CROS and Quality of Life of Elderly Cochlear Implant Recipients and Their Care Givers

Protocol Summary

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Sponsor:	ADVANCED BIONICS
Principal Investigator:	Richard Gurgel
Internal Staff and Sub-Investigators:	**Site Name** / **Staff Names** University of Utah: Richard Gurgel, Martin Carricaburu, Austin Stevens, Lisa Dahlstrom, Diane Tyler, Eun Kyung Jeon, Kathryn Johnson

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Background and Introduction

Study Background and Information:

Cochlear Implants are now a well-accepted treatment for severe to profound hearing impairment. Bilateral cochlear implants are known to provide access to some of the benefits of binaural hearing like improved speech understanding in noise (primarily due to headshadow), improved localization, reduced stress and fatigue, and improved quality of life (e.g., Dunn et al. 2012, Litovsky et al. 2012, Härkönen et al. 2016, Reeder et al. 2014, Agrawal 2008). However, a number of CI recipients are unable to or choose not to be implanted bilaterally for many reasons. Those with acoustic hearing in the contralateral ear can benefit significantly by using a hearing aid in that ear (bimodal hearing) (Ching et el. 2006, Dorman and Gifford 2010, Dorman et al. 2015, Dunn et al. 2005, Firszt et al. 2012, Illg et al. 2014, Farinetti et al. 2015).

Unilateral CI recipients do not have access to advantages of bilateral and bimodal hearing. In addition to reduced speech understanding in noise, especially when the speech source is located towards the non-CI, they can also experience increased stress and fatigue.

About the Nadia Link CROS:

The Naida Link CROS device extends the Naida family of hearing solutions from AB and Phonak for severe-to-profound individuals. Utilizing the proprietary Binaural VoiceStream Technology, an automatic wireless network is established between the Naida CI sound processor and a Naida Link CROS transmitter, Naida Link hearing aid, or second Naida CI sound processor. This wireless network enables the sharing of control signals, and full-bandwidth audio streaming so that all cochlear implant recipients can benefit from hearing from both ears. The Naida Link CROS allows unilateral cochlear implant recipients to hear from wherever they want and walk into any listening situation with more confidence.

Phonak Naída Link CROS device + AB Naída CI sound processor = Naída Link CROS solution

Purpose and Objectives

Purpose and Objectives:

The purpose of this study is to assess the effect of the Naida Link CROS device on speech understanding in challenging listening situations and on the quality of life in unilateral CI recipients and their frequent communication partners. We hypothesize that:

(a) Unilateral CI recipients will obtain higher speech understanding scores with the CROS device in challenging listening conditions

(b) Use of the CROS device will lead to positive changes in ratings on Quality of Life measures for (i) unilateral CI recipients, and (ii) their frequent communication partners

A frequent communication partner (FCP) is an individual (a family member, or a friend, or a care taker, or a significant other, or a colleague, etc.) who has at least two hours of in-person interactions with the CI recipient every week.

Study Population

Age of Participants: 18+

Sample Size:

At Utah:	15
All Centers:	up to 35

Inclusion Criteria:

Study participants' inclusion criteria:

i. Unilateral recipients of Advanced Bionics CII/90K/Ultra implants
ii. Ages 18 years and above
iii. At least 6 months of CI use experience
iv. Current users of a Naida CI Q70 or Q90 processor
v. Do not currently use a Naida Link CROS device
vi. Limited usable/aidable hearing in the contralateral ear
vii. Fluent in spoken English
viii. Willingness to use the CROS device regularly for the study duration
ix. Willingness to follow-up on a biweekly/monthly basis

FCP's participants' inclusion criteria:

i. A FCP of a recipient of a unilateral Advanced Bionics CII/90K/Ultra implants
ii. Ages 18 years and above
iii. Fluent in spoken English
iv. Willingness to participate in the study

Exclusion Criteria:

Exclusion criteria:

i. < 6 months of CI use experience
ii. < 30% sentence recognition scores in quiet with unilateral CI
iii. Inability to participate in speech testing
iv. Inability to follow and complete questionnaires
v. Inability to designate an FCP

FCP's Exclusion criteria:

i. Not a FCP of a recipient of a unilateral Advanced Bionics CII/90K/Ultra implants
ii. Under the age of 18 years
iii. Not fluent in spoken English

Design

Survey/Questionnaire Research
Prospective Clinical Research

Study Procedures

Recruitment/Participant Identification Process:

Participants will be identified by Dr. Gurgel, Lisa Dahlstrom, Katie Johnson.

They will be able to identify current patients that have received the Advanced Bionics implant and have had it for at least 6 months.

Potential participants will be approached in clinic to provide informed consent.

Informed Consent:

Description of location(s) where consent will be obtained:

Consents will be obtained in the ENT clinic at the University of Utah.

