IPRO-306: Midterm Presentation

Planning for Human Implantation of an Intracortical Visual Prosthesis
What is Blindness?

• 10 million Americans
• 1.3 million are legal
• Legally Blind: central visual acuity of 20/200 in good eye (BPC), visual field of < 20 degrees
• 5.5 million > 64 years of age
Use electrical stimulation of the neural tissue to restore function in individuals with disabilities due to damage of the nervous system.

Neural prosthetic devices process input from outside the body & transmit visual information to the nervous system.

Communicates with specific groups of neurons in the visual cortex to restore visual function.
Goal: Research and compile the ethical, medical, psychological, engineering, regulatory, and media/political issues in determining the readiness of implementing an intracortical visual prosthesis in a human volunteer.
Sub Team Structure

- **Medical** - Andrew and Marin
- **Engineering/Regulatory** - Minh and Saurabh
- **Psychological** - Joshua and Peter
- **Ethical** - Joel and Kevin
- **Media/Politics** - Joel, Dawn, and Andrew

Advisors: Professor Troyk and Professor Huyck
Engineering an Intracortical Visual Prosthesis (IVP)
Investigational Device Exemptions (IDE): General Considerations

- Our device is Significant Risk since it’s implanted into the human body. (IDE regulation 21 CFR 812)
- Safety
- Effectiveness
- Volunteer safety is more important than success

IDE Performance Data

- Pre-clinical Data
- Animal Testing
- Clinical Data
DEVICE SAFETY

- **Electrode Safety Issues**
  - Electrode protection
  - Neuron Protection

- **Material Safety**
  - Fluids might leak though were electrodes and silicone meet
  - Difference in silicone grades

**Future Plans:**
- Study regulations for medical and industrial grade materials
- Identify procedures needed for human implantation (pre-clinical data, rehabilitation plan etc.)
Ethics Team

Current Goals
- Extensive research
  - Informed Consent
  - Education of Patient/Guardian
  - Risks vs. Benefits (if any)
  - Length of Care Term, Extent of Responsibility
  - Can volunteers benefit from new, improved technology

Future Plans
- Plan for handling issues with best possible results
Medical Aspects

Research the issues associated with implanting a visual prosthesis.

- Damage
- Reprogramming the brain
- Benefits?

Future Plans

- More fully understand the previously stated issues.
- Study if the device can keep up with degenerating conditions.
- Research the rehabilitation needed after implantation.
Psychology

Research
• Demographics
• “False Hope”
• Rehabilitation

Continuing Research
• Level of adjustment to disability
• Types of blindness

Feedback from the Community
• Surveys
• Focus groups
Goal: Properly transmit the objective of product to the public

Current Research
- Regulations
- Educate public (show how product its advantages)
- Advertisement/Public Relations
- Public reaction and feedback
- Product information release
- Other applications of product

Future Research
- Continue research
- Surveys (research how population would respond to the product)
Sponsors

– Intracortical Visual Prosthesis Team at IIT
  • University of Chicago
  • Huntington Medical Research Institute, Pasadena, CA
  • EIC Laboratories, Norwood, MA
  • Micro Probe Inc, Frederick Maryland
Questions???