

COMIRB Protocol

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD
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Project Title: Evaluation of speech-in-noise performance in cochlear implant recipients using either a conventional hearing aid or a CROS device on the contralateral ear

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I. Hypotheses and Specific Aims:

Speech understanding in noise remains the greatest challenge for individuals utilizing cochlear implants, particularly when the speech of interest originates from the side of the head opposite to the implant. Recent advances in hearing technology allow for an individual to either use a conventional hearing aid or a Contralateral Routing of Signal (CROS) device on the non-implanted ear. Differences in speech understanding may result depending on the specific device chosen by an individual, and these differences may be measureable through speech discrimination measurement protocols.

- Hypotheses:
1. Performance on a speech perception task will vary based on the type of amplification device a listener uses on the ear contralateral to the cochlear implant
 2. As the originating locations of the speech and noise are varied, the amount of benefit seen by specific device configurations (cochlear implant + hearing aid or cochlear implant + CROS) will also vary.
 3. Perceived listening effort will vary as device and speech/noise original locations are varied

- Specific Aims:
1. Quantify the changes in speech in noise perception for adults using a cochlear implant in one ear as the device on the contralateral ear is varied.
 2. Quantify the changes in speech in noise perception for adults using a cochlear implant in one ear as the originating locations of the speech and noise are varied.
 3. Quantify the self-reported amount of listening effort perceived by a listener when listening to speech in noise for a variety of device and speech/noise location configurations.

Consented subjects will fill out a case history form and participate in various speech and hearing tests under 7 conditions which will provide data on which device condition produced the best speech perception in noise results.

This study intends to determine whether or not a CROS device improves speech perception in noise when the source of the speech of interest originates from the side of the head opposite to the implant.

II. Background and Significance:

Speech perception in noise continues to be the greatest challenge for unilateral cochlear implant users, most notably when the desired speech signal is presented to the ear opposite of their cochlear implant processor. Recent advances in hearing technology, as well as the expansion of candidacy criteria for cochlear implantation, has allowed for more individuals with one cochlear implant to take advantage of a device in their non-implanted ear. For those individuals with aidable hearing (thresholds better than 70 dB at any frequency) in the non-implanted ear, the benefit of bimodal hearing (cochlear implant + hearing aid in the non-implanted ear) has been well documented: access to low-frequency acoustic information provides fine-structure and spectral resolution that is lost with the envelope-based signal process strategies of a cochlear implant (Ching, et al., 2004, 2007 ; Gifford, et al., 2007; Zhang, et al., 2010; Dunn, et al., 2005; Morera, et al., 2004). However, for many individuals, the bimodal condition does not provide additional benefit over the cochlear implant alone (Dorman, et al., 2014; Gifford, et al., 2105; Veugen, et al., 2016; Vroegop, et al., 2018). For example, factors that may limit benefit are the level of CI only performance, the degree of hearing loss in the non-implanted ear, and the variety of complex listening conditions (Dorman, et al., 2015; Ching et al., 2007). For those individuals with either objective or subjective lack of benefit from a contralateral hearing aid despite aidable thresholds, a contralateral routing of signal (CROS) device could provide benefit when listening to speech in noise (Ryu, et al., 2014; Kitterick, et al., 2014). In patients with unilateral hearing loss, CROS technology has shown to have both subjective and objective benefits for speech perception in noise and sound localization, however, there is limited or no benefit when noise is presented to the affected ear (noise on the side of the CROS device) (Ryu, et al., 2014). For unilateral cochlear implant users, the difference in benefit of speech perception in noise when using a conventional hearing aid versus a CROS device may be measurable through speech discrimination measurement protocols. For unilateral cochlear implant users, the difference in benefit of speech perception in noise when using a conventional hearing aid or a CROS device may be measurable through speech discrimination measurement protocols.

