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

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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.					
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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?

- A.** Recruitment and implantation of the Hybrid device.
- B.** Collect pre-and post-operative hearing threshold data.
- C.** Collect pre- and post-operative speech perception data.
- D.** Collect music appraisal and pitch data.
- E.** Administer training programs and questionnaires.

What was accomplished under these goals?

Recruitment for newly implanted subjects under this study has 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 have collected pre-operative data on all of our newly implanted subjects (except for the subject who enrolled at his 6 month data point). The data include audiologic, speech perception, localization, and music data. We are also collecting

questionnaire data investigating subjective benefits of speech, spatial, and quality of sound as well as perceived handicap from hearing loss. Audiologic data show that preoperatively, subjects had a mean low frequency PTA of 38 dB HL and a post-operative most-recent PTA of 72 dB HL. This difference is statistically significant ($p=0.00013116$). All but two of the subjects are able to utilize their low-frequency hearing post-operatively. Thus, while these patients lost some of their acoustic hearing, the vast majority retained sufficient low frequency hearing to benefit from combined electric-acoustic stimulation (ie. Hybrid).

Speech perception data using CNC words and AzBio sentences in noise demonstrate that all subjects had an improvement in their speech understanding compared to pre-operatively with bilateral hearing aids. The mean AzBio preimplant score was 18.4% and the mean most recent AzBio postoperative score was 43.6%. The average increase was 25.2% and this was a statistically significant improvement ($p=0.0002915$, paired t-test). The mean CNC pre score was 35.75% and the mean most recent CNC post score was 70.08%. The average increase was 34.3 and this was a statistically significant difference ($p=0.0000015$, paired t-test).

For localization, rather than hope for an improvement in score, we hope for maintenance of localization ability by preserving low frequency hearing. This is because the user needs to have similar processing on each ear to localize (low-frequency acoustic hearing)⁵. If low frequency hearing is significantly compromised the patient must rely exclusively on electrical stimulation in one ear and this coupled with acoustic hearing in the contralateral ear would lead to a significant decrement in sound localization. In this study, the mean Localization preimplant score was 22.67 RMS Error in Degrees and the mean Localization post score was 33 RMS Error in Degrees. A lower score indicates better performance on this test. The average decrement in localization performance following implantation was 10.3 RMS Error in Degrees. Statistically, this difference was not significant at the .05 level using paired t-test ($p=0.06676$). (A nonparametric Wilcoxon signed rank test was also not significant $p=0.07314$). Research has shown that localization in patients with bilateral low-frequency hearing is heavily based upon the symmetry between the two ears⁶. Because there was a significant change in PTA in their implanted ear, it is likely that this asymmetry contributes to this decrement in localization ability. However more subjects are needed to

confirm this finding to statistical significance. Further, it will be important to compare the extent of decrement in sound localization in patients with attempted hearing preservation compared to those receiving a standard implant without attempt at hearing preservation. The later could be expected to perform even poorer than those with even partial hearing preservation (see proposed revised aim 2 below).

Pitch perception data were collected from 4 of the 6 subjects implanted as part of the DoD protocol during this reporting period. Using only the CI (acoustic stimulation turned off), the average change in pitch perception was 6.5. This is not a statistically significant change ($p=.1375$) which is not surprising with only four participants. Using the standard deviation from those four subjects (6.45), the sample size required to detect a statistically significant Pitch difference of 15 with $\alpha=0.05$ and a power of 80% would be $N=16$ or with a power of 90% it would be $N=20$.

The Speech, Spatial, Qualities (SSQ) subjective questionnaire is a common questionnaire to give to implant patients preoperatively and postoperatively to assess the subject's subjective benefit in these three domains. A total score is also calculated. SSQ pre total score was 3.28, and the mean SSQ post total score was 4.86 from 7 people. In this questionnaire, a higher score indicates better perceived benefit. The average increase was 1.57, and using a paired t-test this was a statistically significant difference ($p=0.00532$). When breaking it down by domain, however, speech perception was the only significant domain ($p=0.011$). The Hearing Handicap Inventory (HHIE) questionnaire assesses the level of handicap that a person perceives as a result of hearing loss. A lower score indicates less handicap. The average HHIE score decreased from Pre to Postop. The mean HHIE pre score was 2.54, and the mean HHIE post score was 2.18. The average decrease was .357, but was not significant ($p=.2283$) in this small group.

The results thus far demonstrate that the subjects in this study benefit from improved speech perception which is also consistent with subjective benefit in that domain. When assessing localization, no difference was assessed (although it was nearly significant). This was also consistent with the spatial domain subjective assessment where they did not perceive a change in spatial benefit.

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.

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?

What has not been answered, and maybe be the most critical, is if we can say from these data that hybrid hearing is the clinical direction that we should be going when it comes to the standard of care for veterans/military personnel with severe to profound high frequency hearing loss and poor speech understanding. At the meeting that Dr. Dunn attended at Fort Detrick in August, the surgeons in attendance commented that they do not typically implant patients with hearing preservation (shorter) electrodes because they want patients to have a longer electrode if they lose their hearing. We cannot say, unequivocally, from the data so far that these results would override the perception that these professionals have when it comes to their clinical practice. Addressing this critical question does not deviate from our original application, as the overall purpose was to “study the effectiveness of Nucleus Hybrid hearing preservation cochlear implants (CIs) in veterans and service members exposed to excessive noise resulting in severe hearing loss and reduced communication abilities.” We have recently gotten approval to revise our methodology to enhance recruitment and to better understand the clinical merits of hearing preservation cochlear implant strategies within the VA and military clinics.

We are currently in the process of changing our IRB to continue this study. Once that is accomplished we will begin enrolling subjects with noise-induced hearing loss into our study. We currently have 18 subjects slated for recruitment into this study.

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

This is a summary of the changes to the original and newly revised aims:

Original Specific Aim 1: 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. *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-induced 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).*

Specific Aim 2: 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. *Thus, we 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.

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 outcomes of different lengths of CIs in adult listeners with NIHL
- Evaluate the impact of CIs on quality of life

Approach

- Listeners with NIHL with good low-frequency hearing will receive either a hearing preservation electrode or a standard-length electrode
- Benefit will be evaluated using hearing thresholds, 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 related to extension

CY18-19 Goals – Recruitment and data collection

- Begin subject recruitment
- Collect pre-operative and post-operative data on subjects
- All subjects will be recruited by the end of June, 2019

CY19-20 Goal – Data collection and Dissemination

- Collect post-operative data on subjects
- Analyze data
- Disseminate through conferences
- Write-up results in scholarly journal

Timeline and Cost

Activities	CY	July '18	June '19	July '20
Prepare modification to IRB and HRPO				
Recruitment of subjects				
Pre- and Post- Op data collection				
Data analysis and dissemination of results				
Estimated Budget (\$K)		No-cost extension		

Updated: Annual