IPRO 334 Planning for Human Implantation of a Cortical Visual Prosthesis

ILLINOIS INSTITUTE OF TECHNOLOGY

BACKGROUND

Sponsor

This IPRO project is sponsored by the Intracortical Visual Prosthesis Team at IIT, which includes the University of Chicago, Huntington Medical Research Institutes in Pasadena, CA, EIC Laboratories in Norwood, MA, and Micro Probe Inc in Frederick, Maryland.

Device

For the past two decades there has been intensive research on visual prosthesis around the world and significant technological advancements have been made. The Intracortical Visual Prosthesis Team at IIT has been developing a procedure as well as a prosthetic device which will be implanted within the human visual cortex. The prosthetic consists of a distributed array of stimulator units which create visual perceptions known as phosphenes by sending electric currents through microelectrodes into the brain.

PROBLEM

The IIT team is rapidly approaching a point in their development process where they would like to begin studying the device in a human volunteer. There are a wide variety of factors that need to be considered before the IIT team can begin human implantation. There is a lack of guidelines for selecting volunteers for a human study and it needs to be assessed whether or not the device is ready for implantation. The team is requesting recommendations for how to proceed given the current status of the device and their hopes for implantation in the near future.

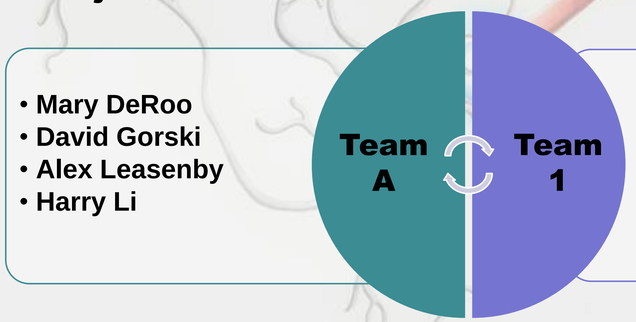
OBJECTIVES

- **To research the current state of the device to provide suggestions and pose questions to the sponsor regarding their progress towards human implantation.**
- **To create a framework for the selection of potential volunteers.**
- **To create a report analyzing the current progress of the sponsor's device and what further action required on behalf of the sponsor to begin human implantation trials.**

METHODOLOGY

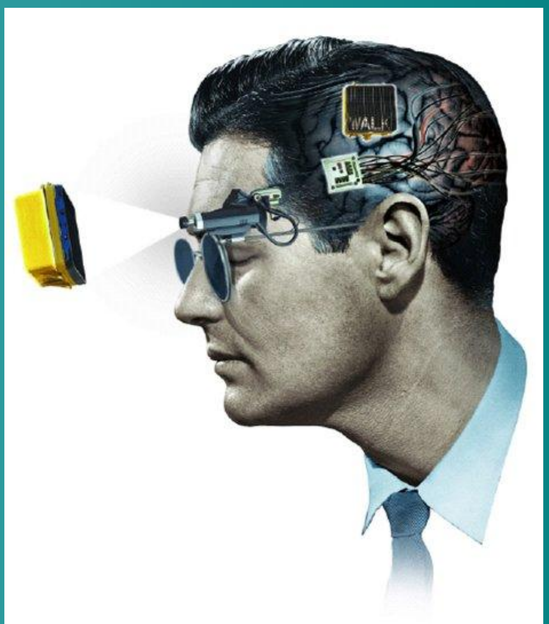
Team A: Subject Selection Team

- Mary DeRoo
- David Gorski
- Alex Leasenby
- Harry Li



Team 1: Recommendations Team

- Aanchal Taneja
- David Bern
- Shanyl Chen
- Tom Kelley
- Maham Subhani



http://neural.iit.edu/visualprosthesis2.htm

IPRO TEAM

- **Members**
  - **David Bern – BME**
  - **Shanyl Chen – BME**
  - **Mary DeRoo – EE**
  - **David Gorski – PSYC**
  - **Tom Kelley – MMAE**
  - **Alex Leasenby – BIOCHEM**
  - **Harry Li – CHEM ENG**
  - **Maham Subhani – PSYC**
  - **Aanchal Taneja – ECE**
- **Faculty Advisors**
  - **Professor Phil Troyk**
  - **Professor Margaret Huyck**

