AWARD NUMBER:
W81XWH-14-2-0019

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

PRINCIPAL INVESTIGATOR:
Marlan Hansen, MD

CONTRACTING ORGANIZATION:

Iowa City VA Research
Iowa City, IA 52246

REPORT DATE: JULY 2019

TYPE OF REPORT:

Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
JULY 2019	Annual	15 JUN 2018 - 14 JUN 2019

4. TITLE AND SUBTITLE
Hearing Preservation Electrodes in Veterans and Military

Servicemembers With Noise-Induced Hearing Loss

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-14-2-0019

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Marlan Hansen, MD

E-Mail: marlan-hansen@uiowa.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Iowa City VA Research Foundation

601 US-6
Iowa City, IA 52246

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	10	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

Page

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 hearing preservation in a NIHL population.

2. KEYWORDS: Hybrid cochlear implant, hearing preservation, noise-induced hearing loss

3. ACCOMPLISHMENTS:

What were the major goals of the project?

A. Recruitment and implantation

B. Collect pre-and post-operative hearing threshold data.

C. Collect pre- and post-operative speech perception data.

D. Collect satisfaction and quality of life measures.

What was accomplished under these goals?

Recruitment for newly implanted subjects under this study has previously moved slowly. We enrolled and implanted 6 newly implanted veterans with the Hybrid L24 cochlear implant at the Iowa City VA Hospital. One subject subsequently dropped out of the study following surgery as he decided that he did not want to participate in a research study. Furthermore, one subject enrolled into our study at his six-month post-operative visit. We also included other Hybrid subjects who were previously implanted at the University of Iowa that are veterans of the military. An additional seven hybrid subjects were followed under this change. We collected pre-operative data on all of our newly implanted subjects (except for the subject who enrolled at his 6 month data point). Most recently, we opened up enrollment to include individuals with NIHL as the primary indication for hearing impairment. Thus, our specific aims changed.

Original and Revised Specific Aim 1. Original: Evaluate the hearing benefits of hearing preservation devices in veterans and military service members with residual low-frequency hearing and high-frequency noise-induced hearing loss. Revised: *Rather than focusing on only veterans and active service members, we propose to study this question from a broader perspective using subjects with noise-induced hearing loss, regardless of current or former military service. We also propose to study this question using all current FDA approved devices that are indicated for hearing preservation (Hybrid L24, Med-EL Flex 20 and 24).* By opening this up to a broader group of patients, we will have a substantially increased number of patients to enroll in our study. This will also allow us to look at this from a perspective of age at implantation, since that has been shown to influence hearing preservation following cochlear implantation. Furthermore, by opening up candidacy to noise-induce hearing loss, we will also be able to recruit women into our study, which is also beneficial to our analysis. Finally, we may also be able to document outcomes whether the cause of hearing loss was a result of a single noise event (such as a blast) or prolonged chronic noise (such as in a shipyard).

Original and Revised Specific Aim 2. Original: Compare the efficacy and preservation of residual hearing in subjects that are implanted with a Hybrid S12 or L24 electrode based on their residual mid-range acoustic hearing. The Hybrid S12 (now the Hybrid SRW) is not yet FDA approved and is limited to inclusion by age. The University of Iowa is the sole site that is conducting a preliminary study with this electrode array; the study is limited to 10 subjects. Furthermore, using this device as a comparison to other now more commonly used FDA-approved devices may not help guide surgeons on which current device is the best choice for their patient. Revised: W*e are proposing to study this question by comparing the efficacy and preservation of residual hearing in subjects implanted with a FDA-approved shorter electrode indicated for hearing preservation to other standard-length electrodes (e.g. Nucleus CI 522) that surgeons (such as those that at the Fort Detrick meeting) are using instead of a hearing preservation device.* Outcomes from this aim will further guide clinical practice in the noise-induced hearing loss population, which is ultimately what this study was designed to accomplish.

Thus far, we have recruited 19 subjects with standard electrodes used for hearing preservation and 33 subjects with NIHL that have been implanted with a hearing preservation electrode. These patients were recruited from our existing database of implanted patients where the subject indicated that the primary cause of their hearing loss was NIHL. All subjects recruited have registered for a cochlear implant research registry where they indicated that there data could be used for this study. The data include audiologic, speech perception, and subjective benefits of speech, spatial, and quality of sound as well as perceived handicap from hearing loss.

