



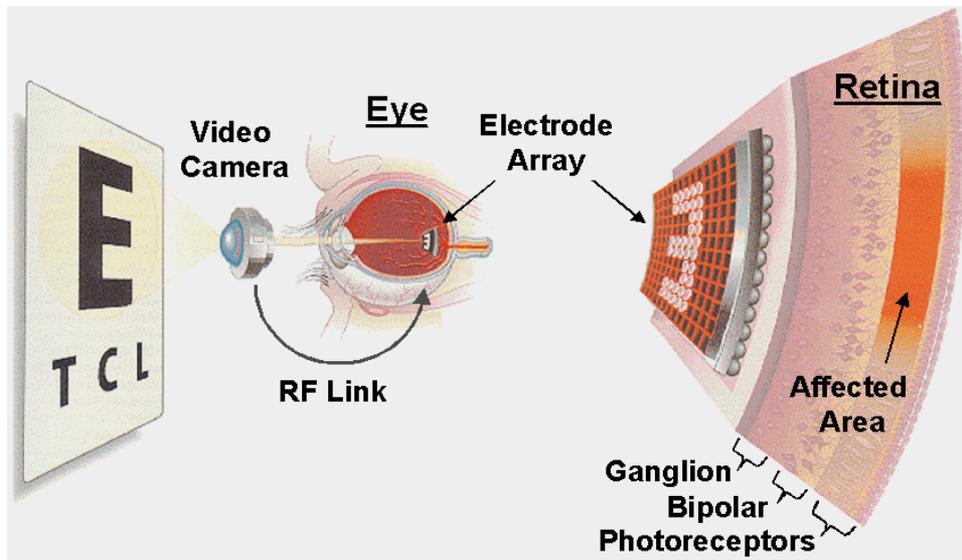
Second Sight

The Argus II Retinal Prosthesis System

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Argus II Study Group

Second Sight Medical Products, Inc., CA
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Retinal Implants



- Retinitis Pigmentosa (RP): affects ~100,000 Americans.

- Characterized by loss of some or all photoreceptor cells in retina.

Approaches:

- Sub-retinal
- Epi-retinal
- Supra-choroidal

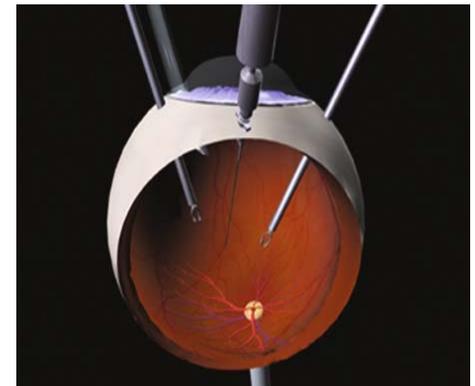
- Implant uses electrical stimulation to bypass defective photoreceptors and stimulate remaining viable retinal cells.
- Image data from an external camera is wirelessly transmitted to the implant which stimulates electrodes in an array on the retina to produce visual percepts.

Second Sight's Retina Implants

- Second Sight was founded in Dec 1998 by Al Mann to develop a commercial epi-retinal implant.
 - 100 employees in US and Europe.
 - Investor and NIH & NSF funding, DOE collaboration.
- Based on research that began in late 80s at Duke and Johns Hopkins (The group later moved to USC).
 - 1-2 hours of stimulation, demonstrated phosphene vision.



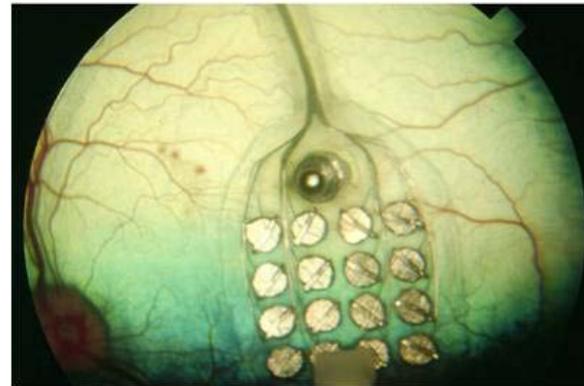
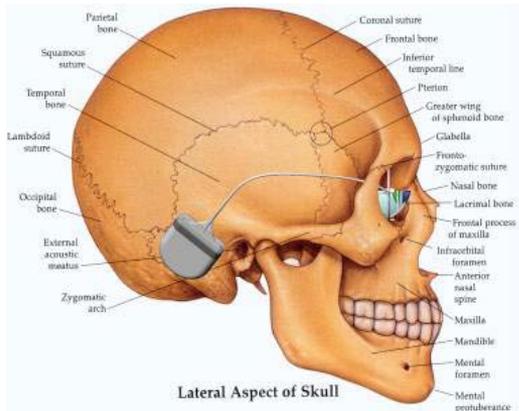
Sylmar Biomedical Park



