AWARD NUMBER: W81XWH-14-2-0019

TITLE: Hearing Preservation Electrodes in Veterans and Military Servicemembers With Noise-Induced Hearing Loss

PRINCIPAL INVESTIGATOR: Dr. Marlan Hansen

CONTRACTING ORGANIZATION: IOWA CITY VA RESEARCH FOUNDATION
IOWA CITY, IA 52246-0000

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14. ABSTRACT

There is a very real need to provide rehabilitative options for veterans and service members with severe noise-induced hearing loss (NIHL). Recent studies indicate that hearing preservation electrodes provide much better auditory rehabilitation compared with hearing aids or traditional length cochlear implants for patients with severe-to-profound high-frequency hearing loss and useable low-frequency hearing. The effectiveness of the hybrid approach for rehabilitation of NIHL has yet to be established. The purpose of this study is to document benefit of the hybrid cochlear implant in this population. This report documents progress during year 1 of the funding period. The initial portion of the year focused on obtaining Iowa/VA IRB and DoD HRPO approval. Following that time period we have focused on recruitment.

15. SUBJECT TERMS
IRB, VA IRB, DoD HRPO approval

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1. **INTRODUCTION:** There is a very real need to provide rehabilitative options for veterans and service members with severe noise-induced hearing loss (NIHL). Recent studies indicate that hearing preservation electrodes provide much better auditory rehabilitation compared with hearing aids or traditional length cochlear implants for patients with severe-to-profound high-frequency hearing loss and useable low-frequency hearing. The effectiveness of the hybrid approach for rehabilitation of NIHL has yet to be established. The purpose of this study is to document benefit of the hybrid cochlear implant in this population
2. **KEYWORDS:** Hybrid cochlear implant, hearing preservation, noise-induced hearing loss
3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**
  - Write Pre-IDE for cochlear implant devices that are not FDA approved for standard practice
  - Obtain IRB approval from UI/VA Human Subjects Office
  - Obtain IRB approval from the DoD Human Research Protection Office (HRPO)
  - Begin recruitment and implantation of the Hybrid device.
  - Began development of training programs and questionnaires
- **What was accomplished under these goals?**
  - The Hybrid L24 cochlear implant was approved for commercial use by the FDA. We are now able to implant the device in individuals who meet the inclusion criteria for the L24 in this grant without and FDA IDE study.
  - The Hybrid S12 device is not yet FDA approved. Thus, in order to implant this device in this study, we are required to obtain a FDA IDE. The current version of the device is being modified to make the device implantable through the round window versus through a cochleostomy. Cochlear Americas (the company that manufactures the hybrid cochlear implant devices) has approved the final version

of this device and an Investigational Device Exemption (IDE) application is being developed.

- We received Iowa/VA IRB approval for the study using this device on October 29, 2014 and approval from the DoD HRPO on December 19, 2014.
- Recruitment has been slow for this project. We have initiated conversations with various individuals within the VA and military branches. We are in the process with scheduling a phone conference with otologists and audiologists within the VA and military systems to discuss recruitment ideas and protocol details. They have stated that they feel that there is a plethora of individuals in the system that will fit the inclusion criteria from a hearing standpoint, but the criterion for age might have to be expanded.
- Developing questionnaires that allow us to personalize the training for each participant. We sought out feedback and input from veterans and the officials in the office of Student Veteran Services within the University of Iowa. We are in the process of validating the questionnaires.

- **What opportunities for training and professional development has the project provided?**

  This project was not intended to provide training and professional development opportunities. However, Dr. Dunn has spoken on several occasions to Nancy Cambron, who is the Chair of the VHA Cochlear Implant Advisory Board, and Maureen Wargo, who is a supervisory audiologist within the VA Pittsburgh Healthcare System. Both have had questions regarding use of the hybrid cochlear implant in veterans. Dr. Dunn also traveled to Cochlear Corporation in June of 2015 for a VA Audiologist Hybrid Training meeting. Dr. Dunn spoke about device outcomes and expectations with several VA audiologists.

- **How were the results disseminated to communities of interest?**

  Nothing to report

- **What do you plan to do during the next reporting period to accomplish the goals?**

During the next year, we plan to obtain an IDE to implant the Hybrid S12 device. Additionally, we plan to begin implantation of both devices in patients who fit inclusion criteria. Furthermore, we also plan to expand the age criterion to older veterans (≤ 70 years of age) in hopes of increasing recruitment numbers.

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**

  Nothing to report

- **What was the impact on other disciplines?**

  Nothing to report

- **What was the impact on technology transfer?**

  Nothing to report

- **What was the impact on society beyond science and technology?**

  Nothing to report

5. **CHANGES / PROBLEMS:**

- **Changes in approach and reasons for change**

  Nothing to report

- **Actual or anticipated problems or delays and actions or plans to resolve them**

  As mentioned previously, recruitment has been slow for this project. We have initiated conversations with various individuals within the VA and military branches and are in the process with scheduling a phone conference with otologists and audiologists within the VA and military systems to discuss recruitment ideas and protocol details. We are considering expanding the age limit for the study. However, we are aware that we will have to obtain permission before implementing this change.

