

CONCLUSIONS

Ultimately, suggestions were made and questions were posed to the IIT Team in the form of a report. The issues addressed included technical and ethical concerns, informed consent, autonomy and other topics researched during the course of the semester. Suggestions were made based on the unbiased viewpoint of the team as well as research performed throughout the semester. While this research brought forth support for our suggestions, it also invoked insightful discussions and questions. Although some of these questions remain unanswered in the report, they should not be ignored and the IIT team needs to consider them as they move forward with their implantation plans. The framework for subject selection as discussed in the objectives of this project remains unfinished, though several suggestions were made for its future completion and possible ethical guidelines were researched and included in the report. It is our team's hope that this report will be found useful to the IIT Intracortical Visual Prosthesis Team in determining what their next steps should be.

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 associated 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.

ACKNOWLEDGEMENTS

The IPRO team would like to thank the Chicago Lighthouse for their generous support and time. We would also like to acknowledge the Intracortical Visual Prosthesis team at IIT for their technical support. In addition, we would like to thank all the people who were interviewed during the course of this IPRO: Leo Towle Ph.D., Attorney Don Weber, and Mike Davis, Ph.D.

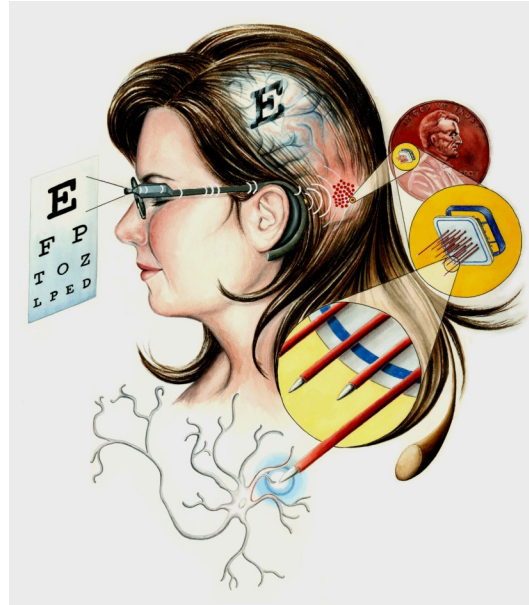


Fig: Artist rendition of the camera-glasses device and the implanted electrode modules with size comparisons to a penny and a human hair.

REFERENCES

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

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

IPRO It takes a team!
INTERPROFESSIONAL PROJECTS PROGRAM

Fall 2009

IPRO 334 Planning for Human Implantation of a Cortical Visual Prosthesis



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BACKGROUND

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.

This IPRO is further exploring the various ethical, medical, cultural, and moral issues and providing suggestions to help ready this device for human implantation, by identifying possible issues that can arise as the project moves forward into the implantation stage. This is something that has been attempted in a previous semester, but the final report lacked defined conclusions.

PROBLEM STATEMENT

The current problem is that there are a wide variety of factors that need to be considered before the IIT team can begin human implantation. One issue is a lack of guidelines for selecting volunteers for a human study. Another, is the assessment of the device and its readiness for implantation. Suggestions must be made from an impartial group (IPRO 334) to assist the IIT team in identifying and solving potential problems.

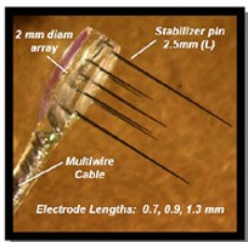


Fig: A picture of the electrodes used during animal testing by the IIT Team. Shows the basic size and composition of the implanted electrodes.

OBJECTIVES

The objective of IPRO 334 was to research the issues that volunteers participating in the sponsors study may feel concerned about from a medical, technical and ethical perspective. To achieve this goal, the team attempted to:

- Create a comprehensive, as well as scientifically and morally justified, framework for the selection of potential volunteers.
- Assemble a report analyzing the current progress of the sponsor's intracortical visual prosthetic device and what further action is required on behalf of the sponsor to begin human implantation trials.



Fig: A picture of an idealized prosthesis design. The brain works to represent things in terms of orientation, texture, and color.

BASIC ORGANIZATION

IPRO 334 began this semester by developing their objectives through team building and brainstorming sessions. As a result of these sessions, the team split into two sub-teams according to the goals created: Team A and Team 1. Team A was meant to deal with questions surrounding volunteer selection, while Team 1 was to focus on regulatory hurdles and analyzing the sponsor's work along with similar devices. Towards the latter half of the semester, team members regrouped to work together and compile a report analyzing the major questions raised during our research.

CRITICAL BARRIERS

The biggest barrier was the lack of essential information available through external sources. Since the sponsors project idea is new to the field, much of the conclusions the team came to had to be extrapolated from similar studies. Hence, most information came from surveying and sorting through research that was related to the sponsors study and using that to provoke conversations and synthesize conclusions.

RESULTS

The IPRO 334 team developed a report to assemble our findings and conclusions, questions to be addressed further, and possible next steps for the IIT team. These issues were approached from the viewpoint of the potential volunteers as well as the viewpoint of 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 also analyzed how potential volunteers should be educated and what they should be included so that they will be adequately informed. It also discussed finding a way to determine autonomy and creating a pre- and post-operation protocol.

The remainder of the report addressed volunteer selection issues such as pre-operative tests and brain plasticity. We also further listed some unanswered questions for future IPROs to investigate.