introduced in Section III.4. In Section III.5, we have characterized the experimental data by assuming a nonmonotonous damage softening function and by modifying the Holzapfel et al. constitutive equation to include residual strain effects [15]. Also, we have developed the corresponding stress-stretch constitutive equations by using the non-Gaussian average-stretch, full-network model of arbitrarily oriented molecular chains [16]. A comparison of the results corresponding to simulated and experimental data is done in Section III.6. Finally, in Section III.7, we address some conclusions related to our experimental observations and theoretical predictions of suture materials.

III.3. EXPERIMENTAL WORK

III.3.1. Suture Materials

Eight batches of two suture commercial manufactures were selected to be tested in uniaxial deformation. The absorbable sutures materials tested were Mono-Plus, Monosyn, polyglycolic acid, polydioxanone, polydioxanone 4–0, poly(glycolide-co-epsilon-caprolactone) (PGC25 3–0); the nonabsorbable suture materials were nylon and polypropylene. The mean diameter values used to characterize the suture samples were taken from suppliers specifications. The mean values considered here were 0.397mm for MonoPlus and Monosyn sutures, 0.334mm for polyglycolic acid 2–0, 0.377mm for polydioxanone 2–0, 0.23mm for polydioxanone 4–0, 0.29mm for PGC25 3–0, 0.247mm for nylon, and 0.241mm for polypropylene.

III.3.2. Uniaxial Tensile Tests

The experimental tests were performed in two electromechanical universal testing machines. The suture materials identified as MonoPlus, Monosyn, polyglycolic acid 2–0, polydioxanone 2–0, nylon, and polypropylene were tested in an MTS Insight 2 tensile machine with a maximum cell load capacity of 2.5 kN while the suture materials of polydioxanone 4–0 and PGC25 3–0 were tested in an Instron tensile machine Model 3365 with a maximum cell load capacity of 1.6 kN. The selected samples length between machine grips was 50 mm. All tests were run at the machine speed of 500 mm/min at the average room temperature value of 24◦ C. All samples were subjected to cyclic loading-unloading conditions to obtain softening and permanent set effects as shown in Figure 3. Figure 3 illustrates that when the suture material is loaded from its virgin state, unloaded, and then reloaded again, its stress magnitude becomes smaller than the stress magnitude at the same amount of stretch during virgin loading.This reduction in the stress magnitude is known as the Mullins effect [4, 5]. This softening effect becomes associated with residual strain or permanent set effects which implies that the initial length of the suture sample has increased during the application of the tensile load. Table 11 illustrates the

experimental average value of residual strain measured in each suture batch. Notice that suture materials response behavior agrees with Nichols et al. qualitative observation on sutures materials [2]. However, to describe quantitatively the stress-softened and permanent set effects observed on suture materials, a material model must be used. Therefore, to understand the physical relationships behind a material model, we first briefly review some basic knowledge on finite deformations, and, then, we shall derive a material model that is based on non-Gaussian statistical mechanics.

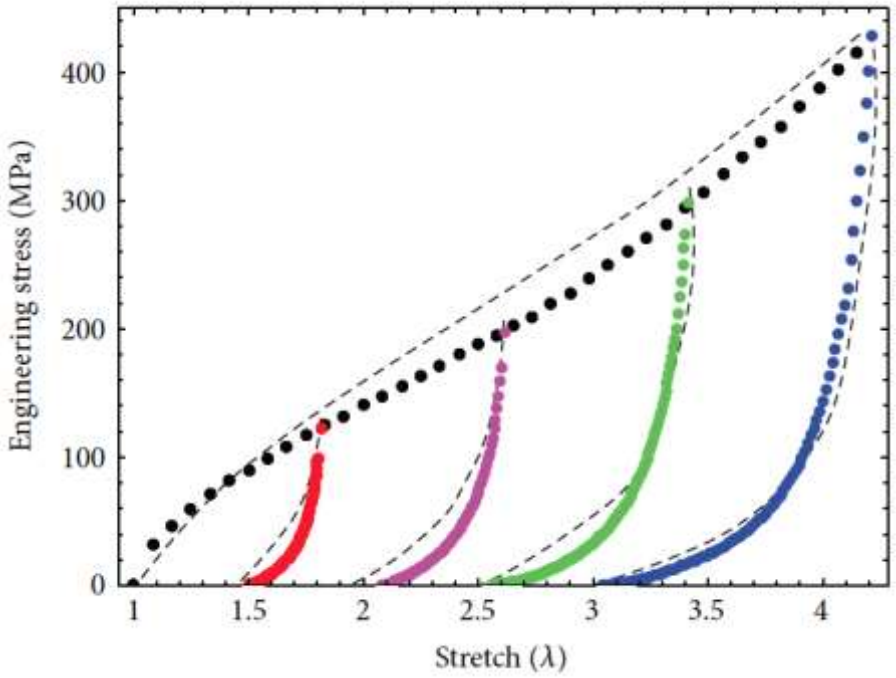


Figure 3. *Experimental data collected from uniaxial tension cyclic loading unloading tests for Monosyn sutures.*

Table 11. Comparison between experimental and predicted residual strain deformations of the selected suture materials.

Suture material	Maximum previous stretch λ_{max}	Experimental residual strain	Predicted residual strain	Error (%)
MonoPlus	2.09363	1.6027	1.498	6.5327
	3.1709	2.3103	2.056	6.9809
	4.2483	2.7361	2.646	3.2930
	5.3309	3.3038	3.234	2.1127
Monosyn	1.8165	1.4996	1.464	2.3739
	2.6165	2.0828	1.962	5.7998
	3.4165	2.5559	2.484	2.8131
	4.2165	3.0550	3.007	1.5711
Polyglycolic acid 2-0	1.22	1.100	1.125	2.2727
	1.44	1.230	1.251	1.7070
	1.66	1.380	1.381	0.0724
	1.88	1.537	1.515	1.4313
Polydioxanone 2-0	1.5	1.200	1.277	6.4166
	2.0	1.512	1.566	3.5714
	2.5	1.815	1.862	3.5895
	3	2.167	2.154	0.5999
Polydioxanone 4-0	1.2	1.051	1.051	0.7347
	1.4	1.101	1.099	1.3187
	1.6	1.149	1.147	0.7879
	1.8	1.194	1.198	0.1115
Poly(glycolide-coepsiloncaprolactone) (PGC25 3-0)	1.3	1.123	1.104	1.7270
	1.6	1.216	1.206	0.8818
	1.9	1.307	1.306	0.0238
	2.20	1.403	1.407	0.2851
Nylon	1.48	1.109	1.235	11.36
	1.96	1.366	1.481	8.4187
	2.44	1.67	1.744	4.4311
	2.92	2.011	2.019	0.3978
Polypropylene	1.4	1.154	1.197	3.72
	1.8	1.361	1.4	2.8655
	2.2	1.564	1.615	3.2608
	2.6	1.855	1.842	0.7008

III.4. BASIC CONCEPTS ON FINITE DEFORMATIONS

We consider the deformation of an incompressible elastic body, which in its natural configuration occupies the region Ω. A material particle is considered to be in its undeformed reference configuration of a body at the place X = X_ke$_k$. After a prescribed deformation the body occupies the region Ω$_c$, the current configuration, and the particle at X moves to the place X = X_ke$_k$ in a common rectangular Cartesian frame φ = {O; e$_k$} with origin O and orthonormal basis e$_k$. Thus, the Cauchy-Green deformation tensor B ≡ FF^T has the form

$$\mathrm{B} = \lambda^2_1\, \mathrm{e}_{11} + \lambda^2_2\, \mathrm{e}_{22} + \lambda^2_3\, \mathrm{e}_{33}, \qquad (1)$$

where e$_{jk}$ ≡ e$_j$ ⊗ e$_k$, e$_i$ are the associated orthonormal principal directions, F is the deformation gradient, and λ_i denote the principal stretches in φ. Note that the magnitude of the strain intensity at a material point X denoted by m is defined by $m \equiv \sqrt{B \cdot B} = \sqrt{\mathrm{tr}\, B^2}$, where tr is the trace operation. In the undeformed state B = 1, the identity tensor and $m = \sqrt{3}$; otherwise, $m > \sqrt{3}$ for all isochoric deformations [8]. Also $m \geq \sqrt{3}$ for all λ, the equality holding when and only when λ = 1, the undeformed state. Recalling that the principal invariants I_k of B are defined by

$$I_1 = \mathrm{tr\ B}, \qquad I_2 = \tfrac{1}{2}[I_1^2 - \mathrm{tr}(B^2)], \qquad I_3 = \det \mathrm{B}, \qquad (2)$$

thus, the magnitude of the strain intensity m is given as

$$m = \sqrt{I_1^2 - 2I_2}. \qquad (3)$$

III.5. A NONMONOTONOUS STRESS-SOFTENING MATERIAL MODEL

To characterize stress-softening effects, there exist in the literature many different micromechanical models have been developed to explain material damage mechanisms. See, for instance, the papers of Govindjee and Simo [6], Ogden and Roxburgh [7], Beatty and Krishnaswamy [8], Elías-Zúñiga and Beatty [9], Elías-Zúñiga [11], Diani et al. [12], de Tommasi et al. [13], Holzapfel et al. [15], Johnson and Beatty [17], de Souza Neto et al. [18], Marckmann et al. [19], Dorfmann and Ogden [20], Kazakeviciute-Makovska and Kacianauskas [21], and references cited therein for an overview of the main features of these models.

In this section, we derive the corresponding equations that describe the non-monotonic behavior of suture biocompatible materials subjected to loading and unloading cycles by assuming that the stress-softened material behavior can be obtained from the virgin material response constitutive equation. Here, we assume an incompressible and isotropic virgin elastic material whose corresponding time independent Cauchy stress constitutive equation has the form

$$\mathrm{T} = -p\mathrm{1} + \aleph_1 (I_1, I_2)\, \mathrm{B} + \aleph_{-1} (I_1, I_2)\, \mathrm{B}^{-1}, \qquad (4)$$

in which T is the Cauchy stress, p is an undetermined pressure, and $\aleph_\Gamma = \aleph_\Gamma(I_1, I_2)$, $\Gamma = 1, -1$, denote the virgin material response functions related to the strain energy function $W = \widehat{W}(I_1, I_2)$, per unit reference volume, in accordance with

$$\aleph_1 = 2W_1, \qquad \aleph_{-1} = -2W_2, \qquad (5)$$

wherein $W_\alpha \equiv \partial\widehat{W}/\partial I_\alpha$ [16]. By using (4), Elías-Zúñiga and Beatty in [9] proposed a damage type model to describe the stress-softened material behavior of the form

$$\tau = F(m;M)\, \mathrm{T}, \qquad (6)$$

in which τ denotes the Cauchy stress in the stress-softened material, M denotes the maximum previous strain at which the material is unloaded from the primary path,

and $F(m;\ M)$ is an isotropic softening function at the damage level $m_{\max} = M$ on the interval $m \in [\sqrt{3},\ M]$ .They assumed that this softening function $F(m;\ M)$ is a monotone increasing function of the strain intensity that satisfies the conditions

$$0 < F(m;M) < 1, \qquad F(M;M) = 1. \tag{7}$$

Based on this assumption, Elías-Zúñiga and Beatty proposed the following softening function:

$$F\ (m;M) = e^{-b\sqrt{(M-m)}}, \tag{8}$$

where b is a dimensionless positive material-softening parameter. After substituting (8) into (6), Elías-Zúñiga and Beatty obtained the following stress-softened phenomenological material model:

$$\tau = e^{-b\sqrt{(M-m)}}T. \tag{9}$$

Theoretical predictions provided by (9) were computed in Elías-Zúñiga and Beatty [9] and Elías-Zúñiga and Beatty [10] and compared to experimental data for uniaxial extension, pure shear, and equibiaxial deformation states. There, the theoretical predictions showed reasonably good agreement with experimental data not only for the virgin loading path but also for the reloading paths. However, Kazakeviciute-Makovska [22] observed that the experimental data when plotted as the normalized stress τ/T versus the stretch ratio $\lambda/\lambda_{\max}$ showed nonmonotonous behavior with the characteristic S-shaped form, and $\lambda_{\max}$ defines the maximum amount of stretch on the primary loading path corresponding to the value at which the unloading starts in a particular deformation cycle. Kazakeviciute-Makovska concluded that, because of the variations in shapes of the curves for different deformation cycles, different values of the softening parameters were needed to fit experimental data for a particular choice of the softening function. Moreover, Kazakeviciute-Makovska showed that the softening function given by (8) fails in predicting the nonmonotonous behavior exhibited by experimental data collected by Mullins and Tobin [5], Cheng and Chen [23], and Mars and Fatemi [24] at higher stretch values.

On the other hand, de Tommasi and coworkers showed the importance of microscopic inhomogeneity to describe known experimental effects observed in amorphous materials such as the transition from diffuse to localized damage as the distribution properties are varied [25]. In fact, they showed that the monotone stress-stretch loading curve behavior is mainly due to a diffuse damage mechanism. They also considered that amorphous materials may be characterized by unstable strain domain, which gives the possibility of having homogeneous or localized damage with nonmonotone primary loading curve.

To confirm these observations, Elías-Zúñiga and Rodríguez in [14] used the nonmonotonous stress-softening function

$$F\,(m;\,M) = e^{-b[(M-m)(m/M)^{\gamma}]^{\alpha}}, \tag{10}$$

where b is a positive softening material parameter and α and γ are positive scaling constants chosen to best fit experimental data. They chose the values of α = 1/2 and γ = 1 for the scaling constants and fit the value of the softening parameter b according to the unloading experimental data of the unloading path at which the amount of stretch has the maximum value. Then, they used the equation

$$\tau = \mathrm{T}e^{-b[(M-m)(m/M)]^{1/2}}, \tag{11}$$

to predict the corresponding stress-softened values during the inflation and deflation of rubber balloons.

To account permanent set effects during the material unloading processes, Elías-Zúñiga and Rodríguez [14] modified Holzapfel et al. model [15] and proposed an energy model based on pseudoelastic theory of the form:

$$W_s = W(\lambda_1,\lambda_2,\lambda_3) + \frac{\mu}{C}\sum_{a=1}^{3}\left[\frac{1}{2}(\lambda_{\max\,a}^{n} - \lambda_a^n)^2 - Cd_0\right], \tag{12}$$

where $W(\lambda_1, \lambda_2, \lambda_3)$ represents the strain energy function associated with the primary loading path, μ is the material shear modulus, C is a positive dimensionless material

constant, d_0 is an integration constant, n is a fitting parameter that in general takes the value of 1/2, λ_a represents the principal stretches, and $\lambda_{\max a}$, a = 1, 2, 3, are the maximum values of the principal stretches at which unloading begins on the primary loading path.

Here, we use the softening function given by (10) and assume that $W(\lambda_1, \lambda_2, \lambda_3)$ is provided by the non-Gaussian Arruda-Boyce constitutive equation for an average-stretch, full-network of arbitrarily oriented molecular chains to predict softening and residual strain effects on suture materials.

III.5.1 A Nonmonotonous Amended Averaged Stretch Material Model.

For this material model, it is well known that the strain energy per unit volume for the loading path is given by

$$W(\lambda_1, \lambda_2, \lambda_3) = \mu\left[N_8\left(\beta\lambda_r + \ln\left(\frac{\beta}{\sinh\beta}\right)\right) - \ln\left(\frac{\beta}{\lambda_r}\right)\right] - C_8, \tag{13}$$

where λ_r is the relative chain stretch defined by

$$\lambda_r = \frac{\lambda_{\text{chain}}}{\lambda_L}, \tag{14}$$

$\lambda_L = \sqrt{N_8}$ represents the fully extended chain stretch, N_8 is the chain number of rigid links, each of length l, λ_{chain} is the chain deformation that in the affine deformation is determined by

$$\lambda_{\text{chain}} \equiv \sqrt{\frac{I_1}{3}}, \tag{15}$$

β defined by $\beta \equiv \mathcal{L}^{-1}(\lambda_r)$ is the inverse of the Langevin function $\mathcal{L}(\beta)$ which is defined as

$$\lambda_r = \mathcal{L}(\beta) \equiv \coth\beta - \frac{1}{\beta}, \tag{16}$$

and c_8 is a constant that ensures that the strain energy density vanishes in the undeformed state [16, 26]. Substitution of (13) into (12) provides the modified non-Gaussian pseudo strain energy per unit volume that accounts for residual strains on the unloading path; that is,

$$W_s = \mu\left[N_8\left(\beta\lambda_r + \ln\left(\frac{\beta}{\sinh\beta}\right)\right) - \ln\left(\frac{\beta}{\lambda_r}\right)\right] + \frac{\mu}{C}\sum_{a=1}^{3}\left[\frac{1}{2}(\lambda_{\max\, a}^{n} - \lambda_a^n)^2\right] + D, \qquad (17)$$

where D is an energy constant.

The Cauchy stress-stretch averaging network model components for the virgin material are obtained by substituting (13) into (4):

$$T_k = -p + \aleph(I_1)\lambda_k^2, \qquad (18)$$

where $\aleph(I_1)$ is a material response function given as

$$\aleph(I_1) \equiv \frac{\mu}{3\lambda_r}\left[\beta + \frac{1}{N_8}\left(\frac{1}{\lambda_r} - \frac{1}{\beta(1-\lambda_r^2-2\lambda_r/\beta)}\right)\right]. \qquad (19)$$

Eliminating the pressure from (18) gives

$$T_j - T_k = -p + \aleph(I_1)\left(\lambda_j^2 - \lambda_k^2\right), \qquad (20)$$

where $j \neq k$ = 1, 2, 3 (no sum). Similarly, the Cauchy stress-stretch

constitutive equation for a stress-softened material can be obtained by substituting (17) into (4) and by using (5) and (11) yields the following stress-softened components:

$$\tau_k = \left[-p + \aleph(I_1)\lambda_k^2 + \frac{\mu\lambda_k}{2C} f_k(\lambda_1, \lambda_2, \lambda_3)\right] \times e^{-b\sqrt{(M-m)(m/M)}},\ k = 1,2,3(\text{nosum}), \qquad (21)$$

where

$$f_k(\lambda_1, \lambda_2, \lambda_3) = \frac{\partial \sum_{a=1}^{3}(\lambda_{\max\, a}^{n} - \lambda_a^n)^2}{\partial \lambda_k}, \qquad (22)$$

Then, on elimination of p from (21), it yields

$$\tau_j - \tau_k = \left[\begin{matrix}\aleph(I_1)\left(\lambda_j^2 - \lambda_k^2\right) \\ +\frac{\mu}{2C}\left(\lambda_j f_j(\lambda_1,\lambda_2,\lambda_3) - \lambda_k f_k(\lambda_1,\lambda_2,\lambda_3)\right)\end{matrix}\right] \times e^{-b\sqrt{(M-m)(m/M)}}, \qquad (23)$$

where, in general, $j \neq k$ = 1, 2, 3 (no sum).

Recalling that, for an incompressible material, the engineering stress σ is related to the Cauchy stress by

$$\sigma = \mathrm{TF}^{-1}, \qquad (24)$$

then, the uniaxial engineering stress-stretch relation for an average-stretch, full-network stress-softened material model is obtained by using (22), (23), and (24):

$$\begin{aligned}\sigma_s = [&\aleph(I_1)(\lambda - \lambda^{-2}) \\ &+\frac{\mu}{C}\left(-n\lambda^{(n-1)}(\lambda_{\max}^n - \lambda^n)\right. \\ &\left.+ n\lambda^{-(1+n/2)}\left(\lambda_{\max}^{-n/2} - \lambda^{-n/2}\right)\right)] \times e^{-b\sqrt{(M-m)(m/M)}},\end{aligned} \qquad (25)$$

Here,

$$m = \sqrt{\lambda^4 + 2\lambda^{-2}}, \qquad (26)$$

and the relative chain stretch which can be obtained from (14) and (15) is given as

$$\lambda_r \equiv \sqrt{\frac{1}{3N_8}(\lambda^2 + 2\lambda^{-1})}. \qquad (27)$$

Of course, other material models may be modified by using (10) and our derived pseudo strain energy per unit volume given by (12) to account for a nonmonotonous stress-softened behavior as well as permanent set effects, respectively.

We next examine the degree of accuracy attained by our proposed material model in predicting experimental data of biocompatible suture materials.

III.6. COMPARISON WITH SUTURE EXPERIMENTAL DATA

To assess the accuracy of the derived constitutive (25) which includes residual strains and has a nonmonotonous stress softening function that describes Mullins effect, we used the experimental data collected during uniaxial extension test of the aforementioned suture material samples. Notice from (25) that only four constitutive material constants and one fitting parameter need to be computed, that is, the shear modulus μ, the chain number of links N, the stress softening parameter b, the residual strain material constant C, and the fitting parameter n. However, we have found that in general the value of n = 1 for the uniaxial stress-softened material model described by (25) provides good fit to the collected experimental data.

We begin with the stress-stretch data for suture samples of MonoPlus and Monosyn materials. Figures 4 and 5 illustrate the predicted engineering stress response curves obtained from (24) and (25). We can see from Figures 4 and 5 that theoretical results are in good agreement with experimental data for the several loading and unloading cycles that exhibit residual strains. The constitutive material constants used to best fit experimental data are μ = 100 MPa, N = 20, b = 0.45, and C = 0.0065 MPa for MonoPlus sutures and μ = 92 MPa, N = 20, b = 0.85, and C=0.0045 MPa for Monosyn material. The amount of error attained between experimental and predicted residual strains is shown in Table 11. From Figures 4 and 5 and Table 11, it is concluded that Monosyn sutures tend to soften and have bigger residual strains than MonoPlus sutures. In all figures, the dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

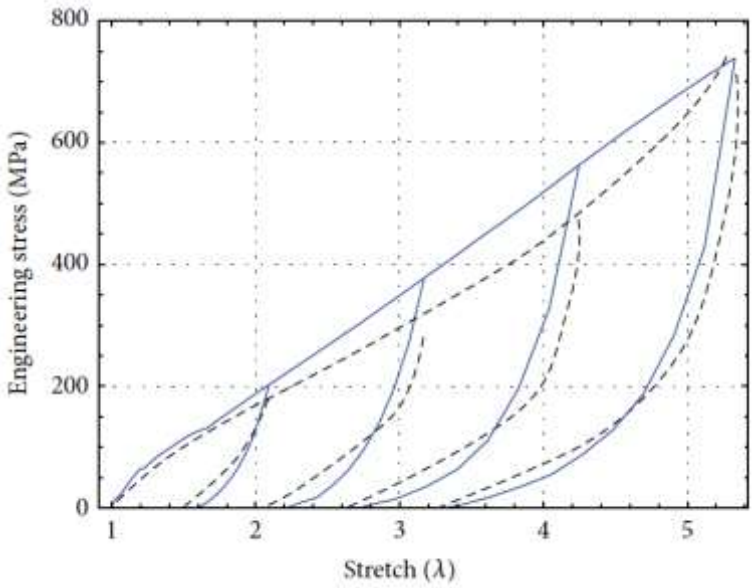


Figure 4. *Engineering stress-stretch data for MonoPlus sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 100MPa, N = 20, b = 0.45, and C = 0.0065MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.*

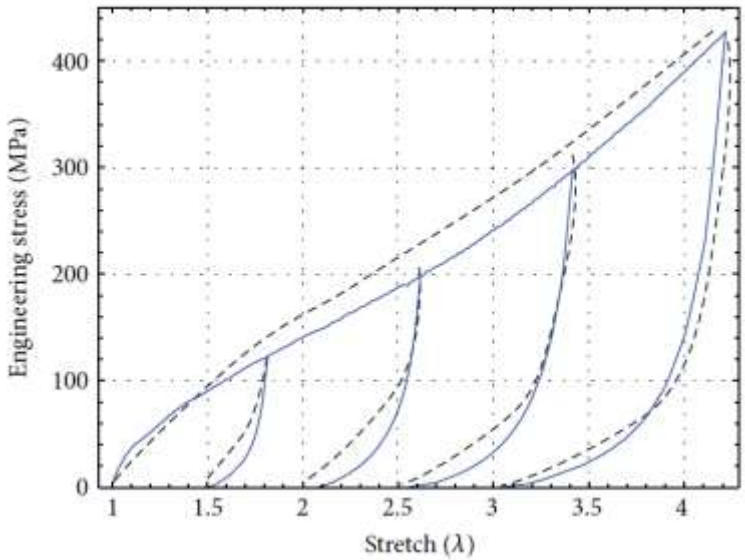


Figure 5. *Engineering stress-stretch data for Monosyn sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 92MPa, N = 20, b = 0.85, and C = 0.0045MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.*

Figures 6 through 9 illustrate the stress-stretch curves collected from polyglycolic acid, polydioxanone, polydioxanone 4.0, and poly(glycolide-co-epsilon-caprolactone) (PGC25 3–0) suture material samples, respectively. We can see from Figures 6, 7, 8, and 9 that the predicted response stress-stretch curves computed from (25) stand in good agreement with experimental data for the several loading and unloading cycles. In these figures, the blue lines represent the experimental collected data, and the dashed black lines represent theoretical results obtained from (24) and (25). The material constants used in the material model are provided by a best fit analysis and these are listed in the figure captions. It is clear from Figures 6–9 that each suture material exhibits different qualitative and quantitative response material behavior. In fact, the amount of softening on the polyglycolic acid 2–0 and polydioxanone 2–0 suture materials is bigger than those of polydioxanone 4.0 and PGC25 3–0.

Finally, Figures 10 and 11 show the stress-stretch curves of the nonabsorbable nylon and polypropylene suture materials. Although the polypropylene sutures are stiffer than the nylon ones, the amount of strength and residual strain are quite similar. Both sutures material experienced stress-softened and permanent set that must be taken into account during suture manipulation to prevent damaging and weakening undesirable effects.

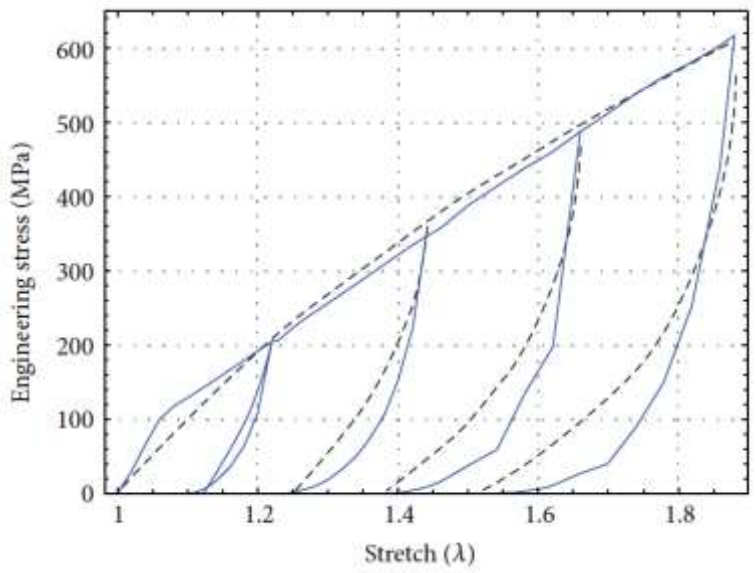


Figure 6. *Engineering stress-stretch data for polyglycolic acid sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 385MPa, $\mathcal{N}$ = 70.5, b = 1.3, and $\mathcal{C}$ = 0.001MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.*

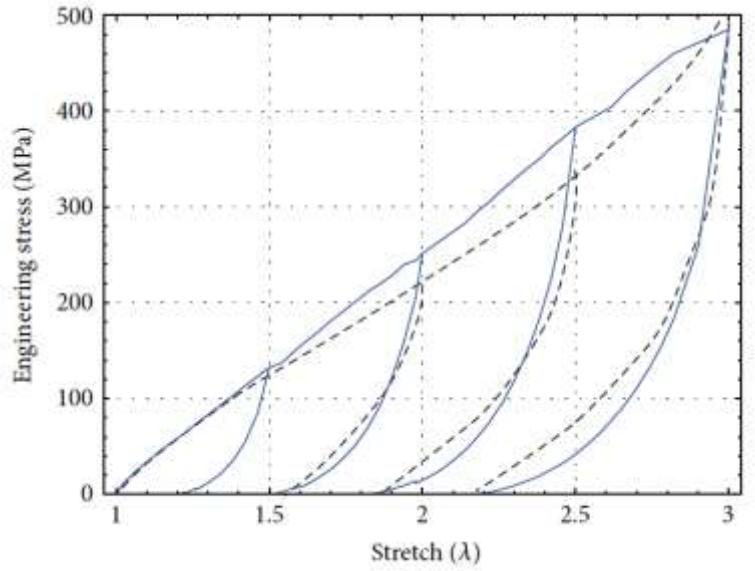


Figure 7. *Engineering stress-stretch data for polydioxanone 2–0 compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 126MPa, $\mathcal{N}$ = 6, b = 0.65, and $\mathcal{C}$ = 0.0035MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.*

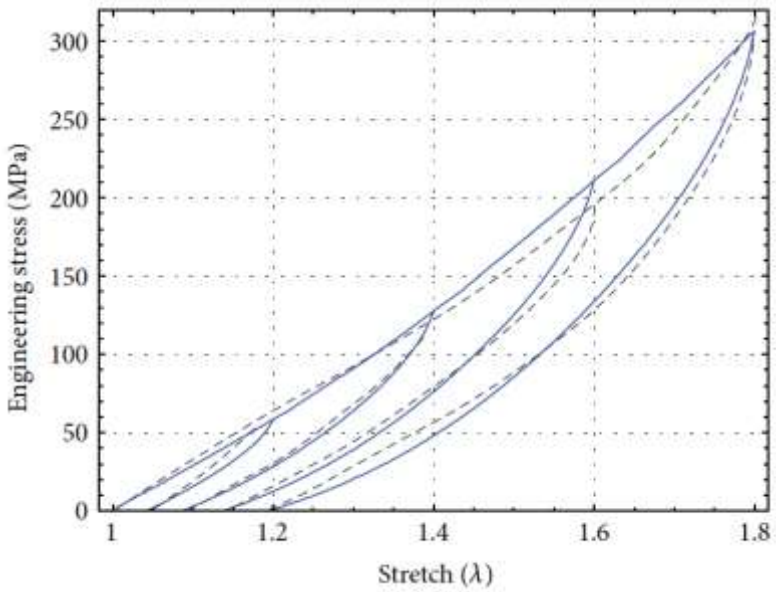


Figure 8. *Engineering stress-stretch data for polydioxanone 4.0 compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 148MPa, N = 1.95, b = 0.445, and C = 0.0115MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.*

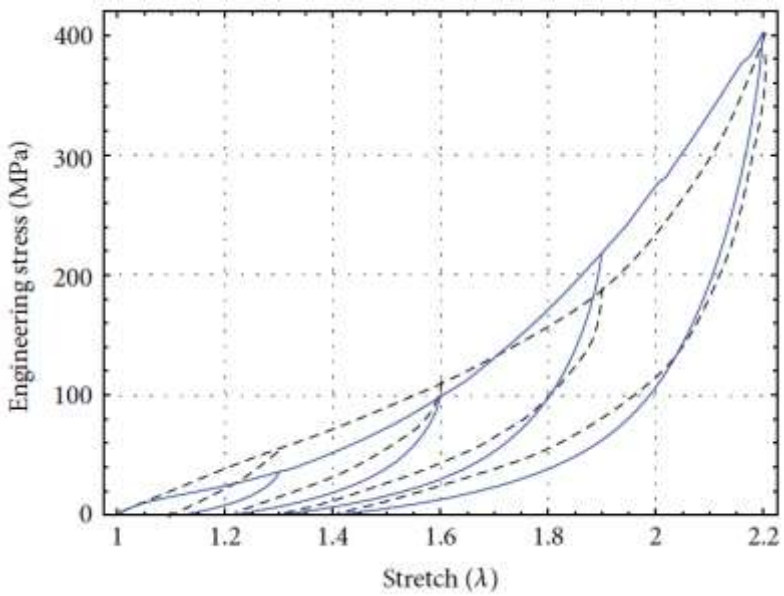


Figure 9. *Engineering stress-stretch data for PGC25 3–0 sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 90MPa, N = 2.35, b = 0.75, and C = 0.012MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.*

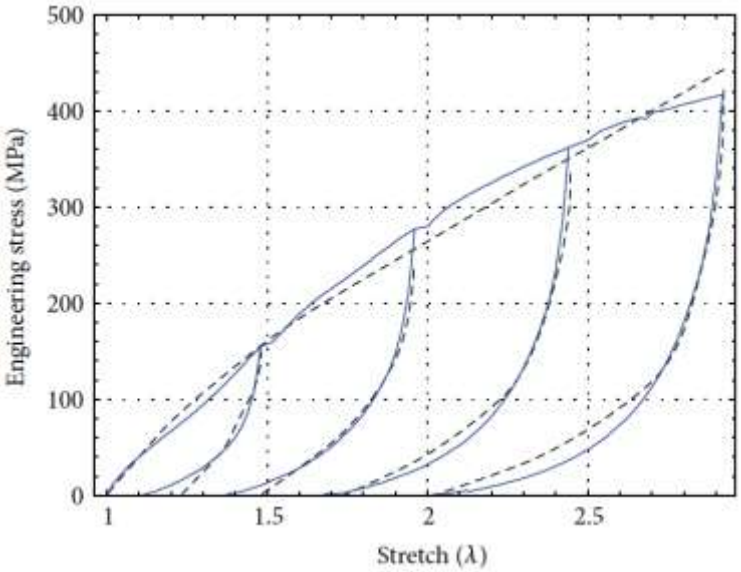


Figure 10. *Engineering stress-stretch data for nylon sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 155MPa, N = 20.5, b = 1, and C = 0.0035MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.*

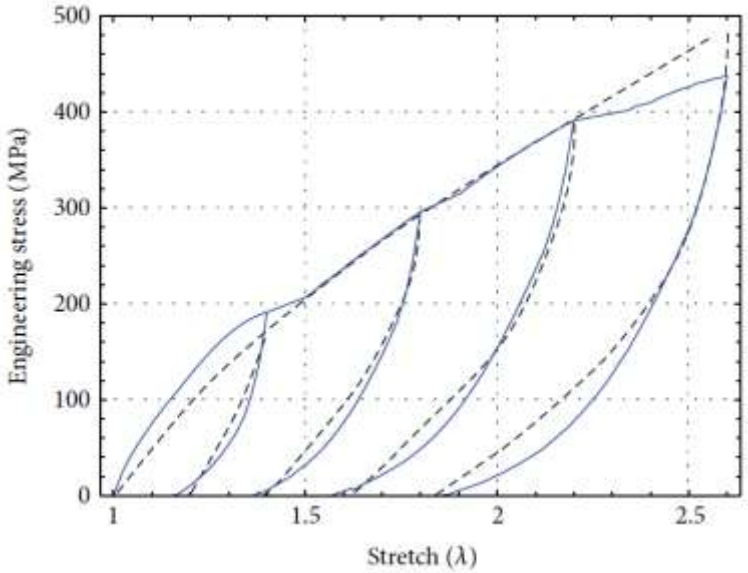


Figure 11. *Engineering stress-stretch data for polypropylene sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 200MPa, N = 30.5, b = 0.65, and C = 0.00265MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.*

III.7. CONCLUSIONS

In this paper, we have examined the material behavior of eight different types of suture materials and found that, when these are subjected to loading and unloading cycles, its stress magnitude becomes lower than that of the virgin material. Furthermore, all tested sutures exhibit residual strains which is related to microstructural material damage upon deformation from the natural, undistorted state of the virgin material. To predict the suture materials response behavior observed during uniaxial tension test, we have introduced a new nonmonotonous stress-softened material model that takes into account permanent set effects for the unloading paths as described by the simple constitutive relation (25).

For each suture material, we have compared experimental data with theoretical predictions obtained from (25). In each case, we have determined the corresponding four material constants: the material shear modulus μ, the chain number of rigid links N, the material softening parameter b, and a positive material constant C that is related to the pseudoelastic residual strain energy. Based on the accuracy of our proposed nonmonotonous model to predict experimental data, we can conclude that the extent of damage of suture biocompatible materials can be conveniently determined by considering its softening behavior observed during experimental tests. Nevertheless, there is a variation in the theoretical predictions, as shown in Table 1, that we believe is due to some viscoelastic effects that were not considered in the proposed material model.

Finally, the present study confirms that stress-softening and residual strain effects appear in the suture materials tested here. The experimental work of this paper proves that suture materials change dramatically when tensile loads are applied during the suturing and healing processes [2]. We have also found that the aforementioned effects are more evident when in vitro sutures are subjected to cyclic loading conditions. However, the results of this new experimental work will be reported in a subsequent paper.

III.7.1 Conflict of Interests

The authors declare that they have no conflict of interests.

III.7.2 Acknowledgements

This work was funded by Tecnológico de Monterrey—Campus Monterrey, through the Research Chair in Nanomaterials for Medical Devices and Research Chair in Intelligent Machines. Additional support was provided by the project FOMIX Nuevo León M0014-2010-30 #145045 and from the European Union Seventh Framework Programme (FP7-PEOPLE-2009) under the grant agreement IRSES no. 247476.

III.8 REFERENCES

1. N. P. Ingle and M. W. King, “Optimizing the tissue anchoring performance of barbed sutures in skin and tendon tissues,” Journal of Biomechanics, vol. 43, no. 2, pp. 302–309, 2010.

2. W. K. Nichols, M. Stanton, D. Silver, andW. F. Keitzer, “Anastomotic aneurysms following lower extremity revascularization,” Surgery, vol. 88, no. 3, pp. 366–374, 1980.

3. M. Poukalova, C. M. Yakacki, R. E. Guldberg et al., “Pullout strength of suture anchors: effect of mechanical properties of trabecular bone,” Journal of Biomechanics, vol. 43, no. 6, pp. 1138–1145, 2010.

4. L. J. Mullins, “Effect of stretching on the properties of rubber,” Journal of Rubber Research, vol. 16, pp. 275–289, 1947.

5. L. Mullins and N. R. Tobin, “Theoretical model for the elastic behavior of filled-reinforced vulcanized rubbers,” Journal of Rubber Chemestry and Technology, vol. 30, pp. 555–571, 1957.

6. S. Govindjee and J. Simo, “A micro-mechanically based continuum damage model for carbon black-filled rubbers incorporating Mullins’ effect,” Journal of the Mechanics and Physics of Solids, vol. 39, no. 1, pp. 87–112, 1991.

7. R. W. Ogden and D. G. Roxburgh, “A pseudo-elastic model for the Mullins effect in filled rubber,” Proceedings of the Royal Society A: Mathematical, Physical and Engineering Sciences, vol. 455, no. 1988, pp. 2861–2877, 1999.

8. M. F. Beatty and S. Krishnaswamy, “Theory of stress-softening in incompressible isotropic materials,” Journal of the Mechanics and Physics of Solids, vol. 48, no. 9, pp. 1931–1965, 2000.

9. A. Elías-Zúñiga and M. F. Beatty, “A new phenomenological model for stress-softening in elastomers,” Zeitschrift fur AngewandteMathematik und Physik, vol. 53, no. 5, pp. 794–814, 2002.

10. A. Elías-Zúñiga and M. F. Beatty, “Stress-softening effects in the transverse vibration of a non-Gaussian rubber string,” Meccanica, vol. 38, no. 4, pp. 419–433, 2003.

11. A. Elías-Zúñiga, “A phenomenological energy-based model to characterize stress-softening effect in elastomers,” Polymer, vol. 46, no. 10, pp. 3496–3506, 2005.

12. J. Diani, M. Brieu, and J. M. Vacherand, “A damage directional constitutive model for Mullins effect with permanent set and induced anisotropy,” European Journal of Mechanics, A/Solids, vol. 25, no. 3, pp. 483–496, 2006.

13. D. de Tommasi, G. Puglisi, and G. Saccomandi, “A micromechanics- based model for the Mullins effect,” Journal of Rheology, vol. 50, no. 4, pp. 495–512, 2006.

14. A. Elías-Zúñiga and C. A. Rodríguez, “A non-monotonous damage function to characterize stress-softening effects with permanent set during inflation and deflation of rubber balloons,” International Journal of Engineering Science, vol. 48, no. 12, pp. 1937–1943, 2010.

15. G. A. Holzapfel, M. Stadler, and R. W. Ogden, “Aspects of stress softening in filled rubbers incorporating residual strains,” in Proceedings of the first European Conference on Constitutive Models for Rubber, A. Dorfmann and A. Muhr, Eds., pp. 189– 193, Rotterdam, The Netherlands, 1999.

16. M. F. Beatty, “An average-stretch full-network model for rubber elasticity,” Journal of Elasticity, vol. 70, no. 1–3, pp. 65–86, 2003.

17. M. A. Johnson and M. F. Beatty, “The mullins effect in uniaxial extension and its influence on the transverse vibration of a rubber string,” Continuum Mechanics and Thermodynamics, vol. 5, no. 2, pp. 83–115, 1993.

18. E. A. de Souza Neto, D. Peric, and D. R. J. Owen, “A phenomenological three-dimensional rate-independent continuum damage model for highly filled polymers: formulation and computational aspects,” Journal of the Mechanics and Physics of Solids, vol. 42, no. 10, pp. 1533–1550, 1994.

19. G. Marckmann, E. Verron, L. Gornet, G. Chagnon, P. Charrier, and P. Fort, “A theory of network alteration for the Mullins effect,” Journal of the Mechanics and Physics of Solids, vol. 50, no. 9, pp. 2011–2028, 2002.

20. A. Dorfmann and R. W. Ogden, “A constitutive model for the Mullins effect with permanent set in particle-reinforced rubber,” International Journal of Solids and Structures, vol. 41, no. 7, pp. 1855–1878, 2004.

21. R. Kazakeviciute-Makovska and R. Kacianauskas, “Modelling of stress softening in elastomeric materials: foundations of simple theories, ”Mechanics Research Communications, vol. 31,no. 4, pp. 395–403, 2004.

22. R. Kazakeviciute-Makovska, “Experimentally determined properties of softening functions in pseudo-elastic models of the Mullins effect,” International Journal of Solids and Structures, vol. 44, no. 11-12, pp. 4145–4157, 2007.

23. M. Cheng and W. Chen, “Experimental investigation of the stress-stretch behavior of EPDM rubber with loading rate effects,” International Journal of Solids and Structures, vol. 40, no. 18, pp. 4749–4768, 2003.

24. W. V. Mars and A. Fatemi, “Observations of the constitutive response and characterization of filled natural rubber under monotonic and cyclic multiaxial stress states,” Journal of Engineering Materials and Technology, vol. 126, no. 1,pp. 19–28, 2004.

25. D. de Tommasi, G. Puglisi, and G. Saccomandi, “Localized versus diffuse damage in amorphous materials,” Physical Review Letters, vol. 100, no. 8, Article ID 085502, pp. 1–4, 2008.

26. A. Elías-Zúñiga and M. F. Beatty, “Constitutive equations for amended non-Gaussian network models of rubber elasticity,” International Journal of Engineering Science, vol. 40, no. 20, pp. 2265–2294, 2002.

IV. EVALUATION OF A SURGICAL SIMULATOR REGARDING ITS PERFORMANCE WHEN USED BY RESIDENTS WITH DIFFERENT LEVELS OF EXPERIENCE

PUBLISHED AS: Flores-Villalba, E.; Díaz-Elizondo, J. A.; Leyva-Alvizo, A.; Fernández-Rangel, E.; Villegas-Cabello, O.; del Real-Romo, Z. “Evaluación de un simulador quirúrgico en función de su desempeño al ser utilizado por residentes con diferentes grados de experiencia” Cirujía y Cirujanos, vol 80, no 2, pp 157-161, 2012.

IV.1. ABSTRACT

Background: Historically, the operating room has been the training setting for both surgeons and students. Nowadays, surgical simulators represent an alternative. In the same way a not-very-well-built mirror cannot reflect trustworthy images (distortion), a not well built, calibrated or programmed simulator will be unable to reflect the training level of the operator. Our aim is to indirectly evaluate the Surgical SIM® simulator.

Methods: Twelve surgical residents were classified as novices, intermediates and experts. 15 tasks were scheduled and performed with three dimensions of evaluation in each task, using the Surgical SIM® simulator. Pearson's correlation test was used for validation.

Results. From the three dimensions evaluated, results showed a statistically significant difference for time ($p = 0.001$), trajectory ($p = 0.01$) and errors ($p = 0.001$) among experience groups.

Conclusions: Effectiveness of Surgical SIM® was indirectly demonstrated.

Key words: Simulator, virtual laparoscopy, validation, and training

IV.2. INTRODUCTION

Historically, the operating room has been the classroom for the surgeon in training. Education in surgery has been based on the learning model introduced by Halsted in the United States [1]. The cognitive learning model in which residents learn while working next to experimented surgeons in a real-life scenario, is the main method through which surgical abilities are taught. The apprentice model is limited by the availability of mentors, their teaching capacity, the variability of the procedures made, and even by the number of available patients for training [2, 3].

Laparoscopy, in particular, requires a difficult sensitive and mechanical coordination, ambidextrous handling, understanding of the lever effect, and perception of depth. These abilities could be difficult to master and, often, require much practice. It has been demonstrated that surgeons without experience have considerably higher rates of complications while completing procedures via laparoscopy and a clear learning curve has been established [4-6].

Along with this, residency programs are always looking for tools to measure their students' technical knowledge and, even more, since the introduction of the reduced work-hours program for residents. Virtual simulation could cover the existing gap between the classroom and patient care while guaranteeing that all students are exposed to common clinical problems; moreover, it permits a resident to experiment a greater variety and a larger number of procedures without the need to wait for a patient with a specific illness to come seeking medical attention [7-10]. On the other hand, it is estimated that a surgical procedure consists of approximately 75% cognitive ability and only 25% surgical ability; however, the use new tools to improve surgeon abilities is completely justified [11].

In surgical education, the mechanical trainers and those of virtual reality have been used to develop specific psychomotor skills and evaluate the surgeon performance. The achievement of these objectives depends on three essential principles: 1) validity, 2) reliability, and 3) viability [12, 13]. Validity refers to how well

the trainer is built, programed or calibrated. This can be verified indirectly by the precision with which it reflects the level of training of its current operator [14-18].

The aim of this study was to evaluate, in an indirect way, the surgical simulator SIM® (METI, Sarasota, Fl).

IV.3. MATERIAL AND METHODS

The evaluation was done at the “Centro de Habilidades de la Escuela de Medicina del Tec de Monterrey” (Tec of Monterrey School of Medicine Skills Center) in Monterrey, Mexico. A laparoscopic surgery virtual simulator, Surgical SIM® (METI, Sarasota, Fl), was used to achieve this evaluation.

Twelve residents, with different levels of experience, were distributed in the following way: 4 novice residents (first year), 4 intermediate experience residents (second year), and 4 advanced experience residents (third and fourth years). Residents were considered novices if they had less than 30 cholecystectomies, intermediate, if they had between 30 and 50, and expert, if they counted more than 50 cholecystectomies during their training [12, 18].

Each resident was required to complete only one exercise out of 15 from the simulator (Table 12); time, trajectory, and number and type of errors committed were registered during the procedure completion. These data were stored in the internal memory of the simulator for their subsequent analysis. The first four tasks corresponded to exercises for orientation and camera handling; the following eight, had the goal of instructing tissue handling; and, the last three corresponded to intracorporeal knot configuration.

Correlations between the resident experience levels and the completed tasks were established through a Pearson analysis, using the statistical package SPSS (Chicago II, version 16). The evaluation of the simulator was determined based on its capacity to reflect significant differences among experience groups. A $p<0.05$ was considered statistically significant.

Table 12. *Tasks made using the virtual simulator Surgical SIM®*

Task
Exercises with Camera
Lens 0 degrees
Lens 30 degrees
Identify and target with 0º lens
Identify and target with 30º lens
Tissue Manipulation
Separate Object
Separate and cut tissue with cautery
Manipulation of tubular object
Manipulation of arrow object
Apply *clips* in the cystic canal
Dissection of gall bladder from liver bed
Suture
Square Knot
Knot in real appearance
Continuous stitch
Interrupted stitch
Interrupted stitch in real appearance

IV.4. RESULTS

Three parameters were evaluated: total time in which each exercise was completed (Table 13), the distance covered by the instrument until a certain task was terminated (Table 14) and the number of errors during the exercise (Table 15).

The average time used in all the tasks was 376 minutes for novices, 250 minutes for intermediate, and 175 minutes for experts ($p<0.001$) with a correlation of -0.842. The total average for trajectories was 677 cm for novices, 608 cm for intermediates, and 364 for experts, with a correlation of -0.697 ($p<0.01$). The evaluated simulator errors were 32 for the novices, 18 for intermediates and only 10 for the expert group ($p<0.0001$).

Five out of 13 measured exercises had a significant correlation for the total exercise time; however, the eight that did not show a statistically significant difference ($p<0.05$), did show a tendency in favor of the more experienced residents.

Regarding the trajectory, a negative correlation was found for all the results. Meaning that to a greater level of experience, a shorter trajectory was covered. Similarly, two of the completed exercises showed statistically significant correlation; even though exercises 2, 6, 7, 8, 12, and 13 showed a strong correlation, it was not statistically significant.

The total errors showed a negative correlation between the level of experience and the number of errors; magnifying the effect for tasks 7, 11, 13, 14, and 15; due to increased technical difficulty. Regarding “errors”, all results had a negative correlation, which supports the original hypothesis.

IV.5. DISCUSSION

This study is the first one in Mexico to evaluate a surgical simulator through tasks done with different levels of surgical experience. In general, all results demonstrated a clear distinction among the different levels of experience of residents who used the simulator. Though not in all areas the differences were statistically significant, the overall result, in each of the simulator evaluations (time, trajectory and errors), demonstrated the operative efficiency of the simulator.

Table 13. *Ranges, averages, and correlations of time (seconds) per task, level of experience, and totals*

	Range (average)				
Task	**Novice**	**Intermediate**	**Expert**	**r**	**p**
Lens 0 degrees	60-90 (75)	52-82 (67.5)	43-68 (53.5)	-0.574	0.05
Lens 30 degrees	325-876 (618)	194-739 (341)	100-336 (259)	-0.528	0.07
Identify and target with 0º lens	49-87 (72)	26-172 (80)	45-52 (47)	-0.276	0.38
Identify and target with 30º lens	298-615 (409)	63-756 (408)	218-346 (282)	-0.332	0.29
Separate the object	61-144 (96)	57-69 (63)	43-55 (51)	-0.685	**0.01**
Separate and cut tissue with cautery	111-197 (149)	104-137 (120)	94-119 (109)	-0.555	0.06
Manipulation of tubular object	59-188 (143)	51-97 (79)	60-102 (77)	-0.585	**0.04**
Manipulation of arrow object	128-254 (178)	107-295 (167)	86-159 (113)	-0.465	0.12
Apply *clips* in the cystic canal	39-65 (54)	40-56 (48)	36-60 (49)	-0.249	0.43
Dissection of gall bladder	156-246 (202)	176-239 (201)	150-312 (207)	-0.065	0.84
Square knot	134-245 (197)	71-327 (173)	36-97 (72)	-0.626	**0.03**
Knot in real appearance	89-276 (173)	63-118 (99)	57-170 (94)	-0.454	0.13
Continuous stitch	629->1200 (960)	170->1200 (639)	197-524 (273)	-0.697	**0.01**
Interrupted stitch	876-1167 (1006)	393-974 (745)	252-757 (472)	-0.82	**0.001**
Interrupted stitch in real appearance	973->1800 (1380)	233-762 (522)	198-719 (467)	-0.755	**0.005**
Total	39->1800 (376)	26->1200 (250)	36-757 (175)	-0.842	**0.001**

r = Pearson correlation, p< 0.05 = statistically significant

Table 14. *Ranges, averages, and correlations of the trajectory (cm) per task, level of experience, and totals*

	Range (average)				
Task	**Novice**	**Intermediate**	**Expert**	**r**	**p**
Lens 0 degrees	125-915 (335)	133-190 (153)	49-151 (120)	-0.369	0.23
Lens 30 degrees	816-2074 (1391)	472-2319 (1034)	168-858 (454)	-0.503	0.11
Identify and target with 0º lens	201-292 (240)	144-585 (309)	172-214 (191)	-0.191	0.55
Identify and target with 30º lens	605-1014 (737)	245-1663 (1001)	456-585 (550)	-0.246	0.44
Separate the object	170-274 (233)	148-240 (195)	109-121 (165)	-0.597	**0.04**
Separate and cut tissue with cautery	240-372 (315)	224-381 (288)	215-288 (245)	-0.527	0.07
Manipulation of tubular object	159-453 (348)	141-284 (216)	162-290 (215)	-0.554	0.06
Manipulation of arrow object	378-715 (577)	339-933 (537)	278-529 (383)	-0.48	0.11
Apply *clips* in the cystic canal	83-122 (104)	65-125 (97)	67-135 (99)	-0.216	0.5
Dissection of gall bladder	218-458 (324)	211-628 (359)	185-433 (269)	-0.242	0.44
Square knot	470-780 (677)	321-1098 (602)	149-305 (222)	-0.673	**0.01**
Knot in real appearance	298-825 (507)	228-527 (349)	188-479 (294)	-0.467	0.12
Continuous stitch	462-1222 (879)	129-462 (237)	302-538 (376)	-0.568	0.08
Interrupted stitch	916-2473 (1616)	1398-3269 (2442)	521-936 (707)	-0.446	0.14
Interrupted stitch in real appearance	1187-2863 (1871)	566-1728 (1299)	524-2683 (1171)	-0.41	0.21
Total	125-2863 (677)	65-3269 (608)	49-2683 (364)	-0.697	**0.01**

r = Pearson correlation, p< 0.05 = statistically significant

Table 15. *Ranges, averages, and correlations of errors per task, level of experience, and totals*

	Range (average)				
Task	**Novice**	**Intermediate**	**Expert**	**r**	**p**
Lens 0 degrees	1-2 (1.25)	1-2 (1.5)	0-2 (0.5)	-0.47	0.123
Lens 30 degrees	25-82 (25.5)	12-32 (38.5)	3-29 (18.75)	-0.493	0.1
Identify and target with 0º lens	0-7 (4)	1-14 (5.25)	1-2 (1)	-0.298	0.356
Identify and target with 30º lens	36-61 (44.5)	5-151 (60)	14-39 (28.75)	-0.232	0.468
Separate the object	2-6 (3)	0-2 (0.75)	0-1 (0.5)	-0.636	0.06
Separate and cut tissue with cautery	8-24 (16.25)	5-14 (7.75)	4-17 (9.25)	-0.482	0.11
Manipulation of tubular object	3-14 (7.75)	0-4 (2.25)	0-6 (1.75)	-0.599	**0.04**
Manipulation of arrow object	5-15 (10.75)	0-18 (7)	2-6 (3.5)	-0.516	0.08
Apply *clips* in the cystic canal	1-4 (2)	0-2 (0.75)	0-3 (1.25)	-0.304	0.33
Dissection of gall bladder	15-21 (17.5)	7-36 (17.5)	10-13 (12)	-0.297	0.348
Square knot	1-10 (4.75)	1-7 (3)	0-1 (0.5)	-0.58	**0.048**
Knot in real appearance	0-5 (1.75)	0-3 (1.5)	0-1 (0.25)	-0.412	0.183
Continuous stitch	104-13 (124.7)	13-112 (56.66)	7-39 (18.75)	-0.822	**0.007**
Interrupted stitch	109-166 (127)	10-43 (32.5)	5-61 (27)	-0.8	**0.002**
Interrupted stitch in real appearance	52-78 (64.33)	14-55 (37.5)	19-41 (29.75)	-0.733	**0.01**
Total	0-166 (32.15)	0-112 (18.161)	0-61 (10.233)	-0.842	**0.001**

r = Pearson correlation, p< 0.05 = statistically significant

The number of errors and the time measurement were the results that rendered more significant correlations, exercises 7 and 5 respectively; so, most probably, they represent the best indicators of performance. However, a definite conclusion cannot be reached from this study; a concurrent and predictive validation is considered necessary in order to demonstrate the correct construction and operation of the simulator.

Oddly, there was no correlation between time and the necessary ability for a virtual dissection of the gallbladder bed. This is remarkable, because it was exactly this type of surgery that served as a parameter to divide the residents into groups with more or less experience. The explanation of this result exceeds the purposes of the present study and it is the reason to proceed to make other types of evaluations in order to show whether it is an effect caused by the simulator itself. It is not well defined how the performance of a task made in the virtual simulator relates to the execution of the same surgical procedure in real life [18]; however, as more studies are done and progressive validation of simulators is obtained, these questions will be solved.

The accelerated medical advances make surgeons keep up to date and have a better understanding and knowledge of the new available technology; additionally, surgeons need to be prepared to make all type of surgical procedures that the specialty demands; and need to keep up to date in the use of new instruments and techniques. On the other hand, we know that during surgical training there is a deficit of knowledge acquisition and development of diverse abilities. Between 5 an 10% of surgeons will never attained a sufficient level of abilities to perform minimally invasive surgery [19]. Therefore, evaluation of didactic instruments is as important as creation of new knowledge; the collaboration of everyone involved is of great importance to achieve these goals.

IV.6. CONCLUSION

It can be concluded that the simulator Surgical SIM®, in general, accurately reflects the different levels of surgeon experience while completing diverse procedures in relation of time used, trajectory covered, and the number of errors registered. Thus, a supposition is made on the correct fabrication, programing, and calibration of the didactic instrument.

IV.7. REFERENCES

1. Halsted WS. The Training of the Surgeon. Bull Johns Hopkins Hosp 1904;15:267-275.

2. Ahlberg G, Enochsson L, Gallagher AG, Hedman L, Hogman C, McClusky DA, et al. Proficiency-based virtual reality training significantly reduces the error rate for residents during their first 10 laparoscopic cholecystectomies. Am J Surg 2007;193(6):797-804.

3. Sultana CJ. The objective structured assessment of technical skills and the ACGME competencies. Obstet Gynecol Clin. North Am 2006;33(2):259-265.

4. Moore MJ, Bennett CL. The learning curve for laparoscopic cholecystectomy. The Southern Surgeons Club. Am J Surg 1995;170(1):55-59.

5. Deziel DJ, Millikan KW, Economou SG, Doolas A, Ko ST, Airan MC. Complications of laparoscopic cholecystectomy: a national survey of 4,292 hospitals and an analysis of 77,604 cases. Am J Surg 1993;165(1):9-14.

6. Joice, P, Hanna GB, Cuschieri A. Errors enacted during endoscopic surgery-a human reliability analysis. Appl Ergon 1998;29(6):409- 414.

7. Gaba,DM. The future vision of simulation in health care. Qual Saf Health Care 2004;13(Suppl 1):2-10.

8. McLaughlin S, Fitch MT, Goyal DG, Hayden E, Kauh CY, Laack TA, et al. Simulation in Graduate Medical Education 2008: A Review fo Emergency Medicine. Acad Emerg Med 2008;15(11):1117-1129.

9. Wayne, DB, Didwania A, Feinglass J, Fudala MJ, Barsuk JH, McGaghie WC. Simulation-Based Education Improves Quality of Care During Cardiac Arrest Team Responses at an Academic Teaching Hospital. A Case-Control Study. Chest 2008;133(1):56-61.

10. Haluck RS, Marshall RL, Krummel TM, Melkonian MG. Are surgery training programs ready for virtual reality? a survey of program directors in general surgery. J Am Coll Surg 2001;193(6):660-665.

11. Satava RM, Gallagher AG, Pellegrini CA. Surgical competence and surgical proficiency: definitions, taxonomy, and metrics. J Am Coll Surg 2003;196(6):933 937.

12. McDougall EM, Corica FA, Boker JR, Sala LG, Stoliar G, Borin JF, et al. Construct validity testing of a laparoscopic surgical simulator. J Am Coll Surg 2006;202(5):779-787.

13. Reznick RK. Teaching and testing technical skills. Am J Surg 1993;165(3):358 361.

14. Taffinder N, Sutton C, Fishwick RJ, McManus IC, Darzi A. Validation of virtual reality to teach and assess psychomotor skills in laparoscopic surgery: results from randomised controlled studies using the MIST VR laparoscopic simulator. Stud Health Technol. Inform 1998;50:124-130.

15. Smith CD, Farrell TM, McNatt SS, Metreveli RE. Assessing laparoscopic manipulative skills. Am J Surg 2001;181(6):547-550.

16. Grantcharov TP, Bardram L, Jensen PM, Rosenberg J. Virtual reality computer simulation as a tool for training and evaluating skills in laparoscopic surgery. Ugeskr Laeger 2001;163:3651-3653.

17. Grantcharov TP, Bardram L, Funch-Jensen P, Rosenberg J. Assessment of technical surgical skills. Eur J Surg 2002;168(3):139-144.

18. Gallagher AG, Smith CD, Bowers SP, Seymour NE, Pearson A, McNatt S, et al. Psychomotor skills assessment in practicing surgeons experienced in performing advanced laparoscopic procedures. J Am Coll Surg 2003;197(3):479-488.

19. Cuschieri A. Whither minimal access surgery: tribulations and expectations. Am J Surg 1995;169(1):9-19.

V. EFFECT OF SURGICAL EXPERTISE LEVEL ON BIOMECHANICAL PROPERTIES OF COMMONLY USED SUTURE MATERIALS AFTER ABDOMINAL WALL FASCIAL CLOSURE

SUBMITTED TO: Díaz-Elizondo, J. A.; Guraieb-Trueba, M.; Baca-Arzaga, A.; Vazquez-Armendariz, J.; Segura-Ibarra, V.; Flores-Villalba, E.; Rodriguez, C.A. “Effect of surgical expertise level on biomechanical properties of commonly used suture materials after abdominal wall fascial closure” Journal of the Mechanical Behavior of Biomedical Materials, 2019

V.1. ABSTRACT

Despite preventive methods and careful surgical technique, surgical site infection and incisional hernias are of main concern after closure of surgical incision and keep haunting abdominal wall wound healing. The aim of this study is to find how surgical expertise level changes biomechanical properties of sutures used in abdominal wall fascial closure (polypropylene, polyglactin 910, polydioxanone).

Surgery residents of different level of experience sutured the abdominal wall fascia of swine models with tree different sutures commonly used for this purpose. A standardized technique was used. Sutures were removed and a tensile stress test was performed on the removed sutures. A total of 81 abdominal fascial closures were performed. Time, Extension, Maximum tensile force, and Maximum Stress were analyzed.

The polydioxanone sutures presented a trend in three variables: extension, tensile force, and stress. The trend shows higher medians in the expert group and lower medians in the novice group. While using polypropylene sutures the expert group medians were the highest, however, a trend was not observed. Polyglactin 910 sutures had a non-specific behavior among the different experience groups or variables. Polypropylene was the material with the lowest F_{tmax} tested and failed at 42.64 (IQR 40.98 – 44.89) N. Regarding the elastic properties of the material, polyglactin demonstrated the least extension of all sutures tested and was 14 (IQR 13.33 – 14.83) mm. This study demonstrates that polydioxanone has a superior F_{tmax} compared to polypropylene and has superior extension at failure properties compared to polyglactin; confirming that Polydioxanone could be the suture of choice of abdominal wall fascial closure.

This study results do not show a statistically significant difference regarding impact of experience level of different general surgery residents in the biomechanical properties of sutures used in abdominal wall fascial closure.

V.2. INTRODUCTION

Despite implementation of preventive methods and careful surgical technique, surgical site infection (SSI) and incisional hernias are of main concern after closure of surgical incision [1- 3]. Both of these complications have a dramatic impact on the healing process, patient outcome, and health care costs. Surgical site occurrences (SSI and incisional hernia) are adversities that keep haunting abdominal wall wound healing. This is particularly true when a midline laparotomy is performed. Surgical site occurrences might be heightened by either patient factors or due to surgical related issues including the surgeon itself.

Wound failure risk factors can be classified as patient or surgeon related. Any cause of reduced blood supply to the wound such as: diabetes mellitus, vascular disease, or smoking, can predispose to development of incisional hernias [4]. Among the patient related factors, these include male sex, advanced age, emergency operation, past medical history (e.g. prior abdominal surgery), comorbidities (e.g. connective tissue disorders), as well as health related habits (e.g. smoking, overweight) and cannot be standardized nor modified, meanwhile surgeon related factors can be modified or standardized with relative ease. The latter include: suturing technique, choosing the suture material, and surgeon expertise, hence, providing an opportunity to decrease surgical site occurrences [5].

While in surgical training, experience and expertise in suture handling and abdominal wall fascial closure is learned progressively. Entrustable professional activities for basic surgical procedures and some complex surgical interventions including abdominal wall fascial closure, are commonly achieved by post-graduate year 2 (PGY-2) while in surgical training [6, 7]. Operative technique and knot tying are surgical skills that are generally taught, learned, and perfected over time. Traditionally, senior residents are believed to have better technical skills than junior residents. However, there is limited evidence in the literature on the role seniority plays in knot security, and whether suture caliber and type also factor into this [8-10].

The effects on biomechanical properties due to excessive twisting on sutures while suturing, has been evaluated using small diameter (3-0/4-0) monofilament and braided sutures used for skin closure. Hennesey et al., demonstrated and concluded that axial twisting while suturing causes changes on biomechanical properties of sutures [11]. It has been proven that longitudinal strain due to a longitudinal tensile stress plays a constant role, changing biomechanical properties of sutures which might influence the outcome of an abdominal wall wound closure [12]. Hypothetically the level of expertise of the surgeon in training is directly related with a modification of the biomechanical properties (maximum tensile force: F_{tmax} – force required for the suture to rupture) of suture materials while performing abdominal wall fascial closure, contributing to the development of surgical site occurrences.

The aim of this study is to find the impact of surgical trainee experience level on changes in biomechanical properties of different suture materials used for abdominal wall fascial closure in a porcine model.

V.3. MATERIALS & METHODS

V.3.1. Models

In accordance with ARRIVE guidelines to reduce, reuse, and replace animal models while experimentation; 4 male porcine models (Yorkshire *sus scrofa*; 30-35 kg; 4-6 months old) were included after being used in approved protocol CICUAL 2013-008 M ("Biochemical and Hemodynamic changes during Laparoscopic vs Open Surgery in Hypovolemic Shock in a Porcine Model") [13]. A 30 cm "midline" laparotomy incision was performed simulating a *linea alba* incision for abdominal wall closure with three different suture materials by general surgery residents with different levels of experience. At the end of the procedure, euthanasia was achieved by a lethal dose of phenobarbital, animal death was confirmed by veterinary staff.

V.3.2. Sutures and Experience Levels

A continuous running suture was made with 3 different suture materials: Prolene (Polypropylene) – 0®, Vicryl Plus (Polyglactin 910) -1®, PDS II (Polydioxanone) - 0® (Ethicon Inc., Cincinnati, OH, USA) by different PGY general surgery residents according to different levels of experience. Experience level was defined as the number of participations as a surgeon in cholecystectomies per year: a) novice: participates in 30 or less, b) intermediate: participates in more than 30 but less than 50, and c) expert: participates in more than 50 [14].

Every general surgery resident used the three materials to suture the incision simulating human abdominal wall fascial closure with a running suture [15]. After each closure, the suture material was removed for further biomechanical analysis. This was performed with assistance of a Kelly clamp (hemostat) sliding the suture to prevent further longitudinal strain while removing them from the abdominal wall fascia.

V.3.3. Suturing Technique

Abdominal wall fascial closure was made according to standardized techniques. A superior stitch was placed in two steps and tied using 4 square knots aided by the needle holder. A continuous running suture was made advancing in a step by step fashion and suture traction was held by the same resident performing the suture. Each stitch was placed 5 mm apart from the wound edge and from the next stitch following a small bite stitch technique [3, 16]. At the end of the incision a final stitch was placed with a 4 square knot aided by the needle holder. Suture retrieval was achieved by cutting the caudal knot and removed by the same surgical supervisor using a hemostat, minimizing suture tension. The sutures were placed in individual containers and labeled for the posterior mechanical testing.

V.3.4. Mechanical Testing

A longitudinal strain test was performed to measure differences in tensile strength. An Instron® 3365 Tensile Tester (Instron Corporation, Nordstrom, MA, USA) using a 5 kN load cell for mechanical testing with the Bluehill® 3 software with parameters described by Chu et al. [17]. The setup included pneumatic side action grips with serrated flat jaw faces. The grips were 10 cm apart and the suture to be tested was placed and held by the jaw faces. A continuous to rupture traction-tension test was set to a constant speed of 100 mm/min. Maximum Tensile Force (N), extension (mm), tensile stress (MPa) over time (sec), and deformation (mm/mm) were analyzed and compared.

A test speed of 100mm/min was used for controls and all samples to ensure repeatable analysis since lower test speeds promoted gradual, rather than sudden, failure making precise identification of the point at which the suture fails. Similar test speeds have been used in the literature [18-21]. All sutures failed at least 2 cm apart from the face jaws placed in the pneumatic grips. No suture slipping was detected while using this set up.

V.3.5. Statistical Analysis

All data analysis was performed using IBM SPSS Statistics®v25-2017 (IBM, Armonk, NY, US). Normality tests were performed prior to a final analysis. A Kruskal-Wallis test was used to compare differences of the experience groups (Novice, Intermediate, and Expert) and the unstrained controls. The measurements included: time to failure (seconds - sec), extension to failure (millimeters - mm), maximum tensile force (Newtons - N), maximum stress (Megapascals - MPa) and deformation (mm/mm). Maximum tensile force (N) between longitudinally strained sutures from all participants and control (unstrained) sutures within the three different suture materials were compared using a Mann-Whitney U test. A p-value <0.05 was considered statistically significant.

V.4. RESULTS

A total of 81 abdominal fascial closures were performed (Table 16). Medians (Md) and interquartile ranges 25-75% (IQR) for Time (seconds) (Figure 12), Extension (mm) (Figure 13), Maximum tensile force (N) (Figure 14) and Maximum Stress (MPa) (Figure 15) were calculated for controls (unstrained - unused) and strained sutures while performing abdominal wall fascial closure for all experience level groups. These results reveal nonstatistically significant differences in the measured biomechanical variables across the different groups, therefore post-hoc tests were not performed (Table 17).

Table 16. *Abdominal fascial closures performed by different experience level residents*
Expert – more than 50 cholecystectomies per year

Experience level	Vicryl® 1	PDS® 0	Prolene® 0	Total
Expert	6	6	6	**18**
Intermediate	10	10	10	**30**
Novice	11	11	11	**33**
Total	**27**	**27**	**27**	**81**

Intermediate – more than 30 but less than 50 cholecystectomies per year
Novice – less than 30 cholecystectomies per year

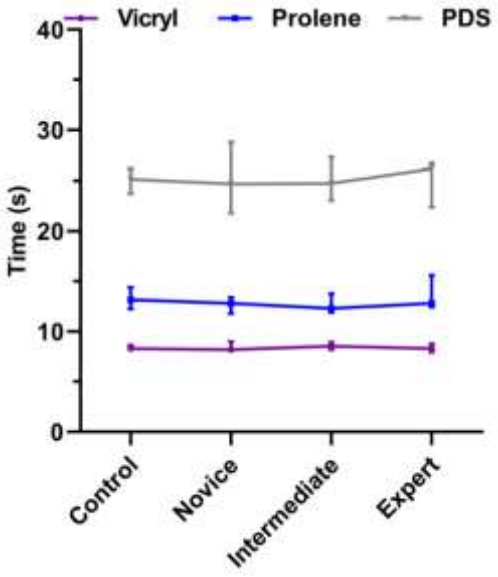


Figure 12. *Total time lapsed (seconds) prior to rupture of the suturing material during the biomechanical testing. Data points are expressed as medians, bars represent 25 and 75% quartiles.*

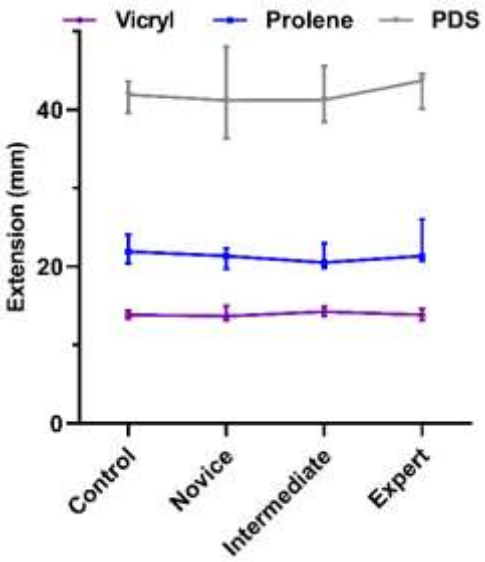


Figure 13. *Median maximum extension prior to rupture of sutures following their use by surgeons with different level of expertise and non-used control sutures. Data points are expressed as medians, bars represent 25 and 75% quartiles.*

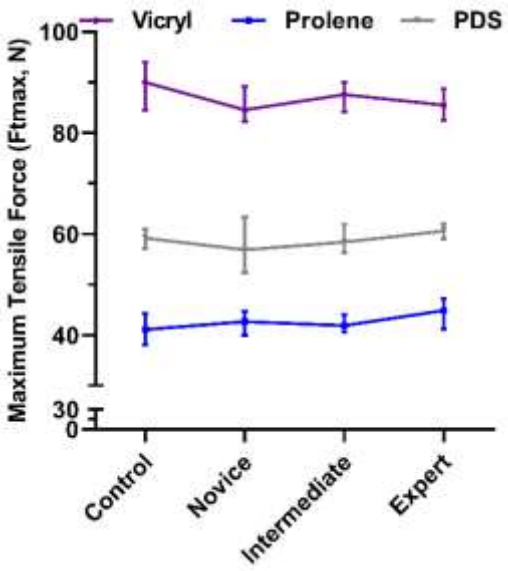


Figure 14. *Tensile strength (Ftmax) withheld by sutures prior to rupture, following their use by surgeons with different level of expertise and non-used control sutures. Data points are expressed as medians, bars represent 25 and 75% quartiles.*

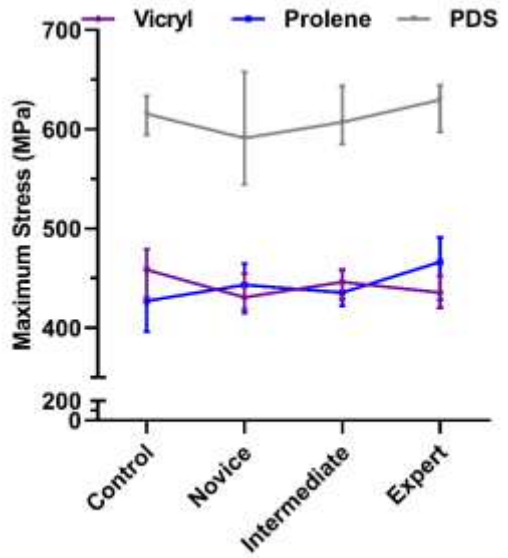


Figure 15. *Maximum stress exerted by the suturing material following their use by surgeons with different level of expertise (novice, intermediate and expert) and non-used control sutures. Measurements where obtained in MegaPascals (MPa). Data points are expressed as medians, bars represent 25 and 75% quartiles*.

Table 17. *Kruskal-Wallis*

	Control	Novice	Intermediate	Expert	*p-value*
Polyglactin 910 (Vicryl Plus®)					
Time (sec)	8.3 (8-8.6)	8.2 (7.9-9)	8.55 (8.2-8.95)	8.3 (7.9-8.77)	0.76
Extension (mm)	13.83 (13.37-14.41)	13.66 (13.16-15)	14.25 (13.67-14.91)	13.83 (13.17-14.62)	0.73
Max. Tensile Force (N)	90 (84.51-94.06)	84.53 (82.24-89.23)	87.58 (84.2-90.04)	85.5 (82.48-88.72)	0.26
Max. stress (mPa)	458.38 (430.41-479.04)	430.55 (418.88-479.04)	446.07 (428.87-458.61)	435.45 (420.11-451.89)	0.26
Polypropylene (Prolene ®)					
Time (sec)	13.15 (12.25-14.42)	12.8 (11.8-13.4)	12.3 (11.9-13.77)	12.8 (12.45-15.6)	0.44
Extension (mm)	21.91 (20.41-24.04)	21.33 (19.6-22.33)	20.5 (19.83-22.96)	21.33 (20.75-26)	0.44
Max. Tensile Force (N)	41.06 (38.1-44.21)	42.64 (39.92-44.68)	41.87 (40.58-44.04)	44.86 (41.21-47.23)	0.81
Max. stress (mPa)	426.84 (396.08-459.54)	443.28 (414.98-464.43)	435.28 (421.83-457.79)	466.33(428.38-490.96)	0.81
Polydioxanone (PDS II ®)					
Time (sec)	25.15 (23.75-26.17)	24.7 (21.8-28.8)	24.75 (23.05-27.32)	26.2 (22.4-26.72)	0.99
Extension (mm)	41.91 (39.58-43.62)	41.16 (36.33-48)	41.25 (38.41-45.54)	43.66 (40.12-44.54)	0.98
Max. Tensile Force (N)	59.2 (57.19-60.96)	56.87 (52.38-63.3)	58.4 (56.28-61.9)	60.57 (58.99-61.99)	0.85
Max. stress (mPa)	615.32 (594.51-633.67)	591.1 (544.49-657.93)	607.07 (585.05-657.93)	629.56 (597.08-644.34)	0.98

$p<0.05$ was considered statistically significant

Measurements of extension (Figure 12) correlated with the known properties of the different materials. PDS® exhibited the highest degree extension, with a mean median of 42 mm, followed by Prolene® and Vicryl® respectively. The degree of extension did not vary among groups in any of the three sutures, none of the differences were statistically significant.

The behavior of maximum tensile force among groups did not vary significantly (Figure 13). All three of the different materials exhibited similar

performance despite the degree of manipulation and their rupture point was similar to that of unstrained sutures. A Mann-Whitney U test showed no statistically significant differences in maximum tensile force (Table 18). Further plotting of force against deformation (Figure 14) revealed similar curve modeling compared to controls, rupturing at similar tension.

Overall, the PDS® sutures presented a trend in three variables: extension, tensile force, and stress. The trend shows higher medians in the expert group and lower medians in the novice group. While using Prolene® sutures the expert group medians were the highest, however, a trend was not observed. Vicryl® sutures had a non-specific behavior among the different experience groups or variables.

Table 18. *Mann-Whitney U test for maximum tensile force*

Maximum Tensile Force (N)			
	Strained (n=27) **Md (IQR)**	**Unstrained (n=4)** **Md (IQR)**	***p-value***
Polyglactin 910	85.95 (62.87-89.23)	90.00 (84.51-94.06)	0.19
Polypropylene	42.64 (40.98-44.89)	41.06 (38.1-44.21)	0.4
Polydioxanone	58.99 (55.97-62.51)	59.20 (57.19-60.96)	0.95

p<0.05 was considered statistically significant

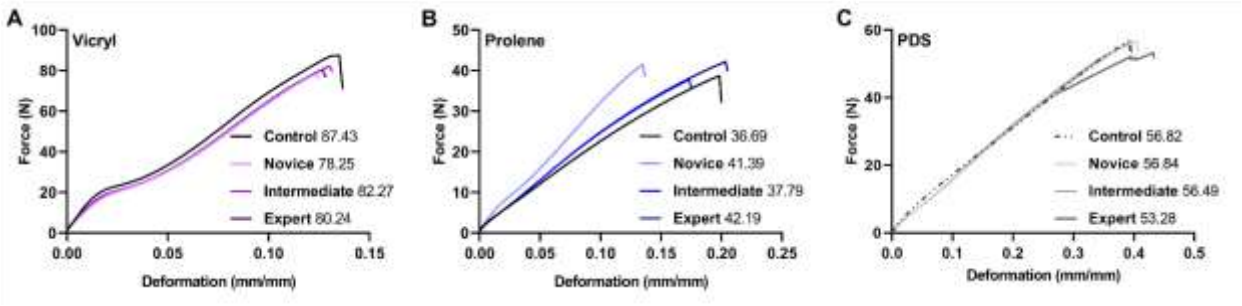


Figure 16. *Force vs deformation curves expressed as (N) and (mm/mm) respectively. Each curve represents average suture behavior among test groups of all materials (A: Vicryl®, B: Prolene® and C: PDS®). Next to the different experience level groups is expressed the average maximum tension force for each one.*

V.5. DISCUSSION

As mentioned earlier, the predisposing surgeon related factors can be modified as training and experience are gained to reduce surgical site occurrence. Experience in suture handling and abdominal wall fascial closure is something usually learned as progression is made while in surgical training. Suturing experience must include adequate scientific knowledge while choosing the appropriate suture material and understanding the behavior of it. Conze and Klinge, calculated that the maximum tensile force of the abdominal wall is defined as 16N/cm, the latter must be taken into account by the surgeon when selecting the appropriate suture material for abdominal wall fascial closure [5].

Multiple studies have recognized and recommend the continuous running suture for closure of abdominal wall fascia with an absorbable monofilament suture with a suture length to wound length ratio of 4:1 with an initial anchoring knot (loop or surgeon's knot) [22-26]. Evidence provided by a double-blind study suggests that performing abdominal wall fascial suturing with small bites (5 mm) rather than large bites (10 mm) can aid in incisional hernia prevention [16]. Currently, an ongoing clinical trial aimed to prove that suturing technique is essential regarding incisional hernia prevention is being carried out by Fortelny et al. [27].

In 1994 Israelsson et al. found that SSI might be as high as 9% and they determined its association with incisional hernia [1, 3]. Other authors have estimated similar rates reporting an incidence of 9 to 20% [21]. Several studies have established the economic burden of SSI reporting an incidence rate between 1.5% and 20%; resulting in an increase of 8-9 days of hospitalization, translated to an increase in related health care costs of up to 19.1 billion Euro per year [28]. Incisional hernia occurrence rate was analyzed in a systematic review and metaregression study which included 14,618 patients. It was estimated that the weighted mean incisional hernia rate at 24 months was approximately 13% [29]. Israelsson et al., in 1996, also analyzed comorbidities associated with incisional hernia, being incarceration and bowel strangulation the most common ones; with a reported

incidence of 6 to 15% and 2% respectively [30]. They concluded that suture technique is a major determinant of incisional hernia occurrence in continuously sutured midline laparotomies. Simple adjustments in technique can considerably improve late operative results.

The effects on biomechanical properties due to excessive twisting on suture material while suturing have been evaluated when using monofilament and braided sutures. Hennesey et al. concluded that excessive twisting does alter the biomechanical properties of sutures, and surgeons must be aware that this can result in a decrease of tensile strength and elasticity of the biomaterial [11]. All surgeons must know the unique characteristics and properties of suturing material in order to adapt their surgical technique to reduce torsional force and avoid changes in biomechanical behavior [11, 12]. While the effect of axial twisting on sutures used in abdominal wall fascial closure was not evaluated in the current study, the results do not exhibit a statistically significant difference among different experience level groups handling sutures.

Longitudinal strain on suture materials starts after the initial loop knot acts as an anchor, allowing a continuous longitudinal strain throughout the continuous running suture material used while performing abdominal wall fascial closure. Several aspects of abdominal wall fascial closure need further investigation. As an example, the effect of surgeon's experience level on the longitudinal strain has not been well addressed. This is one of the few studies that focuses on the modifications of suture's biomechanical characteristics while being handled by different experienced level general surgery residents.

Polyglactin 910 had the highest F_{tmax} of the sutures tested and failed after a force of 85.95 (IQR 62.87 – 89.23) N was applied. Suture characteristics and diameter may have influenced this result. The monofilament absorbable material, polydioxanone, had the second highest F_{tmax}. This biomaterial failed at 58.99 (IQR 55.97 – 62.51) N; while polypropylene was the material with the lowest F_{tmax} tested and failed at 42.64 (IQR 40.98 – 44.89) N. Regarding the elastic properties of the

material, polyglactin 910 demonstrated the least extension of all sutures tested and was 14 (IQR 13.33 – 14.83) mm. This is attributed to its multi-filament arrangement. While polydioxanone was the suture with the most extension 41.33 (IQR 39.33 – 45.66) mm. These findings are consistent with other studies which demonstrated that polyglactin 910 and polydioxanone are stronger than polypropylene [8, 31].

Tensile test of the longitudinally strained sutures showed that tensile force (F_{tmax}) of all sutures was not statistically significantly modified when compared to unstrained controls. Biomechanical changes in 0-polydioxanone showed a non-significant decrease in maximum suture strength from 59.2 (IQR 57.19 – 60.96) N to 58.99 (IQR 55.97 – 62.51) N, representing merely a 0.35% decrease in suture strength (p 0.95). Similarly, longitudinal straining in 1- polyglactin decreased suture strength 4.5% (p 0.19), while 0-polypropylene suture was increased in 3.8% (p 0.4). Polypropylene exhibits biomechanical characteristics modification while being under longitudinal strain stress. Measurements in this study showed an increased in F_{tmax} in all strained polypropylene suture groups when compared to control, this finding might be explained by the stress hardening biomechanical properties of the material prior to rupture or failure [32]. Results of this study demonstrate that polydioxanone has a superior F_{tmax} compared to polypropylene and has superior extension at failure properties compared to polyglactin 910; confirming that polydioxanone could be the suture of choice for abdominal wall fascial closure.

No statistically significant modification in the suture's ability to resist a change in length under tension was encountered. This suggests that longitudinally strained sutures are likely to elongate and keep conforming to the wound. This property should not increase the risk of suture failure and the associated surgical site occurrence. If a suture length to wound length ratio of 4:1 is observed, suture extension under longitudinal strain will preserve tensile strength avoiding risk for suture failure. Surgeons need to be aware that excessive longitudinal strain and axial twisting, might decrease the maximum tensile force (F_{tmax}) of suture materials. While performing a continuous running closure of the abdominal wall fascia, prevention of

excessive longitudinal strain and longitudinal axial twisting should be observed while maintaining a suture length to wound length ratio of 4:1.

Comparing surgeon results without correction for variability in patient risk factors, is often emphasized; as differences may reflect the selection of patients [33]. Even after such correction postoperative morbidity and mortality have been found to vary widely among surgeons [28]. This is often thought to reflect differences in surgical technique that might be related to surgical expertise.

Surgical technique variations and suture material selection can definitely influence outcomes but are not often identified or measured regularly. Therefore, it is of major importance to continue studying if the expertise level might hamper suture biomechanical properties after abdominal wall fascial closure is performed. Suture materials routinely used in abdominal wall fascial closure, according to the results of this study, maintain their biomechanical properties despite being used by surgical trainees with different levels of surgical expertise.

Surgery is still taught via an apprenticeship model. Resident learning is dependent on the patients on service, the teaching expertise, and availability of their attending physicians. Expert teaching surgeons use every case as an explicit and unique learning opportunity, thus maximizing resident learning [34]. Currently, surgeons identified as having an optimal surgical technique are chosen or invited to participate in the teaching and learning process of others. In the apprenticeship model, a senior surgeon sets the example for surgery residents and supervises their progress. Unfortunately, seniority alone does not guarantee the optimal technical performance or teaching – supervising capabilities [35]. Despite knowledge and awareness of the importance of abdominal wall closure, this part of the surgical procedure is sometimes performed with little attention to details by residents without adequate supervision, specifically in surgery or gynecology training programs. There is a lack of information regarding how laparotomy closure techniques are taught and really learned in general surgery and other surgical residency programs.

V.6. CONCLUSION

This study does not show a statistically significant modification regarding impact of experience level of different general surgery residents in the biomechanical properties of sutures used in an abdominal wall fascial closure in a swine model simulating a human abdominal wall.

Results demonstrate that polydioxanone has a superior F_{tmax} compared to polypropylene as well as superior extension at failure properties compared to polyglactin 910, thus supporting that polydioxanone could be the suture of choice of abdominal wall fascial closure.

The skill of the surgeon identified as having an optimal surgical technique could be used for the education of others. Senior surgeons set the example for surgical residents and supervise their development. In this study, general surgery resident experience level alone was not a guarantee of superior suture handling performance. Surgeons must have scientific basis and knowledge to perform adequate suturing technique and material selection for wound closure, particularly in the case of abdominal wall fascial closure. Surgeons should also stay informed about the most up-to-date findings concerning all types of closure techniques and materials.

V.6.1 Highlights

- Surgical Site Occurrences are the main concern after abdominal surgical incisions are sutured
- Longitudinal strain and axial twisting, can decrease tensile force of sutures
- Polydioxanone could be the suture of choice for abdominal wall fascial closure
- Different levels of expertise did not alter tensile strength of sutures in this study
- Scientific basis and knowledge are required to choose materials and perform adequate wound closure

V.6.2 Funding

This work was supported by the Mechanical Engineering and Advanced Materials Department from Escuela de Ingeniería y Ciencias, Centro de Innovación y Desarrollo Estratégico del Producto, and Escuela de Medicina at Tecnológico de Monterrey – Zona Norte

V.6.3 Acknowledgements

This study could not be accomplished without the voluntary participation of the General Surgery Residents from Escuela de Medicina y Ciencias de la Salud – Región Norte at Tecnológico de Monterrey. Christian Carlos Mendoza from Centro de Innovación en Diseño del Producto at Tecnológico de Monterrey was instrumental allowing access to the facilities where all mechanical measurements were made.

V.7. REFERENCES

1. Israelsson, L. and T. Jonsson, Closure of midline laparotomy incisions with polydioxanone and nylon: the importance of suture technique. British journal of surgery, 1994. 81(11): p. 1606-1608.

2. Muysoms, F.E., et al., European Hernia Society guidelines on the closure of abdominal wall incisions. Hernia, 2015. 19(1): p. 1-24.

3. Israelsson, L.A. and D. Millbourn, Closing midline abdominal incisions. Langenbecks Arch Surg, 2012. 397(8): p. 1201-7.

4. Hesselink, V.J., et al., An evaluation of risk factors in incisional hernia recurrence. Surg Gynecol Obstet, 1993. 176(3): p. 228-34.

5. Conze, J. and U. Klinge, Biocompatibility of biomaterials-clinical and mechanical aspects, in Incisional hernia. 1999, Springer. p. 169-177.

6. Williams, Z., et al., An evaluation of abdominal wall closure in general surgical and gynecological residents. Hernia, 2017. 21(6): p. 873-877.

7. Mandel, L.P., G.M. Lentz, and B.A. Goff, Teaching and evaluating surgical skills. Obstet Gynecol, 2000. 95(5): p. 783-5.

8. Kim, J.-C., et al., Comparison of tensile and knot security properties of surgical sutures. Journal of Materials Science: Materials in Medicine, 2007. 18(12): p. 2363-2369.

9. Marturello, D.M., et al., Knot security and tensile strength of suture materials. Vet Surg, 2014. 43(1): p. 73-9.

10. Good, M.M., et al., Surgical knot integrity: effect of suture type and caliber, and level of residency training. J Surg Educ, 2013. 70(1): p. 156-60.

11. Hennessey, D.B., et al., Torsion of monofilament and polyfilament sutures under tension decreases suture strength and increases risk of suture fracture. J Mech Behav Biomed Mater, 2012. 12: p. 168-73.

12. Holmlund, D., Physical properties of surgical suture materials: Stress-strain relationship, stress-relaxation and irreversible elongation. Annals of Surgery, 1976. 184(2): p. 189.

13. Kilkenny, C., et al., Improving bioscience research reporting: the ARRIVE guidelines for reporting animal research. PLoS biology, 2010. 8(6): p. e1000412.

14. McDougall, E.M., et al., Construct validity testing of a laparoscopic surgical simulator. J Am Coll Surg, 2006. 202(5): p. 779-87.

15. Cooney, G.M., et al., The suture pullout characteristics of human and porcine linea alba. J Mech Behav Biomed Mater, 2017. 68: p. 103-114.

16. Deerenberg, E.B., et al., Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet, 2015. 386(10000): p. 1254-1260.

17. Chu, C.C., Mechanical properties of suture materials: an important characterization. Ann Surg, 1981. 193(3): p. 365-71.

18. Campbell, J.A., et al., A biomechanical study of suture pullout in linea alba. Surgery, 1989. 106(5): p. 888-92.

19. DesCôteaux, J.G., et al., Linea alba closure: determination of ideal distance between sutures. J Invest Surg, 1993. 6(2): p. 201-9.

20. Administration, U.F.a.D., Guidance for Industry and FDA Staff-Class II Special Controls Guidance Document: Surgical Sutures. US Department of Health and Human Services, 2003: p. 6-3.

21. Naleway, S.E., et al., Mechanical properties of suture materials in general and cutaneous surgery. J Biomed Mater Res B Appl Biomater, 2015. 103(4): p. 735-42.

22. van 't Riet, M., et al., Meta-analysis of techniques for closure of midline abdominal incisions. Br J Surg, 2002. 89(11): p. 1350-6.

23. Wissing, J., et al., Fascia closure after midline laparotomy: results of a randomized trial. British journal of surgery, 1987. 74(8): p. 738-741.

24. Jenkins, T., The burst abdominal wound: a mechanical approach. British Journal of Surgery, 1976. 63(11): p. 873-876.

25. Gislason, H., J. Grønbech, and O. Søreide, Burst abdomen and incisional hernia after major gastrointestinal operations--comparison of three closure techniques. The European journal of surgery= Acta chirurgica, 1995. 161(5): p. 349-354.

26. Fong, E.D., et al., Tensile strength of surgical knots in abdominal wound closure. ANZ journal of surgery, 2008. 78(3): p. 164-166.

27. Fortelny, R.H., et al., Effect of suture technique on the occurrence of incisional hernia after elective midline abdominal wall closure: study protocol for a randomized controlled trial. Trials, 2015. 16: p. 52.

28. Leaper, D.J., et al., Surgical site infection–a European perspective of incidence and economic burden. International wound journal, 2004. 1(4): p. 247-273.

29. Bosanquet, D.C., et al., Systematic review and meta-regression of factors affecting midline incisional hernia rates: analysis of 14 618 patients. PLoS One, 2015. 10(9): p. e0138745.

30. Israelsson, L.A. and T. Jonsson, Incisional hernia after midline laparotomy: a prospective study. Eur J Surg, 1996. 162(2): p. 125-9.

31. Nobile, L., L. Checchi, and G. Monaco, Experimental analysis of tensile properties of some suturing materials. Journal of Materials Science: Materials in Medicine, 1997. 8(1): p. 53- 56.

32. Callister, W.D. and D.G. Rethwisch, Materials science and engineering: an introduction. Vol. 7. 2007: John Wiley & Sons New York.

33. Copeland, G.P., et al., Risk-adjusted analysis of surgeon performance: a 1-year study. Br J Surg, 1995. 82(3): p. 408-11.

34. Lewis, F.R. and M.E. Klingensmith, Issues in General Surgery Residency Training—2012. Annals of Surgery, 2012. 256(4): p. 553-559.

35. Israelsson, L.A., The surgeon as a risk factor for complications of midline incisions. Eur J Surg, 1998. 164(5): p. 353-9.

VI. CONCLUSIONS AND PERSPECTIVES

VI.1. MESH FOR HERNIA REPAIR

Surgical meshes have become the system of choice for hernia repair. Even though it is not the optimum method, so far, it is the one that has shown a lower rate of recurrence. Currently, there are more than 70 types of meshes commercially available. These are constructed from synthetic materials (absorbable, non-absorbable, or a combination of both) and animal tissue. Despite reducing rates of recurrence, hernia repair with surgical meshes still faces adverse effects such as infection, adhesion, and bowel obstruction. Most of these drawbacks are related to the chemical and structural nature of the mesh itself.

An optimum integration with the abdominal wall and negligible adhesion on the visceral side are the most important after sought features for the “ideal” mesh. A surgical mesh will trigger one of three different responses from the body: it may be integrated, encapsulated or degraded. In order to have a minimal inflammatory response to better integrate it to the body, it is highly important to improve biocompatibility.

To overcome this obstacle, researchers are actively exploring methods to improve biocompatibility, with the goal of developing a mesh that can be effectively incorporated with minimal inflammation and/or infection. Nanofibers have been recently considered as a strong potential intermediary structure to be used as a coating, given their ultralightweight quality, which could contribute to minimize the inflammatory response from the body and given its functional porosity, which could promote cell adhesion and proliferation.

New players in the mesh arena are biosynthetic meshes. They might as well be “fourth generation meshes”. These are being developed and used in clinical trials as a cost-effective alternative to biologic (third generation meshes) and synthetic meshes (first and second generation meshes) [1]. Materials being used for this purpose include biodegradable polymers that allow neovascularization, cellular

proliferation, and integration with no encapsulation. Some commercially available examples include:

Bio-A® - knit mesh made of 67% polyglycolic acid + 33% trimethylene carbonate

Tigr Matrix® - mesh with 2 types of fibers: fast absorption + slow absorption (glycoside and trimethylene carbonate + trimethylene carbonate)

Phasix® - 4-hydroxibutarate mesh (hydrolysis H_2O & CO_2)

Currently biosynthetic mesh has proven to be effective preventing hernia recurrence and adequate quality of life. Further studies are required with a longer patient and outcome follow-up. No inferiority has been demonstrated while compared to biologic or synthetic mesh in a period of 3 – 5 years. They seem to be a good cost alternative [2-4].

The ideal mesh is yet to come [5]. Several aspects need to be considered while choosing and/or manufacturing future meshes for hernia repair:

1.- A film-like barrier can help to protect adhesions when the mesh is placed within the abdominal cavity, avoiding any direct contact of polypropylene to the bowel but requiring permanent fixation, whereas pore constructions permit tissue ingrowth and require less durable fixation. Large pore constructions seem to be superior with regard to the induced intensity of inflammation and fibrosis.

2.- If tension-free conditions cannot be guaranteed, structural stability is necessary to prevent collapse of pores when stretched.

3.- Though there are some coated meshes on the market, current evidence of bioactive functionality is low but may come up in the future.

4.- Fixation of the mesh can be achieved by suture, glue or tacks, whereas glue needs pores, and a film needs permanent fixation. However, with fixation, the immediate functional stress to the prosthesis has to be considered. For many

indications, physiological fibrin and tissue ingrowth alone provide sufficient fixation (e.g. TEP – Totally Extra-Peritoneal hernia repair).

5.- Three-dimensional constructions may support the easy placement of a device, but with the disadvantage of reduced porosity. As 3-dimensional constructions with sufficiently large pores offer the option for tissue regeneration, these may be a valuable future option.

6.- As the development of a long-term complication can never be completely excluded, a postoperative visualization of the textile can help to avoid unnecessary revisions. If indicated, the addition of ferro particles to the polymer fibers allows depiction on MRI with sufficient contrast to adjacent tissues [6].

7.- As even the best implant is not as good as healthy tissue, the indication to use an alloplastic prosthesis always has to be restrictive and is of course influenced by the risk profile of the device as well as of the patient. The surgeon ultimately has to provide an individual risk-benefit assessment.

8.- The incidence of complications from permanent implants accumulates over time; consequently, the age of the patient has an impact on the risk-benefit balance.

9.- As most of the device related complications with comparably rare incidences are not reported within clinical studies, individual experiences may be as valuable as the published literature.

10.- In any case, all patients with an implant should be monitored and recorded in a personal register which some of the public registries can use, providing a highly valuable set of variables for adequate quality control [7, 8].

VI.2. SUTURES

Understanding the biomechanical performance of sutures will help surgeons not only to determine the appropriate clinical application for each type, but also to improve surgical techniques to take advantage of each suture properties.

In the stress-softening and residual strain effect study, the suture material after being subjected to loading and unloading cycles, its stress magnitude became lower than that of the control. All tested sutures exhibit residual strains which are related to microstructural material damage upon deformation from the natural, undistorted state of the control material. To predict the suture materials response behavior observed during uniaxial tension test, a new non-monotonous stress-softened material model that takes into account permanent set effects for the unloading paths as described by the simple constitutive relation has been proposed.

Based on the accuracy of the proposed non-monotonous model to predict experimental data, the extent of damage of suture biocompatible materials can be conveniently determined by considering its softening behavior observed during experimental tests. There is a variation in the theoretical predictions probably due to some viscoelastic effects that were not considered in the proposed model.

The strain effects in suture material study confirms that stress-softening and residual strain effects appear in the suture materials tested. The experimental work of this study proves that suture materials biomechanics change when tensile loads are applied during the suturing and healing processes. The aforementioned effects are more evident when *in vitro* sutures are subjected to cyclic loading conditions. However, the results of this new experimental work will be further investigated and reported in subsequent research.

The study regarding impact of experience level of general surgery residents upon suture biomechanical properties study, does not show a statistically significant difference in biomechanical properties modification of the commonly used sutures in

an abdominal wall fascial closure in a swine model simulating a human abdominal wall.

The results do exhibit modifications in biomechanical properties of sutures after being used for fascial closure. Suture material handling, while performing an abdominal wall fascial closure has a similar behavior as a cyclic load test; although not every suture pass was mechanically measured for stress or strain. These results and findings are in accordance to the stress-softening and residual strain effects in biomechanical properties of suture material study.

Results from the impact of experience level of general surgery residents in biomechanical properties of sutures, demonstrate that polydioxanone has a superior Ftmax compared to polypropylene as well as superior extension at failure properties compared to polyglactin 910; thus, supporting that polydioxanone could be the suture of choice of abdominal wall fascial closure.

Surgeons must have scientific basis and knowledge to perform adequate suturing technique and material selection for wound closure, particularly in the case of abdominal wall fascial closure. Surgeons should also stay informed about the most up-to-date findings concerning all types of closure techniques and materials.

