Retinal Prosthesis for the Blind

James D. Weiland, PhD
Professor of Ophthalmology and Biomedical Engineering
University of Southern California
Retinal Prosthesis
Systems Level Description

- External camera/image processor detects image and performs conversion to digital information
- Telemetry link between external and implanted units
- Implanted unit recovers power and data
- Implanted unit applies commanded stimulus pattern to the retina via a microelectrode array on the surface of the retina
Retinal Prosthesis Clinical Status

• Two devices have regulatory approval
• Clinical trials of others
  – Epi-ret, IMI, Optobionics, Bionic Vision Australia, Nidek
• Patients generally like implants and are happy they participated
• Helps with navigation
• Visual acuity remains an issue for all devices
• Each device has specific challenges that must be addressed
Alpha IMS (Retina Implant GmbH)

Main results
• Light perception
• Letter reading
• Object discrimination
• CE Mark

Main problems
• Longevity (less than 2 years)
• Form Vision
Argus II Retinal Prosthesis
(Second Sight Medical Products, Inc.)

• EU and FDA approval
• 6x10 micro-fabricated electrode array
  – Polymer substrate
  – High surface area platinum
• Improved mobility demonstrated in multi-center clinical trial (n=30)
• Letter reading in majority of subjects
# Second Sight Argus II Study Group

<table>
<thead>
<tr>
<th>Site</th>
<th>Investigators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moorfields Eye Hospital (London, UK)</td>
<td>Lyndon da Cruz[^F], Andrew Webster[^F]</td>
</tr>
<tr>
<td>Johns Hopkins Hospital (Baltimore, MD)</td>
<td>Gislin Dagnelie[^F], James Handa[^F]</td>
</tr>
<tr>
<td>Quinze-Vingts (Paris, France)</td>
<td>José-Alain Sahel[^F], Saddekh Mohand-Said[^F], Pierre-Olivier Barale[^F], Sarah Scheer[^F]</td>
</tr>
<tr>
<td>Manchester Royal Eye Hospital (Manchester, UK)</td>
<td>Paulo Stanga[^F], Susmito Biswas[^F], George Turner[^F]</td>
</tr>
<tr>
<td>Puerto de Hierro (Guadalajara, Mexico)</td>
<td>Arturo Santos[^F], Enrique Roig[^F]</td>
</tr>
<tr>
<td>Doheny Eye Institute (Los Angeles, CA)</td>
<td>Lisa Olmos[^F], Amani Fawzi[^F], Dean Eliott[^F], Mark Humayun[^F][^PC], Rajat Agrawal[^FC], James Weiland[^FI]</td>
</tr>
<tr>
<td>UC San Francisco (San Francisco, CA)</td>
<td>Jacque Duncan[^F], Eugene de Juan[^F][^PC]</td>
</tr>
<tr>
<td>Retina Foundation of the Southwest (Dallas, TX)</td>
<td>David Birch[^F], Eugene Filley[^F], Rand Spencer[^F]</td>
</tr>
<tr>
<td>Hôpitaux Universitaires de Genève (Geneva, Switzerland)</td>
<td>Farhad Hafezi[^F], Avinoam Safran[^F], Joel Salzmann[^F], Marco Pelizzone[^F], Jörg Sommerhalder[^F], Angelica Perez-Fornos[^F]</td>
</tr>
<tr>
<td>Scheie Eye Institute (Philadelphia, PA)</td>
<td>Artur Cideciyan[^F], Samuel Jacobson[^F]</td>
</tr>
<tr>
<td>Wills Eye Hospital (Philadelphia, PA)</td>
<td>Gary Brown[^F], Allen Ho[^F], Carl Regillo[^F], Julia Haller[^F]</td>
</tr>
<tr>
<td>Columbia University (New York, NY)</td>
<td>Lucian del Priore[^F], Steven Tsang[^F]</td>
</tr>
<tr>
<td>Lighthouse International (New York, NY)</td>
<td>Aries Arditi[^F]</td>
</tr>
<tr>
<td>Second Sight Medical Products, Inc.</td>
<td>Robert Greenberg[^LE,P]</td>
</tr>
</tbody>
</table>

Funding/Support: National Institutes of Health Grant EY12893 and Second Sight Medical Products, Inc.
Argus II Clinical Trial

• 30 Subjects at 10 centers in North America and Europe (proceeded by 6 subject Argus I trial at USC)
• All subjects see phosphenes with the System
• All subjects have used the system at home
• Studies to be reviewed (Humayun et al. 2012)
  – Object Localization
  – Motion Discrimination
  – Orientation and Mobility
Square Localization in Argus II Patients

- Square is 2.8” X 2.8”
- 40 trials System ON
- 40 trials System OFF, natural viewing

sample data from USC-001
Compare the mean distance from the center of the target for the two conditions

★ significant difference between the means

27 out of 28 subjects (96%) perform better with the System ON vs. OFF
Direction of Motion

- Target bar is 1.4” wide, speed is chosen based on the subject’s preference
- 80 trials System ON
- 80 trials System OFF, natural viewing

Sample data from JHU-002
Compare the error distributions for the two conditions (target-response direction)
★ = significant difference between the means

16 out of 28 subjects (57%) perform this test better with System ON vs. OFF
1 subject performs it better with the System OFF vs. ON
Orientation & Mobility

Door Task

- 6 trials ON and 6 trials OFF. All tests performed binocularly.
- Success = touching the door or ending the course on the line

Line Task
Door Test

★ p<0.05 (Repeated measures analysis of variance [RM ANOVA])
Line Test

![Graph showing observed average success rates with and without system](image)

- Baseline: 20% (n = 30)
- 3 Month: 26% (n = 27)
- 6 Month: 23% (n = 29)
- 12 Month: 25% (n = 14)
- 18 Month: 23% (n = 13)
- 24 Month: 15% (n = 8)

★ p<0.05 (RM ANOVA)
Mobility Testing
Number Reading
Outdoor mobility

- \movies\Paris subject outdoors.m4v
Argus II Current Status

• Clinical Trial Summary
  – 140 implant years
  – 2 implant failures
  – 3 explanted devices (2 elective, 1 recurrent conjunctival erosion)
  – Subject generally like the device
• CE Mark and FDA Approval for treatment of severe retinitis pigmentosa
• 40 commercial implants, first US commercial implant soon
• Stanislao Rizzo, MD, in Pisa, Italy is leading implant surgeon in Italy
• As of October 1, 2013, CMS approved New Tech Add on (in-patient) and Transitional Pass Through Payments (out-patient)
• Research areas: improving quality of visual experience, provide peripheral vision, use computer vision to emphasize important areas of the scene, brain mapping
Wearable Visual Aid
Wearable Visual Aid - Demos

- ..\movies\tatrc\Blurred_Avi.avi
- ..\movies\tatrc\olts_result_video_nomark.mp4
- ..\movies\tatrc\IMG_0407.MOV
Summary

- Retinal prosthesis show promise to restore partial vision in cases of severe retinitis pigmentosa

- Computer vision systems can provide useful information to help accomplish tasks usually guided by vision and may work in concert with a retinal prosthesis