



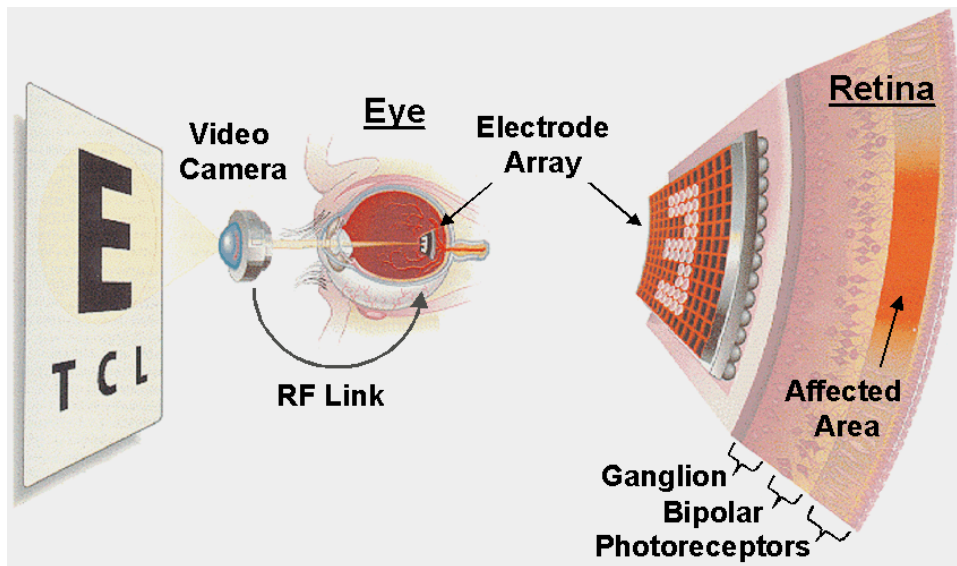
Second Sight

The Argus II Retinal Prosthesis System

David D. Zhou, Ph.D., Jessy D. Dorn, Ph.D., Robert J. Greenberg, M.D., Ph.D.,
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

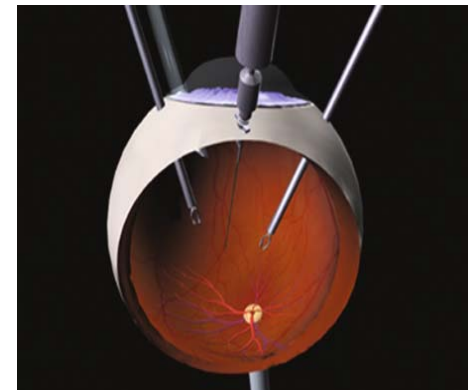
- Implant uses electrical stimulation to bypass defective photoreceptors and stimulate remaining viable retinal cells.
- Image data from an external camera is wirelessly transmitted to the implant which stimulates electrodes in an array on the retina to produce visual percepts.

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.



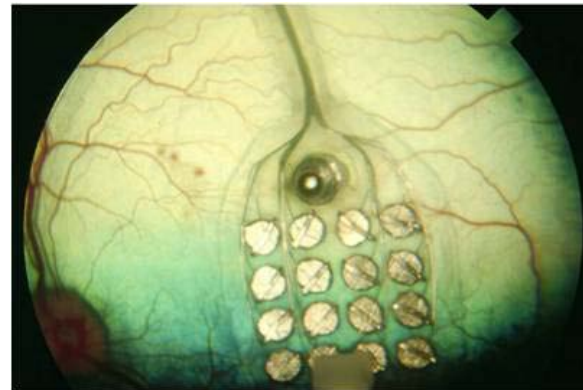
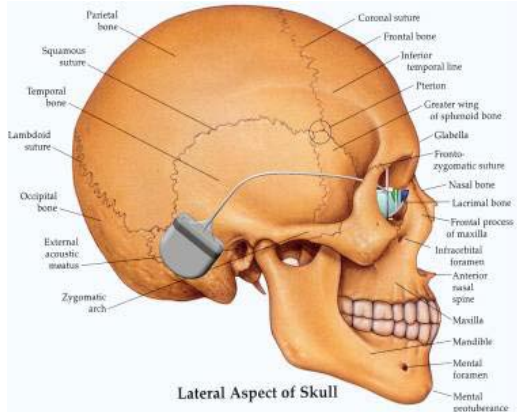
Sylmar Biomedical Park