Modern era has driven technological advances in several ways. Sutures are not exempt of such impact. Type and use specific sutures are on the way. Currently substance “carrying” and “delivery” suture systems are being developed for clinical use [9]. Further advances in suture delivery systems are being designed with improved handling and tissue apposition innovations [10].

VI.3. EDUCATION

The skill of the surgeon identified as having an optimal surgical technique can be used for the education of others. Senior surgeons set the example for surgical residents and supervise their development.

Laparotomy or abdominal wall closure is one of the most basic and fundamental skills necessary for the general surgeon and resident physician. Improper or poor technique usually result in incisional hernias with their associated complications, most of the time demanding surgical reintervention and repair using a mesh.

Despite knowledge of the prominence of abdominal wall closure, this part of the surgical intervention is commonly performed with little attention to detail and, in residency programs, by trainees with minute supervision.

Much has been published related to closure methods and suturing techniques, but much less has been published regarding the teaching and learning of these procedures. All surgeons are familiar with the ‘‘approximate, do not strangulate’’ rule for abdominal/tissue closure, the appropriate amount of tension required for fascial closure is unknown and needs further study.

In surgical training, understanding and skill in suture handling while performing abdominal wall fascial closure is learned progressively. Entrustable professional activities for basic surgical procedures and some complex surgical interventions, including abdominal wall fascial closure, are commonly achieved by post-graduate year 2 (PGY-2) while in surgical training [11, 12]. Operative technique and knot tying are surgical skills that are generally taught, learned, and perfected over time. Traditionally, senior residents are believed to have better technical skills than junior residents. However, there is limited evidence in the literature on the part seniority plays in knot security, and whether suture caliber and type also influence into this [13-15].

In the level of experience impact on biomechanical properties study, general surgery resident experience level alone was not a guarantee of superior suture handling performance. Although timing while fascial closure was not recorded; probably expert level residents performed the abdominal wall fascial closure faster with less attention to detail, meanwhile the intermediate and novice group probably were more attentive to detail while doing so. This can be one of the explanations for no statistical differences when compared; besides the possibly safely overengineered suture material.

Despite the abundant literature on the technical aspects of abdominal wall closure, little is known about the ideal way to incorporate this knowledge into training programs and skills laboratories. There has been recent emphasis in surgical training programs on the formal teaching of surgical skills outside of the operating room and the formation of skills labs to achieve these purposes.

According to the Greenwood Dictionary of Education, active learning is defined as the process of having students engage in regular reflection, self-assessment, problem solving, and attaining knowledge through participation or contribution [16].

Active learning is well supported by evidence to be an effective approach that leads to longer lasting, meaningful learning, though unique challenges exist in its application to surgical education. Some of the challenges include a heightened emphasis on operating room efficiency, patient safety concerns, and duty hour restrictions, which have led to a decrease in patient-based learning experiences for surgical trainees.

Several studies strengthen the evidence that simulation-based training, as part of a structured program and incorporating predetermined proficiency levels, results in skills transfer to the operative setting [17-19]. These strategies promote active learning as well.

Global Operative Assessment of Laparoscopic Skills (GOALS) and the Objective Structured Assessment of Technical Skills (OSATS) are required in all programs that include simulation-based training as a part of the skills acquisition process [20, 21].

Simulation-based learning can be accomplished utilizing high fidelity or low fidelity surgical simulators. Importance relies not on fidelity, but in validation of the simulator for the defined surgical competence and proficiency [22]. This is true for conventional and minimally invasive surgery. Technology driven simulators can incorporate augmented or virtual reality and can also include haptics and tracking and/or grading progress modules. Even so, validation of the simulation is required [22-24].

Validation refers to adequate construction, programing, and calibration of the simulator. This is indirectly verified by the strong correlation between the skills and level of the trainee/resident [23].

The validation of a minimally invasive surgery high fidelity simulator (Surgical SIM®) available at our Institution was designed and carried out. Participation of different level (novice, intermediate, expert) residents performed assigned tasks. Statistically significant better results were obtained in time, instrument trajectory, and errors by the expert group. These results allow assumption of adequate construction, programming, and calibration of the Surgical SIM® simulator rendering it as an adequate learning tool.

Current challenges in surgical education with surgical simulators are the costs of the high-fidelity models. With laparoscopic box trainers, skill acquisition by novice residents and non-laparoscopy practicing surgeons is achievable [25-27]. This has proven to be a good solution for countries with low to medium income. Continuous research in education and tool development supporting active learning need to be kept as a priority in the advancement of the surgical training agenda.

Becoming a surgeon implies having adequate scientific knowledge as well as surgical skills and decision making. Everyday use of biomaterials while performing interventions demands proper choosing and handling. Acquiring the ability to select the correct type of biomaterial and the proper surgical technique for abdominal wall closure and/or hernia repair is not an easy challenge for mentor nor the surgeon in training. Active learning and evidence based surgical practice are of great assistance accomplishing the aforementioned challenge. Technology advances awareness is required in routinely performed interventions and the biomaterials used.

Education is an everchanging activity and process. Different situations and issues continuously shape the way teaching and learning occur. Social an economic factor also contributes in the generational differences, requiring diverse approaches to fulfill the needs to become a well-rounded surgeon.

Being a surgeon and a mentor, while trying to incorporate innovative learning instruments and processes, which includes simulation; the quest for scientific evidence focused on better patient care and outcomes should guide the practice of surgery. Research including the previously mentioned aspects were the trigger to start these multidisciplinary investigations.

VI.4. REFERENCES

1. Kim M, Oommen B, Ross S, Lincourt A, Matthews B, Heniford B, et al. The current status of biosynthetic mesh for ventral hernia repair. Surgical technology international. 2014;25:114-21.

2. Sahoo S, Haskins IN, O'Rourke C, Krpata D, Derwin K, Rosen MJ. Early Patient Morbidity after Open Ventral Hernia Repair with Permanent Synthetic vs Biosynthetic Mesh. Journal of the American College of Surgeons. 2016;223(4):e19.

3. Rosen MJ, Bauer JJ, Harmaty M, Carbonell AM, Cobb WS, Matthews B, et al. Multicenter, Prospective, Longitudinal Study of the Recurrence, Surgical Site Infection, and Quality of Life After Contaminated Ventral Hernia Repair Using Biosynthetic Absorbable Mesh: The COBRA Study. Ann Surg. 2017;265(1):205-11. doi: 10.1097/SLA.0000000000001601. PubMed PMID: 28009747; PubMed Central PMCID: PMCPMC5181129.

4. Roth JS, Anthone GJ, Selzer DJ, Poulose BK, Bittner JG, Hope WW, et al. Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair: 18-month follow-up. Surgical endoscopy. 2018;32(4):1929-36.

5. Klinge U, Park J-K, Klosterhalfen B. 'The Ideal Mesh?'. Pathobiology. 2013;80(4):169-75.

6. Kuehnert N, Kraemer NA, Otto J, Donker HC, Slabu I, Baumann M, et al. In vivo MRI visualization of mesh shrinkage using surgical implants loaded with superparamagnetic iron oxides. Surgical endoscopy. 2012;26(5):1468-75.

7. Muysoms F, Campanelli G, Champault G, DeBeaux A, Dietz U, Jeekel J, et al. EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal wall hernia repair. Hernia. 2012;16(3):239-50.

8. Stechemesser B, Jacob D, Schug-Paß C, Köckerling F. Herniamed: an internet-based registry for outcome research in hernia surgery. Hernia. 2012;16(3):269-76.

9. Mintchev MP, Yadid-Pecht O, Fattouche M. Device for delivery of a substance. Google Patents; 2014.

10. Stopek JB, Cohen MD. Bioactive substance in a barbed suture. Google Patents; 2016.

11. Williams Z, Williams S, Easley HA, Seita HM, Hope WW. An evaluation of abdominal wall closure in general surgical and gynecological residents. Hernia. 2017;21(6):873-7. Epub 2017/10/22. doi: 10.1007/s10029-017-1682-z. PubMed PMID: 29058132.

12. Mandel LP, Lentz GM, Goff BA. Teaching and evaluating surgical skills. Obstet Gynecol. 2000;95(5):783-5. PubMed PMID: 10775747.

13. Kim J-C, Lee Y-K, Lim B-S, Rhee S-H, Yang H-C. Comparison of tensile and knot security properties of surgical sutures. Journal of Materials Science: Materials in Medicine. 2007;18(12):2363-9.

14. Marturello DM, McFadden MS, Bennett RA, Ragetly GR, Horn G. Knot security and tensile strength of suture materials. Vet Surg. 2014;43(1):73-9. Epub 2013/11/19. doi: 10.1111/j.1532-950X.2013.12076.x. PubMed PMID: 24383708.

15. Good MM, Good LB, McIntire DD, Brown SA, Wai CY. Surgical knot integrity: effect of suture type and caliber, and level of residency training. J Surg Educ. 2013;70(1):156-60. Epub 2012/08/14. doi: 10.1016/j.jsurg.2012.06.028. PubMed PMID: 23337686.

16. Collins JW, O'Brien NP. The Greenwood dictionary of education: ABC-CLIO; 2011.

17. Dawe S, Pena G, Windsor J, Broeders J, Cregan P, Hewett P, et al. Systematic review of skills transfer after surgical simulation-based training. British Journal of Surgery. 2014;101(9):1063-76.

18. Luc JG, Antonoff MB. Active learning in medical education: Application to the training of surgeons. Journal of medical education and curricular development. 2016;3:JMECD. S18929.

19. Sturm LP, Windsor JA, Cosman PH, Cregan P, Hewett PJ, Maddern GJ. A systematic review of skills transfer after surgical simulation training. Annals of surgery. 2008;248(2):166-79.

20. Reznick R, Regehr G, MacRae H, Martin J, McCulloch W. Testing technical skill via an innovative “bench station” examination. The American Journal of Surgery. 1997;173(3):226-30.

21. Vassiliou MC, Feldman LS, Andrew CG, Bergman S, Leffondré K, Stanbridge D, et al. A global assessment tool for evaluation of intraoperative laparoscopic skills. The American journal of surgery. 2005;190(1):107-13.

22. Satava RM, Gallagher AG, Pellegrini CA. Surgical competence and surgical proficiency: definitions, taxonomy, and metrics. Journal of the American College of Surgeons. 2003;196(6):933-7.

23. Westwood J, Hoffman H, Stredney D, Weghorst S. Validation of virtual reality to teach and assess psychomotor skills in laparoscopic surgery: results from randomised controlled studies using the MIST VR laparoscopic simulator. Medicine Meets Virtual Reality: art, science, technology: healthcare and evolution. 1998:124.

24. McDougall EM, Corica FA, Boker JR, Sala LG, Stoliar G, Borin JF, et al. Construct validity testing of a laparoscopic surgical simulator. J Am Coll Surg. 2006;202(5):779-87. doi: 10.1016/j.jamcollsurg.2006.01.004. PubMed PMID: 16648018.

25. Diesen DL, Erhunmwunsee L, Bennett KM, Ben-David K, Yurcisin B, Ceppa EP, et al. Effectiveness of laparoscopic computer simulator versus usage of box trainer for endoscopic surgery training of novices. Journal of surgical education. 2011;68(4):282-9.

26. Munz Y, Kumar B, Moorthy K, Bann S, Darzi A. Laparoscopic virtual reality and box trainers: is one superior to the other? surgical endoscopy and other interventional techniques. 2004;18(3):485-94.

27. Derossis AM, Fried GM, Sigman HH, Barkun JS, Meakins JL. Development of a model for training and evaluation of laparoscopic skills. The American journal of surgery. 1998;175(6):482-7.

APPENDIX 1: PUBLISHED ARTICLES AND PATENTS

Appendix 1: Other Published Articles

SCIENTIFIC PAPER JSLS

Irrigation with Bupivacaine at the Surgical Bed for Postoperative Pain Relief After Laparoscopic Cholecystectomy

Gerardo Castillo-Garza, MD, José A. Díaz-Elizondo, MD, Carlos A. Cuello-García, MD, Oscar Villegas-Cabello, MD

ABSTRACT

Purpose: The aim of this study was to evaluate the effect of bupivacaine irrigated at the surgical bed on postoperative pain relief in laparoscopic cholecystectomy patients.

Methods: This study included 60 patients undergoing elective laparoscopic cholecystectomy who were prospectively randomized into 2 groups. The placebo group (n=30) received 20cc saline without bupivacaine, installed into the gallbladder bed. The bupivacaine group (n=30) received 20cc of 0.5% bupivacaine in at the same surgical site. Pain was assessed at 0, 6, 12, and 24 hours by using a visual analog scale (VAS).

Results: A significant difference (P=.018) was observed in pain levels between both groups at 6 hours postoperatively. The average analgesic requirement was lower in the bupivacaine group, but this did not reach statistical significance.

Conclusions: In our study, the use of bupivacaine irrigated over the surgical bed was an effective method for reducing pain during the first postoperative hours after laparoscopic cholecystectomy.

Key Words: Bupivacaine, Irrigation, Laparoscopic cholecystectomy, Postoperative pain.

General Surgery, Tecnologico de Monterrey-Escuela de Medicina y Ciencias de la Salud. Postgraduate Area, Monterrey, N. L. México (Drs. Garza, Elizondo, Cabello).

Evidence Based Medicine Center, Tecnologico de Monterrey, Escuela de Medicina y Ciencias de la Salud, Monterrey, N. L. México (Dr. García).

Irrigation with Bupivacaine at the Surgical Bed for Postoperative Pain Relief After Laparoscopic Cholecystectomy

We sincerely thank all surgical staff at Hospital Metropplitano "Dr Bernardo Sepúlveda" who helped make this protocol possible, especially to the General Surgery and Anesthesology Departments of the Multicenter Program of Tecnologico de Monterrey- SSNL.

Address correspondence to: Gerardo Castillo Garza, Tecnologíco de Monterrey - Escuela de Medicina y Ciencias de la Salud. Posgraduate Area-General Surgery, Ave. Morones Prieto #3000 Pte. Col. Los Doctores, Monterrey, N. L. México 64710, Telephone: 0448110778664, Fax: 83331061, E-mail: dr.gcg@hotmail.com, dr.gcastillo@gmail.com.

DOI: 10.4293/108680812X13291597716221

INTRODUCTION

Laparoscopic cholecystectomy is considered the gold standard treatment for benign gallbladder disease. It is characterized by a short hospital stay and an early return to regular activity. [1,2,3] Strategies to handle the different intraabdominal surgical pathologies with a laparoscopic approach offer a significant benefit compared with the conventional technique. [1,2]

Laparoscopic cholecystectomy has improved surgical outcome in terms of reduced pain and convalescence compared to conventional cholecystectomy.[1,2] However, the postoperative pain is considerable. Pain management with multiple analgesic and opioids has been reported with variable success. [1,2,4]

The pain in the conventional cholecystectomy is a parietal pain. In laparoscopic cholecystectomy, pain is derived from multiple situations: incision pain (somatic), deep intraabdominal pain (visceral), and shoulder pain (visceral pain due to phrenic nerve irritation). [5,6]

In 17% to 41% of the patients, pain is the main cause for staying overnight in the hospital the day of surgery [2–7] and the primary reason why the patients have a longer convalescence. [6,8,9]

Because postoperative pain after laparoscopic surgery is complex, specialists suggest that effective analgesic treatment should be a multimodal support. [3,4,8–15] This type of support consists on establishing empathy with patients, making them feel confident, explaining the procedure and its complications, and administration of a nonsteroidal anti-inflammatory analgesic agent an hour before surgery. [6,10,12–14] It should also include blocking the sensitive aferences (infiltrating the skin with a local anesthetic before any incision), administration of an opioid perioperatively, irrigating a local anesthetic in the peritoneal cavity, providing the patient with fluids and electrolytes.[5,6,8,10,14–20].

The aim of this study was to evaluate the use of the irrigation of a local anesthetic, such as bupivacaine, at the surgical bed for postoperative pain reduction. Secondly, we tried to assess whether this analgesia method reduces the postoperative use of nonsteroidal anti-inflammatory drugs (NSAID).

METHODS

Eligible participants were from 15 to 60 years old, undergoing elective laparoscopic cholecystectomy. We decided to use an experimental, prospective, randomized design. From September 2010 to July 2011, male and female patients were registered. Exclusion criteria were pregnancy, open cholecystectomy, and acute cholecystitis. Patients undergoing chronic treatment with any analgesic or anti-inflammatory agents were also excluded.

This study took place at the Metropolitano "Dr. Bernando Sepúlveda" Hospital in Monterrey, Mexico, from September 2010 to July 2011. It was approved by the Research and Ethics Committee of Tecnologico de Monterrey–Escuela de Medicina y Ciencias de la Salud and the Research and Ethics Committee at Hospital Metropolitano "Dr. Bernando Sepúlveda" where this protocol was performed. Informed and written consent was obtained from all participants in the trial.

Sixty patients undergoing elective laparoscopic cholecystectomy were prospectively randomized into 2 groups with concealment of the random sequence. In the control or placebo group, 20cc of normal saline solution without bupivacaine was irrigated at the surgical bed after laparoscopic cholecystectomy. The experimental group was irrigated with 20cc of bupivacaine 0.5% in normal saline solution.

Before surgery, all the patients underwent upper abdominal ultrasound, EKG, chest X-rays, a complete blood count, liver function test, and a coagulation profile. All patients were referred to the operating room without premedication, and the induction was performed using cisatracurium or vecuronium, propofol, and fentanyl. A customized dose for each patient was used.

A standard operative method was used with a 4-trocar technique in all patients. Pneumoperitoneum was achieved in every case with the use of a Veress needle through a periumbilical incision, and was maintained at 14mm Hg during the entire surgical procedure. After removal of the gallbladder, hemostasis was performed at the surgical bed. After gallbladder extraction, randomization was performed using a computer program (www.randomized.com). Irrigation of the surgical bed was done with the insertion of a feeding tube through the right subcostal port. After irrigation of the gallbladder, gas, instruments, and trocars were removed. No drains were used. There were no complications in the perioperative period in any patient.

Pain was assessed using a visual analog scale (VAS) of 0 to 10. Assessment was carried out in the recovery room at 30 minutes and 60 minutes postoperatively. Measurement in the patients room was performed 6,12, and 24 hours after surgery. All the patients were allowed to receive analgesic medication as needed, and the requirement of these medications was recorded. VAS was explained to every patient. The number "0" was equivalent to no pain, and "10" was the worst pain they ever felt. Administration of analgesics was correlated with the reading of VAS. Timing of the initial administration of analgesics was also recorded. Different IV analgesics, such as nonsteroidal anti-inflammatory drugs (NSAID), were used to reduce the postoperative pain.

Evaluation of postoperative symptoms, such as nausea, vomiting, and fever, were also recorded at the hospital stay. Initiation of oral intake and ambulation were also recorded.

Statistical analysis was performed using a 2-tailed *t* test and chi-square analysis; significance was determined as $P<.05$.

Kaplan-Meier curves and Log Rank test were used to assess differences over time. The descriptive variables were analyzed either by chi-square analysis or Fisher's exact test, as appropriate. $P<.05$ was considered statically significant.

Statistical analysis was performed with SPSS version 13.0 (SPSS, Chicago, IL, USA).

RESULTS

Sixty patients were included in this protocol; 55 were women and 5 were men ranging in age from 15 to 54 years. The average in the bupivacaine group was 29 years and in the control group 36 years. The result was significant for the age in both groups **(Table 1)**.

A significant difference occurred in the average pain levels at 6 hours postoperatively between the control and experimental groups **(Table 2)**. No significant difference occurred between the 2 groups during the other time intervals **(Figure 1)**.

Table 1.
Demographic Data

Characteristics	Bupivacaine Group	Placebo Group	P
Female/Male	30/30	25/30	.520
Age (SD)[a]	29.7 (9.2)	36.7 (9.5)	.01[b]

[a]Statistically significant.
[b]SD=standard deviation.

Table 2.
Comparison Between Groups

Visual Analog Scale [b]	Processing Group (Bupivacaine) n=30	Control Group (Placebo) n=30	P
Pain T0 p50 (p25–p75)	1 (1–2)	2 (1–5)	.070
Pain T6 p50 (p25–p75)	3.50 (2.75–5)	5 (4–5.25)	.02[a]
Pain T12 p50 (p25–p75)	3 (2–4)	4 (3–5)	.605
Pain T24 p50 (p25-p75)	1.50 (1–2)	2 (1–2)	.704

Statistically significant.
[b]p50, median; p25-p50, interquartile rank.

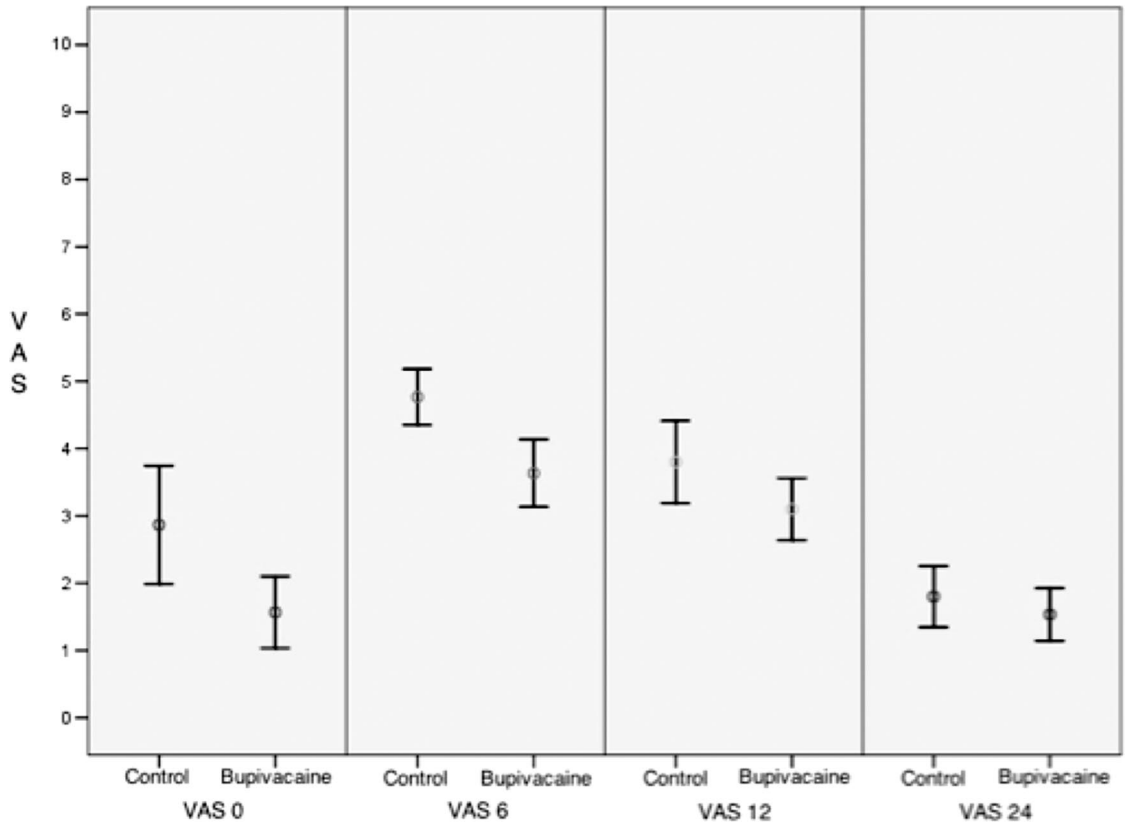


Figure 1. Comparison between pain groups.

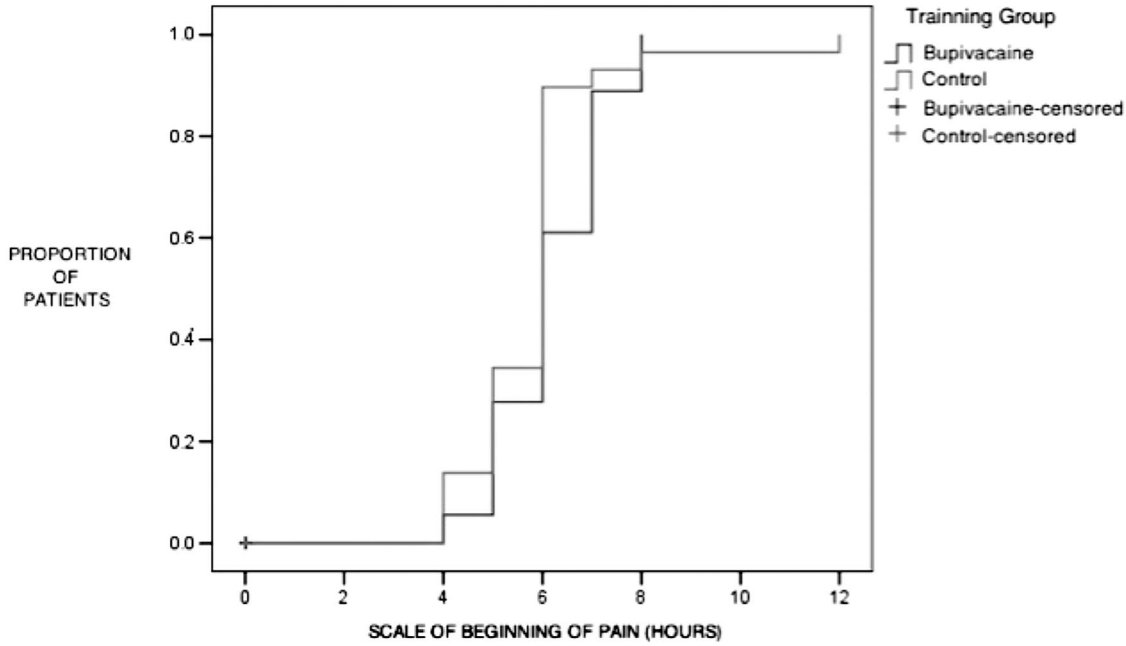


Figure 2. Scale of beginning of pain.

Table 3.
Comparison of Postsurgical Symptoms

Postsurgical Symptoms	Processing Group (Bupivacaine) n=30	Control Group (Placebo) n=30	P
Nausea n (%)	9 (30)	13 (43.3)	.422
Vomiting n (%)	1 (3.3)	1 (3.3)	1
Fever n (%)	0 (0)	1 (3.3)	1

The patients that needed analgesics asked for their first dose at 4 hours postoperative time. The average analgesic requirement was lower in the bupivacaine group, but this did not reach statistical significance **(Figure 2)**.

Nausea was the most common postoperative symptom reported, with an incidence of 30% in the experimental group and 40% in the control group. There was no significant statistical difference. Two patients experienced vomiting, one from each group with no significant difference. Only 1 patient in the control group experienced fever. This patient was treated with 500mg of acetaminophen by mouth every 6 hours during his hospital stay and was discharged the second postoperative day **(Table 3)**.

Oral intake and ambulation are shown in **Table 4**. No statistical differences were found **(Figures 3 and 4)**.

Of the 60 patients included in the study, 47 required intravenous postoperative analgesics; 18 patients were from the bupivacaine group and 29 from the control group. A statistically significant difference (P=.018) **(Table 5)** was observed. This difference was mainly noted at the 6-hour interval postoperatively.

DISCUSSION

Laparoscopic cholecystectomy is one of the most frequently performed elective surgeries. It is a short stay procedure, and therefore, adequate postoperative pain relief is of considerable importance, which makes it ideal for patients.

Postoperative pain in these patients is observed in peaks immediately after surgery and decreases after 24 postoperative hours. The cause of early postoperative pain in laparoscopic cholecystectomy is not clearly understood. This study demonstrates that 0.05% bupivacaine irrigation at the surgical bed decreases pain in laparoscopic cholecystectomy patients. With our results, we assumed that early postsurgical pain was generated by irritation of the

Table 4.
Recovery Indices

Variables [a]	Processing Group (Bupivacaine) n=30	Control Group (Placebo) n=30	P
Time to start eating hr p50 (p25-p75)	8.5 (8–10)	10 (8–12)	.44
Time to walk hr p50 (p25-p75)	12 (9–14)	12 (9.75–14.25)	.28

[a] p50, median; p25-p75, interquartile rank.

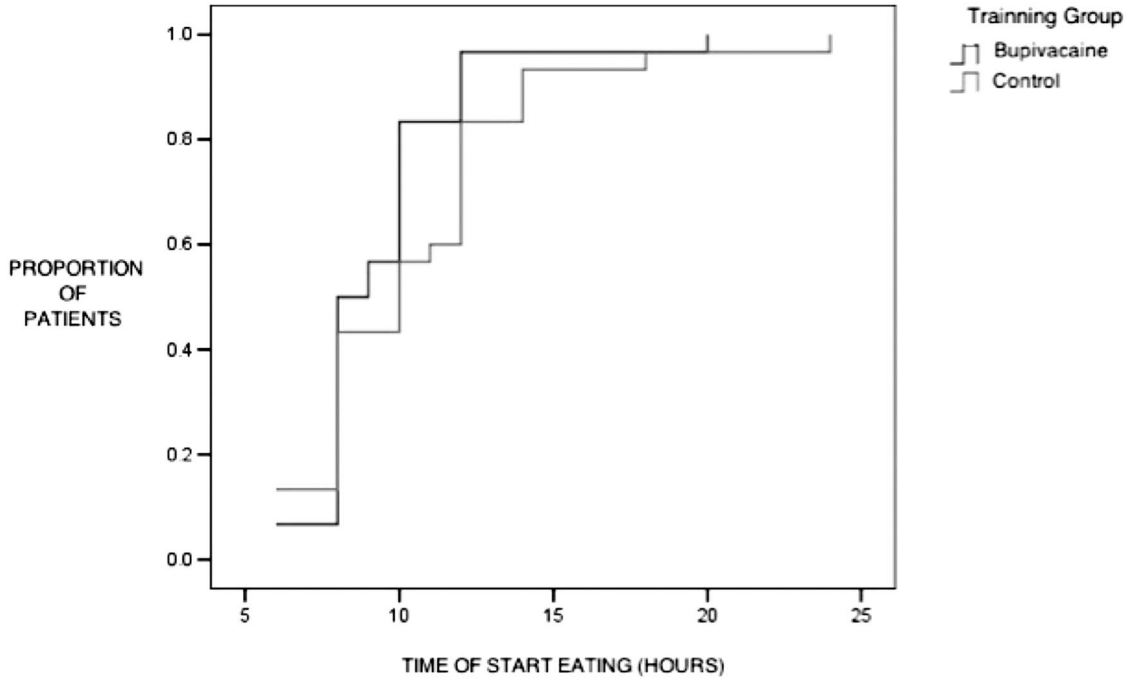


Figure 3. Scale of start eating.

peritoneum, and the application of bupivacaine may relieve this pain.

Of the 30 patients in the bupivacaine group, 12 did not require immediate analgesia based on their VAS recording of tolerable pain. In the placebo group, only 1 patient did not require analgesia. Even so, the pain experienced by both groups was of moderate intensity. The most common location for this pain was the right upper quadrant followed by pain at the trocar sites.

VAS in both groups was significantly different for the decrease in pain in patients irrigated with bupivacaine at 6 postoperative hours. We conclude that there was better control of visceral pain during the first postoperative hours, which may be associated with the time of bupivacaine duration, which is from 3 hours to 10 hours on average.

Importantly, pain is a manifestation that varies from one person to another, depending largely on the pain threshold of each person and how each perceives pain, so today the tools to measure pain are subjective. VAS is based on the results of each patient's verbal comments. This study indicates that it is feasible to perform this type of procedure to have better control of postoperative pain in ambulatory laparoscopic surgery.

The most common postoperative symptom in this study was nausea in 22 patients, and this was not significantly different between groups. It was followed by vomiting in 2 patients and fever in 1 patient. Therefore, we can conclude that the use of bupivacaine can reduce the postoperative pain occurring in the first hours after the surgery. But this does not cause a decrease in other symptoms such as nausea.

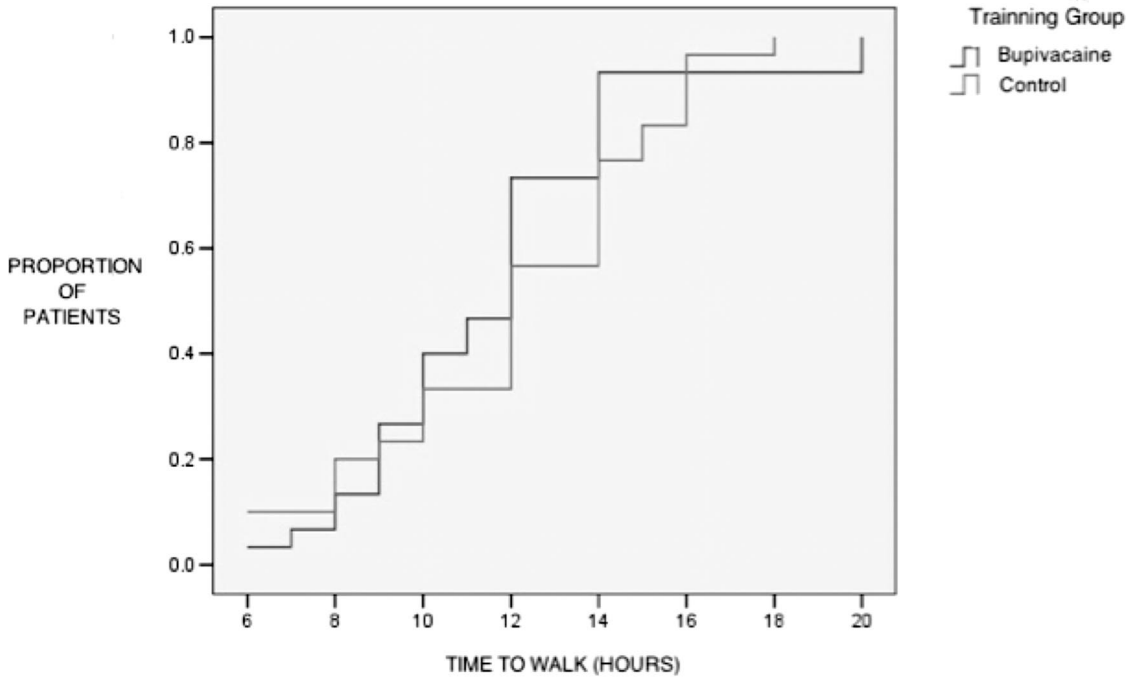


Figure 4. Scale of time to walk.

Table 5.

	Processing Group (Bupivacaine) n=30	Control Group (Placebo) n=30	P
Analgesia Required n (%)	18 (60)	29 (96.7)	.018[a]

[a]Statistically significant.

CONCLUSION

This study demonstrates that irrigation with bupivacaine at the surgical bed in laparoscopic cholecystectomy will significantly lower the intensity of postoperative visceral pain, as well as analgesic consumption in the first postsurgical hours. Because of this, we can establish this protocol for use in laparoscopic cholecystectomies with the purpose of a faster return of the patient to his or her normal life, and thus, a shorter hospital stay. Finally, bupivacaine at the dosage used were very safe and had no significant side effects. Therefore, we can reduce pain in patients who undergo laparoscopic cholecystectomy in ambulatory centers. This practice can become permanent in these cases.

References:

1. Downs SH, Black NA, Devlin HB, et al. Systematic review of the effectiveness and safety of laparoscopic cholecystectomy. *Ann R Coll Surg Engl* 1996;78:241–323.

2. Lau H, Brooks DC. Predictive factors for unanticipated admissions after ambulatory laparoscopic cholecystectomy. *Arch Surg*. 2001;136:1150–1153.

3. Fiorillo MA, Davidson PG, Fiorillo M, et al. 149 ambulatory laparoscopic cholecystectomies. *Surg Endosc*. 1996;10:52–56.

4. Callesen T, Klarskov B, Mogensen, et al. Day case laparoscopic cholecystectomy: feasibility and convalescence. *Ugeskr Laeger*. 1998;160:2095–2100.

5. Bisgaard T, Klarskov B, Rosenberg J, et al. Characteristics and prediction of early pain after laparoscopic cholecystectomy. *Pain*. 2001;90:261–269.

6. David CW. Analgesic treatment after laparoscopic cholecystectomy. *Anesthesiology*. 2006;104:835–846.

7. Tuckey JP, Morris GN, Peden CJ, et al. Feasibility of day case laparoscopic cholecystectomy in unselected patients. *Anaesthesia*. 1996;51:965–968.

8. Bisgaard T, Kehlet H, Rosenberg J. Pain and convalescence

after laparoscopic cholecystectomy. *Ann R Coll Surg Engl*. 2001; 167:84–96.

9. Bisgaard T, Klarskov B, Rosenberg J, et al. Factors determining convalescence after uncomplicated laparoscopic cholecystectomy. *Arch Surg*. 2001;136:917–921.

10. Wills VL, Hunt DR. Pain after laparoscopic cholecystectomy. *Br J Surg*. 2000;87:273–284.

11. Narchi P. Intraperitoneal local anaesthetic for shoulder pain after day case laparoscopic cholecystectomy. *Lancet*. 1991;338: 1569–1573.

12. Pascalucci A. Preemptive analgesia: Intraperitoneal local anesthetic cholecystectomy. A randomized double blind, placebo controlled study. *Anesthesiology*. 1996;85: 11–20.

13. Gordon S. Intraperitoneal ropivacaine and saline were similar in preventing pain after extensive laparoscopic excision of endometriosis. *J Am Assoc Gynecol Laparosc*. 2002;9:29–34.

14. Barnes PJ, Belvisi MG, Rogers DF. Modulation of neurogenic inflammation: Novel approaches to inflammatory disease. *Trend Pharmacol Sci*. 1990;11:185–189.

15. Joris J, Thiry E, Paris P, et al. Pain after laparoscopic cholecystectomy: characteristics and effect of intraperitoneal bupivacaine. *Anesth Analg*. 1995;81:379–384.

16. Edwards ND, Barclay K, Catling SJ, et al. Day case laparoscopy: a survey of postoperative pain and an assessment of the value of diclofenac. *Anaesthesia*. 1991;46:1077–1080.

17. Gupta A, Thorn S, Axelsson K, et al. Postoperative pain relief using intermittent injections 0.5% ropivacaine through a catheter after laparoscopic cholecystectomy. *Anesth Analg*. 2002;95:450–456.

18. Ahmed B, Ahmed A, Tan D, et al. Post-laparoscopic cholecystectomy pain: effects of intraperitoneal local anesthetics on pain control–a randomized prospective double-blind placebo-controlled trial. *Am Surg*. 2008;74:201–9.

19. Lepner U, Goroshina J, Samarutel J. Postoperative pain relief after laparoscopic cholecystectomy: a randomised prospective double-blind clinical trial. *Scand J Surg*. 2003;92:121–124.

20. Kim T, Kang H, Park J, et al. Intraperitoneal ropivacaine instillation for postoperative pain relief after laparoscopic cholecystectomy. *J Korean Surg Soc*. 2010;79:130–136.

RCS ADVANCING SURGICAL STANDARDS

GENERAL SURGERY

Ann R Coll Surg Engl 2012; **94**: 159–164
doi 10.1308/003588412X13171221589810

Gallbladder selection for histopathological analysis based on a simple method: a prospective comparative study

RJ Romero-González[1], A Garza-Flores[1], L Martínez-PérezMaldonado[1], JA Díaz-Elizondo[2], JJ Muñiz-Eguía[3], A Barbosa-Quintana[2]

[1]Monterrey Institute of Technology and Higher Education, Mexico
[2]Hospital San José Tec de Monterrey, Mexico
[3]Hospital Metropolitano 'Dr Bernardo Sepúlveda', Monterrey, Mexico

ABSTRACT

INTRODUCTION After a cholecystectomy, the current and traditional practice is to send each resected gallbladder to the pathologist for analysis. Some reports have suggested the possibility of selecting only those gallbladders that need to be analysed. The purpose of this study was to show a simple method for selecting which gallbladders should be sent to the pathologist.

METHODS A prospective comparative study was carried out. Two 'tests' were performed in 150 patients to detect or rule out gallbladder cancer. The first test included the patient's variables and a macroscopic gallbladder analysis performed by the surgeon (MGAS). The second test was the analysis performed by the pathologist. The results were compared.

RESULTS Of the 150 patients, 132 were women and 18 men; 130 were under 60 years old. One patient had inflammatory bowel disease, seven had changes on ultrasonography and in four cases intra-operative disturbances were observed. During the MGAS, disturbances were found in 30 patients. Eighty-one cases (54%) had at least one or more risk factors for gallbladder cancer.

CONCLUSIONS In almost half of the gallbladders, it would be safe not to send the specimen to the pathology department, decreasing costs significantly.

KEYWORDS

Gallbladder – Adenocarcinoma – Cholecystectomy – Pathology – Diagnosis

Accepted 30 October 2011

CORRESPONDENCE TO

Rey Romero-González, Reguló Madrid 565, Col. Playa Linda, CP 91810, Veracruz, Veracruz, Mexico
T: +52 229 934 3280; F: +52 229 934 3280; E: rey_@hotmail.com

Gallbladder cancer is a very rare malignancy; the overall incidence has been reported as between 0.5% and 2%.[1,2] This disease predominantly affects older women over the seventh decade of life. The most common histological type is adenocarcinoma.[5–6] This is a very aggressive neoplasm that has an extremely poor prognosis; 5-year survival rates of between 5% and 15% have been reported.[7–9] It is believed that the most significant risk factor for gallbladder cancer is the presence of chronic inflammation in the gallbladder wall, which is related to gallstones in 74–92% of cases.[10,11]

Despite the advances in radiological imaging, accurate pre-operative diagnosis is rare and most carcinomas are detected late in the course of the cancer. Simple cholecystectomy is reserved for patients in the T1 stage. Most T2b carcinomas will also be treated with hepatic resection and a regional lymphadenectomy.[12,15] Gallstone disease affects 10–15% of the Western population with an annual incidence of 1 in 200. It is estimated that Mexicans have a prevalence of 6% in men and 20% in women and in countries such as Chile asymptomatic stones are present in up to 50% of the population.[14,15]

The treatment of choice for gallstone disease is laparoscopic cholecystectomy with histopathological analysis of the specimen. By sending each resected gallbladder to the pathologist, costs generated for the health system are very high. In a large retrospective study published in 1998, Taylor and Huang suggested the possibility of analysing selected gallbladders only.[16] After this report, some authors proposed the same hypothesis.[17,18] Nevertheless, most surgeons send every specimen for analysis. The aim of the present study was to compare results between two 'tests' for detecting or ruling out gallbladder cancer in order to be able to select gallbladders that should be sent to the pathology department. The first test comprised a simple method to be carried out by the surgeon and the second was histopathological analysis.

Methods

A prospective comparative study was conducted in one institution between August 2010 and February 2011. Patients

with gallstone disease with surgical intervention at our institution were included in the study. Before the procedure, a specific interrogatory, a physical exploration, routine lab tests (complete blood count, liver function test and, in selected cases, blood chemistry) and abdominal ultrasonography were carried out. The procedure performed in all cases was a cholecystectomy, either laparoscopic or open.

Two 'tests' were carried out for each case: one by the main surgeon and, subsequently, one by the pathologist. The results from both tests were compared. This was a double blind study as the surgeon performed his/her test before the specimen was sent to the pathologist and the pathologist was not informed of the surgeon's observations. The protocol was reviewed and approved by the relevant bioethics committee.

First test: clinical examination by surgeon

The initial test was conducted by 20 surgeons or residents without previous training in macroscopic gallbladder analysis. It was divided into two stages: first, the identification of risk factors and, second, the detection or ruling out of cancer.

During the first stage, the positive risk factors for gallbladder cancer were sought. A patient was considered high risk if he or she had one or more of the following risk factors:

- age ≥60 years;
- history of inflammatory intestinal disease;
- ultrasonography alterations (performed by a Logiq® 7 [GE Healthcare, Little Chalfont, UK] with a 3.5 MHz transducer) that include disproportionate gallbladder wall thickness, polyps, masses and/or ulcers;
- pre-operative and/or intra-operative diagnosis of acute or chronic cholecystitis,[19,20] which was made by the main surgeon and included intractable pain, presence of Murphy's sign, fever, white blood cell elevation, radiological suspicion (ie gallbladder wall thickness >3mm, pericholecystic fluid, sonographic Murphy's sign, air in the gallbladder wall or lumen);
- intra-operative disturbances including anatomy alterations, visible or palpable masses, induration and/or ulcers; and
- disturbances at macroscopic gallbladder analysis performed by the surgeon (MGAS).

The MGAS was started just after the end of the cholecystectomy, still in the operating room, and before sending the specimen to pathology (Fig 1). During the first step of the MGAS, the serosa of the gallbladder was irrigated with water, observed and palpated on its entire surface (Fig 2). In the second step, the gallbladder was incised longitudinally and the mucosa was irrigated, observed and palpated (Figs 3 and 4). During the serosa and mucosa exploration, the surgeon looked for abnormalities that included masses, indurations, calcifications and/or ulcers. Obtained data were collected in an Excel® spreadsheet (Microsoft, Redmond, WA, US). This procedure was performed in less than four minutes in most cases and the only material required was water. The cutting instrument and the gloves were the same that had been used previously during the surgery.

The second stage of the MGAS consisted of a simple question: 'Based on the patient's history, routine laboratory/image tests, intra-operative findings and the macroscopic analysis, do you think that this gallbladder has a malignant disease?' The answer ('yes' or 'no') was documented and later compared with the final diagnosis reported by the pathologist.

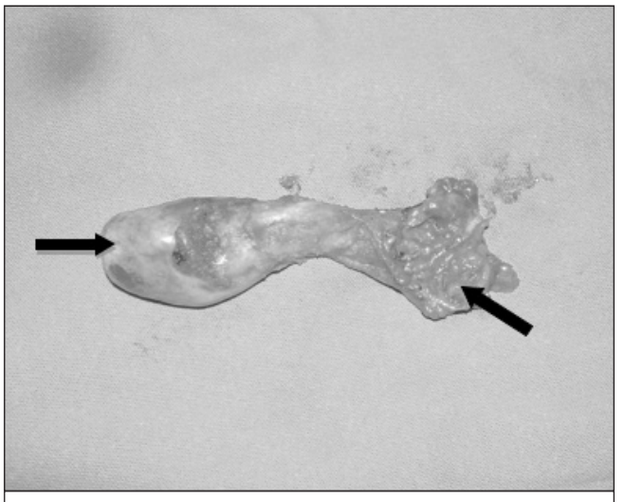


Figure 1 The extracted gallbladder just before the macroscopic analysis performed by the surgeon appears normal. Arrows point to serosa and mucosa.

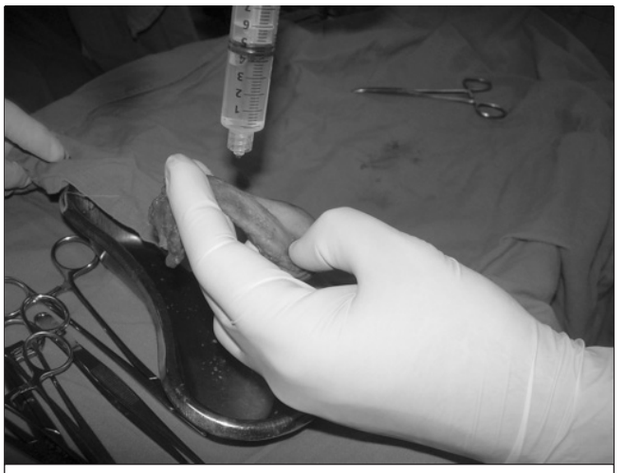


Figure 2 Observation and palpation of serosa during irrigation with saline solution

Second test: histopathological analysis

After the MGAS, the gallbladder was placed in formaldehyde and sent to the pathology department. The pathologist had no knowledge of the first test performed by the surgeon. The histopathological analysis was performed according to guidelines.[21] The gallbladder was observed and palpated searching for lesions, masses or abnormalities on the serosal and mucosal surfaces. If any alteration was found, a sample was taken. After this, three wall samples were taken from the fundus, body and neck. This is because cancer

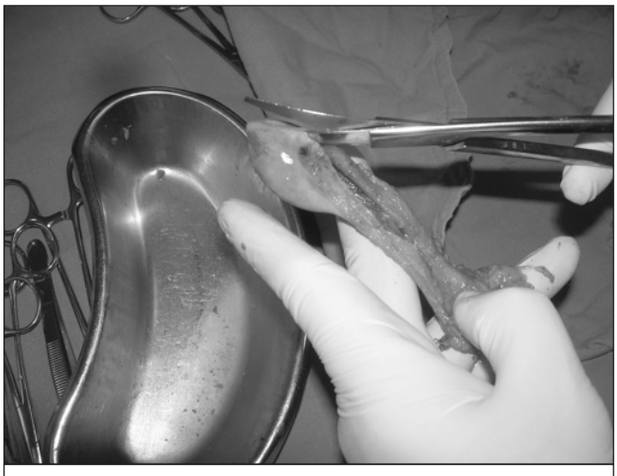


Figure 3 Longitudinal cut to expose the mucosal surface

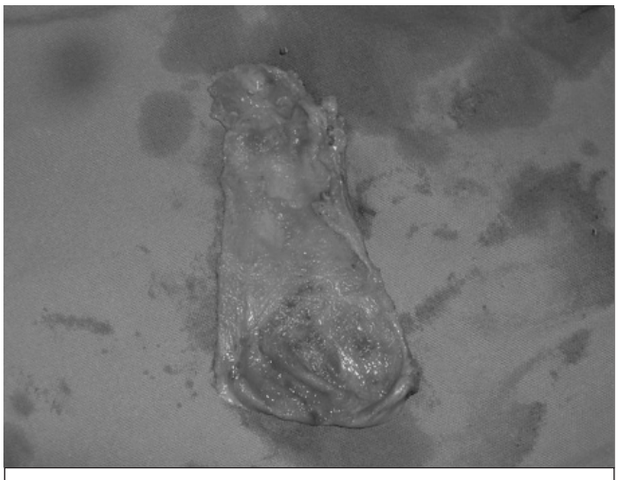


Figure 4 Cleaned mucosal surface

lesions originate predominantly in these sites.[22] The obtained pieces, either from a lesion or from the three routinely biopsied areas, were observed microscopically. If a malignant lesion was confirmed, a proper report was prepared and information was given to the treating surgeon.

Statistical analysis

Descriptive statistics were used to summarise the overall information. A contingency table was used to compare the tests. Data were analysed using SPSS® version 14.0 (SPSS, Chicago, IL, US). Inter-rater reliability to examine the agreement between the 20 treating surgeons/residents who performed the first test was not assessed in this study.

Results

Data from 150 cases were collected (132 women [88%], 18 men [12%]). The mean patient age was 39 years (standard deviation: 16.05 years). Of the 150 patients, 130 (86.6%) were under 60 years old. The histopathological analysis confirmed three gallbladder adenocarcinomas (2%). One patient (0.6%) had a history of inflammatory bowel disease. Seven (4.6%) had alterations on ultrasonography; two of these had malignant disease confirmed by the pathology analysis. Intra-operative disturbances were observed in four cases (2.6%), with three of these having malignant disease. Acute or chronic cholecystitis was diagnosed pre-operatively and/or intra-operatively in 65 cases (43.4%). Stones were found in 147 cases (98%).

Table 1 Cases with risk factors for gallbladder cancer

Risk factor	Cases (*n*=150)
Age ≥60 years	20 (13.4%)
History of inflammatory bowel disease	1 (0.6%)
Image alteration	7 (4.6%)
Pre-operative or intra-operative suspicion of acute or chronic cholecystitis	65 (43.4%)
Intra-operative disturbances (anatomy alteration, visible or palpable masses, induration, ulcers)	4 (2.6%)
MGAS disturbances (serosal and/or mucosal)	30 (20%)
Cases with one or more risk factors	81 (54%)

MGAS = macroscopic gallbladder analysis performed by the surgeon

Table 2 Comparison between the two 'tests'

		Pathologist		
		Positive	Negative	
Surgeon's test	Positive	3	0	3
	Negative	0	147	147
		3	147	

		95% confidence interval
Sensitivity	100%	(49–100%)
Specificity	100%	(98.7–100%)
Likelihood ratio (+)	252	(15.3–4,100)
Likelihood ratio (-)	0.14	(0.01–1.8)
Positive predictive value	85.7	(49–100)
Negative predictive value	99.6	(98.7–100)

Table 3 Characteristics of patients with gallbladder adenocarcinoma. In all three cases, macroscopic gallbladder analysis was performed by the surgeon but a previous biopsy had already been obtained because of obvious intra-operative malignant features. In the third case, it was difficult to ascertain whether the primary neoplasm originated in the pancreas or the gallbladder.

Age/sex	History	Ultrasonography	Intra-operative findings	Clinical stage	Histopathological diagnosis
35F	Abdominal colic pain	Areas of wall thickening	Gallbladder wall and liver induration, palpable ganglia near choledocus	T3N1M0 (stage IIIB)	Adenocarcinoma with invasion beyond serosa
66F	Jaundice	–	Hartmann's pouch wall and choledocus induration	T3N0M0 (stage IIIA)	Adenocarcinoma with invasion beyond serosa
64F	Jaundice and weight loss	Solid mass in head of pancreas confirmed by computed tomography	Gallbladder wall and liver induration, visible liver metastasis	T4N0M1 (stage IV)	Adenocarcinoma with invasion beyond serosa

Table 4 Comparison between the three cancer cases and the proposed risk factors

	Case 1	Case 2	Case 3
Age ≥60 years		✓	✓
Presence of inflammatory bowel disease			
Image alterations	✓		✓
Suspicion of cholecystitis	✓	✓	✓
Intra-operative disturbances	✓	✓	✓
MGAS disturbances	✓	✓	✓
One or more risk factors	✓	✓	✓

MGAS = macroscopic gallbladder analysis performed by the surgeon

During the MGAS, alterations of the serosa were found in 18 gallbladders (12.0%) and alterations of the mucosa in 22 (14.6%). In 127 cases (84.6%), no serosal or mucosal alterations were found. The risk factors are summarised in Table 1.

The second stage was assessed using the response to the question 'Based on the patient's history, routine laboratory/image tests, intra-operative findings and the macroscopic analysis, do you think that this gallbladder has a malignant disease?' made to the main surgeon; the answer was 'no' in 147 cases (98%) and 'yes' in 3 (2%). Pathology reports were similar to surgeons' reports, confirming the presence of neoplasm in the same 3 patients and ruling it out in the other 147. Atypical lesions of the mucosa not associated with gallbladder cancer were not reported by the pathology department.

Table 2 shows the comparison between the two tests. The specific characteristics and positive risk factors of the three cases with malignant disease are listed in Tables 3 and 4.

Discussion

Gallbladder cancer continues to be a very rare entity. Even though some evidence suggests the possibility of diagnosing this malignant disease before pathology analysis, most centres continue to send every extracted gallbladder to the pathology department for its routine analysis. This is mainly because of the lack of large and prospective studies that can give solid evidence to support the hypothesis that sending every gallbladder to the pathologist is not always necessary.

Nevertheless, we believe that selective gallbladder analysis performed by the pathologist (SGAP) is adequate, offering reassurance to the patient and the physician. Taking into account that the incidence of gallbladder cancer is very low and that it is known that more than 90% of patients are over 50–60 years old,[23] then the incidence of gallbladder cancer among people under 60 would be around 0.2–0.3%. Even though the percentage is extraordinarily low, it would be unacceptable to miss a neoplasm in a young patient.

In 2010 Mittal *et al* reported on a 10-year retrospective series in which they detected 13 gallbladder carcinomas.[24] Suspicion was raised pre-operatively and/or intra-operatively in every case. Furthermore, the authors of a UK study in 2007 concluded: '*All cases of invasive carcinoma of the gall bladder showed gross macroscopic abnormal appearance either pre- or intra-operatively. A more selective policy to histological examination of the gall bladder specimens would not miss any invasive malignancy.*'[25]

Unfortunately, the few papers that suggest the possibility of SGAP are retrospective. Prospective, better designed studies are necessary to support the hypothesis. Without a doubt, the most important reason to continue with routine gallbladder analysis performed by the pathologist is the possibility of missing a resectable gallbladder adenocarcinoma. This would have a devastating effect on the patient. The increase in lawsuits and surveillance of daily medical practice makes it difficult to change such procedures and SGAP continues to be just an interesting and almost impossible practice.

Given the epidemiological evidence, we believe that the possibility of missing an invasive gallbladder carcinoma pre or intra-operatively is extremely low. What would therefore

happen if we only sent inflamed or abnormal gallbladders for pathologic analysis and those from patients over 60 years of age? Based on the previously mentioned studies, the possibility of missing a neoplasm would be negligible as most gallbladder cancer cases are diagnosed in people over 60 and/or with wall inflammation and macroscopic abnormalities.[26,27] In spite of the epidemiological evidence, we think it is necessary to perform more tests to be able to provide sufficient certainty to patients while selecting gallbladders for histopathological analysis.

In this study, the main surgeon conducted a macroscopic analysis of the extracted gallbladder. The material cost was close to zero and the time spent was very low. The objective of MGAS is to select cases that for one reason or another should have SGAP. When examining the gallbladder, pathologists use both macroscopic and microscopic analysis. The latter is performed from samples either from macroscopically altered tissue or from areas where carcinomas are most frequently found (fundus, body and neck). Macroscopic examination probably plays the most important role in gallbladder analysis.[21] It may therefore be possible for MGAS to replace the macroscopic assessment carried out by the pathologist.

Some may argue that a pathologist is more experienced than a surgeon at performing meticulous gallbladder analysis but the frequent exposure to the serosal surface during cholecystectomies could mean that surgeons gain sufficient experience to detect abnormal patterns. However, we believe that a complete mucosal and serosal analysis is necessary to definitely rule out a carcinoma. This being the case, it may be feasible for a surgeon to perform a meticulous gallbladder analysis and send only specific specimens to be analysed microscopically.

In our study, all 150 cases had similar reports when comparing MGAS and pathology analysis: 147 patients with no malignant lesions and 3 cases of cancer. In the three cancer cases, MGAS was performed despite not being required since the neoplasm diagnosis was made intra-operatively and confirmed by trans-operative biopsy. Although we think it is possible to diagnose gallbladder cancer before the pathological analysis, we nevertheless limit ourselves to only proposing that a selection of the specimens with risk factors are sent to the pathologist. In this study, the three cases with malignant disease had more than one risk factor (Table 4). It should be noted that in the proposed algorithm only one risk factor is necessary to send the specimen to the pathologist. In 69 of the 150 cases (46%) there were no risk factors and in 81 cases (54%) there was at least one (Table 1).

It is probable that a method for SGAP can save a lot of human and material resources. This is particularly necessary in low income hospitals where economic improvements in other areas could increase benefits for more patients. On the other hand, there may be a risk of missing a dysplastic lesion or a T1 gallbladder carcinoma due to its small size and less obvious macroscopic features. Based on the epidemiological analysis, the possibility of missing one of these lesions is extremely low, especially if gallbladders from patients with advanced age and inflammation suspicion are sent to the pathology department.[28] In addition, the actual treatment for such lesions is a simple cholecystectomy so the patient would have been treated unintentionally in those cases.

Conclusions

We think that in almost half (46%) of the extracted gallbladders it would be safe not to send the specimen to the pathology unit without compromising patient safety. As a result, the budget can be halved. In this study, we have shown a simple and non-expensive method for selecting gallbladders that must be sent to the pathology department. Nevertheless, we believe that further studies with a greater number of cases are necessary to confirm our hypothesis. If we can decrease human and material resources needed for the traditional method for detecting gallbladder carcinoma, we can use those resources in other areas where they are needed more. This would be especially useful in hospitals with a low income.

Acknowledgements

The authors would like to thank the following for their help with this paper: Carlos Cuello García, Felipe González Velázquez, José Pulido Rodríguez and Blanca Oralia Garza Flores.

References

1. Yamamoto H, Hayakawa N, Kitagawa Y *et al*. Unsuspected gallbladder carcinoma after laparoscopic cholecystectomy. *J Hepatobiliary Pancreat Surg* 2005; **12**: 391–398.
2. Kwon AH, Imamura A, Kitade H, Kamiyama Y. Unsuspected gallbladder cancer diagnosed during or after laparoscopic cholecystectomy. *J Surg Oncol* 2008; **97**: 241–245.
3. Frauenschuh D, Greim R, Kraas E. How to proceed in patients with carcinoma detected after laparoscopic cholecystectomy. *Langenbecks Arch Surg* 2000; **385**: 495–500.
4. Frezza EE, Mezghebe H. Gallbladder carcinoma: a 28 year experience. *Int Surg* 1997; **82**: 295–300.
5. Roa I, Araya JC, Villaseca M *et al*. Gallbladder cancer in a high risk area: morphological features and spread patterns. *Hepatogastroenterology* 1999; **46**: 1,540–1,546.
6. Douglass HO, Kim SY, Merpol NJ. Neoplasms of the Gallbladder. In: Holland JF, Frei E, Best RC, eds. *Cancer Medicine*. Baltimore, MD: Lippincott Williams & Wilkins: 1997. pp1,955–1,963.
7. Donohue JH, Stewart AK, Mench HR. The National Cancer Data Base report on carcinoma of the gallbladder, 1989–1995. *Cancer* 1998; **83**: 2,618–2,628.
8. Konstadoulakis MM, Roayaie S, Gomatos IP *et al*. Surgical resection for advanced gallbladder carcinoma. The Mount Sinai experience. *Hepatogastroenterology* 2010; **57**: 1,005–1,012.
9. Kwon SY, Chang HJ. A clinicopathological study of unsuspected carcinoma of the gallbladder. *J Korean Med Sci* 1997; **12**: 519–522.
10. Bartlett DL. Gallbladder cancer. *Semin Surg Oncol* 2000; **19**: 145–155.
11. Tantia O, Jain M, Khanna S, Sen B. Incidental carcinoma gall bladder during laparoscopic cholecystectomy for symptomatic gall stone disease. *Surg Endosc* 2009; **23**: 2,041–2,046.
12. Wakai T, Shirai Y, Hatekayema K. Radical second resection provides survival benefit for patients with T2 gallbladder carcinoma first discovered after laparoscopic cholecystectomy. *World J Surg* 2002; **26**: 867–871.
13. Foster JM, Hoshi H, Gibbs JF *et al*. Gallbladder cancer: defining the indications for primary radical resection and radical re-resection. *Ann Surg Oncol* 2007; **14**: 833–840.
14. Halldestam I, Enell EL, Kullman E, Borch K. Development of symptoms and complications in individuals with asymptomatic gallstones. *Br J Surg* 2004; **91**: 734–738.

15. Méndez-Sánchez N, Chávez-Tapia NC, Uribe M. Gallbladder disease and obesity. *Gac Med Mex* 2004; **140**: S59–S66.
16. Taylor HW, Huang JK. 'Routine' pathological examination of the gallbladder is a futile exercise. *Br J Surg* 1998; **85**: 208.
17. Dix FP, Bruce IA, Krypcyzk A, Ravi S. A selective approach to histopathology of the gallbladder is justifiable. *Surgeon* 2003; **1**: 233–235.
18. Bazoua G, Hamza N, Lazim T. Do we need histology for a normal-looking gallbladder? *J Hepatobiliary Pancreat Surg* 2007; **14**: 564–568.
19. Elwood DR. Cholecystitis. *Surg Clin North Am* 2008; 88: 1,241–1,252.
20. Miura F, Takada T, Kawarada Y *et al*. Flowcharts for the diagnosis and treatment of acute cholangitis and cholecystitis: Tokyo guidelines. *J Hepatobiliary Pancreat Surg* 2007; **14**: 27–34.
21. Lester SC. *Manual of Surgical Pathology*. 2nd edn. Philadelphia, PA: Elsevier; 2006. pp354–358.
22. Sumiyoshi K, Nagai E, Chijiiwa K, Nakayama F. Pathology of carcinoma of the gallbladder. *World J Surg* 1991; **15**: 315–321.
23. Misra S, Chaturvedi A, Misra NC, Sharma ID. Carcinoma of the gallbladder. *Lancet Oncol* 2003; 4: 167–176.
24. Mittal R, Jesudason MR, Nayak S. Selective histopathology in cholecystectomy for gallstone disease. *Indian J Gastroenterol* 2010; **29**: 26–30.
25. Darmas B, Mahmud S, Abbas A, Baker AL. Is there any justification for the routine histological examination of straightforward cholecystectomy specimens? *Ann R Coll Surg Engl* 2007; **89**: 238–241.
26. Eslick GD. Epidemiology of gallbladder cancer. *Gastroenterol Clin North Am* 2010; **39**: 307–330.
27. Portincasa P, Moschetta A, Petruzzelli M *et al*. Gallstone disease: symptoms and diagnosis of gallbladder stones. *Best Pract Res Clin Gastroenterol* 2006; **20**: 1,017–1,029.
28. Roa I, de Aretxabala X, Araya JC, Roa J. Preneoplastic lesions in gallbladder cancer. *J Surg Oncol* 2006; **93**: 615–623.

Evaluación de un simulador quirúrgico en función de su desempeño al ser utilizado por residentes con diferentes grados de experiencia

Eduardo Flores-Villalba, José Antonio Díaz-Elizondo,* Adolfo Leyva-Alvizo,* Everardo Fernández-Rangel,* Oscar Villegas-Cabello,** Zanndor del Real-Romo****

Resumen

Introducción: históricamente, el quirófano ha sido el salón de clases para la formación de cirujanos y para la educación quirúrgica. Una alternativa la representan, hoy en día, los simuladores quirúrgicos. De la misma manera que un espejo mal construido no puede reflejar fidedignamente las imágenes (distorsión) un simulador mal construido, programado o calibrado, no será capaz de reflejar el grado de capacitación del operario en turno. Nuestro objetivo es evaluar, de manera indirecta, el simulador Surgical SIM®.
Material y métodos: 12 residentes de cirugía, que se dividieron en novatos, intermedios y expertos, realizaron 15 tareas con tres dimensiones de evaluación para cada una en el simulador Surgical SIM®. Se utilizó la r de Pearson para establecer correlaciones.
Resultados: los resultados, en general, de las tres dimensiones evaluadas tuvieron diferencias estadísticamente significativas para el tiempo (p = 0.001), para la trayectoria (p = 0.01) y para los errores (p = 0.001).
Conclusión: se demostró, de manera indirecta, la eficiencia del simulador Surgical SIM®.

Palabras clave: simulador, laparoscopia virtual, evaluación, entrenamiento.

Abstract

Background: Historically, the operating room has been the training setting for both surgeons and students. Nowadays, an alternative is represented by surgical simulators. In the same way a not-very-well-built mirror cannot reflect trustworthy images (distortion), a not well-built, calibrated or programmed simulator will be unable to reflect the training level of the operator. Our aim is to indirectly evaluate the Surgical SIM® simulator.
Methods: Twelve surgical residents were classified according to novices, intermediates and experts, and 15 tasks were applied with three dimensions of evaluation in each using the Surgical SIM® simulator. Pearson's correlation test was used to establish validity.
Results. In general, from the three dimensions evaluated, results showed a statistically significant difference for time (p = 0.001), trajectory (p = 0.01) and errors (p = 0.001).
Conclusions: Effectiveness of Surgical SIM® was indirectly demonstrated.

Key words: Simulator, virtual laparoscopy, validation, training.

* Centro de Habilidades de la Escuela de Medicina y Ciencias de la Salud, ITESM, Campus Monterrey.
** Departamento de Cirugía General del Hospital San José del Tecnológico de Monterrey.
*** Residente de Cirugía General del Programa Multicéntrico de Especialidades Médicas del Tecnológico de Monterrey.

Correspondencia:
Eduardo Flores Villalba
Departamento de Ciencias Clínicas
Dirección Médica Hospital San José, Tec de Monterrey
Ave. Ignacio Morones Prieto No. 3000 pte. Col. Doctores
64710 Monterrey, NL., México
Tel.: (81) 83471010 Ext 6168
Correo electrónico: eduardofloresv@gmail.com

Recibido para publicación: 06-06-2011
Aceptado para publicación: 20-09-2011

Introducción

Históricamente, el quirófano ha sido el salón de clases para la formación de cirujanos y la educación quirúrgica se ha basado en el modelo de aprendizaje que introdujo Halsted en Estados Unidos.[1] El modelo cognitivo de aprendizaje en el que los residentes aprenden trabajando, al lado de cirujanos experimentados en un escenario de la vida real, es el principal método con el que se imparten las habilidades quirúrgicas. El modelo del aprendiz se ve limitado por la disponibilidad de mentores, por la capacidad de enseñanza de estos, por la variabilidad de los procedimientos efectuados y hasta por el número de pacientes disponibles para la formación.[2,3]

La laparoscopia, en particular, requiere de una difícil coordinación sensorial y mecánica, manejo ambidiestro, comprensión del efecto de palanca y percepción de la profundidad. Estas habilidades pueden ser difíciles de dominar y, a menudo, requieren de mucha práctica. Se ha demostrado que los cirujanos sin experiencia tienen tasas considerablemente más elevadas de complicaciones al realizar los procedimientos por vía laparoscópica y se ha descrito una clara curva de aprendizaje.[4-6]

Por otra parte, los programas de residencia siempre están en la búsqueda de herramientas para medir los conocimientos técnicos de sus alumnos y más aún desde la introducción del programa de reducción de horas de trabajo para los residentes. La simulación virtual puede cubrir la brecha existente entre el aula y la atención de los pacientes y garantizar que todos los alumnos estén expuestos a problemas clínicos básicos; además, permite a un residente experimentar una mayor variedad y un mayor número de procedimientos sin necesidad de esperar a que un paciente, con una enfermedad específica se presente.[7-10] Por otro lado, se estima que un procedimiento quirúrgico consiste en aproximadamente 75% de habilidad cognitiva y sólo 25% de habilidad quirúrgica; no obstante, se justifica plenamente el uso de nuevas herramientas para mejorar las habilidades de los cirujanos.[11]

En la educación quirúrgica los entrenadores mecánicos y los de realidad virtual se han utilizado para entrenar competencias psicomotoras específicas y evaluar el desempeño de los cirujanos. El logro de estos objetivos depende de tres principios esenciales: 1) validez, 2) confiabilidad, y 3) de viabilidad.[12,13] La validez se refiere a que tan bien está construido, programado o calibrado el entrenador. Esto puede ser verificado indirectamente por la exactitud con que refleje el grado de capacitación del operario en turno.[14-18]

El objetivo de este trabajo fue evaluar, de una manera indirecta, el simulador Surgical SIM® (METI, Sarasota, Fl).

Material y métodos

La evaluación se realizó en el Centro de Habilidades de la Escuela de Medicina del Tec de Monterrey en Monterrey, México. Se utilizó para ello el simulador virtual de cirugía laparoscópica Surgical SIM® (METI, Sarasota, Fl).

Doce residentes, con diferentes grados de experiencia, fueron distribuidos de la siguiente manera: 4 residentes novatos (primer año), 4 residentes con experiencia intermedia (segundo año) y 4 residentes de experiencia avanzada (tercero y cuarto años). Se consideraron novatos los residentes con menos de 30 vesículas operadas, de nivel intermedio aquellos que habían operado entre 30 y 50 y expertos los que tenían más de 50 vesículas operadas durante su entrenamiento.[12,18]

A cada residente se le solicitó realizar un ejercicio único de cada una de 15 tareas del simulador (cuadro I) y se registraron el tiempo, la trayectoria y la cantidad y tipo de errores cometidos durante la realización, mismos que se almacenaron en la memoria interna del simulador para su análisis posterior. Las primeras cuatro tareas correspondieron a ejercicios para la orientación y manejo de la cámara, las siguientes ocho tuvieron como objetivo instruir en el manejo de tejidos y los últimas tres correspondieron a la realización de nudos intracorpóreos.

Se establecieron las correlaciones entre el grado de experiencia de los residentes y las tareas realizadas mediante un análisis de Pearson utilizando el paquete estadístico SPSS (Chicago Il, versión 16,). La evaluación del simulador se determinó con base en su capacidad para reflejar diferencias significativas entre los grados de capacitación de los grupos de residentes. Una $p < 0.05$ fue considerada como estadísticamente significativa.

Cuadro I. Tareas realizadas utilizando del simulador virtual Surgical SIM®

Tarea
Ejercicios con cámara
Lente 0 grados
Lente 30 grados
Identificar y tomar blanco con lente de 0º
Identificar y tomar blanco con lente de 30º
Manipulación de tejido
Separar objeto
Separar y disecar tejido con cauterio
Manipulación de objeto tubular
Manipulación de objeto flecha
Aplicar *clips* en el conducto cístico
Disección de la vesícula del lecho hepático
Sutura
Nudo cuadrado
Nudo en apariencia real
Sutura continua
Sutura interrumpida
Sutura interrumpida en apariencia real

Resultados

Tres parámetros fueron evaluados: el tiempo total en el que se realizó cada ejercicio (cuadro II), la distancia recorrida por el instrumento hasta completar una cierta tarea (cuadro III) y los errores cometidos durante el procedimiento (cuadro IV).

El promedio de tiempo empleado en todas las tareas fue de 376 minutos para los novatos, de 250 minutos para los de experiencia intermedia y de 175 minutos para los expertos ($p < 0.001$) con una correlación de -0.842. El promedio total para las trayectorias fue de 677 cm para los novatos, de 608 cm para los de experiencia intermedia y de 364 para los expertos, con una correlación de -0.697 ($p < 0.01$). Los errores evaluados por el simulador fueron 32 para los novatos, 18 para los residentes de experiencia intermedia y sólo 10 para los considerados expertos ($p < 0.001$).

Cinco de los 13 ejercicios medidos tuvieron una correlación significativa para el tiempo de realización; sin embargo, los ocho restantes, a pesar de no alcanzar una $p < 0.05$ mostraron en todo momento una tendencia en favor de los residentes con mayor grado.

En cuanto a la trayectoria se encontró, para todos los resultados, una correlación negativa; esto es: a mayor "expertise" menor trayectoria recorrida. Asimismo, dos de los ejercicios realizados mostraron correlaciones estadísticamente significativas; sin embargo, aunque los ejercicios 2, 6, 7, 8, 12 y 13 mostraron una correlación fuerte ésta no fue estadísticamente significativa.

El total de errores mostró una correlación negativa entre el grado de experiencia y la cantidad de errores, mostrando un mayor efecto para las tareas 7, 11, 13, 14 y 15, éstas últimas referidas a procedimientos de gran dificultad técnica. Además, en cuanto a la variable "errores" todos los resultados tuvieron una correlación negativa, lo que apoya la hipótesis inicial.

Discusión

Este estudio es el primero en México en evaluar, por medio de tareas realizadas con diferentes grados de aptitud quirúrgica, un simulador quirúrgico. En general, todos los resultados demostraron una clara distinción entre los dife-

Cuadro II. Rangos, promedios y correlaciones de tiempo (segundos) por tarea, grado de experiencia y totales

	Rango (promedio)				
Tarea	Novatos	Intermedios	Expertos	r	*p*
Lente 0 grados	60-90 (75)	52-82 (67.5)	43-68 (53.5)	-0.574	0.05
Lente 30 grados	325-876 (618)	194-739 (341)	100-336 (259)	-0.528	0.07
Identificar y tomar blanco lente de 0º	49-87 (72)	26-172 (80)	45-52 (47)	-0.276	0.38
Identificar y tomar blanco lente de 30º	298-615 (409)	63-756 (408)	218-346 (282)	-0.332	0.29
Separar objeto	61-144 (96)	57-69 (63)	43-55 (51)	-0.685	**0.01**
Separar y disecar tejido con cauterio	111-197 (149)	104-137 (120)	94-119 (109)	-0.555	0.06
Manipulación de objeto tubular	59-188 (143)	51-97 (79)	60-102 (77)	-0.585	**0.04**
Manipulación de objeto flecha	128-254 (178)	107-295 (167)	86-159 (113)	-0.465	0.12
Aplicar *clips* en el conducto cístico	39-65 (54)	40-56 (48)	36-60 (49)	-0.249	0.43
Disección de la vesícula	156-246 (202)	176-239 (201)	150-312 (207)	-0.065	0.84
Nudo cuadrado	134-245 (197)	71-327 (173)	36-97 (72)	-0.626	**0.03**
Nudo en apariencia real	89-276 (173)	63-118 (99)	57-170 (94)	-0.454	0.13
Sutura continua	629->1200 (960)	170->1200 (639)	197-524 (273)	-0.697	**0.01**
Sutura interrumpida	876-1167 ()1006	393-974 (745)	252-757 (472)	-0.82	**0.001**
Sutura interrumpida en apariencia real	973->1800 (1380)	233-762 (522)	198-719 (467)	-0.755	**0.005**
Total	39->1800 (376)	26->1200 (250)	36-757 (175)	-0.842	**0.001**

r = correlación de Pearson. $p < 0.05$ = estadísticamente significativa.

Cuadro III. Rangos, promedios y correlaciones de la trayectoria (cm) por tarea, grado de experiencia y totales

	Rango (promedio)				
Tarea	Novatos	Intermedios	Expertos	r	*p*
Lente 0 grados	125-915 (335)	133-190 (153)	49-151 (120)	-0.369	0.23
Lente 30 grados	816-2074 (1391)	472-2319 (1034)	168-858 (454)	-0.503	0.11
Identificar y tomar blanco lente de 0º	201-292 (240)	144-585 (309)	172-214 (191)	-0.191	0.55
Identificar y tomar blanco lente de 30º	605-1014 (737)	245-1663 (1001)	456-585 (550)	-0.246	0.44
Separar objeto	170-274 (233)	148-240 (195)	109-121 (165)	-0.597	**0.04**
Separar y disecar tejido con cauterio	240-372 (315)	224-381 (288)	215-288 (245)	-0.527	0.07
Manipulación de objeto tubular	159-453 (348)	141-284 (216)	162-290 (215)	-0.554	0.06
Manipulación de objeto flecha	378-715 (577)	339-933 (537)	278-529 (383)	-0.48	0.11
Aplicar *clips* en el conducto cístico	83-122 (104)	65-125 (97)	67-135 (99)	-0.216	0.5
Disección de la vesícula	218-458 (324)	211-628 (359)	185-433 (269)	-0.242	0.44
Nudo cuadrado	470-780 (677)	321-1098 (602)	149-305 (222)	-0.673	**0.01**
Nudo en apariencia real	298-825 (507)	228-527 (349)	188-479 (294)	-0.467	0.12
Sutura continua	462-1222 (879)	129-462 (237)	302-538 (376)	-0.568	0.08
Sutura interrumpida	916-2473 (1616)	1398-3269 (2442)	521-936 (707)	-0.446	0.14
Sutura interrumpida en apariencia real	1187-2863 (1871)	566-1728 (1299)	524-2683 (1171)	-0.41	0.21
Total	125-2863 (677)	65-3269 (608)	49-2683 (364)	-0.697	**0.01**

r = correlación de Pearson. $p < 0.05$ = estadísticamente significativa.

Cuadro IV. Rangos, promedios y correlaciones de errores por tarea, grado de experiencia y totales

	Rango (promedio)				
Tarea	Novatos	Intermedios	Expertos	r	*p*
Lente 0 grados	1-2 (1.25)	1-2 (1.5)	0-2 (0.5)	-0.47	0.123
Lente 30 grados	25-82 (25.5)	12-32 (38.5)	3-29 (18.75)	-0.493	0.1
Identificar y tomar blanco lente de 0º	0-7 (4)	1-14 (5.25)	1-2 (1)	-0.298	0.356
Identificar y tomar blanco lente de 30º	36-61 (44.5)	5-151 (60)	14-39 (28.75)	-0.232	0.468
Separar objeto	2-6 (3)	0-2 (0.75)	0-1 (0.5)	-0.636	0.06
Separar y disecar tejido con cauterio	8-24 (16.25)	5-14 (7.75)	4-17 (9.25)	-0.482	0.11
Manipulación de objeto tubular	3-14 (7.75)	0-4 (2.25)	0-6 (1.75)	-0.599	**0.04**
Manipulación de objeto flecha	5-15 (10.75)	0-18 (7)	2-6 (3.5)	-0.516	0.08
Aplicar *clips* en el conducto cístico	1-4 (2)	0-2 (0.75)	0-3 (1.25)	-0.304	0.33
Disección de la vesícula	15-21 (17.5)	7-36 (17.5)	10-13 (12)	-0.297	0.348
Nudo cuadrado	1-10 (4.75)	1-7 (3)	0-1 (0.5)	-0.58	**0.048**
Nudo en apariencia real	0-5 (1.75)	0-3 (1.5)	0-1 (0.25)	-0.412	0.183
Sutura continua	104-13 (124.7)	13-112 (56.66)	7-39 (18.75)	-0.822	**0.007**
Sutura interrumpida	109-166 (127)	10-43 (32.5)	5-61 (27)	-0.8	**0.002**
Sutura interrumpida en apariencia real	52-78 (64.33)	14-55 (37.5)	19-41 (29.75)	-0.733	**0.01**
Total	0-166 (32.15)	0-112 (18.161)	0-61 (10.233)	-0.842	**0.001**

r = correlación de Pearson. $p < 0.05$ = estadísticamente significativa.

rentes grados de capacitación de los residentes a los que fue expuesto el simulador. Y aunque no en todos los rubros las diferencias fueron estadísticamente significativas el resultado general, en cada una de las evaluaciones del simulador (tiempo, trayectoria y errores), demostró la eficiencia operativa del simulador.

La cantidad de errores y la medición del tiempo fueron los resultados que más correlaciones significativas arrojaron, 7 y 5 respectivamente, por lo que probablemente representen los mejores indicadores de desempeño. Sin embargo, a partir de este estudio no se puede hacer una conclusión definitiva consideramos necesaria una validación concurrente y predictiva para demostrar las correctas construcción y operación del simulador.

Curiosamente, no existió correlación entre el tiempo y la habilidad necesaria para una disección virtual de la vesicular biliar. Esto es notable debido a que justamente esa cirugía sirvió como parámetro para la división de los residentes en grupos con mayor o menor experiencia. La explicación de este resultado rebasa los propósitos del presente estudio y es por ello que se deben de realizar otro tipo de evaluaciones para mostrar si es un efecto propio del simulador. Tampoco está perfectamente definido cómo el rendimiento de una tarea realizada en el simulador virtual se relaciona con la ejecución del mismo procedimiento quirúrgico en la vida real;[18] sin embargo, mientras más estudios se realicen y mayor sea la validez aparente de los simuladores estas preguntas quedarán resueltas.

Los vertiginosos avances de la Medicina obligan a los cirujanos a mantenerse actualizados y a tener una mejor preparación y conocimiento de la tecnología; además de estar preparados para realizar todos los procedimientos que la especialidad requiere y actualizarse en el manejo de los nuevos instrumentos y técnicas. Por otro lado, sabemos que en la formación de los cirujanos existe un déficit de conocimientos y de adquisición de habilidades de diferente tipo. Se ha afirmado que entre 5 y 10% de los cirujanos nunca adquiere un nivel suficiente de habilidades para llevar a cabo la cirugía de mínima invasión.[19] Es por ello que la evaluación de los instrumentos didácticos es tan importante como la creación de nuevo conocimiento; la colaboración de todos es indispensable para la consecución de estos fines.

Conclusión

Se puede concluir que el simulador Surgical SIM®, en general, refleja fidedignamente los diferentes grados de aptitud de los cirujanos al realizar diversos procedimientos en función del tiempo empleado, las trayectorias recorridas y el número de errores registrados. Esto permite presuponer una correcta fabricación, programación y calibración del instrumento didáctico.

Referencias

1. Halsted WS. The Training of the Surgeon. Bull Johns Hopkins Hosp 1904;15:267-275.
2. Ahlberg G, Enochsson L, Gallagher AG, Hedman L, Hogman C, McClusky DA, et al. Proficiency-based virtual reality training significantly reduces the error rate for residents during their first 10 laparoscopic cholecystectomies. Am J Surg 2007;193(6):797-804.
3. Sultana CJ. The objective structured assessment of technical skills and the ACGME competencies. Obstet Gynecol Clin. North Am 2006;33(2):259-265.
4. Moore MJ, Bennett CL. The learning curve for laparoscopic cholecystectomy. The Southern Surgeons Club. Am J Surg 1995;170(1):55-59.
5. Deziel DJ, Millikan KW, Economou SG, Doolas A, Ko ST, Airan MC. Complications of laparoscopic cholecystectomy: a national survey of 4,292 hospitals and an analysis of 77,604 cases. Am J Surg 1993;165(1):9-14.
6. Joice P, Hanna GB, Cuschieri A. Errors enacted during endoscopic surgery-a human reliability analysis. Appl Ergon 1998;29(6):409-414.
7. Gaba DM. The future vision of simulation in health care. Qual Saf Health Care 2004;13(Suppl 1):2-10.
8. McLaughlin S, Fitch MT, Goyal DG, Hayden E, Kauh CY, Laack TA, et al. Simulation in Graduate Medical Education 2008: A Review for Emergency Medicine. Acad Emerg Med 2008;15(11):1117-1129.
9. Wayne DB, Didwania A, Feinglass J, Fudala MJ, Barsuk JH, McGaghie WC. Simulation-Based Education Improves Quality of Care During Cardiac Arrest Team Responses at an Academic Teaching Hospital. A Case-Control Study. Chest 2008;133(1):56-61.
10. Haluck RS, Marshall RL, Krummel TM, Melkonian MG. Are surgery training programs ready for virtual reality? a survey of program directors in general surgery. J Am Coll Surg 2001;193(6):660-665.
11. Satava RM, Gallagher AG, Pellegrini CA. Surgical competence and surgical proficiency: definitions, taxonomy, and metrics. J Am Coll Surg 2003;196(6):933-937.
12. McDougall EM, Corica FA, Boker JR, Sala LG, Stoliar G, Borin JF, et al. Construct validity testing of a laparoscopic surgical simulator. J Am Coll Surg 2006;202(5):779-787.
13. Reznick RK. Teaching and testing technical skills. Am J Surg 1993;165(3):358-361.
14. Taffinder N, Sutton C, Fishwick RJ, McManus IC, Darzi A. Validation of virtual reality to teach and assess psychomotor skills in laparoscopic surgery: results from randomised controlled studies using the MIST VR laparoscopic simulator. Stud. Health Technol. Inform 1998;50:124-130.
15. Smith CD, Farrell TM, McNatt SS, Metreveli RE. Assessing laparoscopic manipulative skills. Am J Surg 2001;181(6):547-550.
16. Grantcharov TP, Bardram L, Jensen PM, Rosenberg J. Virtual reality-computer simulation as a tool for training and evaluating skills in laparoscopic surgery. Ugeskr Laeger 2001;163:3651-3653.
17. Grantcharov TP, Bardram L, Funch-Jensen P, Rosenberg J. Assessment of technical surgical skills. Eur J Surg 2002;168(3):139-144.
18. Gallagher AG, Smith CD, Bowers SP, Seymour NE, Pearson A, McNatt S, et al. Psychomotor skills assessment in practicing surgeons experienced in performing advanced laparoscopic procedures. J Am Coll Surg 2003;197(3):479-488.
19. Cuschieri A. Whither minimal access surgery: tribulations and expectations. Am J Surg 1995;169(1):9-19.

Hindawi Publishing Corporation
Advances in Materials Science and Engineering
Volume 2013, Article ID 249512, 9 pages
http://dx.doi.org/10.1155/2013/249512

Research Article

Stress-Softening and Residual Strain Effects in Suture Materials

Alex Elías-Zúñiga,[1] Beatriz Montoya,[1] Wendy Ortega-Lara,[1] Eduardo Flores-Villalba,[1,2] Ciro A. Rodríguez,[1] Hector R. Siller,[1] José A. Díaz-Elizondo,[2] and Oscar Martínez-Romero[1]

[1] *Centro de Innovación en Diseño y Tecnología, Tecnológico de Monterrey—Campus Monterrey, Avenida E. Garza Sada 2501 Sur, 64849 Monterrey, NL, Mexico*
[2] *Escuela de Medicina y Ciencias de la Salud, Tecnológico de Monterrey—Campus Monterrey, Avenida E. Garza Sada 2501 Sur, 64849 Monterrey, NL, Mexico*

Correspondence should be addressed to Alex Elías-Zúñiga; aelias@itesm.mx

Received 24 March 2013; Accepted 20 May 2013

Academic Editor: Pavel Lejcek

This work focuses on the experimental characterization of suture material samples of MonoPlus, Monosyn, polyglycolic acid, polydioxanone 2–0, polydioxanone 4–0, poly(glycolide-co-epsilon-caprolactone), nylon, and polypropylene when subjected to cyclic loading and unloading conditions. It is found that all tested suture materials exhibit stress-softening and residual strain effects related to the microstructural material damage upon deformation from the natural, undistorted state of the virgin suture material. To predict experimental observations, a new constitutive material model that takes into account stress-softening and residual strain effects is developed. The basis of this model is the inclusion of a phenomenological nonmonotonous softening function that depends on the strain intensity between loading and unloading cycles. The theory is illustrated by modifying the non-Gaussian average-stretch, full-network model to capture stress-softening and residual strains by using pseudoelasticity concepts. It is shown that results obtained from theoretical simulations compare well with suture material experimental data.

1. Introduction

Technical advances in the field of surgery have exponentially grown during the last few years. Progressive research, better understanding of the physiopathological processes behind every procedure, more experienced surgeons, and the increasing interest of biomedical companies in developing new products have made possible the excellent results seen in surgery nowadays.

Sutures have remained for many decades a cornerstone for most surgical procedures. Wound closure, vascular and intestinal anastomosis, structures fixation, bleeding control, and tissue approximation are only a few examples from the many uses sutures are given; however, there is no perfect suture for all purposes, and the enormous variables involved in the cicatrization process make this task a difficult one to achieve.

The ideal suture should have certain characteristics that will abet the therapeutic course; it is supposed to have an adequate tensile strength in each phase of the healing process, should be surgeon friendly, induce minimal or no tissue reaction, and must not stimulate infection. Also it should be biologically inert and should be able to have a suitable response to edema and tolerate the different environments within the human body. Since there is no such a product available at present, it is essential to comprehend not only the biological responses to the materials but also understand the precise behavior of each suture in order to decide on the best and most efficient way to take advantage of each particular property of any given suture [1]. Nichols et al. cautioned surgeons about the handling of sutures by surgical instruments since this could result in premature suture failure [2]. They indicated that their rough handling and the usage of clamps and forceps could damage and weaken these.

Therefore, learning the biomechanical performance of sutures will help surgeons not only to determine the appropriate clinical application for each type but also to improve surgical techniques to take advantage of each suture properties [3].

Some of the most important characteristics of a suture regarding its mechanical material properties are related to

softening and permanent set effects which appear when sutures are subjected to cyclic load, and, thus, the normal stress versus stretch curve shows a reduction on the stress magnitude during the unloading process [4–13]. This stress-softening effect known as the Mullins effect becomes clinically relevant because initial characteristics exhibited by a suture material immediately after it has been manufactured could change dramatically when stress is applied during the suturing and healing processes [2]. Understanding the material response behavior of suture materials could help surgeons in the selection of the most appropriate suture material.

The aim of this work is to characterize the stress-softening and residual strain effects in suture materials such as polyglycolic acid, polydioxanone, nylon, and polypropylene commonly used in surgical procedures when subjected to loading and unloading cycles by developing a phenomenological nonmonotonous stress-softening hyperelastic material model that depends on the amount of strain [14] and permanent set effects [15].

We have organized this paper as follows. In Section 2, we provide detail of the uniaxial experimental tests performed on suture materials. A brief review of the required equations to describe finite deformations of an incompressible elastic material is introduced in Section 3. In Section 4, we have characterized the experimental data by assuming a nonmonotonous damage softening function and by modifying the Holzapfel et al. constitutive equation to include residual strain effects [15]. Also, we have developed the corresponding stress-stretch constitutive equations by using the non-Gaussian average-stretch, full-network model of arbitrarily oriented molecular chains [16]. A comparison of the results corresponding to simulated and experimental data is done in Section 5. Finally, in Section 6, we address some conclusions related to our experimental observations and theoretical predictions of suture materials.

2. Experimental Work

2.1. Suture Materials. Eight batches of two suture commercial manufactures were selected to be tested in uniaxial deformation. The absorbable sutures materials tested were MonoPlus, Monosyn, polyglycolic acid, polydioxanone, polydioxanone 4–0, poly(glycolide-co-epsilon-caprolactone) (PGC25 3–0); the nonabsorbable suture materials were nylon and polypropylene. The mean diameter values used to characterize the suture samples were taken from suppliers specifications. The mean values considered here were 0.397 mm for MonoPlus and Monosyn sutures, 0.334 mm for polyglycolic acid 2–0, 0.377 mm for polydioxanone 2–0, 0.23 mm for polydioxanone 4–0, 0.29 mm for PGC25 3–0, 0.247 mm for nylon, and 0.241 mm for polypropylene.

2.2. Uniaxial Tensile Tests. The experimental tests were performed in two electromechanical universal testing machines. The suture materials identified as MonoPlus, Monosyn, polyglycolic acid 2–0, polydioxanone 2–0, nylon, and polypropylene were tested in an MTS Insight 2 tensile machine with a maximum cell load capacity of 2.5 kN while the suture materials of polydioxanone 4–0 and PGC25 3–0 were tested

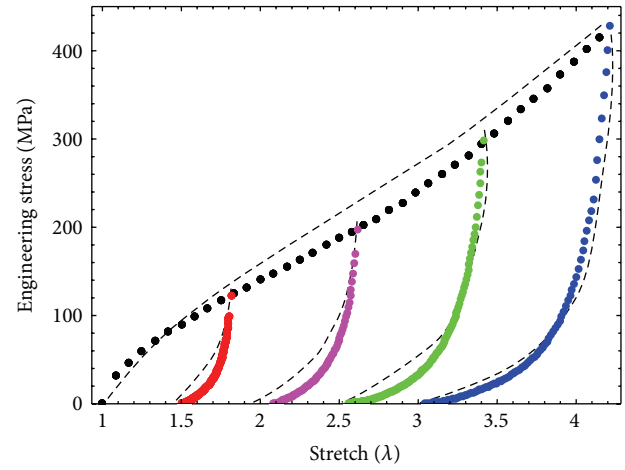


Figure 1: Experimental data collected from uniaxial tension cyclic loading-unloading tests for Monosyn sutures.

in an Instron tensile machine Model 3365 with a maximum cell load capacity of 1.6 kN. The selected samples length between machine grips was 50 mm. All tests were run at the machine speed of 500 mm/min at the average room temperature value of 24°C. All samples were subjected to cyclic loading-unloading conditions to obtain softening and permanent set effects as shown in Figure 1. Figure 1 illustrates that when the suture material is loaded from its virgin state, unloaded, and then reloaded again, its stress magnitude becomes smaller than the stress magnitude at the same amount of stretch during virgin loading. This reduction in the stress magnitude is known as the Mullins effect [4, 5]. This softening effect becomes associated with residual strain or permanent set effects which implies that the initial length of the suture sample has increased during the application of the tensile load. Table 1 illustrates the experimental average value of residual strain measured in each suture batch. Notice that suture materials response behavior agrees with Nichols et al. qualitative observation on sutures materials [2]. However, to describe quantitatively the stress-softened and permanent set effects observed on suture materials, a material model must be used. Therefore, to understand the physical relationships behind a material model, we first briefly review some basic knowledge on finite deformations, and, then, we shall derive a material model that is based on non-Gaussian statistical mechanics.

3. Basic Concepts on Finite Deformations

We consider the deformation of an incompressible elastic body which in its natural configuration occupies the region Ω. A material particle is considered to be in its undeformed reference configuration of a body at the place $\mathbf{X} = X_k\mathbf{e}_k$. After a prescribed deformation the body occupies the region Ω_c, the current configuration, and the particle at $\mathbf{X}$ moves to the place $\mathbf{x} = \mathbf{x}_k\mathbf{e}_k$ in a common rectangular Cartesian frame $\varphi = \{O; \mathbf{e}_k\}$ with origin O and orthonormal basis $\mathbf{e}_k$. Thus, the Cauchy-Green deformation tensor $\mathbf{B} \equiv \mathbf{F}\mathbf{F}^T$ has the form

$$\mathbf{B} = \lambda_1^2\mathbf{e}_{11} + \lambda_2^2\mathbf{e}_{22} + \lambda_3^2\mathbf{e}_{33}, \quad (1)$$

Table 1: Comparison between experimental and predicted residual strain deformations of the selected suture materials.

Suture material	Maximum previous stretch λ_{max}	Experimental residual strain	Predicted residual strain	Error (%)
MonoPlus	2.09363	1.6027	1.498	6.5327
	3.1709	2.2103	2.056	6.9809
	4.2483	2.7361	2.646	3.2930
	5.3309	3.3038	3.234	2.1127
Monosyn	1.8165	1.4996	1.464	2.3739
	2.6165	2.0828	1.962	5.7998
	3.4165	2.5559	2.484	2.8131
	4.2165	3.0550	3.007	1.5711
Polyglycolic acid 2-0	1.22	1.100	1.125	2.2727
	1.44	1.230	1.251	1.7070
	1.66	1.380	1.381	0.0724
	1.88	1.537	1.515	1.4313
Polydioxanone 2-0	1.5	1.200	1.277	6.4166
	2.0	1.512	1.566	3.5714
	2.5	1.815	1.862	3.5895
	3	2.167	2.154	0.5999
Polydioxanone 4-0	1.2	1.051	1.051	0.7347
	1.4	1.101	1.099	1.3187
	1.6	1.149	1.147	0.7879
	1.8	1.194	1.198	0.1115
Poly(glycolide-co-epsilon-caprolactone) (PGC25 3-0)	1.3	1.123	1.104	1.7270
	1.6	1.216	1.206	0.8818
	1.9	1.307	1.306	0.0238
	2.20	1.403	1.407	0.2851
Nylon	1.48	1.109	1.235	11.36
	1.96	1.366	1.481	8.4187
	2.44	1.67	1.744	4.4311
	2.92	2.011	2.019	0.3978
Polypropylene	1.4	1.154	1.197	3.72
	1.8	1.361	1.4	2.8655
	2.2	1.564	1.615	3.2608
	2.6	1.855	1.842	0.7008

where $\mathbf{e}_{jk} \equiv \mathbf{e}_j \otimes \mathbf{e}_k$, $\mathbf{e}_i$ are the associated orthonormal principal directions, $\mathbf{F}$ is the deformation gradient, and λ_i denote the principal stretches in φ. Note that the magnitude of the strain intensity at a material point $\mathbf{X}$ denoted by m is defined by $m \equiv \sqrt{\mathbf{B}\cdot\mathbf{B}} = \sqrt{\mathrm{tr}\,\mathbf{B}^2}$, where tr is the trace operation. In the undeformed state $\mathbf{B} = \mathbf{1}$, the identity tensor and $m = \sqrt{3}$; otherwise, $m > \sqrt{3}$ for all isochoric deformations [8]. Also $m \geq \sqrt{3}$ for all λ, the equality holding when and only when $\lambda = 1$, the undeformed state. Recalling that the principal invariants I_k of $\mathbf{B}$ are defined by

$$I_1 = \mathrm{tr}\,\mathbf{B}, \qquad I_2 = \frac{1}{2}\left[I_1^2 - \mathrm{tr}\left(\mathbf{B}^2\right)\right], \qquad I_3 = \det\mathbf{B}, \quad (2)$$

thus, the magnitude of the strain intensity m is given as

$$m = \sqrt{I_1^2 - 2I_2}. \quad (3)$$

4. A Nonmonotonous Stress-Softening Material Model

To characterize stress-softening effects, there exist in the literature many different micromechanical models have been developed to explain material damage mechanisms. See, for instance, the papers of Govindjee and Simo [6], Ogden and Roxburgh [7], Beatty and Krishnaswamy [8], Elías-Zúñiga and Beatty [9], Elías-Zúñiga [11], Diani et al. [12], de Tommasi et al. [13], Holzapfel et al. [15], Johnson and Beatty [17], de Souza Neto et al. [18], Marckmann et al. [19], Dorfmann and Ogden [20], Kazakevičiute-Makovska and Kačianauskas [21], and references cited therein for an overview of the main features of these models.

