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Five-Year Safety and Performance Results from the Argus II Retinal Prosthesis System Clinical Trial

da Cruz, L.[a], Dorn, J.D.[b], Humayun, M.S.[c], Dagnelie, G.[d], Handa, J.[d], Barale, P.-O.[e], Sahel, J.-A.[e,f,g], Stanga, P.E.[i], Hafezi, F.[c,h,j], Safran, A.B.[f,j], Salzmann, J.[j], Santos, A.[k], Birch, D.[l], Spencer, R.[m], Cideciyan, A.V.[n], de Juan, E.[o], Duncan, J.L.[o], Eliott, D.[c,p], Fawzi, A.[c,q], Olmos de Koo, L.C.[c], Ho, A.C.[r], Brown, G.[r], Haller, J.[d,r], Regillo, C.[r], Del Priore, L.V.[s], Arditi, A.[t], Greenberg, R.J.[b]

[a]Department of Vitreoretinal Surgery, Moorfields Eye Hospital, NHS Foundation Trust, NIHR Moorfields Biomedical Research Centre, London United Kingdom and Department of Brain Science, University College London (UCL), United States

[k]Centro de Retina Medica y Quirúrgica, SC, Tecnológico de Monterrey, Guadalajara, Mexico

Purpose The Argus II Retinal Prosthesis System (Second Sight Medical Products, Inc, Sylmar, CA) was developed to restore some vision to patients blind as a result of retinitis pigmentosa (RP) or outer retinal degeneration. A clinical trial was initiated in 2006 to study the long-term safety and efficacy of the Argus II System in patients with bare or no light perception resulting from end-stage RP. Design Prospective, multicenter, single-arm clinical trial. Within-patient controls included the nonimplanted fellow eye and patients' native residual vision compared with their vision with the Argus II. Participants Thirty participants in 10 centers in the United States and Europe. Methods The worse-seeing eye of blind patients was implanted with the Argus II. Patients wore glasses mounted with a small camera and a video processor that converted images into stimulation patterns sent to the electrode array on the retina. Main Outcome Measures The primary outcome measures were safety (the number, seriousness, and relatedness of adverse events) and visual function, as measured by 3 computer-based, objective tests. Secondary measures included functional vision performance on objectively scored real-world tasks. Results Twenty-four of 30 patients remained implanted with functioning Argus II Systems at 5 years after implantation. Only 1 additional serious adverse event was experienced after the 3-year time point. Patients performed significantly better with the Argus II on than off on all visual function tests and functional vision tasks. Conclusions The 5-year results of the Argus II trial support the long-term safety profile and benefit of the Argus II System for patients blind as a result of RP. The Argus II is the first and only retinal implant to have market approval in the European Economic Area, the United States, and Canada.

SciVal Topic Prominence
Topic: Visual Prosthesis | Retina | prosthetic vision
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MeSH:	Adult; Aged; Blindness; Female; Follow-Up Studies; Humans; Male; Middle Aged; Prospective Studies; Prosthesis Design; Retina; Retinitis Pigmentosa; Time Factors; Treatment Outcome; Visual Acuity; Visual Prosthesis; Visually Impaired Persons

Device tradename:
Argus II Retinal Prosthesis System, Second Sight Medical Products, United States, Watzke sleeve

Manufacturers:
Device manufacturer:
Second Sight Medical Products, United States

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