Acute human trial

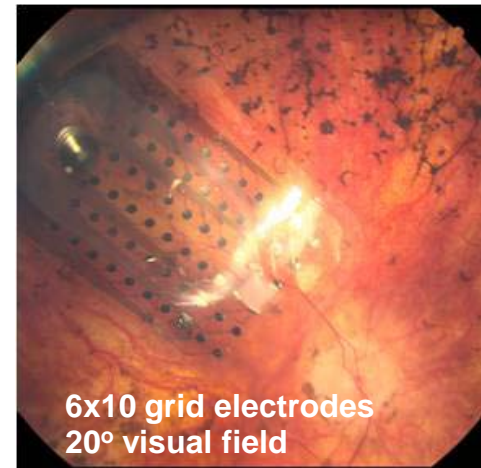
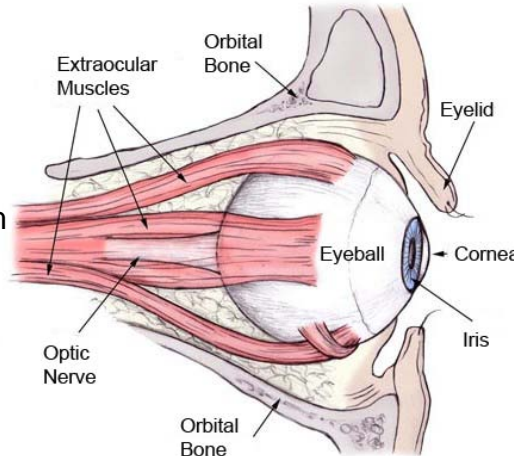
First Design: the Argus I

- 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).

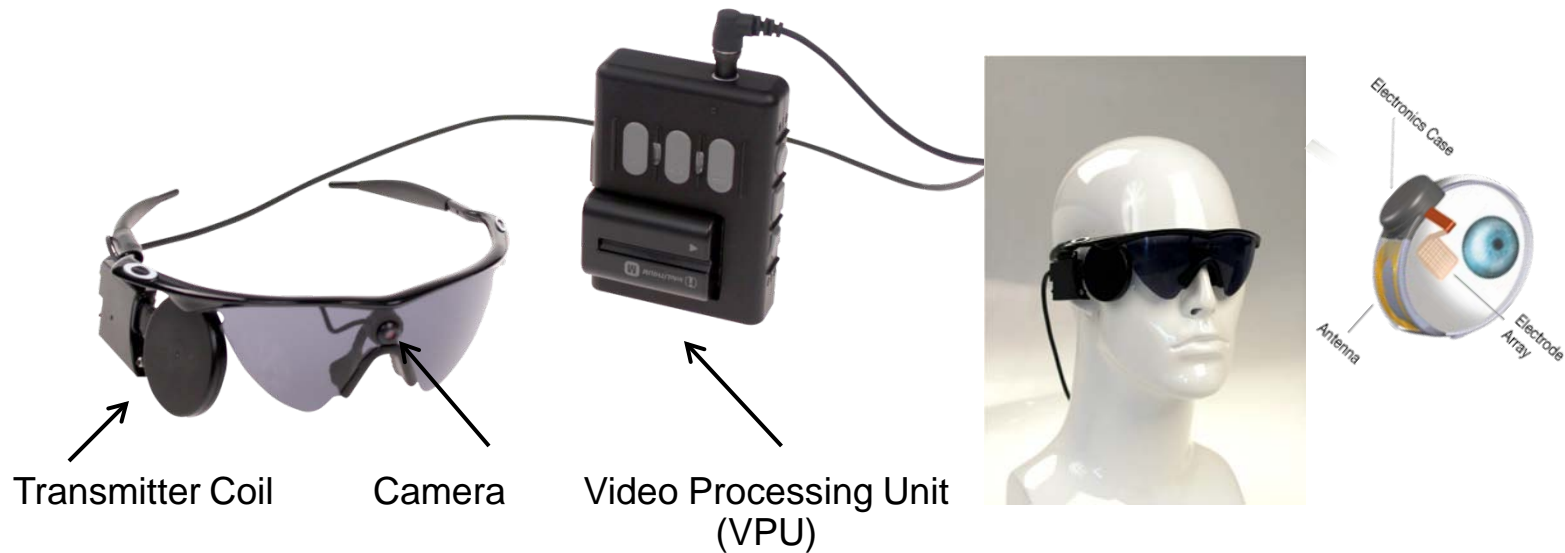


The Argus[®] II Retinal Prosthesis System: Implant

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



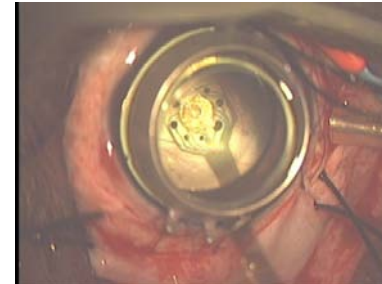
The Argus II Retinal Prosthesis System: External