In this section, we derive the corresponding equations that describe the non-monotonic behavior of suture biocompatible materials subjected to loading and unloading cycles by assuming that the stress-softened material behavior can

be obtained from the virgin material response constitutive equation. Here, we assume an incompressible and isotropic virgin elastic material whose corresponding time independent Cauchy stress constitutive equation has the form

$$\mathbf{T} = -p\mathbf{1} + \aleph_1 (I_1, I_2)\, \mathbf{B} + \aleph_{-1} (I_1, I_2)\, \mathbf{B}^{-1}, \tag{4}$$

in which $\mathbf{T}$ is the Cauchy stress, p is an undetermined pressure, and $\aleph_\Gamma = \aleph_\Gamma(I_1, I_2)$, $\Gamma = 1, -1$, denote the virgin material response functions related to the strain energy function $W = \widehat{W}(I_1, I_2)$, per unit reference volume, in accordance with

$$\aleph_1 = 2W_1, \qquad \aleph_{-1} = -2W_2, \tag{5}$$

wherein $W_\alpha \equiv \partial\widehat{W}/\partial I_\alpha$ [16]. By using (4), Elías-Zúñiga and Beatty in [9] proposed a damage type model to describe the stress-softened material behavior of the form

$$\boldsymbol{\tau} = F(m; M)\, \mathbf{T}, \tag{6}$$

in which $\boldsymbol{\tau}$ denotes the Cauchy stress in the stress-softened material, M denotes the maximum previous strain at which the material is unloaded from the primary path, and $F(m; M)$ is an isotropic softening function at the damage level $m_{\max} = M$ on the interval $m \in [\sqrt{3}, M]$. They assumed that this softening function $F(m; M)$ is a monotone increasing function of the strain intensity that satisfies the conditions

$$0 < F(m; M) < 1, \qquad F(M; M) = 1. \tag{7}$$

Based on this assumption, Elías-Zúñiga and Beatty proposed the following softening function:

$$F(m; M) = e^{-b\sqrt{(M-m)}}, \tag{8}$$

where b is a dimensionless positive material-softening parameter. After substituting (8) into (6), Elías-Zúñiga and Beatty obtained the following stress-softened phenomenological material model:

$$\boldsymbol{\tau} = e^{-b\sqrt{(M-m)}}\mathbf{T}. \tag{9}$$

Theoretical predictions provided by (9) were computed in Elías-Zúñiga and Beatty [9] and Elías-Zúñiga and Beatty [10] and compared to experimental data for uniaxial extension, pure shear, and equibiaxial deformation states. There, the theoretical predictions showed reasonably good agreement with experimental data not only for the virgin loading path but also for the reloading paths. However, Kazakevičiūtė-Makovska [22] observed that the experimental data when plotted as the normalized stress τ/T versus the stretch ratio $\lambda/\lambda_{\max}$ showed nonmonotonous behavior with the characteristic S-shaped form, and $\lambda_{\max}$ defines the maximum amount of stretch on the primary loading path corresponding to the value at which the unloading starts in a particular deformation cycle. Kazakevičiūtė-Makovska concluded that, because of the variations in shapes of the curves for different deformation cycles, different values of the softening parameters were needed to fit experimental data for a particular choice of the softening function. Moreover, Kazakevičiūtė-Makovska showed that the softening function given by (8) fails in predicting the nonmonotonous behavior exhibited by experimental data collected by Mullins and Tobin [5], Cheng and Chen [23], and Mars and Fatemi [24] at higher stretch values.

On the other hand, de Tommasi and coworkers showed the importance of microscopic inhomogeneity to describe known experimental effects observed in amorphous materials such as the transition from diffuse to localized damage as the distribution properties are varied [25]. In fact, they showed that the monotone stress-stretch loading curve behavior is mainly due to a diffuse damage mechanism. They also considered that amorphous materials may be characterized by unstable strain domain, which gives the possibility of having homogeneous or localized damage with nonmonotone primary loading curve.

To confirm these observations, Elías-Zúñiga and Rodrguez in [14] used the nonmonotonous stress-softening function

$$F(m; M) = e^{-b[(M-m)(m/M)^\gamma]^\alpha}, \tag{10}$$

where b is a positive softening material parameter and α and γ are positive scaling constants chosen to best fit experimental data. They chose the values of $\alpha = 1/2$ and $\gamma = 1$ for the scaling constants and fit the value of the softening parameter b according to the unloading experimental data of the unloading path at which the amount of stretch has the maximum value. Then, they used the equation

$$\boldsymbol{\tau} = \mathbf{T}e^{-b[(M-m)(m/M)]^{1/2}} \tag{11}$$

to predict the corresponding stress-softened values during the inflation and deflation of rubber balloons.

To account permanent set effects during the material unloading processes, Elías-Zúñiga and Rodrguez [14] modified Holzapfel et al. model [15] and proposed an energy model based on pseudoelastic theory of the form:

$$W_s = W(\lambda_1, \lambda_2, \lambda_3) + \frac{\mu}{C}\sum_{a=1}^{3}\left[\frac{1}{2}\left(\lambda_{\max a}^n - \lambda_a^n\right)^2 - Cd_0\right], \tag{12}$$

where $W(\lambda_1, \lambda_2, \lambda_3)$ represents the strain energy function associated with the primary loading path, μ is the material shear modulus, C is a positive dimensionless material constant, d_0 is an integration constant, n is a fitting parameter that in general takes the value of 1/2, λ_a represents the principal stretches, and $\lambda_{\max a}$, $a = 1, 2, 3$, are the maximum values of the principal stretches at which unloading begins on the primary loading path.

Here, we use the softening function given by (10) and assume that $W(\lambda_1, \lambda_2, \lambda_3)$ is provided by the non-Gaussian Arruda-Boyce constitutive equation for an average-stretch, full-network of arbitrarily oriented molecular chains to predict softening and residual strain effects on suture materials.

4.1. A Nonmonotonous Amended Averaged Stretch Material Model. For this material model, it is well known that the

strain energy per unit volume for the loading path is given by

$$W(\lambda_1,\lambda_2,\lambda_3) = \mu\left[N_8\left(\beta\lambda_r + \ln\left(\frac{\beta}{\sinh\beta}\right)\right) - \ln\left(\frac{\beta}{\lambda_r}\right)\right] - c_8, \tag{13}$$

where λ_r is the relative chain stretch defined by

$$\lambda_r = \frac{\lambda_{\text{chain}}}{\lambda_L}, \tag{14}$$

$\lambda_L = \sqrt{N_8}$ represents the fully extended chain stretch, N_8 is the chain number of rigid links, each of length l, λ_{chain} is the chain deformation that in the affine deformation is determined by

$$\lambda_{\text{chain}} \equiv \sqrt{\frac{I_1}{3}}, \tag{15}$$

β defined by $\beta \equiv \mathscr{L}^{-1}(\lambda_r)$ is the inverse of the Langevin function $\mathscr{L}(\beta)$ which is defined as

$$\lambda_r = \mathscr{L}(\beta) \equiv \coth\beta - \frac{1}{\beta}, \tag{16}$$

and c_8 is a constant that ensures that the strain energy density vanishes in the undeformed state [16, 26]. Substitution of (13) into (12) provides the modified non-Gaussian pseudo strain energy per unit volume that accounts for residual strains on the unloading path; that is,

$$W_s = \mu\left[N_8\left(\beta\lambda_r + \ln\left(\frac{\beta}{\sinh\beta}\right)\right) - \ln\left(\frac{\beta}{\lambda_r}\right)\right] + \frac{\mu}{C}\sum_{a=1}^{3}\left[\frac{1}{2}\left(\lambda_{\max a}^{n} - \lambda_a^n\right)^2\right] + D, \tag{17}$$

where D is an energy constant.

The Cauchy stress-stretch averaging network model components for the virgin material are obtained by substituting (13) into (4):

$$T_k = -p + \aleph(I_1)\lambda_k^2, \tag{18}$$

where $\aleph(I_1)$ is a material response function given as

$$\aleph(I_1) \equiv \frac{\mu}{3\lambda_r}\left[\beta + \frac{1}{N_8}\left(\frac{1}{\lambda_r} - \frac{1}{\beta\left(1-\lambda_r^2-2\lambda_r/\beta\right)}\right)\right]. \tag{19}$$

Eliminating the pressure from (18) gives

$$T_j - T_k = \aleph(I_1)\left(\lambda_j^2 - \lambda_k^2\right), \tag{20}$$

where $j \neq k = 1, 2, 3$ (no sum). Similarly, the Cauchy stress-stretch constitutive equation for a stress-softened material can be obtained by substituting (17) into (4) and by using (5) and (11) yields the following stress-softened components:

$$\tau_k = \left[-p + \aleph(I_1)\lambda_k^2 + \frac{\mu\lambda_k}{2C}f_k(\lambda_1,\lambda_2,\lambda_3)\right] \times e^{-b\sqrt{(M-m)(m/M)}}, \quad k = 1,2,3\,(\text{nosum}), \tag{21}$$

where

$$f_k(\lambda_1,\lambda_2,\lambda_3) = \frac{\partial\sum_{a=1}^{3}\left(\lambda_{\max a}^{n} - \lambda_a^n\right)^2}{\partial\lambda_k}. \tag{22}$$

Then, on elimination of p from (21), it yields

$$\tau_j - \tau_k = \left[\aleph(I_1)\left(\lambda_j^2 - \lambda_k^2\right) + \frac{\mu}{2C}\left(\lambda_j f_j(\lambda_1,\lambda_2,\lambda_3) - \lambda_k f_k(\lambda_1,\lambda_2,\lambda_3)\right)\right] \times e^{-b\sqrt{(M-m)(m/M)}}, \tag{23}$$

where, in general, $j \neq k = 1, 2, 3$ (no sum).

Recalling that, for an incompressible material, the engineering stress $\boldsymbol{\sigma}$ is related to the Cauchy stress by

$$\boldsymbol{\sigma} = \mathbf{T}\mathbf{F}^{-1}, \tag{24}$$

then, the uniaxial engineering stress-stretch relation for an average-stretch, full-network stress-softened material model is obtained by using (22), (23), and (24):

$$\sigma_s = \left[\aleph(I_1)\left(\lambda - \lambda^{-2}\right) + \frac{\mu}{C}\left(-n\lambda^{(n-1)}\left(\lambda_{\max}^{n} - \lambda^n\right) + n\lambda^{-(1+n/2)}\left(\lambda_{\max}^{-n/2} - \lambda^{-n/2}\right)\right)\right] \times e^{-b\sqrt{(M-m)(m/M)}}. \tag{25}$$

Here,

$$m = \sqrt{\lambda^4 + 2\lambda^{-2}}, \tag{26}$$

and the relative chain stretch which can be obtained from (14) and (15) is given as

$$\lambda_r = \sqrt{\frac{1}{3N_8}\left(\lambda^2 + 2\lambda^{-1}\right)}. \tag{27}$$

Of course, other material models may be modified by using (10) and our derived pseudo strain energy per unit volume given by (12) to account for a nonmonotonous stress-softened behavior as well as permanent set effects, respectively.

We next examine the degree of accuracy attained by our proposed material model in predicting experimental data of biocompatible suture materials.

5. Comparison with Suture Experimental Data

To assess the accuracy of the derived constitutive (25) which includes residual strains and has a nonmonotonous stress softening function that describes Mullins effect, we used the experimental data collected during uniaxial extension test of the aforementioned suture material samples. Notice from

(25) that only four constitutive material constants and one fitting parameter need to be computed, that is, the shear modulus μ, the chain number of links N, the stress softening parameter b, the residual strain material constant C, and the fitting parameter n. However, we have found that in general the value of $n = 1$ for the uniaxial stress-softened material model described by (25) provides good fit to the collected experimental data.

We begin with the stress-stretch data for suture samples of MonoPlus and Monosyn materials. Figures 2 and 3 illustrate the predicted engineering stress response curves obtained from (24) and (25). We can see from Figures 2 and 3 that theoretical results are in good agreement with experimental data for the several loading and unloading cycles that exhibit residual strains. The constitutive material constants used to best fit experimental data are $\mu = 100$ MPa, $N = 20$, $b = 0.45$, and $C = 0.0065$ MPa for MonoPlus sutures and $\mu = 92$ MPa, $N = 20$, $b = 0.85$, and $C = 0.0045$ MPa for Monosyn material. The amount of error attained between experimental and predicted residual strains is shown in Table 1. From Figures 2 and 3 and Table 1, it is concluded that Monosyn sutures tend to soften and have bigger residual strains than MonoPlus sutures. In all figures, the dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

Figures 4 through 7 illustrate the stress-stretch curves collected from polyglycolic acid, polydioxanone, polydioxanone 4.0, and poly(glycolide-co-epsilon-caprolactone) (PGC25 3–0) suture material samples, respectively. We can see from Figures 4, 5, 6, and 7 that the predicted response stress-stretch curves computed from (25) stand in good agreement with experimental data for the several loading and unloading cycles. In these figures, the blue lines represent the experimental collected data, and the dashed black lines represent theoretical results obtained from (24) and (25). The material constants used in the material model are provided by a best fit analysis and these are listed in the figure captions. It is clear from Figures 4–7 that each suture material exhibits different qualitative and quantitative response material behavior. In fact, the amount of softening on the polyglycolic acid 2–0 and polydioxanone 2–0 suture materials is bigger than those of polydioxanone 4.0 and PGC25 3–0.

Finally, Figures 8 and 9 show the stress-stretch curves of the nonabsorbable nylon and polypropylene suture materials. Although the polypropylene sutures are stiffer than the nylon ones, the amount of strength and residual strain are quite similar. Both sutures material experienced stress-softened and permanent set that must be taken into account during suture manipulation to prevent damaging and weakening undesirable effects.

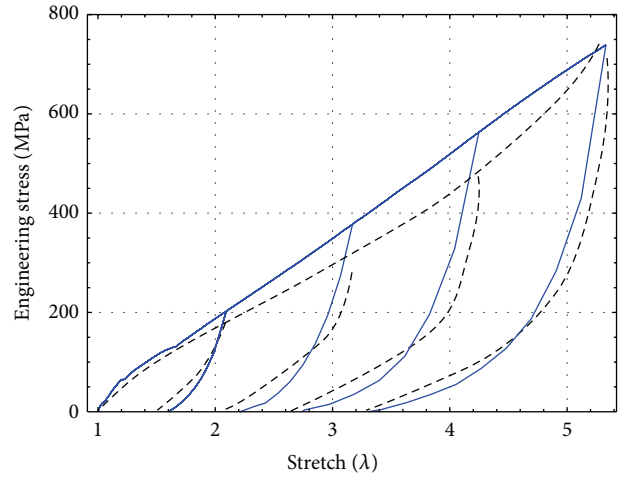


Figure 2: Engineering stress-stretch data for MonoPlus sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which $\mu = 100$ MPa, $N = 20$, $b = 0.45$, and $C = 0.0065$ MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

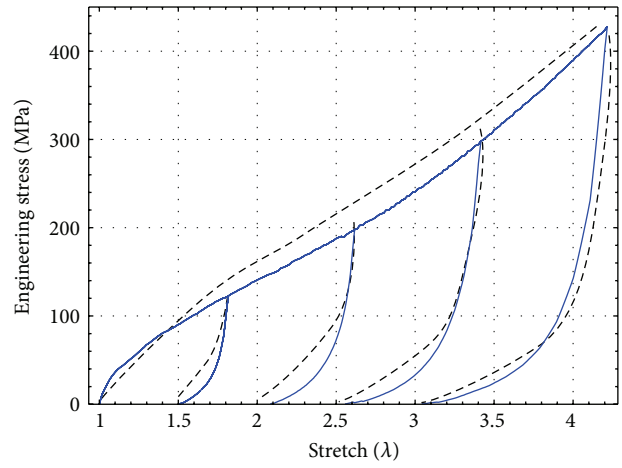


Figure 3: Engineering stress-stretch data for Monosyn sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which $\mu = 92$ MPa, $N = 20$, $b = 0.85$, and $C = 0.0045$ MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

6. Conclusions

In this paper, we have examined the material behavior of eight different types of suture materials and found that, when these are subjected to loading and unloading cycles, its stress magnitude becomes lower than that of the virgin material. Furthermore, all tested sutures exhibit residual strains which is related to microstructural material damage upon deformation from the natural, undistorted state of the virgin material. To predict the suture materials response behavior observed during uniaxial tension test, we have introduced a new nonmonotonous stress-softened material model that takes into account permanent set effects for the unloading paths as described by the simple constitutive relation (25).

For each suture material, we have compared experimental data with theoretical predictions obtained from (25). In each case, we have determined the corresponding four material constants: the material shear modulus μ, the chain number of rigid links N, the material softening parameter b, and a positive material constant C that is related to the pseudoelastic

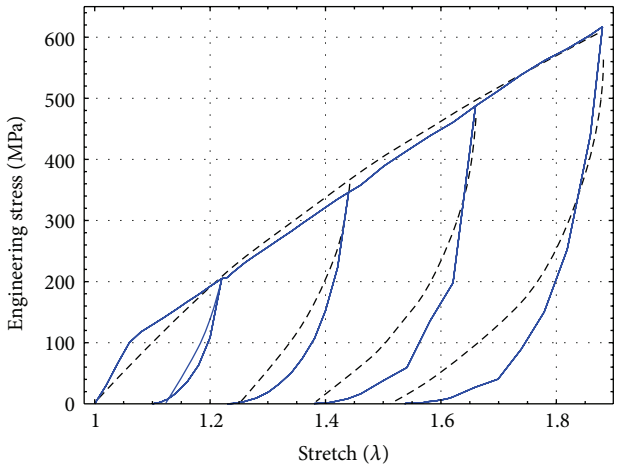


Figure 4: Engineering stress-stretch data for polyglycolic acid sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 385 MPa, N = 70.5, b = 1.3, and C = 0.001 MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

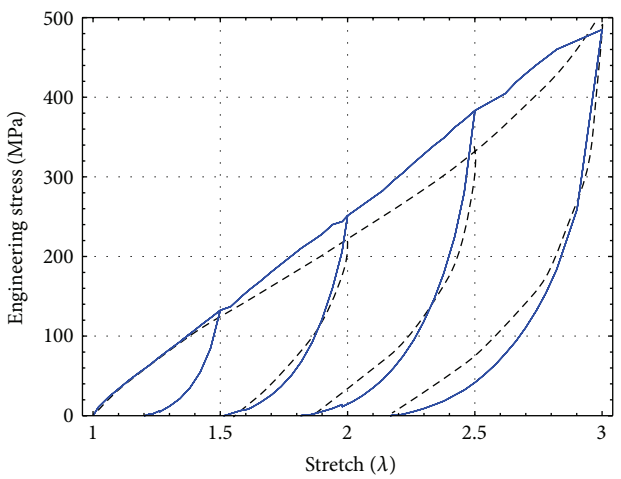


Figure 5: Engineering stress-stretch data for polydioxanone 2–0 compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 126 MPa, N = 6, b = 0.65, and C = 0.0035 MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

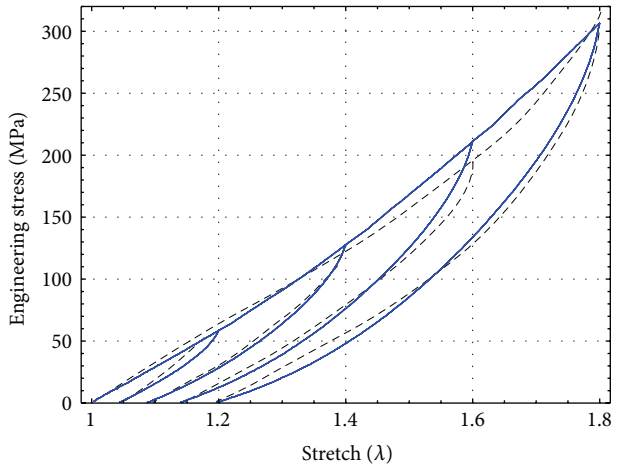


Figure 6: Engineering stress-stretch data for polydioxanone 4.0 compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 148 MPa, N = 1.95, b = 0.445, and C = 0.0115 MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

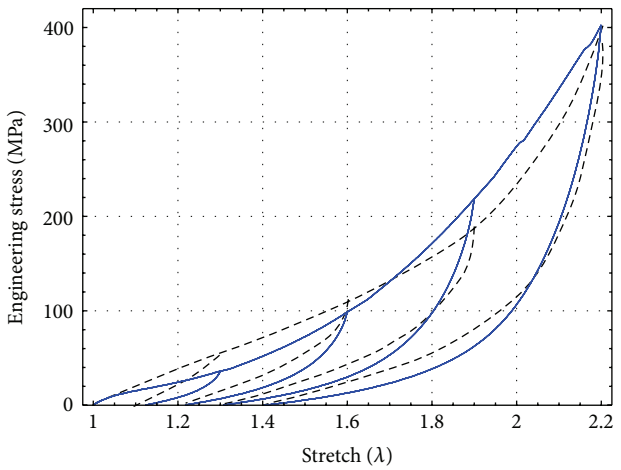


Figure 7: Engineering stress-stretch data for PGC25 3–0 sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which μ = 90 MPa, N = 2.35, b = 0.75, and C = 0.012 MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

residual strain energy. Based on the accuracy of our proposed nonmonotonous model to predict experimental data, we can conclude that the extent of damage of suture biocompatible materials can be conveniently determined by considering its softening behavior observed during experimental tests. Nevertheless, there is a variation in the theoretical predictions, as shown in Table 1, that we believe is due to some viscoelastic effects that were not considered in the proposed material model.

Finally, the present study confirms that stress-softening and residual strain effects appear in the suture materials tested here. The experimental work of this paper proves that suture materials change dramatically when tensile loads are applied during the suturing and healing processes [2]. We have also found that the aforementioned effects are more evident when *in vitro* sutures are subjected to cyclic loading conditions. However, the results of this new experimental work will be reported in a subsequent paper.

Conflict of Interests

The authors declare that they have no conflict of interests.

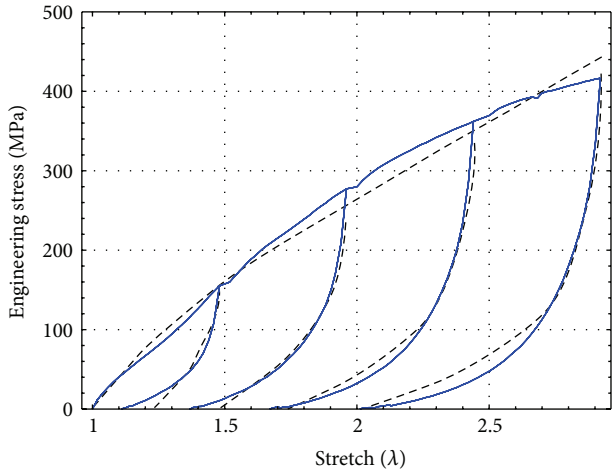


FIGURE 8: Engineering stress-stretch data for nylon sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which $\mu = 155$ MPa, $N = 20.5$, $b = 1$, and $C = 0.0035$ MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

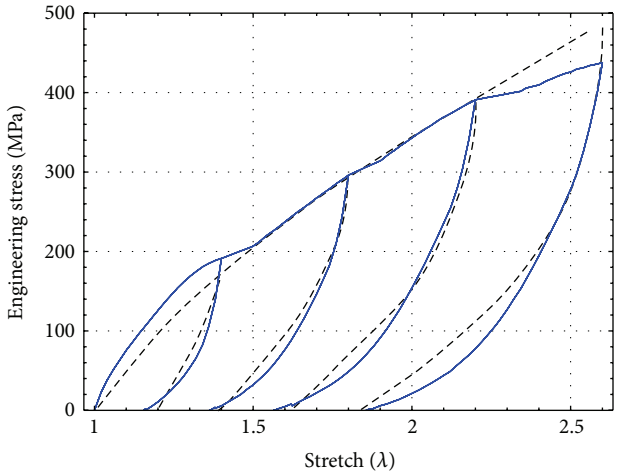


FIGURE 9: Engineering stress-stretch data for polypropylene sutures compared with theoretical predictions of the nonmonotonous amended average-stretch, full-network model for which $\mu = 200$ MPa, $N = 30.5$, $b = 0.65$, and $C = 0.00265$ MPa. The dashed black lines represent theoretical predictions, and the blue solid lines describe experimental data.

Acknowledgments

This work was funded by Tecnológico de Monterrey—Campus Monterrey, through the Research Chair in Nanomaterials for Medical Devices and Research Chair in Intelligent Machines. Additional support was provided by the project FOMIX Nuevo León M0014-2010-30 #145045 and from the European Union Seventh Framework Programme (FP7-PEOPLE-2009) under the grant agreement IRSES no. 247476.

References

[1] N. P. Ingle and M. W. King, "Optimizing the tissue anchoring performance of barbed sutures in skin and tendon tissues," *Journal of Biomechanics*, vol. 43, no. 2, pp. 302–309, 2010.

[2] W. K. Nichols, M. Stanton, D. Silver, and W. F. Keitzer, "Anastomotic aneurysms following lower extremity revascularization," *Surgery*, vol. 88, no. 3, pp. 366–374, 1980.

[3] M. Poukalova, C. M. Yakacki, R. E. Guldberg et al., "Pullout strength of suture anchors: effect of mechanical properties of trabecular bone," *Journal of Biomechanics*, vol. 43, no. 6, pp. 1138–1145, 2010.

[4] L. J. Mullins, "Effect of stretching on the properties of rubber," *Journal of Rubber Research*, vol. 16, pp. 275–289, 1947.

[5] L. Mullins and N. R. Tobin, "Theoretical model for the elastic behavior of filled-reinforced vulcanized rubbers," *Journal of Rubber Chemestry and Technology*, vol. 30, pp. 555–571, 1957.

[6] S. Govindjee and J. Simo, "A micro-mechanically based continuum damage model for carbon black-filled rubbers incorporating Mullins' effect," *Journal of the Mechanics and Physics of Solids*, vol. 39, no. 1, pp. 87–112, 1991.

[7] R. W. Ogden and D. G. Roxburgh, "A pseudo-elastic model for the Mullins effect in filled rubber," *Proceedings of the Royal Society A: Mathematical, Physical and Engineering Sciences*, vol. 455, no. 1988, pp. 2861–2877, 1999.

[8] M. F. Beatty and S. Krishnaswamy, "Theory of stress-softening in incompressible isotropic materials," *Journal of the Mechanics and Physics of Solids*, vol. 48, no. 9, pp. 1931–1965, 2000.

[9] A. Elías-Zúñiga and M. F. Beatty, "A new phenomenological model for stress-softening in elastomers," *Zeitschrift fur Angewandte Mathematik und Physik*, vol. 53, no. 5, pp. 794–814, 2002.

[10] A. Elías-Zúñiga and M. F. Beatty, "Stress-softening effects in the transverse vibration of a non-Gaussian rubber string," *Meccanica*, vol. 38, no. 4, pp. 419–433, 2003.

[11] A. Elías-Zúñiga, "A phenomenological energy-based model to characterize stress-softening effect in elastomers," *Polymer*, vol. 46, no. 10, pp. 3496–3506, 2005.

[12] J. Diani, M. Brieu, and J. M. Vacherand, "A damage directional constitutive model for Mullins effect with permanent set and induced anisotropy," *European Journal of Mechanics, A/Solids*, vol. 25, no. 3, pp. 483–496, 2006.

[13] D. de Tommasi, G. Puglisi, and G. Saccomandi, "A micromechanics-based model for the Mullins effect," *Journal of Rheology*, vol. 50, no. 4, pp. 495–512, 2006.

[14] A. Elías-Zúñiga and C. A. Rodríguez, "A non-monotonous damage function to characterize stress-softening effects with permanent set during inflation and deflation of rubber balloons," *International Journal of Engineering Science*, vol. 48, no. 12, pp. 1937–1943, 2010.

[15] G. A. Holzapfel, M. Stadler, and R. W. Ogden, "Aspects of stress softening in filled rubbers incorporating residual strains," in *Proceedings of the first European Conference on Constitutive Models for Rubber*, A. Dorfmann and A. Muhr, Eds., pp. 189–193, Rotterdam, The Netherlands, 1999.

[16] M. F. Beatty, "An average-stretch full-network model for rubber elasticity," *Journal of Elasticity*, vol. 70, no. 1–3, pp. 65–86, 2003.

[17] M. A. Johnson and M. F. Beatty, "The mullins effect in uniaxial extension and its influence on the transverse vibration of a rubber string," *Continuum Mechanics and Thermodynamics*, vol. 5, no. 2, pp. 83–115, 1993.

[18] E. A. de Souza Neto, D. Perić, and D. R. J. Owen, "A phenomenological three-dimensional rate-idependent continuum damage model for highly filled polymers: formulation and computational aspects," *Journal of the Mechanics and Physics of Solids*, vol. 42, no. 10, pp. 1533–1550, 1994.

[19] G. Marckmann, E. Verron, L. Gornet, G. Chagnon, P. Charrier, and P. Fort, "A theory of network alteration for the Mullins effect," *Journal of the Mechanics and Physics of Solids*, vol. 50, no. 9, pp. 2011–2028, 2002.

[20] A. Dorfmann and R. W. Ogden, "A constitutive model for the Mullins effect with permanent set in particle-reinforced rubber," *International Journal of Solids and Structures*, vol. 41, no. 7, pp. 1855–1878, 2004.

[21] R. Kazakevičiute-Makovska and R. Kačianauskas, "Modelling of stress softening in elastomeric materials: foundations of simple theories," *Mechanics Research Communications*, vol. 31, no. 4, pp. 395–403, 2004.

[22] R. Kazakevičiūtė-Makovska, "Experimentally determined properties of softening functions in pseudo-elastic models of the Mullins effect," *International Journal of Solids and Structures*, vol. 44, no. 11-12, pp. 4145–4157, 2007.

[23] M. Cheng and W. Chen, "Experimental investigation of the stress-stretch behavior of EPDM rubber with loading rate effects," *International Journal of Solids and Structures*, vol. 40, no. 18, pp. 4749–4768, 2003.

[24] W. V. Mars and A. Fatemi, "Observations of the constitutive response and characterization of filled natural rubber under monotonic and cyclic multiaxial stress states," *Journal of Engineering Materials and Technology*, vol. 126, no. 1, pp. 19–28, 2004.

[25] D. de Tommasi, G. Puglisi, and G. Saccomandi, "Localized versus diffuse damage in amorphous materials," *Physical Review Letters*, vol. 100, no. 8, Article ID 085502, pp. 1–4, 2008.

[26] A. Elías-Zúñiga and M. F. Beatty, "Constitutive equations for amended non-Gaussian network models of rubber elasticity," *International Journal of Engineering Science*, vol. 40, no. 20, pp. 2265–2294, 2002.

Caso clínico

CIRUGÍA ENDOSCÓPICA

Vol. 14 No. 3 Jul.-Sep. 2013

Pancreatitis aguda en una paciente con *situs inversus*. Reporte de caso

Luis Alberto Topete González,* Rene Augusto Palomo-Hoil,* José Antonio Díaz-Elizondo,** José Pulido-Rodríguez***

Resumen

Situs inversus totalis es un defecto raro con predisposición genética que puede presentar dificultades en el diagnóstico y manejo de enfermedades abdominales debido a que la anatomía se encuentra en espejo. Presentamos el caso de una mujer diagnosticada con pancreatitis aguda y *situs inversus totalis*. Una vez resuelta la pancreatitis aguda, se programa y realiza colecistectomía por laparoscopia. Después de la cirugía, la paciente tuvo una recuperación exitosa y fue dada de alta del hospital dos días más tarde. Concluimos que existe dificultad técnica al realizar la colecistectomía por laparoscopia en estos pacientes. La disección se realizó de manera segura y confirmamos los reportes previos al realizar la colecistectomía por laparoscopia en *situs inversus totalis*.

Palabras clave: *Situs inversus totalis*, pancreatitis aguda, colecistectomía por laparoscopia.

Abstract

Situs inversus totalis *is a rare defect with genetic predisposition that may present difficulties in the diagnosis and management of abdominal pathology due to mirror-image anatomy. We present the case of a women diagnosed with acute pancreatitis and* situs inversus totalis. *After acute pancreatitis was resolved, the patient was scheduled for a laparoscopic cholecistectomy. After surgery, the patient had a successful recovery and was discharge from the hospital two days later. We concluded that there is technical difficulty performing laparoscopic cholecystectomy in such patients. The dissection was quite safe and confirms the previous reports of safe laparoscopic cholecystectomy in* situs inversus totalis.

Key words: Situs inversus totalis, *acute pancreatitis, laparoscopic cholecystectomy.*

* Residente de Cirugía General. Programas Multicéntricos de Especialidades Médicas de la Escuela Nacional de Medicina del Tecnológico de Monterrey.

** Jefe de Servicio Cirugía General. Hospital «Bernardo Sepulveda» de Secretaría de Salud de Nuevo León. Profesor de Cirugía General. Programas Multicéntricos de Especialidades Médicas de la Escuela Nacional de Medicina del Tecnológico de Monterrey.

*** Instituto de Cirugía del Centro Médico ZambranoHellion-Tec Salud del Tecnológico de Monterrey. Profesor de Cirugía General. Programas Multicéntricos de Especialidades Médicas de la Escuela Nacional de Medicina del Tecnológico de Monterrey.

Correspondencia:
Dr. Luis Alberto Topete González
Residente de Cirugía General
Programas Multicéntricos de Especialidades Médicas de la Escuela Nacional de Medicina del Tecnológico de Monterrey.
Oficina de Posgrado en Cirugía General
Batallón de San Patricio 112 Piso 1
Area Escuela-CM Zambrano Hellion
San Pedro Garza García, Nuevo León, 66278
Cel: 811 799 9836
E-mail: luis_topete@me.com

INTRODUCCIÓN

Situs inversus totalis es un defecto raro con predisposición genética que puede presentar dificultades en el diagnóstico y tratamiento de patología abdominal debido a la distorsión de la anatomía en espejo.[1]

OBJETIVO

Presentamos el caso de una mujer diagnosticada con pancreatitis aguda y *situs inversus totalis*.

REPORTE DE CASO

Mujer de 48 años de edad se presenta con dolor abdominal sin antecedentes de importancia. Inicia padecimiento 24 horas previas a su ingreso con dolor abdominal localizado en epigastrio, transflictivo, de intensidad moderada, acompañado de náuseas y vómito en tres ocasiones de contenido gástrico. Niega acolia y coluria. A la exploración física presenta

signos vitales estables, dolor a la palpación en epigastrio e hipocondrio izquierdo, sin datos de irritación peritoneal. Se solicitan laboratorios donde se observa amilasa sérica de 1,995 UI/L, transaminasa glutámico-pirúvica (TGP) de 320 UI/L, transaminasa glutámico-oxalacético (TGO) de 256 UI/L y deshidrogenasa láctica de 647 UI/L. Se solicita tele de tórax *(Figura 1)* donde se observa dextrocardia y electrocardiograma con desviación del eje cardiaco hacia la derecha, como parte de la valoración preoperatoria. Se realiza ultrasonido de abdomen identificando hígado en lado izquierdo del cuerpo y bazo del lado derecho, vesícula biliar distendida, con pared delgada, en el interior de esta última se observa lito móvil de 12 mm. Se decide su ingreso con diagnóstico de pancreatitis aguda para manejo médico del cuadro. Al segundo día de estancia intrahospitalaria se solicita tomografía de abdomen con contraste IV, donde se advierte líquido peripancreático escaso, así como los cambios anatómicos previamente descritos *(Figura 2)*. Al cuarto día de internamiento, la paciente tolera vía oral y se encuentra asintomática, por lo que se decide programar para colecistectomía por laparoscopia.

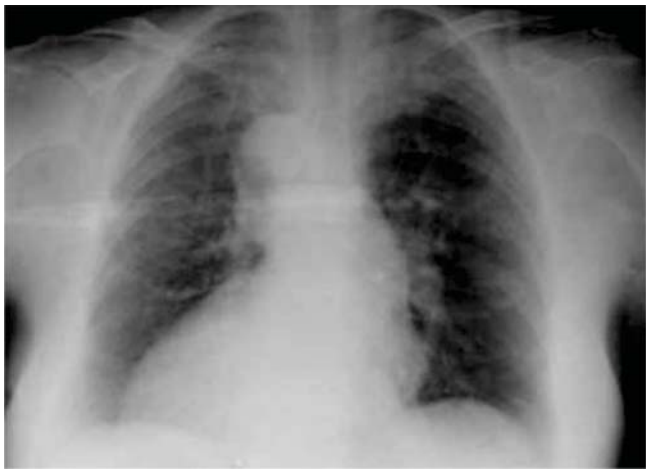


Figura 1. Radiografía de tórax con dextrocardia.

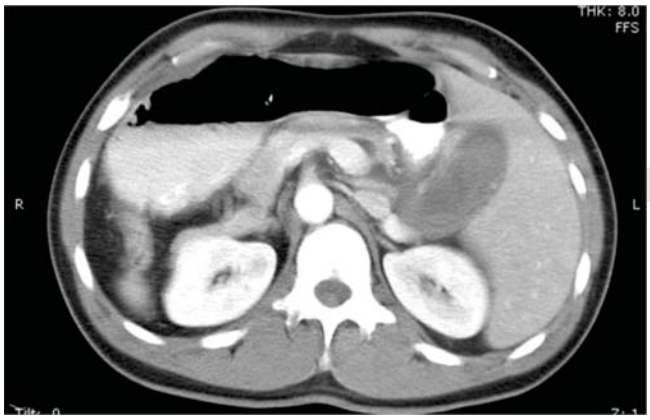


Figura 2. Tomografía de abdomen contrastada.

PROCEDIMIENTO

Se coloca a la paciente en posición supina y tanto el cirujano como el asistente con la cámara se instalan del lado izquierdo; el primer ayudante y el monitor a la izquierda de la paciente. Los trócares son introducidos en espejo del lado izquierdo de la paciente. La disección de Calot se realiza con la mano izquierda por el puerto subxifoideo y, posteriormente, se colocan endoclips en arteria y conducto cístico *(Figura 3)*. La retracción de la bolsa de Hartmann la realiza el primer ayudante. La paciente es dada de alta al segundo día del postoperatorio.

DISCUSIÓN

Concluimos que hay dificultades técnicas al realizar la colecistectomía por laparoscopia en pacientes con *situs inversus totalis*. En este caso la disección se realizó de manera segura confirmando los reportes previos acerca de la seguridad de realizar una colecistectomía por laparoscopia a pesar de la distorsión de la anatomía en espejo y otras anomalías vasculares. Al menos dos tercios de los cirujanos son derechos y, por lo tanto, es necesario para éstos modificar su técnica quirúrgica usual en aras de realizar el procedimiento de manera segura y cómoda.[2] En lugar de cruzar las manos de manera absurda al momento de retraer la bolsa de Hartmann en la disección de las estructuras del triángulo de Calot, sugerimos que la retracción de dicha bolsa sea realizada por el asistente permitiendo, así, al cirujano operar de manera más cómoda y segura.[1-4]

CONCLUSIÓN

En los pacientes con *situs inversus totalis*, el diagnóstico clínico puede ser complicado dado los cambios anatómi-

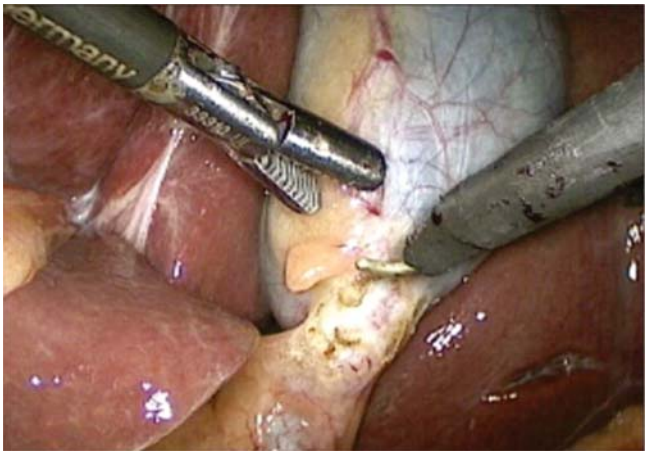


Figura 3. Disección del triángulo de Calot.

cos que se presentan en estos pacientes. Concluimos que hay dificultades técnicas al realizar la colecistectomía por laparoscopia en pacientes con *situs inversus totalis*. La disección se realizó de manera segura y confirmamos reportes previos al realizar la colecistectomía por laparoscopia en *situs inversus totalis*.

REFERENCIAS

1. Borgaonkar VD, Deshpande SS, Kulkarni VV. Laparoscopic cholecystectomy and appendicectomy in *situs inversus totalis*: a case report and review of literature. *J Minim Access Surg*. 2011; 7: 242-245.
2. Oms LM, Badia JM. Laparoscopic cholecystectomy in *situs inversus totalis*: The importance of being left-handed. *Surg Endosc*. 2003; 17: 1859-1861.
3. McKay D, Blake G. Laparoscopic cholecystectomy in *situs inversus totalis*: a case report. *BMC Surg*. 2005; 5: 5.
4. Kamitani S, Tsutamoto Y, Hanasawa K, Tani T. Laparoscopic cholecystectomy in *situs inversus totalis* with "inferior" cystic artery: a case report. *World J Gastroenterol*. 2005; 11: 5232-5234.

Hindawi Publishing Corporation
Case Reports in Surgery
Volume 2014, Article ID 439061, 4 pages
http://dx.doi.org/10.1155/2014/439061

Case Report

Incidental Benign Metastasizing Leiomyoma in a Patient with Bone Sarcoma: A Case Report

Zanndor Jacob del Real-Romo,[1] Carlos Montero-Cantú,[2,3] Oscar Villegas-Cabello,[2] José Antonio Díaz-Elizondo,[2,4] Danae Reyes-Salas,[1] Rene Palomo-Hoil,[1] Guillermo Peralta-Castillo,[1] David Martínez-Sánchez,[1] and Eduardo Flores-Villalba[2,4]

[1] *Escuela de Medicina y Ciencias de la Salud del Tecnológico de Monterrey-TEC Salud, Avenida Doctor Ignacio Morones Prieto 3000, Colonia Los Doctores, 64710 Monterrey, NL, Mexico*
[2] *Hospital San José-TEC Salud, Avenida Doctor Ignacio Morones Prieto 3000, Colonia Los Doctores, 64710 Monterrey, NL, Mexico*
[3] *Universidad Autónoma de Nuevo León, Avenida Francisco I. Madero y Avenida Gonzalitos S/N, Colonia Mitras Centro, 64460 Monterrey, NL, Mexico*
[4] *Hospital Zambrano Hellion-TEC Salud, Batallón San Patricio 112, Colonia Real de San Agustin, 66278 San Pedro Garza García, NL, Mexico*

Correspondence should be addressed to Zanndor Jacob del Real-Romo; zanndor@gmail.com

Received 17 May 2014; Accepted 12 August 2014; Published 26 August 2014

Academic Editor: Angelo Carretta

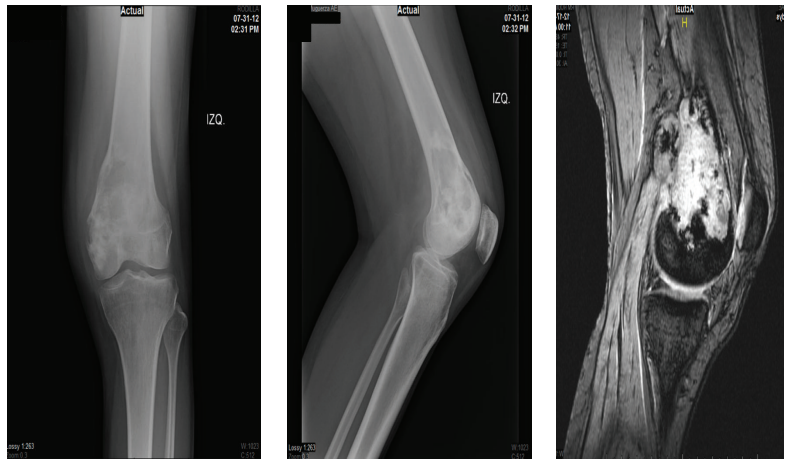
Background. The benign metastasizing leiomyoma is an exceptionally rare entity; it presents with ectopic leiomyoma nodules with a benign pattern. Symptoms vary according to the anatomic location. The diagnosis is histopathological, usually in patients with history of hysterectomy. *Case Presentation*. A 36-year-old female with 2-month history of left knee pain was diagnosed with bone fibrosarcoma. A CT scan showed pulmonary nodules. The patient started neoadjuvant chemotherapy. Conservative surgery of pelvic limb was achieved. A new CT scan reported pulmonary nodules that remained in relation to the previous CT. A nodule resection by thoracotomy and TOB (transoperative biopsy) was performed. The final pathology report described benign proliferative lesions consistent with benign metastatic leiomyoma. *Conclusions*. Benign metastatic leiomyoma is a rare condition presenting with uterine and extrauterine nodules most commonly in the lung. The diagnosis is histopathological. The surgical procedure must be reserved for selected patients.

1. Background

The benign metastasizing leiomyoma is an exceptionally rare entity with few cases reported in the world literature; it is associated with ectopic (extrauterine) leiomyoma nodules with a benign pattern in the lungs [1]. Most patients are asymptomatic and the nodules are discovered incidentally. When symptoms do occur, they vary according to the anatomic location of the lesion [2]. The diagnosis is histopathological, usually in patients with history of hysterectomy. The treatment is hormonal, reserving surgical intervention for selected patients.

2. Case Presentation

A 36-year-old multiparous Mexican woman, married, living in Monterrey, NL, with past medical history of two plastic surgeries, cesarean, and an abortion. She presents with 2-month history of left knee pain, progressive in intensity from a mild discomfort to a severe disabling pain. It increased with walking. The physical examination revealed increased volume of the knee, tenderness, and edema, the X-ray showed a permeative pattern in distal femur (Figures 1(a) and 1(b)) without evidence of fracture; the malignant-looking lesion was corroborated with a MRI (Figure 1(c)). The biopsy was



(a) (b) (c)

Figure 1: ((a) and (b)) Permeative pattern in distal femur; (c) malignant looking lesion is corroborated with a MRI. MRI: magnetic resonance imaging.

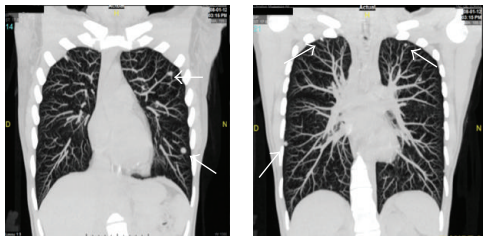


Figure 2: Pulmonary nodules (arrows) in both hemithoraces on a CT scan.

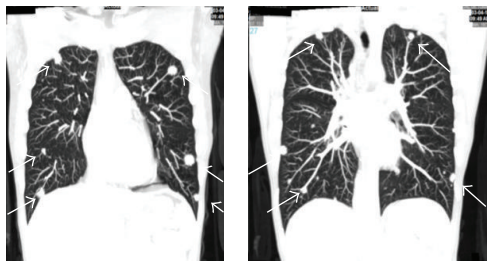


Figure 3: CT scan 3 months later reported multiple pulmonary nodules (arrows) that remain in number and dimension in relation to the previous CT.

consistent with fibrosarcoma. The evidence of pulmonary nodules (smaller than 1 cm) in CT scan suggested metastatic disease in both hemithoraces (Figure 2). The patient started 5 cycles of neoadjuvant cisplatin and doxorubicin, and a conservative surgery of the pelvic limb with resection of distal femur, proximal tibia, and femur prosthesis placement was achieved. Pathology diagnosis reported 100% remission of femur sarcoma after chemotherapy. Months later a CT scan demonstrated that pulmonary nodules remained in number and dimensions in relation to the previous CT scan (Figure 3). Through posterolateral thoracotomy a nonanatomic

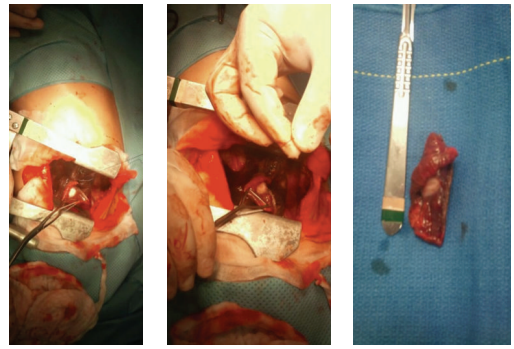


Figure 4: Nonanatomic pulmonary resection of superior and inferior left lobe was performed by posterolateral thoracotomy.

pulmonary segment resection of right superior and inferior lobes with 60 mm blue cartridge GIA stapler (Covidien Surgical, Norwalk, CT, USA) was performed (Figure 4); the transoperatory biopsy described a white nodular lesion of approximately 1 cm extension with benign pattern. The final pathology report described benign fibromuscular proliferative lesions, cells forming nodes, by immunohistochemistry, vimentin, AML, calponin, ALK1, d240, re, and 20% of Ki67, (Figure 5) consistent with benign metastasizing leiomyoma, which was corroborated by three uterine myomas in a pelvic US (Figure 6).

3. Discussion

Benign metastasizing leiomyoma is a rare condition characterized by the presence of extrauterine leiomyoma nodules with the lung being the most common site, although, it has also been reported in skin, pelvis, abdomen, muscle, omentum, inferior vena cava, right atrium, brain, and bone [2]; until 1996 there were 74 cases reported in the literature [1]; there are currently about 150 cases.

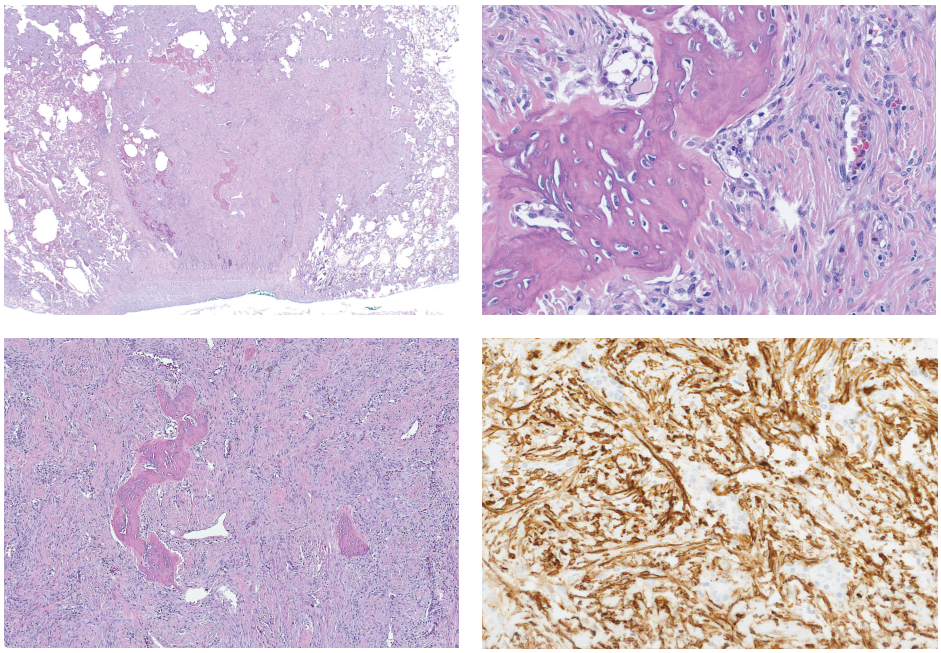


Figure 5: Fibromuscular tissue growth with nonneoplastic ossification; immunohistochemistry nodules composed of cells, vimentin, AML, calponin, ALK1, a240, D, and Ki67 20%. AML: actina de músculo liso (smooth muscle actin).

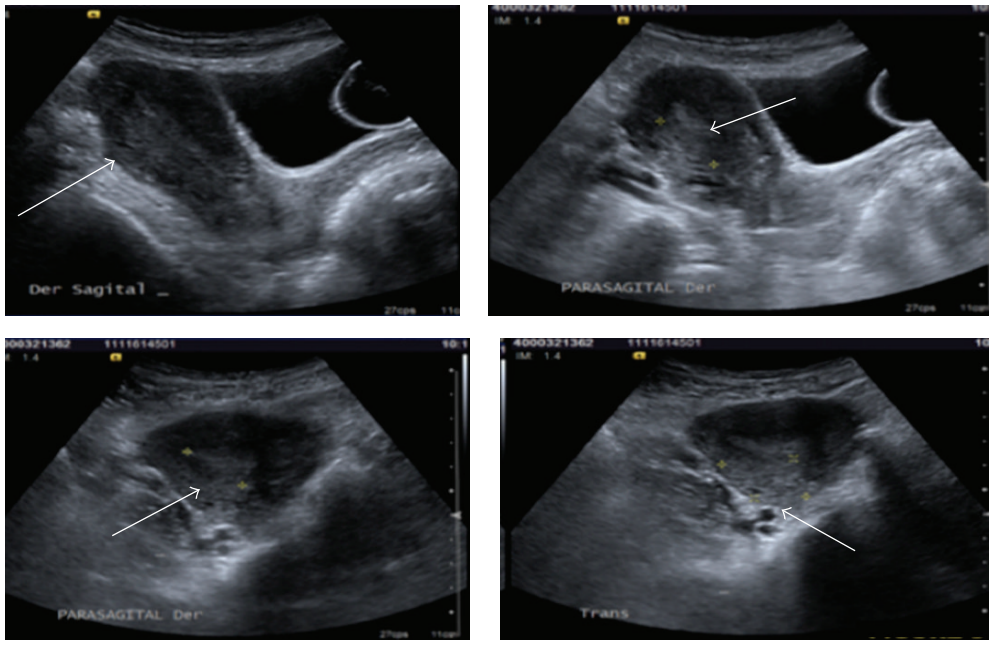


Figure 6: Pelvic US shows uterine myoma in posterior wall of 30 × 25 × 20 mm. Two myomas in the interior wall.

This condition presents with development of leiomyoma lung tumors, well-differentiated and histologically benign behavior due to its low mitotic rate, absence of nuclear pleomorphism, absence of local invasion, and indolent curse. Molecular studies suggest that this is a monoclonal process similar to ordinary leiomyomas [3]. There are some theories about vascular or lymphatic spread or venous dissemination during hysterectomy. Some animal studies suggest that the expansion to other tissues is by haematogenous dissemination, intraperitoneal implantation, or coelomic metaplasia [3, 4].

The disease is asymptomatic and often discovered incidentally; if symptoms are present they would be chest pain, dyspnea, and cough. Pathological and immunohistochemical studies are necessary to exclude lymphangioleiomyomatosis; benign metastasizing leiomyoma is characterized by having

less, smaller, and more limited interstitial lung and visceral muscle destruction [2]. The histological analysis suggests that pulmonary nodules arise from benign uterine lesions after a hysterectomy as treatment for leiomyomas. Due to the expression of estrogen and progesterone receptors, the treatment is based on GnRH agonists, selective receptor modulators of estrogens, aromatase inhibitors, or progestins; oophorectomy can also be considered [1]. Hysterectomy is not necessary for extrauterine disease, although some masses were reported with low-grade uterine sarcoma [4, 5]. The largest series was reported by Kayser et al.; most of the patients had median survival of 43 months after lung biopsy and did not die of benign metastasizing leiomyoma [6].

4. Conclusions

There are variants of clinically and histologically benign uterine leiomyomas. In particular, benign metastasizing leiomyoma is a rare condition with ectopic nodules of uterine leiomyoma in the lung. The diagnosis is histopathological after an incidental finding since its presentation is asymptomatic. The gold standard treatment is based on hormonal therapy. The surgical procedure must be reserved for selected patients.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

References

[1] G. Jautzke, E. Müller-Ruchholtz, and U. Thalmann, "Immunohistological detection of estrogen and progesterone receptors in multiple and well differentiated leiomyomatous lung tumors in women with uterine leiomyomas (so-called benign metastasizing leiomyomas): a report on 5 cases," *Pathology Research and Practice*, vol. 192, no. 3, pp. 215–223, 1996.

[2] J. Egberts, C. Schafmayer, D. O. Bauerschlag, U. Jänig, and J. Tepel, "Benign abdominal and pulmonary metastasizing leiomyoma of the uterus," *Archives of Gynecology and Obstetrics*, vol. 274, no. 5, pp. 319–322, 2006.

[3] K. T. Patton, L. Cheng, V. Papavero et al., "Benign metastasizing leiomyoma: clonality, telomere length and clinicopathologic analysis," *Modern Pathology*, vol. 19, no. 1, pp. 130–140, 2006.

[4] A. O. Awonuga, V. I. Shavell, A. N. Imudia, M. Rotas, M. P. Diamond, and E. E. Puscheck, "Pathogenesis of benign metastasizing leiomyoma: a review," *Obstetrical and Gynecological Survey*, vol. 65, no. 3, pp. 189–195, 2010.

[5] G. Yoon, T.-J. Kim, C.-O. Sung et al., "Benign metastasizing leiomyoma with multiple lymph node metastasis: a case report," *Cancer Research and Treatment*, vol. 43, no. 2, pp. 131–133, 2011.

[6] K. Kayser, S. Zink, T. Schneider et al., "Benign metastasizing leiomyoma of the uterus: documentation of clinical, immunohistochemical and lectin-histochemical data of ten cases," *Virchows Archiv*, vol. 437, no. 3, pp. 284–292, 2000.

Patología
Revista Latinoamericana
www.revistapatologia.com

Utilidad de la biopsia por aspiración con aguja fina en glándula mamaría

Javier García-Rubio[1]
Carlos Soto-Medina[1]
Manuel de Jesús García-Solís[2]
José L. Guzmán-Murguía[3]
José A. Díaz-Elizondo[4]
Oscar Villegas-Cabello[5]

[1] Tecnológico de Monterrey-Escuela de Medicina y Ciencias de la Salud. Cirugía General, programa multicéntrico ITESM-SSNL.
[2] Tecnológico de Monterrey-Escuela de Medicina y Ciencias de la Salud. Residente de quinto año de Cirugía General, programa multicéntrico ITESM-SSNL.
[3] Especialista de Cirugía General. Coordinador clínica de mama, Hospital SSNL-Metropolitano Dr. Bernardo Sepúlveda.
[4] Especialista en Cirugía General-Mastología. Director Centro para el cuidado de la mama, Hospital CIMA-Santa Engracia, Monterrey, N.L. Profesor adjunto de la especialidad de Cirugía General ITESM. Profesor Titular de Curso de Alta Especialidad en Mastología ITESM-CCM.
[5] Profesor del Departamento de Cirugía General y Laparoscopia Avanzada del Tecnológico de Monterrey.

RESUMEN

Objetivo: analizar la correlación citológica de la biopsia por aspiración con aguja fina *vs.* la biopsia escisional para nódulos mamarios en un hospital público; identificar su sensibilidad y su especificidad diagnósticas con el fin de lograr un diagnóstico oportuno que permita proporcionar atención de calidad.

Método: estudio prospectivo y comparativo. Se realizó en una sola institución en el período comprendido de mayo del 2011 a mayo del 2012. Los criterios de inclusión fueron todas las pacientes femeninas de 15 a 70 años de edad que acudieron a consulta por nódulos palpables en la glándula mamaria con toma de biopsia. Se analizaron las siguientes variables: edad, resultado de la biopsia por aspiración con aguja fina y de los estudios histopatológicos de la biopsia escisional.

Resultados: se incluyeron 115 pacientes, la edad promedio fue de 45 años. Las lesiones más frecuentemente encontradas fueron benignas: fibroadenoma en 36 pacientes (31.3%); mastitis inespecífica en 11 pacientes (9.6%); adenosis en 10 pacientes (8.7%); cambios fibroquísticos en 7 pacientes (6%); papiloma intraductal en 7 pacientes (6%) y tumor filoides en 1 paciente (0.9%). La sensibilidad fue de 86.4% y la especificidad de 98.6%; valor predictivo positivo 97.4% y valor predictivo negativo 92.1%.

Conclusión: los resultados sugieren que la biopsia por aspiración con aguja fina en los nódulos mamarios tiene sensibilidad y especificidad altas; es un método de diagnóstico útil en nuestro hospital.

Palabras clave: nódulo mamario, biopsia por aspiración con aguja fina, biopsia escisional, diagnóstico, sensibilidad y especificidad.

Usefulness of Fine Needle Aspiration in mammary gland

ABSTRACT

Objectives: The objective of this study is to analyze the correlation of Fine Needle Aspiration (FNA) vs. excisional biopsy in breast tumors in a Mexican Public Hospital, identifying diagnostic sensibility and specificity. Trying to offer an early diagnostic, and to deliver quality medical attention.

Method: This was a prospective, comparative, experimental study which was done in one Institution from May 2011 through May 2012. The inclusive criterias were all patients 15-70 years, with palpable solid masses in which a biopsy was indicated FNA was performed prior to excisional biopsy. They were analyzed for age, FNA result and excisional biopsy report.

Recibido: 21 de junio de 2014

Aceptado: 5 de noviembre de 2014

Correspondencia: Javier García Rubio
javier_garci_@hotmail.com

Este artículo debe citarse como
García-Rubio J, Soto-Medina C, García-Solís MJ, Guzmán-Murguía JL, Díaz-Elizondo JA, Villegas-Cabello O. Utilidad de la biopsia por aspiración con aguja fina en glándula mamaría. Patología Rev Latinoam 2015;53:69-77.

Results: All patients (115) were female; median age was 45 years. The most frequent lesions were benign: Fibroadenoma 36 patients (31.3%); non specific mastitis 11 patients (9.6%); adenosis 10 patients (8.7%); fibrocystic changes 7 patients (6%); intraductal papyloma 7 patients (6%); phyllodes tumor 1 patient (0.9%). As sensibility of 86.4% with a specificity was 98.6%; positive predictive value 97.4%, and negative predictive value 92.1%.

Conclusions: The results of this study suggest that there is a high sensibility and specificity for FNA on breast lesions, being helpful diagnostic method in our Hospital as a triple test.

Keywords: breast tumors, Fine Needle Aspiration (FNA), excisional biopsy, diagnostic sensibility and specificity.

INTRODUCCIÓN

Los tumores de mama requieren cada vez más un diagnóstico temprano a fin de reducir la morbilidad, la mortalidad y para minimizar los tratamientos; disminuir los costos económicos y sociales de los mismos. Es un padecimiento muy frecuente, de ahí la importancia de su detección temprana para ofrecer un tratamiento oportuno con altas posibilidades de éxito terapéutico.

El cáncer de mama es actualmente el cáncer más frecuente y el de mayor mortalidad entre las mujeres del mundo.[1] El panorama epidemiológico de esta patología en la población mexicana se transformó en los últimos 50 años y el cáncer mamario ha pasado a ser un problema de salud pública. Sus principales factores de riesgo conocidos están asociados con la exposición prolongada a estrógenos, estilos de vida y patrones reproductivos; por esto resultan difíciles de modificar. Reducir la mortalidad requiere, entonces, mejorar la detección temprana y las estrategias de tratamiento.[2] A partir del 2006 el carcinoma mamario se convirtió en la primera causa de muerte en México; según datos del Instituto Nacional de Estadística y Geografía (INEGI) el último año murieron por cáncer de mama casi 14 mujeres cada día.[2] En el año 2011 se modificó la Norma Oficial Mexicana NOM-041-SSA2-2011, la cuál abre la posibilidad para un programa de escrutinio poblacional, en donde llevado de manera óptima se tiene el potencial de reducir entre 20 y 40% la tasa de mortalidad y la carga de la enfermedad en la población de riesgo; se propone que para el diagnóstico en la mujer con nódulo mamario deben evitarse intervenciones innecesarias en caso de lesiones con características claramente benignas. En cuanto a pacientes con sospecha de patología mamaria maligna deben recibir una evaluación diagnóstica que incluya: historia clínica completa con la investigación de factores de riesgo para cáncer de mama, exploración física, estudios de imagen (ultrasonido mamario, mamografía) y toma de tejido histopatológico mediante biopsia; esto constituye la triada de evaluación clave para su diagnóstico y manejo oportuno.[3] La triada diagnóstica de mama (exploración clínica, estudios de imagen y la biopsia) tiene una sensibilidad de 100%.

La biopsia por aspiración con aguja fina es un método simple, rápido y económico para efec-

Patología
Revista Latinoamericana
www.revistapatologia.com

tuar, en la práctica clínica, biopsias de tumores superficiales; es un método que surgió en los años 30 y fue descrito por primera vez por Martin y Ellis.[4,5] En 1952 los Suecos Soderstrom, Lowhagen y sus colaboradores utilizaron extensamente la técnica en el Hospital Karolinska de Estocolmo para diagnosticar nódulos tiroideos, lo cual fue el paso decisivo para su aceptación mundial.[6,7]

La biopsia por aspiración con aguja fina se considera actualmente un procedimiento seguro y económico que puede evitar cirugías innecesarias; diferencia con gran certeza lesiones benignas de las malignas.[8] Es un método inocuo que puede brindarnos el diagnóstico citológico en casos dudosos, sobre todo en nódulos o masas complejas que no duelen o lo hacen muy discretamente, así como en aquellas lesiones que se modifican poco o nada con las fluctuaciones del ciclo menstrual.

Constituye una de las pruebas de elección para evaluar un nódulo mamario, gracias al diagnóstico citológico se ha reducido el numero de operaciones diagnósticas a menos de 50%.[9,10] La función principal de la biopsia por aspiración con aguja fina es asistir en la selección y tratamiento de los pacientes verdaderamente necesitados de un procedimiento quirúrgico.[11] Aunque no exenta de riesgos éstos son mínimos y entre ellos se tiene: hematomas, mastitis, y (muy poco común) neumotórax.[12,13] Ésta, además de ser la técnica de diagnostico de menor costo y facilidad de realización, utiliza una aguja muy delgada y una jeringa, tarda solo unos minutos y puede realizarse en el consultorio, reportándose en algunas series sensibilidad y especificidad entre 85 y 95%.[4,14] Sin embargo, estos resultados dependen de la experiencia de quién realiza la punción, el procesamiento adecuado de la muestra y de la experiencia de quien la interpreta.[15,16] En México se ha utilizado durante varios años en los hospitales de segundo y tercer niveles como método habitual de diagnóstico.[12] En el Hospital Metropolitano se utiliza desde hace varios años pero no se conocen su sensibilidad y especificidad reales en dicho hospital.

El surgimiento de nuevas técnicas, principalmente la biopsia con aguja gruesa, propició en algunas instituciones, entre ellas el Hospital San José, el desplazamiento de la biopsia por aspiración con aguja fina como método de elección para el diagnóstico, fundamentalmente debido al temor de falta de exactitud diagnóstica y a la imposibilidad de distinguir entre cánceres invasores y aquellos que no lo son.

Respecto a la comparación de otros métodos de diagnóstico de nódulos mamarios, con la biopsia por aspiración con aguja fina, no se observan diferencias significativas a pesar de las desventajas que ésta posee, como la de no poder establecer un diagnóstico diferencial entre cáncer invasor o *in situ* y como la de no obtener material suficiente para estudios especiales como los de inmunohistoquímica, invasión angiolinfática, grado nuclear, tipo especiales de cánceres. A pesar de ello sus ventajas son muchas ya que es económica, sencilla y rápida, no se requiere de anestesia u hospitalización y el resultado se obtiene en pocas horas. La importancia de establecer un protocolo de estudio en pacientes con patología mamaria que acuden a la consulta de clínica de mama se centra, principalmente, en la alta incidencia de esta afección.

El objetivo de este estudio fue analizar la correlación citológica de la biopsia por aspiración con aguja fina *vs.* la biopsia escisional para nódulos mamarios en un hospital público, identificando su sensibilidad y especificidad en el diagnóstico. Esto con el fin de disminuir costos y lograr un diagnóstico oportuno que permita proporcionar atención de calidad.

METODOLOGÍA

Este protocolo fue autorizado por los Comités de Investigación y Ética del Tecnológico de Monterrey y del Hospital Metropolitano Dr. Bernardo Sepúlveda de la SSNL, lugar donde se llevó a cabo. Fue un estudio prospectivo y comparativo que se realizó en una sola institución, en el período comprendido de mayo del 2011 a mayo del 2012. Los criterios de inclusión fueron: todas las pacientes entre quince y setenta años de edad, de primer contacto o enviadas a clínica de mama del Hospital Metropolitano, en quienes no se había efectuado biopsia y que acudieron a consulta por nódulos palpables en glándula mamaria. A las que se hubiera requerido tomar biopsia por aspiración con aguja fina y posteriormente biopsia escisional. Se analizaron las siguientes variables: edad, resultado de la biopsia por aspiración con aguja fina y de los estudios histopatológicos de la biopsia escisional.

Se incluyeron 115 pacientes con edad promedio de 45 años, todas referidas a clínica de mama del Hospital-Metropolitano. Del análisis de todas las variables y de la comparación entre biopsia con aguja fina y biopsia escisional para establecer el diagnóstico definitivo de cáncer se obtuvieron los resultados y conclusiones del presente protocolo.

Los resultados fueron expresados como medias con desviaciones estándar o medianas y sus respectivos rangos. Para establecer sensibilidad, especificidad y valores predictivos positivos y negativos se utilizaron las siguientes formulas:[17,18]

$$Sensibilidad = \frac{verdaderos\ (+)}{verdaderos\ (+) + falsos\ (-)}$$

$$Especificidad = \frac{verdaderos\ (-)}{verdaderos\ (-) + falsos\ (+)}$$

$$Valor\ predictivo\ (+) = \frac{verdaderos\ (+)}{resultados\ (+)}$$

$$Valor\ predictivo\ (-) = \frac{verdaderos\ (-)}{resultados\ (-)}$$

Con los resultados también se obtuvieron los valores de verosimilitud (*likelihood ratios*). Para el análisis de los datos se usó el programa de Windows Excel® y el paquete estadístico para ciencias sociales SPSS® versión 18.0.

El material utilizado para tomar la biopsia por aspiración con aguja fina fue el siguiente: antiséptico cutáneo: alcohol o Isodine®. Jeringa de 10 mL, aguja calibre 22 × 32, tela adhesiva, portaobjetos (laminillas) y fijador citológico en aerosol (Cito-Fix®).

La técnica para obtener la muestra fue: localizar el nódulo mediante palpación, delimitar su tamaño, movilidad, profundidad y localización. Se sujeta el tumor. Se efectúa antisepsia. Se toma aguja calibre veintidós montada en una jeringa de 10 mL, se dejan 5 mL de aire a nivel del émbolo de la jeringa, dejando dicho espacio para esparcir la muestra obtenida en la laminilla al finalizar. Se coloca el bisel de la aguja sobre la piel en un ángulo no mayor de noventa grados sobre la masa; se inserta aguja hasta penetrar el nódulo, posteriormente se realiza presión negativa constante con el embolo de la jeringa, aspirando sobre la masa en varias direcciones (arriba, abajo, lados) en varias ocasiones, sin detener la presión negativa. Se retira la aguja y se coloca la muestra sobre una laminilla esparciéndola con otra laminilla. Se fija la muestra y se le identifica con los datos de la paciente para enviarla a tinción de Papanicoláu y a evaluación citológica. Se llevará registro de cada muestra enviada con la firma del receptor. Las muestras de biopsia por aspiración con aguja

Patología
Revista Latinoamericana
www.revistapatologia.com

fina fueron tomadas por médicos residentes de Cirugía General.

Las muestras enviadas fueron evaluadas por los patólogos del Hospital Metropolitano, se clasificaron como benignas, malignas, insuficientes o no concluyentes. Los criterios de inclusión fueron los siguientes: pacientes que acudieron a consulta de la clínica de mama, de primer contacto o referidas de otras unidades médicas por tumor palpable en el seno. Con un rango de quince a setenta años de edad. Los criterios de exclusión fueron: pacientes con biopsias o cirugía de mama previas, pacientes con historia de cáncer de mama.

RESULTADOS

Durante el periodo de estudio se incluyeron 115 pacientes, todas del sexo femenino, la edad promedio fue de 45 años (desviación estándar: 35; valor mínimo-máximo: 20-70). El grupo de edad más afectado fue el de 40 a 49 años (41.7% de los casos) (Cuadro 1). Se identificaron 26 pacientes (29.9%) con antecedentes familiares de cáncer mamario en primer grado de consanguineidad, de éstas sólo 10 fueron diagnosticadas con lesiones malignas. El tamaño del nódulo se identificó mediante ultrasonido en centímetros lineales (eje mayor); el tamaño máximo en la muestra fue de 4 cm (Figura 1).

Respecto a los resultados de la toma de biopsia por aspiración con aguja fina realizada en 115 pacientes se reportó lo siguiente: la muestra de 6 pacientes (5.2%) fue inadecuada; en 39 pacientes (33.9%) fue maligna y en 70 pacientes (60.9%) fue benigna (Cuadro 2). En cuanto a las complicaciones de cada procedimiento se encontró dolor en 9 de las 115 pacientes (7.8%) cuando fueron sometidas a la toma de muestra; en la biopsia escisional el dolor predomino en todos los casos, agregándose hematoma en 3 casos (2.6%) (Cuadro 3].

Cuadro 1. Prevalencia de lesiones según la edad (n = 115)

	Grupo de Edad					
	20-29	30-39	40-49	50-59	60-70	
Total	9	24	48	19	15	115

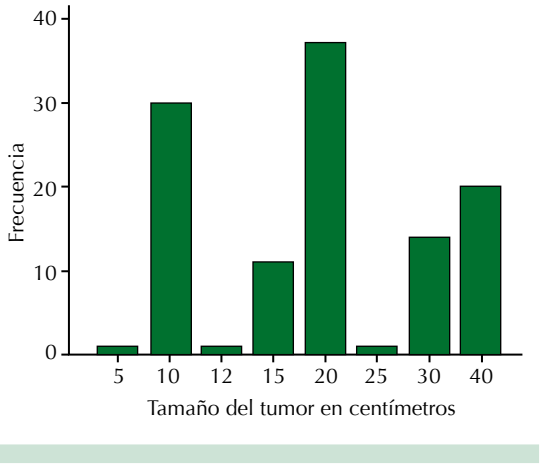


Figura 1. Tamaño del nódulo mamario palpable definido por ultrasonido (n = 115).

Cuadro 2. Resultado de la biopsia por aspiración con aguja fina

Benigna	70
Maligna	39
No concluyente	6
Total	115

Cuadro 3. Complicaciones de la biopsia escisional y frecuencia de complicaciones de la biopsia por aspiración con aguja fina

Biopsia escisional	Complicaciones de la BAAF*		Total
Complicaciones	Ninguna	Dolor	
Dolor	103	9	112
Dolor Hematoma	3	0	3
Ninguno	0	0	0
Total	106	9	115

*BAAF: biopsia por aspiración con aguja fina.

Las afecciones benignas diagnosticadas en el estudio histopatológico definitivo después de la biopsia escisional fueron las siguientes: fibroadenoma en 36 pacientes (31.3%), mastitis en 11 pacientes (9.6%), adenosis en 10 pacientes (8.7%), condición fibroquistica en 7 pacientes (6%), papiloma intraductal en 7 pacientes (6%), tumor filoides benigno en 1 paciente (0.9%) (Figura 2). Después de la revisión de la pieza histológica definitiva extraída por medio de biopsia escisional los diagnósticos de malignidad más frecuentes fueron: cáncer ductal en 31 pacientes (27%), cáncer lobulillar en 8 pacientes (7%), cáncer mixto en 4 pacientes (3.5%) (Cuadro 4, Figura 3).

En cuanto a la localización de los nódulos en la glándula mamaria se encontró lo siguiente: en 52 pacientes se localizo en mama derecha (45.2%) y en 63 (54.8%) en mama izquierda; el diagnostico de malignidad se encontró con mayor frecuencia en la glándula mamaria izquierda (24 pacientes)

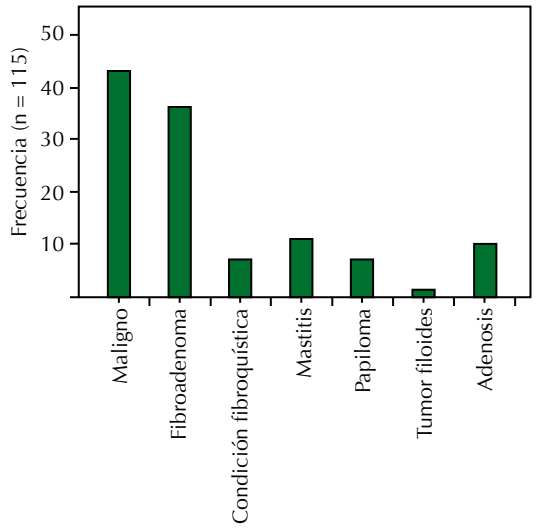


Figura 2. En 72 pacientes se demostró neoplasia de tipo benigno (62.6%); el fibroadenoma fue la lesión más frecuente.

Cuadro 4. Prevalencia de lesiones según la edad y el tipo de neopasia (n = 115)

	Edad					
	20-29	**30-39**	**40-49**	**50-59**	**60-70**	**Total**
Benigno	9	16	31	12	4	72
Cáncer ductal	0	4	12	6	9	31
Cáncer lobulillar	0	2	4	1	1	8
Cáncer mixto	0	2	1	0	1	4
Total	9	24	48	19	15	115

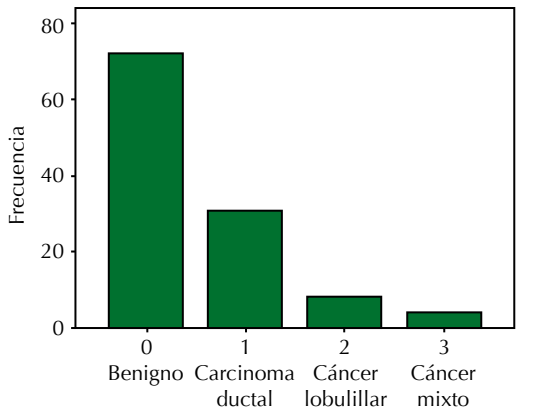


Figura 3. El carcinoma ductal de mama se encontró en 31 de los 115 especímenes enviados a histopatología; representó 72% de las lesiones malignas.

con predominio en el cuadrante superoexterno. Las lesiones benignas se encontraron con mayor frecuencia en la glándula mamaria derecha (40 pacientes) también con predominio de el cuadrante superoexterno.

El tratamiento quirúrgico establecido en las lesiones benignas fue el de la biopsia escisional, realizada en 72 pacientes (62.6%). En el caso de la lesiones malignas, en todas se realizó ganglio centinela con azul patente, valorando la afección axilar con base en este se valoró el

Patología
Revista Latinoamericana
www.revistapatologia.com

tratamiento quirúrgico de vaciamiento axilar: en 32 pacientes (27.8%) se realizó mastectomía radical modificada; en 6 cuadrantectomía sin vaciamiento axilar; en 4 pacientes cuadrantectomía con vaciamiento axilar; en 1 paciente mastectomía simple.

En este estudio se demostró, en comparación con el procedimiento de elección, que la sensibilidad de la biopsia por aspiración con aguja fina fue de 86.4% (0.7622-0.9659); la especificidad fue de 98.6% (0.9859-0.9585); el valor predictivo positivo fue de 97.4% (0.9248-1.02) y valor predictivo negativo de 92.1% (0.8604-0.9817) (Cuadro 5]. Los cocientes de probabilidad o razón de verosimilitud (*likelihood ratios*), razón de verosimilitud (+) fue de 61 (8.72-430.85) y razón de verosimilitud (-) fue de 0.14 (0.0657-0.29911) (Figura 4).

DISCUSIÓN

El objetivo de este estudio fue evaluar si la biopsia por aspiración con aguja fina es útil para detectar la malignidad de los tumores estudiados; así mismo establecer, mediante una correlación diagnóstica, una comparación entre ésta y la biopsia escisional respecto del estudio histopatológico definitivo. Se observó que en nuestro hospital la primera tiene una concordancia citohistológica adecuada, semejante a la de otros estudios. La literatura especializada refiere sensibilidad con la técnica de aguja fina de 85 a 96%, valor predictivo positivo de 90 a 97.5%, especificidad de 99% y valor predictivo negativo de 97%.[19,20]

Cuadro 5. Comparación entre la biopsia con aguja fina y el estudio histopatológico definitivo

	Sensibilidad	Especificidad	VPP	VPN
BAAF *vs.* estudio histopatológico definitivo	86.4%	98.5%	97.4%	91.4%

BAAF: biopsia por aspiración con aguja fina; VPP: valor predictivo positivo; VPN: valor predictivo negativo.

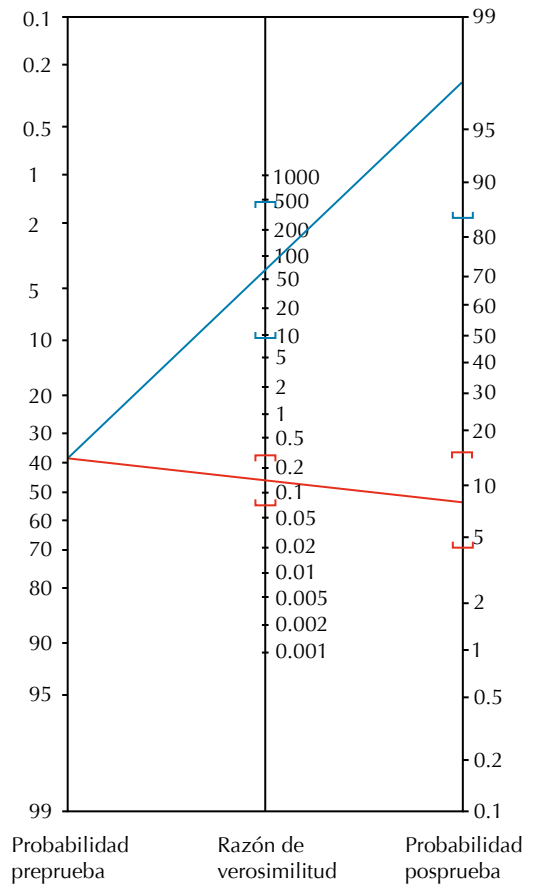


Figura 4. Nomograma de Fagan. Si la biopsia por aspiración con aguja fina es positiva la probabilidad posprueba aumenta a 98% (línea azul hacia arriba); si es negativa la probabilidad disminuye a 8% (línea roja hacia abajo).

Collado y Lima, en Brasil, obtuvieron sensibilidad de 92.1%, especificidad de 98.6%, valor predictivo positivo de 99.4% y valor predictivo negativo de 82.1%.[21] En Alemania el Dr. Albert Ute y sus colegas obtuvieron sensibilidad de 96.5%, especificidad de 90%, valor predictivo positivo de 97.8% y valor predictivo negativo de 94.3%.[22]

Esto es relevante por la alta frecuencia de tumores mamarios en nuestra población. El cáncer de mama es ahora causante, en general, de un mayor número de muertes en México que el cáncer cervicouterino y afecta a mujeres adultas de todas las edades y niveles de ingreso. Actualmente es la primera causa de muerte en México entre las mujeres mexicanas.[2,23]

Después de que se compararon los resultados de nuestro estudio con los observados en la bibliografía mundial, éstos concuerdan. En esta investigación nos dimos cuenta de que en la prueba se obtuvo alta especificidad, sirviendo más para detectar a sujetos sanos con resultados negativos, aunque respecto a la sensibilidad los resultados son adecuados. Todo esto al comparar con el estudio histopatológico definitivo de la biopsia escisional.

La fiabilidad de la biopsia por aspiración con aguja fina depende estrechamente de la calidad de la muestra, de la experiencia del citopatólogo y de quién toma la muestra. Los casos con diagnóstico benigno en biopsia por aspiración con aguja fina pero con un alto índice de sospecha de malignidad deben ser evaluados con material histológico adicional.

CONCLUSIONES

La biopsia por aspiración con aguja fina continúa siendo un método de gran apoyo diagnóstico inicial para orientarnos en el tipo de tumoración (maligna o benigna) palpable de todo paciente; tiene altas sensibilidad y especificidad. Es un estudio práctico de bajo costo para la institución, confiable y tiene pocas complicaciones; es fácil de realizar en un consultorio médico y por eso se considera como de gran utilidad, permite al clínico normar su conducta en el seguimiento y tratamiento de pacientes con este tipo de afección.

El propósito final es proporcionar a nuestros pacientes una mejor certeza diagnóstica para poder ofrecerles un tratamiento médico o quirúrgico más preciso y evitar cirugías innecesarias ante una prueba citológica (de material aspirado con aguja fina) de benignidad. Así mismo, a nuestro hospital se le ofrece una forma de economizar y ahorrar recursos. Reduciendo la estancia intrahospitalaria se utilizan menos recursos inadecuados y se detectan padecimiento malignos de forma temprana.

Observamos que la biopsia por aspiración con aguja fina tiene ventajas, es un estudio propicio para el cribado y para descartar pacientes que no necesitan ser hospitalizados ni incluidos en la toma de exámenes preoperatorios; con ello se evitan costos innecesarios. Es una técnica eficaz y útil en la evaluación de una paciente con masa benigna de mama, siempre como parte de la tríada diagnóstica de abordaje de estas pacientes.

AGRADECIMIENTOS

Agradecemos a todo el personal de la clínica de mama del Hospital Metropolitano Dr. Bernardo Sepúlveda, de la Secretaría de Salud de Nuevo León, así como también a las personas que con su ayuda hicieron posible este protocolo clínico, en especial a los Departamentos de Cirugía General y Patología.

REFERENCIAS

1. Cancer Mondial, International Agency for Research on Cancer, IARC, http://www-dep.iarc.fr
2. María Ester B, Yolanda Villaseñor N, detección del cáncer de mama: Mamografía en México. Cancerología 1 2006: 157-162
3. NORMA Oficial Mexicana NOM-041-SSA2-2011, Para la prevención, diagnóstico, tratamiento, control y vigilancia epidemiológica del cáncer de mama.
4. Chun K, Velanovich V. patient-perceived cosmesis and satisfaction after breast biopsy: comparison of stereotactic incisional, excisional, and wire-localized biopsy techniques. Surgery 2002;131(5):497-501.

Patología
Revista Latinoamericana
www.revistapatologia.com

5. Martín HE, Ellis EB. Biopsy by needle puncture and aspiration. Ann Surg 1930;44:214-217.
6. Soderstrom N. Puncture of goiters for aspiration biopsy. Acta Med Scand 1952;144:237-244.
7. Lowhagen T, Granberg PO, Lundell G, Skinnari P, et al. Aspiration biopsy cytology (ABC) in nodules of the thyroid gland suspected to be malignant. Surg Clin North Am 1979;59:3-18.
8. Arisio R, Cuccorese C, Accinelli G, et al. Role of fine-needle aspiration biopsy in breast lesions: analysis of a series of 4,110 cases. Diagn Cytopathol 1998; 18: 462-6.
9. Miller JM, Hamburger JI, Kini SR. The impact of needle biopsy on the preoperative diagnosis of thyroid nodules. Henry Ford Hosp Med J 1980;28:145-148.
10. Hamberger B, Gharib H, Melton LJ III, Goellner JR, Zinsmeister AR. Fine-needle aspiration biopsy of the thyroid nodules: Impact on thyroid practice and cost of care. Am J Med 1982;73:381-384.
11. Flynn MB, Wolfson SE, Thomas S, Kuhns JG. Fine needle aspiration biopsy in clinical management of head and neck tumors. J Surg Oncol 1990;93:359-362.
12. Hindle W, Arias R, Felix J, Sueda A. Breast Cancer: Adaptation of Fine-needle Aspiration to Office Practice. Clinical Obstetrics & Gynecology 2002;45(3):761-766.
13. Ancona N, de Larios NM. La biopsia por aspiración con aguja fina en glándula mamaria: diagnostico citologico y concordancia histológica y clínica. Rev Hosp Gral Dr. Manuel Gea Gonzalez 2002; 5:79-84
14. Lannin DR, Silverman JF, Walker C. Cost effectiveness of fine needle biopsy of the breast. Ann Surg 1986; 203: 474-480
15. Oertel YC. A pathologist's comments on diagnosis of thyroid nodules by fine-needle aspiration. J Clin Endocrinol Metab 1995;80:1467-1468.
16. Cramer H. Fine needle aspiration cytology of the thyroid. An appraisal. Cancer 2000;90:325-329.
17. Altman DG, Bland M Diagnostic tests 1: sensitivity and specificity. BMJ 1994;308:1552.
18. Altman DG, Bland M Diagnostic tests 2: predictive values. BMJ 1994;309:102.
19. Khattar S, Torp S, Horn T, Krogh I, Court M, Lorentzen T. Ultrasound-guided biopsy of palpable breast masses. European Journal of Ultrasound 1997;6(1):1-7.
20. Agencia de Evaluación de Tecnologías Sanitarias (AETS). Diagnóstico de lesiones mamarias detectadas en cribado poblacional de cáncer de mama mediante mamografía. Madrid, España: Instituto de salud Carlos III; 1999.
21. Collado LM, de Lima RS, Werner B, Torres LF. Value of fine needle aspiration in the diagnosis of the breast lesions. Acta Cytol 1999; 43(4): 587-92.
22. Ute-Susann A, Volker D, Peymann H, Kay G, Frauke H, Bock K, Ramaswamy A. Imprint cytology of core needle biopsy specimens of breast lesions. Acta Cytol 2000; 44: 57-62.
23. Lozano R, Knaul FM, Gómez-Dantés H, Arreola-Ornelas H, Méndez O. Tendencias en la mortalidad por cáncer de mama en México, 1979-2006. Observatorio de la Salud. Documento de trabajo. Competitividad y Salud, Fundación Mexicana para la Salud, 2008.

ELSEVIER

CIRUGÍA y CIRUJANOS

Órgano de difusión científica de la Academia Mexicana de Cirugía
Fundada en 1933

www.amc.org.mx www.elsevier.es/circir

CASO CLÍNICO

Agenesia de la vesícula biliar. Reporte de caso

Ricardo Cavazos-García*, José Antonio Díaz-Elizondo, Eduardo Flores-Villalba y Héctor Alejandro Rodríguez-García

Cirugía General, Programa Multicéntrico de Residencias Médicas, Escuela de Medicina y Ciencias de la Salud del Tecnológico de Monterrey, Monterrey, Nuevo León, México

Recibido el 29 de enero de 2014; aceptado el 5 de agosto de 2014
Disponible en Internet el 7 de julio de 2015

PALABRAS CLAVE
Agenesia vesícula biliar;
Anormalidades congénitas de la vesícula biliar;
Malformación de la vesícula biliar

Resumen
Antecedentes: La agenesia de la vesícula biliar es la malformación menos frecuente de las vías biliares. Su diagnóstico suele realizarse en el transoperatorio. Los estudios de imagen son poco efectivos para detectar esta malformación congénita.
Objetivo: Presentar un caso clínico diagnosticado en el transoperatorio de agenesia de la vesícula biliar, su manejo y una revisión de la literatura.
Caso clínico: Mujer de 62 años de edad, la cual acude a consulta por presentar cólicos biliares de repetición. El reporte de ultrasonido abdominal describe datos compatibles con colecistolitiasis. Al realizar la laparoscopia, no se identificó la vesícula biliar. Se confirmó el diagnóstico por colangiografía transoperatoria.
Discusión: Durante el preoperatorio es difícil identificar a pacientes con agenesia vesicular. Actualmente se recomienda abandonar la laparoscopia cuando se sospecha agenesia vesicular para evitar lesionar las vías biliares, y confirmar el diagnóstico en el postoperatorio por colangiorresonancia magnética.
Conclusiones: La agenesia de la vesícula biliar es una malformación poco frecuente de la vía biliar y el cirujano debe sospechar esta entidad, o bien una variante anatómica, cuando una disección es difícil o bien durante la colecistectomía por laparoscopia en la que se requiere hacer uso de la colangiografía transoperatoria, sobre todo para prevenir una lesión de la vía biliar.

* Autor para correspondencia. Antiguo Camino a Villa de Santiago #3213, Colonia Altavista Sur, C.P. 64740, Monterrey, Nuevo León, México. Tel.: +(818) 115 8230; fax: +83331061.
Correo electrónico: Lmagreco@hotmail.com (R. Cavazos-García).

http://dx.doi.org/10.1016/j.circir.2015.05.043

KEYWORDS
Agenesis of gallbladder;
Congenital abnormalities of gallbladder;
Gallbladder malformation

Gallbladder agenesis. Case report

Abstract
Background: Gallbladder agenesis is a very rare congenital abnormality of the biliary tract. The diagnosis is made during surgery, because all preoperative studies have failed to identify this malformation.

The purpose of this article is to present a case of gallbladder agenesis diagnosed during surgery, its management, and a review of the literature.
Clinical case: The case involves a sixty-two year- old female, referring to repeated biliary colic symptoms. The abdominal ultrasound diagnosed cholelithiasis. It was impossible to identify the gallbladder during surgery. Diagnosis was confirmed by intra-operative cholangiography.
Discussion: Preoperative diagnostic workup has failed to recognise patients with gallbladder agenesis. It is currently recommended to abandon the surgery once this diagnosis is suspected and confirm it by a cholangio-magnetic resonance scan in order to avoid a bile duct injury.
Conclusions: Agenesis of the gallbladder is a rare congenital abnormality of the biliary tree. Every surgeon must keep this rare entity in mind when a ''difficult dissection'' or an anatomic variant is identified during surgery, and make use of an intra-operative cholangiography, mainly to prevent a bile duct injury.

Antecedentes

De acuerdo con Beuran[1], la agenesia de la vesícula biliar fue reportada por primera vez en 1702 por Bergman y, desde entonces, solamente se han reportado 413 casos en la literatura médica mundial. La rareza y baja incidencia de esta dolencia ofrece un motivo para su publicación en una revista mexicana, ya que no existen más de 3 casos reportados en revistas médicas latinoamericanas[2–4]. Es la malformación congénita menos frecuente de las vías biliares. La edad promedio de presentación clínica es 46 años. Tiene prevalencia del 0.007-0.13%, con variación entre series quirúrgicas y series de autopsias. La relación de género femenino y masculino es de 2-3:1 y se asocia a otras malformaciones congénitas en el 40-65%, como xantomatosis cerebrotendinosa, síndrome de Opitz, síndrome de Klippel-Feil, entre otras[5]. La malformación ocurre durante la tercera semana de gestación, en la que el divertículo hepático falla en su porción proximal al formar la vesícula biliar[6].

Se presenta un caso clínico al que se diagnosticó agenesia vesicular durante el transoperatorio; también se describe su manejo, evolución y se hace una revisión de la literatura médica.

Caso clínico

Paciente femenina de 62 años de edad, originaria de Monterrey, Nuevo León que acude a consulta por presentar dolor abdominal de 3 semanas de evolución, tipo cólico, de moderada intensidad, localizado en hipocondrio derecho, irradiado al dorso ipsilateral, que se presenta posterior a la ingesta de colecistocinéticos; niega fiebre, ictericia, coluria y acolia. A la exploración física: hemodinámicamente estable y afebril. Abdomen: globoso a expensas de panículo adiposo, peristalsis presente, blando, depresible, no doloroso a la palpación, con signo de Murphy negativo.

Los estudios de laboratorio se reportan dentro de parámetros normales. Se realizó un ultrasonido abdominal en el cual se reportó la vesícula biliar parcialmente valorable por la presencia de múltiples imágenes ecogénicas, mal definidas con relación a litos, que proyectan sombra acústica posterior e impiden la valoración de la pared y se concluyó colecistolitiasis (fig. 1). Se programó para colecistectomía

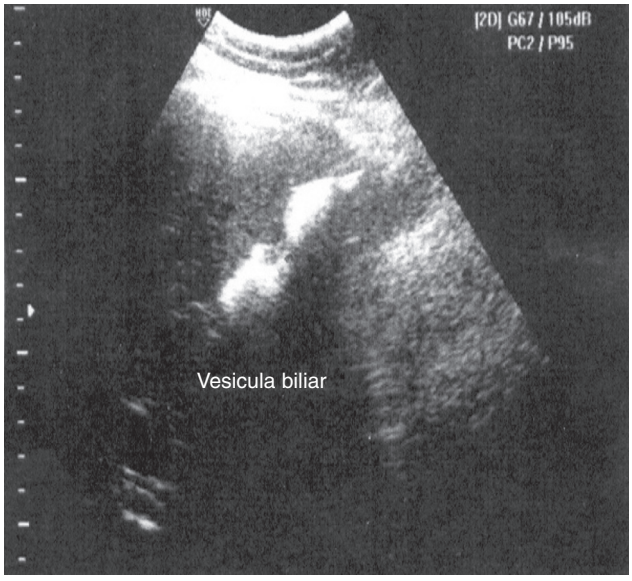


Figura 1 Ultrasonografía que concluye el diagnóstico de colecistolitiasis.

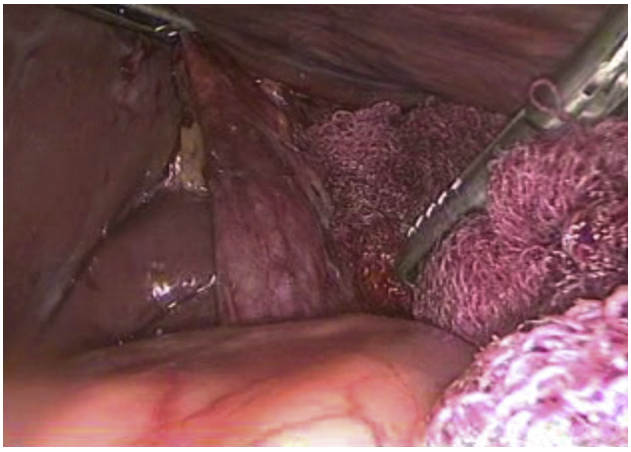


Figura 2 Estructura tubular disecada. Se observa la continuidad desde su emergencia hepática hasta su porción retroduodenal. No se visualiza conducto cístico ni vesícula biliar.

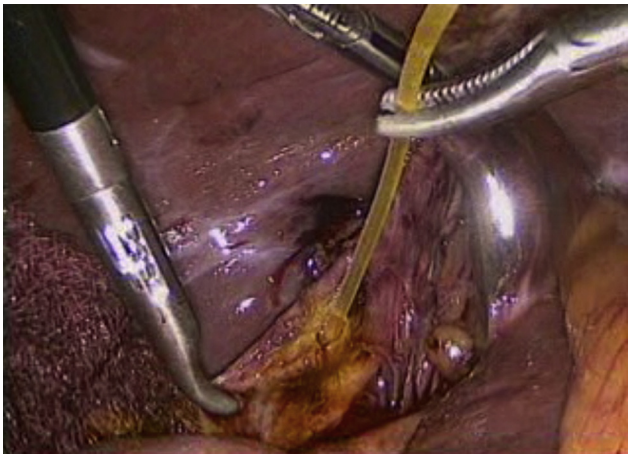


Figura 3 Se realizó colangiografía transoperatoria con catéter de TAO.

por laparoscopia con el diagnóstico de colecistolitiasis. A la disección de lo que aparenta ser la vesícula biliar, observamos la forma tubular de esta estructura (fig. 2). Se realizó colangiografía transoperatoria (fig. 3) que demostró agenesia del conducto cístico y de la vesícula biliar, con adecuado paso del material de contraste a duodeno y sin evidencia de litos (fig. 4). Se buscó intencionadamente la vesícula biliar en todo el abdomen sin lograr encontrarla. Se colocó una sonda en T #10 Fr (fig. 5) en el colédoco y drenaje de Jackson-Pratt #10 Fr abocado al lecho vesicular.

En el postoperatorio presentó evolución favorable y sin evidencia de fuga biliar por el drenaje de Jackson-Pratt. Se egresó al tercer día del postoperatorio por mejoría, con indicaciones para el cuidado de la sonda en T, y cita a la consulta externa para valorar retiro de la sonda en T en 6 semanas.

Discusión

Se estima que el 23% de los pacientes con agenesia vesicular presentarán síntomas típicos de cólico biliar[5]. De estos el

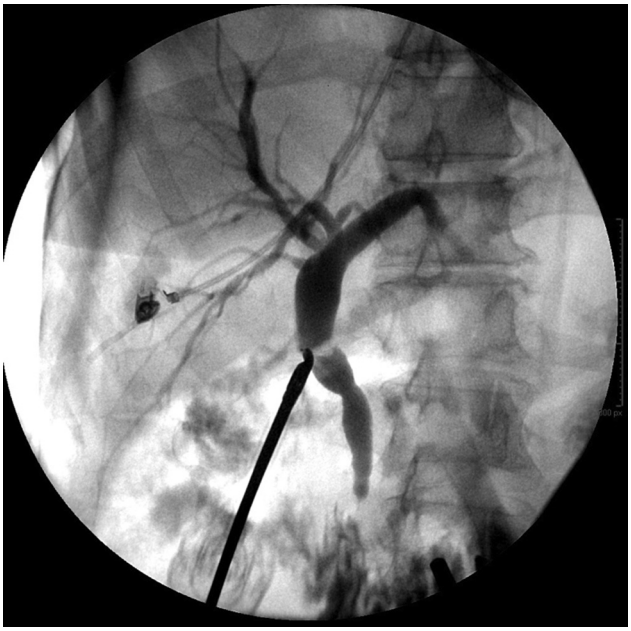


Figura 4 Colangiografía transoperatoria que confirma el diagnóstico de agenesia del conducto cístico y de la vesícula biliar.

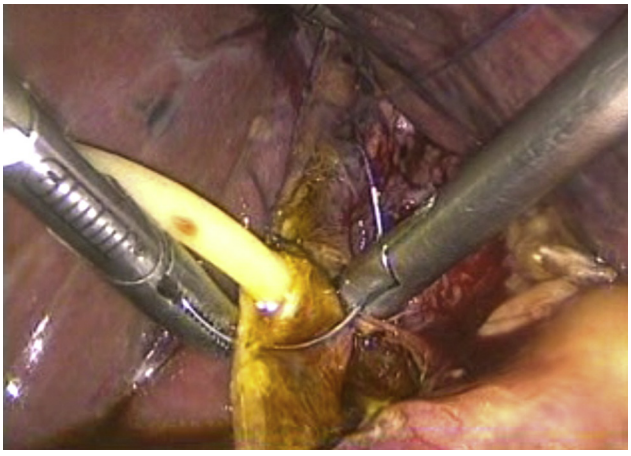


Figura 5 Se coloca sonda en T #10 Fr en el sitio de la coledocotomía y se fija con vycril 4-0.