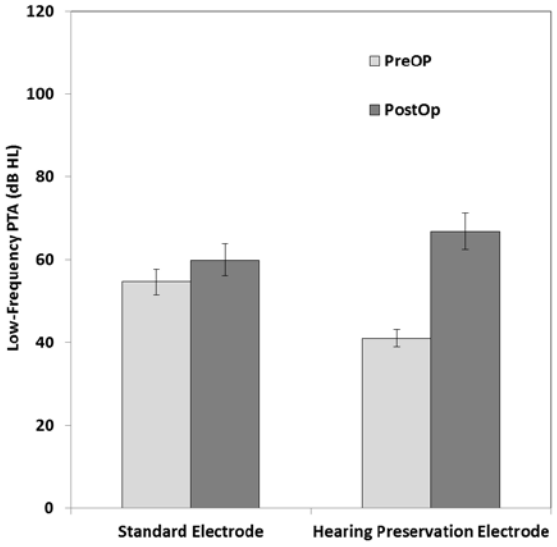

Figure 1. Averaged pre and postoperative pure-tone average thresholds (dB HL) for the Standard electrode and Hearing preservation groups.

Hearing preservation has been maintained in 76% of the 33 patients who were implanted with a hearing preservation electrode (HPE). 93% of the 15 patients (2 have not been connected with their implant) implanted with a standard-length electrode (SE) have hearing preservation. Averaged pre and post-operative low-frequency pure-tone average (LFPTA) at 125, 250, and 500 Hz are shown in Figure 1. The averaged preoperative LFPTA for the SE group was 54 dB HL and the averaged postoperative LFPTA was 60 dB HL demonstrating no significant change in hearing (p=.34). The averaged preoperative LFPTA for the HPE group was 41 dB HL and postoperative average was 67 dB HL, which was significantly poorer (p<.0001). While the SE group started with a poorer LFPTA and the HPE group started with a better LFPTA (significantly different p<.01), there is not a significant difference

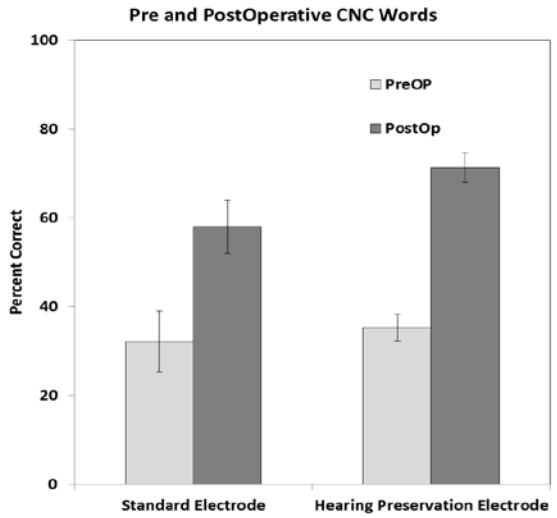

Figure 2. Averaged pre and postoperative CNC word scores (percent correct) for the Standard electrode and Hearing preservation groups.

(p=.31) in averaged LFPTA postoperatively between the two groups.

Postoperatively, as shown in Figure 2, both groups showed significant improvements in their preoperative to postoperative speech perception scores using CNC words ($p<.05$ for SE and $p<.01$ for the HPE group). Preoperatively, there was not a significant difference between scores for two groups (p=.63). Averaged preoperative scores for the standard and HP group were 33% and 35%, respectively. There is no significant difference between the postoperative scores for the SE and the HPE groups (p=.07) with the SE group scoring 59% and the HPE group scoring 71%.

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 several VA attended meetings to discuss device outcomes and expectations. On September 10, 2019, Drs. Hansen, Gantz, and Dunn have invited Lina Kubli to visit the University to discuss implantation in Veteran population.

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?

Over the next year, we will analyze our data and begin working on disseminating the results both in a publication and at a conference.

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:

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

None to report

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 a CI indicated for hearing preservation on listeners with NIHL
- Evaluate outcomes of listeners with NIHL implanted with CIs indicated for hearing preservation vs listeners with NIHL implanted with standard-length electrodes.

Approach

- Listeners with NIHL will receive either a hearing preservation or standard-length 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

CY18 Goal –

✓ IRB and HRPO approval
✓ Recruitment
✓ Collect pre-operative and post-operative data on subjects

CY19 Goal –

✓ Continue Recruitment - First ½ of '19
❑ Finalize subject recruitment - Second ½ of '19
❑ Collect pre-operative and post-operative data on subjects

CY20 Goal –

❑ Finish data collection
❑ Analyze data
❑ Prepare for dissemination of results
❑ Dissemination of results

Updated: Y5, Annual

Hearing Preservation Electrodes

- Nucleus Hybrid L24
- Med-EL Flex 20
- Med-EL Flex 24
- Or other FDA-approved electrode indicated for hearing preservation

Standard Electrode

- Nucleus 522
- Nucleus 532
- Advanced Bionics Slim J
- Med-EL Flex 28
- Or other FDA-approved device

Table 1: Timeline and Cost