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Manufacturing of polymeric biocompatible cranial geometry by single point incremental forming

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Abstract

Incremental Sheet Forming (ISF) technology is used to manufacture customized products and its application to metallic prosthesis manufacturing has been already tested. However, the use of thermoplastic sheets as raw material in ISF is still reduced and therefore the manufacturing of polymer prosthesis by this technology too. In this framework, the objective of the present paper is to obtain a real cranial geometry of a feasible prosthesis manufactured by ISF using a biocompatible polymer. The real geometry of a cranial fracture is acquired from a computer tomography and treated until get a CAD model. From it, the trajectories have been defined and the cranial geometry manufactured.

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Keywords: SPIF; cranial prosthesis; biocompatible polymers

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1. Introduction

Usually, head injuries are produced by a punctual dynamic force; as an object which strikes the cranium or by cranium striking a static object. However, when fractures are produced, these are followed by tensile loads that could generate more fractures on other areas of the cranium.

Prostheses have the objective to patch a damaged area in order to heal the injury. In some cases, prostheses can support bone regeneration.

Cranium prostheses have a serial of characteristics that respond to a list of requirements. At the same time, these requirements are a consequence of the functions that customer expect from the device.

Cranial implants geometries are complex. Moreover, tendency of using custom cranial implants is increasing because of:

- Innovation and evolution of digital modelling and cranial reconstruction.
- Advances on news manufacturing processes.
- To face up to different types and geometries of fractures.
- To improve patient's quality of life.

Therefore, nowadays research is focused on customized prostheses and there is not interesting to develop a standard product to produce in mass series [1]. In those conditions, the easiest and quickest way to manufacture those kinds of geometry is by direct metal laser sintering (DMLS), selective laser sintering (SLS), electrochemical machining (ECM) or deforming plates.

Focusing on material, there are two main groups of cranium prostheses: metallic or plastic. Metallic ones are the most used prostheses because of their load-bearing properties so that, plastic prostheses aren't so used. However, plastic prostheses have some advantages as biodegradation, lightness or providing easier bone fusion so nowadays, research in both materials is being done.

ISF is a relatively new technology useful to manufacture full or scale size prototypes as well as small batch or one-of-a-kind sheet products. The main components of ISF technology are: i) the blank or raw material in sheet form which is fixed by a clamping device, ii) the blank is progressively deformed using a hemi-spherical end forming tool, iii) the movement of the tool is driven by a CNC machine or robot.

The technology of ISF is mainly applied in the automotive and aeronautic sectors, either to obtain functional parts or prototypes. However, there are other fields with an important potential for the technology, such as the biomedical. Several works in the literature used ISF to produce ankle prosthesis [2], cranial implant [3,4], palate implant [5], a part for a knee implant [6] and most recently several maxillofacial implants [7]. There are also some preliminary studies that use ISF for producing medical devices, such as mesoforceps for biopsy [8]. All of these applications have been manufactured using metallic materials. Some biocompatible metallic materials, such as titanium, are very difficult to deform at room temperature. Therefore an additional heating system should be used in order to increase the formability and to produce the desired part. Nowadays, there are scarce publications dealing with the production of any biomedical device or prosthesis manufactured with Incremental Sheet Forming using biocompatible polymers. Fiorentino et al. [9] manufactured a plate prosthesis using a titanium alloy and PCL (polycaprolactone). Although their results were promising, an optimization of the process parameters should be done in order to increase the accuracy of the part. Thus, a niche market where the use of biocompatible polymers manufactured by ISF can provide remarkable advantages in terms of low cost and reduced time to market has been identified.

The first research work in which the feasibility of using ISF to produce parts with thermoplastic materials was demonstrated was done by Franzen et al. [10]. The paper was focused on the evaluation of the performance of PVC (polyvinylchloride) in SPIF applications. The test geometry used was a hyperbolic frustum cone. The formability limits and accuracy were characterized and evaluated by varying some process parameters (sheet thickness and tool diameter). The results identified new deformation mechanisms associated with the polymer behavior.

In another work, Le et al. [11] published the results of a preliminary set of experiments for the SPIF of PP (polypropylene). The influence of the forming parameters and their interaction on the formability was analysed.

The work of Martins et al. [12] has also been focused on the evaluation of the applicability of different polymers in the process of SPIF. Five polymers were studied: POM (polyoxymethylene, which has a high-crystalline structure), HDPE (high density polyethylene), PA (polyamide), PVC, PC (polycarbonate, amorphous structure). For each material FFLDs (Fracture Forming Limit Diagrams) were obtained.