90.1% presentará dolor tipo cólico en hipocondrio derecho, el 66.3% náuseas y vómitos posprandiales, el 37% dispepsia y el 27% coledocolitiasis[5]. Pero, ¿por qué se presentan estos síntomas si no existe vesícula biliar? Esto se explica bajo la teoría de la discinesia biliar, específicamente por la disfunción del esfínter de Oddi. Se ha identificado en animales que la agenesia de la vesícula biliar conlleva anomalías del esfínter de Oddi. Así mismo, es bien reconocido que la inducción del espasmo del esfínter de Oddi reproduce la sintomatología de un cólico biliar. También la prevalencia de coledocolitiasis y dilatación del colédoco es mayor en estos pacientes, 22 y 32% respectivamente, lo que asevera esta teoría[5].

Las investigaciones preoperatorias han fallado para identificar a los pacientes con agenesia vesicular. Es bien conocido que el estudio de imagen de elección para evaluar la vesícula biliar es el ultrasonido; sin embargo, se dificulta

cuando se reporta una vesícula biliar pequeña, escleroatrófica (es un diagnóstico anatomopatológico) o contraída sobre los litos. En 1980, se describió la tríada de WES con la finalidad de realizar el diagnóstico de colecistolitiasis en este tipo de vesículas. WES es un acrónimo que hace referencia en inglés a «wall, echo, shadow», traducido al español como «pared, eco y sombra acústica»; cuando el radiólogo identifica estos 3 componentes en el ultrasonido de la vesícula biliar, se estima que la sensibilidad es hasta del 95% para realizar el diagnóstico de colecistolitiasis[7]. Sin embargo, la gran mayoría de los ultrasonidos realizados en pacientes con agenesia vesicular reportan colecistolitiasis. Esto se explica porque el radiólogo puede confundir el tejido periportal, los pliegues peritoneales subhepáticos, el duodeno o lesiones hepáticas calcificadas con la tríada de WES, resultando en falsos positivos. Por eso el ultrasonido abdominal suele ser falso positivo[5]. La gammagrafía y la colangiopancreatografía retrógrada endoscópica suelen concluir en obstrucciones del conducto cístico, sin reportar agenesia de la vesícula biliar[5]. La colangiorresonancia magnética es un método eficaz para evaluar las vías biliares, no es invasivo y no requiere medio de contraste. Desafortunadamente, tiene un costo elevado y no reemplaza al ultrasonido como estudio de primera elección para las afecciones de la vesícula biliar. Aun así, se debe utilizar como complemento en estudios ultrasonográficos inconclusos[8]. Peloponissios et al.[5] en su revisión bibliográfica realizada desde 1960 hasta el 2003 especifican que todos los casos revisados fueron diagnosticados de manera transoperatoria o en el postoperatorio, solamente exceptuando 2. Por este motivo, «el diagnóstico preoperatorio es probablemente imposible»[8] y se realiza de manera transoperatoria o en el postoperatorio en la mayoría de los casos[5]. Ante la sospecha diagnóstica de agenesia vesicular, Frey en 1967, propuso cumplir ciertos criterios durante el transoperatorio que consistían en evidenciar la ausencia de signos inflamatorios o fibrosis en el lecho vesicular, convertir a laparotomiá y realizar la búsqueda exhaustiva de una vesícula ectópica con kocherización completa, buscándola intencionadamente de manera intrahepática, retrohepática, en el hemiabdomen izquierdo, entre las 2 capas del omento menor, en el ligamento falciforme, de manera retropancreática, retroperitoneal y en la pared anterior. En caso de no encontrarla, se debe realizar una colangiografía transoperatoria con exploración de vías biliares si el colédoco se encuentra dilatado más de 2 cm o si existe coledocolitiasis[9].

Actualmente se recomienda abandonar la laparoscopia cuando se sospecha agenesia vesicular, sobre todo para evitar una lesión de las vías biliares, y confirmar el diagnóstico en el postoperatorio por colangiorresonancia magnética[10]. Con este estudio se cumplen los criterios de Frey, con lo que se evita la disección extensa y la morbilidad que esta conlleva,la colangiografiá transoperatoria, la exploración de viás biliares y, en caso de encontrar coledocolitiasis, se puede optar por la colangiopancreatografiá retrógrada endoscópica con esfinterotomiá y extracción de los litos. De igual manera, si el paciente en el postoperatorio continúa sintomático, se puede optar por un manejo médico con relajantes del músculo liso. Si no ceden los cólicos biliares, se puede realizar una colangiopancreatografía retrógrada endoscópica y una esfinterotomía para aliviar los síntomas[9,11]. De acuerdo con el flujograma diagnóstico y terapéutico propuesto por Malde, si en los estudios preoperatorios para evaluar las vías biliares el radiólogo reporta la vesícula biliar inidentificable, contraída o escleroatrófica, se debe solicitar otro estudio radiológico dependiendo de la disponibilidad local: colangiorresonancia magnética, tomografía computada, colangiopancreatografía retrógrada endoscópica o ultrasonido endoscópico. Si en alguno de estos estudios se confirma el diagnóstico de agenesia vesicular, se ofrece el manejo conservador anteriormente descrito. Si continúa la incertidumbre diagnóstica, Malde recomienda repetir el estudio de imagen una vez ya cedido el episodio agudo[9].

Nosotros recomendamos realizar la colangiografía transoperatoria por punción, para así poder solucionar el dilema diagnóstico durante el transoperatorio y descartar la presencia de alguna otra entidad que pudiese requerir tratamiento quirúrgico (p. ej. vesícula ectópica, intrahepática, coledocolitiasis). Aunque existen autores que deciden no realizarla[12], la colangiografía transoperatoria conlleva una baja morbilidad cuando se realiza de manera adecuada por punción y por laparoscopia, como en este caso.

Conclusión

La agenesia de la vesícula biliar es la malformación menos frecuente de la vía biliar. Sin embargo, quien tiene que lidiar con esta entidad es el cirujano en el transoperatorio, pues como se ha mencionado anteriormente, todos los estudios preoperatorios han fallado para reconocer el diagnóstico. El cirujano debe tener en cuenta esta entidad cuando identifica una «disección difícil», vesícula escleroatrófica o variantes en la anatomía al momento de la colecistectomía por laparoscopia. Debe hacerse uso de la colangiografía transoperatoria para confirmar el diagnóstico, tratar o descartar entidades que necesiten de alguna intervención y, sobre todo, para prevenir una lesión de la vía biliar.

Bibliografía

1. Beuran M. Laparoscopic approach in gallbladder agenesis–an intraoperative surprise. Chirurgia (Bucur). 2010;105(4):531–6.
2. Muñoz HJ, Quirarte CC, Arribas MA, Góngora SM, Cruz RO, Muñoz GR. Agenesia de vesícula biliar. Reporte de caso y revisión de la literatura. Rev Mex Cir Endoscop. 2011;12(1):35–7.
3. Gaxiola Werge R, Gómez Gutiérrez NG, Alcántara Martinez FJ, Valero Ontíveros UJ. Agenesia vesicular y coledocolitiasis. Presentación de una paciente. Cir Gen. 2000;22(4):362–6.
4. Flores-Valencia JG, Vital-Miranda SN, Mondragón-Romano SP, de la Garza-Salinas LH. Agenesia vesicular: reporte de caso. Rev Med Inst Mex Seguro Soc. 2012;50(1):63–6.
5. Peloponissios N, Gillet M, Cavin R, Halkic N. Agenesis of the gallbladder: A dangerously misdiagnosed malformation. World J Gastroenterol. 2005;11(39):6228–31.
6. Singh S, Tayal A, Kaur V. Mystery of absent gall bladder: Surgical concerns and review of literature. JIMSA. 2011;24(2):71.
7. Rybicki FJ. The WES sign. Radiology. 2000;214:881–2.
8. Elorza Orúe JL. Agenesia de la vesícula biliar. Presentación de un caso estudiado por RM-colangiografía. Cir Esp. 2001;69(4):427–8.

9. Malde S. Gallbladder agenesis diagnosed intra-operatively: A case report. J Med Case Rep. 2010;4:285–90.
10. Mittal A, Singla S, Singal R, Mehta V. Gallbladder agenesis with common bile duct stone - A rare case with a brief review of the literature. Turk J Gastroenterol. 2011;22(2): 216–8.
11. Leone V. Isolated agenesis of the gallbladder: A pitfall in laparoscopic cholecystectomy. WebmedCentral LAPAROSCOPY. 2011;2(12). WMC002716.
12. Cano-Valderrama O, Talavera P, Domínguez-Serrano I, Sánchez-Pernaute A, Torres García AJ. Gallbladder agenesis. Presentation of a case. Cir Esp. 2011;89(7):469–78.

A hybrid formulation for soft tissue modeling on real-time surgery simulation

Conference Paper · November 2015

DOI: 10.20906/CPS/CILAMCE2015-0633

9 authors, including:

Paulo Henrique Junqueira Amorim
Centro de Tecnologia da Informação Renato Archer
35 PUBLICATIONS **130** CITATIONS
SEE PROFILE

Jorge Vicente Lopes da Silva
Centro de Tecnologia da Informação Renato Archer
296 PUBLICATIONS **1,123** CITATIONS
SEE PROFILE

Alex Elías-Zúñiga
Tecnológico de Monterrey
112 PUBLICATIONS **734** CITATIONS
SEE PROFILE

A HYBRID FORMULATION FOR SOFT TISSUE MODELING ON REAL-TIME SURGERY SIMULATION

Mario Regino Moreno Guerra

Paulo Henrique Junqueira Amorim

Thiago Franco de Moraes

Jorge Vicente Lopes da Silva

mario.guerra@cti.gov.br

paulo.amorim@cti.gov.br

tfmoraes@cti.gov.br

jorge.silva@cti.gov.br

Three Dimensional Technologies Division, Renato Archer Information Technology Center

SP 65 km 143,6, Campinas, SP 13069-901, Brazil

Ciro Ángel Rodríguez González

Alex Elías Zúñiga

Oscar Martínez Romero

ciro.rodriguez@itesm.mx

aelias@itesm.mx

oscar.martinez@itesm.mx

School of Engineering and Sciences, Tecnológico de Monterrey, ITESM

Eugenio Garza Sada 2501 Sur, Monterrey 64849, Nuevo León, México

José Antonio Díaz Elizondo

Eduardo Flores Villalba

jadiaze@itesm.mx

eduardofloresvillalba@itesm.mx

Medical School and Health Sciences, Tecnológico de Monterrey, ITESM

Eugenio Garza Sada 2501 Sur, Monterrey 64849, Nuevo León, México

Abstract. *On the improvement of surgical training and planning methods, virtual reality and computational mechanics have been applied for the development of technological tools which aim to reduce patient risk in surgical procedures.*

The main focus of this work is modeling and simulation of soft tissue behavior for virtual reality systems. Soft tissues can be consider as composite materials, formed by an isotropic matrix and a bundle of reticular fibers with anisotropic behavior. In order to simulate the material behavior for virtual applications, nonlinear deformations must be calculated on real-time.

In this article, a hybrid formulation called Equivalent Spring-Mass Model (ESMM) is proposed. ESMM is a construction based on a fusion of the Spring-Mass Model (SMM) and an Equivalent Strain Energy Density Function (ESEDF). In this formulation, parameters of one-dimensional elements can be estimated on real-time to reach the strain energy calculated with a complex constitutive model on a pre-computational stage.

ESMM was implemented on a virtual environment for laparoscopic surgery with a liver mesh segmented from medical images using InVesalius Software. The parameters were calculated using experimental data of uniaxial tensile tests of porcine liver parenchyma. ESMM elements shown good results and the estimations predict the tissue behavior.

Keywords: *Soft tissue modeling, Virtual reality, InVesalius, Surgery simulation.*

1 INTRODUCTION

In healthcare and medical area, guarantee security and integrity of the patient during medical procedures is a key issue. In surgical procedures, the degree of expertise, skills, and precision needed on a surgeon is very high, and therefore the learning process on training is a crucial factor on their professional performance, due its importance for increase experience and skills development.

With this in mind, the development of tools for training and surgical planning is a big research concern that can lead to improvement on the medical procedures of today. Virtual reality, among other computational and technological tools applied, allows the surgeon to acquire experience without contact with a living being, being then a risk free and ethical environment for practice of soon-to-be surgeons, or for planning and testing a procedure before being done in the operating room (SEYMOUR, 2008), (ISSENBERG, 2005).

A virtual training system involves the integration of several factors, including: medical imaging, computer graphics, material models, and mechatronic systems for interaction device. A key issue on this kind of devices is to achieve a proper model for prediction of the real behavior and mechanical properties of soft tissues, without affecting the computational performance of the real-time simulation (MORENO, et al. 2014).

In this article is exposed the development of open-source computational tools that allows virtual surgical training, based on interactive real-time simulation. It includes a brief description of geometry acquisition, mathematical model for soft tissue simulation and the generation of the virtual environment implemented in previous work.

2 METHODOLOGY

In order to create a virtual environment close to the reality, it is needed to represent the accurate geometry of the anatomical structures from 3D reconstructions of medical images. Using InVesalius software, a 3D model of anatomical structures can be reconstructed from CT (Computed Tomography) and MRI (Magnetic Resonance Imaging) two-dimensional images (AMORIM, et al., 2011), (CAMILO, et al., 2012). Once reconstructed, this 3D model is processed to remove noise and improve the surface, reduce the amount of vertex and have a uniform meshing, as shown in figure1a.

At this point, the 3D model is a tridimensional triangle mesh which represents the external structure of an organ. A volumetric mesh must be created from this model in order to calculate the behavior of the organ considering the internal stresses and deformation propagation. For this propose an internal skeleton structure, exoskeleton structure or tetrahedral mesh were proposed and applied as shown in figure1c (MORENO, et al., 2012), (MORENO, et al., 2014).

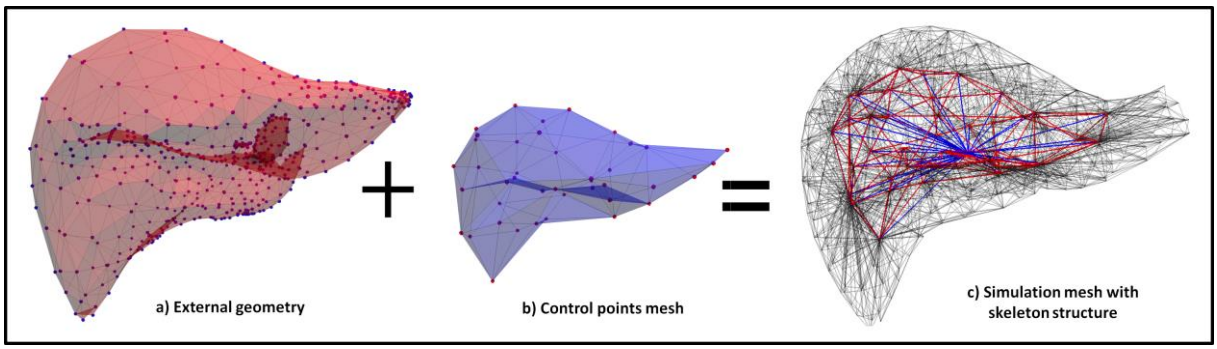


Figure 1. a) External geometry b) Control points mesh c) Simulation mesh with skeleton structure

2.1 Soft tissue modeling

In order to simulate an organ and its response to the user interaction, it is needed the application of a mathematical model that represent the material mechanical properties and the implementation of a computational methods to solve the equations for the particular geometrical model. Due to the application requirement, an appropriate selection of those factors is critical, considering that the algorithms must respond for real-time interaction in the simulation (DELINGETTE, et al., 2004), (ZHANG, et al., 2006), (HALIC, et al., 2009).

A first approach was developed using a construction based on a Spring-Mass Model (SMM) with a multi-level of stiffness. The SMM is a simplification where the object is considered as a set of mass points (vertex) connected by springs (edges) with defined stiffness parameters, as shown in Figure 2 (MORENO, et al., 2012).

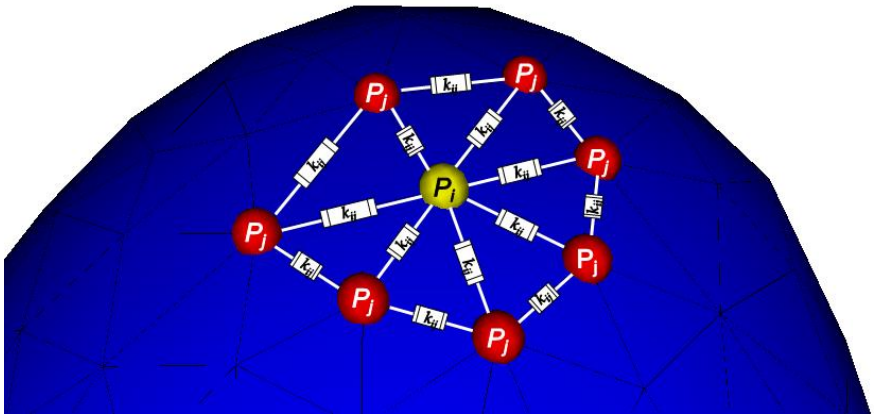


Figure 2. SMM illustration, with point Pi in yellow and neighbors Pj in red

Then, the force F_i on a point P_i is calculated by considering the contribution of all the spring formed between the point P_i and each point P_j in its neighborhood $N(P_i)$. At each time step, the force F_i is calculated using the position of the points at that time, the length of each spring at rest position (L_{ij}) and a stiffness parameter assigned (k_{ij}) regarding the spring level, as shows the following equation:

$$\mathrm{F_i} = \sum_{\mathrm{j}\in\mathrm{N(P_i)}} k_{ij}\left(\left\|P_iP_j\right\| - L_{ij}^0\right)\frac{P_iP_j}{\left\|P_iP_j\right\|} \tag{1}$$

Although SMM allows calculating deformation of an object considering one or more stiffness parameters (proposed on multi-level SMM), it can not represent precisely the behavior of soft tissues, because it is a linear one-dimensional element and the stiffness parameters are constants.

For this case, soft tissues are considered as a composite material. This is because tissues mechanical properties are related to its cellular composition, which is non-uniform. Soft tissues are conformed by a matrix with an isotropic behavior, and a bundle of collagen fibers with an anisotropic behavior (HOLZAPFEL, 2001), (ELÍAS-ZUÑIGA, et al., 2014).

In the literature, there are different models that consider anisotropy and hyperelasticity properties of soft tissues, most based on continuum mechanics to define their Strain Energy Density Function (SEDF). However, the amounts of parameters that need to be calibrated to characterize a particular tissue are considerably high, and some of them cannot represent a wide range of different tissues behaviors. In addition, the main problem still is the computational resources to solve the equations on real-time for a large amount of elements, since most of them are quite complex. Due these issues, a new hybrid model is proposed in this work, constructed by a SMM model combined by an energetic equivalence to a more sophisticated SEDF, which is solved on a pre-computation stage.

For modeling the behavior of soft tissue and biological materials, it is possible to use a construction based on the rule of mixtures of strain energy, proposed by Elías-Zuñiga (2014). In this constitutive model, it was considered finite deformations of hyperelastic materials by applying the rule of mixtures to create an Equivalent Strain Energy Density Function (ESEDF) model, which includes energy contributions from isotropic and anisotropic volumetric fractions of the material (CANTOURNET, et al. 2007), (ELÍAS-ZUÑIGA, et al., 2014).

The ESEDF model defines the strain energy of a material as follow:

$$W_T = (1 - f)W_{iso} + fW_{aniso} \tag{2}$$

Where W_{iso} represent the strain energy of the isotropic part, and W_{aniso} is the anisotropic strain energy contribution of f, which is the anisotropic volumetric fraction. Both energies can be estimated trough formulations based on Arruda-Boyce and Spencer models, by:

$$W_{iso} = \mu\left[N\left(\beta\lambda_r + \ln\left(\frac{\beta}{\sinh\beta} \right) \right) - \ln\left(\frac{\beta}{\lambda_r} \right) \right] + c \tag{3}$$

Where N is the chain number, μ represent the material shear modulus, c is an energy constant, β is the inverse Langevin function of λ_r, and $\lambda_r = \sqrt{\frac{I_1}{3N}}$ (ELÍAS-ZUÑIGA, et al., 2002).

And:

$$W_{aniso} \cong \frac{A_1}{3}(I_{1i} - 3) + \frac{A_2}{9}(I_{1i} - 3)^2 - \frac{2A_1}{3}\ln\sqrt{I_{3i}} \tag{4}$$

Where A_1 and A_2 are energy density fitting parameters, and I_{ki} represent the principal invariants *izotropized* by the consideration of the fibers at (±1,±1,±1) directions (ELÍAS-ZUÑIGA, et al., 2014).

2.2 Equivalent Spring-Mass Model

In the new hybrid model proposed in this work, a SMM model stiffness parameter was defined in function of an energetic equivalence of the ESEDF model, which is pre-computed on a deformation range to avoid time response problems. The strain energy of a linear spring is based on a case of Neo-Hooke model for one-dimensional elements, and will be found the parameter to make it equivalent to ESEDF:

$$W = \frac{\mu}{2}(I_1 - 3) = \frac{\mu_e}{2}\Delta\lambda^2 = W_T \tag{5}$$

Then, it is possible to define parameters for nonlinear springs that will represent individually the behavior of soft tissue in a more accurate way. These stiffness parameters are in function of the pre-computed ESEDF, by energy equivalence, and are calibrated with data of mechanical tests of tissue samples. The stiffness parameter of an element in function of its stretch ratio is:

$$\mu_e = \frac{2}{\Delta\lambda^2}\left[(1 - f)W_{iso} + fW_{aniso} \right] \tag{6}$$

$$\mu_e = \frac{2}{\Delta\lambda^2}\left[(1-f)\left(\mu\left[N\left(\beta\lambda_r + \ln\left(\frac{\beta}{\sinh\beta} \right) \right) - \ln\left(\frac{\beta}{\lambda_r} \right) \right] \right) + f\left(\frac{A_1}{3}(I_{1i} - 3) + \frac{A_2}{9}(I_{1i} - 3)^2 - \frac{2A_1}{3}\ln\sqrt{I_{3i}} \right) \right] \tag{7}$$

In this case, μ_e is calculated for a specific deformation range calibrated from tensile tests data. It is possible to define μ_e for different directions by considering fibers aligned to main axis on the *isotropized* form on Eq. (4), using tensile test data of the oriented tissue.

With the stiffness function defined using an energetic equivalence, the deformation of each element can be calculated with a parameter based on its specific stretch ratio at that time. The angle between the element and a defined dominant fiber orientation (direction cosines of the ith family fiber) of the tissue is used to calculate the equivalence parameter for each direction:

$$\mathrm{k_{ij}} = v_{ij}\left[\mu_{ex}\cos^2\alpha, \mu_{ey}\cos^2\beta, \mu_{ez}\cos^2\gamma\right] \tag{8}$$

Where μ_{ex}, μ_{ey}, μ_{ez}, represent the stiffness functions defined for each direction, v_{ij} a parameter for volumetric compensation and α, β and γ represent the angles between the fiber direction θ and the element orientation $\varnothing_{ij}$ for each axis as shown in figure 3.

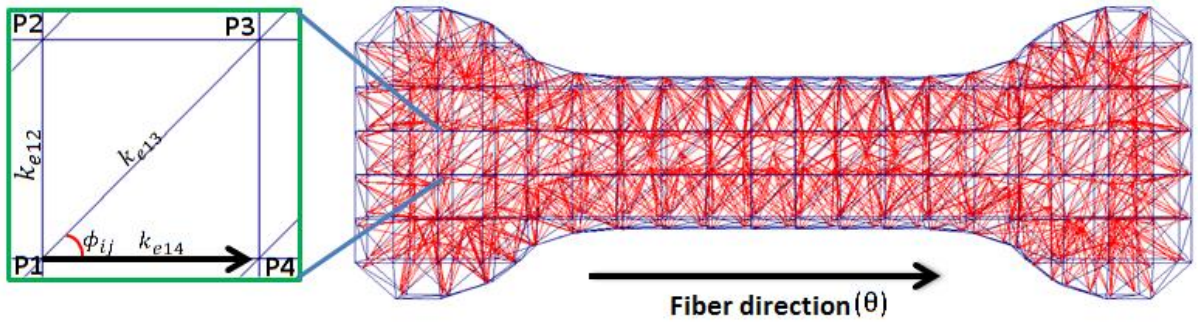


Figure 3. Mesh representation of "dog bone" sample with internal elements

Therefore, applying Eq. (8) on Eq. (1) it is possible to redefine the force F_i on a point P_i as:

$$\mathrm{F_i} = \sum_{\mathrm{j}\in\mathrm{N(P_i)}} v_{ij}\left[\mu_{ex}\cos^2\alpha, \mu_{ey}\cos^2\beta, \mu_{ez}\cos^2\gamma\right]\left(\left\|P_iP_j\right\| - L_{ij}^0\right)\frac{P_iP_j}{\left\|P_iP_j\right\|} \tag{9}$$

This hybrid model will referenced as Equivalent Spring-Mass Model (ESMM). Having established an energetic equivalence, it is possible to calculate μ_e, which represent a stiffness function that make a deformed element achieve the same strain energy than the soft tissue at the same stretch ratio.

3 RESULTS

The ESMM was implemented as material model for a real-time simulation of the behavior of soft tissues using Python and the Visualization Toolkit (VTK). Calibration parameters for ESMM were found using experimental data from uniaxial mechanical tensile tests of porcine liver parenchyma samples.

The characterization of liver parenchyma was achieved with the proposed hybrid model, allowing to predict the behavior of liver tissue on the virtual environment. A comparison between ESMM predictions and experimental data is shown in figure 4.

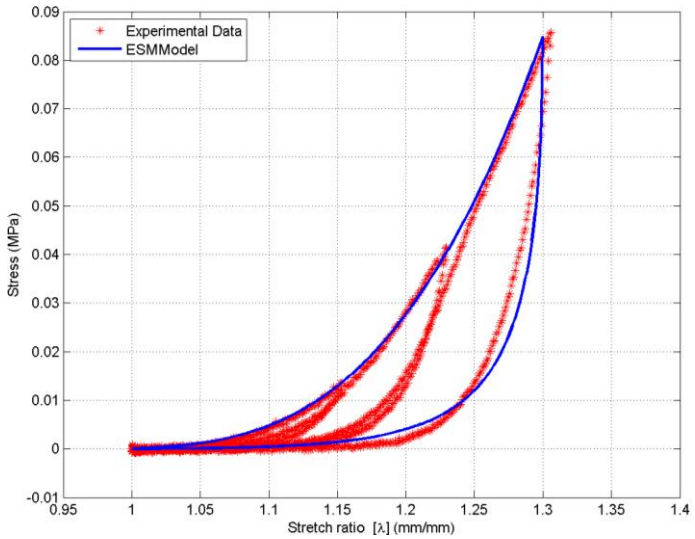


Figure 4. Graphic that show the prediction of the model using μ = 2.973e-06 MPa, N = 1.1074, A1 = 3.9106, A2 = 451.9193, f = 0.0019, b = 5.2022, C = 0.0699. Young's modulus E = 0.67712 MPa (exp data).

Using this ESMM implementation on an initialization stage, the stiffness parameters μ_e were calculated and k_{ij} was defined for each element at each stretch ratio on the 3D geometrical mesh of liver (regardless the orientation, considering $\mu_e = \mu_{ex} = \mu_{ey} = \mu_{ez}$ for this test case). Pre-calculated data was stored to use on the real-time simulation, and the result for the stiffness parameter and the force F_i is shown in figure 5.

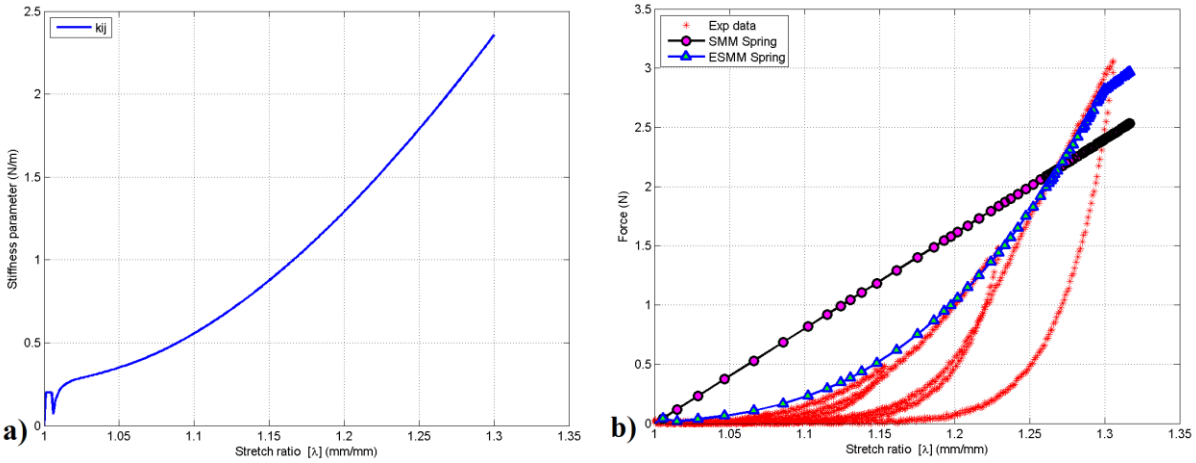


Figure 5. a) Graphic that shows the behavior of μe in function of the stretch ratio, b) Graphic that compares the behavior of a spring of SMM and ESMM with experimental data.

Using the ESMM implementation in this work, it was possible to make a simulation of non-linear elements based on an energetic equivalence with a SEDF in a pre-computed phase.

Stored k_{ij} data for elements on the 3D mesh was used on the virtual environment, and the results for one P_iP_j element were plotted on figure 5b. The interactive simulation of the liver mesh with the ESMM elements is shown on figure 6, running on a virtual environment for laparoscopic surgery developed on previous works (MORENO, et al., 2012), (MORENO, et al., 2014).

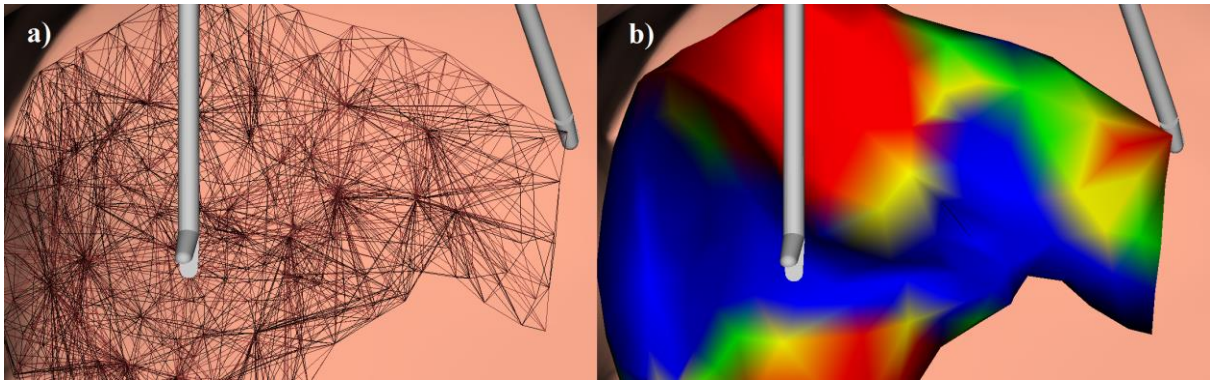


Figure 6. Virtual environment with liver mesh using ESMM springs a) ESMM springs formed with the liver mesh b) Deformation color map of the liver mesh

Since the main objective is to run on a real-time virtual simulation system, the implementation performance of this model was measured. Running the calculation process on an Intel® Core™ i7-4510U @ 2.00GHz with 8GB RAM for a test mesh of 5322 elements, a initialization phase to get the parameters from $\lambda = 1$ to λ_{max} needed 1.43 *s* to read, solve and store data of ESMM. On the simulation, the process required 3.517 *ms* to calculate the deformation of the mesh trough gravity and user interaction. This time lead to a 28 *frames/s* refresh frequency, allowing the interaction between user and virtual environment without significant delay.

4 CONCLUSIONS

The proposed hybrid construction (ESMM) was implemented on a virtual environment and was able to calculate the stiffness parameters for elements to represent an anisotropic non-linear behavior. Each element represents the behavior that a sample of porcine tissue had on the uniaxial tensile test used to calibrate the model.

Although ESMM had good results on this work, the fact that each one-dimensional element has an approximated behavior of the real tissue does not mean that an object composed by these elements simulate the whole organ behavior. This is because the one-dimensional spring elements model the whole organ in just segments, without considering the volume that each one represents. That is why a volumetric compensation parameter was added to the model, in order to considerate the amount of volume that each spring is representing, in function of the simulation mesh construction.

The consideration of volumetric compensations and the implementation of volumetric elements would be researched in future works. Also, the study of tissue properties would continue after the porcine tissue mechanical tests done to calibrate the model on this work, with focus on biaxial tensile test of porcine tissue samples. Applicability of microtomography images of tissue samples will be researched in order to study principal fiber orientation vectors, tissue composition and the anisotropic fraction (*f*).

ACKNOWLEDGEMENTS

The authors of this work are grateful to the *CTI Renato Archer* and *Tecnológico de Monterrey Campus Monterrey* for their support and contributions, in particular to the *Research Chair Nanomaterials for Medical Devices* and the *Research Chair in Intelligent Machines*. This work was also founded by the *Consejo Nacional de Ciencia y Tecnología (CONACYT) in Mexico* and *Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) in Brazil.*

REFERENCES

Amorim, P. H. J., Moraes, T. F., Azevedo, F. S., Silva, J.V.L., 2011. InVesalius: Software Livre de Imagens Médicas. In: *XXXI Congresso da Sociedade Brasileira de Computação, XI WIM Workshop de Informática Médica*, Natal -RN. CSBC 2011. p. 1735-1740.

Camilo, A. A., Amorim, P.H.J., Moraes, T.F., Azevedo, F. S., Silva, J.V.L., 2012. InVesalius: Medical image edition. In: *1st International Conference on Design and Processes for Medical Devices*, 2012, Brescia Italy. PROMED. v.1. p. 279-282.

Cantournet, S., Boyce, M.C., Tsou, A.H., 2007. Micromechanics and macromechanics of carbon nanotube-enhanced elastomers. *Journal of the Mechanics and Physics of Solids*, Elsevier, v.55 (6), p. 1321-1339.

Delingette, H., Ayache, N., 2004. Soft Tissue Modeling for Surgery Simulation. In N. Ayache, *Handbook of Numerical Analysis: Computational Models for the Human Body*, Elsevier, v.12, p. 453-550.

Elías-Zúniga, A., Beatty, M.F., 2002. Constitutive equations for amended non-Gaussian network models of rubber elasticity. *International Journal of Engineering Science*, 40, p. 2265–2294.

Elías-Zuñiga, A., Baylón, K., Ferrer, I., Serenó, L., Garcia-Romeu, M.L., Bagudanch, I., Grabalosa, J., Pérez-Recio, T., Martínez-Romero, O., Ortega-Lara, W., Elizalde, L.E., 2014. On the Rule of Mixtures for Predicting Stress-Softening and Residual Strain Effects in Biological Tissues and Biocompatible Materials. *J. Materials*, v.7, p. 441-456.

Halic, T., Kockara, S., Bayrak, C., Rowe, R., Chen, B., 2009. Soft Tissue Deformation and Optimized Data Structures for Mass Spring Methods. *IEEE International Conference on Bioinformatics and Bioengineering*.

Holzapfel, G.A., 2001. Biomecanics of Soft Tissue, *Handbook of Material Behavior: Nonlinear Models and Properties*, v.3 (10), p. 1057-1071.

Issenberg, S. M., 2005. Features and uses of high-fidelity medical simulations that lead to effective learning: a BEME systematic review. *Medical Teacher*, v.27 (1), p.10-28.

Moreno, M. R., Moraes, T. F., Amorim, P. H. J., Silva, J. V. L., Rodriguez, C. A., 2012. Virtual open source environment for training and simulation of Laparoscopic Surgery. In: XII Workshop de Informática Médica (WIM'2012) -*XXXII Congresso da Sociedade Brasileira de Computação*, Curitiba-PR. v.1, p.1-4.

Moreno, M. R., Amorim, P. H. J., Moraes, T. F., Silva, J. V. L., Quinones, K. L. B., Villalba, E. F., Zuniga, A. E., Rodriguez, C. A., 2014. Soft Tissue Modeling For Virtual Surgery Simulation. In: *XXIV Congresso Brasileiro de Engenharia Biomédica (CBEB2014)*, Uberlândia, MG. XXIV Brazilian Congress on Biomedical Engineering CBEB.

Seymour, N. E., Gallagher, A. G., Roman, S. A., O'Brien, M. K., Bansal, V. K., Andersen, D. K., Satava, R. M., 2002. Virtual Reality Training Improves Operating Room Performance: Results of a Randomized, Double-blinded Study. *Annals of Surgery* v.236 (4), p. 458-464.

Zhang, S., Gu, L., Liang, W., Huang, P., Boehm, J., Xu, J., 2006. The Framework for Real-Time Simulation of Deformable Soft-Tissue Using a Hybrid Elastic Model, In: *Biomedical Simulation, Third International Symposium,* Zurich, Switzerland, Springer-Verlag, p. 75-83.

Hindawi Publishing Corporation
Computational and Mathematical Methods in Medicine
Volume 2016, Article ID 6183679, 10 pages
http://dx.doi.org/10.1155/2016/6183679

Research Article

Influence of PEEK Coating on Hip Implant Stress Shielding: A Finite Element Analysis

Jesica Anguiano-Sanchez,[1] Oscar Martinez-Romero,[1] Hector R. Siller,[1] Jose A. Diaz-Elizondo,[2] Eduardo Flores-Villalba,[1,2] and Ciro A. Rodriguez[1]

[1]*Escuela de Ingeniería y Ciencias, Tecnológico de Monterrey, Avenida Eugenio Garza Sada 2501, 64849 Monterrey, Mexico*
[2]*Escuela de Medicina, Tecnológico de Monterrey, Avenida Eugenio Garza Sada 2501, 64849 Monterrey, Mexico*

Correspondence should be addressed to Ciro A. Rodriguez; ciro.rodriguez@itesm.mx

Received 6 October 2015; Revised 20 January 2016; Accepted 7 February 2016

Academic Editor: Valeri Makarov

Stress shielding is a well-known failure factor in hip implants. This work proposes a design concept for hip implants, using a combination of metallic stem with a polymer coating (polyether ether ketone (PEEK)). The proposed design concept is simulated using titanium alloy stems and PEEK coatings with thicknesses varying from 100 to 400 μm. The Finite Element analysis of the cancellous bone surrounding the implant shows promising results. The effective von Mises stress increases between 81 and 92% for the complete volume of cancellous bone. When focusing on the proximal zone of the implant, the increased stress transmission to the cancellous bone reaches between 47 and 60%. This increment in load transferred to the bone can influence mineral bone loss due to stress shielding, minimizing such effect, and thus prolonging implant lifespan.

1. Introduction

The number of total hip arthroplasties (THA) operations is increasing, reaching more than one million procedures worldwide per year. This technique is a useful treatment option for osteoarthritis and rheumatoid arthritis on the hip joint, allowing the patients to regain pain-free mobility [1]. Although THA is considered a successful procedure, recent projections indicate the number of revision surgeries is expected to increase by 137% in the next 15 years [2]. This is a major problem due to the pain and high costs caused to the patient, together with less favorable results compared to the first procedure, mainly because of the damage cause to the remaining bone after the THA. Hip implants are designed to last for at least 20 years, but their lifespan has reduced by several problems. One of the most commonly recorded indications for revision surgery is aseptic loosening, where stress shielding is a principal factor [3].

According to Wolff's law, bones adapt to the mechanical load they receive. When a person is more active in a specific part of the body, more bone is added to strengthen the tissue, and conversely, if a bone stops receiving load for a prolonged time, the mass of the tissue decreases and bone is lost. Once the hip replacement is conducted, the load is carried mainly by the implant itself and not by the femur. This phenomenon is due to a mismatch in stiffness between the hip implant and femur (almost 10 times higher in implant), with variations related to natural physiological conditions [4]. An insufficient load transfer between bone and implant leads to mineral bone lost and thus to lack of contact between the bone and femur. This effect is known as stress shielding.

The research literature shows two approaches to tackle stress shielding in hip implants: design and/or materials. Several studies have focused on changing the geometry of the hip implant in order to reduce the stress shielding effect [5–8]. Joshi et al. propose a new design and proximal fixation method to reduce stress shielding [5]. Gross and Abel use numerical analysis to show the benefits of using a hollow hip implant design [6]. In order to understand stress shielding, Boyle and Kim analyzed commercially available hip implants with consideration of microlevel bone remodeling [7]. Hirata et al. show that hip implant geometry plays a role in stress

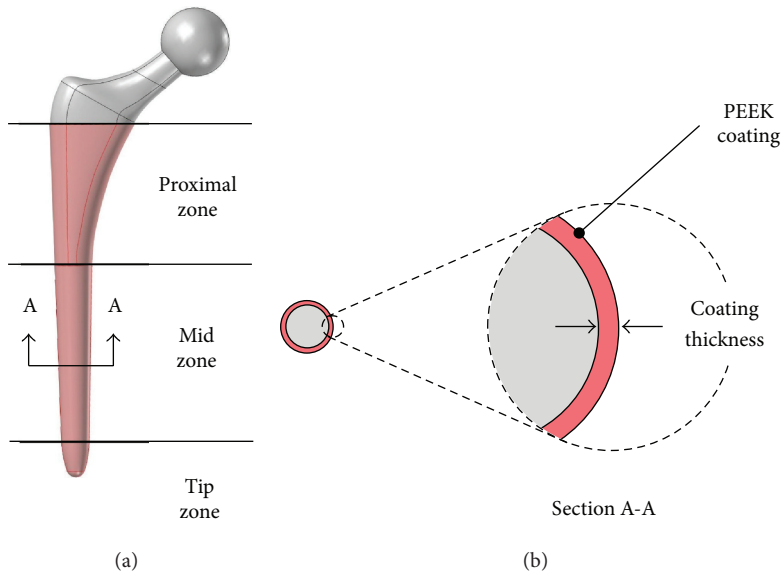


Figure 1: (a) Three-dimensional model for the hip implant coated with PEEK, with proposed coating location indicated in red. (b) Cross section showing the proposed PEEK coating.

shielding, measuring the bone mineral density in patients over a period of one year [8]. The proposed hip implant concept in the study reported here is not based on a geometric approach.

Similar to geometric approach, the literature reports several studies that focus on biomimetic materials for hip implants in order to reduce stress shielding. Bougherara et al. proposed a hip implant based on polymeric composite and a hydroxyapatite-based coating [9]. Oshkour et al. propose a functionally graded hip implant based on stainless steel, titanium alloy, and hydroxyapatite. The simulation results show improvements in the stress shielding [3]. More recently, Tavakkoli Avval et al. showed the benefits of polymeric composite hip implants by conducting a coupled simulation of the bone-implant interaction biomechanics and the bone regeneration process [10].

The study reported here proposes a design concept that combines a metallic stem with an engineered polymer coating. This approach has not been reported in the relevant literature. The proposed polymer has Young's modulus similar to the bone, facilitating load transmission, and therefore, reducing the stress shielding effect. Finite Element analysis provides preliminary validation of the proposed hip implant design concept.

2. Materials and Methods

2.1. Hip Implant Design Concept. The proposed design concept builds on existing technology for press-fit hip implants (see Figure 1). The stem is made out of medical grade of titanium alloy Ti-6Al-4V. The selected material for the coating is polyether ether ketone (PEEK), a well-known biocompatible polymer, used in orthopedic, spine, and dental implants. PEEK and polyaryl ether ketones (PAEKs) had been used as biomaterials since the 1980s [11], due to their structure that confers outstanding chemical resistance, inertness, and thermal stability for *in vivo* conditions. Additionally, for the purpose of this study, PEEK has Young's modulus comparable to that of the bone. Therefore, there is potential to reduce the stiffness mismatch between the femur and the hip implant.

This work investigates how a PEEK coating on a titanium alloy hip implant stem could improve the effective von Mises stress distribution on the femur, comparing a model with uncoated condition to models that have coatings with different thicknesses. An increase in effective von Mises stress values is expected, reducing stress shielding on the femur.

The coating is derived from a hypothetical manufacturing process. The coating thickness is assumed to be uniformly distributed along the surface of the implant stem, starting at the height of lesser trochanter. Figure 1 shows the PEEK coating representation and the modified Gruen zones with proximal, mid, and distal portions [7, 12].

Four different coating thicknesses were analyzed (100, 200, 300, and 400 μm) and compared to the uncoated condition. These thicknesses were chosen in accordance with the standard values for electrophoretic deposition technique (EPD) [13], a method that allows fair PEEK coatings. The geometry of the hip implant is exactly the same for all simulations. The thickness portion of the coating is taken from the cancellous bone with the purpose of mimicking, the THA procedure (see Figure 1).

2.2. Geometric Modeling and Meshing. The standard "Sawbones" Pacific Research Labs Inc. model was used as starting point for the femur [14]. That model modified to create a new geometry of the femur after the THA procedure, on the *PTC Creo*© software. A series of parallel sketches were used in order to create a solid geometry with the least amount of

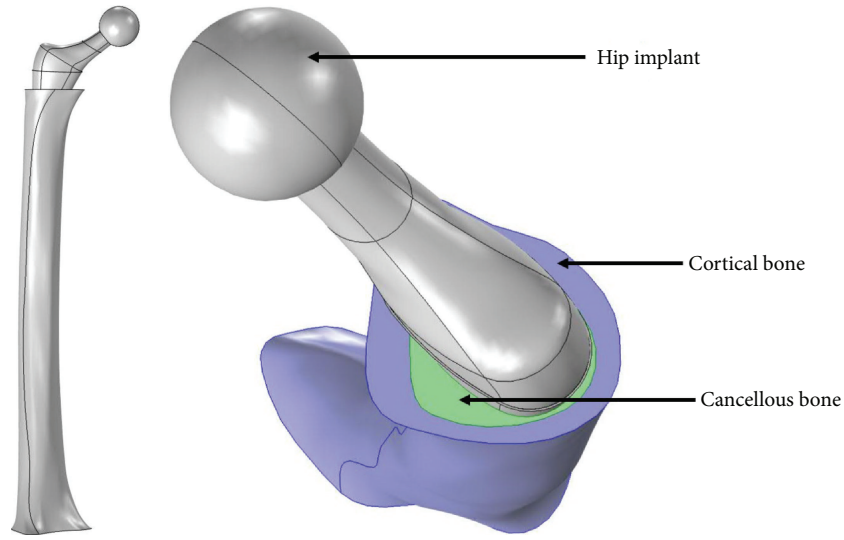


Figure 2: (a) FE model of femur with boundary conditions: 3,000 N in applied load at the femoral implant head and a fixation constraint at the distal end. (b) Top view of the model showing the hip implant, cortical and cancellous bone sections.

sharp edges and therefore facilitate the discretization process. In addition, computerized models of the hip implant and the coating were developed.

Implant model was based on a typical metal-on-metal design. In order to facilitate the analysis, the implant geometry is a simplified version of a commercial implant such as Biomet Bi-Metric®.

Figure 2 shows the complete assembled geometry of the implant, femur, and coating. The coating is assumed to be uniform and perfectly bonded to the stem of the hip implant.

In order to perform structural analysis by Finite Element Method (FEM), the assembly geometry was imported into *COMSOL Multiphysics*© software. The computer model was discretized with different global and local sizes. Due to the complexity of the geometry, tetrahederal elements were necessary. Finally, in order to assure numerical convergence, the most suitable mesh for the study consisted of 1,090,944 tetrahedral elements, with 0.1 and 15.4 mm as the minimum and maximum element size, respectively.

2.3. Material Properties and Boundary Conditions. Four different types materials were considered during numerical analysis: cancellous bone, cortical bone, PEEK coating, and hip implant. All materials are considered to be isotropic based on the part properties derived from common manufacturing techniques such as casting [15] and EPD process for the coating [16]. The hip implant material is of medical grade Ti-6Al-4V.

Mechanical properties of biological tissues vary according to factors such as age, gender, race, and other factors. Average values for cancellous and cortical bone are used [17–19]. The properties for the PEEK 150 XF (polymer used for coating) were obtained from the Victrex data sheet (http://www.victrex.com/). Table 1 shows a summary of the mechanical properties used in the numerical analysis.

Table 1: Material properties used in the FE models for the implanted femur components.

Material	Elastic modulus, E[GPa]	Density, ρ [g/cm^3]	Poisson's ratio, υ
Cancellous bone	0.155	0.20	0.30
Cortical bone	16.70	1.64	0.30
PEEK 150 XF	3.70	1.30	0.40
Ti-6Al-4V	110.00	4.43	0.33

The femur was rigidly fixed at the distal end. The assembly is set to form a union, in order to simulate complete interdigitating of cortical bone, cancellous bone, and PEEK coating. A vertical load of 3,000 N is applied to the femoral implant head, representing 4 times the body weight of a 75 kg patient [17].

3. Results

The results are given in terms of effective von Mises stresses as experienced by the cancellous bone around the hip implant, according to suggested criteria used in previous studies [20]. The three regions mentioned before (proximal, mid, and tip) are used to analyze the change in stress transmitted to the femur. Each of these zones is evaluated independently, comparing a mean value of von Mises stress in the coated with uncoated condition.

3.1. Surface Analysis. *COMSOL Multiphysics* software allows the analysis of von Mises stresses by selecting surfaces and associating nodes on the mesh. The internal surfaces of the femur in contact with the hip implant were divided into proximal, mid, and tip zones. These zones required a different

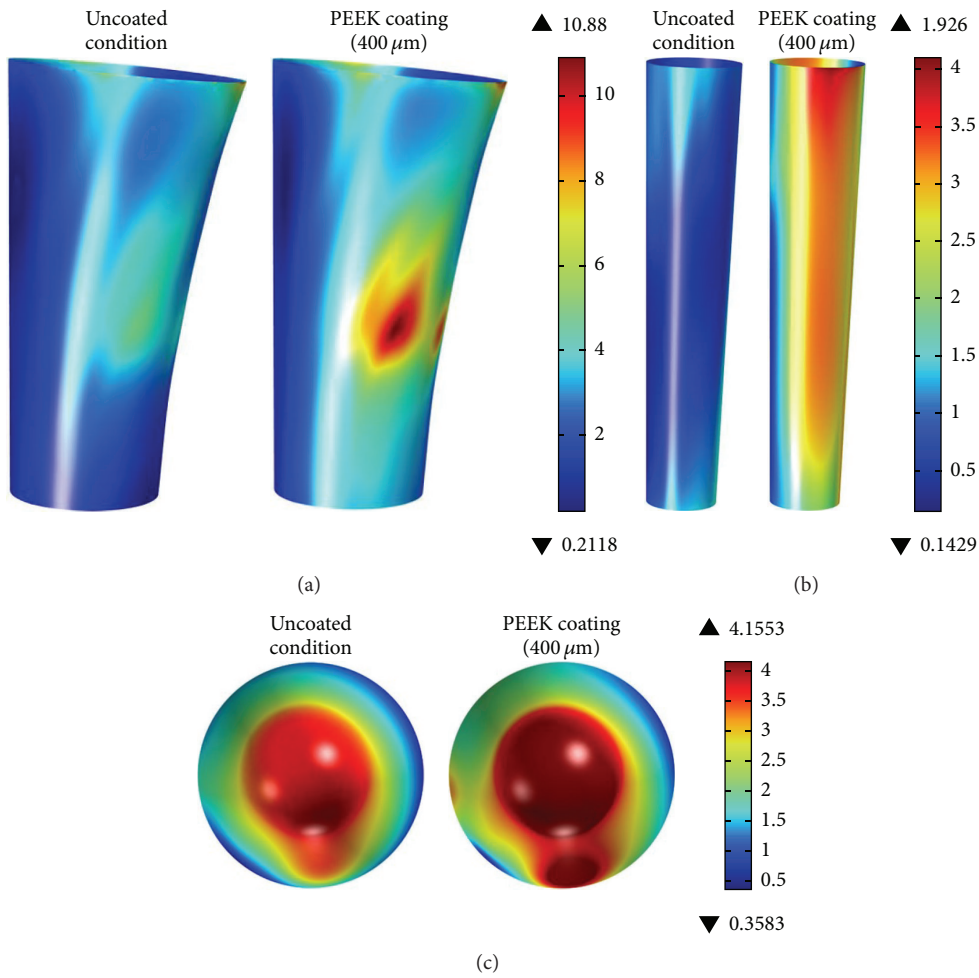


Figure 3: Effective von Mises stress [MPa] at cancellous bone for (a) proximal zone (lateral view), (b) mid zone (lateral view), and (c) tip zones (top view) (uncoated condition on left side and coated condition on the right side).

number of nodes: proximal (6,811 nodes), mid (6,291 nodes), and tip (3,277 nodes).

Figure 3 shows the Finite Element analysis results for effective von Mises stresses in the proximal, mid, and distal zones of the cancellous bone. The comparison of uncoated versus coated conditions (400 μm) shows a significant increase in the transmitted stress to the femur. For the coated condition, stress is almost uniformly distributed in all lateral surfaces, except for a peak zone with a stress value of 10.79 MPa.

In the mid zone (see Figure 3(b)), the difference in stress distribution is more significant compared to the proximal and tip zones. In the case of the tip zone analysis the increase in stress distribution is moderate.

Figure 4 shows the stress values for a curve along each of the zones proposed in this study. Each point represents a node along the curve of analysis. The starting point with length 0 mm is always at the top of the selected zone.

Figure 4(a) shows the effective von Mises stress on a single curve along the proximal zone. As the length increases, the effect of the coating is more noticeable. It is clear that as the coating thickens higher loads are transferred to the femur and, consequently, less stress shielding will be presented. The difference in stress transmission for a coating thickness of 400 μm versus 100 μm is only significant at a length between 35 and 50 mm. Therefore, for the purpose of producing a workable electrophoresis coating, the thickness can be maintained below 400 μm.

Figures 4(b) and 4(c) present the results for mid and tip zone, respectively. The mid zone shows the best results in terms of load transferred to cancellous bone. In Figure 4(b) the behavior of stress distribution changes across the curve length, comparing the uncoated and the coated condition. After 60 mm all lines for each coating thickness almost overlap. For the tip zone, Figure 4(c), values of effective von Mises are higher here than in any other zone of the bone. In this case, the curve of analysis goes around the tip of the implant (see Figure 4(c)).

For comparison, Figure 5 shows the analysis based on maximum principal stress. Similar to the analysis based on effective von Mises stress, the coating shows better transmission of the load to the cancellous bone.

Figure 6 shows the complete surface analysis for the cancellous bone. The results show a clear increase of stress in

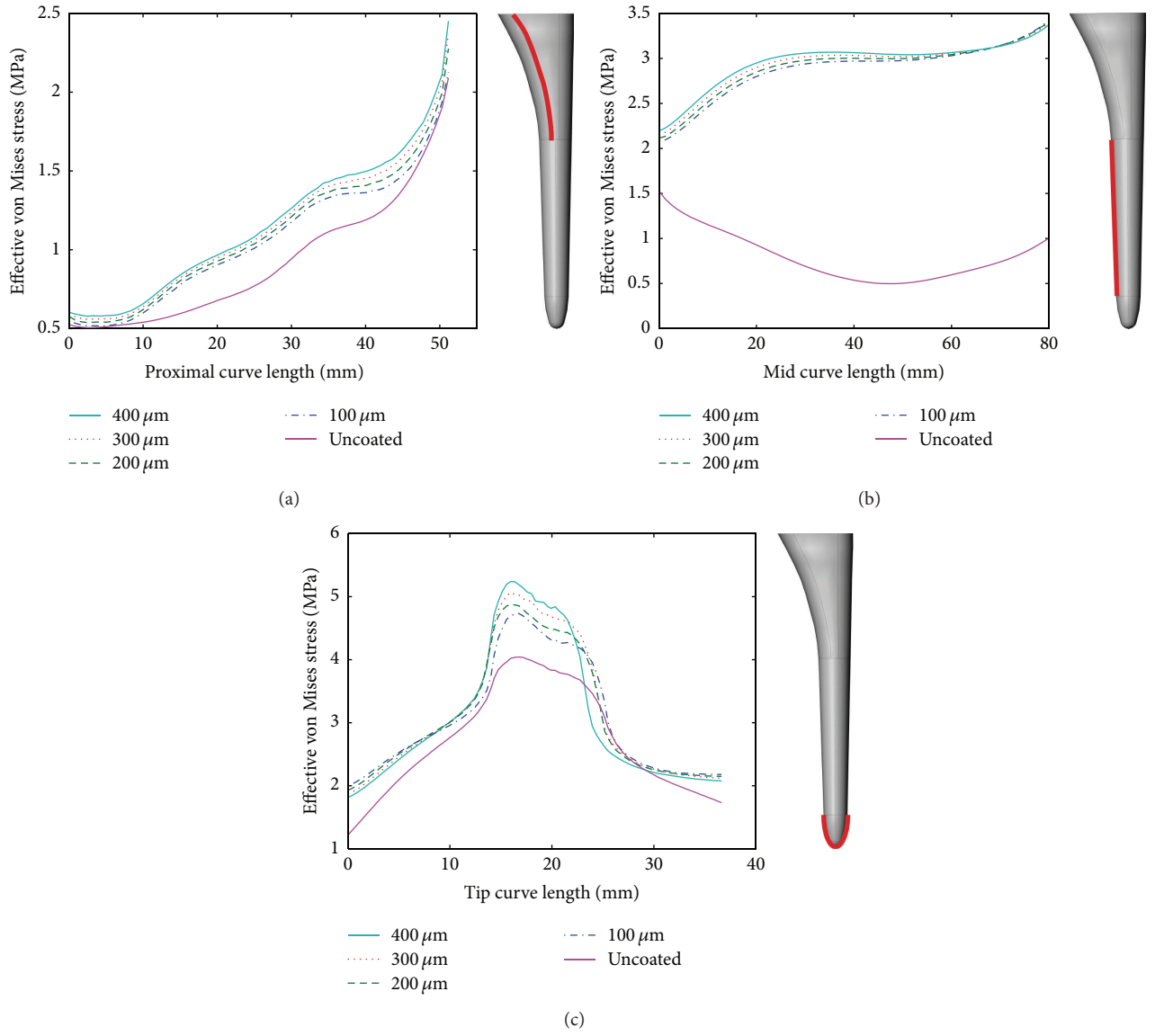


FIGURE 4: Effective von Mises stress [MPa] distribution at the cancellous bone for a curve along the surface: (a) proximal zone, (b) mid zone, and (c) tip zone (solid line: uncoated conditions, dotted lines: 100 μm, 200 μm, 300 μm, and 400 μm coatings).

the lateral faces of the bone with coated condition (red zones). Under the PEEK coating of 400 μm, the highest stress at the cancellous bone is 5.5 MPa.

3.2. Volumetric Analysis of Cancellous Bone. It is important to analyze each zone individually since proximal and mid zones are where higher stress shielding values are reported in the research literature. The current study reports consistent results, where the proximal and mid zones have a more significant role in terms of load transferred to bone, even with the 100 μm coating.

The analysis shown in Figure 7 and Table 2 is based on volumetric average of the effective von Mises stress. It is shown that the gain in load transfer to the bone, for the complete volume of cancellous bone, is 81% for a coating of 100 μm and 92% for a coating of 400 μm. When separating the three zones, the main benefit appears in the proximal and mid zones.

3.3. Volumetric Analysis of Femur. Figure 8 shows the results of the Finite Element analysis for the complete model, including the hip implant and the whole femur during a load application of 3,000 N. As expected, the highest stress concentration is on the neck of the hip implant, reaching 180 MPa. It is important to note that the hip implant is hypothetically made of a medical grade titanium alloy that allows these levels of stress. The stress level for the femur is within acceptable levels.

4. Discussion

4.1. Model Limitations. Some considerations have been taken into account in the model in order to optimize computational

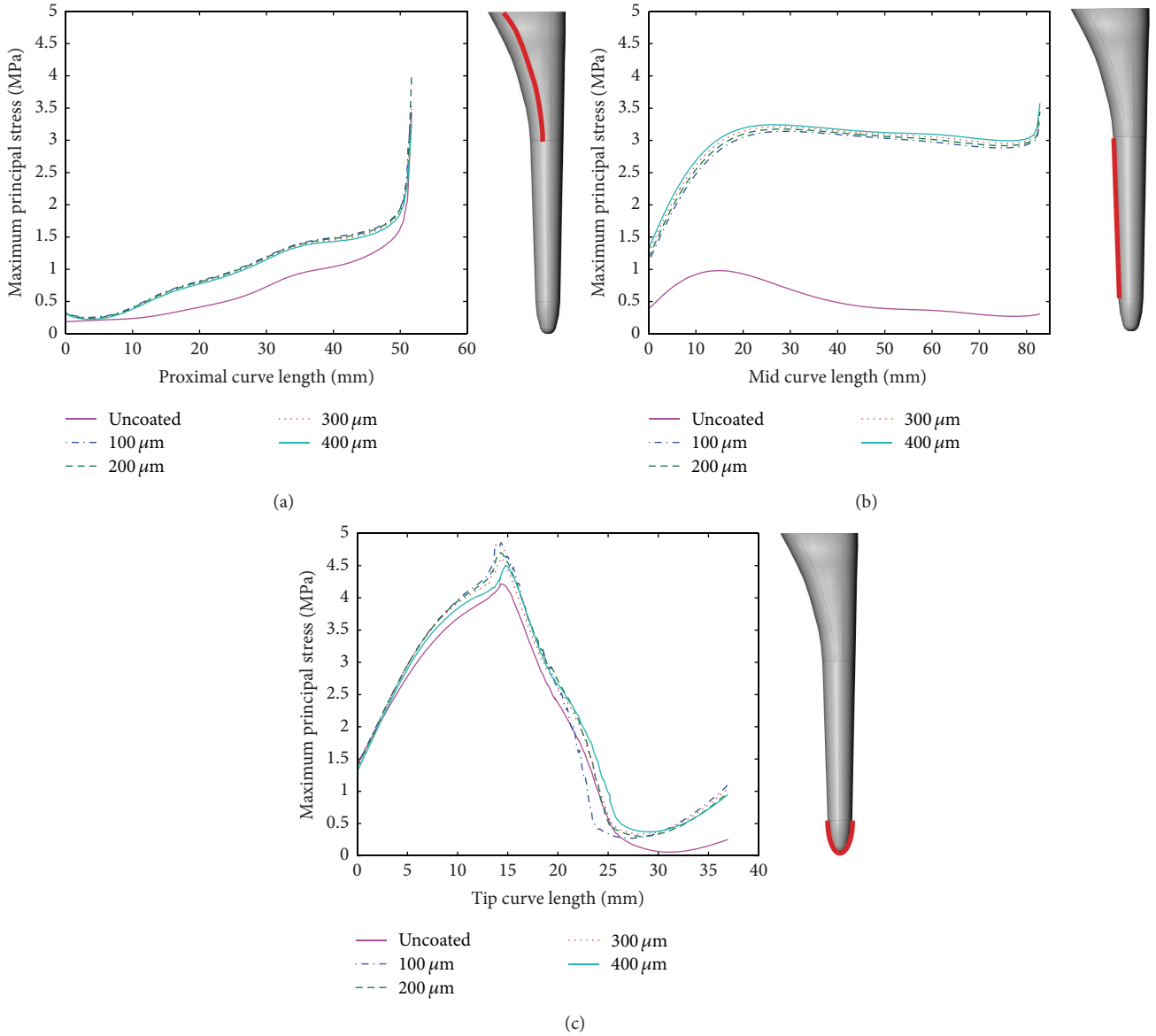


FIGURE 5: Maximum principal stress (compressive stress) [MPa] distribution at the cancellous bone for a curve along the surface: (a) proximal zone, (b) mid zone, and (c) tip zone (solid line: uncoated conditions, dotted lines: 100 μm, 200 μm, 300 μm, and 400 μm coatings).

resources without affecting analysis fundamentals. The model geometry, specifically on the proximal part of the femur, has been simplified and does not exactly correspond to a femur after THA. Given that the proposed design concept is based on press-fit type implants, a porous surface should be considered. Again, in order to reduce computational load, all analysis were conducted assuming smooth surfaces.

The present study is limited by the use of isotropic mechanical properties for bone, in order to assess the viability of the proposed design concept for the implant. A future more detailed study should consider the actual anisotropic mechanical properties of bone, as well as the variations in bone density due to the remodeling process.

Factors such as the muscle surrounding the femur and changes in force angle while walking are not taken into account in this study. For the purpose of knowing the effect of a coating in the load transmission to the bone, these factors are not essential since human femur while walking is mainly subjected to compression from axial loading. Previous studies have also simplified their models in such a fashion [21–23].

4.2. Influence of PEEK Coating and Implant Design on Stress Shielding. Proximal zone presents the higher stress shielding values. During the THA procedure, in order to insert the implant into the femur, cancellous and the intramedullary canal are removed. Then anchoring cement is used to attach the implant to the femur. Since the femur is not a uniform and symmetric geometry, the THA procedure can leave zones with thinner cancellous bone, causing stress peaks as the one seen in the proximal zone in this analysis.

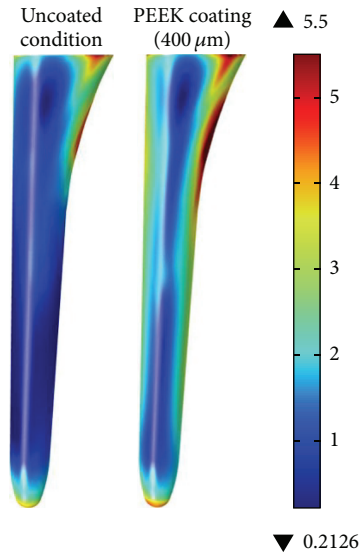


Figure 6: Effective von Mises stress [MPa] at cancellous bone for complete surface (uncoated condition on left side and 400 μm coating on the right side).

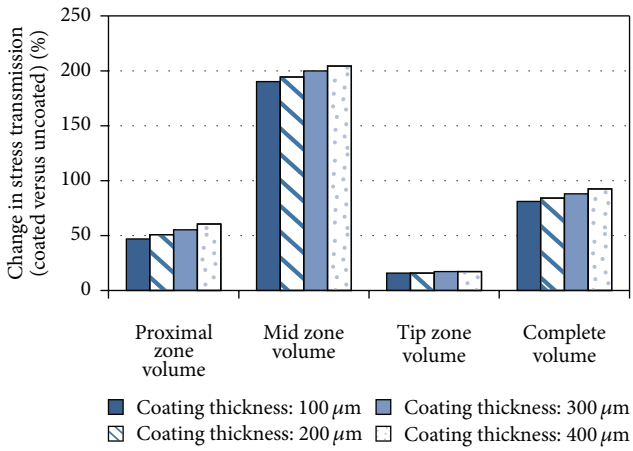


Figure 7: Change in stress transmission to the cancellous bone volume for different thickness of PEEK coatings (see Table 2).

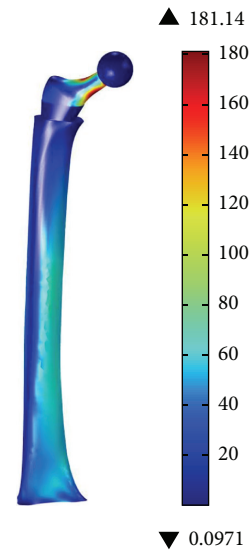


Figure 8: Effective von Mises stress [MPa] for the complete model, using a 400 μm PEEK coating.

The proposed approach shows an increase of 47% in load transfer in the proximal zone with a PEEK coating with 100 μm thickness, while 400 μm thickness improves by 60% the same indicator. This results compare favorably with the work of Gross and Abel [6], where the increment of von Misses stress in the proximal zone increases 32% with the use of hollow stemmed hip implant.

In a comprehensive review of bone tissue fracture, Doblaré et al. [20] suggest that using the effective von Mises stress is appropriate when considering isotropic bone properties. However, in some studies of this nature, brittle material failure criteria are used: maximum principal stress. In terms of principal maximum stress (compressive stress), the current study was compared to the work of Oshkour et al. [3], where axial load is also taken at 3,000 N. The range of maximum principal stress (compressive stress) found is approximately between 0.3 and 5 MPa (see Figure 5), while Oshkour et al. report a similar range between 0.2 and 4 MPa.

The scope of the present study is to validate the design concept of using a PEEK coating to increases load transmission to the bone. Therefore, most of the analysis conducted here was based on effective von Misses stress as first approach.

In order to have a more robust perspective, further studies should be carried out in order to include muscles such as iliotibial tract. In addition, variation of the angle of the femur while walking should be considered in a more in-depth numerical analysis.

The increased stress at the tip of the implant with PEEK coating, compared to uncoated, might be a concern for

Table 2

Coating thickness [μm]	Proximal zone cancellous bone volume		Mid zone cancellous bone volume		Tip zone cancellous bone volume		Complete cancellous bone volume	
	Average stress [MPa]**	Change coated versus uncoated [%]	Average stress [MPa]**	Change coated versus uncoated [%]	Average stress [MPa]**	Change coated versus uncoated [%]	Average stress [MPa]**	Change coated versus uncoated [%]
Uncoated	1.83	—	0.71	—	2.32	—	1.32	—
100	2.69	47	2.06	190	2.69	16%	2.39	81%
200	2.76	51	2.09	194	2.69	16%	2.43	84%
300	2.84	55	2.13	200	2.72	17%	2.48	88%
400	2.94	60	2.16	204	2.72	17%	2.54	92%

**Note: effective von Misses stress.

periprosthetic fracture. Therefore, a more detailed analysis is required in order to consider an implant redesign of the implant tip or elimination of the PEEK coating in that zone.

The proposed approach opens the possibility to improve mechanical behavior without the need to develop a new implant geometry. With an appropriate coating process, any commercially available implant could be treated in order to improve its performance. The present method of coating a hip implant is not limited to a single implant shape. The relative benefit on the proposed approach on stress shielding will certainly depend on the specific implant geometry, given the wide range of commercially available designs.

The study shows that a significant improvement in the implant performance is reached with a modest amount of polymer coating. In this regard, there are several methods available for coating the hip implant with a polymer. The strongest possibility is to use electrophoretic deposition due to scalability and coating consistency. Electrophoretic deposition is proven method for PEEK deposition in steel [24]; thus other metallic substrates could work in a similar way. One area of concern is the adhesion strength of such a coating over a medical grade titanium stem.

4.3. Potential Osseointegration of PEEK Coating. Mineral bone growth, and thus fixation of implant to bone, highly depends on surface roughness and porosity. The use of a PEEK coating on the implant shows the potential to reduce stress shielding, but the question of osseointegration arises. Coatings based on porous hydroxyapatite have been used to promote osseointegration. On the other hand, a number of manufacturing processes are available to generate porous coatings that combine polymers and ceramics. Therefore, this particular issue requires further *in vitro* and *in vivo* studies.

5. Conclusions and Future Work

The current study shows that a PEEK coating on a hip implant can improve the load transfer to the bone, minimizing the stress shielding effect and thus prolonging the implant lifespan. The models with coated condition show a significant change in cancellous bone stress, with increase between 81 and 92% in the volumetric numerical analysis.

Further research is required to refine the proposed design concept and develop an appropriate coating process. Additional numerical analysis is required to consider a wider set of loading conditions, as well as anisotropic bone properties. In terms of manufacturing, different coating processes and PEEK formulations require investigation for the hip implant application.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

Acknowledgments

This research work was possible due to the support by Tecnológico de Monterrey through its Centro de Innovación en Diseño y Tecnología and research group in advanced manufacturing.

References

[1] U. Holzwarth and G. Cotogno, *JCR Scientific and Policy Reports—Total Hip Arthroplasty*, European Commission, 2012.

[2] S. Kurtz, K. Ong, E. Lau, F. Mowat, and M. Halpern, "Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030," *The Journal of Bone & Joint Surgery—American Volume*, vol. 89, no. 4, pp. 780–785, 2007.

[3] A. A. Oshkour, N. A. A. Osman, M. Bayat, R. Afshar, and F. Berto, "Three-dimensional finite element analyses of functionally graded femoral prostheses with different geometrical configurations," *Materials and Design*, vol. 56, pp. 998–1008, 2014.

[4] R. Huiskes, H. Weinans, H. J. Grootenboer, M. Dalstra, B. Fudala, and T. J. Slooff, "Adaptive bone-remodeling theory applied to prosthetic-design analysis," *Journal of Biomechanics*, vol. 20, no. 11-12, pp. 1135–1150, 1987.

[5] M. G. Joshi, S. G. Advani, F. Miller, and M. H. Santare, "Analysis of a femoral hip prosthesis designed to reduce stress shielding," *Journal of Biomechanics*, vol. 33, no. 12, pp. 1655–1662, 2000.

[6] S. Gross and E. W. Abel, "A finite element analysis of hollow stemmed hip prostheses as a means of reducing stress shielding of the femur," *Journal of Biomechanics*, vol. 34, no. 8, pp. 995–1003, 2001.

[7] C. Boyle and I. Y. Kim, "Comparison of different hip prosthesis shapes considering micro-level bone remodeling and stress-shielding criteria using three-dimensional design space topology optimization," *Journal of Biomechanics*, vol. 44, no. 9, pp. 1722–1728, 2011.

[8] Y. Hirata, Y. Inaba, N. Kobayashi, H. Ike, H. Fujimaki, and T. Saito, "Comparison of mechanical stress and change in bone mineral density between two types of femoral implant using finite element analysis," *Journal of Arthroplasty*, vol. 28, no. 10, pp. 1731–1735, 2013.

[9] H. Bougherara, M. Bureau, M. Campbell, A. Vadean, and L. Yahia, "Design of a biomimetic polymer-composite hip prosthesis," *Journal of Biomedical Materials Research, Part A*, vol. 82, no. 1, pp. 27–40, 2007.

[10] P. Tavakkoli Avval, S. Samiezadeh, V. Klika, and H. Bougherara, "Investigating stress shielding spanned by biomimetic polymer-composite vs. metallic hip stem: a computational study using mechano-biochemical model," *Journal of the Mechanical Behavior of Biomedical Materials*, vol. 41, pp. 56–67, 2015.

[11] S. M. Kurtz and J. N. Devine, "PEEK biomaterials in trauma, orthopedic, and spinal implants," *Biomaterials*, vol. 28, no. 32, pp. 4845–4869, 2007.

[12] T. A. Gruen, G. M. McNeice, and H. C. Amstutz, "'Modes of failure' of cemented stem-type femoral components. A radiographic analysis of loosening," *Clinical Orthopaedics and Related Research*, vol. 141, pp. 17–27, 1979.

[13] L. Besra and M. Liu, "A review on fundamentals and applications of electrophoretic deposition (EPD)," *Progress in Materials Science*, vol. 52, no. 1, pp. 1–61, 2007.

[14] P. B. Chang, B. J. Williams, K. S. B. Bhalla et al., "Design and analysis of robust total joint replacements: finite element model experiments with environmental variables," *Journal of Biomechanical Engineering*, vol. 123, no. 3, pp. 239–246, 2001.

[15] J. V. Abellán-Nebot, H. R. Siller, C. Vila, and C. A. Rodríguez, "An experimental study of process variables in turning operations of Ti-6Al-4V and Cr–Co spherical prostheses," *International Journal of Advanced Manufacturing Technology*, vol. 63, no. 9–12, pp. 887–902, 2012.

[16] X. F. Xiao and R. F. Liu, "Effect of suspension stability on electrophoretic deposition of hydroxyapatite coatings," *Materials Letters*, vol. 60, no. 21-22, pp. 2627–2632, 2006.

[17] H. Ebrahimi, M. Rabinovich, V. Vuleta et al., "Biomechanical properties of an intact, injured, repaired, and healed femur: an experimental and computational study," *Journal of the Mechanical Behavior of Biomedical Materials*, vol. 16, no. 1, pp. 121–135, 2012.

[18] W. X. Niu, L. J. Wang, T. N. Feng, C. H. Jiang, and Y. B. Fan, "Effects of bone Young's modulus on finite element analysis in the lateral ankle biomechanics," *Applied Bionics and Biomechanics*, vol. 10, no. 4, pp. 189–195, 2013.

[19] L. Baggi, M. Di Girolamo, G. Vairo, and G. Sannino, "Comparative evaluation of osseointegrated dental implants based on platform-switching concept: influence of diameter, length, thread shape, and in-bone positioning depth on stress-based performance," *Computational and Mathematical Methods in Medicine*, vol. 2013, Article ID 250929, 15 pages, 2013.

[20] M. Doblaré, J. M. García, and M. J. Gómez, "Modelling bone tissue fracture and healing: a review," *Engineering Fracture Mechanics*, vol. 71, no. 13-14, pp. 1809–1840, 2004.

[21] S. Shah, S. Y. R. Kim, A. Dubov, E. H. Schemitsch, H. Bougherara, and R. Zdero, "The biomechanics of plate fixation of periprosthetic femoral fractures near the tip of a total hip implant: cables, screws, or both?" *Proceedings of the Institution of Mechanical Engineers. Part H: Journal of Engineering in Medicine*, vol. 225, no. 9, pp. 845–856, 2011.

[22] E. T. Davis, M. Olsen, R. Zdero, J. P. Waddell, and E. H. Schemitsch, "Femoral neck fracture following hip resurfacing: the effect of alignment of the femoral component," *The Journal of Bone & Joint Surgery—British Volume*, vol. 90, no. 11, pp. 1522–1527, 2008.

[23] D. Wilson, H. Frei, B. A. Masri, T. R. Oxland, and C. P. Duncan, "A biomechanical study comparing cortical onlay allograft struts and plates in the treatment of periprosthetic femoral fractures," *Clinical Biomechanics*, vol. 20, no. 1, pp. 70–76, 2005.

[24] I. Corni, N. Neumann, S. Novak et al., "Electrophoretic deposition of PEEK-nano alumina composite coatings on stainless steel," *Surface and Coatings Technology*, vol. 203, no. 10-11, pp. 1349–1359, 2009.

Hindawi Publishing Corporation
Applied Bionics and Biomechanics
Volume 2016, Article ID 7149182, 9 pages
http://dx.doi.org/10.1155/2016/7149182

Research Article

Design Concepts of Polycarbonate-Based Intervertebral Lumbar Cages: Finite Element Analysis and Compression Testing

J. Obedt Figueroa-Cavazos,[1] Eduardo Flores-Villalba,[1] José A. Diaz-Elizondo,[2] Oscar Martínez-Romero,[1] Ciro A. Rodríguez,[1] and Héctor R. Siller[1]

[1]*Tecnologico de Monterrey, Escuela de Ingeniería y Ciencias, 64849 Monterrey, NL, Mexico*
[2]*Tecnologico de Monterrey, Escuela de Medicina, 64710 Monterrey, NL, Mexico*

Correspondence should be addressed to Héctor R. Siller; hector.siller@itesm.mx

Received 16 November 2015; Revised 29 March 2016; Accepted 18 April 2016

Academic Editor: Tadeusz Mikołajczyk

This work explores the viability of 3D printed intervertebral lumbar cages based on biocompatible polycarbonate (PC-ISO® material). Several design concepts are proposed for the generation of patient-specific intervertebral lumbar cages. The 3D printed material achieved compressive yield strength of 55 MPa under a specific combination of manufacturing parameters. The literature recommends a reference load of 4,000 N for design of intervertebral lumbar cages. Under compression testing conditions, the proposed design concepts withstand between 7,500 and 10,000 N of load before showing yielding. Although some stress concentration regions were found during analysis, the overall viability of the proposed design concepts was validated.

1. Introduction

The combination of biotechnology and 3D printing has led to the rise of 3D bioprinting, which is a processing technique that promises to solve critical issues while finding printable biomaterials, increasing the capacity of precise positioning and including cell sources, in order to be successfully applied in diagnosis, personalized medicine, and regenerative medicine [1]. Literature that demonstrates the disruptiveness of this group of applications is spread out in several fields. Radenkovic et al. suggested the idea of manufacturing personalized human hollow organs with lower architectural complexity using detailed patient information, acquired by medical imaging, appropriate cell type, and 3D printing technology [2]. Other works showed the potential of medical and industrial applications of several classes of 3D printing techniques that may be useful for attending the future demand for organ transplants. For example, Yoo made a comparison among different 3D bioprinting technologies in order to evaluate their impact on human health and medical devices industry [3]. Visser et al. stated that the potential application of 3D bioprinting in medicine will evolve into tissue printing in the near future [4].

3D printing of implants, prosthesis, and other medical devices can be considered an important stage of the full development of 3D bioprinting applications. Particularly, design of prosthesis and implants is nowadays embracing the use of 3D printing technologies as FDM (Fused Deposition Modeling), in order to solve the need for customization and the need for providing a fast response in surgical interventions [5]. Some previous works show that it is possible to satisfy the main features required in customized medical devices such as strength, sterility, dimensional stability, and safety. For example, Rankin et al. used a FDM machine for surgical retractors prototyping. This prototype was sterilized and tolerated the tangential force needed to fulfill the requirements before failure, both before and after exposure to sterilization [6].

A specific case of the need of customized implants is column surgery. This is performed in order to ease pathologies associated with back pain that are sometimes caused by deterioration of surrounding fibrous ring of intervertebral discs, resulting in spinal disc herniation. The column surgery that deals with this illness is usually known as spinal fusion surgery, where the vertebrae gradually fuse into a single body with the introduction of an intervertebral cage implant. Spinal fusion is done most commonly in the lumbar region

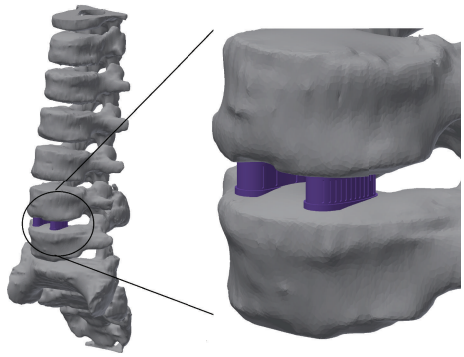


Figure 1: Representation of the lumbar cage implants (vertebrae images courtesy of Centro de Tecnologia da Informação Renato Archer).

of the spine, but it is also used to treat cervical and thoracic regions. The main function of an intervertebral cage implant is to fill the intervertebral space in order to facilitate the process of osseointegration and to provide mechanical support through an optimal load distribution and an interbody fusion balance fixation.

Figure 1 shows the conceptual representation of an intervertebral cage implant system. Typically, intervertebral cage implants are manufactured with medical grade titanium alloys (Ti6Al4V), polyether ether ketone (PEEK), and composite materials. But now, with the appearance of 3D printing and Additive Manufacturing Technologies like Fusion Deposition Modeling (FDM), the potential for developing customer oriented and reliable cage implants is higher. The following sections of this work explain the development of a process chain for taking advantage of FDM in column surgery implants customization.

2. Related Work

There are a limited number of research studies that explore the design and rapid manufacturing of patient-specific implants for column surgery. de Beer and van der Merwe developed a study of the rapid manufacturing of metallic implants. They used computed tomography (CT), direct laser metal sintering (DMLS), and mechanical testing in order to propose a process chain for customization of intervertebral disc implants [7]. In the same matter, Domanski et al. used three Additive Manufacturing Technologies: Fused Deposition Modeling, Powder Based 3D Printing (3DP), and Selective Laser Melting (SLM). They performed Finite Element Analysis for strength validation and they compared surface roughness of each prototype developed [8]. Espalin et al. suggested the use of FDM for the freeform manufacturing of several types of implants. They concentrated their research approach on cranial reconstruction, but they suggested this technique for the customization of orthopedic spacers [9]. Chougule et al. used noninvasive imaging, reverse engineering, and FDM for the development of specific implants for minimum invasive spine surgeries. They suggested that this process chain could provide valuable medical information and powerful diagnostic tool for surgeons to understand the complex internal anatomy of the patient [10]. A work that precedes the one presented here explores the use of FDM and common 3D printing machinery, in the development of design concepts of polymeric spinal surgery implants [11]. It was an exploratory study that evaluated the feasibility of implant customization with this kind of techniques and lays the foundations of the present work.

3. Objective

There is a clear need to evaluate the viability of the use of 3D printing for the customization of column surgery implants. Thus, the main objective of this research is to validate a series of design concepts of a specific case of column implants (called "intervertebral lumbar cages") with the aid of FDM, computational simulations, and experimental testing. Furthermore, this work is intended to lay the basis for the implementation of these medical devices in orthopedic surgeries.

4. Materials and Methods

This section covers the set-up of a proposed process chain for lumbar cage material selection, design, prototyping through FDM, mechanical testing, and Finite Element Analysis.

4.1. Materials. The proposed polymer for this research is PC-ISO (polycarbonate-ISO), an industrial thermoplastic that can be sterilized by several methods like ethylene oxide and gamma radiation, according to the work of Perez et al. In this work sterility testing was performed with successful results for material deposited with FDM process [12]. Cunha et al. evaluated safety and radiation attenuation properties of PC-ISO material and established a method for its clinical use in customized Gynecological Brachytherapy Applicators. The work concluded that PC-ISO is a suitable material for this application in a clinical setting [13].

In the case of the material biocompatibility, there are several studies ordered by the material supplier that confirm that the material is not toxic, does not present allergenic potential, and does not have irritant effects. Among the studies mentioned above there is, for example, the ISO Acute Systemic Injection Test, which was designed for screening PC-ISO extracts for potential toxic effects as a result of a single-dose systemic injection in mice. The study confirmed that the animals did not present signs of toxicity in comparison with the control. Regarding mechanical properties of the chosen material, it has a specified ultimate tensile strength of 57 MPa and a modulus of elasticity of 2 GPa, properties that made this polymer competitive with other engineered materials for implants [11].

4.2. Prototypes. The implant design for FDM took into account several design guidelines for the appropriate deposition of the polymeric material, in order to improve its mechanical performance during tensile or compressive testing and for increasing the dimensional and geometrical accuracy. Some of these design guidelines were formulated by Ahn et al., based on the results of extensive experimentation [14]. Derived from that work, the following guidelines are

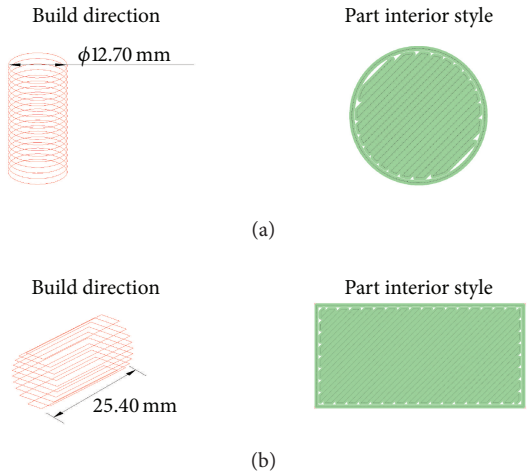


Figure 2: Build direction and part interior style of cylindrical test specimens: (a) transverse-vertical and (b) horizontal-axial configurations.

Table 1: System specifications of FDM machine.

Configuration	
Build envelope (*XYZ*)	406 × 355 × 406 mm
Material delivery	Two build material canisters 1508 cc Two support material canisters 1508 cc Autochangeover between canisters
Material options	PC-ISO
Layer thickness	0.330 mm 0.254 mm 0.178 mm
Support structure	Breakaway Support System (BASS™)

used in this particular case study:

(i) A negative air gap, meaning that two FDM layers partially occupy the same space, will increase both strength and stiffness.

(ii) The build orientation could improve the part accuracy and strength.

Prior to the exploration of patient-specific lumbar cage process chain, cylindrical specimens with two different configurations of build directions were subject to compression strength testing (Figure 2). This procedure was carried out as screening experimentation in order to establish the material mechanical properties for a Finite Element Analysis of the lumbar cage concepts. For the manufacture of the cylindrical specimens and implant design concepts, a FDM machine Stratasys Fortus 400mc was used and two different machine nozzles were configured for the deposition process (Tables 1 and 2). According to the supplier of PC-ISO material, the specific gravity is 1.20, which is equivalent to 0.0012 g/mm^3 in density [15]. Taking as reference this value and the final weights of the cylindrical specimens, the fill percentage obtained with 0.30 mm nozzle is approximately 88% and the

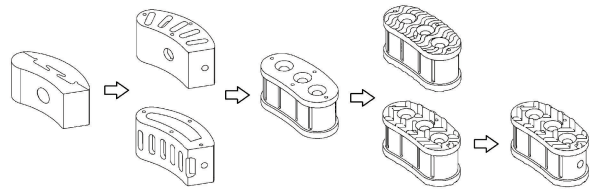


Figure 3: Evolution of lumbar cage design concepts.

Table 2: Fused Deposition Modeling process specifications.

Nozzle diameter	0.30 mm	0.40 mm
Slice height	0.17 mm	0.25 mm
Contour width	0.35 mm	0.50 mm
Part raster width	0.35 mm	0.50 mm
Visible surface raster	0.30 mm	0.43 mm
Internal raster	0.40 mm	0.61 mm

fill percentage obtained with the 0.40 mm nozzle is approximately 92%, which may influence the strength behavior.

The design criteria for lumbar cage geometries were established by the analysis of patents and commercial products, in which the predominant factor found was the load distribution for providing minimum damage to vertebrae [16–19].

It is important to point out that the mechanical response to fatigue testing must be considered in further research since there is evidence in the literature that repetitive loading can cause vulnerability to column mechanical damage [20], and there is limited fatigue data in the literature for FDM deposited materials [21].

The evolution of all design attempts is shown in Figure 3, in which the geometries presented in previous research are also exhibited [11].

In this work, four different lumbar cage design concepts are proposed, as an optimization alternative in the search for appropriate 3D printed implants. These lumbar cage design concepts were tested in a similar set-up to that used for cylindrical specimens. Solid models of the proposed lumbar cages were drawn using a generic CAD tool. The dimensions ranges of the prototypes were about 13.4 mm in width and 28.7 mm in length, having a height of 13 millimeters. Also, all the designs included geometrical features that facilitate osseointegration. It is important to point out that the design concepts include antiskid systems required for appropriate implant fixation, but these geometrical features could generate stress concentration. Figure 4 presents the proposed lumbar cage design: (a) a flat lumbar cage that does not have an antiskid system; (b) a lumbar cage with an antiskid system with undulating features; (c) a lumbar cage with antiskid system with triangular features; and (d) the same geometry that proposed lumbar cage design (c), but with a handling hole in the side view (the handling hole is used to hold the lumbar cage during implantation).

4.3. Compression Strength Testing. Compressive strength tests for each cylindrical specimen and each lumbar cage design concept were conducted using a Shimadzu Universal

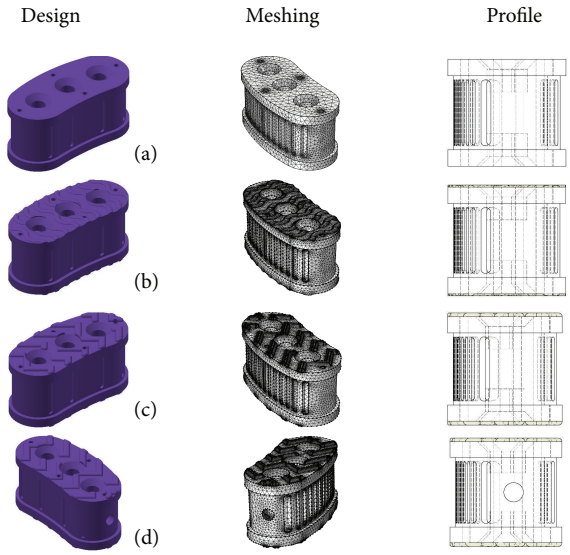


Figure 4: Proposed lumbar cage new designs.

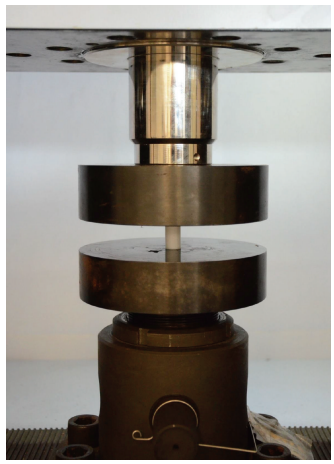


Figure 5: Test system equipped with a 25 kN load cell.

Testing Machine equipped with a 25 kN load cell. The tests performed on cylindrical specimens were based on the "ASTM.D695.2010, Standard Test Method for Compressive Properties of Rigid Plastics" [22], using 6 mm/min as crosshead speed (Figure 5).

4.4. Simulation Settings. The Finite Element Analysis (FEA) was performed with the aid of COMSOL Multiphysics 4.3 software, to automatically generate tetrahedral elements and for performing the computational simulation. It is a common practice to use automatic tetrahedral mesh generators to discretize complex 3D structural components. This type of mesh generators can handle complex geometries with a minimum of human intervention (as compared to, e.g., the manual generation of a mesh of hexahedral elements). The solver used to perform the 3D calculations was embedded in the software. Mesh size was predefined in a range of 0.286 and 2.290 mm with a maximum element growth rate

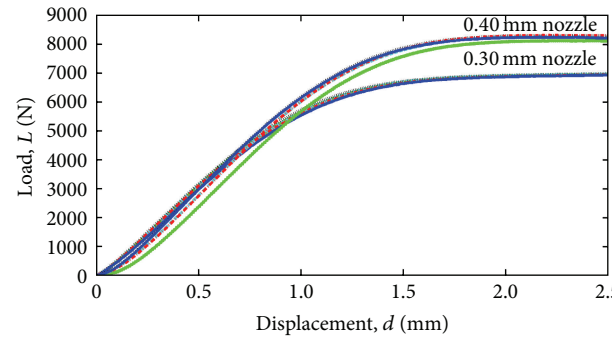


Figure 6: Comparison of the compression test of PC-ISO cylindrical test specimens, printed with 0.30 mm and 0.40 nozzle configuration.

Table 3: Mechanical properties of PC-ISO cylindrical test specimens.

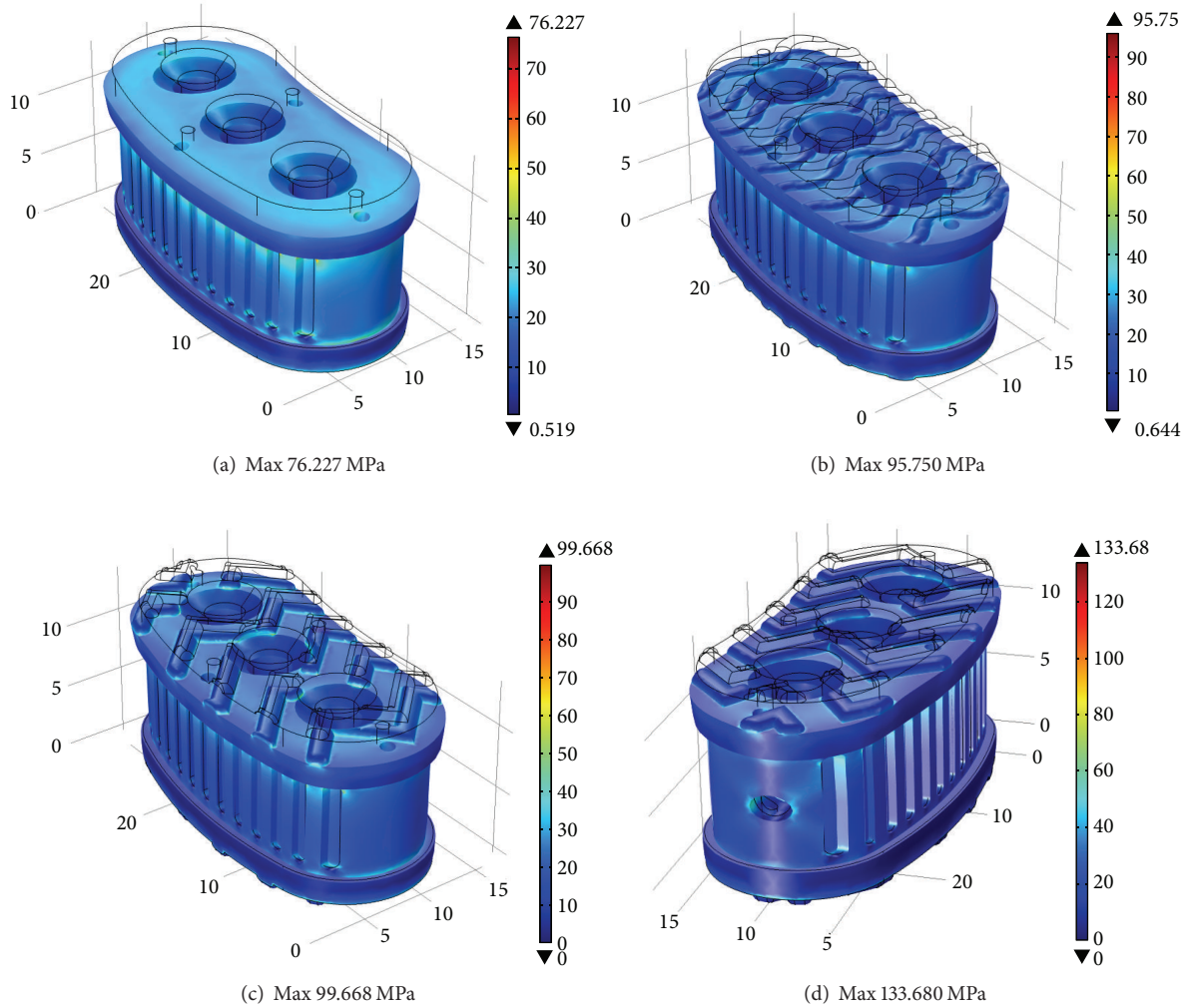
Mechanical properties	Unit	0.30 mm	0.40 mm
Compressive yield strength	MPa	40	55
Young's modulus	GPa	1.2220	1.2580
Poisson's ratio	1	0.3928	0.4287
Density	Kg/m^3	1,060	1,110

of 1.45. Mechanical properties of the proposed lumbar cages were assumed to be homogeneous and linear elastic. The mechanical properties of Table 3 were taken as simulation references for each proposed prototype.

4.5. Reference Column Load. In order to establish a good approximation of the load that must be used for simulating average column loads, an additional literature review was made. Wilke et al. estimated an interdiscal pressure of 1.8 MPa, equivalent of 3,240 N in a disc area of 1800 mm^2, in the L4-L5 disc while an average person was holding a 20 kg object 600 mm away from the chest [23]. Schultz et al. estimated that the interdiscal pressure varies depending on the body position and type of activity, taking values from 0.270 MPa (486 N of load over 1800 mm^2) in a relaxed standing position to 1.62 MPa (2,916 N of load over 1800 mm^2) in the most strenuous task examined [24]. Therefore, considering the average loads from the literature, a 4,000 N axial force was taken as reference load and the bottom face of the prototype was rigidly fixed for motion constraint.

5. Results and Discussion

5.1. Compression Strength Testing. The results of this screening experimentation for horizontal-axial build configuration were discarded since they presented lower strength behavior (7,800 N) in comparison to those with transverse-vertical build configuration for similar conditions (8,300 N). Figure 6 shows results of the compressive strength test of PC-ISO specimens manufactured by 0.30 mm nozzle in transverse-vertical build direction and 0.40 mm nozzle in transverse-vertical build direction. In order to evaluate the repeatability of the FDM process, several replications were conducted. The



(a) Max 76.227 MPa

(b) Max 95.750 MPa

(c) Max 99.668 MPa

(d) Max 133.680 MPa

Figure 7: Volumetric analysis: von Mises stress distribution with 4,000 N as reference load.

