The Argus II Retinal Prosthesis System

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Retinal Implants

- 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.

- 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
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.
First Design: the Argus I

  - 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

- **Faradaic Reactions**
  - $e^- \rightarrow H_2^\uparrow + OH^-$
  - $H_2O \rightarrow H_2 + O_2^\uparrow + H^+
  - $M + e^- \rightarrow M^+$

- **Non-Faradaic Processes**
  - $X^- \rightarrow H + X^+$
Neural Stimulation Pulses

- Biphasic, charge-balanced, cathodic-first current pulse
- Charge density limited to 0.35 mC/cm²
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
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
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).

* 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.
Thank you

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