The aim of the present paper is to provide a preliminary study to evaluate the feasibility of producing customized cranial implants with an acceptable geometrical accuracy using the technology of Single Point Incremental Forming (SPIF) in polymeric biocompatible materials.

2. Methodology

2.1. Geometry

As explained by [13], ISF technology is potentially available to any manufacturing facility having CNC machinery and CAD/CAM software. Nevertheless, there is not yet CAD/CAM software dedicated for ISF. In consequence, several design-manufacturing iterations are required before attaining a satisfactory component.

In order to produce a customized prosthesis, the first step is to obtain medical images using computerized tomography (CT). These images will be processed in a specific software, InVesalius®, to obtain a 3D model. With this information a CAD model of the prosthesis will be developed.

Fig. 1 shows the cranial fracture and the prosthesis needed to heal this injury. Fig. 2 shows the CAD model.

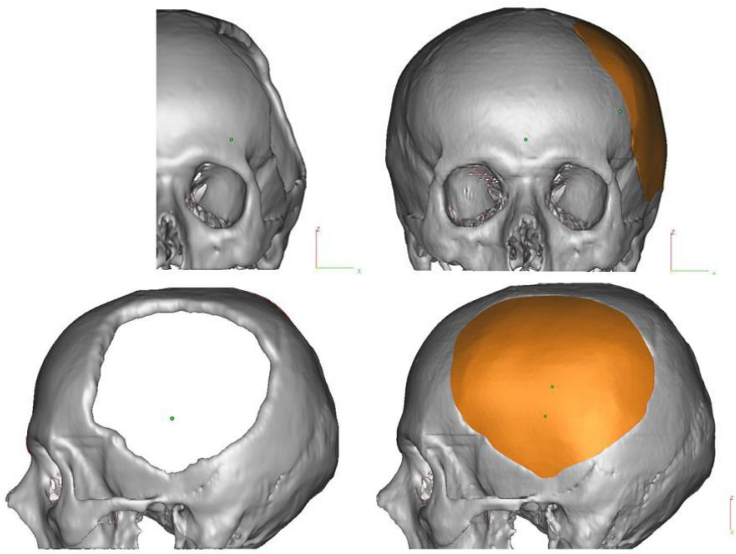

Fig. 1. Cranial fracture (left) and prosthesis (right). Source: Centro de Tecnologia de Informação Renato Archer (CTI).

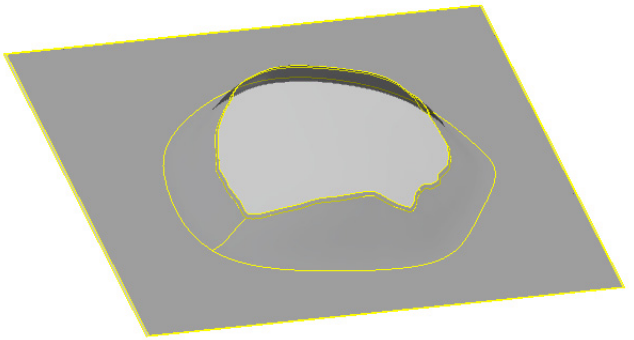

Fig. 2. Prosthesis CAD model.

2.2. Material

Among the biocompatible polymers, polycaprolactone (PCL) is of great interest due to some properties such as a low melting point (59 ºC – 64 ºC), exceptional blend-compatibility, high flexibility, and medium Young's modulus at room temperature which has stimulated extensive research on its potential application in the biomedical field since 1980. Nowadays, the main commercial application of PCL is in the manufacture of biodegradable bottles and films, but according to Khan et al. [14], bio-medical applications such as synthetic wound dressings, encapsulants for drug release systems and contraceptive implants are becoming increasingly common.

PCL it is usually commercially sold as pellets (e.g. for injection moulding applications) or as wire (used for example in 3D printers), however it is quite complicate to commercially obtain PCL in sheet form. Therefore, in order to manufacture the polymer biocompatible sheets, the pellets of PCL are introduced in a square mould. Afterwards, the mould is put on the heating press, at the melting temperature of the polymer. A press of 2.5 Tn is applied during approximately 3.5 min and then the press is increased until 30 Tn during 2 min. Finally, the mould is moved to a cooling press, applying 30 Tn of pressure until reaching the room temperature. This procedure is graphically summarized in Fig. 3.