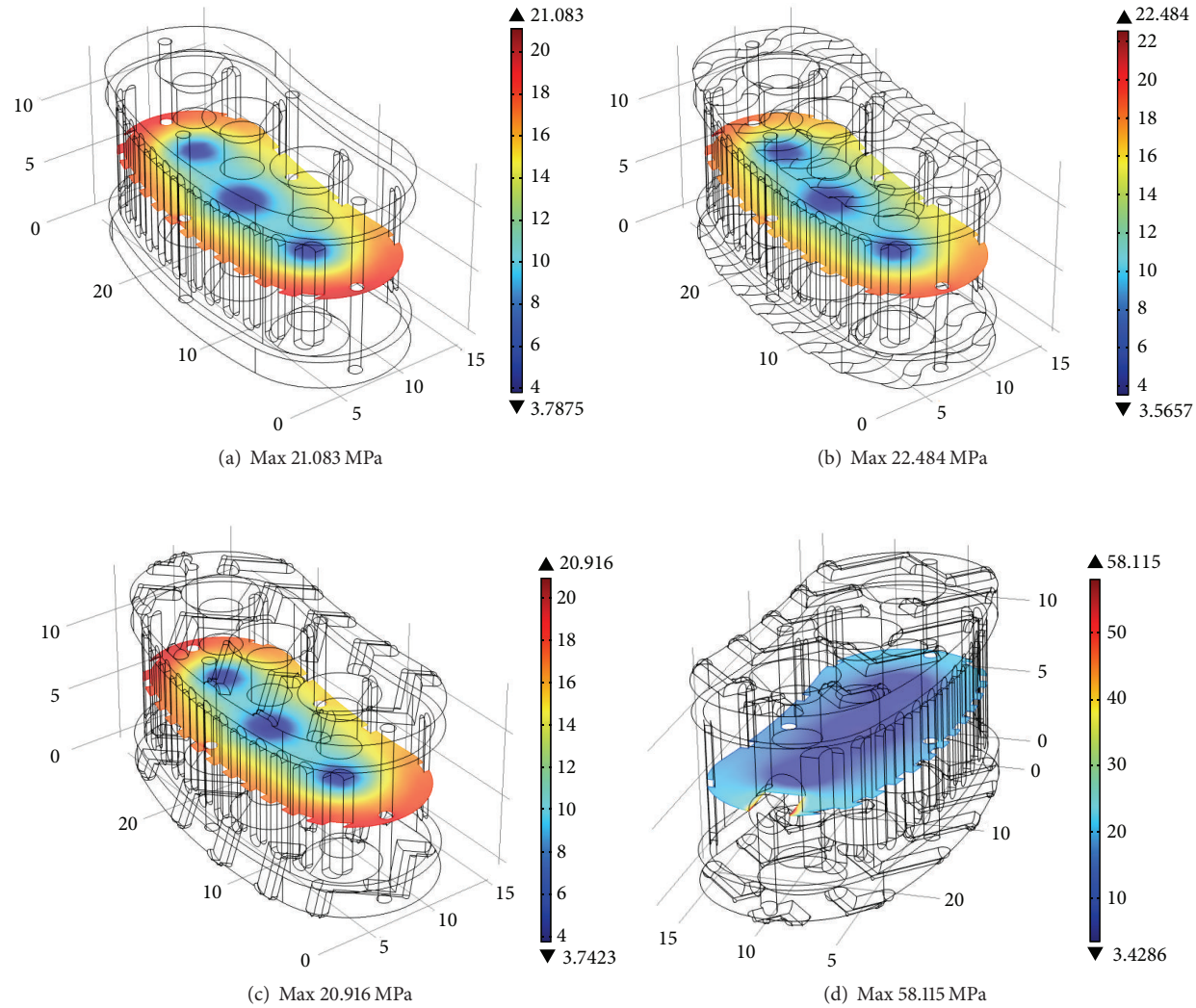
average of these loads was of 7,776 N and the standard deviation was of 102.3 N. Therefore, the process has a deviation error of 1.32% between the five experimental trials, a number that indicates a good repeatability of the process.

Table 3 shows the mechanical properties of PC-ISO cylindrical test specimens obtained from the initial mechanical compressive testing, in order to be used as preliminary data for the Finite Element Analysis. Compressive yield strength was calculated by dividing the load carried by the specimen at the yield point by the original minimum cross-sectional area of the specimen (126.7 mm^2). Figure 6 shows the comparison of the compression test of PC-ISO cylindrical test specimens of both 0.30 mm and 0.40 mm nozzle configurations.

5.2. Simulation Results for Lumbar Cage Concepts. Simulations results are explained in terms of the average von Mises stresses exhibited in different cross sections of the four design concepts. Figure 7 shows the Finite Element Analysis of prototypes manufactured with the 0.40 mm nozzle in a full isometric view, with a top cross-sectional area of 257 mm^2. Using the 4,000 N force as reference load, it is shown that the average von Mises stresses are up to 30 MPa for all prototypes. Complex geometry shows higher maximum von Mises stress. Figure 8 shows the middle cross section with an area of 268 mm^2 for concepts (a), (b), and (c). Concept (d) has a middle cross section area of 262 mm^2. As expected, all design concepts exhibited average von Mises stress of approximately 15 MPa. Stress increases in the outer regions of the cross section due to the complex geometry of the outside surface of the implant. In the case of concept (d), the maximum stress is higher compared to the other concepts due to the stress concentration effect of the handling hole.

Figure 9 shows the cross section of the top plane where the volumetric analysis (from Figure 7) shows the maximum von Mises stress. In this plane, the cross-sectional area is 247 mm^2 due to the blind holes incorporated in the design concept. Average von Misses stress should be 16.2 MPa. Stress concentration regions produce localized values up to 78.8 MPa.

5.3. Experimental Results for Lumbar Cage Concepts. Figure 10 shows a comparison between compressive strength tests of the proposed lumbar cage design (a) manufactured by the 0.30 mm nozzle and 0.40 mm nozzle. It is clearly



(a) Max 21.083 MPa

(b) Max 22.484 MPa

(c) Max 20.916 MPa

(d) Max 58.115 MPa

Figure 8: Cross section analysis for middle plane: von Mises stress distribution with 4,000 N as reference load.

seen from the same figure that the lumbar cage design manufactured by the 0.40 mm nozzle has better mechanical properties than those manufactured by the 0.30 mm nozzle. Further experimentation was limited to the 0.40 mm nozzle configuration.

Figure 11 shows the measured load (L) versus displacement (d) behavior of prototypes manufactured with the 0.40 mm nozzle. The best mechanical behavior is found in those design concepts with simpler geometrical elements, such as design (a) with the flat surface and design (b) with undulating features. However, the design concepts with more complex geometry (such as (c) and (d)) facilitate osseointegration and the surgical procedure during implantation.

5.4. Discussion. Based on the cylindrical samples, the reference compressive yield strength to consider is 55 MPa. The middle plane simulation analysis shows that, on average, stress level is well below the compressive yield strength of the FDM-printed PC-ISO material. Only in the case of concept (d), the maximum stress level exceeds the limit by small percentage (6%).

From the compression testing experimental results of the cylindrical specimens and the design concepts (Figures 6 and 10), the mechanical behavior exhibited at 1 mm of displacement is similar in terms of engineering stress. Specifically, the cylindrical specimens exhibited an approximate engineering stress of 54 Mpa (estimated with a cross section of 126 mm^2 and 6800 N) while the engineering stress at the middle cross section (estimated with 268 mm^2 and 15,000 N) of the design concepts is approximately 55 Mpa.

Local maximum stress levels are above the material strength in some regions. For the top plane analysis, all regions with maximum stress are above the material strength (between 14 and 43% higher stress compared to the material strength). The volumetric analysis shows regions that exceed the material strength by a large percentage (up to 143% in the case of design concept (d)).

In contrast to the FEM analysis results, using 4,000 N as the reference load, the actual compression test shows that the various design concepts are robust. For the case of design concepts (a) and (b), the yield behavior starts at approximately

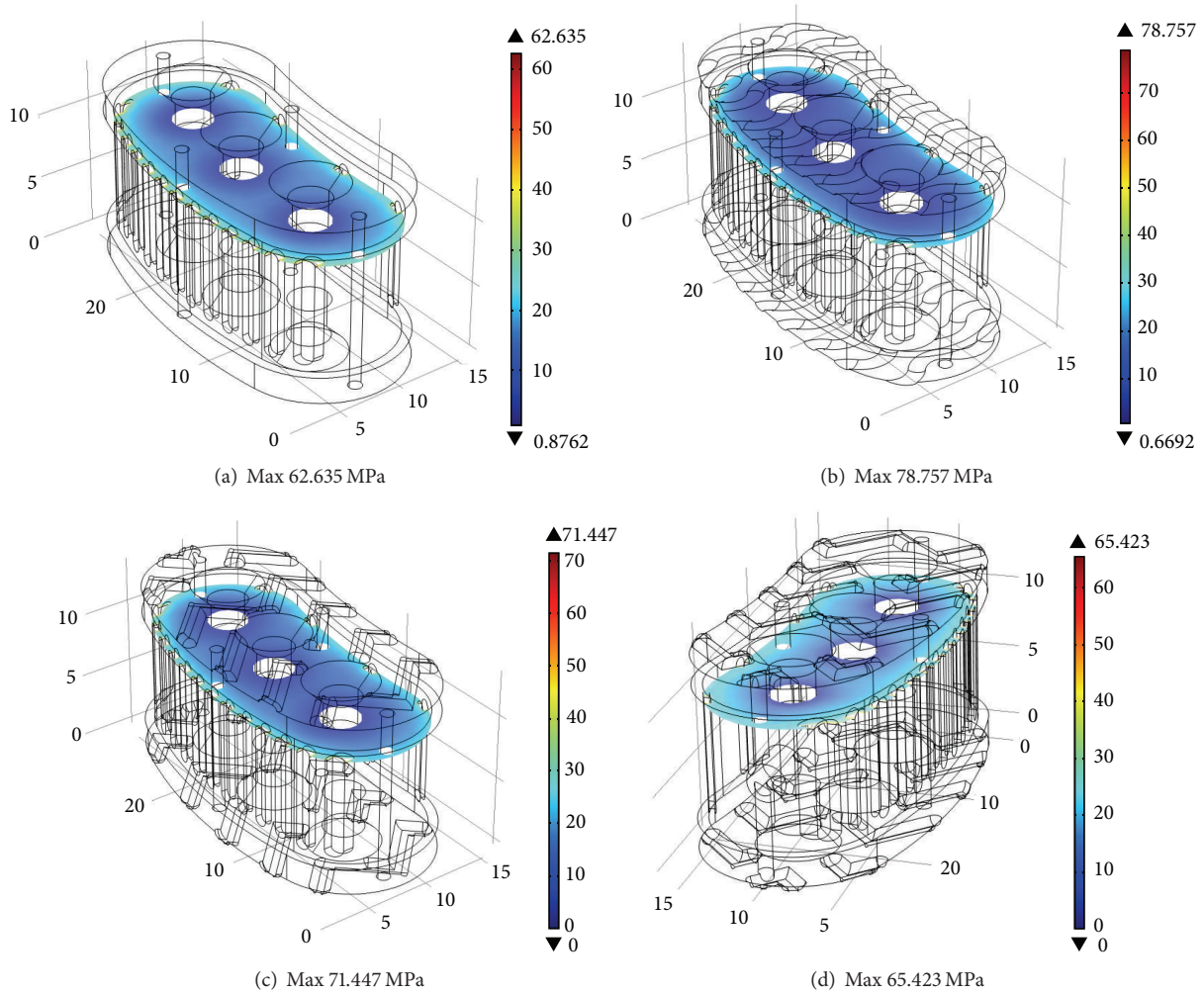


FIGURE 9: Cross section analysis for top plane: von Mises stress distribution with 4,000 N as reference load.

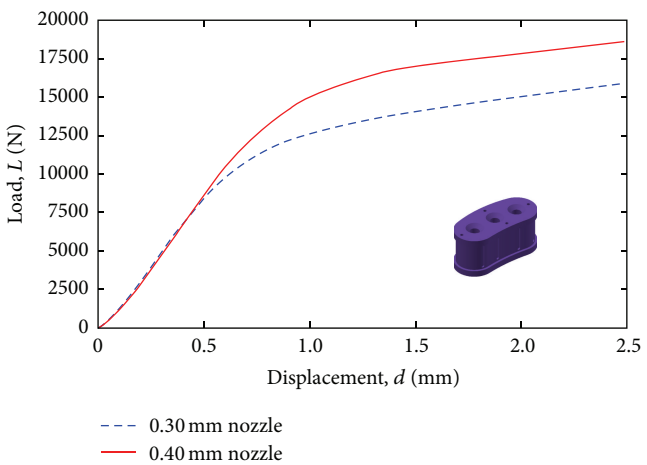


FIGURE 10: Compression testing for design concept (a), with different FDM nozzle configurations (0.30 versus 0.40 mm).

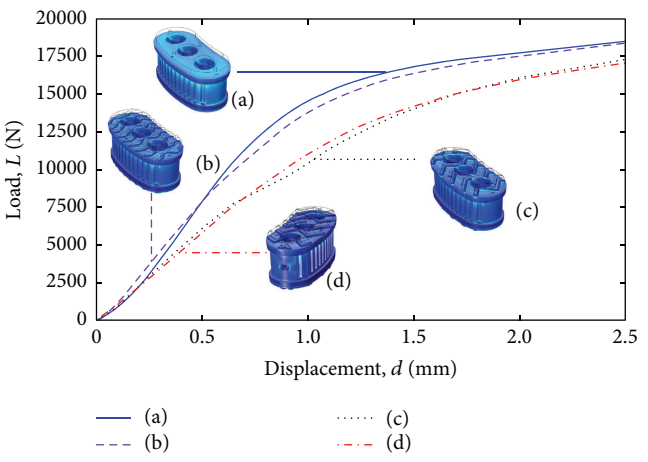


FIGURE 11: Compression testing for all design concepts with 0.40 mm nozzle configuration.

10,000 N. A load of approximately 7,500 N is supported by design concepts (c) and (d) before yielding is observed.

The FDM process cannot produce sharp corners due to geometry of the filament used for generation of each layer.

Therefore, this additive manufacturing process is beneficial to avoid stress concentration regions in the printed intervertebral lumbar cages. In addition, the FEM analysis shows that the stress concentration areas are quite localized. Therefore, it can be concluded that the high loads supported by the different design concepts are due to a combination of (a) localized stress concentration regions, (b) additive manufacturing process that intrinsically reduces stress concentration geometries, and (c) ductile nature of the PC-ISO material.

In order to further validate the proposed design concepts, additional testing under dynamic conditions is needed in order to assess the fatigue response of the material. In terms of the design concepts, additional refinements are required in order to reduce the amount of stress concentration due to sharp changes in geometry.

6. Conclusions and Future Work

This work has shown the viability of FDM-printed intervertebral lumbar cages based on biocompatible polycarbonate (PC-ISO material). Several design concepts are proposed for the generation of patient-specific intervertebral lumbar cages. Finite Element Analysis and compression testing show the viability of the proposed design concepts. The part interior style has a more significant influence than the build direction of the material deposition. Furthermore, PC-ISO material showed a high repeatability in the manufacture process for transverse-vertical build direction and solid part interior style parameters, achieving compressive yield strength of 55 MPa. The literature recommends a reference load of 4,000 N for design of intervertebral lumbar cages. Under compression testing conditions, the FDM-printed intervertebral lumbar cages withstand between 7,500 and 10,000 N of load before showing yielding.

Further research must be carried out with in vitro and in vivo testing in order to guarantee the full viability of the intervertebral lumbar cage implants that have been proposed in this work. Specifically, the validation should be carried out through the analysis of biocompatibility and osseointegration with the surrounding tissue, towards the full integration of 3D printed implants in the medical practice. The benefits of using 3D printing for each specific patient should potentially increase the ergonomics, simplify the procedure, and bring overall better personalized results once validated.

Competing Interests

The authors declare that there are no competing interests regarding the publication of this paper.

Acknowledgments

The authors would like to acknowledge the support of Tecnológico de Monterrey through its Research Group in Advanced Manufacturing. Support was also provided from the MADiT "National Lab of Additive Manufacturing, 3D Digitizing and Computerized Tomography" at Universidad Nacional Autónoma de México and from Centro de Tecnologia da Informação Renato Archer. Finally, the authors of this work would like to express their gratitude to Jan Lammel Lindemann, for his valuable comments.

References

[1] G. Gao and X. Cui, "Three-dimensional bioprinting in tissue engineering and regenerative medicine," *Biotechnology Letters*, vol. 38, no. 2, pp. 203–211, 2016.

[2] D. Radenkovic, A. Solouk, and A. Seifalian, "Personalized development of human organs using 3D printing technology," *Medical Hypotheses*, vol. 87, pp. 30–33, 2016.

[3] S.-S. Yoo, "3D-printed biological organs: medical potential and patenting opportunity," *Expert Opinion on Therapeutic Patents*, vol. 25, no. 5, pp. 507–511, 2015.

[4] J. Visser, F. P. Melchels, W. J. Dhert, and J. Malda, "Tissue printing; the potential application of 3D printing in medicine," *Nederlands Tijdschrift voor Geneeskunde*, vol. 157, no. 52, Article ID A7043, 2013.

[5] V. Petrovic, J. V. Haro Gonzalez, O. Jordá Ferrando, J. Delgado Gordillo, J. R. Blasco Puchades, and L. Portoles Grinan, "Additive layered manufacturing: sectors of industrial application shown through case studies," *International Journal of Production Research*, vol. 49, no. 4, pp. 1061–1079, 2011.

[6] T. M. Rankin, N. A. Giovinco, D. J. Cucher, G. Watts, B. Hurwitz, and D. G. Armstrong, "Three-dimensional printing surgical instruments: are we there yet?" *Journal of Surgical Research*, vol. 189, no. 2, pp. 193–197, 2014.

[7] N. de Beer and A. van der Merwe, "Patient-specific intervertebral disc implants using rapid manufacturing technology," *Rapid Prototyping Journal*, vol. 19, no. 2, pp. 126–139, 2013.

[8] J. Domanski, K. Skalski, R. Grygoruk, and A. Mróz, "Rapid prototyping in the intervertebral implant design process," *Rapid Prototyping Journal*, vol. 21, no. 6, pp. 735–746, 2015.

[9] D. Espalin, K. Arcaute, D. Rodriguez, F. Medina, M. Posner, and R. Wicker, "Fused deposition modeling of patient−specific polymethylmethacrylate implants," *Rapid Prototyping Journal*, vol. 16, no. 3, pp. 164–173, 2010.

[10] V. N. Chougule, A. V. Mulay, and B. B. Ahuja, "Development of patient specific implants for minimum invasive spine surgeries (MISS) from non-invasive imaging techniques by reverse engineering and additive manufacturing techniques," *Procedia Engineering*, vol. 97, pp. 212–219, 2014.

[11] O. Figueroa, C. A. Rodríguez, H. R. Siller et al., "Lumbar cage design concepts based on additive manufacturing," in *High Value Manufacturing: Advanced Research in Virtual and Rapid Prototyping*, P. H. da Silva Bártolo, A. C. S. de Lemos, A. M. H. Pereira et al., Eds., chapter 102, CRC Press, New York, NY, USA, 2013.

[12] M. Perez, M. Block, D. Espalin et al., "Sterilization of FDM-manufactured parts," in *Proceedings of the 23rd Annual International Solid Freeform Fabrication Symposium (SFF '12)*, pp. 285–296, Austin, Tex, USA, August 2012.

[13] J. Cunha, R. Sethi, K. Mellis et al., "WE-F-16A-01: commissioning and clinical use of PC-ISO for customized, 3D printed, gynecological brachytherapy applicators," *Medical Physics*, vol. 41, no. 6, article 514, 2014.

[14] S.-H. Ahn, M. Montero, D. Odell, S. Roundy, and P. K. Wright, "Anisotropic material properties of fused deposition modeling ABS," *Rapid Prototyping Journal*, vol. 8, no. 4, pp. 248–257, 2002.

[15] Stratasys, *Production-Grade Thermoplastic for Fortus 3D Production Systems*, Stratasys, Eden Prairie, Minn, USA, 2015.

[16] B. Schafer and H. Halm, "Intervertebral implant," United States of America Patent US 6,143,032, 2000.

[17] S. A. Webb, A. P. Moreno, M. E. Mitchell, and A. C. Smith, "Spinal implant," United States of America Patent US 7,806,932 B2, 2010.

[18] P. P. Varga and J. W. Ogilvie, "Intervertebral spacer," United States of America Patent US 6,579,318 B2, 2003.

[19] F. K. Fuss and R. J. Sabitzer, "Implant for insertion between spinal column vertebrae," United States of America Patent US 6,562,072 B1, 2003.

[20] M. A. Adams and P. Dolan, "Spine biomechanics," *Journal of Biomechanics*, vol. 38, no. 10, pp. 1972–1983, 2005.

[21] J. Lee and A. Huang, "Fatigue analysis of FDM materials," *Rapid Prototyping Journal*, vol. 19, no. 4, pp. 291–299, 2013.

[22] ASTM D695-10, *Standard Test Method for Compressive Properties of Rigid Plastics*, ASTM International, West Conshohocken, Pa, USA, 2010, https://www.astm.org/.

[23] H.-J. Wilke, P. Neef, B. Hinz, H. Seidel, and L. Claes, "Intradiscal pressure together with anthropometric data—a data set for the validation of models," *Clinical Biomechanics*, vol. 16, supplement 1, pp. S111–S126, 2001.

[24] A. Schultz, G. Andersson, R. Ortengren, K. Haderspeck, and A. Nachemson, "Loads on the lumbar spine. Validation of a biomechanical analysis by measurements of intradiscal pressures and myoelectric signals," *The Journal of Bone & Joint Surgery—American Volume*, vol. 64, no. 5, pp. 713–720, 1982.

Educ Med. 2017;18(1):37–43

Educación Médica

www.elsevier.es/edumed

ORIGINAL

Aprendizaje centrado en las perspectivas del paciente: el caso de las escuelas de medicina en México☆

Silvia Lizett Olivares Olivares, María de los Ángeles Jiménez Martínez, Mildred Vanessa López Cabrera*, José Antonio Díaz Elizondo y Jorge E. Valdez-García

Escuela de Medicina, Tecnológico de Monterrey, Monterrey, Nuevo León, México

Recibido el 3 de marzo de 2016; aceptado el 29 de julio de 2016
Disponible en Internet el 25 de agosto de 2016

PALABRAS CLAVE
Aprendizaje centrado en el paciente;
Aprendizaje clínico;
Estrategias educativas;
Modelo educativo

Resumen

Introducción: La educación médica ha evolucionado en etapas. La más reciente de educación basada en sistemas implica un análisis desde perspectivas de alta complejidad para alinearlas a las necesidades del paciente. De esta forma surge el aprendizaje centrado en las perspectivas del paciente que incluye 4 dimensiones: humana, biomédica, gestión y emprendimiento.

Objetivo: Describir el concepto de aprendizaje centrado en las perspectivas del paciente como estrategia didáctica y explorar su aplicación en las escuelas de medicina de México.

Material y métodos: El método fue exploratorio, descriptivo y transeccional. Se realizó una encuesta a 85 profesores y directivos pertenecientes a escuelas de medicina afiliadas a la Asociación Mexicana de Facultades de Escuelas de Medicina (AMFEM) para evaluar la implementación de las dimensiones del aprendizaje centrado en las perspectivas del paciente en escala Likert de 1 (Totalmente en desacuerdo) a 5 (Totalmente de acuerdo).

Resultados: La media por perspectiva fue: humana (3,76), biomédica (3,72), gestión (3,49) y emprendimiento (3,33). Destaca el mayor énfasis en ¿quién es el paciente? y el menor en ¿cómo puedo mejorar?

Discusión: El modelo presentado evoluciona desde la educación basada en competencias implementadas en la educación a partir de contenidos aislados, a un enfoque en base a perspectivas que colocan en el centro al paciente para abordar desde un mismo caso múltiples competencias del médico.

☆ Este trabajo fue presentado en el V Congreso Internacional de Educación Médica, así como en el III Congreso Internacional de Innovación Educativa.

* Autora para correspondencia.
Correo electrónico: mildredlopez@itesm.mx (M.V. López Cabrera).

http://dx.doi.org/10.1016/j.edumed.2016.07.006

KEYWORDS
Patient-centred learning;
Learning in the clinical setting;
Teaching techniques;
Educational model

Perspectives on patient centred learning: A study in Mexican medical schools

Abstract
Introduction: Medical education has evolved through severel stages. The most recent one, systems-based learning, involves an analysis of complex perspectives an adapting them to patient needs. From this notion, the concept perspectives for patient centred learning emerges. It includes four dimensions: human, biomedical, managerial, and entrepreneurial.
Objective: The aim of this study was to define the perspectives for patient centred learning as a teaching strategy and examine its application in medical schools in Mexico.
Material and methods: The method was exploratory, descriptive and cross-sectional. A questionnaire was completed by 85 faculty members and deans from the Mexican Association of Schools and Faculties of Medicine (AMFEM for its initials in Spanish) to assess the implementation of perspectives for patient centred learning, using a Likert scale from 1 (Total disagreement) to 5 (Total agreement).
Results: The mean calculated by perspective was: human (3.76), biomedical (3.72), management (3.49), and entrepreneurship (3.33). Higher emphasis was placed on who is the patient?, and a lower focus on how the system should be improved?
Discussion: The presented model evolves from a competency based framework implemented in education as isolated contents, to a perspective based focus that places the patient in the centre, analysing the same case from multiple medical skills.

Introducción

A fin de responder a las necesidades y retos del siglo XXI, la educación médica de pregrado requiere un proceso de transformación, el cual es manifestado en diversas etapas desde la diseminación del Informe Flexner[1]. Es así como Frenk[2] identifica 3 grandes generaciones de reformas en Norteamérica. La primera la denomina *educación basada en ciencias*, la cual se estructura con las recomendaciones del Informe Flexner estableciendo un periodo inicial de formación en ciencias básicas seguido de un periodo de entrenamiento clínico[2,3]. Lo anterior, con el objetivo de superar la falta de rigor académico y estandarización observada en las escuelas de medicina.

La segunda generación de reformas, identificada como la *educación basada en problemas*, surgió después de la segunda guerra mundial. De acuerdo con Frenk[2], los principales cambios que se introdujeron con esta reforma curricular fue la enseñanza basada en problemas, el currículum integrado y el aprendizaje centrado en el alumno, donde destaca como pionera la Universidad de McMaster en Canadá. El énfasis de este modelo se mantuvo en la adquisición del conocimiento científico, incorporando nuevos principios para favorecer el aprendizaje activo centrado en el alumno.

Con el inicio del siglo XXI emergió la tercera y más reciente generación de reformas denominada *educación basada en sistemas*. Esta incluye la atención centrada en el paciente y la comunidad; el currículum por competencias; la educación interprofesional; el uso de tecnologías de información en el aprendizaje así como el desarrollo de habilidades de gestión y liderazgo en los profesionales de la salud. En concordancia con esta tercera perspectiva, diversas organizaciones y expertos de universidades de prestigio señalan que el conocimiento científico y la habilidad clínica no son suficientes para responder a los nuevos y complejos retos de la población y los sistemas de salud en este siglo[4,5].

Específicamente sobre la atención centrada en el paciente, Pelzang[6] menciona que el tema ha tenido una significativa expansión en los sistemas de salud de los EE. UU., Reino Unido, Europa y Asia, impulsando el desarrollo de nuevos modelos de formación de profesionales de la salud. Sin embargo, poco se ha profundizado sobre su implementación y desarrollo en los países de Latinoamérica, como el caso de México, donde se centra el presente estudio.

Atención clínica centrada en el paciente

Los modelos de atención clínica centrada en el paciente se han reformulando gradualmente desde el último tercio del siglo pasado, por parte de instituciones de salud (el *Institute of Medicine*, IOM; el *Institute of Health Care Improvement*; el *National Health Council* y la *Joint Commision*), estudios de diversos autores[7–10] y algunas organizaciones de pacientes (*Picker Institute Europe*, *Planet Tree* y la *International Alliance of Patients' Organizations*, IAPO).

No existe consenso en torno a la definición de la atención centrada en el paciente, ni respecto a las dimensiones o aspectos que deben considerarse como parte de este enfoque, según se reporta en diversos artículos y revisiones sistemáticas[11–14]. Gerteis et al.[8] la describen desde una perspectiva *humana* asociándola con respeto a los valores, preferencias y necesidades expresadas por el paciente así como la comunicación y educación asegurando el bienestar físico, alivio del miedo y control de la ansiedad. Stewart et al.[10] la refieren desde una perspectiva *biomédica* considerando la exploración de la enfermedad y su cuidado de forma integral. La IAPO[15] además integra en su definición conceptos de *gestión* refiriendo el acceso oportuno y confiable de la

atención en salud, personal competente en el tratamiento, transiciones adecuadas entre procesos y el involucramiento de la familia en el cuidado del paciente. Diversos autores han hecho énfasis en incorporar de forma gradual la atención centrada en el paciente en políticas públicas, marcos regulatorios y estándares de acreditación de hospitales y escuelas de medicina[16], lo cual le da carácter de *emprendimiento* a la necesidad de transformar los sistemas de salud y otras organizaciones asociadas.

Desgraciadamente, las escuelas de medicina han disgregado cada uno de estos conceptos, centrándose primordialmente en el conocimiento biomédico a nivel individual. De alguna forma, han separado estas 4 perspectivas del paciente y de los sistemas de salud al establecer los contenidos en materias independientes y aisladas que pocas veces incluyen aspectos relacionados con las humanidades, la gestión o la ética.

Integración de la atención centrada en el paciente en la formación médica

Existen diferentes modelos para describir y categorizar las competencias que deben desarrollar los estudiantes y/o profesionales en diferentes áreas disciplinares en el contexto de la educación superior[17,18]. Olivares[19] propone un modelo de competencias con 4 categorías: individual, interpersonal, organizacional y contextual. Las competencias individuales se refieren a los recursos personales que hacen evidente la capacidad que tiene el estudiante o profesional para realizar una determinada tarea. Las competencias interpersonales suponen habilidades para la relación con otros. Las competencias organizacionales son las requeridas para administrar tanto equipos de trabajo como recursos económicos dentro de una organización. Las competencias contextuales o sistémicas consideran destrezas y habilidades relacionadas con la totalidad de un sistema ya que requieren la combinación de imaginación, sensibilidad y habilidad que permite ver cómo se relacionan y conjugan las partes de un todo.

En lugar de competencias independientes, algunos autores del área de liderazgo han utilizado el concepto de perspectivas[20,21] para integrar estas capacidades de una forma más orgánica. La ventaja de estos modelos es que se puede analizar la misma situación desde diferentes filosofías. La perspectiva estructural de Bolman y Deal[20] refiere decisiones racionales atendiendo principios, lineamientos y procedimientos, la cual Adizes[21] nombra como racional, por estar asociada con decisiones en base a datos objetivos. Asimismo incluye la perspectiva de procesos internos. Ambos autores consideran la perspectiva humana, la cual se refiere a las relaciones interpersonales. La perspectiva política atiende aspectos de poder e influencia en el contexto[20]. Estos autores mencionan a la perspectiva simbólica, la cual atiende aspectos filosóficos y culturales de transformación, la cual Adizes describe como sistemas abiertos, los cuales abordan un enfoque multifactorial de reflexión. Si bien el concepto de competencias ha sido ampliamente aceptado y utilizado, este enfoque en perspectivas integra múltiples habilidades en una misma situación bajo estudio, que en el caso de la educación médica debería ser el paciente.

En contraste, los modelos de formación generalmente han estado centrados en el experto y en los aspectos biomédicos de la enfermedad. Es por esto que se requiere evolucionar hacia un modelo colaborativo donde se incluyan las necesidades del paciente y otros elementos del contexto[22,23]. En México, el estudio de Olivares et al.[24] mostró que más del 50% de las escuelas de medicina no han demostrado métodos de innovación en sus prácticas educativas. Los autores concluyen sobre la urgencia de mejorar sus estrategias de medición y aseguramiento del cumplimiento de objetivos tangibles que impacten los sistemas de salud.

Diseño de un modelo formativo de aprendizaje centrado en las perspectivas del paciente

Ante la necesidad de evolucionar hacia una educación que atienda los requerimientos del paciente, los sistemas de salud y la comunidad[25], se diseñó un modelo formativo de aprendizaje centrado en las perspectivas del paciente (ACP). Para diseñar esta propuesta, se transformó la clasificación de competencias de Olivares[19] en un enfoque de perspectivas que pueden abordarse con diferente énfasis según los momentos de enseñanza y del encuentro clínico. Con dichos enfoques se busca fortalecer el conocimiento médico y la competencia clínica que tradicionalmente compone el currículum de educación médica en forma segmentada, con el desarrollo intencional y sistemático para gestionar efectivamente y actuar con un liderazgo transformador en las organizaciones y los sistemas de salud, teniendo como centro al paciente como persona, en su contexto familiar, institucional, ambiental y social.

Leinster[26] señala que la exposición clínica, que se da mediante el contacto de los estudiantes con los pacientes, sin una guía adecuada por parte del profesor es insuficiente para producir el aprendizaje, por lo que se requiere asegurar el involucramiento activo de los estudiantes. De allí la importancia del ACP como vía para sistematizar el desarrollo, retroalimentación y evaluación de las competencias del profesional de la salud a lo largo del currículum, capitalizando cada situación o encuentro con el paciente para reflexionar con las 4 perspectivas. De esta forma el ACP se define como una estrategia didáctica en la que el aprendizaje y la enseñanza se organizan en torno a las necesidades y problemas de salud de pacientes reales, simulados o virtuales[3], desde los enfoques humano, biomédico, de gestión y de emprendimiento, como se muestra en la figura 1.

La parte *humana* se asocia con el entendimiento profundo del individuo desde una perspectiva psicológica, cultural y social, atendiendo su dignidad humana, junto con sus derechos como paciente. Responde a la pregunta ¿quién es el paciente? La perspectiva *biomédica* es el marco de referencia de la disciplina donde convergen las ciencias y el conocimiento médico a nivel conceptual, comprendiendo la condición y estado del paciente y responde a la pregunta ¿cuál es el motivo de consulta del paciente? La *gestión* orienta hacia la eficiencia en el uso de recursos de personal, tiempo, materiales, costo e infraestructura maximizando seguridad y calidad de la atención así como el cumplimiento de la normativa correspondiente durante todo el proceso de intervención. Responde a la pregunta ¿cuál es la mejor alternativa para ayudar al paciente con su motivo de consulta? El *emprendimiento* es la dimensión que permite el entendimiento del contexto en el que está inmerso el individuo

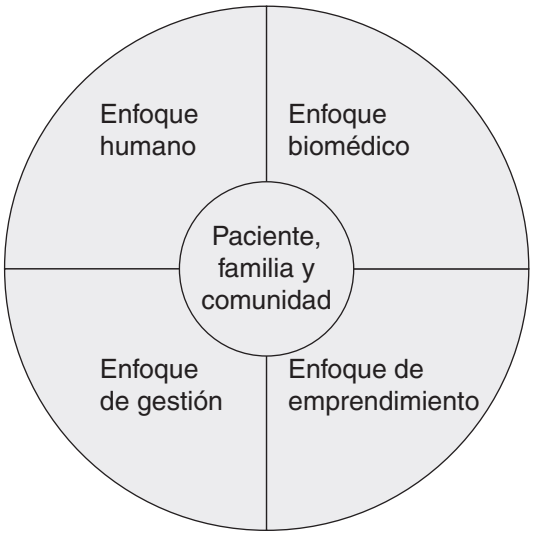


Figura 1 Modelo de aprendizaje centrado en las perspectivas del paciente.

con la posibilidad de extrapolarlo hacia grupos o poblaciones buscando comprender las determinantes sociales de la salud y extender las soluciones para el logro de una transformación social. Responde a la pregunta ¿cómo se podría mejorar la atención o prevenir la situación de este paciente en lo sucesivo?

El ACP procura la integración del aprendizaje de las ciencias básicas y las ciencias clínicas en torno a los problemas que presenta el paciente, con especial énfasis en el cuidado y bienestar del mismo en todas las etapas del proceso de atención[27]: a) conocimiento integral, b) diagnóstico, c) intervención, d) implementación, seguimiento y evaluación, como se muestra en la figura 2.

El presente estudio tiene el objetivo de describir el concepto de ACP como una estrategia didáctica así como explorar su aplicación actual en las escuelas de medicina de México. Por lo que surge la pregunta de investigación: ¿cuál es la autopercepción del grado de aplicación de cada una de estas dimensiones en las escuelas de medicina en México?

Material y métodos

Las actividades realizadas fueron: 1) diseño del instrumento de medición, 2) prueba piloto y 3) análisis de resultados de la encuesta y confiabilidad.

Diseño de la encuesta

Partiendo de la búsqueda en la literatura, se integró un modelo de perspectivas del ACP. Considerando las dimensiones del modelo, se propusieron 4 reactivos para cada una, los cuales fueron evaluados con una escala Likert de 1 (Totalmente en desacuerdo) a 5 (Totalmente de acuerdo).

Prueba piloto

Se realizó una implementación piloto en las escuelas de enfermería que eran miembros de la Federación Mexicana de Facultades y Escuelas de Enfermería (FEMAFEE), la cual fue contestada por 144 profesores, estudiantes y directivos. En base a los resultados obtenidos en la prueba piloto se mejoró la redacción de 2 ítems de la perspectiva de humana.

Fases / Enfoques	Conocimiento integral	Diagnóstico	Intervención	Implementación, seguimiento y evaluación
Psicosocial	¿Quién es el paciente?			¿Cuáles son los elementos psicosociales que debo considerar?
Biomédico	¿Por qué el paciente requiere atención médica?	¿Cuál es la historia clínica de paciente? ¿Cuáles son los heehos e inferencia sobre el diagnóstico sintomático y sindromático?		
Gestión			¿Qué debo y puedo hacer para la atención del paciente? ¿Cuáles son las alternativas de tratamiento?	¿Cómo puedo desarrollar la implementación del tratamiento?
Emprendimiento				¿Cómo podría mejorar el proceeso de atención? Si pudieras prevenir o resolver el padecimiento, ¿Qué pudieras hacer?

Figura 2 Etapas de atención clínica de acuerdo al aprendizaje centrado en las perspectivas del paciente.

Tabla 1 Resultados por perspectiva

Perspectiva	Ítem	Media	Desviación estándar
Humana	El paciente siempre es identificado por los estudiantes como ser humano que tiene un nombre, apellido e historia personal	4,07	1,13
	El paciente es atendido por los estudiantes de acuerdo a su contexto social (familia, trabajo, estudios, condición económica, etc.)	3,59	1,27
	El paciente es reconocido por los estudiantes como individuo cuya dignidad y derechos se anteponen a las voluntades de terceros	4,05	1,11
	El paciente es considerado por los estudiantes como persona porque le dedican tiempo a indagar sobre su espiritualidad y emociones	3,25	1,23
	Total perspectiva:	**3,76**	**1,23**
Biomédica	Los alumnos aprenden sobre conocimientos actualizados de la disciplina	4,18	1,03
	Los alumnos dominan otras disciplinas de conocimiento, como ciencias exactas y humanidades	3,27	1,21
	Los alumnos realizan búsquedas de información basadas en la mejor evidencia científica	3,86	1,11
	Los alumnos aplican el pensamiento crítico para identificar soluciones a necesidades de salud	3,70	1,17
	Total perspectiva:	**3,72**	**1,14**
Gestión	Se ofrecen oportunidades para que los alumnos participen en proyectos para garantizar la calidad y seguridad del paciente	3,61	1,27
	Se ofrecen oportunidades para que los alumnos demuestren acciones de intervención que incluyen dilemas éticos y profesionales	3,71	1,31
	Se ofrecen oportunidades para que los estudiantes dirijan equipos para mejorar la eficacia y eficiencia en el uso de los recursos	3,57	1,4
	Se ofrecen oportunidades para que los estudiantes administren y mejoren indicadores de satisfacción del paciente	3,41	1,51
	Total perspectiva:	**3,49**	**1,14**
Emprendimiento	Durante los estudios los alumnos transforman su comunidad a partir de proyectos concretos	3,59	1,60
	Durante los estudios los alumnos ejecutan acciones educativas y de prevención para evitar problemas de salud	3,88	1,59
	Durante los estudios los alumnos proponen cambios de normativas y políticas institucionales o gubernamentales	3,07	1,82
	Durante los estudios los alumnos generan conocimiento y los transfieren a través de publicaciones	3,29	1,85
	Total perspectiva:	**3,33**	**1,25**

Análisis de resultados de la encuesta y confiabilidad

El método fue exploratorio, descriptivo y transeccional[28,29]. Se realizó una encuesta a 85 profesores y directivos pertenecientes a escuelas de medicina afiliadas a la Asociación Mexicana de Facultades y Escuelas de Medicina (AMFEM) para evaluar su aplicación de las 4 perspectivas del paciente. Se utilizaron 4 reactivos por dimensión para obtener respuestas en escala Likert de 1 (Totalmente en desacuerdo) a 5 (Totalmente de acuerdo).

Se utilizaron los datos para calcular la consistencia interna del instrumento utilizando el alfa de Cronbach. Este coeficiente mide la fiabilidad de una escala utilizando como referencia la correlación entre los distintos ítems. En esta aplicación se obtuvo un alfa de Cronbach de 0,861, el cual fue considerado como aceptable por ser superior a 0,7[30]. Se utilizó estadística descriptiva para analizar las respuestas de los participantes donde se calculó la media de la población bajo estudio. A continuación se describen los resultados obtenidos.

Resultados

De acuerdo a la tabla 1, la perspectiva con una mayor adopción en las escuelas de medicina es la humana con una media de 3,76 y la biomédica con una media de 3,72. En contraste, la que obtuvo una menor implementación fue la de emprendimiento, con una media de 3,33 y una desviación de 1,25.

Dentro de la perspectiva humana, se obtuvo una media superior en el ítem que asegura que el paciente siempre es identificado por los estudiantes como ser humano que tiene un nombre, apellido e historia personal (4,07), y la más baja se encontró en el relacionado con indagación sobre su espiritualidad y emociones.

En la perspectiva biomédica, la media más favorable se obtuvo en la adquisición sobre conocimientos actualizados de la disciplina (4,18), y la menos favorable en el dominio de

otras disciplinas del conocimiento como las ciencias exactas o las humanidades (3,27).

Para la perspectiva de gestión, la media más alta se obtuvo en el ítem de las oportunidades de intervención que incluyen dilemas éticos y profesionales (3,71), y la más baja en las oportunidades para que los estudiantes administren y mejoren indicadores de satisfacción del paciente (3,41).

Por último, en la perspectiva de emprendimiento, el ítem de las oportunidades para proponer cambios normativos y políticas institucionales o gubernamentales (3,07) tuvo la media más baja del instrumento aplicado. La media más alta de esta perspectiva se obtuvo en el ítem de ejecución de acciones educativas y de prevención para evitar problemas de salud (3,88).

Discusión

Los resultados presentados indican un énfasis mayor en la perspectiva humana y biomédica; sin embargo, solo un 16% se autopercibe en el nivel 5 (Totalmente de acuerdo) de la escala en estas dimensiones. Dado que este estudio es exploratorio es importante continuar la investigación sobre los instrumentos utilizados y los resultados obtenidos aquí presentados.

En cuanto a la gestión, estos resultados coinciden con las propuestas de autores que consideran que se requiere hacer énfasis en brindar experiencias a los pacientes que deriven en una mayor satisfacción a partir de una menor cantidad de pruebas diagnósticas y reducción del sobreuso de los servicios médicos así como de la subutilización de los mismos[6]. Como estrategia para fortalecer esta perspectiva, se recomienda abordar los conceptos de calidad y seguridad del paciente, consideraciones éticas y análisis de los costos involucrados al establecer cursos de intervención para cada caso analizado, independientemente si es en escenario virtual, simulado o real. Los pacientes simulados se refieren a casos clínicos y ambiente simulados, en donde el paciente es un modelo o un actor. Los pacientes virtuales se aplican con actividades de aprendizaje basadas en casos clínicos con planteamientos hipotéticos o reales de un paciente, en forma escrita, gráfica o multimedia (casos, videos, comics, iBooks, etc.).

Para favorecer la perspectiva de emprendimiento se recomienda aumentar la incorporación de reflexión sobre estrategias de prevención, protocolos de investigación, educación, tecnología, regulaciones o modelos de negocio que permitan transformar la atención a pacientes en el consultorio, piso de hospital, quirófano, cuidados intensivos, emergencias, laboratorio clínico, o bien en otros escenarios clínicos como en escuelas, empresas, centros comunitarios y organizaciones sociales.

Los beneficios en la atención centrada en el paciente radican en el aumento de su satisfacción respecto al cuidado de su salud y resultados clínicos[15]. Las ventajas de este modelo en la educación residen en su carácter multidimensional, que permite la integración de competencias en el profesional de la salud. Asimismo, posibilita tomar en cuenta, además del desempeño individual, las capacidades de interacción, la organización y el entorno, extrapolando esto último a partir de las necesidades del paciente. También contempla reiterativamente las competencias transversales junto con las disciplinares en los distintos ámbitos de desempeño del profesional de la salud. En síntesis, cambia hacia una nueva visión de la formación integral, orientada a profundizar en la transformación del entorno en el cual el estudiante y futuro profesional se desenvuelve.

Financiación

No se tuvo financiación para esta investigación.

Conflicto de intereses

Los autores declaran no tener ningún conflicto de intereses.

Agradecimientos

Se agradece a la Federación Mexicana de Asociaciones de Facultades y Escuelas de Enfermería (FEMAFEE) la oportunidad de aplicar la encuesta durante el XXXII Congreso Nacional de la FEMAFEE: Educación, Investigación y Cuidado.

Se agradece a la Asociación Mexicana de Facultades y Escuelas de Medicina (AMFEM) la oportunidad de aplicar la encuesta durante la XCVI Reunión Extraordinaria de la AMFEM: Retos y Desafíos de la Educación Médica en el Sistema Nacional de Salud.

Bibliografía

1. Flexner A. Medical education in the United States and Canada. [Internet]. New York: The Carnegie Foundation for Advancement of Teaching; 1910 [citada 27 Feb 2016]. Disponible en: http://archive.carnegiefoundation.org/pdfs/elibrary/Carnegie_Flexner_Report.pdf
2. Frenk J. Health professionals for a new century: Transforming education to strengthen health systems in an interdependent world. Lancet. 2010;376:1923–58.
3. Smith M, Stephen R, Cookson J, Mickendree J, Harden R. Patient-centred learning - back to the future. Med Teach. 2007;29:33–7.
4. AMA. Accelerating change in Medical Education: Creating the Medical School of the future. Chicago: American Medical Association; 2015.
5. MEDINE. Curriculum trends in medical education in Europe in the 21st Century. Association for Medical Education in Europe 2013 Conference; 2013 Ago 21-24 Ago; Prague. Dundee: Medical Education in 2 Europe; 2013.
6. Pelzang R. Time to learn: Understanding patient-centred care. Br J Nurs. 2010;19:912–8.
7. Balint E. The possibilities of patient-centered medicine. J R Coll Gen Pract. 1969;17:269–76.
8. Gerteis M, Edgman-Levitan S, Daley J, Delbanco T. Through the patient's eyes: Understanding and promoting patient-centered care. San Francisco: Jossey-Bass; 1993.
9. Epstein R, Street R. The values and value of patient-centered care. Ann Fam Med. 2011;9:100–3.
10. Stewart M, Brown J, Weston W, McWhinney I, McWilliam C, Freeman T. Patient-centered medicine. Transforming the clinical method. Thousand Oaks, CA: Sage Publishing; 2013.
11. Mead N, Bower P. Patient-centredness: A conceptual framework and review of the empirical literature. Soc Sci Med. 2000;51:1087–110.

12. Robinson J, Callister L, Berry J, Dearing K. Patient-centered care and adherence: Definitions and applications to improve outcomes. J Am Acad Nurse Pract. 2008;20:600–7.
13. Bensberg M. Patient centred care literature review [Internet]. Dandenong: Dandenong District Division of General Practice; 2007 [citado 27 Feb 2016]. Disponible en: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.663.7299&rep=rep1&type=pdf
14. Kitson A, Marshal A, Basset K, Zeitz K. What are the core elements of patient-centred care? A narrative review and synthesis of the literature from health policy, medicine and nursing. J Adv Nurs. 2012;69:4–15.
15. IAPO. What is patient-centred healthcare? A review of definitions and principles [Internet]. Londres: International Alliance of Patients' Organizations; 2004 [citada 27 Feb 2016]. Disponible en: http://iapo.org.uk/sites/default/files/files/IAPO%20Patient-Centred%20Healthcare%20Review%202nd%20edition.pdf
16. Scholl I, Zill J, Harter M, Dirmaier J. An integrative model of patient centeredness. A systematic review and concept analysis. PLOS One. 2014;9:1–9.
17. Bennett N, Dunn E, Carre C. Patterns of core and generic skill provision in higher education. High Educ. 1999;37:71–93.
18. Villa A, Poblete M. Aprendizaje basado en competencias. Bilbao: Universidad de Deusto; 2007.
19. Olivares S. Diverse contemporary issues facing business management education. Hershey, P.A: IGI Global; 2015. Chapter 3, Competencies needed by business graduates.
20. Bolman LG, Deal TE. Reframing organizations: Artristy, choice and leadership. California: Wiley; 2013.
21. Adizes I. Ciclos de vida de la organización. California: Ed. Díaz Santos; 1994.
22. Reid Ponte P, Conlin G, Conway JB, Grant S, Medeiros C, Nies J, et al. Making Patient-centered come alive. J Nurs Adm. 2003;33:82–90.
23. Silow-Caroll S, Alteras T, Stepnick L. Patient-centered care for underserved populations: definition and best practices. Washington: The W. K. Kellogg Foundation; 2006.
24. Olivares SL, Garza A, Valdez JE. Etapas del modelo incremental de calidad: un análisis de las escuelas de medicina en México. Inv Ed Med. 2016;5:24–31.
25. Rodríguez J, Dackiewicz N, Toer D. La gestión hospitalaria centrada en el paciente. Arch Argent pediatr. 2014;112:55–8.
26. Leinster S. Learning in the clinical environment. Med Teach. 2009;31:79–81.
27. Dornan T. Experience based learning. Learning clinical medicine in workplaces [dissertation]. Maastricht: Universitaire Pers Maastricht; 2006.
28. Clark-Carter D. Investigación cuantitativa en psicología: del diseño experimental al reporte de investigación. México: Universidad Iberoamericana; 2002.
29. Hernández R, Fernández C, Baptista LP. Metodología de la investigación. México: McGraw Hill; 2006.
30. Vogt P. Quantitative research methods for professionals. Boston: Pearson/Allyn and Bacon; 2007.

SURGICAL INFECTIONS CASE REPORTS
Volume 1.1, 2016
Mary Ann Liebert, Inc.
Pp. 103–105
DOI: 10.1089/crsi.2016.0029

Case Report

Eosinophilic Acute Appendicitis and Intra-Abdominal Granuloma Caused by *Enterobius vermicularis* in a Pediatric Patient

Ulises Garza-Serna,[1] Alan Ramos-Mayo,[1] Dolores Lopez-Garnica,[1] Javier Lopez-Morales,[1] Jose Diaz-Elizondo,[2] and Eduardo Flores-Villalba[2]

Abstract

Background: *Enterobius vermicularis* infection is one of the most common causes of parasitic infection of the gastrointestinal tract, affecting almost 30% of the pediatric population worldwide.
Conclusion: Although it is unclear whether *E. vermicularis* mimics acute appendicitis by occluding the lumen of the appendix, we present a case of acute appendicitis in a patient with clinical and radiologic signs of appendicitis confirmed by microscopic acute inflammatory changes of the appendix and the presence of an intra-peritoneal granuloma.

Enterobius vermicularis infection is one of the most common parasitic infections in the gastrointestinal tract with an incidence of 4%–28% in the pediatric population [1]. *Enterobius vermicularis* is a parasite that lives exclusively in human beings and has been associated with surgical pathologies and infections such as colitis, peri-anal abscesses, intra-abdominal granulomas, pelvic inflammatory disease, and appendicitis [2]. Its presence on the lumen of the appendix can cause obstruction and simulate signs and symptoms of appendicitis in 0.2%–41.8% [1]. Some series indicate that it does not cause appendicitis [3]. Intra-abdominal granuloma secondary to *E. vermicularis* has been reported once in a 32-year-old female at the fallopian tubes [4]. Here, we present a 12-year-old female with eosinophilic acute appendicitis and intra-abdominal granuloma caused by *E. vermicularis* with histopathologic confirmation.

Case Report

A 12-year-old female presented to the emergency department with a three-day history of abdominal pain that started at the epigastrium and migrated to the right lower quadrant; the pain was associated with anorexia and nausea. The patient received three doses of azithromycin from her primary care physician before presenting at the emergency department. Physical examination revealed McBurney and Rovsing positive signs.

Complete blood count (CBC) showed the presence of eosinophilia without elevated white blood cell count. An abdominal ultrasound showed the presence of a tubular structure 10 mm in diameter confirming appendicitis (Fig. 1).

The patient underwent a laparoscopic appendectomy. The appendix was identified as edematous and an inflammatory process was found incidentally adhered to the anterior abdominal wall.

The laparoscopic appendectomy was completed using endoloops, and immediately after the incision of the base of the appendix with laparoscopic scissors the presence of *E. vermicularis* (pinworms) was observed; these were removed surgically with suction (Fig. 2). The appendix was then removed through the umbilical port.

Pathology confirmed the presence of appendicitis with eosinophils and the presence of nematodes Oxyuroidae *(E. vermicularis);* the abdominal wall lesion with abscess, eosinophils and granulomatous tissue was caused by Oxyuroidae (Fig. 3). The patient was discharged with anti-parasitic medication, which was also provided for all close relatives.

Discussion

Appendicitis and *E. vermicularis* are common in the pediatric population and have been associated since the first description in 1970 [5]. Appendicitis and *E. vermicularis* can

[1]Escuela de Medicina, [2]Escuela de Ingenieria, Instituto Tecnologico y de Estudios Superiores de Monterrey, Monterrey, Nuevo Leon, Mexico.

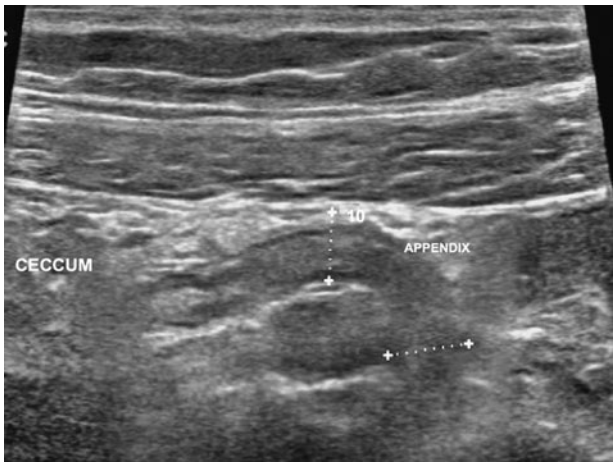


FIG. 1. Transverse ultrasound of the right lower quadrant with a non-compressible 10-mm tubular structure compatible with appendicitis.

coexist without presenting any clinical signs or symptoms and have been described as incidental findings at microscope evaluation, as well as other parasites such as Ascaris and *Trichuris trichiura* [6–8] even in the adult population [9].

The episodic symptoms can be caused by intestinal infestation of *E. vermicularis* that temporarily occlude the lumen of the appendix and simulate appendicitis [10]. In some series this has been described as chronic appendicitis [1] with an elevated count of eosinophils without elevation of the expected white blood cell count [1,10], and can even present as an acute abdomen [11].

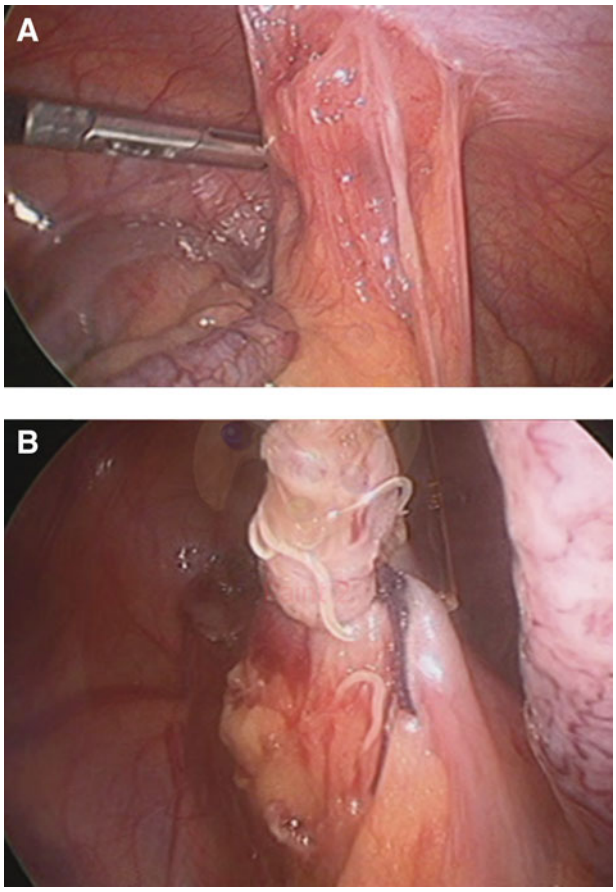


FIG. 2. (**A**) Laparoscopic view of the intra-abdominal wall granuloma. (**B**) Presence of *Enterobious vermicularis* in the lumen of the appendix causing obstruction.

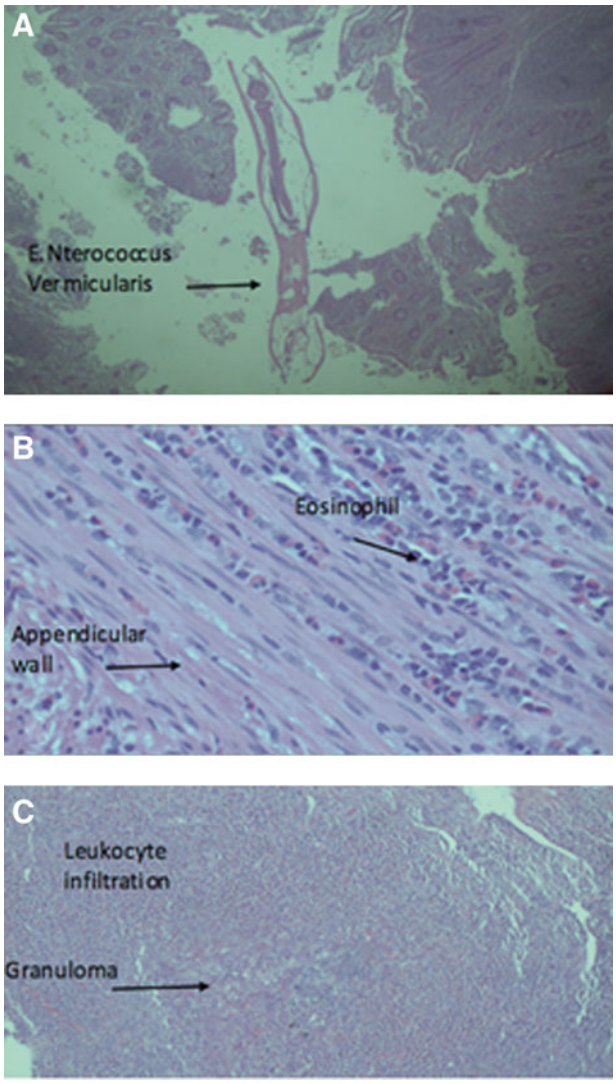


FIG. 3. (**A**) *Enterobius vermicularis* in the lumen of the appendix. (**B**) Eosinophilic infiltrate on the appendiceal wall. (**C**) Abdominal wall granuloma with leucocytes.

The spectrum of appendicitis can be infectious or not, and it is important to identify which one can be caused by parasites, with special attention to those who have episodic symptoms at presentation, without elevation of the white blood cell count, and can benefit of fecal analysis or even from an antiparasitic empiric treatment [10,12,13]. The patient did have antibiotic treatment with azithromycin starting three days before her arrival at the emergency department. Although not the first-line treatment for appendicitis, azithromycin has coverage for gram negative bacteria Enterobacteriaceae [14], which might explain the unresponsiveness to the treatment in this patient. The presence of eosinophilic intra-abdominal granuloma secondary to pinworms is rare [15,16], but it has had been associated with the histologic presence of *E. vermicularis* in the appendix [4,7].

The laparoscopic surgical approach has the advantage of identifying the presence of the intra-abdominal granuloma that can be associated with appendicitis secondary to parasites. It can also identify those parasites that can be free inside in the peritoneal cavity at the time of the base cut of the appendix and remove them from the abdomen [17].

Conclusion

Acute appendicitis can be caused by parasites. Patients who have episodic symptoms of appendicitis and elevation of eosinophils should increase the suspicion of having *E. vermicularis* and a fecal analysis might be warranted. Treatment should be surgical in positive physical and radiologic signs of appendicitis, and anti-parasitic medication must be started for the patient and all close relatives. The use of antibiotics might not be needed in acute eosinophilic appendicitis caused by parasites.

Author Disclosure Statement

No competing financial interests exist.

References

1. Arca MJ, Gates RL, Groner JI, et al. Clinical manifestations of appendiceal pinworms in children: An institutional experience and a review of the literature. Pediatr Surg Int 2004;20:372–375.
2. Ariyarathenam AV, Nachimuthu S, Tang TY, et al. *Enterobius vermicularis* infestation of the appendix and management at the time of laparoscopic appendectomy: Case series and literature review. Int J Surg 2010;8: 466–469.
3. Dahlstrom JE, Macarthur EB. *Enterobius vermicularis*: A possible cause of symptoms resembling appendicitis. Aust NZ J Surg 1994;64:692–694.
4. Vinuela A, Fernandez-Rojo F, Martinez-Merino A. Oxyuris granulomas of pelvic peritoneum and appendicular wall. Histopathology 1979;3:69–77.
5. Mayers CP, Purvis RJ. Manifestations of pinworms. Can Med Assoc J 1970;103:489–493.
6. Pazdziora E, Bura A. [Incidence of pinworms (*Enterobius vermicularis*) in bioptic material from appendices]. Cas Lek Cesk 1973;112:237–239.
7. Alemayehu H, Snyder CL, St. Peter SD, et al. Incidence and outcomes of unexpected pathology findings after appendectomy. J Pediatr Surg 2014;49:1390–1393.
8. Bouree P, Dubourdieu M. [Parasitic appendicitis. Apropos of 4 cases of acute appendicitis]. Bull Soc Pathol Exot Filiales 1984;77:81–89.
9. Panidis S, Paramythiosis D, Panagiotou D, et al. Acute appendicitis secondary to *Enterobius vermicularis* infection in a middle-aged man: A case report. J Med Case Rep 2011;5:559.
10. Sodergren MH, Jethwa P, Wilkinson S, et al. Presenting features of *Enterobius vermicularis* in the vermiform appendix. Scand J Gastroenterol 2009;44:457–461.
11. de Mingo L., Alonso Jimenez L, el Dabete H., et al. [Acute abdomen of unusual cause in children]. Cir Pediatr 1993;6: 46–47.
12. Lamps LW. Appendicitis and infections of the appendix. Semin Diagn Pathol 2004;21:86–97.
13. Lamps LW. Infectious causes of appendicitis. Infect Dis Clin North Am 2010;24:995–1018.
14. William JD. Spectrum of activity of azithromycin. Eur J Clin Microbiol Infect Dis 1991;10:813–820.
15. Kilic S, Ekinci S, Orhan D, et al. *Enterobius granuloma*: An unusual cause of omental mass in an 11-year-old girl. Turk J Pediatr 2014;56:189–191.
16. Arkoulis N, Zerbinis H, Simatos G, et al. *Enterobius vermicularis* (pinworm) infection of the liver mimicking malignancy: Presentation of a new case and review of current literature. Int J Surg Case Rep 2012;3:6–9.
17. Saxena AK, Springer A, Tsokas J, et al. Laparoscopic appendectomy in children with *Enterobius vermicularis*. Surg Laparosc Endosc Percutan Tech 2001;11:284–286.

Address correspondence to:
Dr. Ulises Garza-Serna
Escuela de Medicina
Instituto Tecnologico y de Estudios
Superiores de Monterrey
Av Eugenio Garza Sada 2501 Sur, Tecnológico
Monterrey, Nuevo Leon, 64849
Mexico

E-mail: ugarza@itesm.mx

Cite this article as: Garza-Serna U, Ramos-Mayo A, Lopez-Garnica D, Lopez-Morales J, Diaz-Elizondo J, Flores-Villalba E (2016) Eosinophilic acute appendicitis and intra-abdominal granuloma caused by *Enterobius vermicularis* in a pediatric patient. *Surgical Infections Case Reports* 1:1, 103–105, DOI: 10.1089/crsi.2016.0029

International Journal of Surgery Case Reports 33 (2017) 44–47

Contents lists available at ScienceDirect

International Journal of Surgery Case Reports

journal homepage: www.casereports.com

Laparoscopic partial splenectomy for congenital splenic cyst in a pediatric patient: Case report and review of literature

Ulises Garza-Serna[a,*], Christian Ovalle-Chao[a], David Martinez[a], Eduardo Flores-Villalba[b], Jose A. Diaz-Elizondo[b], Ulises de Jesus Garza-Luna[a]

[a] Escuela de Medicina, Instituto Tecnologico y de Estudios Superiores de Monterrey, Avenida Morones Prieto 3000, Colonia Los Doctores, CP 64710 Monterrey, Nuevo Leon, Mexico
[b] Escuela de Ingenieria, Instituto Tecnologico y de Estudios Superiores de Monterrey, Avenida Eugenio Garza Sada 2501, Sur Col. Tecnológico, 64849, Monterrey, Nuevo Leon, Mexico

ARTICLE INFO

Article history:
Received 20 December 2016
Received in revised form 9 February 2017
Accepted 9 February 2017
Available online 20 February 2017

Keywords:
Non-parasitic splenic cyst
Partial splenectomy
Laparoscopy
Spleen
Case report

ABSTRACT

Non-parasitic splenic cysts (NPSC) are a rare condition that makes difficult to know their true incidence and represent 10% of all benign splenic cysts, they can be either congenital with the presence of epithelial lining that originate from invagination of the capsular mesothelial lining or post-traumatic with absence of epithelial lining. We present our management of a splenic congenital cyst in a pediatric patient. A 10-year-old female patient presented to the clinic complaining with a 3-week abdominal pain at the left upper quadrant. An ultrasound showed an enlarged spleen with a thinned walled cystic image on the lower pole of 5 cm. An abdominal CT confirmed the presence of a splenic cyst at the lower pole of the spleen of 5 cm in diameter. Three-port laparoscopic partial splenectomy was done isolating and dividing the lower splenic artery and vein and the lower pole of the spleen with a vessel sealing device. Management of a non-parasitic splenic cyst is controversial: cystectomy, fenestration, percutaneous drainage and sclerotherapy have been previously described, most of them aiming to preserve spleen function and avoiding overwhelming post-splenectomy infection. Partial splenectomy seems the most effective one in terms of preserving spleen function and avoiding recurrence.

1. Introduction

Non-parasitic splenic cysts (NPSC) are a rare condition that makes difficult to know their true incidence and represent 10% of all benign splenic cysts [2–4]. NPSC are classified based on the presence (congenital) or absence (post-traumatic) of epithelial lining [3]. Management of a non-parasitic splenic cyst is controversial: cystectomy, fenestration, percutaneous drainage and sclerotherapy, partial or total splenectomies have all been described [5–8]; some authors conclude that splenic tissue preservation is recommended to avoid the overwhelming post-splenectomy infection (OPSI) [9]. Here in, we present our management of a splenic congenital cyst in a pediatric patient.

2. Case report

A 10-year-old female patient presented to the clinic complaining with a 3-week abdominal pain at the left upper quadrant. The patient did not have previous medical history. Immunizations were up to date including against *S. pneumonae, N. meningitidis, H. Influenzae*. Weight 34.7 kg, Height 140 cm. Physical examination showed the presence of a left upper quadrant mobile mass with 7 of 10 scale of pain on palpation with no other findings. An ultrasound showed an enlarged spleen with a thinned walled cystic image on the lower pole of 5 cm. An abdominal CT confirmed the presence of a solitary splenic cyst at the lower pole of the spleen of 5 cm in diameter without calcifications (Fig. 1). The patient was then scheduled for surgery. The patient was placed on a right lateral decubitus position. Pneumoperitoneum was done using a Veress needle technique using 15 mm of Hg of intraabdominal pressure. A three port laparoscopic partial splenectomy was done by using one umbilical 12 mm port, and two more 5 mm ports; a 5 mm 30° scope was used; after division of the lower pole short gastric vessels, the lower pole splenic artery was identified and divided with and endo GIA ™ white load stapler 60 mm which was introduced through the 12 mm umbilical port (Fig. 2). Once we divided the lower pole splenic artery it became ischemic, and a demarcation line was observed between poles. The lower pole splenic vein was then divided with clips and a vessel-sealing device (LigaSure ™). The partial splenectomy was completed using vessel-sealing device through the ischemic demarcation line previously observed, and the splenic bed bleeding was controlled using monopolar cautery

* Corresponding author.
E-mail address: ugarza@itesm.mx (U. Garza-Serna).

http://dx.doi.org/10.1016/j.ijscr.2017.02.013

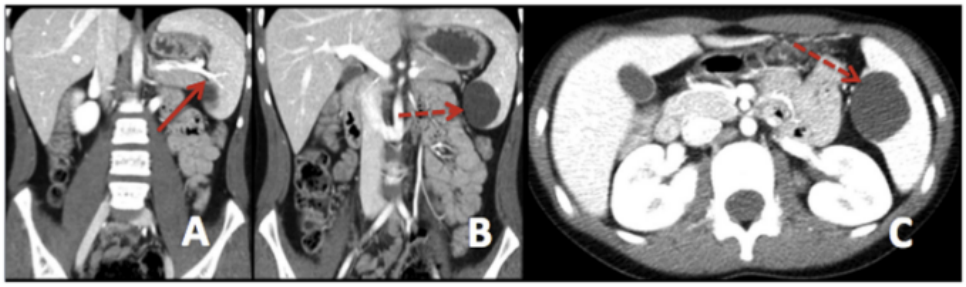


Fig. 1. (A) CT angiogram showing the splenic artery (red arrow) and (B,C) the splenic lower pole cyst (red dashed arrow).

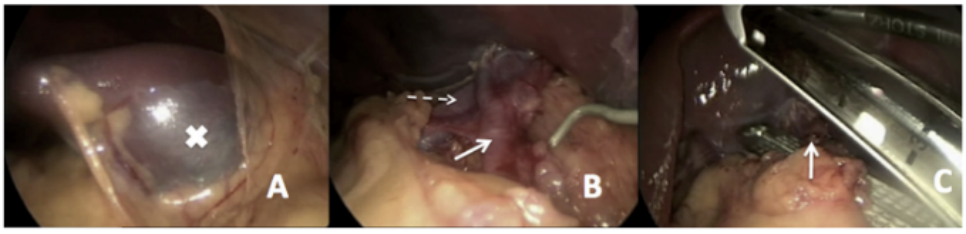


Fig. 2. (A) Laparoscopic view of the splenic lower pole cyst (x), (B, C) and the lower pole splenic artery (white arrow).

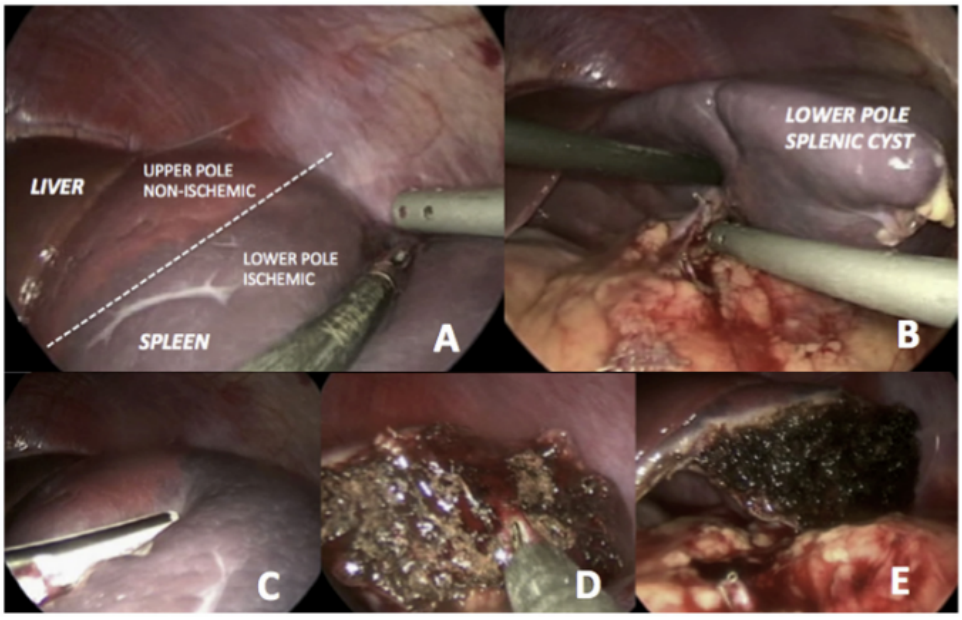


Fig. 3. (A) Upper and lower pole ischemic demarcation line (white dashed line) after division of the lower pole splenic artery, (B) laparoscopic medial view of the splenic cyst, (C, D, E) division of the lower pole of the spleen with a vessel sealing device and monopolar cautery.

and Surgicel SNoW ® (Fig. 3). An endobag was used to remove the specimen and morcellated through the 12 mm umbilical port. No complications were observed. The patient was discharged on post-operative day two. The microscopic analysis showed the presence of epithelial lining on the splenic cyst. One-month follow up at the clinic was uneventful.

3. Discussion

Splenic cysts can be classified in parasitic and non-parasitic cysts, the current management of both it is focused on spleen preservation based on the preoperative localization of the cyst [8].

Hydatidosis is a parasitic infection caused by Echinococcus granulosus and the spleen is the third most common organ involved [9]. It can be solitary in 38% and other locations can be present in 61%. Surgery is the treatment of choice and although total splenectomy seems to be more efective in treating the splenic hydatid cyst, the partial resection of the spleen is safer but could increase the rate of recurrence and postoperative collection [10]. Spontaneous rupture of a hydatid splenic cyst can cause anaphylaxis and should be treated promptly with splenectomy [11]. Percutaneous drainage seems to be unsuccessful [12].

Non-parasitic splenic cysts (NPSC) can be either congenital with the presence of epithelial lining that originate from invagination of the capsular mesothelial lining or post-traumatic with absence of epithelial lining [13]; but recently some other authors have proposed a different classification into congenital, neoplastic, traumatic or degenerative [2]. Post-traumatic splenic pseudocysts include 75% of non-parasitic cysts secondary to a subcapsular or

intraparenchymatous hematoma, by its liquefaction and creation of the fibrous peripheral capsule [14].

Most of the symptoms are related to the size of the cyst which can include diffuse abdominal pain, fullness in the left abdomen, nausea, vomiting, flatulence and diarrhea, thrombocytopenia, complications such as infection, rupture and/or hemorrhage [1,15].

Treatment for asymptomatic small (<5 cm) cysts is regular follow-up with serial imaging [16]. For symptomatic NPSC, ultrasound-guided percutaneous ethanol ablation, total or partial splenectomy, partial cystectomy with marsupialization or cyst-fenestration have all been described although some series do not advice partial cystectomy and/or marsupialization for large cysts [17], because of the high recurrence rate of almost 90% [18]. Spleen preservation is suggested as a standard surgical treatment [1] to avoid overwhelming post-splenectomy infection (OPSI), which has been described in 2.7–10% after total splenectomy [19] with a mortality of 50% [20].

Aspiration of the cyst has been described with a high recurrence rate, and should be reserved for those who are not surgical candidates [21]; some series have added ethanol to the cyst aspiration with promising results for symptomatic small cysts with complete absence in almost 50% after treatment and the other 50% with significant reduction of the size of the cyst, which suggest a reasonable option for either initial or management of recurrence of a NPSC [22].

Partial splenectomy for NPSC that is anatomically suitable for resection has been described previously [23–25] with no recurrence of the splenic cyst, in which the entire cyst is removed with normal splenic tissue making recurrence less likely [17], either single port, laparoscopic or an open approach can be accomplished [26], although it is a high skill technical procedure [27]. From all the treatment options described for NPSC it should be focus on the spleen preservation especially in young population [28,29].

4. Conclusion

Non-parasitic splenic true cysts are a rare condition, which most of them are asymptomatic. Although their true incidence is unknown, there have been several treatments described most of them aiming to preserve spleen function and avoiding overwhelming post-splenectomy infection which has a high mortality, especially in young population. From all of the treatments, partial splenectomy seems the most effective one in terms of preserving spleen function and avoiding recurrence, although it requires a surgeon with technical expertise especially with the laparoscopic approach.

The present paper follows the guidelines of the SCARE criteria for publication [30].

Conflicts of interest

Nothing to declare

Funding

Nothing to declare

Ethical approval

Ethical approval was given to publish this case report

Consent

Consent was obtained to publish this case report

Author contributions

Ulises Garza-Serna, MD- study concept, writing paper.
Christian Ovalle-Chao MD, data collection.
David Martinez, MD- data collection, writing paper.
Eduardo Flores-Villalba, MD- study concept.
Jose A Diaz-Elizondo, MD- Writing Paper.
Ulises de Jesus Garza-Luna, MD – Writing Paper.

Guarantor

The corresponding author and co-authors accept full responsibility for the work.

References

[1] S.B. Ingle, C.R. Hinge, S. Patrike, Epithelial cysts of the spleen: a minireview, World J. Gastroenterol. 20 (2014) 13899–13903, http://dx.doi.org/10.3748/wjg.v20.i38.13899.
[2] L. Morgenstern, Nonparasitic splenic cysts: pathogenesis, classification, and treatment, J. Am. Coll. Surg. 194 (2002) 306–314, http://dx.doi.org/10.1016/S1072-7515(01)01178-4.
[3] H. Golmohammadzadeh, G. Maddah, Y.S. Hojjati, A. Abdollahi, H. Shabahang, Splenic cysts: analysis of 16 cases, Caspian J. Intern. Med. 7 (2016) 217–221.
[4] S.W. Mun, T. Lim, E.H. Hwang, Y.J. Lee, U.B. Jeon, J.H. Park, A case of post-Traumatic pseudocyst in the spleen successfully treated with alcohol sclerotherapy, Pediatr. Gastroenterol. Hepatol. Nutr. 18 (2015) 276–279, http://dx.doi.org/10.5223/pghn.2015.18.4.276.
[5] N. Karia, K. Lakhoo, Complicated congenital splenic cyst: saved by a splenunculus, Afr. J. Paediatr. Surg. 8 (2011) 98–101, http://dx.doi.org/10.4103/0189-6725.79068.
[6] G. Zhang, S. Hu, H. Zhang, K. Wang, L.E.I. Wang, Short clinical report. A novel therapeutic approach to non-parasitic splenic cysts: laparoscopic fenestration and endothelium obliteration, Minim. Invasive Ther. Allied Technol. 16 (2007) 314–316, http://dx.doi.org/10.1080/13645700701201625.
[7] P.D. Sinwar, Overwhelming post splenectomy infection syndrome – Review study, Int. J. Surg. 12 (2014) 1314–1316, http://dx.doi.org/10.1016/j.ijsu.2014.11.005.
[8] S.A. Shabtaie, A.R. Hogan, M.B. Slidell, Splenic Cysts. Pediatr. Ann. 45 (2016) 251–256, http://dx.doi.org/10.3928/00904481-20160523-01.
[9] K. Rasheed, S.A. Zargar, A.A. Telwani, Hydatid cyst of spleen: a diagnostic challenge, N. Am. J. Med. Sci. 5 (2013) 10–20, http://dx.doi.org/10.4103/1947-2714.106184.
[10] H.B. Ameur, N. Affes, C. Abdelhedi, A. Kchaou, S. Boujelbene, M.I. Beyrouti, Hydatid cyst of the spleen: tunisian series of 21 cases, Indian J. Surg. 77 (2015) 515–519, http://dx.doi.org/10.1007/s12262-013-0905-5.
[11] V. Constantin, F. Popa, B. Socea, A. Carâp, C. Bălălău, I. Motofei, P. Banu, D. Costea, Spontaneous rupture of a splenic hydatid cyst with anaphylaxis in a patient with multi-organ hydatid disease, Chirurgia (Bucur) 109 (2014) 393–395.
[12] M. Ozdogan, A. Baykal, M. Keskek, Hydatid cyst of the spleen: treatment options, Int. Surg. 86 (2001) 122–126.
[13] Y.S. Lee, M. Teh, Histogenesis of true splenic cysts: a histological and immunohistochemical study, Ann. Acad. Med. Singapore 22 (1993) 372–376.
[14] R. Kostka, Z. Vernerova, Post-traumatic pseudocyst of the spleen, Rozhl. Chir. 89 (2010) 464–468.
[15] G. Galyfos, Z. Touloumis, K. Palogos, K. Stergios, M. Chalasti, N. Kavouras, et al., CASE REPORT-OPEN ACCESS International Journal of Surgery Case Reports Oversized pseudocysts of the spleen: report of two cases Optimal management of oversized pseudocysts of the spleen, Int. J. Surg. Case Rep. 5 (2014) 104–107, http://dx.doi.org/10.1016/j.ijscr.2013.11.006.
[16] H.Ö. Gezer, O. Pelin, A. Temiz, İ. Emine, Spleen salvaging treatment approaches in non-parasitic splenic cysts in childhood, Indian J. Surg. 78 (2015) 293–298, http://dx.doi.org/10.1007/s12262-015-1373-x.
[17] A.L. Ganti, A. Sardi, J. Gordon, Laparoscopic treatment of large true cysts of the liver and spleen is ineffective, Am. Surg. 68 (2002) 1012–1017.
[18] J.C. Fisher, B. Gurung, R.A. Cowles, Recurrence after laparoscopic excision of nonparasitic splenic cysts, J. Pediatr. Surg. 43 (2008) 1644–1648, http://dx.doi.org/10.1016/j.jpedsurg.2007.12.052.
[19] M.S. El-alfy, M.H. El-sayed, Overwhelming postsplenectomy infection: is quality of patient knowledge enough for prevention? Hematol. J. 5 (2004) 77–80, http://dx.doi.org/10.1038/sj.thj.6200328.
[20] S. Benoist, Median and long-term complications of splenectomy, Ann. Chir. 125 (2000) 317–324.
[21] C.D. Kenney, Y.E. Hoeger, A.K. Yetasook, J.G. Linn, E.W. Denham, J. Carbray, et al., Management of non-parasitic splenic cysts: does size really matter? J. Gastrointest. Surg. 18 (2014) 1658–1663, http://dx.doi.org/10.1007/s11605-014-2545-x.
[22] X. Yang, J. Yu, P. Liang, X. Yu, Z. Cheng, Z. Han, et al., Ultrasound-guided percutaneous ethanol ablation for primary non-parasitic splenic cysts in 15

patients, Abdom. Radiol. 41 (2016) 538–544, http://dx.doi.org/10.1007/s00261-015-0584-8.
[23] Z. Zvizdic, K. Karavdic, Spleen-preserving surgery in treatment of large mesothelial splenic cyst in children–a case report and review of the literature, Bosn. J. Basic Med. Sci. 13 (2013) 126–128.
[24] G. Kalogeropoulos, J.S. Gundara, J.S. Samra, T.J. Hugh, Laparoscopic stapled excision of non-parasitic splenic cysts, ANZ J. Surg. (2013), http://dx.doi.org/10.1111/ans.12367.
[25] B. Farhangi, A. Farhangi, A. Firouzjahi, B. Jahed, Huge epithelial nonparasitic splenic cyst: a case report and a review of treatment methods, Caspian J. Intern. Med. 7 (2016) 146–149.
[26] T.H. Hong, S.K. Lee, Y.K. You, J.G. Kim, Single-port laparoscopic partial splenectomy: a case report, Surg. Laparosc. Endosc. Percutan. Technol. 20 (2010) 164–166, http://dx.doi.org/10.1097/SLE.0b013e3181f13e09.
[27] A.B. Szczepanik, Partial splenectomy for splenic cyst–fifteen years follow-up of surgical treatment, Pol. Merkur. Lekarski 24 (2008) 254–256.
[28] Ö. Boybeyi, I. Karnak, F.C. Tanyel, A.Ö. Ciftci, M.E. Senocak, The management of primary nonparasitic splenic cysts, Turk. J. Pediatr. 52 (2010) 500–504.
[29] A.B. Szczepanik, A.J. Meissner, Partial splenectomy in the management of nonparasitic splenic cysts, World J. Surg. 33 (2009) 852–856, http://dx.doi.org/10.1007/s00268-008-9868-2.
[30] R.A. Agha, A.J. Fowler, A. Saetta, I. Barai, S. Rajmohan, Orgill DP and the SCARE group: the SCARE statement: consensus-based surgical case report guidelines, Int. J. Surg. 34 (2016) 180–186.

Journal of Pediatric Surgery Case Reports 19 (2017) 31–33

Contents lists available at ScienceDirect

Journal of Pediatric Surgery Case Reports

journal homepage: www.jpscasereports.com

Acute-onset of superior mesenteric artery syndrome following surgical correction of scoliosis: Case report and review of literature

Christian Ovalle-Chao [a], Luis Mario Hinojosa-Martinez [b], Alejandro Gutierrez-Castillo [a], Jose Humberto Velazco-De La Garza [a], Eduardo Flores-Villalba [c], Jose Antonio Diaz-Elizondo [c], Ulises Garza-Serna [a, *]

[a] Escuela de Medicina, Instituto Tecnologico y de Estudios Superiores de Monterrey, Monterrey, Mexico
[b] Hospital San Jose - Tec de Monterrey, Mexico
[c] Escuela de Ingenieria, Instituto Tecnologico y de Estudios Superiores de Monterrey, Monterrey, Mexico

ARTICLE INFO

Article history:
Received 13 December 2016
Received in revised form
10 February 2017
Accepted 18 February 2017
Available online 21 February 2017

Keywords:
Superior mesenteric artery syndrome
Wilkie's syndrome
Scoliosis
Bilious emesis
Duodenal obstruction
Spinal fusion
Acute-onset

ABSTRACT

Superior mesenteric artery (SMA) syndrome is a rare condition caused by compression of the third portion of duodenum by the angle between the superior mesenteric artery against the aorta. A rare presentation of SMA syndrome is following scoliosis repair and spinal fusion with a low incidence and most of these patients present with symptoms within one to two weeks or even more after the surgical repair. A high suspicion index after surgical correction of scoliosis with well-known risk factors (low BMI, low percentile of weight for height, and a high degree of change in the Cobb's angles) can anticipate the postoperative diagnosis. Management has been described for postsurgical scoliosis repair with a late onset presentation of SMA syndrome with nutritional support with good success rates, but there is no data for best treatment management for acute onset especially when the surgical correction of the spine causes complete duodenal obstruction and a surgical intervention might be warranted. Here in, we present a 14 year-old boy with an acute 24-h postoperative SMA syndrome following surgical correction of scoliosis.

1. Introduction

Superior mesenteric artery (SMA) syndrome is a rare condition caused by compression of the third portion of duodenum by the angle between the superior mesenteric artery against the aorta, described by Von Rokitansky in 1861 and the first case series report on 1927 by Wilkie [1]. Its overall incidence is unknown [2,3]. Symptoms of SMA syndrome may include nausea, bilious emesis, abdominal pain, early satiety, anorexia, failure to gain weight, indigestion, esophageal reflux, sense of fullness, persistent weight loss, and low BMI [3,4]. SMA syndrome can be developed after scoliosis repair and spinal fusion causing narrowing the aortomesenteric angle with an incidence of 2.5% [5]; most of these patients present with symptoms within one or two weeks and even more after the surgical repair [6,7]; here in, we present to our knowledge the first case report of acute onset (24-h) postoperative SMA syndrome following surgical correction of scoliosis in a 14 year old male patient.

2. Case report

Fourteen (14) year-old male patient with a BMI of 13.4 kg/m^2 [weight 40 kg (2 percentile), height 1.73 m (85 percentile)] was scheduled for thoracolumbar T3-L2 spinal fusion procedure for scoliosis (Cobb's angles: thoracic 70° and lumbar 44°). Past medical and surgical history included umbilical hernia repair and circumcision at 6 years old, with no other medical history. The patient underwent a successful spinal correction of scoliosis (Fig. 1), with a final thoracic angle of 22° and lumbar 10°, with a total increase in height of 8 cm. 24-hours postoperatively the patient developed nausea, bilious vomiting and abdominal pain. A nasogastric tube was placed obtaining bilious output.

An upper gastrointestinal (UGI) series with barium was done showing third portion duodenal obstruction with slight dilatation of the second portion of the duodenum (Fig. 2). An abdominal CT

* Corresponding author. Escuela de Medicina, Instituto Tecnologico y de Estudios Superiores de Monterrey, Mexico.
E-mail address: ugarza@itesm.mx (U. Garza-Serna).

http://dx.doi.org/10.1016/j.epsc.2017.02.008

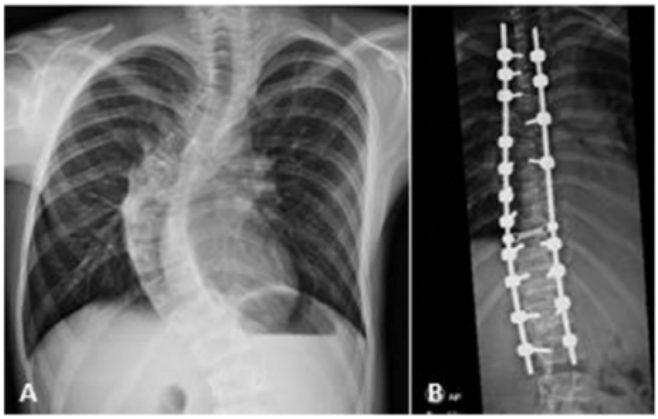


Fig. 1. A) Chest X-ray: Scoliosis with right convexity. B) Postoperative Chest X ray.

angiography confirmed the presence of a narrow aortomesenteric angle of 14° with a 3.8 mm diameter (Fig. 3). A SMA syndrome was diagnosed. The placement of a feeding tube assisted with an upper endoscopy was attempted and was unsuccessful since there was a complete obstruction of duodenum. The patient was then scheduled for surgery and a duodenum-jejunum bypass was done to relieve the obstruction. The patient was discharged one-week after surgery tolerating full oral feeds.

3. Discussion

Superior artery mesenteric syndrome is a rare condition, its overall true incidence is unknown and an incidence of 0.0024–0.034% has been described for the general population in some series, being young adults and women the most commonly affected [1,3,8,9].

Symptoms of obstruction are caused by compression of the third portion of duodenum by the angle between de abdominal aorta and the origin of the SMA, which normally can vary between 20° and 70°; most of the population in general being between 30° and 56°, and an aortomesenteric distance of 10 or 20 mm [1,10]. An angle between 6 and 16° and an aortomesenteric angle distance 2–8 mm confirms its diagnosis [11]. Our patient had an angle of 14° and an aortomesenteric diameter of 3.8 mm after the surgical correction based on the CT angiography.

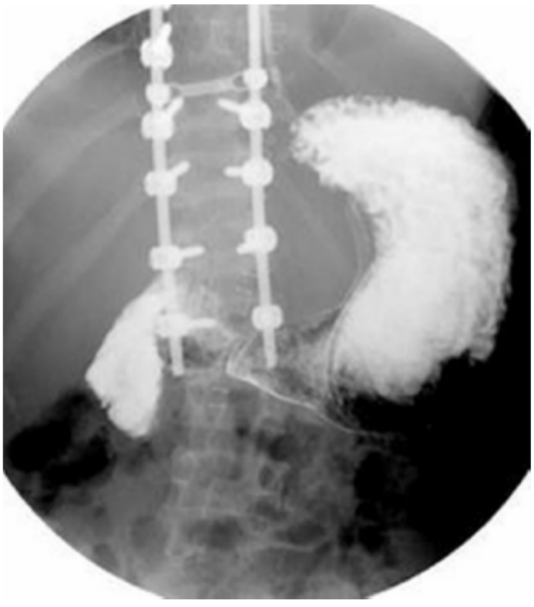


Fig. 2. UGI series with barium: Third portion duodenal obstruction and dilatation of the second duodenal portion.

Conditions that can cause the SMA syndrome has been associated most commonly to catabolic states and malnutrition such as rapid weight loss, AIDS, cancer, cerebral palsy, high degree burns, anorexia nervosa, drug abuse and patients with very low body mass index or as on our case after scoliosis repair and spinal fusion [5,8,12–14].

The surgical correction of scoliosis causes realignment and longitudinal traction of the aorta increasing the height of the patient and subsequently causing narrowing of the angle between the aorta and the superior mesenteric artery, causing obstruction of the third portion of the duodenum [10], especially in patients with a BMI <18 or a weight percentile for height of 5% that suggests low or no periphery duodenal visceral fat which is a well-known risk factor [14,15]. Our patient met the previous risk factors with a BMI of 13.4 kg/m^2 and a weight percentile for height of 2% which predicted the postoperative SMA syndrome. The correctional change in curvature angles in the sagittal and coronal planes also plays a role in SMA syndrome risk. A greater Cobb's angle correction is accompanied by a greater increase in patient height [5]; our patient had preoperatively a thoracic 70° and lumbar 44° and postoperatively thoracic angle of 22° and lumbar 10° with an increase of 8 cm in height.

Usually the SMA syndrome following spinal fusion for scoliosis presents one week postoperatively, with an average of between day 5 or 6 [10,11,16]. Progressive weight loss recurrent vomiting, abdominal distension, marked dehydration, bilious vomiting are some common features described and usually presented as a late onset [6,7]. Although we predicted a postoperative SMA syndrome on our patient [10], we did not expect such an acute onset. This can be explained by the fact of the complete duodenal obstruction caused by the 8 cm sudden increase in height after the spinal fusion and narrowing of the aortomesenteric angle, causing a 24-h postoperatively bilious vomiting.

Although there is no gold standard for diagnosis of SMA syndrome, some series suggest that both UGI series and CT angiography will be necessary for diagnosis [1,11,17]. On our patient an UGI showed obstruction of the third portion of duodenum, and an abdominal CT angiography confirmed an aortomesenteric 14° angle and a 3.8 mm distance.

Management of the overall SMA syndrome with nutritional support has a success rate of 71%–85% [1,18], with a recurrence rate of 15% [1], and treatment should be at least for a period of 6 weeks [19], including patients who develop SMA syndrome with late onset symptoms following spinal fusion with some series having good outcomes [10]; placement of an enteral tube beyond the ligament of Treitz or parenteral nutrition, postural changes such as postprandial left lateral decubitus, prone or knee-chest position and nasogastric decompression have all been described as a good option to increase the aortomesenteric fat and the aortomesenteric angle allowing the relief of the duodenal obstruction [1,11,16]. Nevertheless, all of these reports were made for patients who developed symptoms one week after the procedure, none of these describes management after an acute onset with complete duodenal obstruction that was confirmed with endoscopy and for that reason we were unable to offer this option to our patient, in fact the nutritional management is not always successful and surgical intervention might be needed [3].

We decided to perform a duodenum-jejunum anastomosis since it remains as the surgery of choice; it has a 90% success rate and

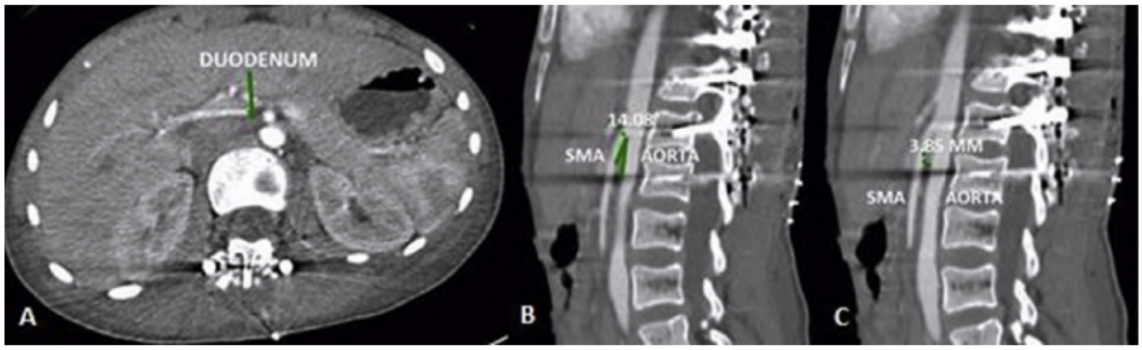


Fig. 3. Abdominal CT angiography: A) Duodenal impingement. B) Aortomesenteric angle of 14°. C) Aortomesenteric diameter of 3.8 mm.

allows the functional preservation of the pylorus [2]. Some other surgical options have been described including the ligament of Treitz division or Strong Procedure, and gastro-jejunum bypass. Strong procedure has the advantage of keeping the intestinal integrity and it is feasible [11], but has a 25% failure rate [20]. Gastro-jejunum anastomosis provides appropriate gastric decompression but fails in liberating completely the duodenal obstruction, leading to the persistence of symptoms, needing a duodenum-jejunum bypass in some cases [2]. Finally, some authors support the resection of the abnormal duodenal segment instead of performing a bypass of the third portion of the duodenum, arguing that SMA syndrome is a variation of a motility disorder more than a real mechanical obstruction [21] with unknown success and failure rates. Laparoscopic or open approaches are well described and both have the similar success rates as the open approach [20].

4. Conclusion

SMA syndrome is a well-described complication after surgical correction of scoliosis especially in patients with high risk factors such as low BMI and low percentile of weight for height; most of these symptoms have a late onset within a week or later. Postoperative 24-h bilious vomiting should increase the suspicion of complete duodenal obstruction caused by the sudden increase in patient height and the narrowing of the aortomesenteric angle. Although conservative treatment has been described for the late onset postoperative SMA syndrome with good rates of success, there is no data on patients with acute onset presentation with an almost complete duodenal obstruction and a surgical intervention might be warranted. More data is needed to predict which patient will develop acute versus late onset SMA symptoms after surgical correction of scoliosis.

References

[1] Lee TH, Lee JS, Jo Y, Park KS, Cheon JH, Kim YS, et al. Superior mesenteric artery syndrome: where do we stand today? J Gastrointest Surg 2012;16(12):2203–11. http://dx.doi.org/10.1007/s11605-012-2049-5.

[2] Yakan S, Caliskan C, Kaplan H, Denecli AG, Coker A. Superior mesenteric artery syndrome: a rare cause of intestinal obstruction. Diagn Surg Manag Indian J Surg 2013;75(2):106–10. http://dx.doi.org/10.1007/s12262-012-0423-x.

[3] Oguz A, Uslukaya O, Ülger BV, Turkoglu A, Bahadir MV, Bozdag Z, et al. Superior mesenteric artery (Wilkie's) syndrome: a rare cause of upper gastrointestinal system obstruction. Acta Chir Belg 2016;116(2):81–8. http://dx.doi.org/10.1080/00015458.2016.1139830.

[4] Marecek GS, Barsness KA, Sarwark JF. Relief of superior mesenteric artery syndrome with correction of multiplanar spinal deformity by posterior spinal fusion. Orthopedics 2010;33(7):519. http://dx.doi.org/10.3928/01477447-20100526-26.

[5] Kim JY, Kim HS, Moon ES, Park JO, Shin DE, Lee GK, et al. Incidence and risk factors associated with superior mesenteric artery syndrome following surgical correction of scoliosis. Asian Spine J 2008;2(1):27–33. http://dx.doi.org/10.4184/asj.2008.2.1.27.

[6] Lam DJ, Lee JZ, Chua JH, Lee YT, Lim KB. Superior mesenteric artery syndrome following surgery for adolescent idiopathic scoliosis: a case series, review of the literature, and an algorithm for management. J Pediatr Orthop B 2014;23(4):312–8. http://dx.doi.org/10.1097/BPB.0000000000000050.

[7] Tsirikos AI, Anakwe RE, Baker AD. Late presentation of superior mesenteric artery syndrome following scoliosis surgery: a case report. J Med Case Rep 2008;2:9. http://dx.doi.org/10.1186/1752-1947-2-9.

[8] Verhoef PA, Rampal A. Unique challenges for appropriate management of a 16-year-old girl with superior mesenteric artery syndrome as a result of anorexia nervosa: a case report. J Med Case Rep 2009;3:127. http://dx.doi.org/10.1186/1752-1947-3-127.

[9] Lee MG, Terry SI. Arteriomesenteric duodenal occlusion associated with strongyloidiasis. J Trop Med Hyg 1989;92(1):41–5.

[10] Zhu ZZ, Qiu Y. Superior mesenteric artery syndrome following scoliosis surgery: its risk indicators and treatment strategy. World J Gastroenterol 2005;11(21):3307–10. http://dx.doi.org/10.3748/wjg.v11.i21.3307.

[11] Welsch T, Büchler MW, Kienle P. Recalling superior mesenteric artery syndrome. Dig Surg 2007;24(3):149–56. http://dx.doi.org/10.1159/000102097.

[12] Merrett ND, Wilson RB, Cosman P, Biankin AV, et al. Superior mesenteric artery syndrome: diagnosis and treatment strategies. J Gastrointest Surg 2009;13(2):287–92. http://dx.doi.org/10.1007/s11605-008-0695-4.

[13] Sun Z, Rodriguez J, McMichael J, Walsh RM, Chalikonda S, Rosenthal RJ, et al. Minimally invasive duodenojejunostomy for superior mesenteric artery syndrome: a case series and review of the literature. Surg Endosc 2015;29(5):1137–44. http://dx.doi.org/10.1007/s00464-014-3775-4.

[14] Smith BG, Hakim-Zargar M, Thomson JD. Low body mass index: a risk factor for superior mesenteric artery syndrome in adolescents undergoing spinal fusion for scoliosis. J Spinal Disord Tech 2009;22(2):144–8. http://dx.doi.org/10.1097/BSD.0b013e31816b6b9a.

[15] Shah MA, Albright MB, Vogt MT, Moreland MS. Superior mesenteric artery syndrome in scoliosis surgery: weight percentile for height as an indicator of risk. J Pediatr Orthop 2003;23(5):665–8.

[16] Shiu JR, Chao HC, Luo CC, Lai MW, Kong MS, Chen SY, et al. Clinical and nutritional outcomes in children with idiopathic superior mesenteric artery syndrome. J Pediatr Gastroenterol Nutr 2010;51(2):177–82. http://dx.doi.org/10.1097/MPG.0b013e3181c7bdda.

[17] Ezzedien Rabie M, Ogunbiyi Olajide, Al Qahtani Abdullah Saad, Taha Sherif BM, El Hadad Ahmad, El Hakeem Ismail. Superior mesenteric artery syndrome: clinical and radiological considerations. Surg Res Pract 2015:628705. http://dx.doi.org/10.1155/2015/628705.

