Effects of Interaural Loudness and Pitch Mismatch in SSD-CI Outcomes

Protocol

Version 1.0

6-23-22

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NCT No: NCT05494632

Unique protocol ID: 202206085

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Study Summary

Individuals with single-sided deafness (SSD) i.e., normal hearing in one ear and severe to profound hearing loss in the other, struggle with daily communication due to the severe impact that listening with one ear has on speech understanding in background noise and sound localization (Firszt et al, 2017). Additionally, SSD reduces quality of life by increasing listening effort, fatigue, and social isolation (Wie et al, 2010). Cochlear implantation of the deaf ear can partially restore hearing to that ear, and since FDA approval of cochlear implants (CIs) for SSD in 2019, the number of SSD-CI recipients has increased. Studies indicate CI benefit for SSD-CI recipients (Buss et al, 2018, Firszt et al, 2012); however, some individuals still perform poorly with a CI, despite short-term deafness and restoration of bilateral input (Litovsky et al, 2019, Sladen et al, 2017). Bilateral input, i.e., sound input to both ears, is necessary for effective binaural processing. Binaural processing cues such and interaural (between ear) loudness differences and interaural timing differences are used by individuals to understand speech in noise and to localize sound. Effective binaural processing depends on similar loudness growth functions at each ear (Francart et al, 2013, Blamey et al, 2000). Pilot data from our lab suggests that loudness growth for SSD-CI recipients is unequal between the CI ear and the normal hearing ear. This difference in loudness growth between ears is known as interaural loudness mismatch. We aim to equalize loudness growth between the normal hearing ear and CI ear through CI speech processor program modifications. Equalizing loudness growth between ears of SSD-CI recipients may improve binaural processing cues and in turn, speech understanding in noise and localization ability.

Binaural processing is also affected when signals of equal frequency are not matched in pitch at each ear (Francart et al, 2007) In adults with bilateral CIs, differences between ears in electrode insertion depth resulted in interaural pitch mismatch, which was thought to impede binaural abilities (Kan et al, 2013). SSD-CI present distinct complications because of large differences in frequency representation between the CI and the normal hearing ears (Fu et al, 2017). To what degree an interaural pitch mismatch can be overcome is unclear. Some studies suggested CI users adapt to pitch mismatch (Reiss et al, 2014),while others have shown less evidence of adaptation (Tan et al, 2017). Some studies have shown improved speech recognition for bilateral CI users when interaural pitch mismatch was decreased through self-selected modifications of the CI program's frequency allocation table (Svirsky et al, 2015). Our pilot data demonstrated a relation between interaural pitch mismatch and speech understanding in noise for bilateral CI recipients. Decreasing the pitch mismatch between the normal hearing ear and the CI ear of SSD-CI recipients could improve speech understanding in noise and localization ability.

Background and Significance

Effective binaural processing depends on similar loudness growth functions at each ear (Francart et al, 2013, Blamey et al, 2000). The use of interaural level differences (ILDs), perceived as loudness differences, to locate sound is critical given the inability of CI recipients to use interaural time differences (ITDs) in binaural processing (Francart et al, 2013, Litovsky et al, 2012). In CI recipients with SSD, perceived interaural loudness differences may not be valid indicators of interaural level differences because the CI compresses amplitude (Dorman et al, 2015). Studies suggest better preservation of ILDs may contribute to improved localization and understanding in noise. For example, the use of linked, rather than independently-operated automatic gain controls, better preserved natural ILDs and improved binaural perception in normal hearing adults listening with and without CI simulations (Spencer et al, 2019, Schwartz et al, 2013). Since SSD-CI recipients use only one device, an approach to improve their use of ILDs is to match perceived loudness at each ear (Buss et al, 2018).