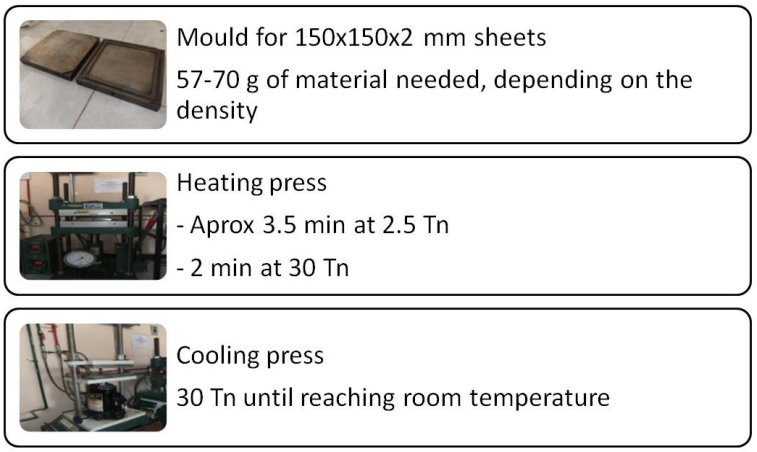

Fig 3. Procedure for manufacturing biocompatible polymer sheets.

2.3. Experimental set-up

The experimental tests were conducted in a 3-axis milling machine. A fixture system compound by a blank supporting die allocated between the bottom and top plate of the ISF fixture was bolted on the force measurement system. The blank sheet was placed between the clamping and the top plate (Fig. 4). The dimensions of the blank sheets were 150x150x2 mm and the effective working area was 120x120 mm. The forming was made with a hemispherical Vanadis 23 steel tool. In order to decrease friction effects, the interface between tool and blank was lubrified using oil.

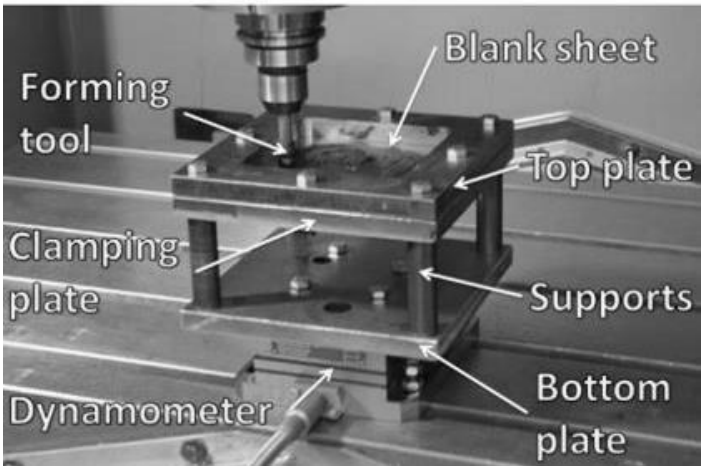

Fig. 4. SPIF process experimental set-up.

The selection of the process parameters has been done according to the results obtained from previous experiments that allowed increasing the knowledge regarding the polymer behaviour during the ISF process [15]. It was demonstrated that spindle speed had an important effect on the heat generation due to the friction between the tool and the blank. For higher spindle speeds, which lead to an increase of the temperature, the forming force was reduced and the formability was increased.

In the present case, it has been used a free spindle speed, in order to minimize the friction between the tool and the blank and therefore the increase in the forming temperature. This is because it is necessary to guarantee that the forming temperature does not reach the melting temperature of PCL which is very low as mention in the previous section. The tool diameter is 6 mm, the step down 0.2 mm and the feed rate is 3000 mm/min.

Once the final part is obtained, a portable 3D scanning system Handyscan® 3D 300 is used to acquire the final dimensions and compare them with the CAD file. The real and the designed surfaces are aligned and several sections are obtained to be able to quantify the deviations.

3. Results and discussion

This section presents the accuracy of the cranial implant produced by SPIF. Fig. 5 shows the manufactured cranial implant using PCL and Fig. 6 shows the superposition of the real part and the designed part surfaces.

Fig. 7 quantifies the deviations on a central section of the part. This section has been chosen because is where the major differences between the real and the designed part can be found. From this figure it can be observed that the major deviations are in the steepest zones, in which the degree of deformation is higher, obtaining deviations from 2.5 to 4 mm. In the central part of the implant, the deviations are lower and more homogeneous, between 0.6 and 1.2 mm. The lateral zones have deviations although the sheet is not deformed, however, when the sheet is released from the frame of the fixture system, the material recovers due to the springback effect.

