Ophthalmology
Volume 122, Issue 8, 1 August 2015, Pages 1547-1554

Long-Term Results from an Epiretinal Prosthesis to Restore Sight to the Blind

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Abstract
Purpose Retinitis pigmentosa (RP) is a group of inherited retinal degenerations leading to blindness due to photoreceptor loss. Retinitis pigmentosa is a rare disease, affecting only approximately 100 000 people in the United States. There is no cure and no approved medical therapy to slow or reverse RP. The purpose of this clinical trial was to evaluate the safety, reliability, and benefit of the Argus II Retinal Prosthesis System (Second Sight Medical Products, Inc, Sylmar, CA) in restoring some visual function to subjects completely blind from RP. We report clinical trial results at 1 and 3 years after implantation. Design The study is a multicenter, single-arm, prospective clinical trial. Participants There were 30 subjects in 10 centers in the United States and Europe. Subjects served as their own controls, that is, implanted eye versus fellow eye, and system on versus system off (native residual vision). Methods The Argus II System was implanted on and in a single eye (typically the worse-seeing eye) of blind subjects. Subjects 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. Results A total of 29 of 30 subjects had functioning Argus II Systems implants 3 years after implantation. Eleven subjects experienced a total of 23 serious device- or surgery-related adverse events. All were treated with standard ophthalmic care. As a group, subjects performed significantly better with the system on than off on all visual function tests and functional vision assessments. Conclusions The 3-year results of the Argus II trial support the long-term safety profile and benefit of the Argus II System for patients blind from RP. Earlier results from this trial were used to gain approval of the Argus II by the Food and Drug Administration and a CE mark in Europe. The Argus II System is the first and only retinal implant to have both approvals.

SciVal Topic Prominence
Topic: Visual Prosthesis | Retina | prosthetic vision
Prominence percentile: 96.468

Indexed keywords

EMTREE medical terms:	Adult; aged; Article; camera; clinical article; clinical evaluation; conjunctival dehiscence; conjunctival erosion; controlled study; cornea opacity; device safety; endophthalmitis; Europe; female; follow up; function test; functional assessment; human; hypotony; keratitis; male; medical device complication; multicenter study; outcome assessment; personal experience; priority journal; prospective study; retina detachment; retina tear; retinal implant; United States; uveitis; vision; visual function test; blindness; clinical trial; electrode implant; microelectrode; middle aged; pathophysiology; physiology; prosthesis implantation; reproducibility; retinitis pigmentosa; single blind procedure; Vision, Low; visual acuity; visual prosthesis
MeSH:	Adult; Aged; Blindness; Electrodes, Implanted; Female; Follow-Up Studies; Humans; Male; Microelectrodes; Middle Aged; Prospective Studies; Prosthesis Implantation; Reproducibility of Results; Retinitis Pigmentosa; Single-Blind Method; Vision, Low; Visual Acuity; Visual Prosthesis

Device tradename:
Argus II, Second Sight Medical Products, United States

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

- **ISSN:** 01616420
- **CODEN:** OPHTD
- **Source Type:** Journal
- **Original language:** English
- **DOI:** 10.1016/j.ophtha.2015.04.032
- **PubMed ID:** 26162233
- **Document Type:** Article
- **Publisher:** Elsevier Inc.