Acute human trial

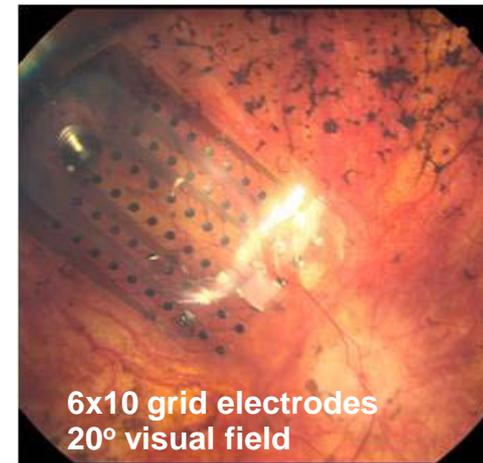
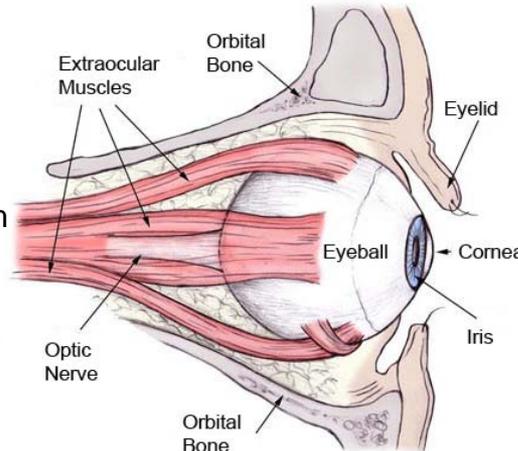
First Design: the Argus I

- Developed and clinically tested Argus[®] I prosthesis for proof of concept in 6 US subjects (2002 – present).
 - Based on Advanced Bionics' cochlear implant technology – with modified electronics.
 - 4x4 Pt disks in silicone.
 - Modified sound processor to video processing unit (VPU).