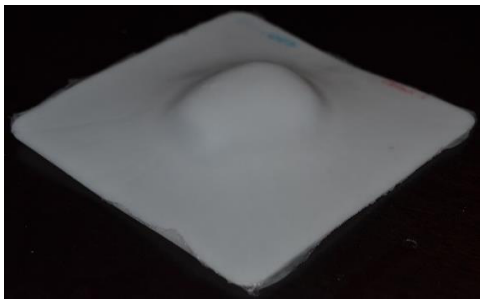

Fig. 5. Manufactured cranial implant using SPIF.

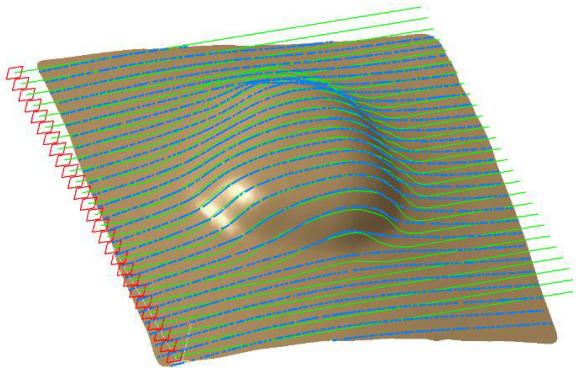

Fig. 6. Superposition of the manufactured (blue lines) and designed (green lines) parts.

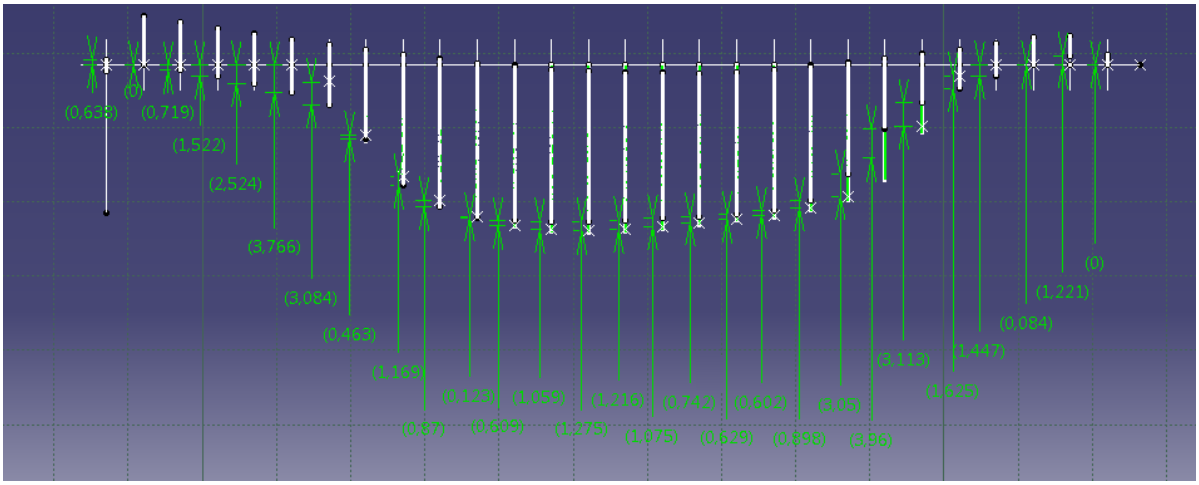

Fig. 7. Deviations between the manufactured and designed parts.

As it can be noticed the results are very promising because it has been demonstrated the viability of producing a part with ISF using a biocompatible polymer obtaining an acceptable accuracy, even using the simplest ISF process variant, SPIF. In order to improve the results, several strategies could be performed, such as a modification of the toolpath or by using the TPIF process variant with a full negative die.

4. Conclusions

The results of the present paper have demonstrated that is possible to obtain a real cranial implant using a biocompatible polymer (PCL) by SPIF. However, to improve the accuracy it would be necessary to use a full negative die, hence shift into Two Point Incremental Forming. Moreover, several iterations involving the modification of the tool-path could be necessary.

The prosthesis manufacturing using a thermoplastic polymer by ISF technology should not be faced directly. It is necessary to deeply characterize the material and to obtain knowledge about the polymer behaviour under the ISF conditions. In the present case, this knowledge has been extrapolated from previous works of the authors, that pointed out which were the most suitable process parameters in order to ensure the manufacturability of thermoplastic parts by SPIF using non-biocompatible polymers. In future work, an analogous study will be carried out using the biocompatible polymer tested in this work. Furthermore, it is not only crucial to obtain a satisfactory dimensional accuracy, also the mechanical properties of the manufactured cranial implant should be tested in order to guarantee the biomechanical requirements.

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