Spatial separation of the desired speech signal and the competing noise should improve speech understanding in the presence of noise (e.g. Cherry et al., 1953; Moore; Van Hoesel, 2003; Hawley et al., 2004). Spectral contributions of this separation include binaural squelch (spatial release from masking). This is an ability of the central auditory system to process sound from each ear and interpret it with a higher signal to noise ratio by comparing interaural time and level differences. Additionally, the head shadow effect, in which the head creates an acoustic barrier, leads to an increased SNR in the ear furthest from the noise (e.g. Schleich, 2004; Kidd et al., 1998). An individual receiving auditory stimulation to only one ear may be able to recognize the general location of the sound because the

incoming signal would be louder on the side of stimulation; but perceiving the location and direction of sounds requires the use of interaural time and level differences (Ching, et al., 2007). Access to these level differences with hearing aids and cochlear implants depends on the devices ability to preserve timing information. While timing cues are well preserved by hearing aids, cochlear implants do not carry timing cues: all current processing strategies extract the temporal envelope of the incoming signal, which is then amplitude-modulated to a fixed-rate pulsatile carrier; they do not reproduce the fine temporal structure of sounds that are necessary for perceiving ITDs (Smith, et al., 2002). Because low-frequency information is not conveyed by the place of stimulation or by the temporal fine structure of the firing pattern, combining the preserved low-frequency timing information that is preserved by a hearing aid with the high-frequency information via cochlear implant, bimodal users may be more likely to benefit from this cue (Ching et al., 2007). The benefits of speech perception in binaural listeners comes from head shadow effect and binaural squelch (Zurek, 1993). The head shadow effect creates a SNR that is different between the two ears due to the physical location of the head between the two ears so that the listener can focus on the signal with the better SNR; this advantage results in a 3 dB advantage (Bronkhorst, 1992). If the SNR at the two ears is the same, the binaural auditory system is able to combine inputs from both ears to reduce the impact of noise for better speech understanding. Binaural release of masking can improve speech intelligibility by up to 12 dB when the speech and noise originate from different directions (Plomp, 1981; Litovsky, et al., 2002). By using a hearing aid in the contralateral ear, unilateral cochlear implant patients may be able to benefit from some of these separation cues. For cochlear implant users, the benefit of separating the speech and noise signals may be impacted by the specific location of the speech and noise signals in combination with the use of the contralateral hearing technology.

Individuals with hearing loss have difficulty understanding everyday conversations, particularly in the presence of background noise (Tyler, et al., 1993; Peelle, 2017; Mattys, et al., 2012). In addition to decreased speech recognition, hearing loss also increases listening effort (e.g. Rabbitt, 1009; Hick and Tharpe, 2002). Listening effort increases as cognitive demand increases: as people with hearing loss attempt to listen to speech in noise, the increased listening effort causes their cognitive capacity to be limited, leaving fewer mental resources available for simultaneous cognitive tasks, such as recall, environmental monitoring, and following a conversation (Hick and Tharpe, 2002; Fraser, et al., 2010). Unilateral hearing loss can also contribute to increased listening effort, even when the desired signal is presented to the better ear (Ferberstein, 1992). Amplification has been shown to decrease listening effort in individuals with hearing loss, particularly when the hearing aids have some type of noise reduction algorithm (Picou, et al., 2013; Murphy, et al., 2000). Although cochlear implants do incorporate noise reduction similar to hearing aids (such as fixed and adaptive mic beam formers, or front end noise reduction algorithms) for unilateral cochlear implant users, listening effort is still negatively impacted by the unaided contralateral ear. Unilateral cochlear implant recipients who use a hearing aid or a CROS device on their non-implanted ear may have reduced listening effort, depending on the location of the speech signal and noise as well as which device they are using.

III. Preliminary Studies/Progress Report:

This study is the first of its kind here at the University of Colorado School of Medicine. Dr. Anderson is the Director of Audiology at UCHHealth as well as a research audiologist for the Department of Otolaryngology at the University of Colorado School of Medicine. Dr. Anderson has executed numerous research studies surrounding the settings and usage of hearing aids.

IV. Research Methods

A. Outcome Measure(s):

Primary Outcomes: Results of speech in noise tests

Secondary Outcomes: Results of perceived listening effort ratings; Results of acceptability ratings

B. Description of Population to be Enrolled:

Up to 50 patients will be enrolled in this study. Subjects to be enrolled in this study will already have a clinical relationship with a professional in the adult ENT and Audiology clinics at University of Colorado Hospital or will meet the inclusionary criteria. Only candidates who are eligible will be invited to participate.

The targeted population for this study are Advanced Bionics cochlear implant recipients between the ages of 18 and 99 years old and must have 12 months of listening experience. Proficient English speakers will be targeted for this study.

