COMIRB
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Principal Investigator: Melinda Anderson, PhD
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Study Title: Evaluation of speech-in-noise performance for individuals using a cochlear implant and a conventional hearing aid or CROS device

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about the effectiveness of the Contralateral Routing of Signal (CROS) device when it is placed on the non-implanted ear on individuals with Advanced Bionics Cochlear Implants. The CROS device is made to improve speech understanding in loud environments when the speech source is on the side of a person's head without the cochlear implant. You are being asked to be in this research study because you are between the ages of 18 and 99 years old and you have been using an Advanced Bionics Cochlear Implant with a Q90 processor for at least 6 months.

Other people in this study

Up to *50* people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to complete two scheduled visits to complete four assessments. If testing is tiring, you may choose to complete the testing over three visits.

For this study, you will wear your cochlear implant with a combination of nothing on the other ear, a hearing aid on the other ear, or the CROS device on the other ear. You will be fit for optimal settings of these devices before undergoing listening tests.

The four assessments are:

- **Case History:** you will fill out a case history form which include questions about your hearing and cochlear implant/hearing aid history.

- **Hearing test:** you will have a hearing test in a hearing booth much like what you experience at a regular audiology visit. The audiologist will test your hearing with no devices (left and right) and with just your cochlear implant.

- **Programming**: You will have your cochlear implant re-programmed to work with the hearing aid and CROS devices. Your hearing aid may be re-programmed as well. If you do not have a hearing aid, you will receive a loaner hearing aid for the study.

- **Speech Perception in Noise Test (IEEE):** Sentences will be read to you with background noise. You will be scored on how many words you can correctly repeat. You will undergo this testing wearing hearing devices in three different manners:

    - CI Alone
    - CI and hearing aid
    - CI and CROS device

    For each of the above listening manners, you will be tested five times with speech and noise coming from different directions. You will be tested fifteen total times across two to three visits.

    After each test, you will rate each listening condition for ease of listening and preference.

What are the possible discomforts or risks?

Discomforts you may experience while in this study are listed by procedure below:

- **Fatigue/Boredom** – completing the various assessments may be inconvenient and may take up to four hours over the course of two to three visits. It is possible you may feel tired, bored, or an inability to concentrate. If this occurs you will be offered breaks and you can choose to add the third visit.

- **Research Data** - There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the CROS device. This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

- This research is being sponsored by Advanced Bionics, the manufacturer of the CROS device and your Cochlear Implant.

Will I be paid for being in the study?

You will be paid $60.00 for completing the study. You will be paid $20.00 for the first visit and $40.00 at your final visit.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Anderson immediately. Her phone number is 303-724-9316.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Anderson. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Anderson at 303-724-9316. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Anderson with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Melinda Anderson, PhD
University of Colorado
Department of Otolaryngology
12631 E 17th Ave, B205

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Advanced Bionics, who is the company paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Your social security number
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, procedure results
- Research Visit and Research Test records
- Hearing evaluation and speech perception in noise test results

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you

during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Witness Signature:_____ Date_____

Witness Print Name:_____

Witness of Signature

Witness of consent process