Pilot data from our lab suggest loudness growth for SSD-CI recipients is unequal between ears. We obtained loudness growth measures for the normal hearing ear and the CI ear in 9 SSD-CI recipients. SSD-CI recipients used their everyday speech processor program. The average interaural loudness mismatch between the normal hearing and CI ears was 7.7 dB. Individual variability in interaural loudness mismatch was seen among the 9 SSD-CI recipients. For example, the average interaural loudness mismatch was 5.6 dB for Participant 1 and 15.4 dB for Participant 2. Modifications were made to Participant 2's CI speech processor program to reduce interaural loudness mismatch. After program modifications, the average interaural loudness mismatch for Participant 2 decreased from 15.4 to 11.9 dB; Participant 2 reported that the new program was louder but still comfortable and speech understanding was improved. We propose that large interaural loudness mismatch may impede binaural abilities and the integration of the acoustic and electric signals for SSD-CI listeners. Program modifications to equalize loudness growth may improve these abilities.

As noted above, binaural processing is also affected when signals of equal frequency are not matched in pitch at each ear. Our pilot data on 22 bilateral CI recipients shows large interaural pitch mismatches relate to speech understanding in noise. We found that the greater the pitch mismatch between ears, the poorer the speech understanding in noise. We want to extend this work to SSD-CI recipients. Through CI program modifications, we aim to decrease the pitch mismatch between the CI ear and the normal hearing ear to improve binaural listening abilities, specifically speech understanding in noise and sound localization.

<u>Study Objectives</u>

Study Objective: Improve SSD-CI recipients’ speech understanding in noise, localization abilities, and sound quality through CI speech processor program modifications that reduce interaural loudness and pitch mismatch.

Hypothesis: We hypothesize that interaural loudness and pitch mismatch reduce binaural processing cues and contributes to performance outcomes, specifically speech understanding in noise and localization. We aim to improve binaural cues through speech processor program modifications that reduce interaural mismatches.

<u>Study Design</u>

Study 1 will focus on interaural loudness mismatch. Study 2 will focus on interaural pitch mismatch. SSD-CI recipients with at least 6 months of CI experience will participate in Study 1 and 2. Some individuals may participate in both studies. Study 1 and Study 2 each have 4 study sessions, lasting between 1-3 hours per session. Participants will be in each study for approximately 8-10 weeks. 15-20 participants will participate in each study.

Study 3 will also focus on interaural pitch mismatch, but participants will be newly implanted, i.e., have no long-term experience with a Nucleus CI. Participants will have chosen to be implanted with a Nucleus CI and be scheduled for CI surgery or will have had CI surgery prior to being enrolled in the study. Participants in Study 3 will be assigned to one of two groups, Group A or Group B. Both groups will participate in 5 study sessions, lasting between 1-3 hours per session. Participants will be in the study for approximately 14 weeks. 8-10 participants will participate in Study 3.

Inclusion Criteria

Participants for the proposed study will be adults with single-sided deafness. Participants will have at least 6 months experience with their cochlear implant or will be newly implanted with the cochlear implant.

Inclusion criteria for the experienced CI user group and the newly implant group are as follows:

- 18 years of age and older
- Postlingual onset of SSD
- Pure tone average (PTA) at 500, 1000, and 2000 Hz of less than or equal to 30 dB HL in the contralateral ear, known as the normal hearing ear
- Implanted with or chosen to be implanted with a Nucleus cochlear implant
- Full insertion of electrode array

Exclusion Criteria

- Not meeting the inclusion criteria

Informed Consent

The principle investigator, with the help of other research team members, will identify potential participants from our cochlear implant patient population. We will send the recruitment letter and the consent form to potential participants or a research team member will provide the consent form to the potential participant while the potential participant is in our offices for a clinical appointment. It will be indicated via the letter or the team member that potential participants who are interested in study participation or who have questions about participation should contact either the principal investigator or the other audiologists on the study team. Once a potential participant calls our office or tells us directly that they are interested in participation in the study, he/she will be scheduled to come to the cochlear implant offices.

At the first study visit (while in a private room), the potential participant will be asked if they have read the consent form. If not, they will be asked to read the form at that time. The consent form will then be reviewed by the potential participant with the research team member discussing each section of the consent form. The potential participant will be given an opportunity to ask questions and have them answered. Individuals who are still interested in participating will sign & date the consent form, as will the research member who is consenting the participant. One aspect of the individuals participation that will be highlighted in this discussion is the ability to withdraw from the study at any point for any reason - that their participation is entirely voluntary.