Inclusion Criteria:

1. Subjects between the ages of 18 years (inclusive) and 99 years (inclusive, subjects over the age of 89 will be recorded to be 89 years old).
2. Utilizes a Naida Q90 processor, or is able to effectively fit using a laboratory Naida Q90 I processor.
3. At 6 months post activation, any one low frequency (125, 250, and 500 Hz) \leq (better than) 90 dB HL in non-implanted ear.
4. Advanced Bionics CII or later generation Cochlear Implant recipient with at least 12 months of listening experience (i.e. at least 12 months post-activation)
5. Minimum auditory-only, open-set speech recognition scores using sentence-based assessment of 40% in quiet.

Exclusion Criteria:

1. C1 internal device (Naida processor currently not compatible)
2. Non-English speakers
3. Unwilling to sign the informed consent

C. Study Design and Research Methods

Consented subjects will fill out a case history form and participate in various speech and hearing tests under 15 conditions which will provide data on which device condition(s) produce the best speech perception in noise results.

Recruitment Methods:

Subjects will primarily be recruited from the University of Colorado Hospital (UCH) Hearing and Balance Clinic. Patients seen in a UCH Hearing and balance Clinic (Anschutz Medical Campus, Boulder Health Center, or Lone Tree Medical Center) who meet the inclusion criteria may be recruited for participation in this study. Participants may be initially contacted face-to-face, by flyer, by letter or by telephone. Subjects will not be called or contacted by email more than 3 times total (telephone and email contacts together).

Depending on success of recruitment, some subject may be recruited from other local audiology clinics. A letter will be sent to the audiologists of these clinics and the audiologists will hand out flyers to subjects who meet criteria.

Participation, or non-participation, will have no bearing on the clinical care received by the patient in the clinical setting.

Consent Process:

An investigator trained to both the study and the Department of Otolaryngology's standard Operating Procedure for conducting informed consent will conduct the consent process with the potential subject. The consent discussion will take place in a private clinic room. Patients will be encouraged to ask questions and to take their time to consider enrollment into the study.

One of the primary outcomes of this study is speech perception testing which involves subjects repeating sentences back to the audiologist in English. For this reason, we will not enroll non-English speaking subjects. This study does not provide a benefit to subjects and therefore does not in any way cause a disadvantage to non-English speaking subjects.

Study Visits:

Subjects enrolled into the study will be expected to visit the clinic outside of standard of care visits as outlined in the following schedule of events:

	Visit 1	Visit 2	Visit 3
Case History	X		
Hearing Evaluation	X		
Speech in Noise test	X	X	X ⁰
Listening effort rating scale	X	X	X ⁰
Acceptability rating scale	X	X	X ⁰
Self-report measure of device benefit	X	X	X ⁰

X⁰- This study is designed so subjects may complete all testing procedures in 2 visits. However, if subjects feel overwhelmed by the length of the visit, they may choose to break up their tests into up to 3 visits.

Study timeline:

The expected total participation time for subjects is two (2) visits but may extend to three (3) visits. There are no required timeframes for the visits to be completed. It is anticipated that all visits will be completed within one month's time. The expected total amount of time across all visits is four (4) hours.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Consented subjects will fill out a case history form and participate in various speech and hearing tests under fifteen (15) conditions which will provide data on which device condition produced the best speech perception in noise results. In addition, study personnel will review the medical charts of enrolled subjects for the following information pertinent to the study.

The data include the following:

- Name
- Medical Record Number
- Date of birth (to calculate age)
- Other pathology data that is related to study aims
- Other medical conditions and comorbidities

Research versus Standard of Care:

All procedures outlined in this protocol are considered research.

All devices (study hearing aid and study CI sound processors) will be programmed following the consenting process, case history, and hearing evaluation. The study hearing aid (Phonak/ AB Link) will be programmed for the non-implanted ear using the AB Bimodal fitting formula in the Phonak fitting software in accordance with clinical best practices, including real ear verification. Real ear verification assures that hearing aid is providing appropriate audibility for the subject. A static omni mic setting will be used. The sound cleaning feature of NoiseBlock will be enabled.

Two study Naida CI Q90 sound processors will be used. The first study processor will be initialized to work with the study hearing aid. A study program will be created using the participant’s everyday program as the baseline. Mic mode will be set to omni directional. If the ClearVoice strategy is enabled in the baseline program, the clinical setting will be noted and used. If ClearVoice is disabled in the baseline program, it will be activated and set to ‘medium’ strength. Other sound cleaning algorithms like WindBlock, SoundRelax, EchoBlock, autoUltraZoom, UltraZoom will be disabled.