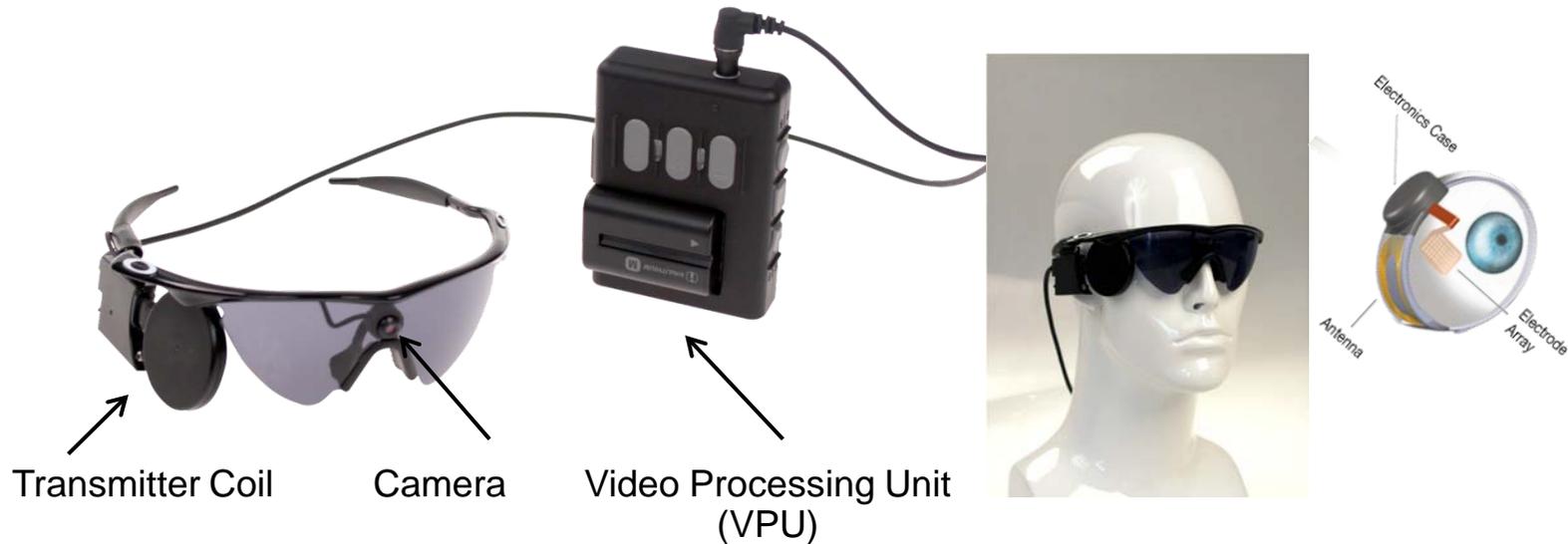


The Argus[®] II Retinal Prosthesis System: Implant

- A slim package with 60 independently controlled electrodes.
- Intra-orbital placement, reduced surgical time.



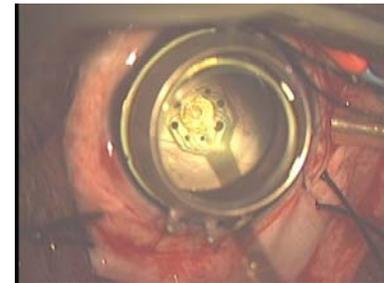
The Argus II Retinal Prosthesis System: External



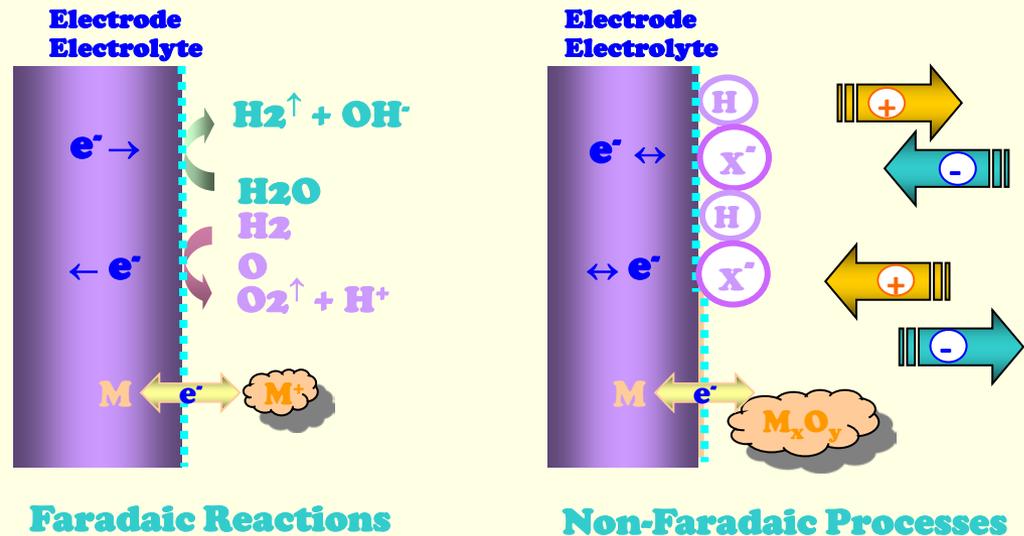
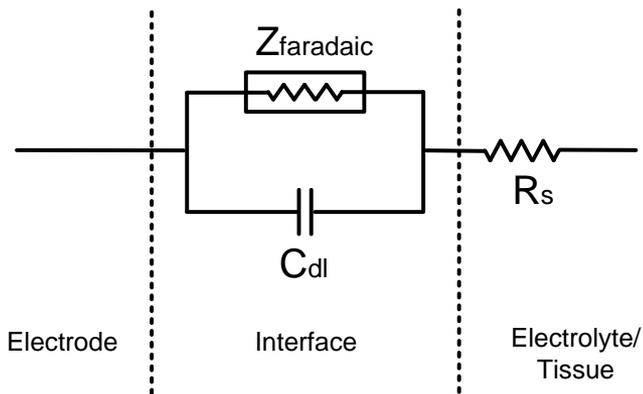
- Visual input received from video camera mounted on glasses and converted to a stimulation pattern by a body-worn processor.
- Wireless transmission of data and power to the implant.
- Subjects can adjust image processing.