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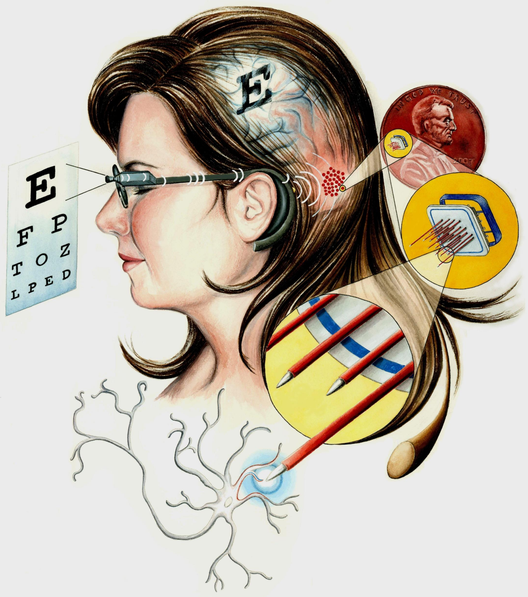
RESULTS

- The IPRO 334 team created a report summarizing the issues we addressed, additional things that should be addressed, and what the next step should be from the viewpoint of both the potential volunteers as well as the researchers.
- Technical and ethical concerns were addressed. Technical concerns were issues such as testing for functionality, heat dissipation, failure mode effect analysis, and the testing matrix. The ethical concerns portion addressed the fact that there was no specific code of ethics for the project, compensation, and what should be done if people withdraw from the study after implantation was performed.
- A section of the report analyzed what should be included in the informed consent so that it can be ensured that the patient is adequately educated. It also discussed finding a way to determine autonomy and creating a pre- and post-operation protocol.
- The last portion addressed volunteer selection issues such as pre-operative tests and brain plasticity. We also further listed some unanswered questions for future IPROs to investigate.

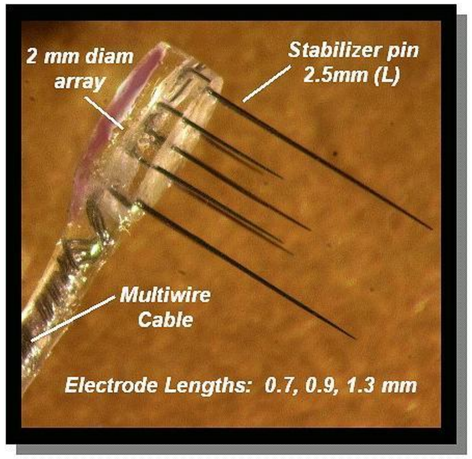
CONCLUSIONS

Ultimately, suggestions were made and questions were posed to the IIT Team in the form of a report. Throughout the semester we did large amounts of research in order to assess the current status of the device and to create a framework for subject selection. This part of the objectives remains unfinished, though several suggestions were made for its future completion. The research also gave a better understanding of the sponsor's device and similar devices. We assessed the risks of the device and its readiness for human implantation. Furthermore, we created a report for the sponsor which included technical and ethical concerns, information about the informed consent, autonomy, volunteer selection, and some unanswered questions which the IIT team needs to consider as they move forward with their plans. It is our hope that this report will be found useful to the team in determining their next step.



FUTURE WORK

Future members of this IPRO would need to address the unanswered questions described in the report compiled this semester. The framework for subject selection must be further developed; supplementing it with new suggestions. Also, future members may want to further investigate the risks associate with this specific device. This IPRO has discovered the risks associated with similar devices, but there may be risks specific to this device which have not been discovered or researched yet.



http://neural.iit.edu/images/HMRI_electrodes_small.jpg

http://neural.iit.edu/visualprosthesis2.htm

ACKNOWLEDGEMENTS

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