A second study CI sound processor will be initialized to work with the study CROS. The study CROS device will not require any additional programming and will work “out of the box” in conjunction with the CROS initialized CI sound processor.

Prior to initiating any of the study assessments and following the consenting process, hearing devices will be fit on the participant. Both devices will be programmed following the consenting process, case history, and hearing evaluation. The study hearing aid (Phonak/ AB Link) will be programmed for the non-implanted ear using the AB Bimodal fitting formula in the Phonak fitting software in accordance with clinical best practices, including real ear verification. Real ear verification assures that hearing aid is providing appropriate audibility for the subject. CROS device fitting will be programmed to communicate with the cochlear implant processor

Following device programming, participants will be tested on the specified conditions in a predetermined randomized order (both for device used and for order of condition assessed). The table below outlines each procedure:

Chart Review	Purpose
Cochlear Implant Information	Collect information regarding cochlear implant (date of surgery, specifications of internal and external cochlear implant equipment)
Datalogging	Characterize typical listening environment of participant as identified by the cochlear implant datalogging

Test Type	Purpose	Standard Test	Description	Length of Time
Informed Consent	Assure participant is providing consent prior to			15 minutes

Test Type	Purpose	Standard Test	Description	Length of Time
	initiating any study tasks			
Case History	Capture information regarding the subject's hearing and cochlear implant/ hearing aid history	Case History Questionnaire (attached)	Questionnaire queries history of cochlear implant and hearing aid use, medical history related to hearing health and auditory system, and other factors that may influence hearing status.	10 minutes
Hearing Evaluation	Quantify the hearing status of the subject	pure tone air and bone conduction	Assess unaided thresholds for both right and left ears, assess cochlear-implant aided thresholds.	20 minutes
Hearing Device Fitting	Program the hearing aid and CROS device	Fitting/Real ear measures of hearing aid and link CROS with CI	Assess amount of sound in ear canal to assure that sound is appropriately audible based on hearing loss of non-implanted ear.	30 minutes
Speech Perception in Noise Test	Quantifiable measurement of a subject's ability to process speech in an environment with competing sound	Sentence in noise assessment	Sentences are presented with competing noise. Speech will be presented at 60 dBA. Level of noise will be adaptive, and will assess the SNR needed for 50% correct. Specific conditions are noted below.	10 minutes per condition (150 minutes total)
Listening effort and acceptability rating scales	Obtain subjective rating of the degree of difficulty and desirability presented by each listening condition	Listening Effort and Acceptability Scale (attached)	Following each speech-in-noise condition, the listener will rate the amount of effort required to complete the task and the acceptability for listening with the assessed device settings.	Included in speech-in-noise conditions above

Conditions assessed for Speech Perception:

1. Speech presented at non-CI side (CI only) and noise presented diffusely
2. Speech presented at non-CI (CI+HA ON) and noise presented diffusely
3. Speech presented at non-CI (CI+CROS ON) and noise presented diffusely

4. Speech presented at CI side and noise presented diffusely (CI only)
5. Speech presented at CI side and noise presented diffusely (CI+HA ON)
6. Speech presented at CI side and noise presented diffusely (CI+CROS ON)

7. Speech presented to the front, noise presented diffusely (CI-only)
8. Speech presented to the front, noise presented diffusely (CI+HA ON)
9. Speech presented to the front, noise presented diffusely (CI+CROS ON)

10. Speech presented at non-CI side (no device) and noise presented at CI-ear (+90° and -90°)
11. Speech presented at non-CI side (CI+HA ON) and noise presented at CI-ear (+90° and -90°)
12. Speech presented at non-CI side (CI+CROS ON) and noise presented at CI-ear (+90° and -90°)

13. Speech and noise presented from front (CI only)
14. Speech and noise presented from front (CI+HA ON)
15. Speech and noise presented from front (CI+CROS ON)

Description of procedures and related risks:

Test	Risk	Rationale
All	Accidental sharing of information	Because patients are recruited into this study, this study could not be done without the use of some PHI for contacting subjects.
Speech Perception in Noise Test	Boredom	Speech Perception testing poses very little risk to subjects. Each of the evaluations proposed here are standard clinical protocols.