Charge Injection Mechanisms

Electrical stimulation of biological tissue with metal electrodes requires the flow of ionic charge in the biological tissue

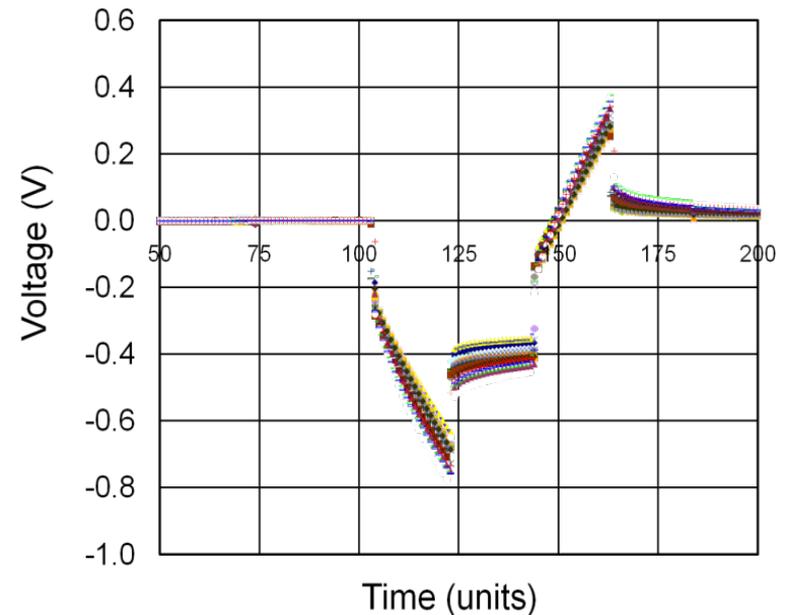
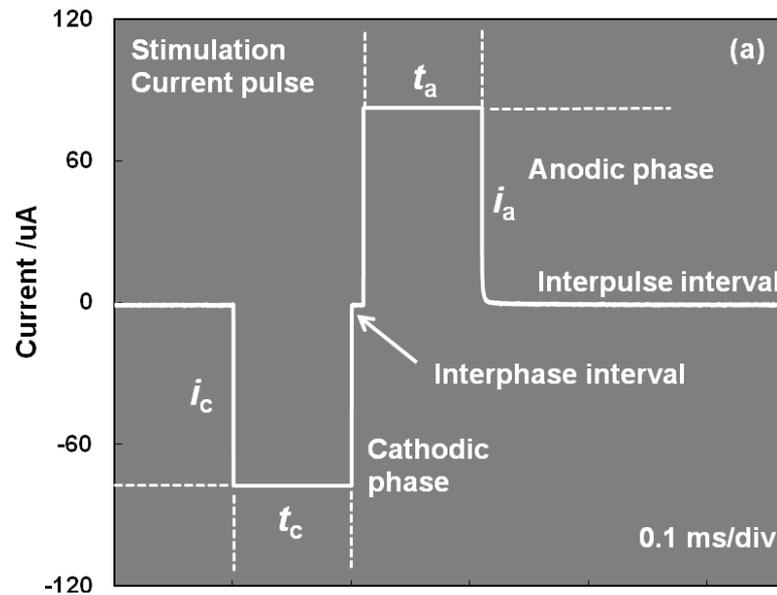