[18] Xu L, Yu W, Jiang J, Feng X, Li N. Nutrition support treatment for refractory constipation patients complicated with superior mesenteric artery syndrome. Zhonghua Wei Chang Wai Ke Za Zhi 2014;17(10):972–6.

[19] Shin MS, Kim JY. Optimal duration of medical treatment in superior mesenteric artery syndrome in children. J Korean Med Sci 2013;28(8):1220–5. http://dx.doi.org/10.3346/jkms.2013.28.8.1220.

[20] Merrett ND, Wilson RB, Cosman P, Biankin AV, et al. Superior mesenteric artery syndrome: diagnosis and treatment strategies. J Gastrointest Surg 2009;13(2):287–92. http://dx.doi.org/10.1007/s11605-008-0695-4.

[21] Reed NR, Kalra M, Bower TC, Vrtiska TJ, Ricotta 2nd JJ, Gloviczki P. Left renal vein transposition for nutcracker syndrome. J Vasc Surg 2009;49(2):386–93. http://dx.doi.org/10.1016/j.jvs.2008.09.051. discussion 393-4.

Surgical Site Infection Rate Drops to 0% Using a Vacuum-Assisted Closure in Contaminated/ Dirty Infected Laparotomy Wounds

GERARDO LOZANO-BALDERAS, M.D., ALEJANDRO RUIZ-VELASCO-SANTACRUZ, M.D., JOSÉ ANTONIO DÍAZ-ELIZONDO, M.D., JUAN ANTONIO GÓMEZ-NAVARRO, M.D., EDUARDO FLORES-VILLALBA, M.D.

Escuela de Medicina, Tecnologico de Monterrey, San Pedro Garza García, Mexico

Wound site infections increase costs, hospital stay, morbidity, and mortality. Techniques used for wounds management after laparotomy are primary, delayed primary, and vacuum-assisted closures. The objective of this study is to compare infection rates between those techniques in contaminated and dirty/ infected wounds. Eighty-one laparotomized patients with Class III or IV surgical wounds were enrolled in a three-arm randomized prospective study. Patients were allocated to each group with the software Research Randomizer® (Urbaniak, G. C., & Plous, S., Version 4.0). Presence of infection was determined by a certified board physician according to Centers for Disease Control's Criteria for Defining a Surgical Site Infection. Twenty-seven patients received primary closure, 29 delayed primary closure, and 25 vacuum-assisted closure, with no exclusions for analysis. Surgical site infection was present in 10 (37%) patients treated with primary closure, 5 (17%) with primary delayed closure, and 0 (0%) patients receiving vacuum-assisted closure. Statistical significance was found between infection rates of the vacuum-assisted group and the other two groups. No significant difference was found between the primary and primary delayed closure groups. The infection rate in contaminated/dirty-infected laparotomy wounds decreases from 37 and 17 per cent with a primary and delayed primary closures, respectively, to 0 per cent with vacuum-assisted systems.

Nosocomial infections are prevalent both in industrialized and emergent countries. The World Health Organization reports an average nosocomial infection rate of 8.7 per cent.[1] Wound site, urinary tract, and upper respiratory airways infections being the most common. In Mexico, nosocomial infection rate is 7.7 per cent of all hospital discharges, from which 26 per cent are attributed to surgical site infections.[2]

Wound site infections increase both costs and hospital stay for the patient,[2–4] and carry a higher morbidity and mortality.[5] In abdominal surgical procedures, it is also the most relevant prognostic factor for developing postincisional hernias.[6–8]

Surgical wounds can be classified as clean, clean contaminated, contaminated, and infected, with a rate of infection of 10 to 20 per cent for contaminated and 20 to 40 per cent for infected wounds.[9] Depending on the scenario, the techniques used for wounds management after laparotomy are primary or delayed primary closure and the use of vacuum-assisted devices, which improve blood circulation and enhance cellular division rate in the wound.[10–12]

The objective of this study is to compare infection rates between primary, delayed primary, and vacuum-assisted closures in contaminated and dirty/infected laparotomy wounds.

Methods

Eighty-one patients were enrolled in a three-arm randomized prospective study, approved by the hospital's ethics committee. Inclusion criteria were a minimum age of 18 years and a laparotomy wound Class III or IV, according to the Centers for Disease Control's Surgical Wound Classification.[9] Patient allocation to the different closure methods was made with the software Research Randomizer® just before fascia closure.

A double antibiotic scheme with a cephalosporin and metronidazole was used in all patients. In the three groups, the fascia was closed with polyglycolic acid 0 running

Protocol Registration

The protocol can be found in ClinicalTrials.gov, under the title Comparison of Surgical Site Infection Rate between Primary, Delayed Primary, and Vacuum-Assisted Closures.

ClinicalTrials.gov Identifier: NCT02649543.

Address correspondence and reprint requests to Eduardo Flores Villalba, M.D., Escuela de Medicina, Tecnologico de Monterrey, Batallón de San Patricio 112 Piso 1 Ote. Col. Real San Agustín, San Pedro Garza García, NL 66278, México. E-mail: eduardofloresvillalba@itesm.mx.

TABLE 1. *Variable Analysis and Comparison between the Three Groups Based on Anthropometric, Personal History and Relevant Laboratory Data*

Variable	Closed Vacuum System		Delayed Primary Closure		Primary Closure		*P* value
	Number (%)	Median (IQR)	Number (%)	Median (IQR)	Number (%)	Median (IQR)	
Female gender	6 (24)		13 (44.8)		7 (25.9)		0.185
Age		32 (22–46)		39 (22.5–53)		30 (20–43)	0.592
BMI		25.9 (24.3–27.3)		27.8 (25.2–28.8)		26.7 (24.5–29.3)	0.112
DM II	4(16)		5 (17.2)		6 (22.2)		0.826
Tobacco use	5 (20)		4 (13.8)		3 (11.1)		0.654
Preoperative transfusion	0 (0)		3 (10.3)		1 (3.7)		0.203
Trichotomy	20 (80)		18 (62.1)		22 (81.5)		0.182
Surgical time		120 (100–190)		120 (90–180)		120 (90–180)	0.428
Class III wound	12 (48)		9 (31)		9 (33.3)		0.388
Albumin		3.6 (3.4–3.95)		3.4 (3.0–3.7)		3.4 (3.0–3.7)	0.061
Total protein		6.6 (6.5–6.9)		6.5 (6.35–6.9)		6.5 (6.2–6.9)	0.305

IQR, interquartile range.

suture. In those patients with primary closure, subcutaneous tissue was approximated with polyglycolic acid 3-0, and polypropylene 2–0 was used for the skin. For those with a delayed primary closure, the wound was left open for at least seven days, after which closure with a polypropylene 2-0 suture took place if no clinical signs of infection were observed by a certified board surgeon. For the rest of the patients, the VAC® (Vacuum Assisted Closure, KCI, San Antonio, Texas) system was used with routine changes of dressings every 48 hours, and until healthy granulation tissue was found a surgeon decided to close it.

Discharge of the patients took place only after the wound healed with no complications. Revision of the wounds took place on a daily basis while the patient remained hospitalized, as well as in scheduled follow-up appointments and open consultations as required by the patient in a 30-day period after the surgery. The presence of surgical site infection was determined by a certified board physician. Centers for Disease Control's Criteria for Defining a Surgical Site Infection, as stated in the Guideline for Prevention of Surgical Site Infection[9] were used as definite criteria for all three wound closures.

Social, demographic, medical, and surgical (both preoperative and postoperative) data were registered. A descriptive analysis expressed as total and percentages, medians, and interquartile ranges was made. Comparison between groups was assessed using the Kruskal-Wallis, Mann-Whitney *U*, or χ^2 as appropriate. A *P* value of less than 0.05 was considered significant.

Results

Eighty-one patients were enrolled and analyzed, 27 patients (33%) received primary closure, 29 (36%) delayed primary closure, and 25 (31%) vacuum-assisted closure. There were no patient losses or exclusions. All the patients analyzed were intervened in a 6-month period, from January to July 2014.

TABLE 2. *Acute Abdomen Diagnoses*

Diagnosis	Number (%)
Perforated acute apendicitis	35 (43.21)
Stab wound	14 (17.28)
Acute diverticulitis	9 (11.11)
Strangulated hernia	7 (8.64)
Others	16 (19.75)

Demographic and baseline data are included in Table 1. Main diagnoses leading to surgery are shown in Table 2. Class IV wounds were more common, with 51 (63%) cases. Surgical site infection was present in 10 (37%) patients treated with primary closure, 5 (17%) patients with primary delayed closure, and none of the patients receiving vacuum-assisted delayed closure. There were no readmission cases during the follow-up period. No organ/space infections were identified in the study. All groups were compared to determine any significant infection rate difference (Table 3).

Discussion

There are several published clinical trials comparing the benefits of vacuum-assisted closure systems over the primary and delayed primary closures for surgical wounds; however, there is no standard of care.

Traditionally, closure by second intention, is recommended for both Classes III and IV laparotomy wounds.[9] However, the infection rate of Class III wounds using such technique is reported at 10 to 20 per cent, whereas the rate for Class IV wounds ascends up to 20 to 40 per cent.[9] Similar infection rates were found in our study with such technique. Although a minor rate of infection was seen in the delayed primary closure compared with the primary closure, no significant difference was found, as stated by other authors.[8, 13]

TABLE 3. *Surgical Site Infection Rate Comparison between Groups*

Group	Closed Vacuum System (*P*)	Delayed Primary Closure (*P*)	Primary Closure (*P*)
Closed vacuum system	–	0.029	0.001
Delayed primary closure	0.029	–	0.095
Primary closure	0.001	0.095	–

There is increasing evidence of the efficacy of vacuum-assisted systems in the prevention of surgical wound infection, with rates of 0 per cent reported worldwide.[14–17] Our study replicated these results, with a significant difference over the primary and delayed primary closures. Although lesser costs by using vacuum-assisted systems have been reported,[18] further evaluation in our health system is still necessary.

The obtained results emphasize the importance of postoperative wound care, being the most relevant factor the election of the closure technique to use. If future studies replicate these results in a cost-effective manner, the use of vacuum-assisted devices should be recommended routinely for closure of Classes III and IV laparotomy wounds.

Limitations of this study are the small sample size and the lack of a multicenter design, which highlights the need for posterior studies.

Conclusions

The infection rate in contaminated/dirty-infected laparotomy wounds decreases from 37 and 17 per cent with a primary and delayed primary closures, respectively, to 0 per cent with vacuum-assisted systems.

REFERENCES

1. Tikhomirov E. WHO programme for the control of hospital infections. Chemioterapia 1987;6:148–51.

2. Fukuda H, Morikane K, Kuroki M, et al. Impact of surgical site infections after open and laparoscopic colon and rectal surgeries on postoperative resource consumption. Infection 2012;40:649–59.

3. Kusachi S, Kashimura N, Konishi T, et al. Length of stay and cost for surgical site infection after abdominal and cardiac surgery in Japanese hospitals: multi-center surveillance. Surg Infect (Larchmt) 2012;13:257–65.

4. Pommerening MJ, Kao LS, Sowards KJ, et al. Primary skin closure after damage control laparotomy. Br J Surg 2015;102: 67–75.

5. Ponce-de-Leon S. The needs of developing countries and the resources required. J Hosp Infect 1991;18 Suppl A:376–81.

6. Bucknall TE, Cox PJ, Ellis H. Burst abdomen and incisional hernia: a prospective study of 1129 major laparotomies. Br Med J (Clin Res Ed). 1982;284:931–3.

7. Anthony T, Bergen PC, Kim LT, et al. Factors affecting recurrence following incisional herniorrhaphy. World J Surg 2000; 24:95–100, discussion 1.

8. Carlson MA, Ludwig KA, Condon RE. Ventral hernia and other complications of 1,000 midline incisions. South Med J 1995; 88:450–3.

9. Mangram AJ, Horan TC, Pearson ML, et al. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol 1999;20:250–78, quiz 79–80.

10. Greene AK, Puder M, Roy R, et al. Microdeformational wound therapy: effects on angiogenesis and matrix metalloproteinases in chronic wounds of 3 debilitated patients. Ann Plast Surg 2006; 56:418–22.

11. Venturi ML, Attinger CE, Mesbahi AN, et al. Mechanisms and clinical applications of the vacuum-assisted closure (VAC) Device: a review. Am J Clin Dermatol 2005;6:185–94.

12. Cuccia G, Mucciardi G, Morgia G, et al. Vacuum-assisted closure for the treatment of Fournier's gangrene. Urol Int 2009;82: 426–31.

13. Bhangu A, Singh P, Lundy J, et al. Systemic review and meta-analysis of randomized clinical trials comparing primary vs delayed primary skin closure in contaminated and dirty abdominal incisions. JAMA Surg 2013;148:779–86.

14. Hougaard HT, Ellebaek M, Holst UT, et al. The open abdomen: temporary closure with a modified negative pressure therapy technique. Int Wound J 2014;11(Suppl 1):13–6.

15. Franklin ME, Alvarez A, Russek K. Negative pressure therapy: a viable option for general surgical management of the open abdomen. Surg Innov 2012;19:353–63.

16. Bui TD, Huerta S, Gordon IL. Negative pressure wound therapy with off-the-shelf components. Am J Surg 2006;192: 235–7.

17. Leininger BE, Rasmussen TE, Smith DL, et al. Experience with wound VAC and delayed primary closure of contaminated soft tissue injuries in Iraq. J Trauma 2006;61:1207–11.

18. Dowsett C, Davis L, Henderson V, et al. The economic benefits of negative pressure wound therapy in community-based wound care in the NHS. Int Wound J 2012;9:544–52.

membranes

MDPI

Review

Past, Present and Future of Surgical Meshes: A Review

Karen Baylón [1], Perla Rodríguez-Camarillo [1], Alex Elías-Zúñiga [1], Jose Antonio Díaz-Elizondo [2], Robert Gilkerson [3] and Karen Lozano [4,*]

1 Centro de Innovación en Diseño y Tecnología, Tecnológico de Monterrey, Campus Monterrey, Monterrey 64849, Mexico; karen.baylon@itesm.mx (K.B.); A01139114@itesm.mx (P.R.-C.); aelias@itesm.mx (A.E.-Z.)
2 Escuela de Medicina, Tecnológico de Monterrey, Campus Monterrey, Monterrey 64849, Mexico; jadiaze@itesm.mx
3 Departments of Biology and Clinical Laboratory Sciences, The University of Texas Rio Grande Valley, Edinburg, TX 78539, USA; robert.gilkerson@utrgv.edu
4 Mechanical Engineering Department, The University of Texas Rio Grande Valley, Edinburg, TX 78539, USA
* Correspondence: karen.lozano@utrgv.edu; Tel.: +1-956-665-7020

Received: 15 June 2017; Accepted: 17 August 2017; Published: 22 August 2017

Abstract: Surgical meshes, in particular those used to repair hernias, have been in use since 1891. Since then, research in the area has expanded, given the vast number of post-surgery complications such as infection, fibrosis, adhesions, mesh rejection, and hernia recurrence. Researchers have focused on the analysis and implementation of a wide range of materials: meshes with different fiber size and porosity, a variety of manufacturing methods, and certainly a variety of surgical and implantation procedures. Currently, surface modification methods and development of nanofiber based systems are actively being explored as areas of opportunity to retain material strength and increase biocompatibility of available meshes. This review summarizes the history of surgical meshes and presents an overview of commercial surgical meshes, their properties, manufacturing methods, and observed biological response, as well as the requirements for an ideal surgical mesh and potential manufacturing methods.

Keywords: surgical mesh; hernia repair; abdominal wall reconstruction; biocompatibility

1. Introduction

A hernia is defined as a protrusion or projection (prolapse) of an organ through the wall of the cavity where it is normally contained [1]. There are many types of hernia, mostly classified according to the physical location, with the abdominal wall being the most susceptible site. Specifically, reports show that the most frequently seen hernia is the inguinal hernia (70–75% of cases), followed by femoral (6–17%) and umbilical (3–8.5%) hernias [2]. Hernias are also found in other sites such as the ventral or epigastric hernia, located between the chest cavity and the umbilicus.

Hernias can be uncomfortable and are sometimes accompanied by severe pain, which worsens during bowel movements, urination, heavy lifting, or straining [3]. Occasionally, a hernia can become strangulated, which occurs when the protruding tissue swells and becomes incarcerated. Strangulation will interrupt blood supply and can lead to infection, necrosis, and potentially life-threatening conditions [4].

Hernia repair is one of the most common surgical procedures performed globally. It is estimated that there are over 20 million hernia repair procedures per year worldwide [5]. The number of procedures has been increasing and is predicted to further increase due to several risk factors such as

obesity and prior abdominal surgeries [6]. Hernia repairs provide an important revenue stream for hospitals, estimated at $48 billion/year in the United States [7].

The use of hernia mesh products to surgically repair or reconstruct anatomical defects has been widely adopted: in fact, more than 80% of hernia repairs performed in United Sates use mesh products [8]. The surgical mesh firmly reinforces the weakened area and provides tension-free repair that facilitates the incorporation of fibrocollagenous tissue [9]. However, there are many types of meshes and there is a strong controversy regarding optimum performance and success of surgical procedures. Researchers have investigated metals, composites, polymers and biodegradable biomaterials in their quest to attain the ideal surgical mesh and implantation procedure [10]. The sought-after characteristics are inertness, resistance to infection, the ability to maintain adequate long-term tensile strength to prevent early recurrence, rapid incorporation into the host tissue, adequate flexibility to avoid fragmentation, non-carcinogenic response and the capability to maintain or restore the natural respiratory movements of the abdominal wall [9].

Currently, utilized surgical meshes exhibit many but not all of the desired characteristics [8]. Therefore, current research efforts focus on providing potential solutions that range from the utilization of novel materials to new designs that could ameliorate existent shortcomings [11]. The aim of this review is to illustrate the current research in surgical meshes used for hernia repair. This review provides a perspective of existent commercial surgical meshes, their properties, manufacturing procedures, and observed biological responses. Furthermore, the article seeks to establish the requirements for an ideal surgical mesh and potential manufacturing procedures.

2. History

In 1890, Theodor Billroth suggested that the ideal way to repair hernias was to use a prosthetic material to close the hernia defect [12]. Many materials were used, but all failed due to infections, rejections, and recurrences [13]. Surgeons concluded that the main problem was built upon the multifilament suture material, which has been proven unsuitable in many other surgical procedures [14]. Surgeons became disenchanted with the popular cotton and silk sutures because of the frequently observed rejection syndrome and resultant endless recurring infections. The use of such sutures to secure mesh in place undoubtedly contributed to aggravate the existing bias against the surgical meshes [15].

In 1955, Dr. Francis Usher focused his attention on the materials that could solve existing problems. Nylon, Orlon, Dacron and Teflon were studied and were observed to have a variety of shortcomings such as: foreign body reaction, sepsis, rigidity, fragmentation, loss of tensile strength and encapsulation [16]. All of these precluded the acceptance of polymeric materials. After reading an article about a new polyolefin material (Marlex), which demonstrated remarkable properties, Usher started to develop a woven mesh [17]. Two years later, the marlex prostheses were implemented. These were made of large pores, which facilitated incorporation despite infections. The growth of tissue through its interstices was the main difference when compared to previous materials. After a few days of surgical incorporation, fibroblast activity was noticed to increase, more collagen was induced without giant cells, and the whole system gained strength [18]. Despite the numerous advantages of the woven and knitted polyethylene mesh, Usher continued the search for better systems. He soon found that knitted polypropylene had many more advantages: it could be autoclaved, had firm borders coupled with two-way stretching, and could be rapidly incorporated. Finally, in 1958, Usher published his surgical technique using a polypropylene mesh, and 30 years later the Lichtenstein repair (known today as "tension-free" mesh technique) was popularized for hernia repair [18]. Even when the benefits of meshes were accepted, the recollection of evidence-based cases was required to statistically quantify their advantages. In 2002, the European Union Hernia Trialists Collaboration, a group of surgical trialists who have participated in randomized trials of open mesh or laparoscopic groin hernia repair, analyzed 58 randomized controlled trials and concluded that the use of surgical meshes was superior to other techniques [19]. In particular, they noted fewer recurrences and less postoperative pain with

mesh repair. These results were supported by other studies that demonstrated that hernia repair using surgical meshes reduced the risk of hernia recurrence compared to hernia reconstruction through other methods, in 2.7% vs. 8.2% in ventral hernia repair cases and by 50–75% of improvement through surgical meshes in inguinal repair [8].

Today, many surgeons agree that use of a prosthetic mesh is the preferred way to repair hernias. It should be emphasized that in the past, the success of repair was evaluated based on the strength and permanency of the mesh itself, not on the degree of scar tissue or other factors, which subsequently develop in and around the mesh [20]. The biocompatibility of the material has proven to be a strong contributor in the rejection of the prosthesis due to scar tissue developed by the immunological system. When a surgical mesh is implanted and lacks appropriate biocompatibility (either due to the material that it is made of or its structural design) the body responds by encapsulating the foreign system leading to the formation of a stiff scar which consequently results in poor tissue incorporation, causing hernia recurrence or infection of the mesh. A large percentage of meshes then have to be removed: approximately 69% of the explanted meshes are due to prosthesis infection [21].

Although the only treatment is surgery, there are new surgical procedures that ameliorate postoperative side effects such as the laparoscopic approach. Open surgery repair is performed by making an incision in the abdomen to identify and dissect the hernia sac through the subcutaneous tissues and fascia. Once the hernia sac is dissected away from any adjacent structures and examined for contents (intestine or any other tissues), these are inserted back into the peritoneal space, and hernia repair is carried out. Repair can be executed in two ways: (1) primary repair and (2) patch or mesh. The first involves sewing the tissue of the abdominal wall using sutures, while the second technique relies in the placement of a mesh to cover the hernia defect and reinforce surrounding tissue, fixing it with fibrin glue, staples or sutures.

In the case of a laparoscopic procedure, the surgeon starts by making several small incisions in the abdominal wall surrounding the hernia sac, in order to introduce surgical instruments and a laparoscope. In one of the incisions, carbon dioxide gas is introduced into the abdomen. The mesh or patch is then introduced, unrolled and fixed with staples or tacks. The procedure then continues with the release of the gas from the abdomen and closure of cutaneous incisions with sutures [22].

3. Current Research on Surgical Meshes

Most surgical meshes used currently are chemically and physically inert, nontoxic, stable and non-immunogenic. However, none of them are biologically inert, a property related to the mesh physiology and its role into the hernia repair process [23]. Implantation of any prosthetic material is quickly followed by an extraordinarily complex series of events that mark the initiation of the healing process [14]. As for the physiology of abdominal mesh implantation, perhaps the greatest concern, and hence the area that most research focuses on, is inflammation and wound healing [24]. The passive substrate of the biomaterials in conjunction with devitalized tissues can actively contribute to bacterial growth, resulting in infection, which delays the wound healing process [25].

The introduction of a foreign material into the body triggers a healing response characterized by one of three stereotypical reactions: (1) destruction or lysis, (2) inclusion or tolerance, and (3) rejection or removal. When an implant is introduced into the body, the immune system recognizes it as a foreign material and therefore attempts to destroy it [26]; immunosuppressive drugs must be administered to prevent the body from attacking it [27]. The rejection of an implant is primarily driven by the immune response of the T lymphocytes (T cells). The T cells are stimulated by the presence of an antigenic determinant on the foreign material. T cells are reproduced faster than the time required for immunosuppressants to interfere with its proliferation, therefore resulting in rejection of the implant given the large number of T cells attacking the foreign material [28].

Inflammation is the reaction of vascularized living tissue to injury and is the primary biological reaction to implanted medical devices. In the case of implanted meshes, the inflammatory response is presented in four stages that are related both temporally and hierarchically [29]. Immediately

after implantation, prosthetics adsorb proteins, which create a coagulum around it [30]. Coagulums are composed of albumin, fibrinogen, plasminogen, complement factors and immunoglobulins [31]. Platelets adhere to the proteins releasing a host of chemoattractants that invite other cells such as polymorphonucleocytes (PMNs), fibroblasts, smooth muscle cells and macrophages to the area in a different sequence [32]. The chemotaxis process is defined as the movement of cells towards a preferred migration site triggered by a chemical stimulus [33]. The attraction of PMNs, also known as neutrophils, to the wound site is attributed to chemotaxis, and is observed as the first stage of biological response to the injured site. During the first stage or acute phase of inflammation, neutrophils phagocytize microorganisms. The neutrophil may also degenerate and die during this process, releasing its cytoplasmic and granular components near or over the surface of the prosthesis, which may also mediate the subsequent inflammatory response [34].

When the acute inflammatory response is unable to eliminate the injurious agent or restore injured tissue to its normal physiological state, the condition could progress into a state of chronic inflammation, known as second stage of inflammation. In this stage, monocytes that have migrated to the wound site during the acute inflammatory response rapidly differentiate into macrophages. In addition to macrophages, other primary cellular components such as plasma cells and lymphocytes actively contribute to the inflammatory process. Macrophages increasingly populate the area to consume foreign bodies as well as dead organisms and tissue [14].

In most of the cases where chronic inflammation is related to a medical device or biomaterial, the inflammation process will lead to an immune response or foreign body reaction, corresponding to the third stage of inflammation, where chronic inflammation macrophages fuse into a foreign body giant cell as a response to the presence of large foreign bodies [35]. Foreign body reaction is a complex defense reaction involving: foreign body giant cells, macrophages, fibroblast, and capillaries in varying amounts depending upon the form and topography of the implanted material [36].

The fourth stage of inflammation occurs in the wound healing phase and is characterized by the replacement of damaged tissue with various cells that specialize in secreting extracellular matrix materials to form a scar [14]. Wound healing and scar formation follow the initiation of inflammation, but their progression and the magnitude of scarring can be affected by the degree of persistent inflammatory activity as well as the severity of the primary injury [37].

Fibroblasts are cells that mediate the wound healing phase. These cells enter the wound site two to five days after the injury occurs, typically once the inflammatory phase has ended. Fibroblasts proliferate at the wound site, reaching peak levels after one to two weeks. The main function of fibroblasts is to synthesize extracellular matrix and collagen to maintain the structural integrity of connective tissues; at the end of the first week, these are the only cells in charge of collagen deposition. Cells involved in the regulation of inflammation, angiogenesis (formation of new blood vessels from preexisting vasculature) and further connective tissue reconstruction attach to, proliferate, and differentiate on the collagen matrix laid down by fibroblasts [26].

From a histological standpoint, the interaction between prosthesis and organism is characterized by three main aspects: size of tissue reaction; cell density; and fibroblastic activity. As mentioned, fibroblastic activity peaks one to two weeks post-wounding, usually on the 8th day for the intraperitoneal plane and on the 10th day for the extraperitoneal plane. The optimum quantity of fibroblasts needed for a successful integration of the mesh is achieved approximately two weeks after wounding. Further accumulation of fibroblasts will cause an inflammatory phase with increased fibrosis and faster prosthesis integration associated with paresthesia and pain. Furthermore, the inflammatory process could cause contraction and shrinkage of the mesh, resulting in adhesions and fistulas, leading to prosthesis rejection and eventually explantation [25].

The wound repair process described above creates a mesh integration due to the conformational changes of the proteins. This integration is progressive, starting from the prosthesis implantation that is accompanied by the foreign body reaction followed by the inclusion of the prosthesis, which occurs within the first two weeks. The process is finalized as the overall strength increases gradually, which

last about 12 weeks and results in a relatively less elastic tissue that has only 70–80% of the strength of the native connective tissue [32].

Although integration and collagen deposition that result from the inflammatory response provide long-term strength, as pointed out, an aggressive integration could also be harmful to the tissue that surrounds the wound site causing a severe body reaction, inflammation, fibrosis, infection, and mesh rejection [23]. The fibrotic reaction generated by the body when a prosthetic material is introduced, such as in the case of surgical meshes for a hernia repair, is governed by the chemical nature of the material implanted and its physical characteristics. The integration and overall healing process of implantable surgical meshes is highly dependent upon the intrinsic mesh characteristics such as, the primary material, filament structure, tailored coatings, and pore size.

Research in abdominal wall repair has provided valuable information on the parameters, properties, and design of the meshes that influence the immune reaction of the body to the prosthesis as well as the optimal parameters to reduce fibrosis [38,39]. These factors are discussed below.

3.1. Elasticity and Tensile Strength

A deterioration of the tensile strength of the mesh or a strained mesh could potentially lead to hernia recurrence or a poor functional result. Hence, materials employed in surgical meshes must possess the minimum mechanical properties necessary to withstand the stresses placed on the abdominal wall. The maximum intra-abdominal pressure generated in a healthy adult occurs when coughing or jumping and is estimated to be approximately 170 mmHg. Given this information, the mesh used to repair abdominal hernias must withstand at least 180 mmHg (20 kPa) before failing [38].

The tension placed on the abdominal wall can be calculated using Laplace's law relating the tension, pressure, thickness, and diameter of the abdominal wall. According to the thin-walled cylinder model, the total tensile strength is independent of the thickness of the layer. Hence, a physiological tensile strength of 16 N/cm is defined, using a pressure of 20 kPa (2 N/cm^2 as the maximum pressure to be experienced in the intra-abdominal wall), and 32 cm as the longitudinal diameter of the abdominal wall [39].

Studies over human abdominal walls have demonstrated that at the maximum tensile strength of 16 N/cm, the abdominal wall in males presents a natural mean distension of 23% $\pm$ 7% and 15% $\pm$ 5% when tissue is stretched in vertical and horizontal direction, respectively. In females, a distension of 32% $\pm$ 17% and 17% $\pm$ 5% in vertical and horizontal stretching has been observed [40].

3.2. Pore Size

Porosity plays a key role in the reaction of the tissue to the prostheses. Bacterial growth and cell proliferation are highly dependent upon porosity and pore size. Bacterial colonies are established principally in the spaces between pores and fibers. Macroporous meshes that have large pores have shown to facilitate entry of macrophages, fibroblasts and collagen fibers that will constitute the new connective tissue, integrate the prosthesis to the organism and prevent colonization of bacteria. Large pores have shown easy infiltration of immunocompetent cells, providing protection from infection [25]. Microporous meshes, with pores of <10 µm, have shown a higher rejection rate given that scar tissue rapidly bridges small pores resulting in minimum integration, these meshes are associated with chronic inflammation.

Although it would be helpful to classify pore size in a standard form, currently, there is not a formal classification. Earl and Mark proposed the following: very large pore: >2000 µm; large pore: 1000–2000 µm; medium pore: 600–1000 µm; small pore: 100–600 µm and microporous (solid) <100 µm [32,41].

3.3. Weight (Density)

Prostheses can be classified as: heavy-weight (HW), when they are above 80 g/m^2; mediumweight (MW), between 50 and 80 g/m^2; light-weight (LW), between 35 and 50 g/m^2; and ultra-lightweight, below 35 g/m^2 [25]. While a heavy-weight mesh is produced with heavy materials, small pore size and high tensile strength, a light-weight is composed of thin filaments with large pores, generally

larger than 1 mm. Given that light-weight meshes contain less material, results have shown that less pronounced foreign body reaction is to be expected. A decreased inflammatory response results in better tissue incorporation [42].

3.4. Constitution

Surgical meshes could be fabricated using monofilament or multifilament (twisted) systems. A surgical mesh formed of monofilament yarns provides satisfactory reinforcement ability, but with stiffness and limited pliability. In contrast, a surgical mesh formed of multifilament yarns is soft and pliable. However, multifilament yarns meshes tend to harbor infectious matter such as bacteria, increasing erosion rates by 20–30% [43]. Particularly, the small void areas or interstitial spaces between the multifilament yarns may promote the replication and breeding of such bacteria, which measures approximately 10 μm.

3.5. Material Absorption

Surgical meshes could be made from an absorbable or non-absorbable material. Non-absorbable meshes can withstand the mechanical requirements, are easy to shape intraoperative and have long-term stability. However, complications such as mesh stiffness over time, hernia recurrence, mesh erosion, and adhesions have been documented. On the other hand, absorbable meshes were developed to reduce these long-term complications. These meshes favor postoperative fibroblast activity. Nevertheless, after prosthesis absorption, the resulting scar tissue is not as strong as it was, and alone is insufficient to provide the needed strength and could result in hernia recurrence.

3.6. Commercially Available Surgical Meshes

The ideal mesh should be able to be held in situ by peripheral sutures, resist the possibility of loading under biaxial tension (coughing or lifting actions) without failure especially during the early postoperative period, and should promote a fast and organized response from fibrous tissue with minimal inflammation [3].

Given the difficulty to find a single surgical mesh that fulfills all of the "ideal" characteristics, there are more than 70 meshes for hernia repair available in the market. These are classified according to the composition or type of material as: (1) first generation (synthetic non-absorbable prosthesis), (2) second generation (mixed or composite prosthesis), and (3) third generation (biological prosthesis).

3.6.1. First Generation Meshes

First generation surgical meshes are predominantly based on polypropylene (PP) systems. In 1958, the first polypropylene mesh was used to repair an abdominal wall; it was a heavyweight mesh with small pores. Due to intense fibrotic reactions, the search for an "ideal" mesh continued. In 1998, a lightweight first generation mesh was introduced: this system had larger pores and smaller surface area [38,43]. First generation meshes are mostly classified into three categories: (1) macroporous meshes, (2) microporous meshes, and (3) macroporous meshes with multifilament or microporous components.

Macroporous prostheses are characterized by a pore size larger than 75 μm. Polypropylene has been the material of choice with several brand names such as: Marlex, Prolene®, Prolite®, Atrium® and Trelex®.

Microporous meshes have smaller pores, commonly less than 10 μm and commonly made from expanded polytetrafluoroethylene (e-PTFE) under the brand name Gore-Tex® (AZ, USA).

Macroporous meshes with multifilament or microporous components contain plaited multifilamentary threads in their composition, the space between the threads is less than 10 μm and their pores are larger than 75 μm. Several systems are in the market such as: plaited polyester (PL) meshes (Mersilene® and Parietex®); plaited polypropylene (SurgiPro®, Minneapolis, MN, USA), and perforated polytetrafluoroethylene (PTFE) (Mycromesh® and MotifMesh®) [25]. Table 1 shows the classification of commercially available first generation surgical meshes.

Table 1. Classification of commercially available first generation surgical meshes [38].

Product (Manufacturer)	Material	Pore Size (mm)	Absorbable	Weight (g/m^2)	Filament	Mechanical Properties	Advantages and Disadvantages
Vicryl (Ethicon)	Polyglactin	0.4	Yes, fully (60–90 days)	56	Multifilament	Tensile strength of 78.2 ± 10.5 N/cm in longitudinal direction and 45.5 ± 13.5 N/cm in transverse direction.	Eliminates the risk of infectious disease transmission. Usually results in hernia recurrence after complete absorption
Dexon (Syneture)	Polyglycolic acid	0.75	Yes, fully (60–90 days)	56	Multifilament	N.A.	Adhesions fade as the mesh is absorbed. It is controversial whether the fibrous ingrowth into the prosthesis is sufficient to accomplish a permanent repair.
Sefil (B-Baun)	Polyglycolic acid	0.75	Yes, fully (60–90 days)	56	Multifilament	N.A.	High anatomic adaptability and low risk of late secondary infection. Retain 50% of its strength for 20 days.
Marlex (BARD)	PP	0.8	No	80–100	Monofilament	Tensile strength of 58.8 N/cm	High tensile strength. Evokes a chronic inflammatory reaction.
3D Max (BARD)	PP	0.8	No	80–100	Monofilament	Tensile strength of 124.7 N/cm	Anatomically designed. Reduced patient pain. Adhesions risk.
Polysoft (BARD)	PP	0.8	No	80–100	Multifilament	Burst strength of 558 N and a stiffness of 52.9 N/cm	Low infection risk. Not used in extraperitoneal spaces as produce dense adhesions *.
Prolene (Ethicon)	PP	0.8	No	80–100	Monofilament	Tensile strength of 156.5 N/cm	Facilitates fibrovascular ingrowth, infection resistance and improve compliance. Adhesions risk.
Surgipro (Autosuture)	PP	0.8	No	80–100	Multifilament	Tensile strength of 41.8 N/cm in longitudinal direction and 52.9 N/cm in transverse direction	High tensile strength, ease of handling and position and retains properties in vivo. Difficult complete wound healing caused by mesh structure.
Prolite (Atrium)	PP	0.8	No	80–100	Monofilament	Tensile strength of 138 N/cm	Monofilaments aligned in parallel spaced angles to maximizing material flexibility in two dimensions and a smooth and very uniform open architecture. Adhesions risk.
Trelex (Meadox)	PP	0.8	No	80–100	Multifilament	N.A.	*
Atrium (Atrium)	PP	0.8	No	80–100	Monofilament	Tensile strength of 56.2 N/cm	High tolerance to infection. Adhesions risk.

Table 1. *Cont.*

Product (Manufacturer)	Material	Pore Size (mm)	Absorbable	Weight (g/m^2)	Filament	Mechanical Properties	Advantages and Disadvantages
Premilene (B-Braun)	PP	0.8	No	80–100	Monofilament	Tensile strength of 41.4 N/cm in longitudinal direction and 36.5 N/cm in transverse direction	Mesh adaptation to the longitudinal and latitudinal axes of the connective tissue where is used for the reinforcement, rapid healing and tissue penetration. Adhesions risk.
Serapren (smooth)	PP	0.8	No	80–100	Multifilament	N.A.	*
Parietene (Covidien)	PP	0.8	No	80–100	Multifilament	Tensile strength of 38.9 $\pm$ 5.2 N/cm in longitudinal direction and 26.6 $\pm$ 4.2 N/cm in transverse direction	*
Prolene Light (Covidien)	PP	1.0–3.6	No	36–48	Monofilament	Tensile strength of 20 N/cm	Greater flexibility. Not used in intraperitoneal spaces as produce dense adhesions.
Optilene (B-Baun)	PP	1.0–3.6	No	36–48	Monofilament	Tensile strength of 58 N/cm	Soft, thin and pliable. Ideal for inguinal hernia repair to reduce chronic pain. Not used in extraperitoneal spaces as produce dense adhesions.
Mersilene (Ethicon)	POL	1.0–2.0	No	40	Multifilament	Tensile strength of 19 N/cm	Low infection risk. Evokes an aggressive macrophage and giant cell rich inflammatory reaction, followed by a dense fibrous ingrowth.
Goretex (Gore)	e-PTFE	0.003	No	Heavyweight	Multifilament	Minimum tensile strength of 16 N/cm	Smooth and strong. Evokes a chronic inflammatory reaction.

PP: Polypropylene. POL: Polyester. e-PTFE: Expanded polytetrafluoroethylene. N.A, Information not available in literature. * Duplicated properties.

3.6.2. Second Generation Meshes

Despite the improvements made within the first generation meshes (Table 1), which include high tensile strength in order to support intra-abdominal pressure, several complications such as hernia recurrence, infection, and adhesions still prevailed. Therefore, second generation meshes were developed combining more than one synthetic material into their composition. Nearly all of these kinds of meshes continued to use PP, PL or e-PTFE but now in combination with each other and/or with other materials such as titanium (Ti), omega 3, poliglecaprone 25 (PGC-25) and polyvinylidene fluoride (PVDF) as composite systems.

The main advantage of these composite meshes relied in the fact that these could be employed in intraperitoneal spaces causing minimal adhesion formation to neighboring surfaces given that each side of the mesh is tailored to specific needs. These meshes therefore require a specific orientation during implantation; the visceral side has a microporous surface to prevent visceral adhesion, whereas the non-visceral side is often macroporous to allow parietal tissue ingrowth. There are two categories of composite meshes: absorbable and permanent (non-absorbable). Absorbable composite meshes require hydration prior to usage, are not amenable to modification, mitigate viscera-mesh related complications, and can aid in tissue ingrowth. Parietex® is the first composite mesh to offer a resorbable collagen barrier on one side to limit visceral attachments combined with a three-dimensional polyester knit structure on the other side, to promote tissue ingrowth. Permanent composite meshes can be modified to fit specific applications and present less visceral adhesions and complications, taking advantage of the properties of both macro and micro porous meshes. Dual Mesh®(W.L. Gore & Associates, Inc., AZ, USA), Dulex® and Composix® (both manufactured by Bard Davol Inc., Providence, RI, USA) are some of the brand name meshes included in this category [42]. Table 2 lists some of the commercially available second generation surgical meshes.

3.6.3. Third Generation Meshes

Even with the improvements made on the second generation meshes (Table 2) where composite systems were designed to maintain the mechanical stability of first generation meshes (Table 1) and reduce inflammation and infection risk by mesh surface modification, the problems encountered with second generation meshes, such as the prevalence of adhesions, led to the development of biologic prostheses. Biologic mesh materials are based on collagen scaffolds derived from donor sources and they represent the so-called third generation meshes. Dermis from human, porcine, and fetal bovine sources are decellularized to leave only the highly organized collagen sources in addition to the dermal products included in porcine small intestine submucosa and bovine pericardium. The concept of these surgical meshes is that they provide a matrix for native cells to populate and generate connective tissue that could replace the tissue in the hernia defect [25]. Table 3 lists some of the commercially available third generation surgical meshes.

Third generation surgical meshes (Table 3) serve as biological scaffolds for repopulation and revascularization of host cells, showing a superior biocompatibility than first and second generations. These meshes do not trigger an inflammatory response from the body, though their high cost has hampered their wide acceptance.

Table 2. Classification of commercially available second generation surgical meshes [38].

Product (Manufacturer)	Material	Pore Size (mm)	Absorbable	Weight (g/m^2)	Filament	Mechanical Properties	Advantages and Disadvantages
Vypro, Vypro II (Ethicon)	PP/polyglactin 910	>3	Partially (42 days)	25 & 30	Multifilament	Tensile strength of 16 N/cm	Significantly decreased rates of chronic pain. Higher rate of hernia recurrence.
Gore-Tex Dual Mesh Dual Mesh Plus (Gore)	e-PTFE	0.003–0.022	No	Heavyweight	Multifilament	Minimum tensile strength of 16 N/cm (Gore-Tex Dual Mesh) and 157.7 N/cm (Dual Mesh Plus)	Promotes host tissue growth and reduces tissue attachment. Infection risk.
Parietex (Covidien)	POL/collagen	>3	Partially (20 days)	75	Multifilament	Elasticity of 3.5 at 16 N	Short-term benefit for anti-adhesion property. Greater infection rate (57%).
Composix EX Dulex (BARD)	PP/e-PTFE	0.8	No	Lightweight	Monofilament	N.A.	Minimizes adhesions and provides optimal tissue ingrowth. Infection risk.
Proceed (Ethicon)	PP/cellulose	Large	Partially (<30 days)	45	Monofilament	Tensile strength of 56.6 N/cm	Low rates of hernia recurrence (3.7%). Risk of formation of visceral adhesions.
DynaMesh IPOM (FEG Textiltechnik)	PP/PVDF	1–2	Partially	60	Monofilament	Tensile strength of 11.1 ± 6.4 N/cm in longitudinal direction and 46.9 ± 9.7 N/cm in transverse direction	Minimal foreign body reaction. Adhesions risk.
Sepramesh (Genzyme)	PP/sodium	1–2	Partially (<30 days)	102	Monofilament	N.A.	Reduces adhesions and the optimal tissue ingrowth is promoted. Sticky consistency difficult the surgeon manipulation.
Ultrapro (Ethicon)	PP/PGC-25	>3	Partially (<140 days)	28	Monofilament	Tensile strength of 55 N/cm	Reduced inflammatory response. Adhesions risk.
Ti-Mesh (GfE)	PP/titanium	>1	No	16 & 35	Monofilament	Tensile strength of 12 N/cm (mesh of 16 g/m^2) and 47 N/cm (mesh of 35 g/m^2)	Reduced inflammatory response. Low tensile strength.
C-Qur (Atrium)	PP/omega 3	>1	Partially (120 days)	50	Monofilament	Ball burst strength of 170 ± 20.1 N	Short-term benefit for anti-adhesion property. No significant difference for adhesion grade or amount relative to other meshes.

PP: Polypropylene. e-PTFE: Expanded polytetrafluoroethylene. POL: Polyester. PVDF: Polyvinylidene fluoride. PGC-25: poliglecaprone 25. N.A, Information not available in literature.

Table 3. Classification of commercially available third generation surgical meshes [38].

Product (Manufacturer)	Material	Tensile Strength (MPa)	Advantages	Disadvantages
Surgisis (Cook)	Porcine (small intestine submucosa)	4	No refrigeration is required. Long history of safety data.	Requires hydration. Susceptible to collagenases.
FlexHD (J&J)	Human (acellular dermis)	10	No refrigeration or rehydration is required.	N.A.
AlloMax (Davol)	Human (acellular dermis)	23	No refrigeration or rehydration is required. Available in large sizes.	Hydration required.
CollaMend (Davol)	Porcine/Bovine (xenogenic acellular dermis)	11	No refrigeration or rehydration is required. Available in large sizes.	N.A.
Strattice (LifeCell)	Porcine/Bovine (xenogenic acellular dermis)	18	Available in large sheets.	Limited long-term follow up.
Permacol (Covidien)	Porcine/Bovine (xenogenic acellular dermis)	39	No refrigeration or rehydration is required. Available in large sizes.	N.A.
XenMatrix (Davol)	Porcine/Bovine (xenogenic acellular dermis)	14	Available in large sheets.	Limited long-term follow up.

N.A. Information not available in literature.

3.7. Manufacturing Processes for Surgical Meshes

Surgical meshes are produced from different synthetic materials and in different mesh structures, the knitted structure being the most common [44]. Surgical filaments are mainly manufactured by extrusion processes and then knitted accordingly. As mentioned, meshes are typically manufactured from PL, PP, PTFE, e-PTFE, PVDF and composite materials (e-PTFE/PP) [45]. The knitting pattern can be significantly altered resulting in a broad range of properties. Thickness, pore size, tensile strength, flexural rigidity, and surface texture are highly dependent upon the knitting pattern; the resultant interplay among these characteristics imparts different performance [44]. These characteristics, besides altering the biocompatibility of the mesh given its affinity to cells, also dictate the mechanical properties of the mesh such as rigidity and deformation. Knitted meshes are a subset of the non-woven mesh configuration. However, there is much more order and consistency with pore size using a knitted design [46]. Knitting, by definition, is the construction of a fabric or cloth from the interlocking of threads through the formation of loops. Recent studies have been focused on treating the surgical mesh as a high-tech textile rather than as a prosthesis [44].

3.7.1. The Extrusion Process

Melt extrusion is the least expensive and simplest form of fiber extrusion [47]. This process consists of melting the polymer pellets through a combination of applied heat and friction. The molten polymer is then forced under high pressure through a small orifice or a "shower head" spinneret. The molten polymer flows out of the spinneret and freezes into a solid fiber, which is then typically reheated and drawn numerous times to further align the molecules and hence strengthen the fiber [48].

Most of the surgical meshes are made from filaments initially developed to be used for surgical sutures. Surgical sutures are made from polymers like PP [49], PL [50], e-PTFE [51] or PVDF [52] monofilaments and have been successfully used by the medical profession for decades. Filaments used for surgical sutures have to possess several characteristics such as [53]:

1. Ability to attach to needles by the usual procedure.
2. Capability to be sterilized using ethylene oxide or ultraviolet radiation.
3. Ability to pass easily through tissue.
4. Ability to resist breakdown without developing an infection.
5. Possess minimal reaction with tissue.
6. Maintain its in vivo tensile strength over extended periods.

used for surgical sutures have to possess several characteristics such as [53]:

1. Ability to attach to needles by the usual procedure.
2. Capability to be sterilized using ethylene oxide or ultraviolet radiation.
3. Ability to pass easily through tissue.
4. Ability to resist breakdown without developing an infection.
5. Possess minimal reaction with tissue.
6. Maintain its in vivo tensile strength over extended periods.

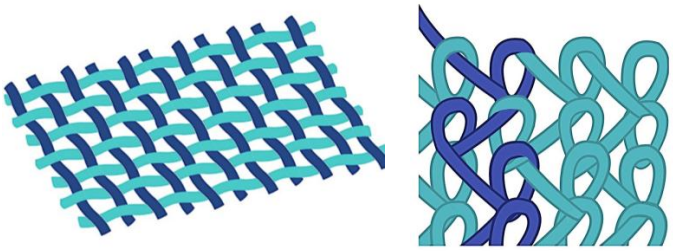
Commonly, the monofilaments used for surgical meshes have diameters in the range of 100–300 microns [54]. Multifilaments have also gained attention and have been used to fabricate surgical meshes. Lubricants are commonly applied to these filaments before the yarns are knitted. Suitable lubricants can be either hydrophobic lubricants [55] or hydrophilic lubricants such as polyalky glycol [56].

Commonly, the monofilaments used for surgical meshes have diameters in the range of 100–300 microns [54]. Multifilaments have also gained attention and have been used to fabricate surgical meshes. Lubricants are commonly applied to these filaments before the yarns are knitted. Suitable lubricants can be either hydrophobic lubricants [55] or hydrophilic lubricants such as polyalky glycol [56].

3.7.2. The Knitting Process

During the knitting process, fibers or yarns are curved to follow a meandering path and not oriented unilaterally as in weaving; therefore, the resulting fabric tends to be much more flexible and elastic than woven fabrics. The basic structure of a knitted fabric consists of courses and wales. Courses are rows running across the width of the fabric, while wales are columns running across the length of the fabric. When the wales are perpendicular to the course of the fiber/yarn, this is called weft knitting. When the courses and wales are approximately parallel to the direction of the fiber/yarn, the process is known as warp knitting [57]. Figure 1 shows a warp structure.

During the knitting process, fibers or yarns are curved to follow a meandering path and not oriented unilaterally as in weaving; therefore, the resulting fabric tends to be much more flexible and elastic than woven fabrics. The basic structure of a knitted fabric consists of courses and wales. Courses are rows running across the width of the fabric, while wales are columns running across the length of the fabric. When the wales are perpendicular to the course of the fiber/yarn, this is called weft knitting. When the courses and wales are approximately parallel to the direction of the fiber/yarn, the process is known as warp knitting [57]. Figure 1 shows a warp structure.



(**a**) (**b**)

Figure 1. Schematic of: (**a**) woven; and (**b**) warp knitted structures.

Figure 1. Schematic of: (**a**) woven; and (**b**) warp knitted structures.

Warp knits and weft knits have been generated for use as implantable meshes to repair specific tissue sites and organs, such as those needed in hernia repair. Because of the looped stitches, the knitted structure is soft, flexible, and stretchable. It easily adapts to the movement of the human body [58], and has high elasticity, tensile strength, bursting strength and excellent porosity, which are key requirements for any implantable device that needs to mimic the biomechanical characteristics of the abdominal wall: tension of 16 N/cm with a 38% elasticity [38]. Given the interweaving, warp-knitted materials have a fixed structure that neither loosens nor peels off during cutting, regardless of the direction [55]. These material systems have been successfully commercialized and currently used worldwide. Table 4 lists some commercially available meshes classified according to the knitted technique, material, and type of filament.

Warp knits and weft knits have been generated for use as implantable meshes to repair specific tissue sites and organs, such as those needed in hernia repair. Because of the looped stitches, the knitted structure is soft, flexible, and stretchable. It easily adapts to the movement of the human body [58], and has high elasticity, tensile strength, bursting strength and excellent porosity, which are key

Table 4. Classification of commercially available surgical meshes [59].

Mesh	Structural Textile Technique	Polymer	Fiber
Marlex	Woven	PP	Mono
Prolene®	Warp	PP	Mono
Atrium®	Warp	PP	Mono
Vypro®	Warp	PP/PG-910	Multi
UltraPro®	Warp	PP/PGC-25	Mono
TiMesh®	Warp	PP/Ti	Mono
DualMesh®	Warp	e-PTFE	Foil *
Mersilene®	Warp	Polyethylene Terephthalate (PET)	Multi
Dynamesh®	Warp	PVDF	Mono
Vycril®	Woven	Resorbable undyed Polyglactin	Multi
Gore-Tex®	Woven	e-PTFE	Multi

* Membrane/patch.

The most commonly used systems in the knitting manufacturing process are the Tricot [60] and Raschel knitting machines [61], which are used to create warp or weft knitting structures [62]. Warp knitted meshes are the most popular system used to repair hernia defects, and are manufactured using the Raschel machine with a basic configuration consisting of two bars where latch-type needles are collectively mounted (running the full knitting width of the machine) and guide bars to hold yarn beams individually. The needle bars follow up and down movements, while the guide bars move back and forth across the needles of each bar to form continuous loops. The warp knit fabric design and lapping sequence is controlled by the shagging or traverse motion of the guide bars [63].

In principle, the Tricot knitting machine is very similar to the Raschel knitting; the only difference is the use of spring beard or compound needles instead of the latch needles used in the Raschel knitting machine. In addition, Tricot sinkers not only performed the function of holding down the loops whilst the needles rise as Raschel sinkers, but also support the fabric loops. The small angle of fabric take-away and the type of knitting action in Tricots creates a gentle and lower tension on the knitted fabric, ideal for high-speed production of fine gauge [64].

A double Raschel warp knitting machine (DR 16 EEC/EAC) has 16 guide bars and enables the production of textiles with different yarn materials and counts. The machine is equipped with two different gauges, E18 and E30. This system allows the design of a mesh configuration that could be adjusted to match given design parameters such as size, shape, Young modulus, and porosity [65]. The ultimate mechanical properties of the meshes are determined by the intrinsic properties of the filaments and the final configuration of the knitted fabrics.

4. Future Perspectives

Despite the clinical success and vast body of knowledge that has been gained regarding manufacturing of surgical meshes, material properties, and surgical procedures, it is obvious that the ideal mesh has not been developed. It is well known that meshes still suffer from contraction and/or infection after implantation [66]. Furthermore, adhesions between the visceral side of the mesh and adjacent organs still occur. These complications may have serious consequences, such as chronic pain, intestinal obstruction, bowel erosion, or hernia recurrence. All of these problems have opened a great number of opportunities to create a new generation of surgical meshes [67]. This new generation will have to show a better integration with the tissue of the abdominal wall, but no adhesions on the visceral side. Based on the ideas of van't Riet [68], Ebersole [69] and Xu [70], new alternatives rely broadly on surface mesh modification by novel coatings to existent meshes and/or integration of nanofiber based systems.

4.1. Coatings

A variety of biocompatible and biodegradable natural and synthetic polymers are being investigated. Extensive research focuses in the development of a bi-layer composite hernia mesh in order to minimize the risk of infections and reduce adhesions on the visceral side [71,72]. Materials that had been studied are: Polylactic acid (PLLA) [20], oxygenated regenerated cellulose (ORC) [67], n-vinyl pyrrolydone (NVP) and n-butylmethacrylate (BMA) [67], polyglycolic acid (PGA) [73], carboxymethylcellulose (SCMC) [74], omega-3 fatty acid [75], messenchymal stem cells (RMSC) [76], human dermal (HDF) and rat kidney fibroblasts (RKF) [76], collagen [77–79], chitosan [80], nanocrystalline silver particles (NCSP) [81] and titanium [82,83]. Table 5 shows some of the properties that have made these materials attractive as active ingredients in surgical meshes [71,80,84–86].

Most of the recently published literature still presents PP surgical meshes as the "gold standard" though with surface modifications made with materials mentioned in Table 5. Studies have primarily concentrated on: thickness and concentration of the materials used in the coating to be in contact with the visceral and/or abdominal side (Ex: 95% of oxidized collagen and 5% of chitosan) [26] and surface density (measured in g/m^2). The following Table 6 presents a summary of the obtained results based on the inflammatory response and percentage of adhesion.

Table 5. Material properties of surgical mesh coatings.

PLLA/PGA	ORC/SCMC	NVP/BMA	Omega-3 Fatty Acid	RMSC/HDF/RKF	Collagen/Chitosan	NCSP	Titanium
Variable degradation rate	Reduce mesh adhesions	Reduce mesh adhesions	Minimal risk of mesh contraction	Affinity towards fibroblasts	Weak tensile properties	Anti-inflammatory	Provides mechanical integrity
Hydrophilicity	Absorbable	Hydrophilicity	Absorbable	Favourable cell adhesion	Negligible effect on biomechanical properties	Antimicrobial	Non-absorbable

PLLA: Polylactic acid. PGA: Polyglycolic acid. ORC: Oxygenated regenerated cellulose. SCMC: Carboxymethylcellulose. NVP: N-vinyl pyrrolydone. BMA: N-butylmethacrylate. RMSC: Messenchymal stem cells. HDF: Human dermal. RKF: Rat kidney fibroblasts. NCSP: Nanocrystalline silver particles.

Table 6. Examples of surgical mesh coating parameters.

Reference	Analyzed Parameter	
	Material	**Surface Density**
Pascual et al. [86]	Oxidized collagen Chitosan	Oxidized collagen 95%/ Chitosan 5%
Ciechańska et al. [71]	MBC	6.7 g/m^2 (one side) 5.31 g/m^2 (two sides)
Cohen et al. [81]	NCSP	310 g/m^2 640 g/m^2 1130 g/m^2
Niekraszewics et al. [85]	Chitosan	20 g/m^2 (one side) 20 g/m^2 (two sides)

MBC: Modified bacterial cellulose. NCSP: Nanocrystalline silver particles.

In general, the new composite meshes show highly improved performance regarding peritoneal regeneration and visceral adhesion [84]. These studies have developed composite surgical meshes with high potential for adoption. Further studies with a focus on long-term adhesion and structural performance will complement obtained results.

4.2. Nanofibers

Nanofiber systems made from a large variety of materials have been explored extensively in the last decade. Scaffolds for tissue regeneration are strongly deemed as a potential application of these systems [87]. Mimicking the extracellular matrix (ECM) is vital to control cell behavior, such as adhesion, proliferation, migration, and differentiation. Tissue Engineering (TE) has been extensively explored to provide answers associated with current problems encountered in the interaction of the surgical meshes with the human body. One of the challenges of TE is to mimic the natural extracellular matrix (ECM) of the abdominal wall to promote an efficient integration. Researchers are actively exploring the implementation of nanofiber systems to effectively mimic the ECM [88–90].

Nanofibrous structures present several advantages, such as high specific surface area for cell attachment, higher microporous structure and a 3D micro environment for cell–cell and cell–biomaterial contact, these being associated with unique physical and mechanical properties. These structures when compared with commercial surgical meshes possess higher porosity and smaller pore size. These properties make nanofiber systems suitable for biomaterials used in wound care, drug delivery, and scaffolds for tissue regeneration [20,44,91].

Scaffolds for tissue engineering must possess a porous structure able to facilitate cell migration, a balance between surface hydrophilicity and hydrophobicity for cell attachment, mechanical properties comparable to natural tissue, and biocompatibility. Studies have shown that the abovementioned characteristics are also highly influenced by average diameter of the fibers and pore size. Effective cell attachment and proliferation has been observed in fiber systems with average diameters smaller than 1 µm and average pore size of 14 µm [92]. In commercially available meshes, even when it has been shown that cells are able to proliferate in micrometer/macrometer regimes, the cells in fact have difficulty attaching and proliferating. Cells are seen around the fibers whereas, on nanofiber based meshes, the cells attach to the fibers and quickly proliferate while making strong contact with underlying nanofibers, therefore promoting interlayer growth.

The application of nanofiber systems has been hampered due to its poor mechanical properties and nanofiber availability. Most of the available studies have focused on nanofibers prepared through solution processes. The properties of the developed fibers can be controlled by different parameters such as utilized solvent, concentration of polymer, processing methods, and ambient conditions. For example, in the case of nanofibers made of polypropylene (one of the highly used polymers for commercially available surgical meshes), decahydronaphthalene (decalin) and cyclohexane have been

used as preferred solvents. Polypropylene nanofibers prepared with cyclohexane exhibited a rougher surface when compared to the fibers prepared with decalin, suggesting that the surface morphology of the nanofibers depend on the boiling point of each solvent [93]. When stress–strain behaviors of the nanofibers are investigated, a tensile strength of 61.4 ± 1.5 MPa with 35.2% ± 1.7% of strain, and a Young modulus of 174.6 ± 1.7 MPa was obtained for the decalin based nanofibers, whilst the cyclohexane nanofibers exhibit a tensile strength of 18.2 ± 1.1 MPa with 46.7% ± 1.2% of elongation and a Young modulus of 39.1 ± 1.4 MPa [94]. The abovementioned results were obtained from bundles of nanofibers rather than individual fibers, these properties are strongly dependent on fiber orientation within the tested sample, bonding between fibers, and slip of one fiber over another [94].

Regarding nanofiber availability, there are several methods to prepare nanofiber systems. These methods include wet chemistry, Electrospinning (ES) [95] and Forcespinning® (FS) [96] techniques. Most of the available literature has used ES processes; these studies have proven the potential of these nanofiber systems towards solving many of the challenges encountered in TE. ES processes have been limited to laboratory-based research given the challenges associated with increasing yield and opportunity to work with melt based systems. FS, a technique that has been recently introduced is based on developing nanofibers through the application of centrifugal forces. The method has been proven effective to produce yields that could satisfy industry requirements (i.e., several hundred meters per minute) as well as to produce nanofibers from melt based systems therefore removing the requirement of a solvent and subsequently the potential contamination of the materials with toxic organic solvents, and cost associated with the solvent itself and solvent recovery procedures. Other scaffolds had been produced by 3D printing procedures. Such biomimetic scaffolds are promising techniques as they could allow precise control over the geometry and microstructure [46,97].

Table 7 presents a summary of recently published work regarding the manufacture of nanofiber based surgical meshes.

Table 7. Nanofiber based surgical meshes.

Nanofiber Material	Manufacturing Process	Diameter (nm)	Tensile Strength (MPa)	Advantages and Disadvantages	Reference
Poly-ε-caprolactone (PCL)	Electrospinning	1280 ± 330	3.11 ± 1.09	Better adhesion, growth, metabolic activity, proliferation and viability of 3T3 Fibroblasts. Lack of in vivo testing.	[87,98]
Polydioxanone (PDO)	Electrospinning	860 ± 420	3.76 ± 0.49	Bioresorbable polymer. Reduction of long-term foreign body response (LTFBR). No fulfill the mechanical requirements.	[99]
Polylactide-Co-Glycolide (PLGA 8218)	Electrospinning	3280 ± 570	6.47 ± 0.41	Exceed the minimum mechanical requirements for hernia repair applications. Bioresorbable polymer. Reduction of LTFBR. Lack of in vivo testing.	
PLLA	Electrospinning	1480 ± 670	3.59 ± 0.25	In vivo advantages. Exceed the minimum mechanical requirements for hernia repair applications. Lack of in vivo testing.	
Polyurethane (PU)	Electrospinning	890 ± 330	18.9 ± 5.9	Elastic deformation.	
PET	Electrospinning	710 ± 280	3.17 ± 0.23	Adequate mechanical attributes. No evidence of intestinal adhesions. Trigger of a large foreign body reaction.	[100]
PET/Chitosan	Electrospinning	3010 ± 720	2.89 ± 0.27	Adequate mechanical attributes. No evidence of intestinal adhesions. Trigger of a large foreign body reaction.	
PCL/Collagen	Electrospinning	1000	2.13 ± 0.36	Biological and biomechanical stable, support skeletal muscle cell ingrowth and neo-tissue formation	[101]

PCL: Poly-ε-caprolactone. PDO: Polydioxanone. PLGA 8218: Polylactide-Co-Glycolide. PU: Polyurethane. PET: Polyethylene terephthalate.

Nanofiber systems are certainly showing a strong potential to be used in the next generation of surgical meshes, the increased availability (FS process) will certainly promote the development of practical applications. Nanofiber developed through the FS system have shown promising results regarding adhesion, growth, metabolic activity, proliferation, and viability of 3T3 cells [70,102]. It is expected that these systems will be used in combination with existent commercial meshes to satisfy other requirements such as mechanical strength needed to bear the intra-abdominal pressure exerted by human body and implantation requirements to mention some. Future studies in this area will include the effect of nanofiber morphology, mesh design (i.e., uniaxial aligned, radially aligned, orthogonally patterned) needed to improve structural properties, and in vivo testing.

In summary, this review synergistically complements recent reviews made in this important area. Table 8 presents a comparative table with recent published reviews [38,103–106]. Besides having in common the history and present scenario, this review also presents information regarding manufacturing methods (manufacturing of these meshes has a strong influence in the medical results, therefore the ultimate functionality will be strongly dependent upon the manufacturing method) and future perspectives.

Table 8. Aspects related to hernia meshes compared in recently published reviews.

	Baylon et al. (This Review)	**Brown et al. [38]**	**Sanbhal et al. [103]**	**Guillaume et al. [104]**	**Todros et al. [105]**	**Todros et al. [106]**
Introduction	√	√	√	√	√	√
History	√	√	-	-	-	-
Present Scenario	√	√	√	√	√	√
Properties Discussed	Elasticity/tensile strength Pore Size Weight (density) Constitution Material absorption	Tensile strength Pore Size Weight Reactivity/Biocompatibility Elasticity Constitution Shrinkage Complications	Weight Pore Shape, size/porosity Mesh elasticity/strength	Properties discussed for particular meshes, varies from the type of mesh being discussed.	Pore size Density thickness	Biomechanical properties Uniaxial tensile testing Biaxial tensile testing Ball burst testing
Surgical Mesh	√	√	√	√	√	√
Manufacturing Processes	> 2 processes considered	-	-	-	-	-
Future Perspectives	2 perspectives considered	-	√	√	-	-
Comments	Comparison of meshes divided by generations: First generation (18 meshes), second generation, (10 meshes), third generation (7 meshes)	Comparison of meshes divided by constitution, Multi (3 meshes), multifilament and monofilament (13 meshes), and foil (1 mesh). Biomaterial meshes (10 meshes)	Comparison between synthetic meshes (15 meshes) Comparison between composite meshes (12 meshes)	Meshes divided by Biologically Derived Matrices, Biodegradable synthetic structures, Anti-inflammatory mesh, Meshes with enhanced cytocompatibility, Anti-adhesive Mesh, Antibacterial meshes. Review also discusses mesh fixation, self-expanding systems, post-implantation visible mesh, cell coated meshes, and growth factor loaded meshes.	Comparison between synthetic surgical meshes: HWPP (5 meshes), LWPP (6 meshes), PET (1 mesh), ePTFE (1 mesh), PVDF (1 mesh) Comparison between Multilayered meshes (10 meshes)	Comparison between synthetic surgical meshes: HWPP (5 meshes), LWPP (3 meshes), PET (1 mesh), ePTFE (1 mesh), PVDF (1 mesh). Comparison between Multilayered Meshes (10 meshes)
Total meshes compared	35	27	27	-	24	21

5. Conclusions

Surgical meshes have become the system of choice for hernia repair. Even though it is not the optimum method, so far it is the one that has shown a lower rate of recurrence. Currently, there are more than 70 types of meshes commercially available. These are constructed from synthetic materials (absorbable, non-absorbable, or a combination of both) and animal tissue. Despite reducing rates of recurrence, hernia repair with surgical meshes still faces adverse effects such as infection, adhesion, and bowel obstruction. Most of these drawbacks are related to the chemical and structural nature of the mesh itself.

An optimum integration with the abdominal wall and negligible adhesion on the visceral side are the most important after sought features for the "ideal" mesh. A surgical mesh will trigger one of three different responses from the body: it may be integrated, encapsulated or degraded. In order to have a minimal inflammatory response to better integrate it to the body, it is highly important to improve biocompatibility.

To overcome this obstacle, researchers are actively exploring methods to improve biocompatibility, with the goal of developing a mesh that can be effectively incorporated with minimal inflammation and/or infection. Nanofibers have been recently considered as a strong potential intermediary structure to be used as a coating, given their ultralightweight quality, which could contribute to minimize the inflammatory response from the body and given its functional porosity, which could promote cell adhesion and proliferation.

Acknowledgments: The authors gratefully acknowledge support received by the National Science Foundation Partnership for Research and Education in Materials (PREM) award under Grant No. DMR-1523577: The University of Texas Rio Grande Valley–University of Minnesota Partnership for Fostering Innovation by Bridging Excellence in Research and Student Success. This work was also funded by Tecnológico de Monterrey—Campus Monterrey, through the Research group of Nanotechnology and Devices Design. Additional support was provided by Consejo Nacional de Ciencia y Tecnología (CONACYT), Project Number 242269, Mexico.

Author Contributions: As a review article, all authors contributed to the writing, editing and revision of the manuscript. All authors contributed equally to the development of this review article.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Williams, L.S.; Hopper, P.D. *Understanding Medical-Surgical Nursing*, 5th ed.; F.A. Davis: Philadelphia, PA, USA, 2015; p. 770.
2. Dabbas, N.; Adams, K.; Pearson, K.; Royle, G.T. Frequency of abdominal wall hernias: Is classical teaching out of date? *J. R Soc. Med. Short Rep.* **2011**, *2*, 1–6. [CrossRef] [PubMed]
3. Bendavid, R.; Abrahamson, J.; Arregui, M.E.; Flament, J.B.; Phillips, E.H. *Abdominal Wall Hernias: Principles and Management*, 1st ed.; Springer: New York, NY, USA, 2001.
4. Heniford, B.T. *Hernia Handbook*, 1st ed.; Carolinas HealthCare System: Charlotte, NC, USA, 2015.
5. Kingsnorth, A. Treating inguinal hernias: Open mesh Lichtenstein operation is preferred over laparoscopy. *BMJ* **2004**, *328*, 59–60. [CrossRef] [PubMed]
6. Li, X.; Kruger, J.A.; Jor, J.W.; Wong, V.; Dietz, H.P.; Nash, M.P.; Nielsen, P.M. Characterizing the ex vivo mechanical properties of synthetic polypropylene surgical mesh. *J. Mech. Behav. Biomed. Mater.* **2014**, *37*, 48–55. [CrossRef] [PubMed]
7. CORDIS: Community Research and Development Information Service. Available online: http://cordis.europa.eu/result/rcn/178015_en.html (accessed on 9 June 2017).
8. Bard Davol Inc. Available online: https://www.davol.com/index.cfm/_api/render/file/?method=inline&fileID=90027245-5056-9046-9529B0C67424C711 (accessed on 9 June 2017).
9. Pandit, A.S.; Henry, J.A. Design of surgical meshes—An engineering perspective. *Technol. Heal. Care* **2004**, *12*, 51–65.
10. Melero Correas, H. Caracterización Mecánica de Mallas Quirúrgicas Para la Reparación de Hernias Abdominales. Master Thesis, Universitat Politècnica de Catalunya, Barcelona, Spain, November 2008.

11. Zhu, L.-M.; Schuster, P.; Klinge, U. Mesh implants: An overview of crucial mesh parameters. *World J. Gastrointest. Surg.* **2015**, *10*, 226–236. [CrossRef] [PubMed]
12. Billroth, T. *The Medical Sciences in the German Universities: A Study in the History of Civilization*; Welch, W.H., Ed.; Macmillan: New York, NY, USA, 1924.
13. Chowbey, P. *Endoscopic Repair of Abdominal Wall Hernias*, 2nd ed.; Byword Books: Delhi, India, 2012.
14. Greenberg, J.A.; Clark, R.M. Advances in suture material for obstetric and gynecologic surgery. *Rev. Obstet. Gynecol.* **2009**, *2*, 146–158. [CrossRef] [PubMed]
15. LeBlanc, K.A. *Laparoscopic Hernia Surgery an Operative Guide*, 1st ed.; CRC Press: New Orleans, LA, USA, 2003.
16. Usher, F.C.; Fries, J.G.; Ochsner, J.L.; Tuttle, L.L. Marlex mesh, a new plastic mesh for replacing tissue defects. II. A new plastic mesh for replacing tissue defects. *AMA Arch. Surg.* **1959**, *78*, 138–145. [CrossRef] [PubMed]
17. Usher, F.C.; Hill, J.R.; Ochsner, J.L. Hernia repair with Marlex mesh. A comparison of techniques. *Surgery* **1959**, *46*, 718–728. [PubMed]
18. Klinge, U.; Klosterhalfen, B.; Birkenhauer, V.; Junge, K.; Conze, J.; Schumpelick, V.J. Impact of polymer pore size on the interface scar formation in a rat model. *Surg. Res.* **2002**, *103*, 208–214. [CrossRef] [PubMed]
19. EU Hernia Trialists Collaboration. Repair of groin hernia with synthetic mesh: Meta-analysis of randomized. *Ann. Surg.* **2002**, *235*, 322–332. [CrossRef]
20. Stowe, J.A. Development and Fabrication of Novel Woven Meshes as Bone Graft Substitutes for Critical Sized Defects. Ph.D. Thesis, Clemson University, Clemson, SC, USA, May 2015.
21. Hawn, M.T.; Gray, S.H.; Snyder, C.W.; Graham, L.A.; Finan, K.R.; Vick, C.C. Predictors of mesh explantation after incisional hernia repair. *Am. J. Surg.* **2011**, *202*, 28–33. [CrossRef] [PubMed]
22. Carbajo, M.A.; Martín del Olmo, J.C.; Blanco, J.I.; De la Cuesta, C.; Toledano, M.; Martín, F.; Vaquero, C.; Inglada, L. Laparoscopic treatment vs open surgery in the solution of major incisional and abdominal wall hernias with mesh. *Surg. Endosc.* **1999**, *13*, 250–252. [CrossRef] [PubMed]
23. Schumpelick, V.; Fitzgibbons, R.J. *Hernia Repair Sequelae*, 1st ed.; Springer: Berlin/Heidelberg, Germany, 2010.
24. Bendavid, R. *Prostheses and Abdominal Wall Hernias*, 1st ed.; R.G. Landes Co.: Austin, TX, USA, 1994.
25. Zogbi, L. The Use of Biomaterials to Treat Abdominal Hernias. In *Biomaterials Applications for Nanomedicine*, 1st ed.; Pignatello, R., Ed.; InTech: Rijeka, Croatia, 2008; Volume 18, pp. 359–382.
26. Anderson, J.M. Biological Response to Materials. *Annu. Rev. Mater. Res.* **2001**, *31*, 81–110. [CrossRef]
27. Batchelor, A.W.; Chandrasekaran, M. *Service Characteristics of Biomedical Materials and Implants*, 1st ed.; Imperial College Press: London, UK, 2004.
28. Santambrogio, L. *Biomaterials in Regenerative Medicine and the Immune System*, 1st ed.; Springer Internatinal Publishing Switzeerland: Cham, Switzerland, 2015.
29. Acevedo, A. Mallas sintéticas Irreabsorbibles su desarrollo en la cirugía de las hernias abdominals. *Revista Chilena Cirugía* **2008**, *60*, 457–464. [CrossRef]
30. Tang, L.; Ugarova, T.P.; Plow, E.F.; Eaton, J.W. Molecular determinates of acute inflammatory response to biomaterials. *J. Clin. Investig.* **1996**, *97*, 1329–13234. [CrossRef] [PubMed]
31. Busuttil, S.J.; Ploplis, V.A.; Castellino, F.J.; Tang, L.; Eaton, J.W.; Plow, E.F. A central role for plasminogen in the inflammatory response to biomaterials. *J. Thromb. Haemost.* **2004**, *2*, 1798–1805. [CrossRef] [PubMed]
32. Earle, D.B.; Mark, L.A. Prosthetic Material in Inguinal Hernia Repair: How Do I Choose? *Surg. Clin. N. Am.* **2008**, *88*, 179–201. [CrossRef] [PubMed]
33. Schaechter, M. *Encyclopedia of Microbiology*, 3rd ed.; Academic Press: Cambridge, MA, USA, 2009.
34. Jacob, B.P.; Ramshaw, B. *The SAGES Manual of Hernia Repair*, 1st ed.; Springer: New York, NY, USA, 2013.
35. Ramshaw, B.; Bachman, S. Surgical materials for ventral hernia repair. *Gen. Surg. News* **2007**, *34*, 1–15.
36. Anderson, J.M.; Rodriguez, A.; Chang, D.T. Foreign Body Reaction to Biomaterials. *Semin. Immunol.* **2008**, *20*, 86–100. [CrossRef] [PubMed]
37. Chu, C.-C.; von Fraunhofer, J.A.; Greisler, H.P. *Wound Closure Biomaterials and Devices*, 1st ed.; CRC Press LLC: Boca Raton, FL, USA, 1997.
38. Brown, C.N.; Finch, J.G. Which mesh for hernia repair? *Ann. R. Coll. Surg. Engl.* **2010**, *92*, 272–278. [CrossRef] [PubMed]
39. Klinge, U.; Klosterhalfen, B.; Schumpelick, V. Foreign Body Reaction to Meshes of Used for the Repair of Abdominal Wall Hernias. *Eur. J. Surg.* **1999**, *165*, 665–673. [PubMed]
40. Junge, K.; Klinge, U.; Prescher, A.; Giboni, P.; Niewiera, M.; Schumpelick, V. Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants. *Hernia* **2001**, *5*, 113–118. [CrossRef] [PubMed]

41. Pourdeyhimi, B.J. Porosity of surgical mesh fabrics: New technology. *Biomed. Mater. Res.* **1989**, *23* (Suppl. A1), 145–152. [CrossRef]
42. Bilsel, Y.; Abci, I. The search for ideal hernia repair; mesh materials and types. *Int. J. Surg.* **2012**, *10*, 317–321. [CrossRef] [PubMed]
43. Winters, J.C.; Fitzgerald, M.P.; Barber, M.D. The use of systhetic mesh in female pelvic reconstructive surgery. *BJU Int.* **2006**, *98*, 70–76. [CrossRef] [PubMed]
44. Halm, J.A. Experimental and Clinical Approaches to Hernia Treatment and Prevention. Ph.D. Thesis, Erasmus University Rotterdam, Rotterdam, The Netherlands, October 2005.
45. Cortes, R.A.; Miranda, E.; Lee, H.; Gertner, M.E. Biomaterials and the evolution of hernia repair II: Composite meshes. In *Surgery*, 2nd ed.; Norton, J., Barie, P.S., Bollinger, R.R., Chang, A.E., Lowry, S., Mulvihill, S.J., Pass, H.I., Thompson, R.W., Eds.; Springer: New York, NY, USA, 2008; Volume 11, pp. 2305–2315.
46. Tamayol, A.; Akbari, M.; Annabi, N.; Paul, A.; Khademhosseini, A.; Juncker, D. Fiber-based tissue engineering: Progress, challenges, and opportunities. *Biotechnol. Adv.* **2013**, *31*, 669–687. [CrossRef] [PubMed]
47. Blair, T. *Biomedical Textiles for Orthopaedic and Surgical Applications: Fundamentals, Applications and Tissue Engineering*, 1st ed.; Woodhead Publishing: Cambridge, UK, 2015.
48. King, M.W.; Gupta, B.S.; Guidoin, R. *Biotextiles as Medical Implants*, 1st ed.; Woodhead Publishing: Cambridge, UK, 2013.
49. Listner, G. Polypropylene Monofilament Sutures. U.S. Patent 3630205 A, 28 December 1971.
50. Hutton, J.D.; Dumican, B.L. Braided Polyester Suture and Implantable Medical Device. U.S. Patent 6203564 B1, 20 March 2001.
51. Gore, R.W. Process for Producing Porous Products. U.S. Patent 3953566 A, 27 April 1976.
52. Pott, P.P.; Schwarz, M.L.R.; Gundling, R.; Nowak, K.; Hohenberger, P.; Roessner, E.D. Mechanical properties of mesh materials used for hernia repair and soft tissue augmentation. *PLoS ONE* **2012**, *7*. [CrossRef] [PubMed]
53. Lennard, D.J.; Menezes, E.V.; Lilenfeld, R. Pliabilized Polypropylene Surgical Filaments. U.S. Patent 4,911,165 A, 27 March 1990.
54. Laurencin, C.T.; Nair, L.S.; Bhattacharyya, S.; Allcock, H.R.; Bender, J.D.; Brown, P.W.; Greish, Y.E. Polymeric Nanofibers for Tissue Engineering and Drug Delivery. U.S. Patent 7235295 B2, 26 June 2007.
55. Zhukovsky, V.; Rovinskaya, L.; Vinokurova, T.; Zhukovskaya, I. The Development and Manufacture of Polymeric Endoprosthetic Meshes for the Surgery of Soft Tissues. *Autex Res. J.* **2002**, *2*, 204–209.
56. Rousseau, R.A.; Dougherty, R. Knitted Surgical Mesh. U.S. Patent 6638284 B1, 28 October 2003.
57. Schumpelick, V.; Nyhus, L. *Meshes: Benefits and Risks*, 1st ed.; Springer: Berling/Heidelberg, Germany, 2004.
58. Cobb, W.S.; Peindl, R.M.; Zerey, M.; Carbonell, A.M.; Heniford, B.T. Mesh terminology 101. *Hernia* **2009**, *13*, 1–6. [CrossRef] [PubMed]
59. Klosterhalfen, B.; Junge, K.; Klinge, U. The lightweight and large porous mesh concept for hernia repair. *Expert Rev. Med. Devices* **2005**, *2*, 1–15. [CrossRef] [PubMed]
60. Wang, X.; Han, C.; Hu, X.; Sun, H.; You, C.; Gao, C.; Haiyang, Y. Applications of knitted mesh fabrication techniques to scaffolds for tissue engineering and regenerative medicine. *J. Mech. Behav. Biomed. Mater.* **2011**, *4*, 922–932. [CrossRef] [PubMed]
61. Camp Tibbals, E., Jr.; Leinsing, K.R.; DeMarco, P.B. Flat-Bed Knitting Machine and Method of Knitting. U.S. Patent 6158250 A, 12 December 2000.
62. Dougherty, R.; Vishvaroop, A. Surgical Tricot. U.S. Patent DE60020350 T2, 11 May 2006.
63. Ting, H. A Study of Three Dimensional Warp Knits for Novel Applications as Tissue Engineering Scaffolds. Master Thesis, North Caroline State University, Raleigh, NC, USA, August 2011.
64. Spencer, D.J. *Knitting Technology: A Comprehensive Handbook and Practical Guide to Modern Day Principles and Practices*, 2nd ed.; Pergamon Press: Oxford, UK, 1983.
65. Deichmann, T.; Michaelis, I.; Junge, K.; Tur, M.; Michaeli, W.; Gries, T. Textile Composite Materials for Small Intestine Replacement. *Autex Res. J.* **2009**, *9*, 105–108.
66. Raz, S. *Warp Knitting Production*, 1st ed.; Melliand Textilberichte: Heidelberg, Germany, 1987.
67. Emans, P.J.; Schreinemacher, M.H.; Gijbels, M.J.; Beets, G.L.; Greve, J.W.; Koole, L.H.; Bouvy, N.D. Polypropylene Meshes to Prevent Abdominal Herniation: Can Stable Coatings Prevent Adhesions in the Long Term? *Ann. Biomed. Eng.* **2009**, *37*, 410–418. [CrossRef] [PubMed]

68. Van't Riet, M.; de Vos van Steenwijk, P.J.; Bonthuis, F.; Marquet, R.L.; Steyerberg, E.W.; Jeekel, J.; Bonjer, H.J. Prevention of Adhesion to Prosthetic Mesh: Comparison of Different Barriers Using an Incisional Hernia Model. *Ann. Surg.* **2003**, *237*, 123–128. [CrossRef]
69. Ebersole, G.C.; Buettmann, E.G.; MacEwan, M.R.; Tang, M.E.; Frisella, M.M.; Matthews, B.D.; Deeken, C.R. Development of novel electrospun absorbable polycaprolactone (PCL) scaffolds for hernia repair applications. *Surg. Endosc. Other Interv. Tech.* **2012**, *26*, 2717–2728. [CrossRef] [PubMed]
70. Xu, F.; Weng, B.; Gilkerson, R.; Materon, L.A.; Lozano, K. Development of tannic acid/chitosan/pullulan composite nanofibers from aqueous solution for potential applications as wound dressing. *Carbohydr. Polym.* **2015**, *115*, 16–24. [CrossRef] [PubMed]
71. Ciechańska, D.; Kazimierczak, J.; Wietecha, J.; Rom, M. Surface Biomodification of Surgical Meshes Intended for Hernia Repair. *Fibres Text. East. Eur.* **2012**, *96*, 107–114.
72. Karamuk, Z.E. Embroidered Textiles for Medical Applications: New Design Criteria with Respect to Structural Biocompatibility. Ph.D. Thesis, Swiss Federal Institute of Technology Zurich, Zurich, Switzerland, 2001.
73. Norton, J.A.; Barie, P.S.; Bollinger, R.R.; Chang, A.E.; Lowry, S.F.; Mulvihill, S.J.; Pass, H.I.; Thompson, R.W. *Surgery*, 2nd ed.; Springer: New York, NY, USA, 2008.
74. Yelimlieş, B.; Alponat, A.; Cubukçu, A.; Kuru, M.; Oz, S.; Erçin, C.; Gönüllü, N. Carboxymethylcellulose coated on visceral face of polypropylene mesh prevents adhesion without impairing wound healing in incisional hernia model in rats. *Hernia* **2003**, *7*, 130–133. [CrossRef] [PubMed]
75. Franklin, M.E.; Voeller, G.; Matthews, B.D.; Earle, D.B. The Benefits of Omega-3 Fatty Acid-Coated Mesh in Ventral Hernia Repair. *Spec. Rep.* **2010**, *37*, 1–8.
76. Gao, Y.; Liu, L.J.; Blatnik, J.A.; Krpata, D.M.; Anderson, J.M.; Criss, C.N.; Posielski, N.; Novitsky, Y.W. Methodology of fibroblast and mesenchymal stem cell coating of surgical meshes: A pilot analysis. *J. Biomed. Mater. Res. B. Appl. Biomater.* **2014**, *10*, 797–805. [CrossRef] [PubMed]
77. Kidoaki, S.; Kwon, I.K.; Matsuda, T. Mesoscopic spatial designs of nano- and microfiber meshes for tissue-engineering matrix and scaffold based on newly devised multilayering and mixing electrospinning techniques. *Biomaterials* **2005**, *26*, 37–46. [CrossRef] [PubMed]
78. Lamber, B.; Grossi, J.V.; Manna, B.B.; Montes, J.H.; Bigolin, A.V.; Cavazzola, L.T. May polyester with collagen coating mesh decrease the rate of intraperitoneal adhesions in incisional hernia repair? *Arq. Bras. Cir. Dig.* **2013**, *26*, 13–17. [CrossRef] [PubMed]
79. Van't Riet, M.; Burger, J.W.; Bonthuis, F.; Jeekel, J.; Bonjer, H.J. Prevention of adhesion formation to polypropylene mesh by collagen coating: A randomized controlled study in a rat model of ventral hernia repair. *Surg. Endosc.* **2004**, *18*, 681–685. [CrossRef] [PubMed]
80. Niekraszewicz, A.; Kucharska, M.; Wawro, D.; Struszczyk, M.H.; Kopias, K.; Rogaczewska, A. Development of a Manufacturing Method for Surgical Meshes Modified by Chitosan. *Fibres Text. East. Eur.* **2007**, *15*, 105–109.
81. Cohen, M.S.; Stern, J.M.; Vanni, A.J.; Kelley, R.S.; Baumgart, E.; Field, D.; Libertino, J.A.; Summerhayes, I.C. In Vitro Analysis of a Nanocrystalline Silver-Coated Surgical Mesh. *Surg. Infect. (Larchmt)* **2007**, *8*, 397–404. [CrossRef] [PubMed]
82. Junge, K.; Rosch, R.; Klinge, U.; Saklak, M.; Klosterhalfen, B.; Peiper, C.; Schumpelick, V. Titanium coating of a polypropylene mesh for hernia repair: Effect on biocompatibility. *Hernia* **2005**, *9*, 115–119. [CrossRef] [PubMed]
83. Scheidbach, H.; Tannapfel, A.; Schmidt, U.; Lippert, H.; Köckerling, F. Influence of Titanium Coating on the Biocompatibility of a Heavyweight Polypropylene Mesh. *Eur. Surg. Res.* **2004**, *36*, 313–317. [CrossRef] [PubMed]
84. Niekraszewicz, A.; Kucharska, M.; Wawro, D.; Struszczyk, M.H.; Rogaczewska, A. Partially Resorbable Hernia Meshes. *Prog. Chem. Appl. Chitin Its Deriv.* **2007**, *12*, 109–114.
85. Niekraszewicz, A.; Kucharska, M.; Struszczyk, M.H.; Rogaczewska, A.; Struszczyk, K. Investigation into Biological, Composite Surgical Meshes. *Fibres Text. East. Eur.* **2008**, *16*, 117–121.
86. Pascual, G.; Sotomayor, S.; Rodríguez, M.; Bayon, Y.; Bellón, J.M. Behaviour of a New Composite Mesh for the Repair of Full-Thickness Abdominal Wall Defects in a Rabbit Model. *PLoS ONE* **2013**, *8*, 1–16. [CrossRef] [PubMed]
87. Plencner, M.; East, B.; Tonar, Z.; Otáhal, M.; Prosecká, E.; Rampichová, M.; Krejčí, T.; Litvinec, A.; Buzgo, M.; Míčková, A.; Nečas, A.; et al. Abdominal closure reinforment by using polypropylene mesh functionalized with poly-ε-caprolactone nanofibers and growth factors for prevention of incisional hernia formation. *Int. J. Nanomed.* **2014**, *9*, 3263–3277. [CrossRef] [PubMed]

88. Alves da Silva, M.L.; Martins, A.; Costa-Pinto, A.R.; Costa, P.; Faria, S.; Gomes, M.; Reis, R.L.; Neves, N.M. Cartilage Tissue Engineering using electrospun PCL nanofiber meshes and MSCs. *Biomacromolecules* **2010**, *11*, 3228–3236. [CrossRef] [PubMed]
89. Popat, K. *Nanotechnology in Tissue Engineering and Regenerative Medicine*, 1st ed.; CRC Press: Boca Raton, FL, USA, 2010.
90. Vasita, R.; Katti, D.S. Nanofibers and their applications in tissue engineering. *Int. J. Nanomedicine* **2006**, *1*, 15–30. [CrossRef] [PubMed]
91. Dorband, G.C.; Liland, A.; Menezes, E.; Steinheuser, P.; Popadiuk, N.M.; Failla, S.J. Surgical Fastening Device and Method for Manufacture. U.S. Patent 4,671,280 A, 9 June 1987.
92. Brown, P.; Stevens, K. *Nanofibers and Nanotechnology in Textiles*, 1st ed.; CRC Press: Boca Raton, FL, USA, 2007.
93. Watanabe, K.; Kim, B.S.; Kim, I.S. Development of Polypropylene Nanofiber Production System. *Polym. Rev.* **2011**, *51*, 288–308. [CrossRef]
94. Watanabe, K.; Nakamura, T.; Kim, B.S.; Kim, I.S. Effect of organic solvent on morphology and mechanical properties of electrospun syndiotactic polypropylene nanofibers. *Polym. Bull* **2011**, *67*, 2025–2033. [CrossRef]
95. Huang, Z.-M.; Zhang, Y.Z.; Kotaki, M.; Ramakrishna, S. A review on polymer nanofibers by electrospinning and their applications in nanocomposites. *Compos. Sci. Technol.* **2003**, *63*, 2223–2253. [CrossRef]
96. Padron, S.; Fuentes, A.; Caruntu, D.; Lozano, K. Experimental study of nanofiber production through forcespinning. *J. Appl. Phys.* **2013**, *113*. [CrossRef]
97. Yarlagadda, P.; Chandrasekharan, M.; Shyan, J.Y. Recent Advances and Current Developments in Tissue Scaffolding. *Biomed. Mater.* **2005**, *15*, 159–177.
98. Plencner, M.; Prosecká, E.; Rampichová, M.; East, B.; Buzgo, M.; Vysloužilová, L.; Hoch, J.; Amler, E. Significant improvement of biocompatibility of polypropylene mesh for incisional hernia repair by using poly-ε-caprolactone nanofibers functionalized with thrombocyte-rich solution. *Int. J. Nanomedicine* **2015**, *10*, 2635–2646. [CrossRef] [PubMed]
99. Chakroff, J.; Kayuha, D.; Henderson, M.; Johnson, J. Development and Characterization of Novel Electrospun Meshes for Hernia Repair. *Int. J. Nanomedicine* **2015**, *2*, 1–9. [CrossRef]
100. Veleirinho, B.; Coelho, D.S.; Dias, P.F.; Maraschin, M.; Pinto, R.; Cargnin-Ferreira, E.; Peixoto, A.; Souza, J.A.; Ribeiro-do-Valle, R.M.; Lopes-da-Silva, J.A. Foreign Body Reaction Associated with PET and PET/Chitosan Electrospun Nanofibrous Abdominal Meshes. *PLoS ONE* **2014**, *9*, 1–10. [CrossRef] [PubMed]
101. Zhao, W.; Ju, Y.M.; Christ, G.; Atala, A.; Yoo, J.J.; Lee, S.J. Diaphragmatic muscle reconstruction with an aligned electrospun poly(ε-caprolactone)/collagen hybrid scaffold. *Biomaterials* **2013**, *34*, 8235–8240. [CrossRef] [PubMed]
102. Xu, F.; Weng, B.; Materon, L.A.; Gilkerson, R.; Lozano, K. Large-scale production of ternary composite nanofiber membrane for wound dressing applications. *J. Bioact. Compat. Polym. Biomed. Appl.* **2014**, *29*, 646–660. [CrossRef]
103. Sanbhal, N.; Miao, L.; Xu, R.; Khatri, A.; Wang, L. Physical structure and mechanical properties of knitted hernia mesh materials: A review. *J. Ind. Text.* **2017**. [CrossRef]
104. Guillaume, O.; Teuschl, A.H.; Gruber-Blum, S.; Fortelny, R.H.; Redl, H.; Petter-Puchner, A. Emerging trends in abdominal wall reinforcement: Bringing bio-functionality to meshes. *Adv. Healthc. Mater.* **2015**, *4*, 1763–1789. [CrossRef] [PubMed]
105. Todros, S.; Pavan, P.G.; Natali, A.N. Synthetic surgical meshes used in abdominal wall surgery: Part I—Materials and structural conformation. *J. Biomed. Mater. Res. Part B: Appl. Biomater.* **2017**, *105*, 689–699. [CrossRef] [PubMed]
106. Todros, S.; Pavan, P.G.; Pachera, P.; Natali, A.N. Synthetic surgical meshes used in abdominal wall surgery: Part II—Biomechanical aspects. *J. Biomed. Mater. Res. Part B: Appl. Biomater.* **2017**, *105*, 892–903. [CrossRef] [PubMed]

CASE REPORT – OPEN ACCESS

International Journal of Surgery Case Reports 39 (2017) 317–320

Contents lists available at ScienceDirect

International Journal of Surgery Case Reports

journal homepage: www.casereports.com

Surgical management of late bullet embolization from the abdomen to the right ventricle: Case report

Ramos Mayo Alan Elison*, Diaz Elizondo Jose Antonio, Segura Marin Hector, Lopez Garnica Dolores, Treviño Garza Francisco Xavier

Escuela de Medicina, Instituto Tecnologico y de Estudios Superiores de Monterrey, Monterrey, Avenida Morones Prieto 3000, Colonia Los Doctores, CP 64710, Mexico

ARTICLE INFO

Article history:
Received 25 June 2017
Received in revised form 29 August 2017
Accepted 30 August 2017
Available online 4 September 2017

Keywords:
Bullet embolization
Right ventricle foreign body
Migrating foreign bodies
Case report

ABSTRACT

INTRODUCTION: Secondary embolus from gun projectile is a rare entity, it represents a clinical and therapeutic dilemma because the potential complications involving central and peripheral circulation. Each case reported in the literature represents a challenge because their unique and different clinical scenarios.
PRESENTATION OF CASE: We present the management of a 33-year-old man with past history of a gunshot wound on left flank with no evidence of any exit wounds, treated with exploratory laparotomy without removing the gunshot bullet from the abdomen. The patient presents 6 years later with non-productive cough and retrosternal pain with no other symptoms; the patient underwent a chest x-ray, electrocardiogram, thoracoabdominal CT, echocardiogram and cardiac catheterization and showed a bullet in the right ventricular floor. The projectile was extracted by sternotomy with extracorporeal circulation through the right atrium, without any complications.
DISCUSSION: In 1834, Thomas David reported for the first time a wood-fragment embolization. There have been reported less than 200 cases including embolization of other materials; most of the gunshot bullet embolization cases reported on literature were reported after war. Clinical manifestations are associated with the anatomical site of embolism and mortality rate for a retained bullet is 6% associated with complication in 25% of cases. Mortality rate decreases to 1–2% if the bullet is removed.
CONCLUSION: There are no established guidelines about the management of migrating foreign bodies or bullets, however, conservative, endovascular and surgical management have been proposed. In the cases of bullet embolization to the thoracic cavity, surgery represents a safe, low risk approach with high success rates.

1. Introduction

Secondary embolus from gun projectile is a rare entity with few published cases in the literature. It represents a clinical and therapeutic dilemma because of the potential complications involving central and peripheral circulation, including pulmonary complications [1,2]. There have been reported less than 200 cases including embolization of other materials [3,4]. Clinical manifestations are associated with the anatomical site of embolism and mortality rate for a retained bullet is 6% associated with complication in 25% of cases. Mortality rate decreases to 1–2% if the bullet is removed [5]. We present a case of a retained and late bullet embolization, from the abdominal cavity to the right ventricle. Treated conservative initially and six years later after receiving a penetrating gunshot trauma, a sternotomy was performed. This patient was treated in a private practice hospital by a cardiothoracic surgeon.

2. Case report

A 33-year-old man with no personal, family or psychosocial history presented to the emergency department after receiving a gunshot wound on left flank with no evidence of any exit wounds. The patient had stable vital signs and no clinical data of abdominal tenderness at admission. Abdominal CT showed free intra-abdominal fluid and a gunshot bullet on the pelvic cavity medial to the iliopsoas muscle, the chest x- ray showed no abnormalities (Fig. 1). An exploratory laparotomy was performed finding 2500 ml of blood in the abdomen. A grade I and III vascular lesions were found in the jejunum mesentery and left iliac vein respectively; and a grade II intestinal lesion in the distal sigmoid. All the lesions were repaired and the gunshot bullet was not extracted because of hemodynamic instability at the moment. At that time,

* Corresponding author at: Avenida Morones Prieto 3000, Colonia Los Doctores, CP 64710, Monterrey, Nuevo Leon, Mexico.
E-mail addresses: alan_erm@hotmail.com, alanramos8524@gmail.com (R.M. Alan Elison).

http://dx.doi.org/10.1016/j.ijscr.2017.08.049

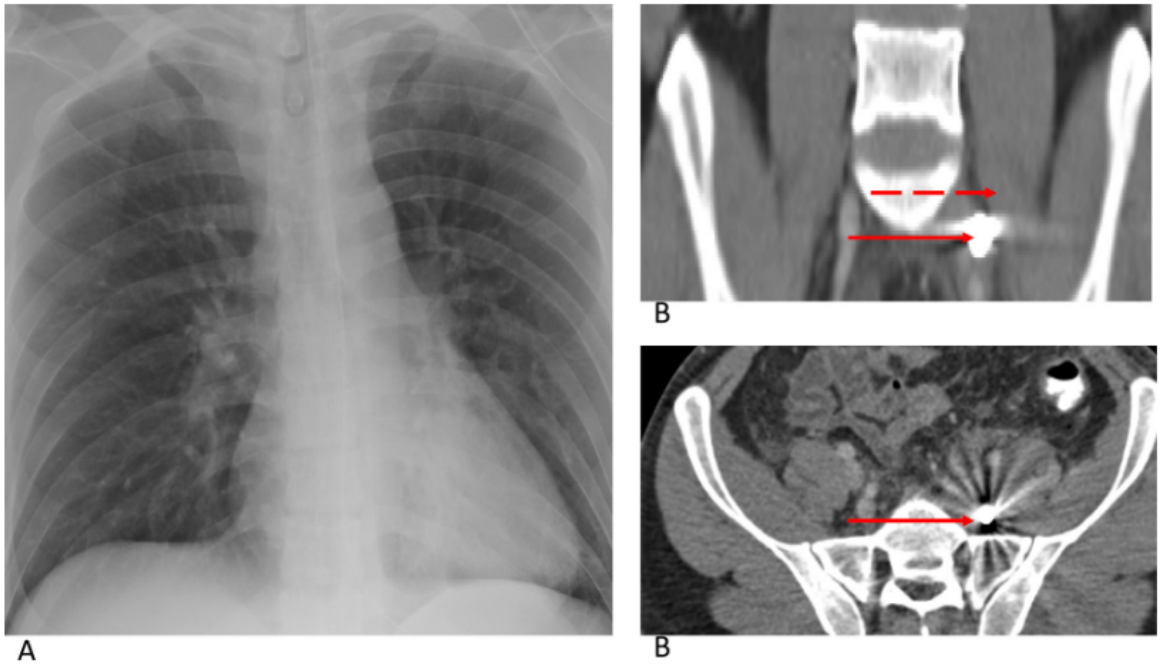


Fig. 1. (A) Chest X ray showing no abnormalities. (B) Abdominal CT showing a bullet (red arrow) medial to the iliopsoas muscle (red dashed arrow).

the patient was treated by a general surgeon in a private practice hospital.

The patient presents 6 years later with non-productive cough and retrosternal pain with no other symptoms. Physical exploration was non-remarkable. A chest x-ray and thoracoabdominal CT showed a radiopaque artefact on the ventricular floor. An EKG, transthoracic echocardiogram and cardiac catheterization were performed showing no disruptions or alterations in the cardiac anatomy and physiology (Fig. 2).