Study Procedures

Study 1 - Interaural Loudness Mismatch in Experienced SSD-CI recipients

Session 1: Testing with the participant's everyday speech processor program and creating an experimental program. Hearing thresholds for each ear will be obtained. Word recognition testing will be completed in the CI alone listening condition. The normal hearing ear will be plugged and muffed or masking noise will be used to isolate the CI ear. Speech recognition in noise testing will be completed in the bilateral listening condition, i.e., CI ear and normal hearing ear. Localization testing will be completed in the bilateral listening condition. During localization testing, the participant hears a word from 1 of 15 loudspeakers. The participant states the loudspeaker number from which the word came. Participants will complete the SSQ questionnaire asking them how well they hear in a number of listening situations and asking them to rate the quality of sound that they hear. Each participant's loudness growth for each ear will be measured to determine their interaural loudness mismatch. An experimental program will be created based on the loudness mismatch. Participants will wear the experimental program home.

Session 2: Adjustment to the experimental program. After using the experimental program for 1 week, the participant will return to the center. Loudness growth functions will be obtained with the CI alone using the experimental program. Further adjustments may be made based on the loudness growth functions. Participants will take home the experimental program for 5 more weeks.

Session 3: Testing with the experimental program. The same word recognition, speech recognition in noise, and localization measures that were administered in Session 1 will be completed with the experimental program. The SSQ questionnaire will be completed. Both the everyday and experimental programs will be placed on the participant's speech processor. The participant will take home both programs to compare for 2 weeks. A listening questionnaire will be given to the participant to complete at home and return at session 4. The listening questionnaire asks the participant to rate their speech understanding with each program in a number of listening situations.

Session 4: Testing with both the everyday and experimental programs. The same word recognition, speech recognition in noise, and localization measures that were administered in Session 1 and 3 will be completed with both programs. The listening questionnaire will be discussed.

Study 2 - Interaural pitch mismatch in Experienced SSD-CI Recipients

Session 1: Testing with the participant's everyday program and creating an experimental program. Hearing thresholds for each ear will be obtained. Word recognition testing will be completed in the CI alone listening condition. The normal hearing ear will be plugged and muffed or masking noise will be used to isolate the CI ear. Speech recognition in noise and localization testing will be completed in the bilateral listening condition, i.e., CI ear and normal hearing ear. Participants will complete the SSQ questionnaire.

An experimental speech processor program will be placed on the participant's speech processor. The experimental speech processor program will be identical to the participant's everyday program except for the frequency boundaries assigned to each electrode. The frequency boundaries in the experimental map are assigned to each electrode to reduce the pitch mismatch between the CI ear and the normal hearing ear. The experimental frequency boundary assignments are based on work done at WU using CT imaging of the cochlear implant (Skinner et al, 2007; Teymouri et al, 2011) and the characteristic frequencies of the spiral ganglion cells in the cochlea (Strakhovskya et al, 2007).

Session 2: Adjustment to the experimental program. After using the experimental program for 1 week, the participant will return to the center for continued adjustments if needed. Participants will take home the experimental program for 5 more weeks.

Session 3: Testing with the experimental program. The same word recognition, speech recognition in noise, and localization measures that were administered in Session 1 will be completed with the experimental program. The SSQ questionnaire will be completed. Both the everyday and experimental programs will be placed on the participant's speech processor. The participant will take home both programs to compare for 2 weeks. A listening questionnaire will be given to the participant to complete at home and return at session 4. The listening questionnaire asks the participant to rate their speech understanding with each program in a number of listening situations.

Session 4: Testing with both the everyday and experimental programs. The same word recognition, speech recognition in noise, and localization measures that were administered in Session 1 and 3 will be completed with both programs. The listening questionnaire will be discussed.