Minimizing risks:

In order to minimize the risk of unintentionally sharing research data, paper records (which is limited to the informed consent/HIPAA B combined document) will be stored in a locked cabinet secured to a wall. In addition, access to electronic records will be limited to only study personnel. Subjects will be offered breaks if they feel tired, bored or an inability to concentrate.

Other risks:

Other risks of participation in the study include the potential of sharing research data with individuals outside of the research team. In order to minimize the risk of unintentionally sharing research data, paper records (which is limited to the informed consent/HIPAA B combined document) will be stored in a locked cabinet secured to a wall. In addition, access to electronic records will be limited to only study personnel. Because subjects may return for multiple visits, it is necessary to maintain identifiable data as part of the study records. This makes it possible to connect data from one visit to the next. All research data including identifiable fields will be maintained in REDCap. Identifiable fields will be marked appropriately within the database so that specific permissions are required for their exportation to any other media.

Adverse Event Reports:

Due to the minimal risk nature of this study, it is not anticipated that subjects will require care for adverse events. However, if a subject experiences an adverse event requiring medical attention, the patient will be offered treatment at the Otolaryngology Outpatient Clinic. Any adverse events and/or Unanticipated Adverse Events will be treated using the standard of care for the specific problem.

Adverse events will be recorded if and when they occur. If an adverse event is unanticipated or serious, then a report will be filed to COMIRB as soon as possible but within no more than 5 days of the event.

Withdrawn subjects

Subjects who are enrolled but choose not to complete all visits will be considered withdrawn from the study. If a subject withdraws from the study, it may not be possible to retract all data about that subjects from the database because information will be shared with the sponsor intermittently throughout the study.

Data Collection Tools

Study data will be collected and managed using REDCap (Research Electronic Data Capture). REDCap is a secure web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The system was developed by a multi-institutional consortium which includes University of Colorado–Denver and was initiated at Vanderbilt University. The database is hosted at the University of Colorado–Denver Development and Informatics Service Center (DISC), which will be used as a central location for data processing and management. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the DISC. This iterative development and testing process results in a well-planned data collection strategy for individual studies. REDCap also includes a powerful tool for building and managing online surveys. The research team can create and design surveys in a web browser and engage potential respondents using a variety of notification methods. REDCap is flexible enough to be used for a variety of types of research and provides an intuitive user interface for database and survey design and data entry.

E. Potential Scientific Problems:

There are no known scientific problems at this time.

F. Statistical Analysis Plan

Sample Size Estimate:

The standard deviation for speech reception thresholds (SRTs) for individuals with cochlear implants was used for an estimate of within group variation. This value, obtained from a similar analysis of an Advanced Bionics device versus a Cochlear Corporation device (Gifford & Revit 2010), is estimated to be 3.2 dB.

This study will utilize a modified eight-period crossover design for the two treatments, where 4 sequences will be used for each hearing device. A power analysis was conducted using simulations to detect a difference in speech reception thresholds of 2 dB between two groups at an alpha level of 0.05. A sample size of 14 subjects total provides 90% power to detect a difference in speech reception thresholds of 2 dB. To assess the accuracy of these simulations, other non-simulated power analyses showed similar results, even though these methods do not directly apply this study's design. This change of 2 dB is a clinically meaningful difference that we consider a realistic expectation of the intervention, the CROS device, in this study. Although no attrition is expected, we will recruit up to 50 subjects which will give more power so that the interactions can be estimated more accurately.

Statistical Analysis Plan:

Statistical analysis will be carried out using SAS. A linear mixed model will be fit with SAS PROC MIXED using a random subject effect. The primary outcome, speech reception threshold (dB), will be regressed on the main effect of treatment (CROS hearing device vs. conventional hearing aid), signal location (directly to the CI ear vs. opposite), and noise location (directly to the subject's non-CI ear vs. diffuse in the room), as well as the interactions between device type and locations. This method provides valid handling of occasional missing observations. Contrasts will be used within the model to estimate both overall effects and differences in conditions.

G. Summarize Knowledge to be Gained:

This study intends to determine whether or not a conventional hearing aid or a CROS device utilized on the ear contralateral to cochlear implantation improve speech perception in noise when the source of the speech of interest originates from the side of the head opposite to the cochlear implant.

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