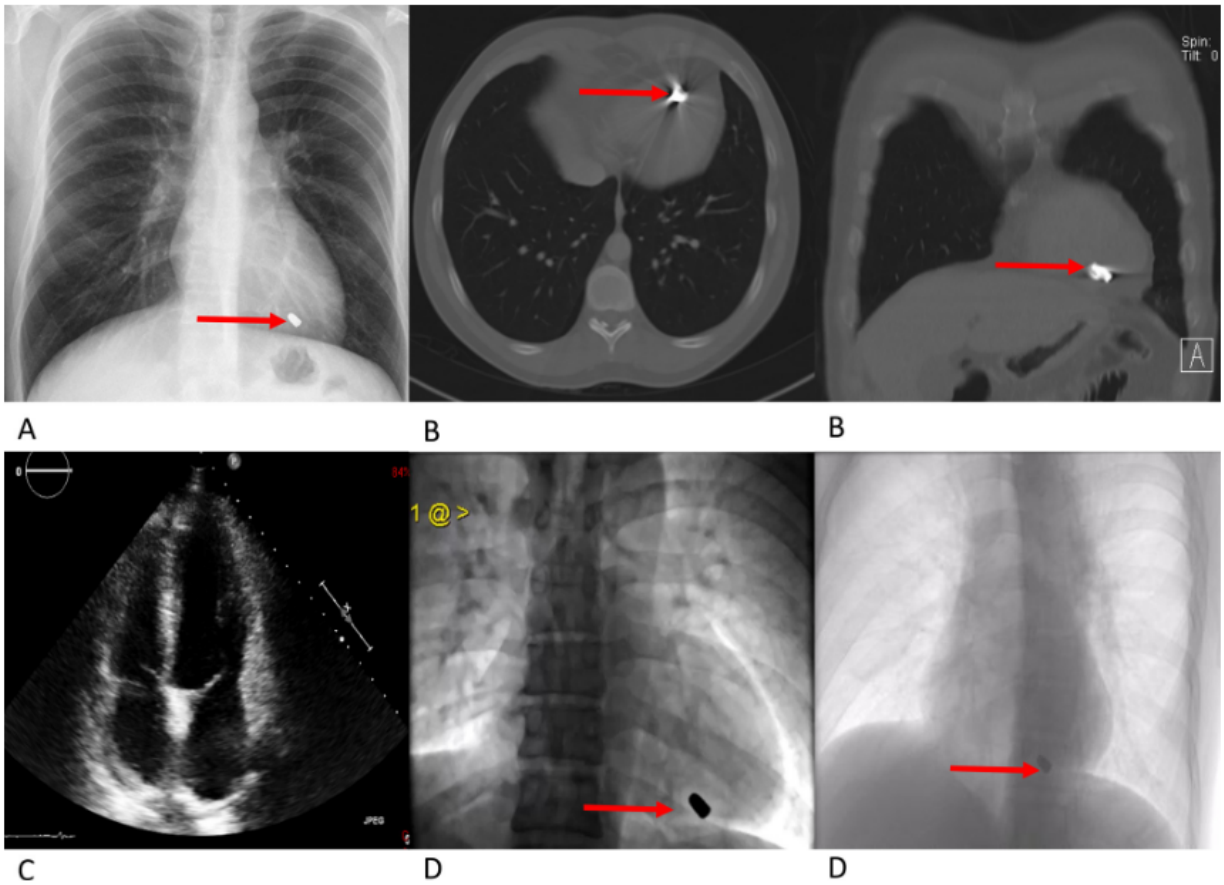


Fig. 2. (A) Chest X ray, (B) Thorax CT and (D) Cardiac catheterization showing and artefact or bullet on the ventricular floor (red arrow). (C) Echocardiogram and (D) Cardiac catheterization showed no abnormalities in cardiac anatomy or physiology.

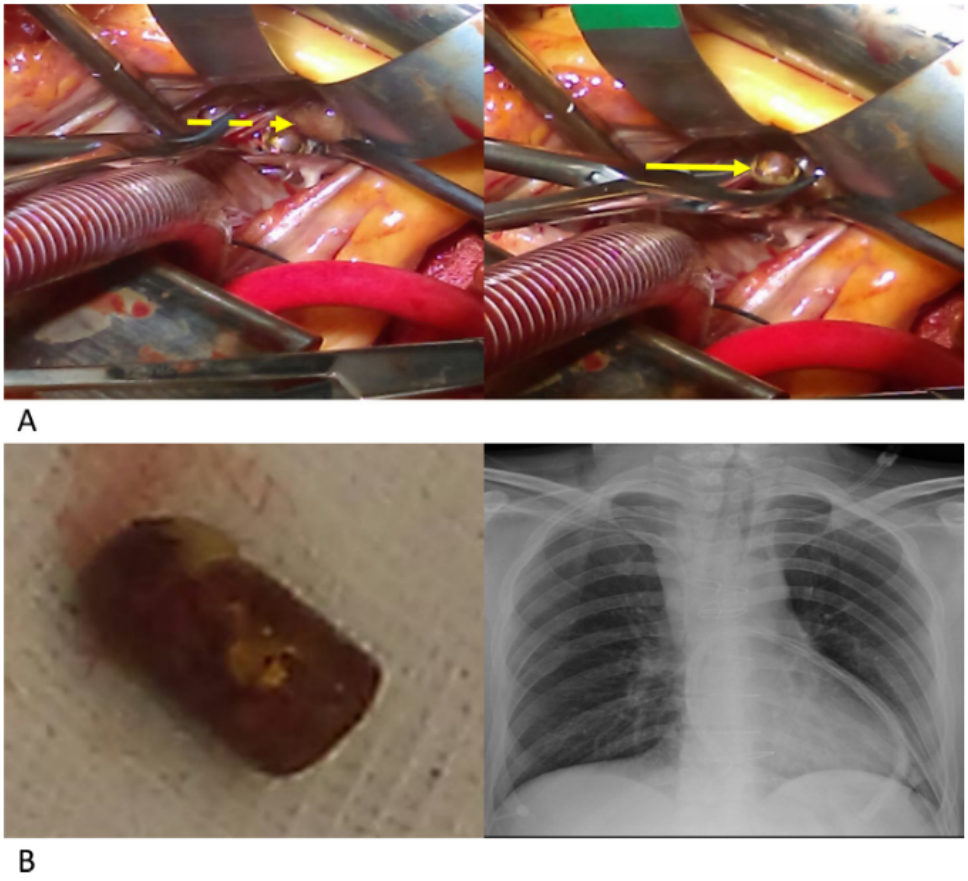


Fig. 3. (A) Bullet (yellow arrow) extraction from ventricular septum (yellow dashed arrow). (B) Projectile 20 × 10 mm. (C) Chest X ray after surgical procedure.

Because of the high risk for pulmonary embolization, surgical exploration was planned. An sternotomy was performed by a cardiothoracic surgeon, the patient was submitted to extracorporeal circulation, the projectile was identified in the ventricular septum and it was extracted through an incision in the right atrium without presenting any complication associated to the procedure. The projectile measured 20 × 10 mm (Fig. 3).

The patient had complete recovery from surgery and didn't need ventilatorey or dynamic support during its course. He was discharged 6 days after surgery with full resolution of the symptoms and without any complication. Six-month follow up at the clinic was uneventful.

3. Discussion

In 1834, Thomas David reported for the first time a wood-fragment embolization from the venous circulation to the right ventricle in a 10-year-old male patient [1,2]. There have been multiple reports from foreign bodies that migrate to the pulmonary artery or the right ventricle like hypodermic needles, intravenous catheters, bone fragments, and bullets [3]. There have been reported less than 200 cases including embolization of other materials; most of the gunshot bullet embolization cases reported on literature were reported after war. A revision during Vietnam war reported a 0.3% incidence [1,2,4]. Foreign bodies can enter venous system through a direct protrusion into the lumen or by a slower erosion of the vascular wall and can be presented up to 14 years later [1,10].

Clinical manifestations are associated with the anatomical site of embolism, arterial embolization is presented as ischemic distal disease while venous embolization is symptomatic in 70% of cases, generally associated with occupation on left ventricle and pulmonary artery [2,4,6]. Imaging studies are primordial for diagnosis confirmation. X-rays from the site the projectile first impacted and the finding of it in another body cavity raises the suspicious for diagnosis [4]. Some authors recommend CT, transthoracic or transesophagic ecocardiogram and cardiac catheterism even though there is no consensus for an algorithm for diagnostic approach [7–9].

The mortality rate for a retained bullet is 6% associated with complication in 25% of cases. Mortality rate decreases to 1–2% if the bullet is removed [5]. Other authors suggest it should be removed only in patients that are symptomatic, with a size less than 5 mm, irregular structure,proximal to an artery, located at left cardiac cavities and those creating electrocardiographic, hemodynamic or systemic alterations [11,12]. A 40-case series reported after second world war with follow up to 20 years, showed 25% incidence of pericarditis with conservative management and observation. One case developed left-ventricle hypertrophia secondary to aortic valve lesion [13]. There are follow up cases with conservative management in which there was pulmonary artery embolization with no complications reported [14]. Another alternative for management is endovascular treatment, which is an option in those hemodynamically stable patients with gunshot embolization to the pulmonary artery, intraarterial or any of the cardiac chambers [2,15].

4. Conclusion

Even though an algorithm of treatment does not exist for this pathology, each patient should be individualized. Invasive treatment should be avoided unless necessary; each clinical scenario

should be analyzed by an expert team to propose the best therapeutic approach for the patient. The present paper follows the guidelines of the SCARE criteria [16] for publication.

Conflicts of interest

Nothing to declare.

Funding

Nothing to declare.

Ethical approval

Ethical approval was given to publish this case report.

Consent

Consent was obtained to publish this case report.

Author contribution

Alan Ramos Mayo, MD- study concept, writing paper, data collection.

Jose Antonio Diaz Elizondo, MD- study concept, writing paper, approval of final manuscript.

Francisco Xavier Treviño Garza, MD- study concept, approval of final manuscript.

Hector Segura Marin, MD- data collection, writing paper.

Dolores Lopez Garnica, MD- data collection, writing paper.

Registration of research studies

researchregistry2355.

Guarantor

The corresponding author and co-authors accept full responsibility for the work.

References

[1] K.L. Mattox, A.C. Beall Jr., C.L. Ennix, M.E. DeBakey, Intravascular migratory bullets, Am. J. Surg. 137 (2) (1979) 192–195.
[2] G.G. Fernandez-Ranvier, P. Mehta, U. Zaid, K. Singh, M. Barry, A. Mahmoud, Pulmonary artery bullet embolism-Case report and review, Int. J. Surg. Case Rep. 4 (5) (2013) 521–523.
[3] E.P. Howanitz, K.D. Murray, T.A. Galbraith, P.D. Myerowitz, Peripheral venous bullet embolization to the heart: case report and review of the literature, J. Vasc. Surg. 8 (1) (1988) 55–58.
[4] K.R. Miller, M.V. Benns, J.D. Sciarretta, B.G. Harbrecht, C.B. Ross, G.A. Franklin, et al., The evolving management of venous bullet emboli: a case series and literature review, Injury 42 (5) (2011) 441–446.
[5] R.T. Padula, S.C. Sandler, R.C. Camishion, Delayed bullet embolization to the heart following abdominal gunshot wound, Ann. Surg. 169 (4) (1969) 599–602.
[6] X.H. Lu, Z.J. Lu, J. Hu, J.X. Song, S.L. Chen, Bullet migration from the knee to the heart after a gunshot injury: a case report, Chin. Med. J. (Engl.) 124 (10) (2011) 1590–1592.
[7] R.T. Bonk, S.D. Harrison, M.H. Meissner, Intravascular bullet localization by sonography, AJR Am. J. Roentgenol. 167 (1) (1996) 152.
[8] M.W. Hashimi, D.R. Jenkins, B.W. McGwier, C.V. Massey, M.A. Alpert, Comparative efficacy of transthoracic and transesophageal echocardiography in detection of an intracardiac bullet fragment, Chest 106 (1) (1994) 299–300.
[9] G. LiMandri, L.A. Gorenstein, J.P. Starr, S. Homma, J. Auteri, A.S. Gopal, Use of transesophageal echocardiography in the detection and consequences of an intracardiac bullet, Am. J. Emerg. Med. 12 (1) (1994) 105–106.
[10] F.L. Shannon, B.L. McCroskey, E.E. Moore, F.A. Moore, Venous bullet embolism: rationale for mandatory extraction, J. Trauma 27 (10) (1987) 1118–1122.
[11] S.K. Gandhi, B.C. Marts, B.M. Mistry, J.W. Brown, R.M. Durham, J.E. Mazuski, Selective management of embolized intracardiac missiles, Ann. Thorac. Surg. 62 (1) (1996) 290–292.
[12] J.B. Lundy, E.K. Johnson, J.M. Seery, T. Pham, J.D. Frizzi, A.B. Chasen, Conservative management of retained cardiac missiles: case report and literature review, J. Surg. Educ. 66 (4) (2009) 228–235.
[13] E.F. Bland, G.W. Beebe, Missiles in the heart: a twenty-year follow-up report of World War II cases, N. Engl. J. Med. 274 (19) (1966) 1039–1046.
[14] J.B. Kortbeek, J.A. Clark, R.C. Carraway, Conservative management of a pulmonary artery bullet embolism: case report and review of the literature, J. Trauma 33 (6) (1992) 906–908.
[15] M. Ghanaat, C. Goldenberg, J. Walsh, S.J. Sclafani, Endovascular management of an intracardiac bullet, Injury 46 (1) (2015) 166–168.
[16] R.A. Agha, A.J. Fowler, A. Saeta, I. Barai, S. Rajmohan, D.P. Orgill, et al., The SCARE Statement: consensus-based surgical case report guidelines, Int. J. Surg. 34 (2016) 180–186.

Educ Med. 2018;xxx(xx):xxx–xxx

Educación Médica

www.elsevier.es/edumed

ORIGINAL

Percepciones de los profesores sobre de la deshonestidad en estudiantes de Medicina: prevalencia, motivaciones e implicaciones

Dulce María López Sotomayor, Irma Elisa Eraña Rojas, Nancy de los Ángeles Segura-Azuara, Ismael David Piedra Noriega, José Antonio Díaz Elizondo y Mildred Vanessa López Cabrera*

Escuela de Medicina y Ciencias de la Salud, Instituto Tecnológico y de Estudios Superiores de Monterrey, Monterrey, Nuevo León, México

Recibido el 26 de febrero de 2018; aceptado el 2 de julio de 2018

PALABRAS CLAVE
Deshonestidad académica;
Integridad;
Prevalencia;
Motivadores;
Implicaciones;
Percepción de los profesores

Resumen

Introducción: La deshonestidad académica son actitudes y acciones que toma el estudiante con la finalidad de obtener beneficio. Poco se conoce sobre el efecto de los profesores en este fenómeno. El objetivo de esta investigación fue conocer la percepción de los docentes sobre la prevalencia, motivación e implicaciones de la deshonestidad académica, así como analizar su rol en la incidencia de estas conductas.

Métodos y materiales: Fue un estudio cuantitativo, descriptivo y transversal para el que se aplicó un cuestionario de 39 ítems que valora el modelo que explica la deshonestidad en los factores de prevalencia, motivación e implicaciones. Se analizaron las medias considerando como factores para la prueba ANOVA los años de experiencia y la etapa de la carrera en la que participa.

Resultados: Los profesores indican que las conductas más frecuentes son que el alumno obtenga crédito en trabajos en los que no participó, y plagio en actividades y tareas, con una media de 2,13 y 2,18, respectivamente. De los motivadores, los más implicados son la obtención de mayores calificaciones y las facilidades que ofrecen las nuevas tecnologías, con una media de 3,91 y 3,82, respectivamente. Sobre las implicaciones, aunque los profesores aseguran que alguna vez han sido testigos de la deshonestidad, solo un 48,2% ha abierto la conversación con los estudiantes durante su clase.

* Autor para correspondencia. Dirección postal: Av. Morones Prieto N.° 3000 Pte. Col. Los Doctores. Código postal: 64710, Monterrey, Nuevo León, México

Correo electrónico: mildredlopez@itesm.mx (M.V. López Cabrera).

https://doi.org/10.1016/j.edumed.2018.07.009

Cómo citar este artículo: López Sotomayor DM, et al. Percepciones de los profesores sobre de la deshonestidad en estudiantes de Medicina: prevalencia, motivaciones e implicaciones. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.07.009

Discusión: Es necesario fortalecer las políticas institucionales que faciliten los métodos de reporte y seguimiento a situaciones de riesgo. En particular, un punto de interés es el de desvincular de los profesores la documentación de evidencia y la responsabilidad del proceso.

KEYWORDS
Academic dishonesty;
Integrity;
Prevalence;
Motivator;
Implications;
Faculty perceptions

Faculty perceptions of dishonesty on medical students: Prevalence, motivations and implications

Abstract
Introduction: Academic dishonesty are attitudes and actions taken by the student in order to obtain benefits. Little is known about the effect of teachers on this phenomenon. The objective of this research was to study the perception of teachers about the prevalence, motivation and implications of academic dishonesty on students, as well as to analyze their role in the incidence of these behaviors.
Methods and materials: The study was quantitative, descriptive and cross-sectional. A questionnaire of 39 items that assesses the model that explains the dishonesty in the factors of prevalence, motivation and implications. The means were analyzed considering as factors for the ANOVA test: the years of experience and the stage of the career in which the faculty participates.
Results: The faculty members indicate that the most frequent behaviors are: the student that obtains credit for work where he / she did not participate, and plagiarism in activities and tasks, with an average of 2.13 and 2.18 respectively. Of the motivators, the most involved are: obtaining higher grades, and the easiness offered by new technologies, with an average of 3.91 and 3.82 respectively. On the implications, although the professors claim that they have witnessed dishonesty, only 48.2% have opened the conversation with the students during their class.
Discussion: It is necessary to strengthen the institutional policies that enable the methods of reporting and monitoring risk situations. Particularly, a point of interest is removing the responsibility of faculty about the documentation of evidence and the responsibility of the process itself.

Introducción

La deshonestidad académica se define como el comportamiento intencional que transgrede la ética y el profesionalismo en el proceso de enseñanza-aprendizaje, con el propósito de obtener una mejor calificación o un crédito que no le corresponde al estudiante[1]. Sin embargo, esta definición es distinta para los diferentes actores implicados en el aprendizaje, considerando la visión de directivos, administradores, profesores y los mismos estudiantes. Esto acarrea problemas si las instituciones no tienen una definición puntual de estas conductas y de los procesos que deben ponerse en marcha en caso de incurrir en alguna de ellas.

Las faltas a la integridad académica afectan a los alumnos, egresados y profesores de la institución[2], al generar un entorno de competencia injusta y comprometer su reputación[2,3]. Además, el tema es trascendental, ya que estas conductas rebasan el área académica y tienen incidencia también en la vida personal, profesional y ciudadana. Este efecto es particularmente relevante en el área de la salud, ya que estos médicos en formación tendrán, en un futuro cercano, la responsabilidad de la vida de los pacientes[3]. En particular en la atención hospitalaria, algunas investigaciones han encontrado fraudes en la atención en lo que respecta a tratamientos o cirugías que pudieron ser evitados[4,5].

Existe una estrecha relación en la deshonestidad académica entre los factores de prevalencia, motivación y sus implicaciones (fig. 1).

Prevalencia

La prevalencia de la deshonestidad se refiere a la frecuencia o el grado en el que se presentan faltas a la honestidad. Estas faltas pueden ser muy variadas, por ejemplo, usar apoyos o notas en exámenes, o realizar plagio de actividades o tareas. Vaamonde y Omar[1] distinguen 4 principales actos de deshonestidad: prácticas deshonestas en exámenes, plagio, dar excusas falsas y deshonestidad académica digital.

Diversas instituciones educativas han realizado investigaciones para estudiar este fenómeno; el análisis de los resultados ha permitido implementar diversos programas como medidas de corrección. Algunos de estos programas se refieren a la definición de códigos o reglamentos, la generación de campañas específicas para la concienciación y la

Cómo citar este artículo: López Sotomayor DM, et al. Percepciones de los profesores sobre de la deshonestidad en estudiantes de Medicina: prevalencia, motivaciones e implicaciones. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.07.009

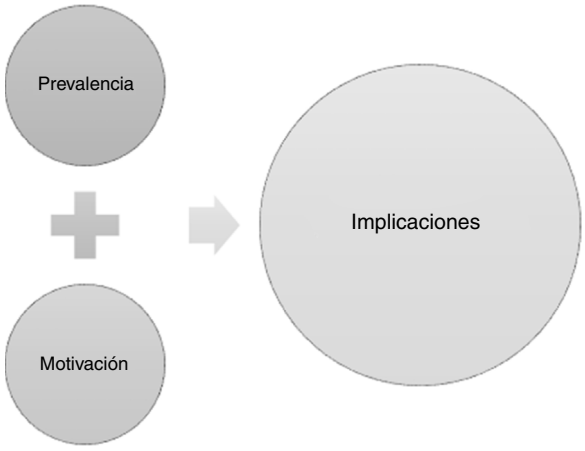


Figura 1 Modelo de la deshonestidad académica.

realización de ejercicios prácticos de reflexión mediante el uso de dilemas éticos; sin embargo, estas medidas parecen no tener efectos directos, ya que las cifras continúan aumentando con el paso del tiempo[2].

Motivadores

Los motivadores se refieren a los factores que impulsan a los individuos a perseguir conductas de riesgo para cometer actos de deshonestidad académica. Algunas hipótesis plantean que los alumnos con bajo rendimiento académico tienen mayor probabilidad de participar en este tipo de actividades, ya que obtendrían mayor beneficio en comparación con los que tienen mayor aprovechamiento[6]. Asimismo, los que participan en actividades extracurriculares demandantes tienen mayor riesgo debido al cansancio físico o al poco tiempo que tienen para estudiar o realizar sus tareas. Otro elemento preponderante es el síndrome de *burnout*, el cual supone una respuesta inapropiada a estresores emocionales e interpersonales en el trabajo[6,7]. La facilidad y accesibilidad de la información para cometer actos deshonestos también es un factor.

Es un consenso que el clima organizacional tiene un efecto en el fenómeno: en entornos donde no hay persecución de estas conductas, no hay castigos, consecuencias ni definiciones específicas de deshonestidad académica. La teoría del aprendizaje social de Bandura[8] enfatiza el impacto del entorno para la toma de decisiones y refiere que las normas sociales permisivas y la percepción de normalidad de la deshonestidad entre los compañeros tienen una fuerte influencia. Es entonces cuando el currículo oculto repercute en la aceptación de conductas como algo común. Esto último se refiere a los aprendizajes que se obtienen en la escuela mediante las acciones del personal que ahí labora y de los mismos estudiantes; esto juega un papel importante en la educación del alumno acerca de lo que es lícito durante su estancia dentro de la institución[9].

Implicaciones

Aunque la educación en valores y ética que conforma la identidad de los estudiantes comienza desde etapas tempranas, y son elementos inherentes a la cultura y el carácter, estos elementos son influidos continuamente mediante la exposición a entornos a lo largo de su vida[3].

En esta área, los profesores tienen un papel importante, ya que ellos son los que tienen contacto directo y diario con los estudiantes, y son los que tienen mayor sensibilidad para identificar las faltas a la integridad. De igual forma, ellos podrían propiciar o prevenir actitudes deshonestas. Por ejemplo, algunos profesores con bajas expectativas de sus alumnos llegan a ignorar las sospechas de un acto deshonesto porque no creen que su penalización tenga impacto en la mejora de su desempeño. Algunos autores afirman que la discusión sobre el juicio y la moral es evitada por parte de los profesores debido a una falta de interés y desvinculación con ellos[10]. El tema es poco abordado por los docentes y, generalmente, se discute solo cuando se ha perdido el control de la situación y cuando ha salido al público. Además, algunos podrían no querer perseguir estas conductas debido al esfuerzo adicional que implica la recolección de evidencia y el seguimiento de un proceso burocrático largo.

Existen pocos estudios acerca de la percepción de profesores y los que pocos disponibles están enfocados en las motivaciones de las acciones deshonestas. No se encontraron investigaciones dedicadas a las características individuales del profesor o relacionadas con la percepción de la deshonestidad, por lo que este estudio investigó el efecto de la experiencia del profesor y su participación en las áreas preclínicas y clínicas de la carrera de Medicina en la percepción de la prevalencia y motivaciones de estas conductas.

El objetivo de esta investigación fue conocer la percepción de los profesores sobre la prevalencia, motivación e implicaciones de la deshonestidad académica y analizar si existe algún factor personal del docente que aumente el riesgo a que los alumnos cometan faltas de deshonestidad académica.

Material y métodos

Se realizó un estudio cuantitativo, descriptivo y transversal sobre el fenómeno de la deshonestidad académica a través de variables que explican el modelo teórico presentado. Es de carácter descriptivo y transversal, al documentar las percepciones de la deshonestidad en un momento específico.

Los profesores realizan su práctica docente en la carrera de Medicina de una universidad privada al norte de México. Se diseñó un instrumento de 39 ítems que evalúa 3 secciones: las primeras (prevalencia y motivadores) fueron valoradas mediante la escala de Likert de 5 niveles, en la que el 5 se refiere a una observación muy frecuente o a total acuerdo y la última se enfoca en las implicaciones que tiene este problema en los profesores. La encuesta fue distribuida a través de correo electrónico y la participación en este estudio fue voluntaria y anónima. Se obtuvo consentimiento de los participantes y se les explicó que el manejo de la información era estrictamente para fines de investigación educativa y que no tendría ningún efecto en su relación con la institución.

Para el análisis, se utilizó el *software* Minitab 2017, con el que se calculó la estadística descriptiva que permitiera la valoración de las tendencias para cada uno de los factores evaluados, estimando la media y desviación estándar. Se analizaron además las tendencias en la media por ítem,

Cómo citar este artículo: López Sotomayor DM, et al. Percepciones de los profesores sobre de la deshonestidad en estudiantes de Medicina: prevalencia, motivaciones e implicaciones. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.07.009

Tabla 1 Media en las percepciones de los profesores sobre la prevalencia de distintas actitudes deshonestas

Ítem	Total	Etapa de la carrera donde tiene participación docente		Años de experiencia docente		
		Preclínica	Clínica	<5	De 5 a 14	>14
Alumno que se copia de un compañero durante el examen	**1,84**	1,86	1,82	1,78	1,90	1,83
Alumno que comparte con compañeros preguntas de exámenes que no han presentado	**1,95**	1,75	2,14	2,22	1,95	1,67
Alumno que vende/compra exámenes	**1,34**	1,29	1,39	1,39	1,40	1,22
Externo que suplanta a un alumno durante una evaluación	**1,00**	1,00	1,00	1,00	1,00	1,00
Alumno que utiliza apuntes en el examen	**1,41**	1,32	1,50	1,28	1,35	1,61
Alumno que plagia en actividades/tareas	**2,18**	2,18	2,18	2,44	2,20	1,89
Alumno que plagia en trabajos finales	**1,84**	1,75	1,93	1,89	2,00	1,61
Alumno que entrega múltiples veces el mismo trabajo sin autorización del profesor	**1,41**	1,36	1,46	1,44	1,40	1,39
Alumno que comparte trabajos/tareas con alumnos que aún no llevan la materia	**1,98**	2,04	1,93	2,17	2,00	1,78
Alumno que obtiene crédito de un trabajo en equipo, en el que no participó	**2,13**	2,18	2,07	2,17	2,15	2,06
Alumno que obtiene acceso a cuentas de correo o sistemas de manera no autorizada	**1,46**	1,36	1,57	1,44	1,45	1,50
Alumno que inventa/altera historias clínicas o notas médicas	**1,80**	1,43	2,18	1,72	1,75	1,94
Alumno que falsifica su participación en actividades clínicas	**1,61**	1,21	2,00	1,57	1,60	1,67
Alumno que inventa resultados en trabajos de investigación	**1,34**	1,21	1,46	1,33	1,30	1,39

considerando como factores para la prueba ANOVA los años de experiencia y la etapa de la carrera en la que participa como docente.

Resultados

Se tuvo una participación de 56 profesores. El 50% de los participantes imparten clases en la etapa preclínica de la carrera y el 50% en la etapa clínica. Un 32,1% de los profesores tienen menos de 5 años de experiencia docente, un 35,8% tienen entre 5 y 14 años de experiencia y un 32,1% tienen más de 15 años.

Se estimó la estadística descriptiva de la prevalencia de actitudes deshonestas, es decir, la frecuencia con que los profesores observan estas conductas, cuyos resultados se presentan en la tabla 1. De acuerdo al análisis de varianza ANOVA, existe una diferencia estadísticamente significativa entre aquellas que demuestran mayor frecuencia y las menos frecuentes ($p < 0,05$). Los profesores reportan que las acciones más frecuentemente observadas fueron alumno que plagia en actividad y tareas, y alumno que obtiene crédito por un trabajo en equipo en el que no participó, con una media de 2,18 y 2,13, respectivamente. Las acciones menos observadas fueron alumno que vende o compra exámenes y externo que suplanta a un alumno durante una evaluación, con una media de 1,34 y 1,00, respectivamente.

Se analizó también, como factor de incidencia en la frecuencia de observación de las actitudes deshonestas, la etapa de la carrera donde los profesores realizan su mayor participación docente y los años de experiencia docente; sin embargo, estos demostraron no ser un elemento de importancia, al no encontrar una diferencia estadística significativa ($p > 0,05$).

Cómo citar este artículo: López Sotomayor DM, et al. Percepciones de los profesores sobre de la deshonestidad en estudiantes de Medicina: prevalencia, motivaciones e implicaciones. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.07.009

Tabla 2 Media en las percepciones sobre las motivaciones de la deshonestidad académica

		Etapa de la carrera donde tiene mayor participación		Años de experiencia docente		
Ítem	Total	Preclínica	Clínica	<5	De 5 a 14	>14
Volumen de actividad académica o clínica de los alumnos	**2,52**	2,75	2,29	2,22	2,50	2,83
Mala administración del tiempo por parte de los alumnos	**3,70**	3,89	3,50	3,67	3,65	3,78
Desconocimiento del capítulo de integridad académica del Reglamento Académico	**2,63**	2,46	2,79	2,33	2,85	2,67
Mantener la beca o apoyo económico para sus estudios	**3,23**	3,36	3,11	2,78	3,25	3,67
Obtener una mayor calificación	**3,91**	4,11	3,71	3,67	3,95	4,11
Percepción de que la tarea o temas no afianzan su formación profesional	**2,89**	2,82	2,96	2,72	2,55	3,44
No se evalúa la honestidad académica	**3,23**	3,25	3,21	3,06	3,10	3,56
Dificultad de que el profesor identifique la deshonestidad	**3,43**	3,46	3,39	3,22	3,70	3,33
Percepción de impunidad de la deshonestidad	**3,79**	3,82	3,75	3,61	3,85	3,89
Falta de seguimiento y supervisión de los trabajos del alumno	**3,43**	3,36	3,50	3,44	3,65	3,17
Discordancia entre los objetivos de aprendizaje y la expectativa del profesor	**2,75**	2,54	2,96	2,50	2,90	2,83
Poca competencia del profesor en las tecnologías de información	**2,77**	2,82	2,71	2,56	3,15	2,56
Aceptación de la deshonestidad académica por sus pares	**3,07**	3,29	2,86	2,83	3,40	2,94
Facilidad que las tecnologías emergentes ofrecen para la obtención o almacenamiento instantáneo de información	**3,82**	3,89	3,75	3,56	3,85	4,06

Se evaluaron los principales motivadores que los estudiantes tienen para mantener actitudes deshonestas (tabla 2) y los resultados de la prueba ANOVA mostraron una diferencia estadísticamente significativa entre aquellas que demuestran mayor frecuencia y las menos frecuentes ($p < 0,05$). Los profesores reportaron que los factores más importantes son: obtener una mayor calificación y la facilidad que las tecnologías emergentes ofrecen para la obtención y almacenamiento instantáneo de información, con una media de 3,91 y 3,82, respectivamente. Las acciones menos observadas fueron: volumen de actividad académica o clínica de los alumnos y el desconocimiento del capítulo de integridad académica del Reglamento de Alumnos, con una media de 2,52 y 2,63, respectivamente.

Los motivadores se analizaron también por la etapa de la carrera donde los profesores realizan su mayor participación docente y los años de experiencia docente, sin embargo, no se demostraron como elementos de importancia, al no encontrar una diferencia estadística significativa ($p > 0,05$).

Al indagar con los profesores respecto a las veces que han abordado el tema de la deshonestidad académica con sus alumnos, un 33,93% indicó que lo había hecho de manera grupal; el 8,93% lo hab-a abordado de manera individual con un alumno en particular; el 48,21% lo hab-a hecho de ambas maneras y el 8,93% no hab-a discutido el tema en los oltimos 10 años. Al revisar con los participantes la raz>n por la que no se persiguen estos actos de deshonestidad, sus principales respuestas fueron: falta de evidencia tangible (48,21%), falta de tiempo para dar seguimiento a un tr mite administrativo (25,00%) y falta de apoyo institucional hacia los profesores (21,43%).

Cómo citar este artículo: López Sotomayor DM, et al. Percepciones de los profesores sobre de la deshonestidad en estudiantes de Medicina: prevalencia, motivaciones e implicaciones. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.07.009

Discusión

Los egresados se llevan con ellos los aprendizajes académicos, técnicos y los valores que pondrán en práctica en su vida profesional, personal y ciudadana. Particularmente en la atención hospitalaria, algunas investigaciones han encontrado fraudes en la atención en lo que respecta a tratamientos o cirugías que pudieron ser evitados[4,5]. Por lo anterior, las instituciones educativas deben privilegiar el conjunto de valores y habilidades que desarrollan los médicos en formación, sin tomar como única referencia las calificaciones para medir el desempeño.

Estudios en diferentes regiones geográficas han encontrado rangos muy variables de incidencia de conductas deshonestas con alumnos de instituciones de educación superior que van desde el 4,7% hasta el 87,6%[4,11-14]. Este amplio rango se debe a las diferentes concepciones de prácticas y estudio de conductas deshonestas específicas.

La tolerancia a la copia es interpretada por los alumnos como que es una conducta permitida por lo que, además de que incurren, reinciden en ella. Lo más alarmante es que desde su punto de vista personal ellos podrían considerarlas como una falta a la integridad. Las consecuencias o penalizaciones poco severas promueven la participación mediante una cultura de impunidad. Asimismo, cuando la institución educativa no tiene definiciones claras de qué considera deshonestidad académica o no las hace públicas, el alumno puede incurrir en ellas, ya que depende de sus criterios personales por falta de dirección en este sentido. Por otro lado, estas conductas pueden ser promovidas mediante prácticas que enaltezcan a los alumnos con mejores calificaciones, al darles retribuciones positivas o al permitirles participar en actividades selectas sin importar la forma de haberlas obtenido.

De tal forma que es una responsabilidad para las instituciones educativas de nivel profesional el tener impacto en las conductas y profesionalismo de los alumnos antes de que egresen a la vida laboral. Los planes de estudios en las carreras de ciencias de la salud, además de prepararlos para practicar todo lo aprendido en la universidad, los forman con un factor diferenciador de ser médicos, enfermeros, nutriólogos y odontólogos, íntegros, éticos y profesionales, que es su principal carta de presentación.

Un actor principal en este proceso formativo es el profesor, quien, al estar en contacto directo con los estudiantes, puede influir en la prevención, motivación y reporte de conductas deshonestas. Los docentes comparten la responsabilidad de mantener los métodos de evaluación actualizados, otorgar retroalimentación oportuna y ofrecer un entorno académico que suponga un reto intelectual para los estudiantes. Este estudio contribuye a la generación de conocimiento mediante el restablecimiento de la perspectiva del docente para entender este fenómeno.

Una de las principales motivaciones reportadas fue el deseo de obtener una mayor calificación. Esto se puede explicar de distintas maneras porque, generalmente, los alumnos que demuestran un alto rendimiento académico en su promedio tienen oportunidad de participar en concursos académicos, deportivos, artísticos o de investigación. Además, el promedio académico es utilizado como referencia para otorgar oportunidades de intercambios en el extranjero, la selección de plaza de servicio social e incluso para el acceso a estudiar un posgrado.

Entre las acciones más frecuentes encontradas en este estudio, se encuentran el plagio en actividades y tareas, y la obtención de crédito por trabajos en los que no participan, y ambas implican el trabajo con sus pares. Brimble y Stevenson-Clarke[15] coinciden en esto y reportan que la incidencia de la obtención del crédito por trabajos en los cuales no tuvo participación es de las conductas más frecuentes. Presentan, además, que el tener más tiempo para contestar un examen al continuar escribiendo respuestas, aunque ya se hubiera terminado el tiempo de la aplicación, también es común. Los autores aseguran que las motivaciones detrás de estas fueron el ayudar a un amigo, el creer que no está mal y la percepción de que otros estudiantes lo hacen también.

La investigación no encontró una relación directa entre la experiencia del profesor, o su participación en diferentes etapas de la carrera, con la observación de conductas deshonestas. Algunas iniciativas consideran que esto pueden repercutir, por ejemplo, en que un profesor novato no tenga la formación en pedagogía que lo prepare para promover un ambiente de honestidad académica, por lo que ofrecen cursos básicos de docencia que permitan prepararlos para relacionarse con estudiantes del siglo XXI que son inquisitivos, competitivos y nativos digitales. Un elemento destacado en nuestros resultados es que los profesores consideran que el acceso a la tecnología es un motivador principal que facilita la disponibilidad constante de información y contenido, y que estos favorecen conductas deshonestas. Esto coincide con la percepción de la comunidad educativa de que el ambiente muy tecnológico hace que sea mucho más fácil el acceso y mal uso de recursos de información, sobre todo, porque en la actualidad su uso puede llegar darse en cualquier momento y lugar.

Una de las principales limitaciones de este estudio es la baja respuesta de los profesores. Las encuestas enviadas a través de correo electrónico son las que se han visto que obtienen el porcentaje de respuesta más bajo, al compararlo con otros medios de aplicación[16]; sin embargo, otros estudios sobre la deshonestidad han obtenido tasas de respuesta similares en encuestas enviadas por correo electrónico a profesores[17]. Por otro lado, Brimble y Stevenson-Clarke[15] encontraron que, en la mayoría de los actos deshonestos, los profesores tienen una percepción de la frecuencia menor en comparación con lo que ocurre en la realidad, por lo que los resultados de la prevalencia de este estudio pueden ser subestimados.

Es necesario fortalecer las políticas institucionales que faciliten la inclusión de métodos de reporte y seguimiento a situaciones de riesgo, y que estén pensadas en el usuario que hace el reporte. McCabe y Treviño[6] afirman que uno de los factores que inciden en los reportes de faltas es que los profesores deben realizar largos procedimientos burocráticos que forman parte de las políticas departamentales para documentar la copia en estudiantes. No obstante, Nadelson[17] dice que las personas están dispuestas a seguir los procesos, pero no cuentan con la documentación o evidencias que son necesarias para hacer la conducta pública. Algunos otros factores son que los profesores prefieren lidiar con el problema de forma personal y directa con el estudiante involucrado, al considerar que esto puede tener un

Cómo citar este artículo: López Sotomayor DM, et al. Percepciones de los profesores sobre de la deshonestidad en estudiantes de Medicina: prevalencia, motivaciones e implicaciones. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.07.009

mayor impacto en su formación[18]. En la institución donde se realizó el estudio, se han implementado diversas medidas para hacerle frente: la definición de un capítulo de integridad académica en el Reglamento de Alumnos, el rediseño de un proceso para el reporte de faltas y la concienciación mediante campañas sobre el impacto de la deshonestidad en su formación profesional. Estudios futuros deben ahondar en el efecto de la implementación de medidas de este tipo en la comunidad estudiantil.

Conflicto de intereses

Los autores declaran no tener ningún conflicto de intereses.

Agradecimientos

Al Dr. Manuel Pérez Jiménez, decano de la Región Norte de la Escuela de Medicina y Ciencias de la Salud del Tecnológico de Monterrey, a las Direcciones de Ciencias Básicas, Ciencias Médicas Básicas y Ciencias Clínicas de la Carrera de Médico Cirujano de la misma institución, en especial a la Dra. Belinda Carrión por las facilidades para la realización de este estudio.

Particular agradecimiento a los profesores que compartieron su visión con esta investigación para la mejora de la experiencia del programa.

Bibliografía

1. Vaamonde JD, Omar A. La deshonestidad acad,mica como un constructo multidimensional. Rev Latinoam Estud Educ. 2008;38:7–27.
2. Diez-Martínez E. Deshonestidad académica de alumnos y profesores: Su contribución en la desvinculación moral y corrupción social. Sinéctica. 2014;1:1–17.
3. Sousa RN, Conti VK, Salles AA, Mussel ICR. Deshonestidad académica: efectos sobre la formación ética de los profesionales de la salud. Rev Bioét. 2016 diciembre;24:459–68.
4. Ruhnke GW, Doukas DJ. Trust in residents and board examinations: When sharing crosses the boundary. Mayo Clin Proceedings. 2013 May;88:438–41.
5. Kukolja Taradi S, Taradi M, Zoran Z. Croatian medical students see academic dishonesty as an acceptable behaviour: A cross-sectional multicampus study. J Med Ethics. 2012;38:376.
6. McCabe DL, Treviño LK. Individual and contextual influences on academic dishonesty: A multicampus investigation. Res Higher Educ. 1997;38:379–96.
7. Vinodh RS, Pradeep C. Evaluation of burnout syndrome in medical students. J Pharm Chem Biol Sci. 2016;4:299–306.
8. Bandura A. Social foundations of thought and action. Englewood Cliffs: Prentice Hall; 1986.
9. Massialas BG, Allen RF. Critical issues in teaching social studies. Belmont,CA: Wadsworth Publishing Company; 1996.
10. Tefera T, Kinde G. Faculties' perception and responses to academic dishonesty of undergraduate students in Education, Business and Economics. Ethiop J Educ Sci. 2009;4:57–72.
11. Baldwin DC, Daugherty SR, Rowley BD, Schwarz MR. Cheating in medical school: A survey of second-year students at 31 schools. Acad Med. 1996;71:267–73.
12. Dans PE. Self-reported cheating by students at one medical school. Acad Med. 1996;71:S70–2.
13. Salahi Yekta A, Lupton RA, Khadem Maboudi AA. Attitudes, perceptions, and tendencies of the Iranian students in medical fields towards cheating and academic dishonesty. J Paramed Sci. 2010;4:35–41.
14. Sierles F, Hendricky I, Circle S. Cheating in medical school. J Med Educ. 1980 febrero;55:124–5.
15. Brimble M, Stevenson-Clarke P. Perceptions of the prevalence and seriousness of academic dishonesty in Australian universities. Aust Educ Res. 2005;32:19–44.
16. Sheehan KB. E-mail survey response rates: A review. J Comput Mediat Commun. 2006;6(2.).
17. Nadelson S. Academic misconduct by university students: Faculty perceptions and responses. Plagiary: Cross-Disciplinary Studies in Plagiarism. Fabrication, and Falsification. 2007:67–76.
18. Nuss E. Academic integrity: Comparing faculty and student attitudes. Improving College and University Teaching. 1984;32:140–4.

Cómo citar este artículo: López Sotomayor DM, et al. Percepciones de los profesores sobre de la deshonestidad en estudiantes de Medicina: prevalencia, motivaciones e implicaciones. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.07.009

Educ Med. 2018;xxx(xx):xxx–xxx

Educación Médica

www.elsevier.es/edumed

ORIGINAL BREVE

Incremento de síndrome de burnout en estudiantes de Medicina tras su primer mes de rotación clínica

Andrea Monserrat Guillén-Graf[a], Eduardo Flores-Villalba[a,b,*], José Antonio Díaz-Elizondo[a], Ulises Garza-Serna[a], Ricardo Ernesto López-Murga[a], Daniela Aguilar-Abisad[a], Jose Felipe Muñoz-Lozano[a] y Larisa Rentería García[a]

[a] *Escuela de Medicina y Ciencias de la Salud, Tecnológico de Monterrey, Monterrey, Nuevo León, México*
[b] *Escuela de Ingeniería, Tecnológico de Monterrey, Monterrey, Nuevo León, México*

Recibido el 12 de abril de 2018; aceptado el 12 de septiembre de 2018

PALABRAS CLAVE
Medicina;
Burnout;
Estudiantes;
Internado

Resumen

Introducción: Se ha demostrado que el desarrollo de burnout en los médicos se inicia desde su formación académica y puede repercutir en su vida personal.

Objetivo Evaluar la prevalencia de burnout al inicio y tras un mes de rotación clínica.

Material y métodos: Se empleó el Maslach Burnout Inventory-Human Services Survey de 22 reactivos. Se evaluaron al inicio de la rotación, después de un período vacacional, y después de un mes de rotación clínica. Se estableció la prevalencia y las diferencias entre las 2 mediciones.

Resultados: Veintiún (12,3%) alumnos presentaban síntomas de severidad al inicio del trimestre y 34 (19,8%) después del primer mes (p = 0,059). Tras eliminar la realización personal, 54 (31,6%) y 76 (44,2%) alumnos presentaron severidad en el resto de las dimensiones (p = 0,016), respectivamente.

Conclusión: Después de un mes de exposición clínica se presentó un incremento significativo en la presencia de cansancio emocional, despersonalización y burnout.

KEYWORDS
Medicine;
Burnout;
Students;
Rotation

Increase in burnout syndrome in medical students during their first month of clinical rotation

Abstract

Introduction: It has been demonstrated that the development of burnout in physicians begins during their academic training and it can affect their personal life.

Objective: To evaluate the prevalence of burnout in medical students at the beginning, and after one month of clinical rotation.

* Autor para correspondencia.
Correo electrónico: eduardofloresvillalba@itesm.mx (E. Flores-Villalba).

https://doi.org/10.1016/j.edumed.2018.09.003

Cómo citar este artículo: Guillén-Graf AM, et al. Incremento de síndrome de burnout en estudiantes de Medicina tras su primer mes de rotación clínica. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.09.003

Materials and methods: We evaluated students at the beginning of surgical clinical rotation and one month after using the Maslach Burnout Inventory-Human Services Survey. The prevalence and differences between the 2 measurements were calculated.
Results: Twenty-one (12.3%) students showed symptoms of severity at the beginning, and 34 (19.8%) after the first month ($P = .059$). After eliminating the personal accomplishment scale, 54 (31.6%) and 76 (44.2%) students had severity of symptoms in the rest of the dimensions at the beginning and after one month, respectively ($P = .016$).
Conclusion: Medical students showed an increase in the presence of severe burnout, as well as emotional exhaustion and depersonalisation after one month of clinical rotation.

Introducción

Se ha demostrado que el desarrollo de burnout en los médicos se inicia desde su formación académica[1,2]. Los estudiantes de Medicina en comparación con individuos del mismo rango de edad de la población general tienen una calidad de vida mental mucho menor[2]. Su vida profesional puede describirse como impredecible y, en ocasiones, no tienen control sobre muchos detalles[3]. Condiciones como una inconformidad con el ambiente de estudio, relaciones negativas con sus superiores, el apoyo que brindan las facultades, los cambios constantes de rotaciones y las características personales del individuo contribuyen a que se presente esta entidad[1,3]. Particularmente, durante las rotaciones clínicas, las cuales implican guardias nocturnas y menos horas de sueño, los estudiantes tienen mayor riesgo de sentirse así[1,4].

Las consecuencias del burnout en esta etapa pueden llevarlos a conductas de deshonestidad académica, comportamientos poco profesionales y un menor interés por actividades altruistas. Los estudiantes con burnout también suelen tener una opinión menos asertiva sobre el profesionalismo de sus compañeros y profesores, lo cual conlleva un impacto negativo en su proceso de aprendizaje[5]. Además, puede repercutir en su vida personal, hasta una mayor probabilidad de cometer suicidio[2].

El burnout en los estudiantes de Medicina puede ser reversible y prevenible. Por tanto, es de importancia identificar los factores que predisponen a esta condición para posteriormente analizar la posibilidad de nuevas alternativas para reducir su incidencia en esta población[2].

El presente estudio tiene como objetivo evaluar la prevalencia de burnout en estudiantes de Medicina al inicio y tras un mes de rotación clínica en un sistema de 80 h de trabajo por semana.

Material y métodos

Se diseñó un estudio observacional y descriptivo. Se llevó a cabo en la Escuela de Medicina y Ciencias de la Salud del Tecnológico de Monterrey, durante un período de 2 años.

Se solicitó la participación a estudiantes de la licenciatura de Médico Cirujano que estaban cursando su rotación clínica de Cirugía General. Estas asignaturas se realizan tanto en hospitales públicos como privados de tercer nivel y están bajo un régimen de 80 h semanales de trabajo, con guardias cada tercer o cuarto día.

Los alumnos fueron evaluados en 2 momentos: al inicio del trimestre, después de un período vacacional de 15 días, y posteriormente, tras un mes de experiencia en campo clínico.

Se excluyeron todos aquellos que se negaran a participar en el estudio de forma voluntaria, los que no concluyeron todas las preguntas del cuestionario, o cuyas respuestas no estuvieran de acuerdo con el formato solicitado.

Para estimar la prevalencia de burnout se empleó el Maslach Burnout Inventory-Human Services Survey de 22 reactivos[3,6]. Se evaluaron las 3 dimensiones: cansancio emocional, despersonalización y realización personal. De acuerdo con lo establecido tradicionalmente, se considera que los participantes tienen síntomas de burnout si presentan unos niveles de agotamiento emocional (≥ 27), despersonalización (≥ 10) y realización personal (< 33) altos[7]. No obstante, la tendencia actual en algunos estudios es a no utilizar la realización personal para categorizar a las personas con burnout[8], por lo que se calculó la prevalencia de un burnout alterno que no incluyera este criterio.

Análisis estadístico

Se utilizó el programa SPSS® (Chicago, IL, Estados Unidos; versión 23) para la creación de una base de datos con los resultados cuantitativos obtenidos y posteriormente el análisis estadístico de los resultados. Se evaluaron las frecuencias absolutas y relativas, las medianas y los rangos intercuartiles según correspondiera. Se emplearon las pruebas de χ^2 para evaluar frecuencias y U de Mann-Whitney para medianas.

Consideraciones éticas

Se solicitó la autorización de cada uno de los participantes antes de la aplicación de la encuesta y, al estar de acuerdo, firmaron el consentimiento informado para el uso confidencial de la información obtenida.

Cómo citar este artículo: Guillén-Graf AM, et al. Incremento de síndrome de burnout en estudiantes de Medicina tras su primer mes de rotación clínica. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.09.003

Tabla 1 Características sociodemográficas (N = 172)

Variable	n (%)	Mediana (RIC)
Sexo		
Femenino	91 (53)	
Masculino	81 (47)	
Foráneo		
Sí	124 (72)	
No	48 (28)	
Tipo de rotación		
Pública	68 (39)	
Privada	104 (61)	
Bebidas alcohólicas por semana		
0	80 (47)	
1-7	78 (45)	
8-13	9 (5)	
≥ 14	5 (3)	
Horas de trabajo por semana		72 (60-80)
Horas de sueño por día		5 (4-6)
Horas dedicadas al estudio por semana		15 (9-22)
Horas de ejercicio por semana		1 (0-3)
Horas dedicadas a pasatiempos por semana		3 (1-5)

Tabla 2 Resultados por dimensión de la escala Maslach Burnout Inventory al inicio y tras un mes

	Inicio		Un mes después		p
	n (%)	Mediana (RIC)	n (%)	Mediana (RIC)	
Cansancio emocional		25 (19-34)		32 (21-40)	0,001*
Despersonalización		9 (5-13)		11 (6-16)	0,033*
Realización personal		38 (33-42)		37 (32-42)	0,105
Burnout (CE, DP, RP)	21 (12)		34 (20)		0,059
Burnout «alterno» (CE, DP)	54 (32)		76 (44)		0,016*

CE: cansancio emocional; DP: despersonalización; RP: realización personal.
* Significativo con p < 0,05.

Resultados

Se incluyeron un total de 343 encuestas en 172 alumnos, de los cuales 91 (53%) fueron mujeres y 124 (72%) afirmaron ser foráneos. Los factores demográficos y las preguntas con factores que han sido relacionados con el síndrome de desgaste emocional se encuentran en la tabla 1.

Un total de 21 (12,3%) alumnos presentaba síntomas de severidad en las 3 dimensiones al inicio del trimestre; tras un mes existió un aumento, con un total de 34 (19,8%) sujetos (p = 0,059). Tras eliminar el criterio de realización personal, 54 (31,6%) y 76 (44,2%) alumnos presentaron severidad en el resto de las dimensiones al inicio y después de un mes, respectivamente, con un aumento significativo (p = 0,016). Los resultados se resumen en la tabla 2.

Discusión

Los estudios pioneros sobre el burnout surgieron a partir de observaciones realizadas en el ambiente laboral de personas que se dedicaban al sector salud o a prestar servicios humanos, al ser un grupo de la población que suele lidiar con condiciones de mayor demanda emocional[9]. Actualmente se estima que aproximadamente un 50% de los estudiantes de Medicina experimenta o ha experimentado burnout[1,2] y sus consecuencias son apreciables en su proceso de aprendizaje.

Se ha descrito que los médicos en especialidades de primera línea presentan un mayor riesgo de experimentar burnout[4]. En este estudio, se observó que los estudiantes de Cirugía General, Ginecología y Obstetricia y Medicina Interna obtuvieron medianas de severidad para cansancio emocional y despersonalización después de un mes de rotación clínica. Sin embargo, es importante resaltar que a pesar de que los estudiantes tuvieron un período de descanso académico de 15 días, los resultados obtenidos al inicio de la rotación indican valores muy cercanos a los establecidos como límites de corte. Esto pudiera ser explicado con base en estudios previos, en los cuales los estudiantes de Medicina en su fase preclínica también sufren de burnout[1].

Asimismo, las horas trabajadas por semana se han asociado con un mayor riesgo de agotamiento[4]. A pesar de que la percepción del alumno en este estudio es de 72 h de trabajo por semana en las encuestas realizadas, el currículum

Cómo citar este artículo: Guillén-Graf AM, et al. Incremento de síndrome de burnout en estudiantes de Medicina tras su primer mes de rotación clínica. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.09.003

está basado en semanas de 80 h de exposición clínica de promedio, el mismo que se ha establecido como límite para el trabajo de estudiantes y residentes en otros países[8].

Para la evaluación, se consideró diagnóstico de burnout en los estudiantes unos puntajes de severidad en las dimensiones de despersonalización, agotamiento emocional y realización personal[4]. Sin embargo, a diferencia de lo tradicionalmente establecido, diversos autores ponen en duda la centralidad de una realización personal baja para su diagnóstico[3]. Se ha argumentado también la tendencia a clasificar a las personas como «con» o «sin» burnout; sin embargo, el agotamiento profesional varía a lo largo del tiempo de manera continua, por lo que es más relevante reportar los puntajes de cada dimensión y clasificarlos por nivel de severidad[3].

Existe escasa información sobre cuándo se establecen los síntomas de burnout en los estudiantes de Medicina. Este estudio demuestra un incremento significativo de burnout en el primer mes de exposición clínica; tomando en cuenta que la rotación hospitalaria es de un año, las implicaciones evidenciadas nos llevan a pensar que estos niveles llegarán a ser alarmantes al final de la carrera. Sin embargo, será importante establecer en futuros estudios el incremento de burnout durante los meses posteriores y estudiar si existen mecanismos de adaptación que detengan la progresión del síndrome.

Se ha descrito que los estudiantes de Medicina con burnout no solicitan ayuda por temor a sufrir discriminación por parte de sus superiores, y cuando lo hacen, generalmente es por síntomas de agotamiento emocional y no por despersonalización. Asimismo, tienen un mayor estigma con respecto al tratamiento de los problemas de salud mental[7]. Por lo antes mencionado, resulta relevante conocer esta información para establecer estrategias específicas y oportunas para el abordaje de este síndrome.

Aunque no estaba dentro de los objetivos de este estudio, observamos que las horas de sueño no son las óptimas y que el tiempo dedicado a otras actividades, como ejercicio o pasatiempos, es menor de 30 min diarios en promedio, lo que puede interpretarse como una dedicación prácticamente completa a sus actividades académicas y clínicas. Será importante plantear estudios que nos den mayor información acerca de estas variables.

Dentro de las limitaciones del estudio se puede señalar que no se indagó sobre posibles factores que desencadenan burnout dentro de sus rotaciones. Se ha descrito que los estudiantes que sufren o han sufrido algún tipo de maltrato por parte de sus superiores deben ser considerados como más vulnerables a desarrollar burnout, sin la posible influencia de otras variables[10]. Asimismo, no se evaluó la coexistencia de enfermedades psiquiátricas en los estudiantes. Sería importante, además, dar un seguimiento a los participantes a lo largo de sus rotaciones y analizar el cambio entre las diferentes especialidades que van cursando.

Conclusión

En este estudio se demuestra que después de un mes de rotación clínica en un programa de exposición de 80 h a la semana, los estudiantes de Medicina presentan un incremento significativo en la presencia de burnout severo, así como de cansancio emocional y despersonalización de manera independiente.

Conflicto de intereses

Los autores declaran no tener ningún conflicto de intereses.

Bibliografía

1. Dyrbye LN, Thomas MR, Harper W, Massie FS Jr, Power DV, Eacker A, et al. The learning environment and medical student burnout: A multicentre study. Med Educ. 2009;43:274–82.
2. Dyrbye LN, Thomas MR, Massie FS, Power DV, Eacker A, Harper W, et al. Burnout and suicidal ideation among U. S. medical students. Ann Intern Med. 2008;149:334–41.
3. Eckleberry-Hunt J, Kirkpatrick H, Barbera T. The problems with burnout research. Acad Med. 2018;93:367–70.
4. Shanafelt TD, Boone S, Tan L, Dyrbye LN, Sotile W, Satele D, et al. Burnout and satisfaction with work-life balance among US physicians relative to the general US population. Arch Intern Med. 2012;172:1377–85.
5. Brazeau CM, Schroeder R, Rovi S, Boyd L. Relationships between medical student burnout, empathy, and professionalism climate. Acad Med. 2010;85 10 Suppl:S33–6.
6. Maslach C, Jackson SE, Leiter MP. Maslach Burnout Inventory Manual. 3rd ed. Palo Alto, CA: Consulting Psychologists; 1996.
7. Dyrbye LN, Eacker A, Durning SJ, Brazeau C, Moutier C, Massie FS, et al. The impact of stigma and personal experiences on the help-seeking behaviors of medical students with burnout. Acad Med. 2015;90:961–9.
8. Maslach C, Schaufeli WB, Leiter MP. Job burnout. Annu Rev Psychol. 2001;52:397-422.
9. Stevens RM. Surgical resident education of medical students in the 80-hour workweek. Curr Surg. 2005;62:74-5.
10. Cook AF, Arora VM, Rasinski KA, Curlin FA, Yoon JD. The prevalence of medical student mistreatment and its association with burnout. Acad Med. 2014;89:749–54.

Cómo citar este artículo: Guillén-Graf AM, et al. Incremento de síndrome de burnout en estudiantes de Medicina tras su primer mes de rotación clínica. Educ Med. 2018. https://doi.org/10.1016/j.edumed.2018.09.003

Educ Med. 2018;19(S3):306–312

Educación Médica

www.elsevier.es/edumed

ORIGINAL

Evaluación de la calidad de campos clínicos para la enseñanza en pregrado en México☆

Isaac Heriberto Rodríguez Alvarez, Mildred Vanessa López Cabrera*, José Antonio Díaz Elizondo, José Juan Góngora Cortés y Karla Patricia Pacheco Alvarado

Tecnológico de Monterrey, Escuela de Medicina y Ciencias de la Salud, Monterrey, Nuevo León, México

Recibido el 14 de julio de 2017; aceptado el 14 de julio de 2017
Disponible en Internet el 14 de octubre de 2017

PALABRAS CLAVE
Calidad de programas;
Campos clínicos;
Enseñanza clínica

Resumen

Introducción: La formación del alumno de medicina es dinámica y multifactorial, requiere de entrenamiento constante con los recursos necesarios bajo la tutela de un profesor clínico que le guíe a desarrollar su máximo potencial.

El objetivo de esta investigación fue diseñar y validar un instrumento que permita conocer la percepción de los alumnos sobre la calidad de los campos clínicos donde participan en sus rotaciones.

Material y métodos: Es un estudio de tipo cuantitativo, observacional, descriptivo, prospectivo y transversal. La población participante fueron los 148 alumnos del quinto año de la carrera de medicina de una universidad privada al norte de México. Se elaboró una herramienta de 30 ítems que evalúa la calidad de los campos clínicos en tres variables: estructura, tutoría, y proceso enseñanza-aprendizaje, en una escala Likert de 4 niveles que va desde 1, totalmente en desacuerdo, a 5, totalmente de acuerdo. Para el estudio se considera el análisis de ítem para evaluar la consistencia interna, así como la prueba ANOVA, prueba Tukey, y estadística descriptiva para estudiar las tendencias por factores y por servicio.

Resultados: Se obtuvo un alfa de Cronbach de 0,9549. La media del factor de estructura fue 3,64, la media de tutoría fue 4,03 y la de proceso enseñanza-aprendizaje, 4,18. El servicio que recibió una evaluación más favorable fue Pediatría, obteniendo una diferencia significativa en los elementos de estructura (p = 0,008) y tutoría (p = 0,003).

☆ El trabajo será presentado como ponencia de investigación en el 4.º Congreso Internacional de Innovación Educativa en Ciudad de México, México, y en el XX Encuentro Estatal de Investigación en Salud en Monterrey, México.

* Autor para correspondencia.
Correo electrónico: mildredlopez@itesm.mx (M.V. López Cabrera).

https://doi.org/10.1016/j.edumed.2017.07.007

Discusión: Aunque la media observada en la percepción de los alumnos indica un nivel adecuado de la tutoría y el proceso de enseñanza aprendizaje, al hacer un análisis por sede se observa una amplia variación de la calidad de enseñanza ofrecida. Como instituciones educativas esto es un foco de atención porque significa que los alumnos no adquieren ni desarrollan sus competencias de igual manera en todos los campos clínicos.

KEYWORDS
Quality of programs;
Clinical fields;
Clinical teaching

Assessment of the quality of clinical fields for undergraduate medical education in Mexico

Abstract
Introduction: Medical student training is dynamic and multifactorial. It requires continuing education and training under the tutelage of a clinic professor, who will guide the student to develop optimal potential.

The objective of this study was to design and validate a tool to measure student perception on the learning quality of clinical rotations.

Material and methods: The study is quantitative, observational, descriptive, prospective, and cross-sectional. The study sample was consisted of 148 fifth-year medical students from a private university in northern Mexico. A 30 item questionnaire was developed to assess quality of clinical stewardships in three variables: structure, tutoring, and teaching-learning process. A five-level Likert scale from 1, absolutely disagree, to 5, absolutely agree, was used. The study used item analysis to estimate internal consistency, as well as ANOVA, Tukey and descriptive statistics to assess the tendencies by factors and stewardship.

Results: Cronbach alpha was 0.9549. The structure factor mean was 3.64, tutoring 4.03, and teaching-learning process 4.18. Paediatrics received the most favourable evaluation by obtaining a significant difference in the element structure ($P = .008$) and tutoring ($P = .003$).

Discussion: Even though the mean observed among tutoring and teaching-learning process indicates an adequate level of student perception, under the analysis per field, a significant variation was found in the quality of learning experience. As an academic institution, this is a concern because students are not acquiring or developing the same level of skills in all stewardships.

Introducción

Aprender de pacientes reales en el ejercicio clínico es de excelencia para la educación médica; si aunado a ello se le integra una tutoría constante y un ambiente enriquecedor de experiencias continuas, este se convierte en un medio para el desarrollo del proceso enseñanza-aprendizaje. El internado de pregrado o sus equivalentes son esenciales en la formación de los estudiantes de medicina, ya que en este ambiente es donde se realizará la cohesión de todas las teorías aprendidas durante su formación en las aulas con el ejercicio clínico realizado y supervisado.

La tendencia en educación superior está orientada al apego a estándares internacionales para ofrecer una enseñanza de calidad. La carrera de medicina no es ajena a las transformaciones y mejoras en materia educativa, a través de la historia se pueden identificar estos grandes hitos. Olivares los identifica como aprendizaje basado en ciencia, aprendizaje basado en problemas, aprendizaje basado en competencias y aprendizaje basado en perspectivas[1]. En estas etapas se modificó el alcance del currículo, empezando centrado en el contenido disciplinar y migrando hacia la demostración de la capacidad de innovación. La Secretaría de Salud menciona que organizaciones de salud, instituciones educativas, profesores y estudiantes deben incorporar continuamente nuevos recursos que les permitan obtener una mayor calidad de la experiencia educativa[2].

En México, existen organismos que evalúan las universidades formadoras de profesionales de la salud mediante un proceso de acreditación o afiliación como el Consejo Mexicano de Acreditación de Escuelas de Medicina (COMAEM) y la Asociación Mexicana de Facultades y Escuelas de Medicina (AMFEM), mientras que el control de la calidad de los campos clínicos es regido por: leyes, normas oficiales mexicanas, reglamentos estatales, políticas internas de los hospitales y las políticas y acuerdos de colaboración entre las universidades y hospitales que dictaminan el deber ser de la operación[3], entre los cuales existen diferentes elementos declarados como indispensables; por ejemplo, en materia de regulación de las instalaciones y servicios de los establecimientos para la atención médica en la formación de recursos humanos para la salud con el propósito de asegurar las condiciones necesarias para el desarrollo de los profesionales en campos clínicos. Y otros que se encuentran más alineados a

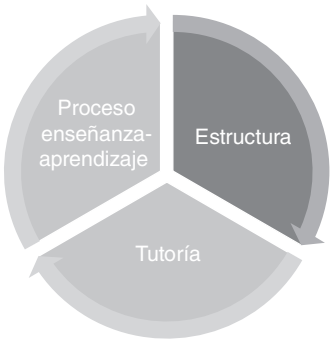


Figura 1 Modelo de enseñanza en ambientes clínicos.

las oportunidades de aprendizaje clínico, procedimental y actitudinal propio de su disciplina.

La educación es un proceso continuo que se extiende a lo largo de la vida del individuo. Este proceso surge de diferentes formas, algunos de manera formal y otros informales dentro de la vida en sociedad[4]. La educación en el ambiente clínico integra ambos formatos, lo cual es una de sus fortalezas porque integra el apoyo del tutor académico para aprender diversas patologías, pero estas están asociadas a un contexto real de práctica profesional. Tradicionalmente, se dice que el médico se hace en el hospital, no en las aulas. Esto último implica que la educación médica debe desarrollarse en un entorno altamente complejo, donde se diseñan experiencias significativas y enriquecedoras desde el punto de vista quirúrgico o ambulatorio, y donde también se vela por el contenido académico y espacios para la retroalimentación propios de la pedagogía. De acuerdo con Sánchez et al.[5], esta sigue siendo la modalidad más efectiva para adquirir y fortalecer conocimientos, actitudes y destrezas que hacen del médico un profesional en su área.

El modelo de enseñanza en ambientes clínicos se caracteriza por los elementos de estructura, tutoría y supervisión, y el proceso enseñanza-aprendizaje, como se muestra en la figura 1.

Estructura

Desde el punto de vista del programa de estudios, los alumnos que están inscritos en una facultad de medicina deben estar sujetos a su supervisión y evaluación[6]. Aunado a esto rotan por hospitales del sector público o privado, donde ocupan una posición en la estructura de recursos humanos del hospital. La importancia exacta de esa posición varía según las necesidades de cada hospital, el grado de control que ejerce la facultad de medicina y la voluntad de la alta dirección. Desde el marco normativo, se considera interno de pregrado al alumno que cursa la licenciatura en medicina en una institución de educación médica que ha acreditado los ciclos académicos que su respectivo plan de estudios establece y se incorpora como becario a las unidades aplicativas para su educación y adiestramiento[7].

De acuerdo con Martínez et al.[8], la calidad de la atención se define como la obtención del máximo beneficio para el paciente con riesgos mínimos, mediante la optimización del uso de recursos, incluyendo estos últimos: tecnología, infraestructura y capital humano. En la Secretaría de Salud actualmente se cuenta con normas que regulan la calidad de los campos clínicos donde se otorga esta atención a los pacientes[3].

En México, la NOM-234-SSA1-2003, llamada Utilización de campos clínicos para ciclos clínicos e internado de pregrado, considera elementos indispensables en la regulación de las instalaciones y servicios de los establecimientos para la atención médica en la formación de recursos humanos para la salud, a fin de vigilar el derecho a la protección de la salud y preservar la calidad de los servicios de salud mientras se desarrollan las actividades de aprendizaje y enseñanza tutorial ante el paciente[3]. Esta norma considera como estructura: disposiciones generales, disposiciones para ciclos clínicos y disposiciones para el internado de pregrado. La tabla 1 describe los elementos que forman parte de cada una de estas variables.

El plan de desarrollo del estudiante está estructurado en bloques de aprendizaje llamados rotaciones, los cuales tienen un contenido teórico y actividades clínicas prácticas[9]. Estas últimas son un modelo del ejercicio del médico en su contacto con pacientes, completando el desarrollo de competencias; la participación activa construye la identidad profesional, que cambia de novatos a maestros en la práctica continua. Las estructuras de rotaciones están constituidas por tareas en modalidades que varían en tiempo y duración dependiendo del servicio clínico en el que estén rotando; dentro de estas tareas se encuentran: visita a pacientes, casos clínicos, consulta de pacientes ambulatorios, guardias hospitalarias, asistencias quirúrgicas, entre otras.

Proceso enseñanza-aprendizaje

Barrientos et al.[10] aseguran que el propósito de la enseñanza clínica es que el médico sea competente en habilidades clínicas, conocimientos, actitudes interpersonales, razonamiento clínico y destrezas técnicas. De acuerdo con Graue[11], el médico en formación, entendiendo como tal a estudiantes, internos o residentes, se enriquece de la clínica si puede ir añadiendo la experiencia real a sus conocimientos abstractos. Esta forma de enseñanza es cotidiana y muchas veces inconsciente, pero debe ser continua. Un ejemplo es el pase de visita de un enfermo con una determinada patología, hacer preguntas concretas de acuerdo con el nivel de conocimientos esperado, y enriquecerlas con todo aquello que ha sido insuficientemente respondido. Esta práctica añade nueva información a los esquemas de memoria del aprendiz, fortaleciendo la elaboración y asociación de ideas, propias del razonamiento clínico[12].

Sánchez et al.[5] enfatizan que la calidad en el aprendizaje, la enseñanza y formación técnica que los estudiantes de medicina reciben durante el año de internado de pregrado es esencial. Dentro de este periodo de tiempo se forjan los perfiles mediante los cuales los estudiantes de medicina en un futuro conformarán la manera de ejercerse y de desempeñarse como profesionistas.

Tutoría y supervisión

La educación clínica es un proceso compartido en el cual interactúan diferentes actores con roles y responsabilidades específicas. Sánchez et al.[5] describen como la tríada del aprendizaje clínico: paciente, estudiante y tutor. El

Tabla 1 Estructura de la NOM-234-SSA1-2003 Utilización de campos clínicos para ciclos clínicos e internado de pregrado

Estructura	Descripción
Disposiciones generales	Cumplimiento de requisitos mínimos de infraestructura, equipamiento, pacientes, recurso humano y tecnológico para la enseñanza Pertenecer al catálogo de campos clínicos autorizados Convenio entre instituciones de salud y educativas Autorizar la utilización de campos clínicos a instituciones educativas acreditadas o en proceso Programas académicos con los requisitos mínimo que marca la NOM-234-SSA1-2003
Disposiciones para ciclos clínicos	Marca actividades y requisitos de las operaciones dentro de los procesos de enseñanza-aprendizaje otorgados en el campo clínico
Disposiciones para internado de pregrado	Toma en cuenta los requisitos de las disposiciones para ciclos clínicos Refiere un mínimo de elementos como camas censables, guardias a realizar, apoyos y ayudas mínimas a los alumnos, existencia de personal de base o contratado, médicos supervisores o asesores y servicios de especialidades que se encuentren en el campo clínico (Medicina interna, Pediatría, Cirugía general, Ginecoobstetricia, Urgencias, Medicina familiar o Proyección a la comunidad)

paciente representa en sí una experiencia de aprendizaje, de manera directa o indirecta; sin embargo, no es posible pronosticar los casos o patologías que se recibirán en un hospital, lo que vuelve estas experiencias a un carácter oportunístico. El estudiante tiene la responsabilidad de adquirir el dominio de una actividad, por ello es necesaria la repetición constante en diferentes escenarios clínicos que cuenten con elementos indispensables como son la infraestructura y los tutores[10]. El médico, en su papel como tutor, realiza acciones enfocadas a la enseñanza y a la orientación durante la práctica para maximizar el rendimiento del estudiante en el ambiente clínico, al brindar asistencia imparcial y formativa. Al ser considerado un experto en el manejo de su área, es él quien realiza la retroalimentación al estudiante durante y después de la práctica; además, coadyuva a determinar los objetivos de aprendizaje, verificar su cumplimiento y desarrollar estrategias didácticas para superar deficiencias[10,13].

En el caso de los hospitales donde no hay suficiente personal, muchas veces los alumnos desempeñan una alta carga de las tareas de atención a pacientes, mientras que en otros casos su labor es más la de apoyo. Algunos autores afirman que cuando el hospital es universitario, las facultades de medicina influyen positivamente en la calidad formativa de la experiencia[6]. El objetivo es que los alumnos aprendan a resolver problemas de salud de pacientes bajo la supervisión de un tutor, el cual es un médico docente con grado de especialista que actúa como un modelo a seguir de su profesión[9]. Méndez et al.[14] consideran que ciertos programas formativos tienen más fortalecido su proceso teórico-práctico debido a la alta demanda que presentan, como, por ejemplo: Medicina interna, Medicina familiar, Ginecología y obstetricia, Cirugía, Pediatría y Urgencias.

Objetivo

El objetivo de esta investigación fue diseñar y validar un instrumento que permita conocer la percepción de los alumnos que participan en rotaciones en campos clínicos sobre la calidad de estos para la enseñanza.

Material y métodos

Este estudio es de tipo cuantitativo, observacional, descriptivo, prospectivo y transversal. El diseño tiene una metodología cuantitativa al estudiar un fenómeno de forma estandarizada, mediante pasos sistemáticos que acotan en variables el comportamiento de los sujetos de estudio. Se considera observacional ya que la exposición ocurre sin la participación del investigador, quien realiza observación y registro de los acontecimientos con intervención mínima en el curso natural de estos[15,16]. Se elige un análisis descriptivo donde se le asigna un atributo a cada una de las variables del modelo teórico, y se mide la información de manera independiente y conjunta sobre estas[17]. Es prospectivo ya que la ocurrencia del evento se registra durante el estudio[15,18]. Es de corte transversal porque se efectúa en un momento determinado reflejando el evento de interés, una vez terminada la rotación de cada especialidad del alumno.

Muestra

La población participante fueron los 148 alumnos inscritos en el periodo de julio del 2016 a junio del 2017, lo que corresponde al quinto año de la carrera de medicina. Ellos realizaron las rotaciones en los trimestres: julio a septiembre del 2016, octubre a diciembre del 2016, enero a marzo del 2017, y abril a junio del 2017. El estudio se realizó en una universidad privada al norte de México. Los alumnos fueron invitados a participar voluntariamente en el estudio y recibieron información de que esta encuesta sería aplicada de manera anónima y la información recolectada sería confidencial.

Instrumento

Se elaboró una herramienta basada en la NOM-234-SSA1-2003 Utilización de campos clínicos para ciclos clínicos e internado de pregrado, la cual considera elementos indispensables en la regulación de las instalaciones y servicios de los establecimientos para la atención médica en la formación de recursos humanos para la salud (tabla 2). Esta

Tabla 2 Tendencias por elemento del campo clínico

Elemento	Ítem	Media	
Estructura	1.- Los recursos pedagógicos (aulas, biblioteca y hemeroteca) de las instalaciones apoyan la rotación para el ejercicio profesional	3,79	3,64
	2.- Las aulas, consultorios y servicios hospitalarios son accesibles; y su operación está coordinada para su uso académico	3,97	
	3.- Parte de las actividades del estudiante de medicina en la sede hospitalaria es sustituir al personal de contrato	2,52	
	4.- El área de hospitalización es apropiada para la enseñanza	4,03	
	5.- En el área donde realizó la rotación hay personal responsable del servicio todo el año las 24 horas del día	4,12	
	6.- Las áreas de descanso, aseo personal y comedor están en estado óptimo para el uso de los estudiantes	3,42	
Tutoría	7.- El tutor asesora y evalúa las actividades de la rotación de forma objetiva	4,06	4,03
	8.- El programa que lleva a cabo el tutor corresponde a la temática y contenido de la rotación	4,24	
	9.- Los encuentros con pacientes fueron suficientes para ejercer y mejorar el conocimiento médico clínico	4,10	
	10.- El tiempo y calidad de las actividades de enseñanza en el consultorio son adecuados	4,02	
	11.- El responsable de enseñanza del hospital se interesa por el aprendizaje de los estudiantes	3,93	
	12.- El tutor está a cargo de pacientes que corresponden a la especialidad de la rotación que realizan los estudiantes	4,35	
	13.- El tutor de la rotación participa en la toma de decisiones directivas	4,10	
	14.- La cantidad de alumnos en la rotación es ideal y permite el desarrollo de un aprendizaje clínico	4,27	
	15.- La cantidad de alumnos por tutor y paciente es ideal para el desarrollo de un aprendizaje clínico	4,35	
	16.- Durante la rotación desarrolló actividades sin asesoría o supervisión, lo que implica posibles demandas por responsabilidades o riesgo legal	2,65	
	17.- El programa designa tutores para cada rotación y módulo	4,28	
Proceso enseñanza - aprendizaje	18.- El gabinete, laboratorio clínico y de patología ofrecen oportunidades de aprendizaje adicionales, como la interpretación y análisis de resultados	3,77	4,18
	19.- El programa expresa de una forma objetiva la evaluación teórico-práctica de las actividades	4,11	
	20.- Durante las guardias enfrentó situaciones que me permiten desarrollar mis aprendizajes en el entorno clínico	4,23	
	21.- Las facilidades que se le proporcionaron, como por ejemplo: beca, alimento, uniforme y atención médica, sirven de apoyo para su desempeño en el área clínica	3,46	
	22.- Los derechos y obligaciones de los estudiantes están claramente expresados en el reglamento del campo clínico	3,82	
	23.- Durante la rotación se participa en sesiones clínicas, clínico-patológicas y presentaciones de casos clínicos	4,38	
	24.- Se hace revisión de literatura para investigar las diferentes patologías de la rotación con un enfoque basado en evidencias	4,31	
	25.- Se logra integrar el conocimiento teórico y analítico de la fisiopatología y la semiología de las distintas entidades patológicas que se presentaban en las entregas de guardia y pases de visita	4,31	
	26.- Se realizan actividades académicas en aulas, las cuales corresponden a lo establecido en el programa	4,27	
	27.- Dentro de la rotación se reconocen las patologías que necesitan ser atendidas por subespecialidades para un manejo apropiado	4,39	
	28.- Las actividades en el área de hospitalización, guardias y de consulta externa mejoraron el desarrollo de mis habilidades como médico	4,37	
	29.- Dentro de la rotación se reconocen las patologías más frecuentes en la práctica así como su tratamiento básico	4,45	
	30.- Durante la rotación se integraron conocimientos, habilidades y actitudes necesarias para atender los principales padecimientos, así como su tratamiento básico	4,43	

Tabla 3 Análisis por rotación

Rotación	Estructura	Tutoría y supervisión	Proceso enseñanza - aprendizaje	Total
Cirugía	3,50	3,93	4,10	3,84
Ginecología y obstetricia	3,58	4,09	4,14	3,93
Medicina interna	3,59	3,89	4,12	3,86
Pediatría	3,87	4,20	4,32	4,13

herramienta fue validada en contenido por 9 expertos, mediante una entrevista estructurada, en la que indicaron la pertinencia de los ítems y la claridad de la redacción. Se consideró la participación de estos expertos debido a su nivel de experiencia como investigadores en educación médica: en sus perfiles destacan por más de 5 años dedicados a docencia en ciencias de la salud y 10 años ejerciendo como médicos especialistas. Se utilizó una escala tipo Likert de 5 niveles que va desde 1, totalmente en desacuerdo, a 5, que representa totalmente de acuerdo.

Procedimiento

Dentro de la encuesta se analizaron los servicios de las especialidades de Cirugía, Ginecología-obstetricia, Medicina interna y Pediatría de los hospitales: Hospital San José, Hospital Zambrano Hellion, Hospital Metropolitano Dr. Bernardo Sepúlveda, Hospital Clínica NOVA, Sindicato Nacional de Trabajadores de la Educación (SNTE) Sección 50, Hospital Regional Materno-Infantil de Alta Especialidad. Los alumnos fueron distribuidos dentro de estos servicios permaneciendo en cada uno 3 meses. Al concluir cada rotación, se enviaba el instrumento vía correo institucional.

En el análisis estadístico se utilizó el alfa de Cronbach para evaluar la consistencia interna del instrumento. Este valor varía entre 0 y 1, donde valores más cercanos al 1 representan mayor confiabilidad. Vogt[19] considera como apropiados los valores superiores a 0,7. De igual forma se utilizó estadística descriptiva para estudiar las tendencias por factores y por ítems, además de una prueba ANOVA para estimar la respuesta ante cada elemento, utilizando como factor los distintos servicios donde realizaron la rotación. Posteriormente, se utilizó una prueba post hoc de Tukey para estimar si los comportamientos de los distintos servicios podían agruparse. La prueba ANOVA realiza una comparación de medias cuando se tienen a partir de 3 grupos para contrastar; en esta se tiene una hipótesis nula donde se utiliza el valor de p para evaluar si existe una diferencia estadística entre las medias. Se considera una confiabilidad del 95%, por lo que se compara el valor de p teniendo como referencia 0,05. La prueba Tukey brinda intervalos de confianza para todas las diferencias de los pares de medias controlando un nivel de significación en conjunto para todas las comparaciones. Como herramienta se consideró el software de Minitab 16.

Resultados

Se recolectaron 542 evaluaciones de los campos clínicos. Como parte del análisis de ítem se obtuvo un alfa de Cronbach de 0,9549, lo cual es considerado como válido. Las medias por dimensiones fueron: 3,64 para estructura, 4,03 para tutoría y 4,18 para proceso enseñanza-aprendizaje. Esto indica que los estudiantes perciben la dimensión de estructura con mayores deficiencias con respecto a las otras dos. El ítem con una percepción menos favorable fue el 16, «Durante la rotación desarrolló actividades sin asesoría o supervisión, lo que implica posibles demandas por responsabilidades o riesgo legal». Esto refleja que los estudiantes no perciben la guía de un tutor en el proceso de enseñanza-aprendizaje dentro del campo clínico, no cumpliendo, desde el punto de vista pedagógico, ni con la fortaleza de educación que integra el apoyo del tutor dentro del campo clínico en el contexto de la práctica profesional[5].

Al ahondar en el análisis por rotación, las tendencias se presentan en la tabla 3. El servicio que recibió una evaluación más favorable fue Pediatría, con una media de 4,13, obteniendo una diferencia significativa en los elementos de estructura ($p = 0,008$) y tutoría ($p = 0,003$).

Discusión

Este estudio permite conocer la opinión de uno de los actores importantes dentro de los escenarios clínicos: el médico en formación. La importancia de recibir retroalimentación de parte de los alumnos sobre la calidad de los campos clínicos es trascendental ya que ellos, al estar inmersos en los procesos de atención clínica, son quienes tienen la sensibilidad del estado de la infraestructura hospitalaria y resultados propios de la interacción con el paciente. Además, son quienes poseen una visión integral para mejorar el proceso de enseñanza-aprendizaje dentro de los campos clínicos. Como parte de la evaluación de la efectividad del programa, este análisis de los procesos vivenciales cobra relevancia ya que dentro de poco los alumnos estarán realizando su servicio social en comunidades, para posteriormente egresar como médicos generales, y se debe garantizar un nivel mínimo de competencia y de vivencia que los prepare para ejercer sus conocimientos en un contexto real.

Esta evaluación realizada a través del instrumento nos aporta datos de interés para el desarrollo de estrategias para la educación médica; es conveniente replicar el instrumento en diversos hospitales de distintas regiones para conocer la variabilidad de la percepción de los estudiantes, tratando de abarcar no solo las especialidades troncales, sino otras especialidades o subespecialidades donde realicen su práctica hospitalaria; todo ello con el fin de conocer la percepción del médico en formación desde el punto de vista de personal involucrado en los procesos asistenciales del paciente.

La visión panorámica que otorga el contar con campos clínicos alineados completamente indica su idoneidad para la

enseñanza, a fin de que puedan realizar una buena práctica y un entrenamiento clínico homogeneizando a lo largo de las distintas sedes hospitalarias. De no tener un apego adecuado a la norma, este instrumento permitiría detectar áreas de oportunidad, a fin de realizar los reportes necesarios con las autoridades competentes, proponiendo el desarrollo de planes de mejora en los programas académicos o instituciones, en virtud de que no es factible conseguir que una estudiante realice aprendizaje y trabajo en el campo clínico con calidad y eficiencia si no se cuenta con los elementos mínimos.

Se debe asegurar la continuidad de la formación de los estudiantes de medicina dentro de los campos clínicos, sin importar si son públicos o privados. El aplicar la normatividad vigente puede disminuir la variabilidad en la oferta del programa formativo que se ofrece en ambos sectores; sin embargo, es necesario reforzar la normatividad, así como crear documentos de trabajo que presenten la información en un lenguaje claro y aterrizado a los contextos específicos. Estas guías para la aplicación de la práctica educativa deben asegurar el ejercicio médico en este entorno y etapa de formación para cohesionar lo teórico y lo práctico, lo cual es propio de las instituciones educativas en salud, para poder egresar médicos capaces de resolver problemas de salud.

Conflicto de intereses

Los autores declaran no tener ningún conflicto de intereses.

Bibliografía

1. Olivares SL. Aprendizaje centrado en las perspectivas del paciente. En: Olivares SL, Valdez J, editores. Aprendizaje centrado en el paciente. Monterrey: Editorial Médica Panamericana; 2017.
2. Cruz R, Martínez S, Martínez E. Revisión y diferencias de los sistemas de evaluación de la calidad para la atención médica en México. Avances. 2011;9:43–9.
3. Secretaría de Salud. Norma Oficial Mexicana NOM-234-SSA1-2003, Utilización de campos clínicos para ciclos clínicos e internado de pregrado. México: Diario Oficial de la Federación; 2005.
4. Moreno L, García JJ, Urbina C, García GS. Actividad docente facilitadora para la adquisición de aprendizajes significativos y compromiso social. Educ Med. 2013;2:140–7.
5. Sánchez M, Aguirre HG, Torres F. La Educación clínica en las residencias médicas: retos y soluciones [Internet]. Seminario El Ejercicio Actual de la Medicina. Mexico; 2006 [consultado 13 Jun 2016]. Disponible en: http://www.medicinaysalud.unam.mx/seam2k1/2006/abr02_ponencia.html
6. Frenk J. La atención médica, la enseñanza de la medicina y el mercado de trabajo para los médicos: el internado en México. Educ Méd Salud. 1984;18:329–42.
7. Secretaría de Gobernación. Reglamento por el que se establecen las bases para la realización del Internado de Pregrado de la Licenciatura en Medicina. México: Diario Oficial de la Federación; 1983.
8. Martínez A, van Dick MA, Nápoles F, Robles J, Ramos A, Villaseñor I. Hacia una estrategia de garantía de calidad: satisfacción en la utilización de los servicios médicos. Cad Saúde Pública. 1996;12:399–403.
9. Tecnológico de Monterrey, Escuela de Medicina. Metodología de enseñanza del médico cirujano [Internet]; 2016 [consultado 15 May 2016]. Disponible en: http://emcs.mty.itesm.mx/wp/?page_id=117
10. Barrientos M, Durán V, León A, García S. La práctica deliberada en la educación médica. Rev Fac Med UNAM. 2015;58:48–55.
11. Graue E. Los fundamentos del aprendizaje y el aprendizaje en medicina. Seminario El Ejercicio Actual de la Medicina. Mexico; 2008.
12. Valdez JE, López MV. Perspectiva biomédica. En: Olivares S, Valdez J, editores. Aprendizaje centrado en el paciente. Monterrey: Editorial Médica Panamericana; 2017.
13. Hudson JN, Tonkin AL. Clinical skills education: Outcomes of relationships between junior medical students, senior peers and simulated patients. Med Educ. 2008;42:901–8.
14. Méndez JF, Mendoza H, Torruco U, Sánchez M. El médico residente como educador. Educ Med. 2013;2:154–61.
15. Hernández-Avila M, Garrido-Latorre F, López-Moreno S. Diseño de estudios epidemiológicos. Salud Publica Mex. 2000;42:144–54.
16. Manterola C, Otzen T. Estudios observacionales. Los diseños utilizados con mayor frecuencia en investigación clínica observational. Int J Morphol. 2014;32:634–45.
17. Hernández R, Fernández C, Baptista P. Metodología de la investigación. 4.ª ed. Mexico: McGraw-Hill; 2006.
18. Franco-Monsreal J, Lara-Zaragoza EB, Villa-Ruano N, Ramón-Canul LG, Cardeña-Bozziere IM, Flores-Primo A, et al. Los estudios epidemiológicos. Temas Cienc y Tecnol. 2011;15:51–8.
19. Vogt WP. Quantitative research methods for professionals. Boston: Pearson; 2007.

IMPI

TÍTULO DE PATENTE No. 351489

Titular(es): CENTRO DE TRAUMA Y CIRUGIA ESPECIALIZADA, S.A. DE C.V.; INSTITUTO TECNOLOGICO Y DE ESTUDIOS SUPERIORES DE MONTERREY

Domicilio: Avenida Maestro Israel Cavazos 1305, Parque Industrial La Silla, 67193, Guadalupe, Nuevo León, MÉXICO; Avenida Eugenio Garza Sada # 2501 Sur, Colonia Tecnológico, 64849, Monterrey, Nuevo León, MÉXICO

Denominación: DISPOSITIVO AUTOEXPANDIBLE DE FUSIÓN INTERVERTEBRAL LUMBAR.

Clasificación: **CIP:** A61F2/44
CPC: A61F2/44

Inventor(es): JOSÉ ALFREDO FLORES ZAHER; HÉCTOR RAFAEL SILLER CARRILLO; CIRO ÁNGEL RODRIGUEZ GONZÁLEZ; JOSÉ ANTONIO DÍAZ ELIZONDO; RAMIRO RAMÍREZ GUTIÉRREZ

SOLICITUD

Número:	Fecha de Presentación:	Hora:
MX/a/2011/013732	15 de Diciembre de 2011	16:24

Vigencia: Veinte años

Fecha de Vencimiento: 15 de diciembre de 2031

Fecha de Expedición: 21 de agosto de 2017

La patente de referencia se otorga con fundamento en los artículos 1º, 2º fracción V, 6º fracción III, y 59 de la Ley de la Propiedad Industrial.

De conformidad con el artículo 23 de la Ley de la Propiedad Industrial, la presente patente tiene una vigencia de veinte años improrrogables, contada a partir de la fecha de presentación de la solicitud y estará sujeta al pago de la tarifa para mantener vigentes los derechos.

Quien suscribe el presente título lo hace con fundamento en lo dispuesto por los artículos 6º fracciones III y 7º bis 2 de la Ley de la Propiedad Industrial (Diario Oficial de la Federación (D.O.F.) 27/06/1991, reformada el 02/08/1994, 25/10/1996, 26/12/1997, 17/05/1999, 26/01/2004, 16/06/2005, 25/01/2006, 06/05/2009,06/01/2010, 18/06/2010, 28/06/2010, 27/01/2012 y 09/04/2012); artículos 1º, 3º fracción V inciso a), 4º y 12º fracciones I y III del Reglamento del Instituto Mexicano de la Propiedad Industrial (D.O.F. 14/12/1999, reformado el 01/07/2002, 15/07/2004, 28/07/2004 y 7/09/2007); artículos 1º, 3º, 4º, 5º fracción V inciso a), 16 fracciones I y III y 30 del Estatuto Orgánico del Instituto Mexicano de la Propiedad Industrial (D.O.F. 27/12/1999, reformado el 10/10/2002, 29/07/2004, 04/08/2004 y 13/09/2007); 1º, 3º y 5º inciso a) del Acuerdo que delega facultades en los Directores Generales Adjuntos, Coordinador, Directores Divisionales, Titulares de las Oficinas Regionales, Subdirectores Divisionales, Coordinadores Departamentales y otros subalternos del Instituto Mexicano de la Propiedad Industrial. (D.O.F. 15/12/1999, reformado el 04/02/2000, 29/07/2004, 04/08/2004 y 13/09/2007).

El presente oficio se signa con firma electrónica avanzada (FIEL), con fundamento en los artículos 7 BIS 2 de la Ley de la Propiedad Industrial; 3o de su Reglamento, y 1 fracción III, 2 fracción V, 26 BIS y 26 TER del Acuerdo por el que se establecen los lineamientos para el uso del Portal de Pagos y Servicios Electrónicos (PASE) del Instituto Mexicano de la Propiedad Industrial, en los trámites que se indican.

LA DIRECTORA DIVISIONAL DE PATENTES
NAHANNY CANAL REYES

Cadena Original:
NAHANNY MARISOL CANAL REYES|00001000000403252793|Servicio de Administración Tributaria|1695||MX/2017/83864|MX/a/2011/013732|Titulo de patente normal|1223|GAGV|Pág(s) 1|1fCmunXifH44Utc4Z3kajX7/RQw=

Sello Digital:
gxVIdeYlAMOAWsq2V5rNrMH6qzUSfLnrAwbbwVPsgtrH67F+HJTQo2YxyUC5kaba5GtH+rQxN6OKgDzj/0eYIhktK
1tqG/wtEoWumbOXQ/gsBwEo15INP9LzyQY+DBT6wsa7mH9eahhKiuEOzodf9xgKTkODAj10hyq2HfUm5eTE75WAptI
o805guQREE//QFBaZYOghJA3dMZH4h6LPWWTNTIY/zQrlB0mDGCCa6t5F23vGPGmgDpnSi9RvHUCkpG7dEoWbkntCD
lA0h9UOxWO5To8d+//tjV1kci2uiy0SPmAU5jHbZB+efFEz0hu15n+S0l2rsX6Uoa5qS/q0Q==

Arenal No. 550, Piso 1, Pueblo Santa María Tepepan, Xochimilco, 16020,
Ciudad de México.
(55)53340700 www.gob.mx/impi

MX/2017/83864

IMPI

TÍTULO DE PATENTE No. 348947

Titular(es): INSTITUTO TECNOLÓGICO Y DE ESTUDIOS SUPERIORES DE MONTERREY

Domicilio: Avenida Eugenio Garza Sada # 2501 Sur, Colonia Tecnológico, 64849, Monterrey, Nuevo León, MÉXICO

Denominación: MÉTODO DE ENFRIAMIENTO PARA AUMENTAR LA MAQUINABILIDAD DEL TEJIDO ÓSEO.

Clasificación: **CIP:** A61F2/28
CPC: A61F2/28

Inventor(es): ALEX ELIAS ZÚÑIGA; HÉCTOR RAFAEL SILLER CARRILLO; CIRO ANGEL RODRÍGUEZ GONZÁLEZ; ERIKA GARCIA LOPEZ; ARTURO MARBÁN GONZÁLEZ; JOSÉ ANTONIO DÍAZ ELIZONDO

SOLICITUD

Número:	Fecha de Presentación:	Hora:
MX/a/2011/013844	16 de Diciembre de 2011	11:02

Vigencia: Veinte años

Fecha de Vencimiento: 16 de diciembre de 2031

Fecha de Expedición: 29 de marzo de 2017

La patente de referencia se otorga con fundamento en los artículos 1º, 2º fracción V, 6º fracción III, y 59 de la Ley de la Propiedad Industrial.

De conformidad con el artículo 23 de la Ley de la Propiedad Industrial, la presente patente tiene una vigencia de veinte años improrrogables, contada a partir de la fecha de presentación de la solicitud y estará sujeta al pago de la tarifa para mantener vigentes los derechos.

Quien suscribe el presente título lo hace con fundamento en lo dispuesto por los artículos 6º fracciones III y 7º bis 2 de la Ley de la Propiedad Industrial (Diario Oficial de la Federación (D.O.F.) 27/06/1991, reformada el 02/08/1994, 25/10/1996, 26/12/1997, 17/05/1999, 26/01/2004, 16/06/2005, 25/01/2006, 06/05/2009,06/01/2010, 18/06/2010, 28/06/2010, 27/01/2012 y 09/04/2012); artículos 1º, 3º fracción V inciso a), 4º y 12º fracciones I y III del Reglamento del Instituto Mexicano de la Propiedad Industrial (D.O.F. 14/12/1999, reformado el 01/07/2002, 15/07/2004, 28/07/2004 y 7/09/2007); artículos 1º, 3º, 4º, 5º fracción V inciso a), 16 fracciones I y III y 30 del Estatuto Orgánico del Instituto Mexicano de la Propiedad Industrial (D.O.F. 27/12/1999, reformado el 10/10/2002, 29/07/2004, 04/08/2004 y 13/09/2007); 1º, 3º y 5º inciso a) del Acuerdo que delega facultades en los Directores Generales Adjuntos, Coordinador, Directores Divisionales, Titulares de las Oficinas Regionales, Subdirectores Divisionales, Coordinadores Departamentales y otros subalternos del Instituto Mexicano de la Propiedad Industrial. (D.O.F. 15/12/1999, reformado el 04/02/2000, 29/07/2004, 04/08/2004 y 13/09/2007).

El presente oficio se signa con firma electrónica avanzada (FIEL), con fundamento en los artículos 7 BIS 2 de la Ley de la Propiedad Industrial; 3o de su Reglamento, y 1 fracción III, 2 fracción V, 26 BIS y 26 TER del Acuerdo por el que se establecen los lineamientos para el uso del Portal de Pagos y Servicios Electrónicos (PASE) del Instituto Mexicano de la Propiedad Industrial, en los trámites que se indican.

LA DIRECTORA DIVISIONAL DE PATENTES
NAHANNY CANAL REYES

Cadena Original:
NAHANNY MARISOL CANAL REYES|00001000000403252793|Servicio de Administración Tributaria|1695||MX/2017/52847|MX/a/2011/013844|Título de patente normal|1220|RRGO|Pág(s) 1|ZvuxXmj0jwqRzGwEKjemkbs6hb8=

Sello Digital:
pPCj9c2/Anxv3Mwzz7ikGaAh6DoY4Ho145Ldmo+QTYRHQbEDA8H4f3tpMCWbPdatR+qRFb19EGaOmE2kx0BfPeyDGe
zvzwRbBG+rqxndjZ15MCQKITz5ISWswk3JXCYEHKNDZGwRqOQduQ8xLBFPsBRUw67WSu8XGdWQjEtEeHBdqzazBKxy
PN70yPaGPnKuwT2qv3Di5zJlzRAHjR3LHtm/pZC9+b0oL3kMJbxmp3uhl/8E1kFxg5FBnINii7zGnR4Ym4L8t6XIFn
7UuAKRY8UVSnxSKhFngos9rlBWcvzgpE9D8gDieRxJ3SEJ0TwniB9al4T1uM7w2azcMV9MNQ==

APPENDIX 2: CONFERENCE PRESENTATIONS & MEETING PARTICIPATIONS

Appendix 2: Conference and Meeting Participations

Index

COLEGIO DE ESPECIALISTAS EN CIRUGÍA GENERAL DEL ESTADO DE NUEVO LEÓN, A.C.

Monterrey, N. L. a 23 de Abril 2018

Dr. José Antonio Díaz Elizondo

Estimado Dr. Díaz

El Colegio de Especialistas en Cirugía General del Estado de Nuevo León A. C. tiene el honor de invitarlo a usted a participar en el XXIX Congreso Anual del Colegio de Especialistas en Cirugia General del Estado de Nuevo León A. C. "Retos Actuales en Cirugía". Reunión Noreste Regional de la Asociación Mexicana de Cirugía General y XL Reunión Noreste del Capítulo Colegio Americano de Cirujanos, le hace una cordial invitación como moderador.

"Modulo Hernias" 14 Junio 11:00 a.m.

Las cuales se llevarán a cabo en el Auditorio del Hotel Four Points Galerías en el marco de nuestra reunión

Esperamos contar con su valiosa colaboración en el desarrollo de nuestro evento Académico.

Gracias de antemano por su atención y quedo de Usted.

Atentamente

Dr. José Eduardo García Flores
Presidente

Tel. 01 81 83 47 0160

La Facultad de Medicina de la UANL a través de la Subdirección de Educación Continua, otorga el presente

RECONOCIMIENTO

a

Dr. Antonio Díaz Elizondo

Por su participación como PROFESOR con el tema

"Fuentes de energía"

en el

Congreso "Cirugía Endoscópica: A XXV años de su Inicio, Estatus Actual y Proyección Futura"

Realizado en el Auditorio del Doctors Hospital
del 27 al 29 de noviembre de 2014

"Alere Flammam Veritatis"
Monterrey, N.L. 27 de noviembre de 2014.