Faradaic and non-Faradaic mechanisms



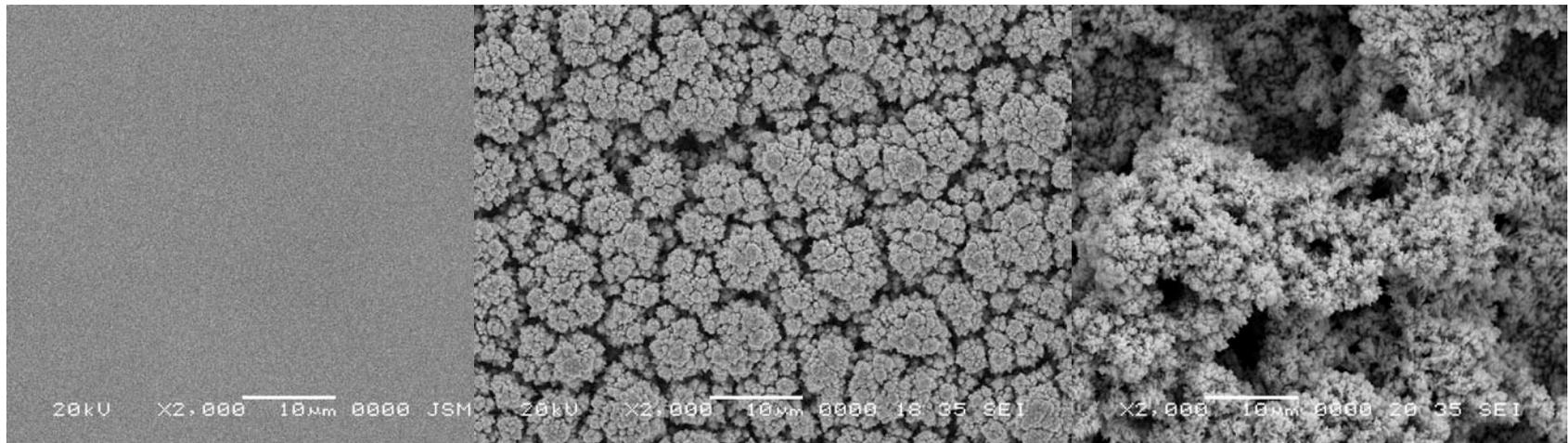
Neural Stimulation Pulses

- Biphasic, charge-balanced, cathodic-first current pulse
- Charge density limited to 0.35 mC/cm^2



Advanced Pt Electrode Materials

- Charge capacity is proportional to the electrochemical area of an electrode instead of its geometric surface area
- Solid Pt with smooth surface can't handle high charge injection density
- Pt black has very high surface area but is too soft for implantation
- Pt gray is similar to Pt black except that it is significantly more mechanically stable



Shiny Pt

Pt Gray

Pt Black

Long-term Reliability - Bench Testing

- Hermetic Package – Microelectronics
 - Demonstrated long-term survival over 10 years
- Thin-film electrode arrays
 - Provided long-term safe stimulation without corrosion or material degradation for over 26 years.
- Finished implants
 - Reached more than 10 years of lifetime in accelerated testing
- Device Biocompatibility
 - A series of tests per ISO-10993 and FDA G95-1 Guidelines



Dynamic lifetime test setup

Clinical Trial

- Multi-center, prospective, single-arm, non-randomized trial (2007-present)
- 5-year follow-up per subject (optional extension to 10 years)
- 30 subjects (age 58 +/-10, range 28 – 77) with severe to profound outer retinal degeneration have been implanted an average of 4.6 ± 1.1 years (range 3.5 to 5.9)*.
- Cumulatively, this represents 130+ subject-years clinical data with only one device failure (at 4 years post-implant).
- <http://clinicaltrials.gov/show/NCT00407602>.

* Range excludes one subject explanted at 14 months post-implant

Benefits of the Argus II System

The Argus II System can improve patient's orientation and mobility, activities of daily living, and well-being:

- Locate doors and windows
- Sort light and dark clothes
- Stay within a crosswalk
- Avoid obstacles
- Feel more socially connected
- Enjoy being “visual” again
- Tracking players on a field
- Watching fireworks

Summaries

- The bench testing and clinical trial demonstrated that Argus II can reliably withstand long-term implant (> 5 years) in a significant number of subjects (130+ subject-years) with an acceptable safety profile.
- Using the system, blind subjects showed improved performance on visual tasks, and results are sustained out to 5 years.
- The System received CE Mark in 2011 and FDA approval in 2013. Reimbursement applications pending; commercial launch in the US planned for 2013.



Second Sight

Thank you

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