Description of the consent process(es), including the timing of consent:

For the Cochlear Implant Patient: A study team member will provide the patient with an information form on the study design that should be read to and/or discussed with the patient in an understandable way. In this document, patients willing to consent to participate in this study will be informed of the nature, extent, design and conduct of the study and their consent will be obtained in writing prior to inclusion to the study schedule. Patients will be given the opportunity to ask questions and will be informed of their right to withdraw from the study at any time, for any reason. For the Communication Partner: A study team member will provide the communication partner with an information form on the study design that should be read to and/or discussed with the partner in an understandable way. In this document, communication partners are informed about the nature and extent of their participation in the study. Their consent will be obtained in writing prior to inclusion to the study schedule. Communication partners will be given the opportunity to ask questions and will be informed of their right to withdraw from the study at any time, for any reason. Communication partners will be informed that they are not required to participate even if the Cochlear implant patient wishes to enroll. The study team will ensure that the participants know that enrollment in the study is voluntary.

Procedures:

Screening:

The PI will refer eligible patients to the study team. Someone from the team will present the study to the patient for recruitment. After recruiting, following will be mailed to the participants to be completed prior to the study visit and hand carried to visit 1:

For each CI subject:

i. Informed consent form
ii. APS-SSD (Schafer et al, 2013, modified by H. Snapp, 2017)
iii. Nijmegen questionnaire (adapted from Hinderink et al, 2000)

For each CI subject's frequent communication partner:

i. Informed consent form
ii. SOS-HEAR

Following are the procedures for visit 1 (Estimated total duration of 2 hours):

a. Review and sign consent forms and the pre-intervention questionnaires for CI subjects and their FCPs (15 minutes)
b. Collect demographic information (15 minutes)
c. Conduct unaided pure-tone audiometry using insert earphones for each ear (15 minutes)
d. Connect CI participant's own Naida CI processor to SoundWave to obtain the following pre-intervention data-logged information (5 minutes):
    i. Duration of daily CI use
    ii. The proportion of time spent in noisy environments (by level)
e. Program the study CI processor (5 minutes):
    i. Initialize the processor to communicate with CROS
    ii. Create a study program using recipients' everyday program as a baseline:
        i. Use omnidirectional mic mode
        ii. 100% T-Mic
        iii. If ClearVoice is OFF in baseline program, activate it and set it to medium in the study program. Increase M-levels globally, based on recipient's feedback.
f. Measure benefit in speech understanding with CI only and with CI+CROS in the following listening configurations (50 minutes)
    i. $Speech_{Front}$
    ii. $Speech_{CROS(Off)}$
    iii. $Speech_{CROS(Off)}Noise_{CI}$
    iv. $Speech_{CROS(On)}Noise_{CI}$
g. Program recipients' own Naida CI processor for the take-home phase (5 minutes):
    i. Program 1 would be the same as the CI recipient's preferred everyday program but with CROS activated

ii. Program 2: noise program with CROS enabled:
    i. UltraZoom (if own processor is a Naida CI Q70)
    ii. StereoZoom (if own Q90
h. Provide instructions for chronic use of the new CI programs and CROS (10 minutes)

Following are the procedures for visit 2 (Estimated total duration of 1 hour):

a. Obtain post-intervention questionnaire ratings from CI recipients (complete on the same forms that were used for pre-intervention ratings) (30 minutes)
    i. APS-SSD (Schafer et al., 2013, modified by H. Snapp, 2017)
    ii. Nijmegen questionnaire (adapted from Hinderink et al., 2000)
b. Obtain post-intervention questionnaire ratings from FCPs (complete on the same form that was used for pre-intervention ratings) (to be completed while the CI recipients are working on their questionnaires)
    i. SOS-HEAR
c. Connect participant's own Naida CI processor to SoundWave to obtain the following post-intervention data-logged information: (conducted while participants are completing questionnaires)
    i. Duration of daily CI use
    ii. The proportion of time spent in noisy environments (by level)
d. Program the study Naida CI Q90 for sound booth testing: (conducted while participants are completing questionnaires)
    i. Program 1: Same as that used for speech testing in visit 1
    ii. Program 2: Same as P1 but with UltraZoom ON.
e. Measure benefit in speech understanding with CROS device at the same SNR that was used in visit 1 (15 minutes)
    i. $S_{CROS(On)}N_{CI}$ (with P1, to assess the effect of chronic experience)
    ii. $S_{Front}N_{Back}$ (with P1 and with P2, to assess the benefit of UltraZoom)
f. Review study findings. The recipients can choose if they want to keep the CROS device for everyday use at this point. They would be advised that they would be responsible for any extended warranty needs. Program settings will be based on patient preference and clinical judgment. (15 minutes)

Participants will also be contacted over the course of the take-home phase to ensure compliance and obtain additional insight into device use and effect. Contact will be over phone or email as per their preference. Frequency will be every 2 weeks for the first 3 months and monthly after that until visit 2. Following questions will be asked:

- How many days in the past two weeks/ one month did you use the CROS device?

- On an average, how many hours a day did you use the CROS device?

- In which situations(s) did you find the CROS device most helpful?

- Did you use the noise program?

- Were there any situations where you only listened with the CI processor (with the CROS turned off or muted)?

o Why?

- How many days in the past two weeks did you communicate with your FCP in person?

Procedures performed for research purposes only:
The quality of life surveys and hearing tests are all for research.

Statistical Methods, Data Analysis and Interpretation

Statistical methods, data analysis, and interpretation:

- Questionnaire ratings: Wilcoxon Signed Rank Test
- Speech understanding scores: ANOVA, paired sample t-Tests
- Correlation between changes measured via speech perception scores and questionnaires