Dr. med Santos Guzmán López
DIRECTOR

Dr. Félix Ramón Cedillo Salazar
SUBDIRECTOR DE EDUCACIÓN CONTINUA

SUBDIRECCIÓN DE EDUCACIÓN CONTINUA

La Facultad de Medicina de la UANL a través de la Subdirección de Educación Continua, otorga el presente

RECONOCIMIENTO

a

Dr. José Antonio Díaz Elizondo

Por su participación como MODERADOR en el

XXV Congreso Anual del Colegio de Especialistas en Cirugía General del Estado de Nuevo León. 7a. Reunión Regional de la Asociación Mexicana de Cirugía Endoscópica "Cirugía Moderna Basada en Evidencia"

Realizado en el Auditorio del OCA Medical Center del 5 al 7 de junio de 2014.

"Alere Flammam Veritatis"
Monterrey, N.L., 7 de junio de 2014.

Dr. med Santos Guzmán López
DIRECTOR

Dr. Félix Ramón Cedillo Salazar
SUBDIRECTOR DE EDUCACIÓN CONTINUA

SUBDIRECCIÓN DE EDUCACIÓN CONTINUA

La Facultad de Medicina de la UANL a través de la Subdirección de Educación Continua, otorga el presente

RECONOCIMIENTO

a

Dr. José Antonio Díaz Elizondo

Por su participación como PROFESOR con el tema
"Bases físicas e historia de la laparoscopia"
en el

XXV Congreso Anual del Colegio de Especialistas en Cirugía General del Estado de Nuevo León.
7a. Reunión Regional de la Asociación Mexicana de Cirugía Endoscópica
"Cirugía Moderna Basada en Evidencia" Curso-Taller Pre-Congreso Propedéutico de Cirugía Endoscópica

Realizado en el Auditorio del OCA Medical Center el 4 de junio de 2014.

"Alere Flammam Veritatis"
Monterrey, N.L., 4 de junio de 2014.

Dr. med Santos Guzmán López
DIRECTOR

Dr. Félix Ramón Cedillo Salazar
SUBDIRECTOR DE EDUCACIÓN CONTINUA

SUBDIRECCIÓN DE EDUCACIÓN CONTINUA

LA ASOCIACIÓN PANAMEÑA DE CIRUGÍA

OTORGA EL PRESENTE **CERTIFICADO** A:

DR. JOSÉ DÍAZ ELIZONDO

EN CALIDAD DE **CONFERENCISTA** EN EL

CONGRESO NACIONAL DE CIRUGÍA 2017

DADO EN LA CIUDAD DE PANAMÁ 29, 30 DE NOVIEMBRE Y 1 DE DICIEMBRE DE 2017

DR. NICOLAS JUAN LIAKÓPULOS
PRESIDENTE
ASPACI

DR. ALFREDO MACHARAVIAYA
PRESIDENTE
COLEGIO MÉDICO DE PANAMÁ

Tecnológico de Monterrey

Monterrey N.L. 31 de mayo del 2018

A quien corresponda:

El Dr. Juan Jaime Díaz Osuna presentó el día 26 de Octubre de 2017 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Pertinencia de la colangiografía transoperatoria en pacientes tratados con colecistectomía quirúrgica en dos hospitales privados de Monterrey."

Fungieron como asesores principales del Dr. Díaz Osuna los doctores:

- Dr. Adolfo Leyva Alvizo como director de tesis
- Dr. José Antonio Díaz Elizondo como co-director de tesis

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 31 de mayo del 2018

A quien corresponda:

La Dra. Ana Guadalupe Garza Maldonado presentó el día 24 de Octubre de 2017 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"El índice neutrófilo linfocítico en relación al grado de severidad en diverticulitis aguda y su potencial uso pronóstico para decisiones terapéuticas tempranas: un estudio retrospectivo multicéntrico."

Fungieron como asesores principales de la Dra. Garza Maldonado los doctores:

- Dr. Luis Enrique Salgado Cruz como director de tesis
- Dr. José Antonio Díaz Elizondo como co-director de tesis

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 31 de mayo del 2018

A quien corresponda:

El Dr. Rodrigo Ceja González presentó el día 11 de Octubre de 2017 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Validación de apariencia contenido y constructo de un dispositivo de simulación laparoscópica portátil de bajo costo y fabricado con tecnología de impresión 3D."

Fungieron como asesores principales del Dr. Ceja González los doctores:

- Dr. José Antonio Díaz Elizondo como director de tesis
- Dr. Eduardo Alejandro Flores Villalba como co-director de tesis

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 31 de mayo del 2018

A quien corresponda:

El Dr. Alan Elison Ramos Mayo presentó el día 30 de Octubre de 2017 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"La evaluación por un cirujano de hernias y pared abdominal mejora el diagnóstico y abordaje terapéutico de pacientes con endometriosis de pared abdominal."

Fungieron como asesores principales del Dr. Ramos Mayo los doctores:

- Dr. José Antonio Díaz Elizondo como director de tesis
- Dr. Gerardo Gil Galindo como co-director de tesis

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

El Dr. Roberto Alatorre Adame presentó el día 12 de Octubre del 2016 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Control de calidad en la atención del paciente post-quirúrgico de Apendicectomía y Colecistectomía como método para identificación temprana de complicaciones"

Fungieron como asesores del Dr. Alatorre Adame los doctores:

- Dr. Luis Enrique Salgado Cruz
- Dr. José Antonio Díaz Elizondo

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

El Dr. Orestes Valles Guerra presentó el día 25 de Julio del 2016 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Estudio de Integración de Material Protésico con Plasma Rico en Plaquetas para Reparación de Hernias en Modelo Animal"

Fungieron como asesores los doctores:

- Dr. Eduardo Alejandro Flores Villalba
- Dr. José Antonio Díaz Elizondo

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

La Dra. Ana Irma Vargas Sáenz presentó el día 11 de Octubre del 2016 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"La Importancia de la E-Cadherina para la Clasificación del Carcinoma Lobulillar en el Hospital de Referencia del Sector Salud del Estado de Nuevo León"

Fungieron como asesores de la Dra. Vargas Sáenz los doctores:

- Dra. María Teresa Mireles Aguilar
- Dra. Cynthia Mayté Villarreal Garza
- Dr. Salomón Alvarado Ramos
- Dr. José Antonio Diaz Elizondo
- Dra. Natalia Vilches Cisneros

Dr. Manuel de Jesús García Solís

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

La Dra. Alejandra Mariel Franco Martínez presentó el día 30 de Septiembre del 2016 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Multicentric Study on the Relationship between Obesity and Acute Diverticulitis in the Young"

Fungieron como asesores de la Dra. Franco Martínez los doctores:

- Dr. José Antonio Díaz Elizondo
- Dr. Luis Enrique Salgado Cruz
- Dr. Salomón Alvarado Ramos

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

El Dr. Victor Hugo Ávalos Gómez presentó el día 26 de Julio del 2016 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"COMPARACIÓN DE LA CALIDAD DE VIDA DE LAS PACIENTES CON CANCER DE MAMA; ENTRE LA CIRUGIA CONSERVADORA DE MAMA Y MASTECTOMÍA RADICAL MODIFICADA EN EL HOSPITAL METROPLITANO Y HOSPITAL SAN JOSE TEC DE MONTERREY"

Fungieron como asesores los doctores:

- Dr. Servando Cardona Huerta
- Dr. Salvador Valdovinos Chavez
- Dr. José Antonio Díaz Elizondo

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

El Dr. Luis Alberto Topete González presentó el día 26 de Octubre del 2015 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Alteraciones Hemodinámicas durante Cirugía Laparoscópica versus Abierta en un Modelo Porcino Euvolémico"

Fungieron como asesores del Dr. Topete González los doctores:

- Dr. Eduardo Alejandro Flores Villalba
- Dr. José Antonio Díaz Elizondo

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

La Dra. Montserrat Guraieb Trueba presentó el día 27 de Octubre del 2015 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Caracterización biomecánica de diferentes de materiales de sutura, posterior a su utilización para el cierre de fascia en un modelo porcino, por residentes de Cirugía General de diversos grados académicos."

Fungieron como asesores de la Dra. Guraieb Trueba los doctores:

- Dr. Eduardo Alejandro Flores Villalba
- Dr. José Antonio Díaz Elizondo

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

TECNOLÓGICO
DE MONTERREY

Monterrey N.L. 27 de Noviembre del 2014

A quien corresponda:

El Dr. Juan José Monrreal Alanis presentó el día 23 de Octubre del 2014 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Factores de Riesgo Asociados a Lesión de Vía Biliar en pacientes con Colecistectomía Convencional y laparoscópica en el Hospital Metropolitano Dr. Bernardo Sepúlveda"

Fungió como asesores del Dr. Monrreal Alanis los doctores:

- Dr. José Antonio Díaz Elizondo
- Dr. José Pulido Rodríguez
- Dr. Eduardo Flores Villalba

Quedo a sus órdenes,

Escuela de Medicina y Ciencias de la Salud
TECNOLÓGICO DE MONTERREY

ÁREA DE POSGRADO

Dr. Daniel Humberto Méndez Lozano
Coordinador de Investigación Clínica en Posgrado
Área de Posgrado
Escuela de Medicina y Ciencias de la Salud
Correo: danielmendez@itesm.mx

eam/

Campus Monterrey
Eugenio Garza Sada 2501
64849, Monterrey, N.L., México
Tel: 52/81 8358 2000

TECNOLÓGICO
DE MONTERREY

Monterrey N.L. 27 de Noviembre del 2014

A quien corresponda:

El Dr. Orlando Espinosa Morquecho presentó el día 9 de Octubre del 2014 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Dibujo preopoeratorio de la línea de Kaplan para la prevención de complicaciones y secuelas en la liberación de túnel del carpo"

Fungió como asesores del Dr. Espinosa Morquecho los doctores:

- Dr. José Alfredo Neira Garza
- Dr. Eduardo Flores Villalba
- Dr. José Antonio Díaz Elizondo

Quedo a sus órdenes,

Escuela de Medicina y Ciencias de la Salud
TECNOLÓGICO DE MONTERREY

ÁREA DE POSGRADO

Dr. Daniel Humberto Méndez Lozano
Coordinador de Investigación Clínica en Posgrado
Área de Posgrado
Escuela de Medicina y Ciencias de la Salud
Correo: danielmendez@itesm.mx

eam/

Campus Monterrey
Eugenio Garza Sada 2501
64849, Monterrey, N.L., México
Tel: 52/81 8358 2000

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

El Dr. Ricardo Javier Rodríguez Ávila presentó el día 27 de Octubre del 2015 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"El uso del ketorolaco como analgésico preventivo para medir su contribución al dolor postoperatorio"

Fungieron como asesores del Dr. Rodríguez Ávila los doctores:

- Dr. José Antonio Díaz Elizondo
- Dr. Eduardo Alejandro Flores Villalba

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 31 de mayo del 2018

A quien corresponda:

El Dr. Ernesto Garza Vázquez presentó el día 19 de Octubre de 2017 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Calidad de la Atención Clínica.

El tema desarrollado fue:

"Impacto del desabasto de medicamentos en la seguridad del paciente hospitalizado en la Unidad de Terapia Intensiva de Adultos en una Institución Pública de Segundo Nivel."

Fungieron como sinodales del Dr. Garza Vázquez los doctores:

- Ing. Román Martínez Martínez
- Dra. Marisela González Guzmán
- Dr. José Antonio Díaz Elizondo

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

La Dra. Elizabeth Sánchez Guillén presentó el día 31 de Octubre del 2016 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Calidad de la Atención Clínica.

El tema desarrollado fue:

"Evaluación de los Intervalos de Tiempo para la Interpretación de Mamografias de la Secretaria de Salud de Nuevo León"

Fungieron como sinodales de la Dra. Sánchez Guillén los doctores:

- Dr. José Antonio Díaz Elizondo
- Dra. Cynthia Villarreal Garza
- Dr. Manuel de Jesús Ramirez Sánchez

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

El Dr. Jorge Alberto Santiago Sánchez presentó el día 24 de Octubre del 2016 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Ginecología y Obstetricia.

El tema desarrollado fue:

"PERSISTENCIA Y RECURRENCIA DE LESIONES DE ALTO GRADO (NIC 3), CAR-CINOMA IN SITU Y CARCINOMA MICROINVASOR EN PACIENTES TRATADAS MEDIANTE CONO CERVICAL"

Fungieron como sinodales del Dr. Santiago Sánchez los doctores:

- Dr. Carlos Villegas Cruz
- Dr. José Antonio Díaz Elizondo
- Dr. Rogelio Armando Lozano Galván

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

El Dr. Ricardo Javier Rodríguez Ávila presentó el día 27 de Octubre del 2015 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"El uso del ketorolaco como analgésico preventivo para medir su contribución al dolor postoperatorio"

Fungieron como sinodales del Dr. Rodríguez Ávila los doctores:

- Dr. Fernado Cantú Flores
- Dr. Abelardo Eduardo García Cantú
- Dr. José Antonio Díaz Elizondo

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

Tecnológico de Monterrey

Monterrey N.L. 3 de mayo del 2017

A quien corresponda:

El Dr. Yefté Efraín Silva López presentó el día 5 de Octubre del 2015 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Calidad de la Atención Clínica.

El tema desarrollado fue:

"Uso del Examen Clínico Objetivo Estructurado como herramienta de entrenamiento y evaluación de la competencia clínica de comunicación con el paciente, percepción de alumnos,docentes y actores"

Fungieron como sinodales del Dr. Silva López los doctores:

- Dr. José Antonio Díaz Elizondo
- Dra. Silvia Lizett Olivares Olivares
- Dra. Karla Patricia Pacheco Alvarado

Quedo a sus órdenes,

Dra. Gabriela Guzmán Navarro
Coordinadora de Acreditaciones e Investigación
Posgrados Clínicos
Escuela de Medicina y Ciencias de la Salud
TecSalud – Tecnológico de Monterrey
gabriela.guzman@itesm.mx

/jlpl

TECNOLÓGICO
DE MONTERREY

Monterrey N.L. 28 de Noviembre del 2014

A quien corresponda:

El Dr. Joaquín Eduardo Ortíz Díaz presentó el día 8 de Octubre del 2014 su defensa de Tesis, como parte de los requisitos de graduación de la especialidad en Cirugía General.

El tema desarrollado fue:

"Cirugía electiva de hernias de la pared abdominal con anestesia local en un hospital rural. Un estudio comparativo"

Fungieron como sinodales del Dr. Ortíz Díaz los doctores:

- Dr. José Antonio Díaz Elizondo
- Dr. Gerardo Gil Galindo
- Dr. Gerardo Cesar Saldaña Lozano

Quedo a sus órdenes,

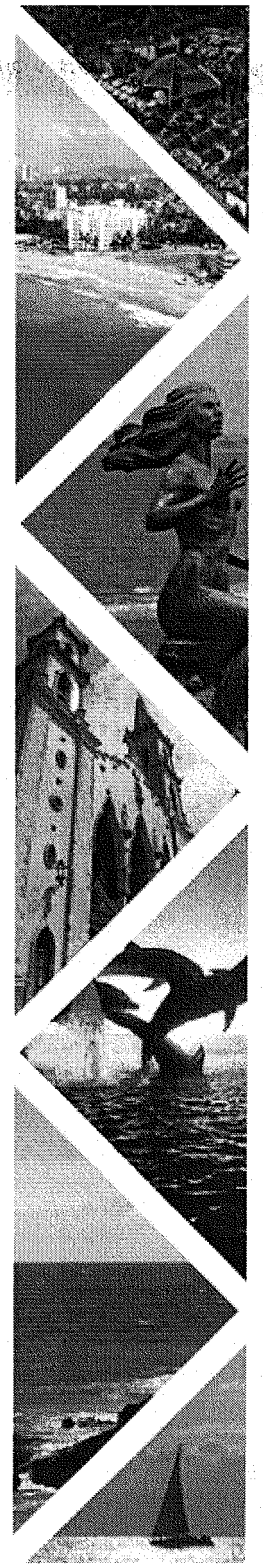
Escuela de Medicina y Ciencias de la Salud
TECNOLÓGICO DE MONTERREY

ÁREA DE POSGRADO

Dr. Daniel Humberto Méndez Lozano
Coordinador de Investigación Clínica en Posgrado
Área de Posgrado
Escuela de Medicina
Correo: danielmendez@itesm.mx

eam/

Campus Monterrey
Eugenio Garza Sada 2501
64849, Monterrey, N.L., México
Tel: 52/81 8358 2000



VI Congreso Internacional de Educación Médica
International Congress of Medical Education

V Congreso Internacional de Simulación
International Congress of Simulation in Medical Education

amfem
Asociación Mexicana de Facultades y Escuelas de Medicina, A.C.

La Asociación Mexicana de Facultades y Escuelas de Medicina A.C.
le otorga la presente:

CONSTANCIA

a:

Andrea Monserrat Guillén Graf
Ricardo Ernesto López Murga
Rodrigo Ceja González
José Antonio Díaz Elizondo
Eduardo Flores Villalba
Ciro Ángel Rodríguez González

Por haber presentado el trabajo libre

Validación de un simulador de laparoscopia fabricado con impresión 3D

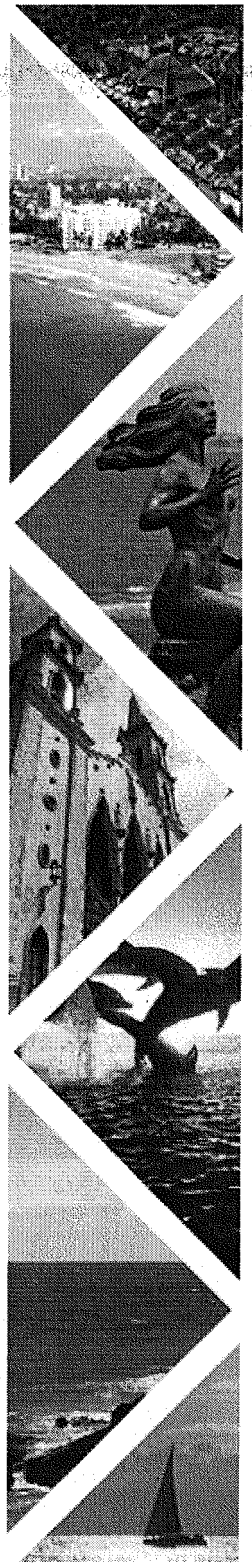
SELLO DIGITAL

2018-06-20 18:23:37 || AUTORTRABAJOLIBRE || 24 || 0091 || 0171 || 898dc2c947cee718e4afd7dfcb2f1a09 || c3b86052d1fc94bd11c279a17f3f25e1 || 1ff1de774005f8da13f42943881c655f || 4a9d7045e0fa7fd3475790650c424a4d || d3b930bd55893ff76153efdba9f87d23

Dr. Roberto F. Solís Hernández
Vicepresidente AMFEM

Dr. Julio César Gómez Fernández
Presidente AMFEM
Coordinador General VI CIEM

Dr. Luis Felipe Abreu Hernández
Coordinador de Trabajos Libres



VI Congreso Internacional de Educación Médica
International Congress of Medical Education

V Congreso Internacional de Simulación
International Congress of Simulation in Medical Education

amfem
Asociación Mexicana de Facultades y Escuelas de Medicina, A.C.

La Asociación Mexicana de Facultades y Escuelas de Medicina A.C.
le otorga la presente:

CONSTANCIA

a:

Ricardo Ernesto López Murga
Andrea Monserrat Guillén Graf
José Antonio Díaz Elizondo
Eduardo Flores Villalba

Por haber presentado el trabajo libre

Asociación del síndrome de burnout y tipo de personalidad en alumnos de medicina en rotación clínica

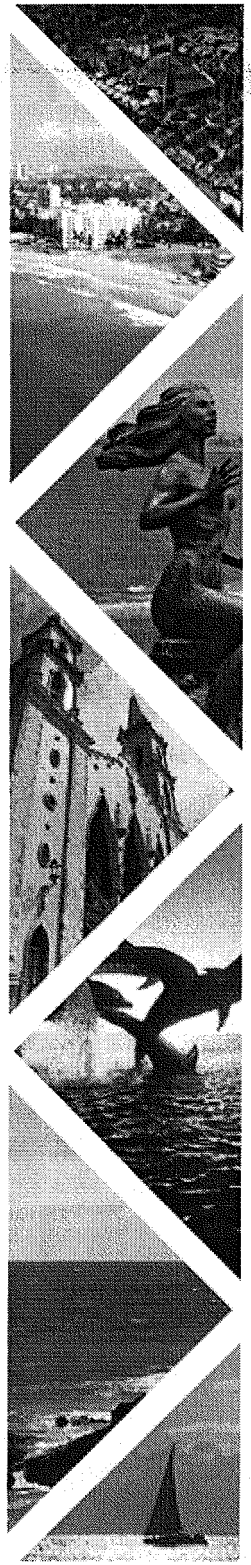
SELLO DIGITAL

2018-06-20 18:23:59 || AUTORTRABAJOLIBRE || 24 || 0107 || 0171 || 898dc2c947dee718e4afd7dfcb2f1a09 || 13448471d89a9cd8d7f71026a0334ec8 || 1ff1de774005f8da13f42943881c655f || 4a9d7045e0fa7fd3475790650c424a4d || fe421925d8958379fb8f59795bc9edb2

Dr. Roberto F. Solís Hernández
Vicepresidente AMFEM

Dr. Julio César Gómez Fernández
Presidente AMFEM
Coordinador General VI CIEM

Dr. Luis Felipe Abreu Hernández
Coordinador de Trabajos Libres



VI Congreso Internacional de Educación Médica
International Congress of Medical Education

V Congreso Internacional de Simulación
International Congress of Simulation in Medical Education

amfem

La Asociación Mexicana de Facultades y Escuelas de Medicina A.C.
le otorga la presente:

CONSTANCIA

a:

Andrea Monserrat Guillén Graf
Ricardo Ernesto López Murga
José Antonio Díaz Elizondo
Eduardo Flores Villalba

Por haber presentado el trabajo libre

Prevalencia de burnout en estudiantes de medicina durante una rotación clínica

SELLO DIGITAL

2018-06-20 18:23:30 || AUTORTRABAJOLIBRE || 24 || 0090 || 0171 || 898dc2c947cee718e4afd7dfcb2f1a09 || 8b23187c36f529bf661e3fd5b29060c1 || 1ff1de774005f8da13f42943881c655f || 4a9d7045e0fa7fd3475790650c424a4d || 3a9d4662b740189aa7b11d8f20462714

Dr. Roberto F. Solís Hernández
Vicepresidente AMFEM

Dr. Julio César Gómez Fernández
Presidente AMFEM
Coordinador General VI CIEM

Dr. Luis Felipe Abreu Hernández
Coordinador de Trabajos Libres

Asociación Mexicana de Cirugía Endoscópica, A.C.

XXVI CONGRESO INTERNACIONAL DE CIRUGÍA *Endoscópica*

Otorga la presente

CONSTANCIA

a

Dr. César Jaurrieta Rico

Hector Segura Marin, Jose Pulido Rodríguez, Alan Ramos Mayo, Mario Rodarte Shade, Jose Antonio Díaz Elizondo, Eduardo Flores Villalba

Por la presentación de su trabajo libre en la categoría **CARTEL**
"Efectos del Acondicionamiento Preoperatorio sobre las Habilidades Quirúrgicas Laparoscópicas en Residentes de Cirugía"
que se presentaron dentro de las actividades del XXVI Congreso Internacional de Cirugía Endoscópica 2017 celebrado del 02 al 06 de Mayo Acapulco, Guerrero.

Valor curricular 5 puntos Autor, 3 puntos Coautor

Dr. David Velázquez Fernández Comité Científico	Dra. Adriana Hernández López Presidente	Dr. Martín Vega de Jesús Secretario

La Federación Mexicana de Colegios de Obstetricia y Ginecología, A.C.

Otorga la presente

Constancia a los Drs.:

Fernando Ayala Aguilera, Alejandro de Jesus Fernández Gómez,
Rodrigo del Toro Rojas, María Isabel Lazos Medina y José Antonio Díaz Elizondo.

Por su participación en el Concurso de Trabajos de Investigación Básica:

"Victor Espinosa de los Reyes Sánchez"

Del 67° Congreso Mexicano de Ginecología y Obstetricia en Mérida, Yucatán.

Con el trabajo:

Utilidad de simulación con pacientes estandarizadas para el desarrollo de competencias clínicas y de comunicación en alumnos de pregrado de medicina en Ginecología y Obstetricia.

10 de noviembre de 2016, Mérida, Yucatán.

Dr. Sergio Fajardo Dueñas.
Presidente.

Dr. Juan de Dios Maldonado Alvarado.
Vicepresidente.
Comité de Actividades Científicas.

Dr. Francisco José Bernárdez Zapata.
Primer Secretario Propietario.

Dra. Paola Iturralde Rosas Priego.
Tesorera.

CN#20-16
15 PUNTOS.

Referencia: Investigación Básica – VIII.

Asociación Mexicana de Cirugía General, A.C.
Federación Mexicana de Colegios de Especialistas en Cirugía General, A.C.

Otorga la presente

CONSTANCIA

a

DR. ROBERTO ALATORRE

JOSÉ PULIDO RODRIGUEZ, JOSÉ DÍAZ ELIZONDO

ISO 9001:2008 CERTIFIED SYSTEM ATR

Nuestra Calidad
está Certificada
en los procesos: Atención al Socio, EMC,
GRH, Científico (ECOS y Congreso).
Certificado número: 222
Vigencia: 11-08-2018
Norma de referencia:
NMX-CC-9001-IMNC-2008

Por la presentación de su trabajo libre en la categoría **"CARTEL"**

ABSCESO DEL MÚSCULO ILIOPSOAS; DIAGNÓSTICO, TRATAMIENTO Y EVOLUCIÓN EN UNA SERIE DE 18 CASOS

que se presentó dentro del
40° Congreso Internacional de Cirugía General 2016,
que se llevó a cabo del **29 de Octubre al 3 de Noviembre en la ciudad de Mérida, Yucatán.**

40 CONGRESO INTERNACIONAL DE CIRUGÍA GENERAL
MÉRIDA YUCATÁN 29 OCTUBRE 3 NOVIEMBRE 2016
CENTRO DE CONVENCIONES SIGLO XXI

Dr. Víctor Hugo Guerrero Guerrero
Secretario General

Dr. Héctor F. Noyola Villalobos
Presidente

Dr. Samuel Kleinfinger Marcuschamer
Comité de Educación Médica Continua

VI CONGRESO NACIONAL
DE EDUCACIÓN MÉDICA
APRENDIZAJE CENTRADO EN EL PACIENTE

Tecnológico de Monterrey
Escuela de Medicina

amfem

SALUD

ISSSTE

IMSS

EL INSTITUTO MEXICANO DEL SEGURO SOCIAL
Otorga la presente

CONSTANCIA

Al trabajo de investigación

Diseño de un instrumento para la evaluación integral de estudiantes en el campo clínico

Autor(es): Lucio-Ramírez César Alberto, Díaz-Elizondo José Antonio, Nigenda-Álvarez Juan Pablo, Jiménez-Martínez María de los Ángeles, López-Cabrera Mildred Vanessa, Olivares-Olivares Silvia Lizett

MONTERREY, N.L. DEL 19 AL 21 DE OCTUBRE DE 2016

Dr. Carlos Lavalle Montalvo
Vice Presidente ACANEMED

Dra. Lydia Zerón Gutiérrez
Presidente ACANEMED

Dr. Jorge E. Valdez García
Presidente Capítulo Norte ACANEMED

XXIV Congreso Internacional de Cirugía Endoscópica

Asociación Mexicana de Cirugía Endoscópica, A.C.
Colegio Mexicano de Cirugía Endoscópica, A.C.

2 al 6 de Mayo 2015 • Puerto Vallarta, México

Otorga la presente

Constancia a:

DR. MONTSERRAT GURAIEB TRUEBA

COAUTORES: DÍAZ EJA, FLORES VEA, SILVA AEE, CEJA GR

POR LA PRESENTACIÓN DEL TRABAJO LIBRE (CATEGORÍA CARTEL)
MANEJO LAPAROSCÓPICO DE UN ADENOMIOMA GÁSTRICO CON TEJIDO
PANCREÁTICO ABERRANTE: REPORTE DE UN CASO

XXIV Congreso Internacional de **Cirugía Endoscópica**

CENTRO INTERNACIONAL DE CONVENCIONES
CELEBRADO DEL 2 al 6 DE MAYO DE 2015, PUERTO VALLARTA, JALISCO.

Dr. Vicente González Ruíz
PRESIDENTE

Dr. Eduardo Moreno Paquentín
COORDINADOR DEL COMITÉ CIENTÍFICO

Dr. Samuel Kleinfinger Marcuschamer
SECRETARIO

XXIV Congreso Internacional de Cirugía Endoscópica

Asociación Mexicana de Cirugía Endoscópica, A.C.
Colegio Mexicano de Cirugía Endoscópica, A.C.

2 al 6 de Mayo 2015 • Puerto Vallarta, México

Otorga la presente

Constancia a:

DR. MONTSERRAT GURAIEB TRUEBA

COAUTORES: DÍAZ E.J.A., FLORES V.E.A., GUAJARDO N.D.A., NUNGARAY G.C.R., PALOMO H.R.A.

POR LA PRESENTACIÓN DEL TRABAJO LIBRE (CATEGORÍA CARTEL) MANEJO DE LA ENFERMEDAD DE LA VESÍCULA BILIAR EN PACIENTES CON SITUS INVERSUS TOTAL: SERIE DE CASOS Y REVISIÓN DE LA LITERATURA

XXIV Congreso Internacional de Cirugía Endoscópica

CENTRO INTERNACIONAL DE CONVENCIONES
CELEBRADO DEL 2 al 6 DE MAYO DE 2015, PUERTO VALLARTA, JALISCO.

Dr. Vicente González Ruíz
PRESIDENTE

Dr. Eduardo Moreno Paquentín
COORDINADOR DEL COMITÉ CIENTÍFICO

Dr. Samuel Kleinfinger Marcuschamer
SECRETARIO

Tecnológico de Monterrey

1ERCONGRESO INTERNACIONAL DEINNOVACION EDUCATIVA

El Instituto Tecnológico y de Estudios Superiores de Monterrey, a través de la Vicerrectoría de Innovación Educativa otorga el **SEGUNDO** lugar del

PREMIO A LA INNOVACIÓN EDUCATIVA 2014

en la categoría de **INNOVACIÓN ACADÉMICA EN SALUD**

a

José Antonio Díaz Elizondo

por su trabajo

Taller de integración multidisciplinaria con el método de caso: Aspectos legales de la medicina, bioética, calidad y seguridad del paciente

presentado en el marco del

1er Congreso Internacional de Innovación Educativa

que se llevó a cabo los días 15, 16 y 17 de diciembre 2014,
en el Campus Ciudad de México.

Manuel Tamez Sánchez
Vicerrector de Innovación Educativa

Claudia Susana López Cruz
Líder de Experimentación y Medición de Impacto

Ciudad de México, diciembre 2014

1ER.CONGRESO INTERNACIONAL DEINNOVACIÓN EDUCATIVA

Tecnológico de Monterrey

Monterrey, N.L., 4 de febrero del 2015

A quien corresponda,

Por medio de la presente se hace constar que el trabajo titulado

"Rotación Clínica de Cirugía General en la Escuela de Medicina del Tecnológico de Monterrey: Un modelo de aprendizaje teórico-práctico"

con la autoría de

- **José Antonio Díaz Elizondo**
- **Eduardo Alejandro Flores Villalba**
- **Manuel Pérez Jiménez**

fue presentado como parte de las actividades que se llevaron a cabo en el ***1er. Congreso Internacional de Innovación Educativa***, que se celebró en el Campus Ciudad de México los días 15, 16 y 17 de diciembre del 2014.

Se extiende la presente constancia para los fines que al(los) interesado(s) convenga(n). Sin más por el momento me despido quedando a sus órdenes para cualquier duda o aclaración a la presente.

Atentamente,

Dra. Claudia Susana López Cruz
Coordinadora General
1er Congreso Internacional de Innovación Educativa
Vicerrectoría de Innovación Educativa
Tecnológico de Monterrey

1ER.CONGRESO INTERNACIONAL DEINNOVACIÓN EDUCATIVA

Tecnológico de Monterrey

Monterrey, N.L., 4 de febrero del 2015

A quien corresponda,

Por medio de la presente se hace constar que el trabajo titulado

"Taller de integración multidisciplinaria con el método de caso: Aspectos legales de la medicina, bioética, calidad y seguridad del paciente"

con la autoría de

- **Karla Patricia Pacheco Alvarado**
- **Ofelio Garza Rodríguez**
- **Mary Ana Cordero Díaz**
- **María del Pilar González Amarante**
- **José Antonio Díaz Elizondo**

fue presentado como parte de las actividades que se llevaron a cabo en el ***1er. Congreso Internacional de Innovación Educativa***, que se celebró en el Campus Ciudad de México los días 15, 16 y 17 de diciembre del 2014.

Se extiende la presente constancia para los fines que al(los) interesado(s) convenga(n). Sin más por el momento me despido quedando a sus órdenes para cualquier duda o aclaración a la presente.

Atentamente,

Dra. Claudia Susana López Cruz
Coordinadora General
1er Congreso Internacional de Innovación Educativa
Vicerrectoría de Innovación Educativa
Tecnológico de Monterrey

TECNOLÓGICO DE MONTERREY®

8° CONGRESO DE INNOVACIÓN Y TECNOLOGÍA EDUCATIVA

La Dirección de Investigación, Innovación y Tecnología Educativa de la Vicerrectoría Académica

Otorga la presente constancia a

José Antonio Díaz Elizondo

por la presentación del trabajo

"Simuladores Virtuales y de Realidad Aumentada para la Enseñanza de Habilidades de Cirugía Laparoscópica Utilizando Tablets y Teléfonos Inteligentes como Plataformas Tecnológicas."

dentro del

8° Congreso de Innovación y Tecnología Educativa

efectuado del 11 al 13 de diciembre de 2013.

Ing. Iván Chávez Peñaloza
Director de Investigación, Innovación y Tecnología Educativa

Monterrey, N.L., 13 de diciembre de 2013.

37° CONGRESO INTERNACIONAL DE CIRUGÍA GENERAL

Asociacion Mexicana de Cirugía General, A.C.

Colegio de Postgraduados en Cirugía General. A.C.

Federación Nacional de Colegios y Asociaciones de Especialistas en Cirugía General, A.C.

27 DE OCTUBRE AL 1 DE NOVIEMBRE

ACAPULCO, GUERRERO

40 Aniversario

ISO 9001:2008 CERTIFIED SYSTEM

EXTIENDE LA PRESENTE CONSTANCIA A:

DR. GERARDO LOZANO BALDERAS

DÍAZ-ELIZONDO JA, FLORES-VILLALBA E, GARZA-RODRIGUEZ D

Por la presentación de su trabajo libre en la categoría **"CARTEL"**

"ANÁLISIS COMPARATIVO DE MANEJO DE HERIDAS ABDOMINALES CONTAMINADAS Y SUCIAS, CON O SIN APLICACIÓN DE UN SISTEMA CERRADO DE SUCCIÓN PARA LA PREVENCIÓN DE INFECCIONES EN EL SITIO QUIRÚRGICO"

Que se presento dentro del XXXVII Congreso Internacional de Cirugía General 2013
celebrado del 27 de Octubre al 1 de Noviembre
en Acapulco, Guerrero.

Dr. Enrique Luque de León	Dr. Ernesto A. Ayala López	Dr. José Luis Martínez Ordaz
Presidente	Coordinador Comité	Coordinador
AMCG, CPCG, FNCAECG	Educación Médica Continua	Comité Científico

1er CONGRESO AMCR SRS LATINOAMERICA
4to CONGRESO LATINOAMERICANO DE CIRUGÍA ROBÓTICA

ASOCIACIÓN MEXICANA DE CIRUGÍA ROBÓTICA
AMCR

OTORGA LA PRESENTE

CONSTANCIA

A: **Dr. José Antonio Díaz Elizondo**

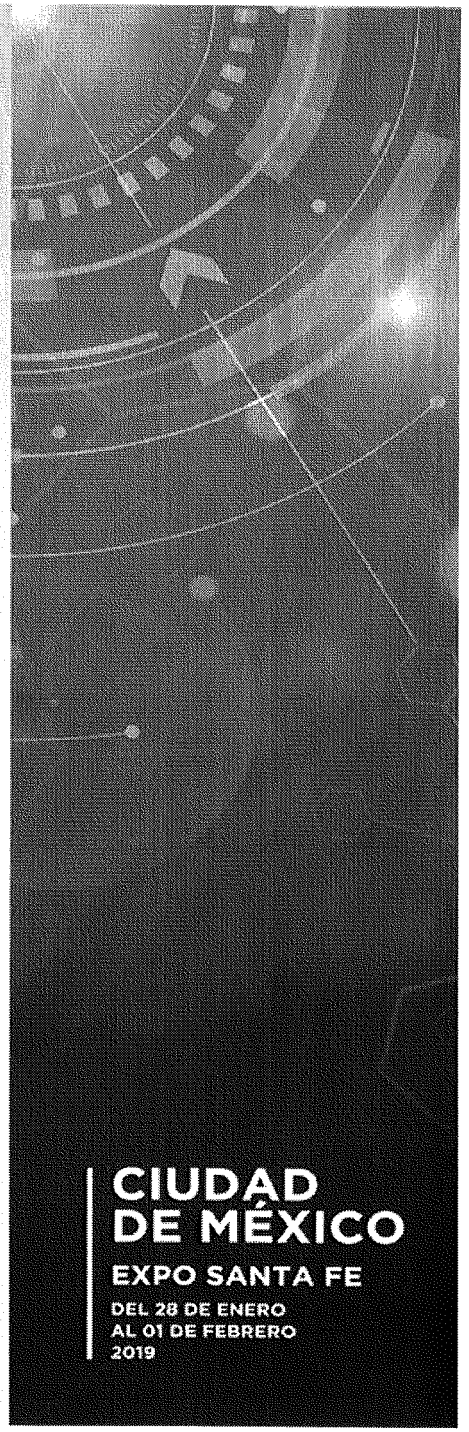
POR SU VALIOSA ASISTENCIA AL
PRIMER CONGRESO AMCR SRS LATINOAMÉRICA.

Dr. Luis E. Gallardo Valencia
Pdte. Mesa directiva AMCIR

Dr. Javier A. Kuri Osorio
Vicepresidente Mesa directiva AMCIR

Dr. Eduardo Parra Dávila
Pdte. Mesa directiva SRS LATAM

Dra. Itzel Vela Sarmiento
Tesorero AMCIR



1er CONGRESO AMCIR SRS LATINOAMERICA
4to CONGRESO LATINOAMERICANO DE CIRUGÍA ROBÓTICA

ASOCIACIÓN MEXICANA DE CIRUGÍA ROBÓTICA
AMCIR

OTORGA LA PRESENTE

CONSTANCIA

A: **Dr. José Antonio Díaz Elizondo**

POR SU VALIOSA ASISTENCIA AL CURSO PRECONGRESO

Esófago-gastro & Hernia

Dr. Luis E. Gallardo Valencia
Pdte. Mesa directiva AMCIR

Dr. Javier A. Kuri Osorio
Vicepresidente Mesa directiva AMCIR

Dr. Eduardo Parra Dávila
Pdte. Mesa directiva SRS LATAM

Dra. Itzel Vela Sarmiento
Tesorero AMCIR

CIUDAD DE MÉXICO
EXPO SANTA FE
DEL 28 DE ENERO
AL 01 DE FEBRERO
2019

Minimally Invasive Surgery Week 2018
The #1 MIS Meeting
August 29 - September 1, 2018
Sheraton New York Times Square Hotel, New York, New York, USA

CME Record of Attendance

Diaz-Elizondo	Jose Antonio
LAST NAME	FIRST NAME

Inst. Cirugia - CM Zambrano Hellion Batallon San Patricio 112 Piso 4

ADDRESS

Monterrey	Nuevo Leon	Mexico	66278
CITY	STATE	COUNTRY	ZIP

jadiaze@itesm.mx	528188880575	
EMAIL	TELEPHONE	FAX

Continuing Medical Education (CME) - U.S. Physicians
The Society of Laparoendoscopic Surgeons (SLS) is accredited by the Accreditation Council for Continuing Medical Education for physicians. The SLS designates this live activity for a maximum of 23.00 *AMA PRA Category 1 Credits™* toward the AMA Physician's Recognition Award. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Number of Credits Claimed

	Available Credits	Credits Claimed
Wednesday, August 29, 2018	7.25 Credits	7.25
Thursday, August 30, 2018	7.75 Credits	7.75
Friday, August 31, 2018	7.00 Credits	7.00
Saturday, September 1, 2018	1.00 Credits	1.00
Max Total Credits for MISWeek 2018	**23.00 Credits**	**23**

The SLS certifies that **Jose Antonio Diaz-Elizondo** has participated in the live activity titled "Minimally Invasive Surgery Week 2018" on August 29-September 1, 2018 at the Sheraton New York Times Square Hotel, New York, NY and is awarded **23** *AMA PRA Category 1 Credit(s)™.*

Raymond J. Lanzafame, MD, MBA
Executive Director

UNIVERSIDAD NACIONAL AUTÓNOMA DE MÉXICO
FACULTAD DE MEDICINA
DIVISIÓN DE ESTUDIOS DE POSGRADO
SUBDIVISIÓN DE GRADUADOS Y EDUCACIÓN CONTINUA

otorga la presente

CONSTANCIA

al

DR. JOSÉ ANTONIO DÍAZ ELIZONDO

como
profesor asociado
del
curso

HERNIA UNIVERSITY WORKSHOP

organizado por la

COORDINACIÓN DE CURSOS QUIRÚRGICOS AVANZADOS DE POSGRADO, FACULTAD DE MEDICINA, UNAM

con una participación de 12 h.

del 31 de agosto al 1° de septiembre de 2018

"POR MI RAZA HABLARÁ EL ESPÍRITU"

DR. JULIO M. CACHO SALAZAR
JEFE DE LA SUBDIVISIÓN DE GRADUADOS Y EDUCACIÓN CONTINUA

EDUCACIÓN CONTINUA
U N A M

Clave: AC12618
Libro: 3
Foja: 371
Modalidad: Presencial

Horas teóricas:	5
Horas prácticas:	7
Horas totales:	12

UNIVERSIDAD NACIONAL AUTÓNOMA DE MÉXICO
FACULTAD DE MEDICINA
DIVISIÓN DE ESTUDIOS DE POSGRADO
SUBDIVISIÓN DE GRADUADOS Y EDUCACIÓN CONTINUA

otorga la presente

CONSTANCIA

al

DR. JOSÉ ANTONIO DÍAZ ELIZONDO

como
profesor adjunto
del
curso-taller

MASTER WEEK CADAVER LAB

organizado por la

COORDINACIÓN DE CURSOS QUIRÚRGICOS AVANZADOS DE POSGRADO
FACULTAD DE MEDICINA, UNAM

con una participación de 12 h.

del 28 de febrero al 1° de marzo de 2018

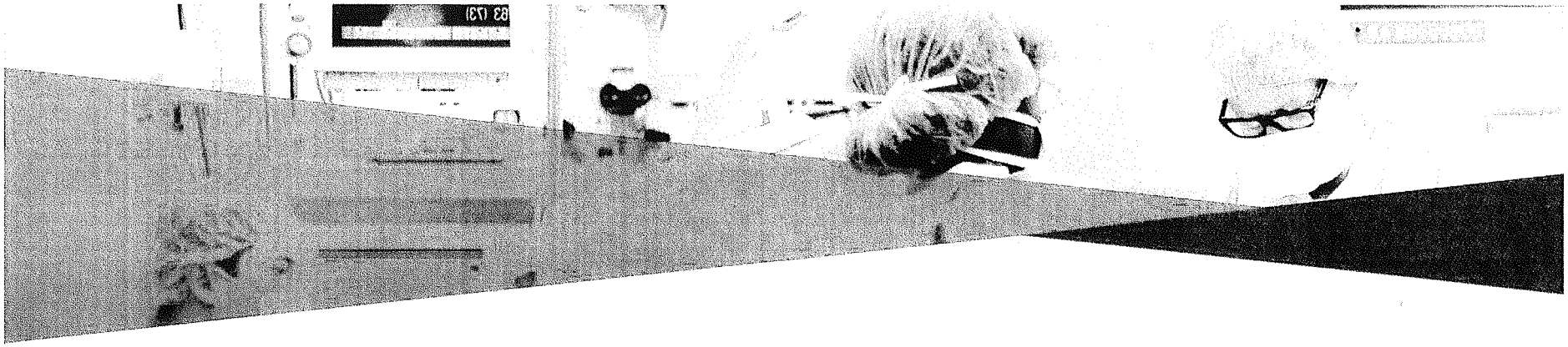
"POR MI RAZA HABLARÁ EL ESPÍRITU"

DR. JULIO M. CACHO SALAZAR
JEFE DE LA SUBDIVISIÓN DE GRADUADOS Y EDUCACIÓN CONTINUA

Clave: AC12518
Libro: 3
Foja: 370
Modalidad: Presencial

EDUCACIÓN CONTINUA
U N A M

Horas teóricas:	5
Horas prácticas:	7
Horas totales:	12



Extendemos la presente constancia al:

Dr.(a) **Díaz Elizondo José Antonio**

Por su participación en el curso:

Hernia University Workshop

Realizado el 2 y 3 de Marzo del 2018 con valor curricular de 20 horas.

Dr. Eduardo F. Moreno Paquentin
Presidente AMCG/FMCEGG

Dr. Jose luis Limon
Presidente AMCE

Dr. Eduardo Parra Davila
Profesor titular

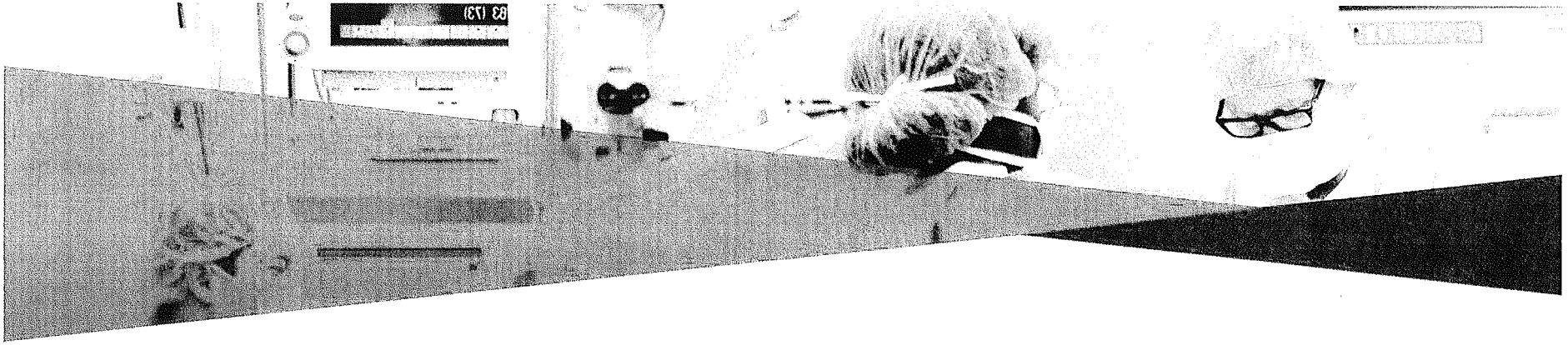
Dr. Flavio Malcher M.
Profesor titular

Asociación Mexicana de Cirugía Endoscópica A.C.

BARD has joined BD

BD

FOLIO AMCE
28818



Extendemos la presente constancia al:

Dr. Díaz Elizondo José Antonio

Por su participación en el curso:

Master Week Cadaver Lab

Realizado el 28 de Febrero y 1 de Marzo del 2018 con valor curricular de 8 horas.

Dr. Eduardo F. Moreno Paquentin
Presidente AMCG/FMCEGG

Dr. Jose luis Limon
Presidente AMCE

Dr. Eduardo Parra Davila
Profesor titular

Dr. Flavio Malcher M.
Profesor titular

Asociación Mexicana de Cirugía Endoscópica A.C.

BARD has joined BD

BD

FOLIO AMCE
23855

LA ASOCIACIÓN PANAMEÑA DE CIRUGÍA

OTORGA EL PRESENTE **CERTIFICADO** A:

DR. JOSÉ DÍAZ ELIZONDO

EN CALIDAD DE **PARTICIPANTE** EN EL

CONGRESO NACIONAL DE CIRUGÍA 2017

DADO EN LA CIUDAD DE PANAMÁ 29, 30 DE NOVIEMBRE Y 1 DE DICIEMBRE DE 2017

SE HACE ACREEDOR A 20 HORAS CRÉDITOS

COLMED – 097-2017

DR. NICOLAS JUAN LIAKÓPULOS
PRESIDENTE
ASPACI

DR. ALFREDO MACHARAVIAYA
PRESIDENTE
COLEGIO MÉDICO DE PANAMÁ

Tecnológico de Monterrey
Escuela de Medicina

Otorga a:

Jose Antonio Díaz Elizondo

La presente

Constancia

Por su participación en el curso

Actualidades en Regulaciones Nacionales e Internacionales y Calidad en la Investigación Clínica

Monterrey, N.L., 04 de Noviembre 2016

Dr. Jorge E. Valdez García
Decano
Escuela de Medicina
Tecnológico de Monterrey

Dr. Federico Ramos Ruiz
Presidente
Comité de Ética en Investigación
Escuela de Medicina

VI CONGRESO NACIONAL
DE EDUCACIÓN MÉDICA
APRENDIZAJE CENTRADO EN EL PACIENTE

Tecnológico de Monterrey
Escuela de Medicina

amfem

SALUD
SECRETARÍA DE SALUD

ISSSTE

IMSS

EL INSTITUTO MEXICANO DEL SEGURO SOCIAL
Otorga la presente

CONSTANCIA

A

Dr. Jose Antonio Diaz Elizondo

Por su valiosa asistencia al Congreso.

MONTERREY, N.L. DEL 19 AL 21 DE OCTUBRE DE 2016

Dr. Carlos Lavalle Montalvo
Vice Presidente ACANEMED

Dra. Lydia Zerón Gutiérrez
Presidente ACANEMED

Dr. Jorge E. Valdez García
Presidente Capítulo Norte ACANEMED

VI CONGRESO NACIONAL
DE EDUCACIÓN MÉDICA
APRENDIZAJE CENTRADO EN EL PACIENTE

Tecnológico de Monterrey
Escuela de Medicina

amfem

SALUD
SECRETARÍA DE SALUD

ISSSTE

IMSS

EL INSTITUTO MEXICANO DEL SEGURO SOCIAL
Otorga la presente

CONSTANCIA

A

Dr. Jose Antonio Diaz Elizondo

Por su valiosa asistencia al taller La medicina frente a los retos sociales del país.

MONTERREY, N.L. DEL 19 AL 21 DE OCTUBRE DE 2016

Dr. Carlos Lavalle Montalvo
Vice Presidente ACANEMED

Dra. Lydia Zerón Gutiérrez
Presidente ACANEMED

Dr. Jorge E. Valdez García
Presidente Capítulo Norte ACANEMED

Tecnológico de Monterrey
Escuela de Medicina

Otorga a:

Jose Antonio Díaz Elizondo

La presente

Constancia

Por su participación en el curso

Evaluación de Estudios Clínicos y Protocolos de Investigación

Monterrey, N.L., 30 Julio de 2016

Dr. Jorge E. Valdez García
Decano
Escuela de Medicina
Tecnológico de Monterrey

Dr. Federico Ramos Ruiz
Presidente
Comité de Ética en Investigación
Escuela de Medicina

Tecnológico de Monterrey
Escuela de Medicina

JOHNS HOPKINS
MEDICINE

Otorga el presente Diploma a

José Antonio Diaz Elizondo

Por haber completado exitosamente el

Foro Internacional de Liderazgo en Salud

Otorgado en la Ciudad de México

El 20 de Mayo de 2016

Dr. Jorge E. Valdez García
Decano
Escuela Nacional de Medicina
Tecnológico de Monterrey

Irma Purisch, M.B.A.
Managing Director
Johns Hopkins Medicine International
Johns Hopkins Medicine

CERTIFICATE OF PARTICIPATION

Antonio Diaz, MD

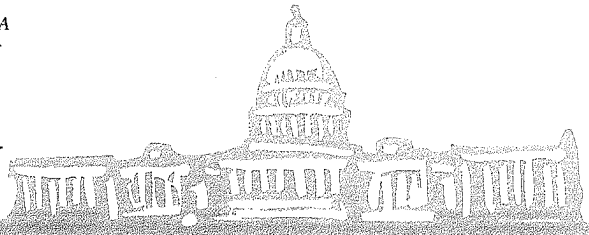
This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of The Medical Educator Consortium (MEC) and Americas Hernia Society. The Medical Educator Consortium is accredited by the ACCME to provide continuing medical education for physicians.

The Medical Educator Consortium, designates this live activity for a maximum of *27 AMA PRA Category 1 Credits*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

AHS AMERICAS HERNIA SOCIETY
North America • Central America • South America

William Hope, MD
AHS Program Chair

Mike Rosen, MD
AHS President



AMERICAN COLLEGE OF SURGEONS

DIVISION OF EDUCATION

JOINT PROVIDERSHIP PROGRAM

CONTINUING MEDICAL EDUCATION CERTIFICATE

Jose Antonio Diaz-Elizondo

has participated in the educational activity titled:

Montefiore Medical Center

32nd Annual Controversies, Problems & Techniques in Surgery

December 16-18, 2015–New York, NY

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint providership of the American College of Surgeons and the Montefiore Medical Center. The American College of Surgeons is accredited by the ACCME to provide continuing medical education (CME) for physicians.

The American College of Surgeons designates this live activity for a maximum of 13.0 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Of the *AMA PRA Category 1 Credits™* listed above, a maximum of 0.0 credits meet the requirements for Self-Assessment.

AMERICAN COLLEGE OF SURGEONS
Inspiring Quality:
Highest Standards, Better Outcomes
100+years

Ajit K. Sachdeva, MD, FRCSC, FACS
Director, Division of Education
Blended Surgical Education and Training for Life

A. TOTAL *AMA PRA Category 1 Credits™*: 13

B. Of the credits claimed in line A, the SELF-ASSESSMENT credits earned were: 0.0

**The content of this activity may meet certain mandates of regulatory bodies. If line(s) C-G appear, please note that ACS has not and does not verify the content for such mandates with any regulatory body. Individual physicians are responsible for verifying the content satisfies such requirements.*

2DO.CONGRESO INTERNACIONAL DE INNOVACIÓN EDUCATIVA

"Transformando la educación para los retos del futuro"

Tecnológico de Monterrey

Por medio de la presente hacemos constar que

José Antonio Díaz Elizondo

formó parte del 2do. Congreso Internacional de Innovación Educativa del Tecnológico de Monterrey desarrollando la actividad de

Participante

dentro de la convocatoria del 2do. Congreso Internacional de Innovación Educativa, que se llevó a cabo en el Campus Ciudad de México del 14 al 16 de diciembre de 2015 con una duración de 25 hrs.

Cordialmente,

Dr. José Escamilla de los Santos
Presidente del Comité Organizador
2do. Congreso Internacional de Innovación Educativa
Tecnológico de Monterrey

Dra. María Soledad Ramírez Montoya
Presidenta del Comité Científico
2do. Congreso Internacional de Innovación Educativa
Tecnológico de Monterrey

La Facultad de Medicina de la UANL a través de la Subdirección de Educación Continua y la Asociación Mexicana de Cirugía General, A.C., y la Federación Mexicana de Colegios de Especialistas en Cirugía General, A.C., Otorgan la presente

Constancia

Con un Valor Curricular de 2 Créditos Académicos equivalentes a 20 horas de Educación Continua.

a

Dr. José Antonio Díaz Elizondo

Por su asistencia al

"XXXIX Congreso Internacional de Cirugía General"

Realizado en Cintermex, del 2 a 5 de noviembre de 2015.

"Alere Flammam Veritatis"
Monterrey, N.L. 5 de noviembre de 2015.

Dr. med. Santos Guzmán López
DIRECTOR DE LA FACULTAD DE MEDICINA

Dr. Félix Ramón Cedillo Salazar, FACC
SUBDIRECTOR DE EDUCACIÓN CONTINUA

Dr. Abraham Pulido Cejudo
PRESIDENTE DE LA ASOCIACIÓN MEXICANA DE CIRUGÍA GENERAL, A.C.

La Facultad de Medicina de la UANL a través de la Subdirección de Educación Continua y la Asociación Mexicana de Cirugía General, A.C., y la Federación Mexicana de Colegios de Especialistas en Cirugía General, A.C., Otorgan la presente

Constancia

Con un Valor Curricular de 1 Crédito Académico equivalente a 10 horas de Educación Continua.

a

Dr. José Antonio Díaz Elizondo

Por su asistencia al Curso Taller

"Cirugía científica y metodología de la investigación quirúrgica"

Realizado en el Salón 201 en Cintermex, del 2 a 5 de noviembre de 2015.

"Alere Flammam Veritatis"

Monterrey, N.L. 5 de noviembre de 2015.

Dr. med. Santos Guzmán López
DIRECTOR DE LA FACULTAD DE MEDICINA

Dr. Félix Ramón Cedillo Salazar, FACC
SUBDIRECTOR DE EDUCACIÓN CONTINUA

Dr. Abraham Polido Cejudo
PRESIDENTE DE LA ASOCIACIÓN MEXICANA DE CIRUGÍA GENERAL, A.C.

Federación Mexicana de Colegios de Especialistas en Cirugía General, A.C.
Asociación Mexicana de Cirugía General, A.C.

Nuestra Calidad
está Certificada
en los procesos: Atención al Socio, EMC,
GRH, Científico (ECOS y Congreso).
Certificado número: 222
Vigencia: 11-08-2018
Norma de referencia:
NMX-CC-9001-IMNC-2008

Otorga la presente

CONSTANCIA

a

DR. JOSÉ ANTONIO DÍAZ ELIZONDO

Por su ***Asistencia al Curso " PGII-11 Cirugía científica y metodología de la investigación quirúrgica "*** que se presentó dentro del XXXIX Congreso Internacional de Cirugía General 2015 celebrado del 31 de Octubre al 5 de Noviembre en Monterrey, Nuevo León.

Dr. José Luis Martínez Ordaz
Coordinador
Comité Científico

Dr. Abraham Pulido Cejudo
Presidente
AMCG / CPCG / FMCECG

Dr. Juan Carlos Hernández Marroquín
Coordinador
Educación Médica Continua

XXXIX Congreso Internacional de Cirugía General

Tecnológico de Monterrey
Escuela de Medicina

XCVI
REUNIÓN NACIONAL
EXTRAORDINARIA DE LA AMFEM

La Asociación de Facultades y Escuelas de Medicina, A. C.
otorga el presente

RECONOCIMIENTO

a:

José Antonio Díaz Elizondo

Por haber participado en la

XCVI Reunión Extraordinaria de la AMFEM 2015:
RETOS Y DESAFÍOS DE LA EDUCACIÓN MÉDICA EN EL SISTEMA NACIONAL DE SALUD

Dr. Ricardo León Bórquez, M.C.A.
Presidente
Asociación de Facultades y Escuelas de Medicina

Dr. Jorge Eugenio Valdez García
Decano
Escuela Nacional de Medicina

Monterrey, Nuevo León del 26 al 28 de octubre

La Asociación Mexicana de Hernia, A.C.

AMH
ASOCIACIÓN MEXICANA DE HERNIA A.C.

FELH
Federación Latinoamericana de Hernia
Federação Latinoamericana de Hernia

otorga la presente

CONSTANCIA

a:

JOSÉ ANTONIO DÍAZ ELIZONDO

por su participación como asistente al

IV CONGRESO INTERNACIONAL DE HERNIA 2015

Realizado en la ciudad de Monterrey, N.L. del 22 al 24 de julio 2015
con valor curricular de 30 Hrs.

Dr. Gerardo Gil Galindo
Presidente de la AMH

Dr. Flavio Malcher
Secretario General FELH

La Facultad de Medicina de la UANL a través de la Subdirección de Educación Continua, el Colegio de Especialistas en Cirugía General del Estado de Nuevo León, A.C. El Colegio de Especialistas en Cirugía General del Estado de Tamaulipas, A.C. El American College of Surgeons, la Asociación Mexicana de Cirugía General, A.C. El Colegio de Posgraduados en Cirugía General, A.C., y la Federación Nacional de Colegios de Especialistas en Cirugía General, A.C. Otorgan la presente

Constancia

Con un Valor Curricular de 2 Créditos Académicos equivalentes a 18 horas de Educación Continua.

a

Dr. José Antonio Díaz Elizondo

Por su asistencia al

"XXVI Congreso Anual del Colegio de Especialistas en Cirugía General del Estado de Nuevo León, A.C. -Ciencia, Arte y Filosofía en Cirugía General-. XXXVII Reunión Intercapítular Capítulo Noreste del Colegio Americano de Cirujanos. I Congreso del Colegio de Especialistas en Cirugía General del Estado de Tamaulipas, A.C."

Realizado en el Auditorio del Doctors Hospital del 11 al 13 de junio de 2015.

"Alere Flammam Veritatis"
Monterrey, N.L. 13 de junio de 2015.

Dr. med. Santos Guzmán López
DIRECTOR

Dr. Noé Núñez Jasso
PRESIDENTE DEL COLEGIO DE ESPECIALISTAS EN CIRUGÍA GENERAL DEL ESTADO DE NUEVO LEÓN

Dr. Guillermo Guerrero Torres
PRESIDENTE DEL COLEGIO DE ESPECIALISTAS EN CIRUGÍA GENERAL DEL ESTADO DE TAMAULIPAS

Dr. Félix Ramón Cedillo Salazar, FACC
SUBDIRECTOR DE EDUCACIÓN CONTINUA

Dr. Carlos Augusto Gutiérrez Torres, FACS
PRESIDENTE DEL CAPÍTULO NOROESTE DEL COLEGIO AMERICANO DE CIRUJANOS

Dr. Abraham Pulido Cejudo
PRESIDENTE DE LA ASOCIACIÓN MEXICANA DE CIRUGÍA GENERAL, COLEGIO DE POSGRADUADOS EN CIRUGÍA GENERAL, FEDERACIÓN MEXICANA DE COLEGIOS DE ESPECIALISTAS EN CIRUGÍA GENERAL

XXIV Congreso Internacional de Cirugía Endoscópica

PASIÓN · ENTREGA · SABIDURÍA

Asociación Mexicana de Cirugía Endoscópica, A.C.
Colegio Mexicano de Cirugía Endoscópica, A.C.

2 al 6 de Mayo 2015 • Puerto Vallarta, México

Otorga la presente

Constancia a:

DR. JOSE ANTONIO DIAZ ELIZONDO

POR SU ASISTENCIA AL

XXIV Congreso Internacional de **Cirugía Endoscópica**

CENTRO INTERNACIONAL DE CONVENCIONES
CELEBRADO DEL 2 al 6 DE MAYO DE 2015, PUERTO VALLARTA, JALISCO.

Dr. Vicente González Ruíz
PRESIDENTE

Dr. Eduardo Moreno Paquentín
COORDINADOR DEL COMITÉ CIENTÍFICO

Dr. Samuel Kleinfinger Marcuschamer
SECRETARIO

TECNOLÓGICO
DE MONTERREY

Otorga la presente Constancia a

José Antonio Diaz Elizondo

Por su participación en el Curso

Evolución de la Cirugía Robótica en México

Otorgado en la ciudad de Monterrey

El día 24 de Enero de 2015

Dr. Jorge E. Valdez García
Decano
Escuela de Medicina del
Tecnológico de Monterrey

Dra. Gabriela Villarreal Levy
Directora
Educación Continua y Extensión
Escuela de Medicina del
Tecnológico de Monterrey

TECNOLÓGICO
DE MONTERREY

Constancia de Capacitación
Monterrey, N.L. 29 de octubre de 2015

A quien corresponda:

Por medio de la presente hago constar que el **Dr. José Antonio Díaz Elizondo**, con número de nómina L00767897, asistió al **Programa de Desarrollo de Habilidades de Investigación** durante el periodo semestral Enero-Mayo 2015; acreditando dicho programa con un total de **40 horas**.

Los detalles de esta capacitación así como cualquier otra información podrán ser proporcionados por el Departamento de Capacitación de la Escuela.

Atentamente,

Dra. Silvia Olivares Olivares
Directora del Área de Innovación
y Calidad Académica
Escuela Nacional de Medicina
Tecnológico de Monterrey

Campus Monterrey
Eugenio Garza Sada 2501
64849, Monterrey, N.L., México
Tel: 52/81 8358 2000

Tecnológico de Monterrey

1ER.CONGRESO INTERNACIONAL DEINNOVACIÓN EDUCATIVA

El Instituto Tecnológico y de Estudios Superiores de Monterrey, a través de la Vicerrectoría de Innovación Educativa otorga el presente

RECONOCIMIENTO

a

JOSÉ ANTONIO DÍAZ ELIZONDO

por su participación en el
1er Congreso Internacional de Innovación Educativa
que se llevó a cabo los días 15, 16 y 17 de diciembre 2014,
en el Campus Ciudad de México con una duración de 24 horas.

Manuel Tamez Sánchez
Vicerrector de Innovación Educativa

Claudia Susana López Cruz
Coordinadora General del CIIE

Ciudad de México, diciembre 2014

EL TECNOLÓGICO DE MONTERREY

a través de la Vicerrectoría de Profesional
otorga el presente Reconocimiento a

José Antonio Díaz Elizondo

por su participación en el curso

"Translational Medicine: Scientific Innovation and Human Health"

CADI
Cursos de Actualización en las Disciplinas

Lic. Gerardo Isaac Campos Flores
Director de Desarrollo Académico
Campus Monterrey

Dr. Guillermo García-Cardeña
Instructor

Monterrey, N.L. a 3 de diciembre de 2014

La Facultad de Medicina de la UANL a través de la Subdirección de Educación Continua,
Doctors Hospital y el Colegio de Especialistas en Cirugía General del Estado de Nuevo León, A.C.
Otorgan la presente

CONSTANCIA

Con un Valor Curricular de 2 Créditos Académicos equivalentes a 20 horas de Educación Continua.

a

Dr. José Antonio Díaz Elizondo

Por su asistencia al

Congreso "Cirugía Endoscópica: A XXV Años de su Inicio, Estatus Actual y Proyección Futura"

Realizado en el Auditorio del Doctors Hospital del 27 al 29 de noviembre de 2014.

"Alere Flammam Veritatis"
Monterrey, N.L., 29 de noviembre de 2014.

Dr. med. Santos Guzmán López
DIRECTOR

Dr. med. Marco Antonio Ponce Camacho
DIRECTOR MÉDICO
DOCTORS HOSPITAL

Dr. Félix Ramón Cedillo Salazar, FACC
SUBDIRECTOR DE EDUCACIÓN CONTINUA

Dr. César Alejandro Peña Ceniceros
PRESIDENTE DEL COLEGIO DE ESPECIALISTAS EN CIRUGÍA GENERAL DEL ESTADO DE NUEVO LEÓN, A.C.

Tecnológico de Monterrey
Escuela de Medicina

La Academia Nacional de Educación Médica
y La Escuela de Medicina del Tecnológico de Monterrey

otorgan la presente:

CONSTANCIA

a:

Dr. José Antonio Díaz Elizondo

Por su asistencia al:

Simposio Nacional de Educación Médica

Dr. José Francisco González Martínez
Presidente de la Academia Nacional de Educación Médica

Monterrey, N. L., 3 de octubre del 2014

Dr. Jorge Eugenio Valdez García
Decano de la Escuela Nacional de Medicina
Tecnológico de Monterrey

TECNOLÓGICO
DE MONTERREY

Otorga la presente Constancia a

José Antonio Díaz Elizondo

Por su participación en el

Skills Lab sobre el Manejo del Abdomen Abierto (AA)

Otorgado en la Ciudad de Monterrey

El 16 de Junio de 2014

Dr. Jorge E. Valdez García
Decano
Escuela Nacional de Medicina
Tecnológico de Monterrey

Dr. Braulio Aarón Crisanto Campo
División de Cirugía General y Endoscopía
Hospital Dr. Manuel GEA González
Clínica de Páncreas

La Facultad de Medicina de la UANL a través de la Subdirección de Educación Continua, el Colegio de Especialistas en Cirugía General del Estado de Nuevo León, A.C. la Asociación Mexicana de Cirugía Endoscópica, la Asociación Mexicana de Cirugía General, A.C. el Colegio de Posgraduados en Cirugía General, A.C., la Federación Nacional de Colegios y Asociaciones de Especialistas en Cirugía General, A.C. OCA Hospital y el Colegio Mexicano de Especialistas en Coloproctología, A.C. Otorgan la presente

CONSTANCIA

Con un Valor Curricular de 2 Créditos Académicos equivalentes a 18 horas de Educación Continua.

a

Dr. José Antonio Díaz Elizondo

Por su asistencia al

XXV Congreso Anual del Colegio de Especialistas en Cirugía General del Estado de Nuevo León. 7a. Reunión Regional de la Asociación Mexicana de Cirugía Endoscópica "Cirugía Moderna Basada en Evidencia"

Realizado en el Auditorio del OCA Medical Center del 5 al 7 de junio de 2014.

"Alere Flammam Veritatis"
Monterrey, N.L., 7 de junio de 2014.

Dr. med. Santos Guzmán López
DIRECTOR

Dr. Félix Ramón Cedillo Salazar, FACC
SUBDIRECTOR DE EDUCACIÓN CONTINUA

Dr. César Alejandro Peña Ceniceros
PRESIDENTE DEL COLEGIO DE ESPECIALISTAS EN CIRUGÍA GENERAL DEL ESTADO DE NUEVO LEÓN, A.C.

Dr. Juan Carlos Mayagoitia González
PRESIDENTE DE LA ASOCIACIÓN MEXICANA DE CIRUGÍA GENERAL, A.C.
COLEGIO DE POSGRADUADOS EN CIRUGÍA GENERAL, A.C.
FEDERACIÓN NACIONAL DE COLEGIOS Y ASOCIACIONES DE ESPECIALISTAS EN CIRUGÍA GENERAL, A.C.

Dr. Vicente González Ruiz
PRESIDENTE DE LA ASOCIACIÓN MEXICANA DE CIRUGÍA ENDOSCÓPICA

Dr. Gustavo Enrique Saldaña Flores
DIRECTOR MÉDICO
OCA HOSPITAL

Dr. Oscar Durán Ramos
PRESIDENTE DEL COLEGIO MEXICANO DE ESPECIALISTAS EN COLOPROCTOLOGÍA, A.C.

EL TECNOLÓGICO DE MONTERREY

a través de la Vicerrectoria Académica
otorga el presente Reconocimiento a

José Antonio Díaz Elizondo

por su participación en el curso

"Fundamentals in Leadership and Management Education"

CADI
Cursos de Actualización en las Disciplinas

Ing. María Norma Yépiz Guerrero
Directora de Desarrollo Académico
Campus Monterrey

Judy Mckimm
Instructora

Paul Kneath JONES
Instructor

Monterrey, N.L. A 28 de Mayo de 2104

ASOCIACIÓN MEXICANA DE CIRUGÍA ENDOSCÓPICA, A.C.
COLEGIO MEXICANO DE CIRUGÍA ENDOSCÓPICA, A.C.

XXIII Congreso Internacional de Cirugía Endoscópica
World Trade Center Veracruz
Del 30 de abril al 4 de mayo de 2014

OTORGA
LA PRESENTE CONSTANCIA A:

DR. JOSE ANTONIO DIAZ ELIZONDO

POR SU ASISTENCIA AL

XXIII CONGRESO INTERNACIONAL DE CIRUGÍA ENDOSCÓPICA
WORLD TRADE CENTER VERACRUZ

CELEBRADO DEL 30 DE ABRIL AL 4 DE MAYO DE 2014,
BOCA DEL RIO, VERACRUZ

DR. JUAN PABLO PANTOJA MILLAN
PRESIDENTE

DR. MAURICIO SIERRA SALAZAR
COORDINADOR DEL COMITÉ CIENTÍFICO

DRA. ADRIANA HERNÁNDEZ LÓPEZ
SECRETARIA

CERTIFICATE OF PARTICIPATION

16TH ANNUAL HERNIA REPAIR

MARCH 12-15, 2014 | LAS VEGAS

Antonio Diaz-Elizondo

HAS PARTICIPATED IN THE 16TH ANNUAL HERNIA REPAIR
MARCH 12-15, 2014 | LAS VEGAS, NV

Poster# 129 - Posherpetic Abdominal Wall Pseudohernia

Continuing Medical Education
The 16th Annual Hernia Repair meeting is accredited by the Medical Educator Consortium, to provide the following CME activity for medical specialists. The 16th Annual Hernia Repair is designated for a maximum of *26.5 AMA PRA Category 1 Credit(s).*™ Each Medical specialist should claim only those hours of credit that he/she actually spent in the education activity.

Brent D. Matthews, MD
Program Chair

AHS AMERICAS HERNIA SOCIETY
North America • Central America • South America

Michael J. Rosen, MD
Program CO-Chair

La Facultad de Medicina de la UANL a través de la Subdirección de Educación Continua, OCA Hospital, el Colegio Mexicano de Especialistas en Coloproctología, A.C. la Sociedad de Gastroenterología de Nuevo León, A.C. y el Colegio de Especialistas en Cirugía General del Estado de Nuevo León, A.C. Otorgan la presente

CONSTANCIA

Con un Valor Curricular de 1.5 Créditos Académicos equivalente a 15 horas de Educación Continua.

a

Dr. José Antonio Díaz Elizondo

Por su asistencia al

Congreso Regional Norte "Maestro Dr. Fidel Rodríguez Rocha"
Monterrey, N.L. México -Actualidades en Coloproctología-

Realizado en el Auditorio del OCA Medical Center los días 9, 10 y 11 de enero de 2014.

"Alere Flammam Veritatis"
Monterrey, N.L., 11 de enero de 2014.

Dr. med Santos Guzmán López
DIRECTOR

Dr. Gustavo Enrique Saldaña Flores
DIRECTOR MÉDICO
OCA HOSPITAL

Dr. César Antonio Marrufo García
PRESIDENTE DE LA SOCIEDAD DE GASTROENTEROLOGÍA DE NUEVO LEÓN, A.C.

Dr. Félix Ramón Cedillo Salazar
SUBDIRECTOR DE EDUCACIÓN CONTINUA

Dr. Oscar Durán Ramos
PRESIDENTE DEL COLEGIO MEXICANO DE ESPECIALISTAS EN COLOPROCTOLOGÍA, A.C.

Dr. César Alejandro Peña Ceniceros
PRESIDENTE DEL COLEGIO DE ESPECIALISTAS EN CIRUGÍA GENERAL DEL ESTADO DE NUEVO LEÓN, A.C.

EL TECNOLÓGICO DE MONTERREY

a través de la Vicerrectoria Académica
otorga el presente Reconocimiento a

José Antonio Díaz Elizondo

por su participación en el curso

"Biología Molecular y Modelos Animales en Medicina Traslacional"

CADI
Cursos de Actualización en las Disciplinas

Ing. María Norma Yépiz Guerrero
Directora de Desarrollo Académico
Campus Monterrey

Shohreh Issazadeh Navikas
Instructora

Monterrey, N.L. a 20 de Diciembre de 2013

Investigator Site Personnel ICH GCP Training Certificate

TransCelerate BIOPHARMA INC.
ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

Roche/Genentech certifies that Jose Antonio Diaz Elizondo **has**

Name of Trainee

completed Good Clinical Practice training meeting "Minimum Criteria for ICH E6 GCP Investigator Site Personnel Training*," identified by TransCelerate BioPharma, Inc., entitled

Good Clinical Practice (Investigator Version), version #2.0 on 12 MAR 2019

Date (dd-MON-yyyy)

This certificate reflects that Sponsor, not Transcelerate BioPharma, certifies that an investigator and/or trainee has completed training meeting the Minimum Criteria to facilitate mutual recognition of site training and qualification. This is not a legal document, and does not certify compliance with any applicable laws or regulations. A list of GCP Training Solutions meeting the minimum criteria is maintained on TransCelerate's website http://transceleratebiopharmainc.com.

**TransCelerate BioPharma, Inc. Operating Principles for ICH GCP Investigator Training* 7 February 2013, version 1.1*

La Asociación Mexicana de Cirugía General A.C. y BD otorgan la presente

CONSTANCIA

Al(a) Dr(a). **JOSÉ ANTONIO DÍAZ ELIZONDO**

Por haber concluido exitosamente el curso **"Hernia U- Cadáver Lab 2019"**,

que se llevó a cabo en la CDMX el día 31 de Marzo del 2019, Con valor curricular de siete horas y media.

Dra. Elena López Gavito
Presidente AMCG

Dr. José Luis Beristain Hernández
Coordinador titular del
CECMI-AMCG

Lic. Gabriela Pineda Molina
Director Unidad de Negocios BDI

BD

-Desde 1973-

VITA

gob.mx

CONACYT

CURRICULUM VITAE ÚNICO

JOSÉ ANTONIO DÍAZ ELIZONDO

Datos personales

Calle y número (ext/int) | Colonia | C.P.

Ciudad o localidad | Delegación o municipio | País y entidad fed | Nacionalidad

Fecha de nacimiento | Lugar de nacimiento | Género | Estado civil

Identificaciones

CVU	
CURP	
RFC	

Correo

Business	

Teléfono

Business	
Main	

Desempeño profesional

Adscripcion actual

2000-Ene-03	DIRECTOR DEL DEPTO DE CIENCIAS CLÍNICA. | HOME | MEX | EUGENIO GARZA SADA | 2501 | INSTITUTO TECNOLOGICO DE ESTUDIOS SUPERIORES DE MONTERR | MONTERREY | MONTERREY | MONTERREY | MONTERREY | MONTERREY

Desempeño profesional	
Experiencia laboral	
2007-Nov-15	, 0, , DIRECCIÓN DE CIENCIAS CLÍNICAS, EDUCACIÓN, Y 320000 321300 321301 Principales logros: Poder participar en el proceso de transformación del modelo educativo de Clínicas para el Pregrado en la Carrera de Medicina y la Carrera de Nutrición. Ayudar en la definición del modelo para implementación del modelo de Clínicas en los otros Campus donde se desarrolla la Carrera de Medicina
2007-May-01	, 62, , TESORERO, CIRUGÍA GENERAL Y LAPAROSCOPÍA AVANZADA, Y 320000 321300 321301 Líneas de investigación: CONSULTORÍA EN EFICIENTIZACIÓN DE PROCESOS DE ATENCIÓN Y UTILIZACIÓN DE RECURSOS CONSULTA MÉDICA Y QUIRÚRGICA Principales logros: En Consultores en Cirugía Monterrey, SC; logramos establecernos formalmente como agrupación y empresa dando servicios especializados y consultoría para la prevención, tratamiento y rehabilitación de patología quirúrgica. Ser una empresa a quien los algunos terceros pagadores e instituciones privadas de salud solicitan consultoría para el desarrollo de una mejor eficiencia y calidad en los procesos de atención médica relacionada a Cirugía General.
2005-Feb-01 2006-Sep-16	, 62, , DIRECTOR, ADMINISTRACIÓN DE UN HOSPITAL GENERAL DE 220 CAMAS Y 1200 EMPLEADOS, N 320000 321500 0 Principales logros: Formalización de estructura y procesos para Clínica de Atención Integral para pacientes con HIV-SIDA Acreditación por Seguro Popular para: Prematurez, Cirugía Catarata, Acreditación del capítulo de infraestructura para certificación por Consejo Salubridad Negociación y presentación de proyecto formal de Programa Multicéntrico de Especialidad con todas las Universidades Estatales Arranque formal de Programa Multicéntrico de Especialidades Medicas con el ITESM Arranque de Programa de Medicina Integrada y de Emergencias Médico-Quirúrgicas con la UdeM
2004-Ene-15 2005-Feb-04	, 62, , SUBDIRECTOR, VERIFICACIÓN DE LA ADECUADA ATENCIÓN MÉDICA Y LA ADECUADA INTERACCIÓN DE LOS SERVICIOS Y DEPARTAMENTOS, Y 320000 321500 0 Líneas de investigación: ASISTENCIA EN LA ADMINISTRACIÓN DE UN HOSPITAL DE 220 CAMAS Y 1200 EMPLEADOS

Desempeño profesional	
	Principales logros: Incremento en productividad y utilización de unidad quirúrgica. Implementación de "triage" en área de Emergencias. Eficiencia en el proceso de asignación de citas en Consulta Externa Verificación del proceso de educación en Pregrado con UdeM y de Posgrado con UANL
2000-Ene-20	, 0, , PROFESOR DE CIRUGÍA, CIRUGÍA DE MÍNIMA INVASIÓN, Y 320000 321300 321301 Líneas de investigación: EDUCACIÓN SIMULACIÓN Principales logros: Haberme podido incorporar y participar en la redefinición - rediseño del programa actual. Participar activamente en la formación y establecimiento del Programa Multicéntrico (SSNL-ITESM) de la Especialidad de Cirugía General. Estar dentro del grupo de asesores para las tésis de los residentes.
2000-Ene-03	, 62, , CIRUJANO GENERAL Y LAPAROSCOPÍA AVANZADA, CONSULTA MÉDICA Y QUIRÚRGICA EN CONSULTORIO MÉDICO PRIVADO, N 320000 321300 321301 Líneas de investigación: CIRUGÍA GENERAL Y LAPAROSCOPÍA AVANZADA Principales logros: Regreresar a Monterrey al término de un entrenamiento de subespecialidad en Laparoscopía Avanzada y poder iniciar una actividad como Cirujano General en el ámbito privado. Poder formar parte del grupo de médicos especialistas adecuadamente credencializados en el Estado de Nuevo león para ejercer la Cirugía General. Contar con privilegios sin restricciones de ningún tipo para el ejercico de la Cirugía General y Laparoscopía Avanzada en los hospitales privados de la Ciudad de Monterrey. Poder seguir participando en con el gremio en la Asociación Regional de Cirugía, así como en las Asociaciones Nacionales.

Producción científica	
Año de publicación	Artículos
2013	**STRESS-SOFTENING AND RESIDUAL STRAIN EFFECTS IN SUTURE MATERIALS ISSN: 16878434**

	16878442, Elías-Zúñiga, A., Montoya, B., Ortega-Lara, W., Flores-Villalba, E., Rodríguez, C.A., Siller, H.R.,Martínez-Romero, O.,Díaz-Elizondo, J.A., **Advances in Materials Science and Engineering** Vol. Pag. 0-0
2013	**CLINICAL, IMAGING, AND CYTOPATHOLOGICAL CHARACTERISTICS AS PREDICTIVE FACTORS FOR BENIGN OR MALIGNANT BREAST DISEASE IN PATIENTS PRESENTING NIPPLE DISCHARGE,** Ortiz-Nino J, Guzman-Murguia JL, Diaz-Elizondo JA, **Annals of Surgical Oncology** Vol. 20 Pag. 91-91
2012	**GALLBLADER SELECTION FOR HISTOPATHOLOGICAL ANALYSIS BASED ON A SIMPLE METHOD: A PROSPECTIVE COMPARATIVE STUDY ISSN:1478-7083 (ELECTRONIC),** Romero-gonzalez RJ, Garza-Flores A, Martinez-Perez Maldonado L, Diaz-Elizondo JA, Muñiz-Eguia J, Barbosa-Quintana A, **Annals of the royal college of surgeons of england** Vol. 94 Pag. 159-159
2012	**EVALUATION OF A SURGICAL SIMULATOR AS USED BY STUDENTS WITH DIFFERENT EXPERIENCE LEVELS ISSN:0009-7411,** Flores-Villalba E, Diaz-Elizondo JA, Leyva-Alvizo A, Fernandez-Rangel E, Villegas-Cabello O, Del Real-Romo Z, **Cirugía y Cirujanos** Vol. 80 Pag. 157-157
2012	**SPLENIC TUBERCULOSIS ISSN:1557-8674 (ELECTRONIC),** Rodarte-Shade M, Diaz-Elizondo JA, **Surgical Infections** Vol. 13 Pag. 420-420
2012	**IRRIGATION WITH BUPIVACAINE AT THE SURGICAL BED FOR POSTOPERATIVE PAIN RELIEF AFTER LAPAROSCOPIC CHOLECYSTECTOMY ISSN:1086-8089,** Castillo-Garza G, Diaz-Elizondo JA, Cuello-Garcia C, Villegas-Cabello O, **Journal of the society of laparoendoscopic surgeons** Vol. 16 Pag. 105-105
2007	**COLECTOMÍA SUBTOTAL LAPAROSCÓPICA. RESULTADOS EN EL TEXAS ENDOSURGERY INSITUTE ISSN:0009-7411,** César Gálvez-Hernández, Morris Emory Franklin, Oscar Villegas-Cabello, José Díaz-Elizondo, Jorge Manuel Treviño, Dulce Salazar-López, **Cirugía y Cirujanos** Vol. 75 Pag. 443-443
2006	**ESPLENECTOMÍA LAPAROSCÓPICA. EXPERIENCIA DE 12 AOS ENDOS INSTITUCIONES PRIVADAS ISSN:0009-7411,** Morris Franklin,César Antonio Gálvez-Hernández, Jorge Treviño, Oscar Villegas-Cabello, Román González-Ruvalcaba, José Díaz-Elizondo, **Cirugía y Cirujanos** Vol. 74 Pag. 443-443
2006	**MORBIDITY OF LAPAROSCOPIC SURGERY FOR COMPLICATED APPENDICITIS: AN INTERNATIONAL STUDY ISSN:0930-2794 (LINKING),** J. Cueto, B. D¿Allemagne, J. A. Vázquez-Frias, S. Gomez, F. Delgado, L. Trullenque, R. Fajardo, S. Valencia, L. Poggi, J. Ballí, J. Diaz, R. González, J. H. Mansur and M. E. Franklin, **Surgical Endoscopy** Vol. 20 Pag. 717-717
2000	**LAPAROSCOPIC-ASSISTED COLONOSCOPIC POLYPECTOMY: THE TEXAS ENDOSURGERY INSTITUTE EXPERIENCE ISSN:0012-3706 (PRINT),** Franklin, M. E., Diaz-E, J. A., Abrego, D., Parra-Davila, E., and Glass, J. L., **Diseases of the Colon & Rectum** Vol. 43 Pag. 1246-1246
2000	**HOW TO PREVENT PORT-SITE METASTASES IN LAPAROSCOPIC COLORECTAL SURGERY ISSN:1432-2218 (ELECTRONIC),** J. E. Balli, M. E. Franklin, J. A. Almeida, J. L. Glass, J. A. Diaz and M. Reymond, **Surgical Endoscopy** Vol. 14 Pag. 1034-1034
2000	**LAPAROSCOPIC SURGERY FOR STAGE III COLON CANCER: LONG-TERM FOLLOW-UP ISSN:0930-2794 (PRINT),** M. E. Franklin, G. B. Kazantsev, D. Abrego, J. A. Diaz-E, J. Balli and J. L. Glass, **Surgical Endoscopy** Vol. 14 Pag. 612-612
1999	**ARE THERE LIMITS ON WHAT CAN BE DONE LAPAROSCOPICALLY FOR BENIGN COLON DISEASE?,** Diaz-E, JA (Diaz-E, JA); Franklin, ME (Franklin, ME); Abrego, D (Abrego, D); Glass, JL (Glass, JL); Balli, JE (Balli, JE); Kazantsev, GB (Kazantsev, GB), **GASTROENTEROLOGY** Vol. 16 Pag. 1307-1307
1999	**IS INTRAOPERATIVE COLONOSCOPY HELPFUL DURING LAPAROSCOPIC COLON PROCEDURES?,** Kazantsev, GB (Kazantsev, GB); Franklin, ME (Franklin, ME); Velez, JP (Velez, JP); Glass, JL (Glass, JL); Abrego, D (Abrego, D); Diaz-E, JA (Diaz-E, JA), **GASTROENTEROLOGY** Vol. 16 Pag. 1324-1324
1999	**5 YEAR FOLLOW UP ON ANTI-REFLUX SURGERY FOR BARRETTS ESOPHAGITIS,** Franklin, M. E., Diaz-E, J. A., Otero, R., Glass, J. L., Balli, J. E., Kazantsev, G. B., and Obregon, L., **Gastroenterology** Vol. 116 Pag. 79-79
1996	**PROSPECTIVE COMPARISON OF OPENVS. LAPAROSCOPIC COLON SURGERY FOR**

	CARCINOMA. FIVE YEAR RESULTS ISSN:0012-3706 (PRINT), Morris E. Franklin Jr., Daniel Rosenthal, Daniel Abrego-Medina, James P. Dorman, Jeffrey L. Glass, Richard Norem and Antonio Diaz, **Diseases of the Colon & Rectum** Vol. 39 Pag. 35-35
0	**AN OPEN SOURCE APPROACH FOR VIRTUAL REALITY IN LAPAROSCOPIC SURGERY SIMULATOR,** Moreno-Guerra, Mario;Rodriguez, Ciro; Di¿az-Elizondo, Jose¿ Antonio; Flores-Villalba, Eduardo; Silva, Jorge; Renato Archer; Elias-Zuniga, Alex, **International Journal of Computer Integrated Manufacturing** Vol. Pag. 0-0

Año de publicación	Capítulos de libros
2008	**TRATAMIENTO ANTIBIÓTICO,** Tratado de cirugía general COMITÉ EDITORIAL DE LA ASOCIACIÓN MEXICANA DE CIRUGÍA GENERA EL MANUAL MODERNO S.A. DE C.V.
2004	**LAPAROSCOPIC INTRAPERITONEAL ONLAY MESH HERNIA REPAIR,** Laparoscopic Surgery of the Abdomen SPRINGER SPRINGER NEW YORK 6
2002	**THE INTRAPERITONEAL ONLAY MESH PROCEDURE FOR GROIN HERNIAS,** Nyhus and Condon's hernia ROBERT J. FITZGIBBONS, A. GERSON GREENBURG, LLOYD MILTON NYH LIPPINCOTT WILLIAMS & WILKINS 8
2001	**LAPAROSCOPIC INTRAPERITONEAL ONLAY MESH REPAIR,** Abdominal wall hernias: principles and management ROBERT J. FITZGIBBONS, A. GERSON GREENBURG, ROBERT BENDAVID SPRINGER 3
2000	**MECHANICAL MEANS FOR PREVENTION OF TROCAR SITE CANCER IMPLANTATION,** Port-site and wound recurrences in cancer surgery: incidence, pathogenesis, prevention MARC A. REYMOND, H. JAAP BONJER, FERDINAND KÖCKERLING SPRINGER 6

Fechas	Participación en congresos
2013	WHY HERNIA REPAIR RESEARCH? MEX N
2013	STANDARIZED GOAL EVALUATION FOR SURGICAL SIM MEX N
2011	RELIDAD VIRTUAL VS CIRUGÍA LAPAROSCÓPICA MEX N
2010	ESPLENECTOMÍA LAPAROSCÓPICA EN PACIENTE INMUNOSUPRIMIDO POR TUBERCULOSIS ESPLÉNICA Y PERITONEAL: REPORTE DE UN CASO MEX N
2009	REPARACIÓN LAPAROSCÓPICA DE UNA HERNIA MEX N
2013	MANEJO ENDOVASCULAR DE LA DISECCIÓN AORTICA POR TRAUMA TORÁCICO CONTUSO MEX E
2013	TRATAMIENTO DEL TUMOR DE GIST RECIDIVANTE, REPORTE DE UN CASO MEX N
2011	RESECCIÓN INTESTINAL DE COLON SIGMOIDES Y REPARACIÓN DE FÍSTULA COLO-VESICAL POR LAPAROSCOPÍA MEX E
2011	ABSCESO HEPÁTICO AMIBIANO DEL LÓBULO IZQUIERDO: MANEJO LAPAROSCÓPICO DEL PACIENTE NO CANDIDATO A PUNCIÓN POR RADIOLOGÍA INTERVENCIONISTA MEX E
0	DESCRIPCIÓN DE LA REGIÓN INGUINAL DESDE LA PERSPECTIVA LAPAROSCÓPICA DURANTE EL TEP MEX E
2010	CISTECTOMÍA RADICAL LAPAROSCÓPICA ASISTIDA POR ROBOT: REPORTE DE UN CASO Y ANÁLISIS DEL PAPEL DE LA CIRUGÍA ROBÓTICA EN REGÓN PÉLVICA MEX E
1999	ARE THERE LIMITS TO WHAT CAN BE DONE LAPAROSCOPICALLY FOR BENIGN COLON DISEASE? USA E
1999	FIVE YEAR FOLLOW-UP ON ANTI-REFLUX SURGERY FOR BARRETT¿S ESOPHAGU USA E
1999	NEEDLESCOPIC SURGERY FOR BASIC AND ADVANCED PROCEDURES: EXPERIENCE OF A

Producción científica	
	LAPARO-ENDOSCOPIC SURGICAL CENTER USA E
1999	SAFETY AND LONG TERM RESULTS OF MID AND LOW RECTAL CANCER TREATED BY LAPAROSCOPIC RESECTION USA E
1999	LAPAROSCOPIC LOW ANTERIOR RESECTION FOR MID AND LOW RECTAL CANCER CHE E
1999	LONG TERM RESULTS FOR LAPAROSCOPIC COLON CANCER RESECTION MEX E
1999	CHOLEDOCODUODENOSTOMY MEX E
1999	OPERATING ROOM SET UP FOR LAPAROSCOPIC COMMON BILE DUCT EXPLORATION THROUGH CHOLEDOCOTOMY USA E
0	HOW TO PREVENT PORT-SITE METASTASIS IN LAPAROSCOPIC COLO-RECTAL SURGERY USA E
1999	INTRA-PERITONEAL ONLAY MESH HERNIOPLASTY MEX E
1999	SHOULD COMPLICATED VENTRAL/INCISIONAL HERNIAS BE APPROACHED LAPAROSCOPICALLY? USA E
1999	CIRUGÍA ANTI-REFLUJO: NUESTRA TÉCNICA Y RESULTADOS MEX E
1998	MANEJO LAPAROSCÓPICO DE PACIENTES CON ACALASIA MEX N
1997	LAPAROSCOPIC SPLENECTOMY MEX E
1997	ESPLENECTOMÍA LAPAROSCÓPICA MEX N
1997	HERNIOPLASTÍA INTRAPERITONEAL POR LAPAROSCOPÍA MEX N
1996	HERNIOPLASTÍA INGUINAL INTRAPERITONEAL POR LAPAROSCOPÍA MEX N
1996	AGENESIA VESICULAR: REPORTE DE UN CASO Y REVISIÓN DE LA LITERATURA MEX N
1996	AGENESIA VESICULAR: REPORTE DE UN CASO Y REVISIÓN DE LA LITERATURA MEX N
1996	100 CASOS CONSECUTIVOS DE CIRUGÍA COLO-RECTAL EN EL HOSPITAL SAN JOSÉ-ITESM MEX N
1994	10 AOS DE CIRUGÍA CARDIOVASCULAR EN EL HOSPITAL SAN JOSÉ-ITESM MEX E

Formación académica	
Fecha obtención	Niveles/grados académicos
	SUBESPECIALISTA EN CIRUGÍA LAPAROSCÓPICA AVANZADA, , , , , UNITED STATES, TX, ,
	RESIDENCIA DE CIRUGÍA GENERAL, , AEIE-14426, , , MEXICO, NL, ,
	MÉDICO CIRUJANO, , 1944067, , , MEXICO, NL, ,
Fecha evaluación	Idiomas
	Spanish Y N N 3 3 3 0

Formación académica

Certificaciones medicas

2008-Dic-01	, 98007,,
2003-Jul-01	, 98007,,
1998-May-01	, 98007,,

Formación de recursos humanos

Docencia

2005-Ene-01	Médico Cirujano Clínica Ambulatoria de Cirugía General
2000-Mar-01	Especialidad en Cirugía General Atención médica en cirugía general X
2000-Mar-01	Especialidad en Cirugía General Atención médica del servicio social profesional en cirugía general
2000-Mar-01	Especialidad en Cirguía General Atención médica en cirugía general VIII
2000-Mar-01	Especialidad en Cirugía General Atención médica en cirugía general VII
2000-Mar-01	Especialidad en Cirugía General Atención médica en cirugía general VI
2000-Mar-01	Especialidad en Cirguía General Atención médica en cirugía general V
2000-Mar-01	Especialidad en Cirguía General Atención médica en cirugía general IV
2000-Mar-01	Especialidad de Cirugía General Atención médica en cirugía general III
2000-Mar-01	Especialidad en Cirugía General Atención médica en cirugía general II
2000-Mar-01	Especialidad en Cirugía General Atención Médica en Cirugía General I

Tesis dirigidas

	Incidencia de rechazo de malla en hernias postinasionales estudio retrospectivo 5
2012-May-28	Caracterísitica Clínicas, Radiológicas y Citopatológicas como factor predictive de Patología Mamaria benigna en pacientes con Secreción por el Pezón 5 Y
2011-Dic-16	relación entre nivel de radioactividad y presencia de metastasis en biopsia de ganglio centinela por cancer de mama 5 Y
2011-Dic-14	Análisis de la factibilidad y aceptación de la introducción de herramientas electrónicas para captura de información para generación de base de datos en un programa de residencia 5
2011-Dic-05	Uso adecuado de antibioticos profilacticos en el Hospital San José 5
2011-Nov-30	Correlación citohistológica de biopsia por aspiración con aguja fina vs biopsia excisional para nódulo de mama en un hospital público 5 Y
2011-Nov-18	Comparación del uso de malla de polipropileno (no absorbable) vs malla poliglecaprone 25 / polipropileno (parcialmente absorbable) en hernioplastías inguinales 5 Y
2011-Oct-17	determinación der amilasa en drenajes en cirugía de esófago y estómago para decision de perforación y fugas tempranas 5 Y
2011-Sep-26	Bupivacaina vs placebo en lecho quirúrgico para control de dolor posoperatorio en Colecistectomía por Laparoscopía 5 Y
2011-Sep-12	Comparación de técnicas de fijación de malla en hiatoplastia 5 Y
2011-Jun-17	Comparación de anastomosis intestinales hechas a mano (sutura) versus c/n grapadora 5 Y
2010-Dic-15	Cierre primario de la herida quirúrgica en appendicitis complicada: es correcta nuestra conducta? 5 Y

Formación de recursos humanos	
2010-Nov-25	análisis comparativo de la estancia intra-hospitalaria entre el uso de anesthesia local y bloqueo epidural en los pacientes intervenidos de hernioplastía inguinal con malla en el Hospital Metropolitano 5 Y
2010-Nov-23	Comparación entre síntomas y hallazgos de laboratorio y gabinete entre apendicitis aguda y apéndices blancas 5 Y
2010-Nov-23	Estudio Comparativo de anastomosis intracorpórea versus extracorporeal en pacientes sometidos a hemicolectomía derecha laparoscópica 5 Y
2010-Nov-19	Impacto de la nutrición periferica en pacientes con anastomosis primaria intestinal 5
2010-Ene-31	El uso del expansor tisular externo en el manejo de las ulceras cronicas 5 Y
2009-Dic-01	Colectomía laparoscópica vs abierta en Enfermedad Diverticular. 5 Y
2009-Nov-02	El USO DE PIRFENIDONATOPICAEN EL TRATAMIENTO DE CICATRICES PATOLÓGICAS 5 Y
2009-Sep-01	Tratamiento endoscópico de fugas anastomóticas secundarias a Bypass Gástrico por Laparoscópía: Una serie de 4 casos 5 Y
2008-Dic-01	Validación constructiva de un simulador virtual y desempeo de residentes de cirugía 5 Y
2008-Nov-03	Manejo de heridas con sistema cerrado de succión con materiales de fácil acceso 5 Y
2008-Nov-03	Uso del Ketorolaco trometamina como analgesia preventiva en colecistectomía por laparoscopia 5 Y
2007-Sep-03	Antibióticos profilácticos y orales posquirúrgicos vs. Sólo antibióticos profilácticos en la prevención de infección del sitio quirúrgico en la colecistectomía convencional: un estudio prospectivo aleatorizado 5 Y
2006-Sep-04	Esplenectomía Laparoscopica 5 Y
2006-Sep-04	EL Ultrasonido de Abdomen como diagnostico en la apendicitis aguda 5 Y

Distinciones y premios	
Distinciones	
2012	MEXICO, Jurado Examen Oral Presidente CONSEJO MEXICANO CIRUGIA GENERAL
2008	MEXICO, Jurado Examen Oral Presidente CONSEJO MEXICANO CIRUGIA GENERAL
2007	MEXICO, Jurado Examen Oral Presidente CONSEJO MEXICANO CIRUGIA GENERAL
2005	MEXICO, Jurado Examen Oral Presidente CONSEJO MEXICANO CIRUGIA GENERAL
2004	MEXICO, Jurado Examen Oral Presidente CONSEJO MEXICANO CIRUGIA GENERAL
2003	MEXICO, Jurado Examen Oral Presidente CONSEJO MEXICANO DE CIRUGIA GENERAL