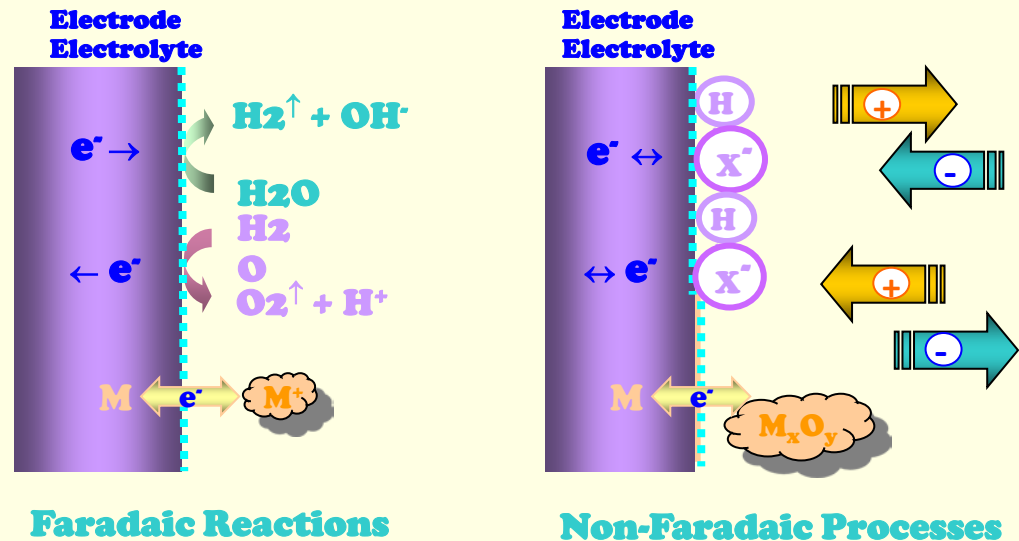
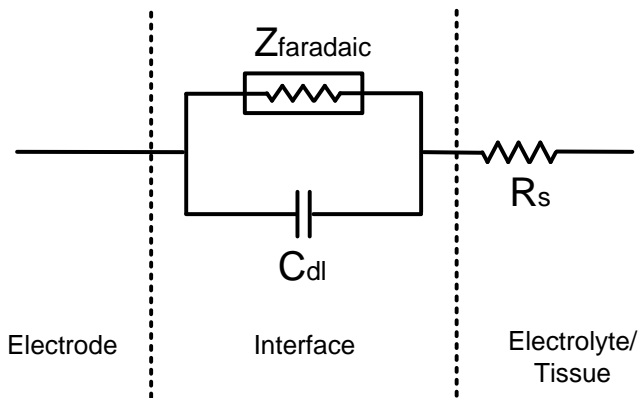
- Visual input received from video camera mounted on glasses and converted to a stimulation pattern by a body-worn processor.
- Wireless transmission of data and power to the implant.
- Subjects can adjust image processing.

Charge Injection Mechanisms

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

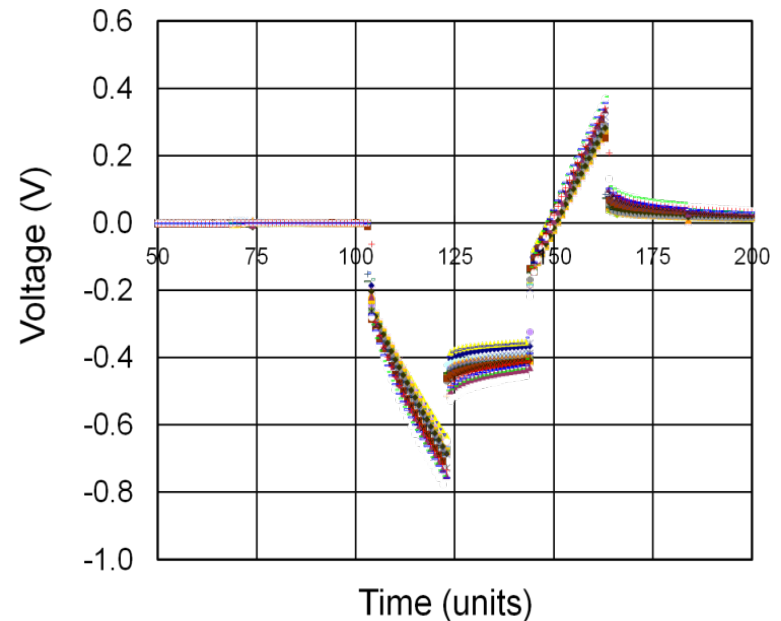
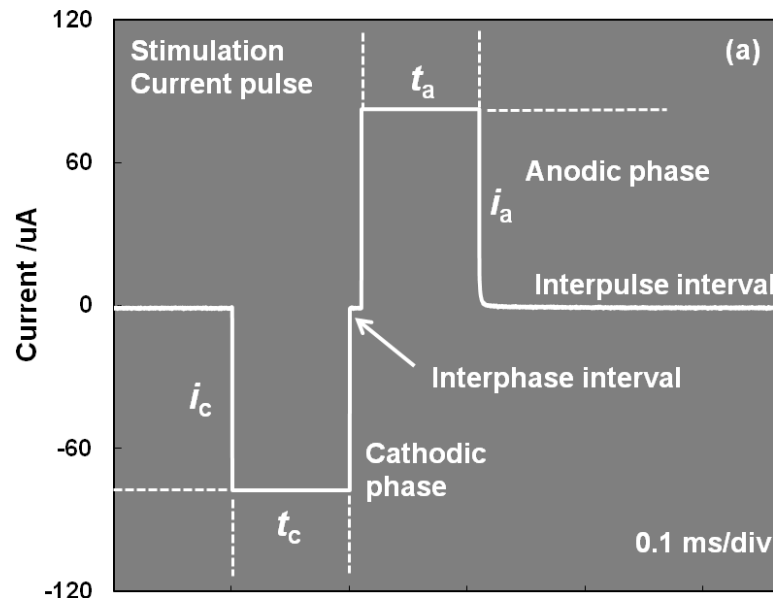