Study 3 will also focus on interaural pitch mismatch, but participants will be newly implanted, i.e., have no long-term experience with a Nucleus cochlear implant. Participants will be assigned to one of two groups, Group A or Group B. Participants in group A will initially use the manufacturer's default frequency boundary (FB) assignments (the FB assignments typically used clinically) in their speech processor program. Participants in group B will initially use the experimental FB assignments (FB assignments to reduce pitch mismatch between ears) in their speech processor program. All participants will use both the experimental and default FB assignments during the study. The order in which participants are assigned to each group will be counterbalanced, i.e., the first participant will be assigned to Group A, and the second participant will be assigned to Group B, etc. The goal is to have and equal number of participants in each group.

<u>*Group A*</u>

Session 1: Participants programmed with Default FBs at Initial activation of CI or shortly after the initial activation. Use Default FBs for 6 weeks.

Session 2: Testing with Default FBs after 6 weeks. Participants programmed with Experimental FBs. Use Experimental FBs for 6 weeks.

Session 3: Program adjustments after 1 week use of Experimental FBs, if needed.

Session 4: Testing with Experimental FBs after 6 weeks use. Default and Experimental FB programs both placed on participants' processors. Use Default and Experimental FB programs for 2 wks.

Session 5: Testing with Default and Experimental FB programs after 2 weeks use of both.

<u>*Group B*</u>

Session 1: Participants programmed with Experimental FBs at Initial activation of CI or shortly after the initial activation. Use Experimental FBs for 6 weeks.

Session 2: Testing with Experimental FBs after 6 weeks. Participants programmed with Default FBs. Use Default FBs for 6 weeks.

Session 3: Program adjustments after 1 week use of Default FBs, if needed.

Session 4: Testing with Default FBs after 6 weeks use. Default and Experimental FB programs both placed on participants' processors. Use Default and Experimental FB programs for 2 weeks.

Session 5: Testing with Default and Experimental FB programs after 2 weeks use of both.

The same test measures, test conditions and questionnaires administered in Studies 1 and 2 will also be administered in Study 3 during the testing sessions.

Test Measures

Hearing thresholds: Auditory Thresholds via insert earphones for the NH ear and FM tone sound field threshold levels using the CI alone are obtained. The NH ear will be plugged and muffed or masked to ensure CI alone responses.

Speech Recognition in Quiet: *CNC words* are presented at 60 dB SPL from a loudspeaker at 0°azimth in the CI alone condition (NH ear plugged and muffed or masked).

Speech Recognition in Noise: The R-Space uses an 8-loudspeaker, 360º array, and diffuse restaurant noise (60 dB SPL). Sentences are from 0º azimuth and level is adapted (2 dB increments) based on responses. Scores represent the SNR for 50% accuracy. BKB SIN sentences are presented with sentences from the front and noise from the front, towards the left ear, and towards the right ear. Scores represent the SNR for 50% accuracy. Participants listen in the bilateral condition.

Localization: Localization in Quiet employs 15 loudspeakers 10º apart covering a 140º arc. Words are presented randomly (60 dB SPL ±9 dB) from one of 10 active loudspeakers (±70º, ±50º, ±30º, ±20º, ±10º). The participant aligns to 0º azimuth, and after each presentation, indicates the loudspeaker location number. Results yield RMS error in degrees. Participants listen in the bilateral condition.

Participant Questionnaires: Participants rate hearing ability in daily life using the Speech, Spatial and Qualities of Hearing Scale (SSQ) across three domains: speech understanding, spatial hearing and quality of hearing. Participants compare Everyday and Exp maps using a listening questionnaire developed at WU.

Interaural Loudness Mismatch: The loudness of sounds is judged at each ear across a range of levels to obtain loudness growth (LG) functions and an estimate of interaural loudness mismatch. Participants use their everyday CI program and settings. Stimuli (2.5-sec segments of the speech-like International Speech Test Signal; ISTS) are presented in the sound field (0° azimuth, 25 to 80 dBC SPL in 5-dB steps); participants rate loudness on a continuous scale from "Heard Something" to "Very Loud." There are 4 presentations per level and ear condition (NH ear, CI off; CI alone [NH ear plugged/muffed or masked]). The overall interaural loudness mismatch estimate is the average magnitude of the difference in sound level (in dB) at each ear, for sounds judged equally loud.