- **Changes that had a significant impact on expenditures**

  Nothing to report

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

  Nothing to report

- **Significant changes in use or care of human subjects**

  Nothing to report

- **Significant changes in use or care of vertebrate animals.**

  Not applicable

- **Significant changes in use of biohazards and/or select agents**

  Not applicable

6. **PRODUCTS:**

   Nothing to report

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

(1) Name: Marlan Hansen
Project Role: PI
Nearest person month worked: 1
Contribution to Project: Assisted in IRB/HRPO submission and recruitment.

(2) Name: Bruce Gantz
Project Role: Co-PI
Nearest person month worked: 1
Contribution to Project: Assisted in IRB/HRPO submission and recruitment.

(3) Name: Camille Dunn
Project Role: Investigator
Nearest person month worked: 3
Contribution to Project: Assisted in IRB/HRPO application; discussed project with VA staff; developed CRF forms; developed marketing forms for recruitment.

(4) Name: Diane Burke
Project Role: Study Coordinator
Nearest person month worked: 3
Contribution to Project: Prepared the IRB/HRPO submission; assisted in the development of marketing forms for recruitment.

(5) Name: Kate Gfeller

Project Role: Investigator
Nearest person month worked: 1
Contribution to Project: Began development on the training programs

(6) Name: Virginia Driscoll
Project Role: Research Assistant
Nearest person month worked: 1
Contribution to Project: Began development on the training programs

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

  Nothing to report

- **What other organizations were involved as partners?**

  Nothing to report

- **QUAD CHARTS:** Attached.

8. SPECIAL REPORTING REQUIREMENTS:

Nothing to report

9. **APPENDICES:**

Nothing to report

Hearing Preservation Electrodes in Veterans and Military Service Members with Noise-Induced Hearing Loss

Award Number: W81XWH-14-2-0019 Log Number: DM130040

PI: Marlan Hansen, MD. **CO-PI:** Bruce Gantz, MD **Org:** Clinical and Rehabilitative Medicine Research Program **Award Amount:** $2 mil

Problem and Military Relevance

- High percentage of veterans and military service members suffer Noise-induced hearing loss (NIHL).
- HL gives rise to substantial fiscal burden for the VA
- NIHL results in significant communicative, social and economic burden to veterans and service members

Study Aim(s)

- Evaluate the benefit of different lengths of hybrid CIs on veterans and service members with HF NIHL
- Evaluate the impact of hearing loss rehabilitation with short electrode CIs on quality of life.

Approach

- Veterans and military service members with HF NIHL will receive a L24 or S12 short electrode
- Benefit will be evaluated by comparing speech perception, music recognition, localization, and quality of life prior to implantation and over the first year following implantation.
- Benefit will be assessed as a function of device length.

Goals/Milestones

CY14 Goal – Design protocol, FDA IDE, and test measures
✓ Design protocol and regulatory guidelines
✓ Begin recruitment of subjects
✓ IRB and HRPO approval

CY15 Goals – Recruitment and data collection
☐ Continue subject recruitment
☐ Collect pre-operative and post-operative data on subjects

CY16 Goal – Recruitment and data collection
☐ Finalize subject recruitment
☐ Collect pre-operative and post-operative data on subjects

CY17 Goal – Data collection, data analysis, dissemination
☐ Finish data collection
☐ Analyze data and prepare for dissemination of results

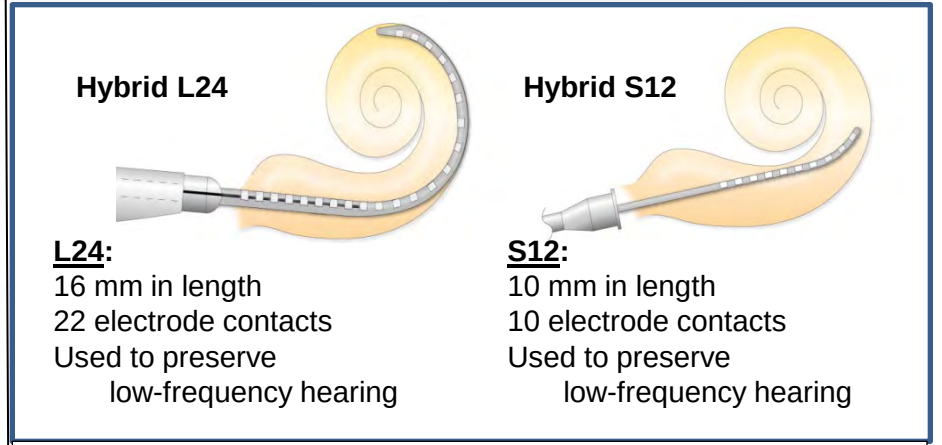

Figure 1. Schematic of Hybrid electrodes within the cochlea. The L24 (left) has 22 electrode contacts and is implanted into the cochlea 16 mm . The S12 (right) has 10 electrode contacts and is implanted into the cochlea 10 mm. Both electrodes are used to preserve low-frequency acoustic hearing.

Timeline and Cost

Activities CY	14	15	16	17
Prepare protocol and test measures, submit FDA IDE				
Recruitment of subjects				
Pre- and Post- Op data collection				
Data analysis and dissemination of results				
Estimated Budget ($K)	**$500**	**$500**	**$500**	**$500**

Updated: Annual