Faradaic and non-Faradaic mechanisms



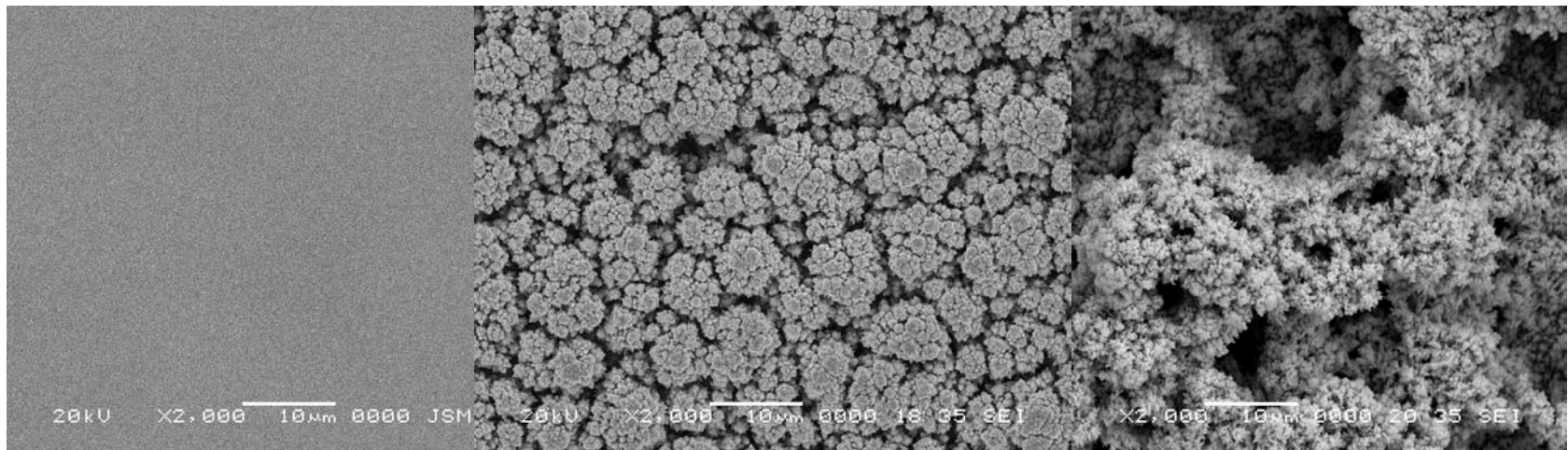
Neural Stimulation Pulses

- 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



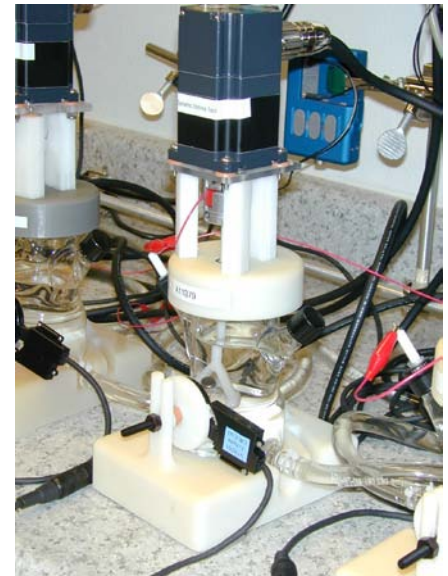
Shiny Pt

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 4.61.1 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

David Zhou, Chief Scientist
818-833-5042
dzhou@2-sight.com