CI program modifications based on loudness mismatch: Program modifications are made to obtain equal loudness at each ear when the same sound level (dB SPL) is presented to each ear. First, each electrode's threshold level (T-level) and maximum-comfort level (C-level) are measured. T-levels are set to 100% detection, and C levels are set to loud but comfortable. Loudness is then balanced between adjacent electrodes. While listening to 65 dB SPL connected discourse in the sound field, C-levels are raised until participants report equal loudness between ears. CI sound field thresholds are obtained to ensure thresholds of ~20 dB HL across frequencies. Program modifications to improve loudness growth for soft and very soft sound include adjusting T- and C-levels, microphone sensitivity, and enabling ADRO. Noise suppression settings may be disabled to better equate sound quality between ears.

Experimental FBs based on CT Imaging at WU: The average insertion angle for each electrode will be determined using measurements obtained from a large number of Nucleus CI recipients. The characteristic frequency of the stimulated spiral ganglion cells, based on the average of each electrode's angular insertion, will be the basis for creating the Experimental FBs. Modifications will primarily alter apical electrode frequency allocations; the normal ear may compensate for missing low frequency information not processed by the CI.

For all 3 studies, datalogging will be checked using the programming software at each session to determine the amount of time per day the participant is using the speech processor.

<u>Study Risks</u>

Risks for participants in Studies 1 and 2: Participants may prefer the everyday program over the experimental program. Changes will be made to the experimental program to optimize the sound quality. Participants may get tired, bored or frustrated during the speech recognition and localization testing. Breaks will be given to prevent boredom and fatigue.

Risks for participants in Study 3: Participants may not like the new frequency boundary assignment, after wearing the first frequency assignment for 6 weeks. Participants may prefer the original frequency assignment over the new assignment. Adjustments will be made to the new frequency assignment to optimize the sound quality. Participants may get tired, bored or frustrated during the speech recognition and localization testing. Breaks will be given during the testing to prevent boredom or fatigue.

<u>Study Benefits</u>

The potential benefit to the participants is that reducing interaural loudness and pitch mismatch through adjustments of their speech processor program could improve their speech understanding in noise and localization abilities.

The benefits to society may be that we find reducing interaural loudness and pitch mismatch beneficial to SSD-CI recipients. We can then provide speech processor programming guidelines to cochlear implant audiologists who are working with these patients.

<u>Participant Withdrawal</u>

Any participant can discontinue the study at any time without prejudice. The site's PI may also discontinue a participant at any time if health is a risk or if the participant is uncooperative and otherwise impacting the integrity of the data. All withdrawals will be documented including the reason for withdrawal.

Summary of Analysis Methods

Studies 1 and 2: Data are examined for distributional abnormalities and outliers that might indicate the need for transformations. Initial analyses for both studies 1 and 2 are completed prior to CI modifications and use a regression model that includes the selected outcome measure, primary predictor variables. Other analyses are ANOVAs that include repeated measures: Studies 1 & 2, results before and after program modifications; Study 3, Session. Study 3 also includes the frequency boundary program in the analyses.

Power Analysis

Based on previous work, we estimate 20 participants per study will be needed to complete studies 1 and 2. The exact number needed will depend to a certain extent on the amount of variability we have in participant demographic factors such as length of time with substantial hearing loss or age at onset of hearing loss. As the study proceeds, we may learn that additional participants are needed. If so, we will submit a modification to the protocol. In study 3, we are collecting pilot data on 8-10 participants. Again, we may learn that additional participants are needed and will submit a modification to the protocol if needed.

Data Review

Jill Firszt, the PI, and research team members, Laura Holden, and Noel Dwyer, will review the data from all participants on a periodic basis.

Participant Reimbursement

Participants will be paid $15.00/hr for participation. Mileage will be reimbursed at the current government rate. Parking will be paid.

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