

The Vanderbilt Bill Wilkerson Center for Otolaryngology and Communication Sciences

Image-Guided Cochlear Implant Programming Research

A. Research description

This document summarizes how to participate in two ongoing cochlear implant studies at Vanderbilt. One study looks at cochlear implant electrode placement using CT (Computed Tomography) scans from before and after cochlear implant surgery. The other study tests how adjustments to cochlear implant programs (maps) change how a patient hears. For patients who participate in both studies, we can test a new process for using information from CT images to adjust cochlear implant programs and measure how this new process changes how a patient hears. This new process is called “Image-guided cochlear implant programming.” The remainder of this document outlines how to participate in the two studies. The study to test the image-guided cochlear implant programming process could include turning off cochlear implant electrodes, changing signal levels, and changing frequency settings. This is a trial and results may vary. If a new research program (map) can be made, it could decrease, increase, or not change how well a patient hears. After the study, patients can choose to keep the new program or return to their original program.

B. Study design

Taking part in the studies will require up to three visits to Vanderbilt for each ear studied:

1st Visit-Get a CT scan if needed and 1st Audiology Visit: If the patient has already had a CT scan after their CI surgery as part of their routine care, it may not need to be done again. The research team will need to look at the CT scan to see whether or not it can be used. After the CT scan has been done or if a prior CT scan can be used, the patient will complete a set of hearing tests with their existing program (map). Once this is done, the research team will make a new research program (map) change. The patient will use the new research program (map) for about 3-4 weeks at which time they will return for the 2nd Audiology Visit.

2nd Audiology Visit: The patient will complete a set of hearing tests with their research program (map). Once this is done, the research team may make a 2nd research program (map) change. The patient will use the 2nd research program (map) for about 3-4 weeks at which they will return for the 3rd Audiology Visit. If a 2nd research program (map) is not created, the patient can decide whether or not they want to keep the research program (map) or go back to their original program.

3rd Audiology Visit: The patient will complete a set of hearing tests with the 2nd research program (map). The patient can decide whether they want to keep the 1st or 2nd research program (map) or go back to their original program (map).

Patients who have cochlear implants in both ears may be able to take part in the study for both ears. In this case, the patient will need to repeat the Audiology Visits for the second ear.

C. Participant Requirements

To be able to participate in the studies, patients are required to:

- Be at least 18 years old. Future studies may include younger participants.

- Have had a temporal bone CT scan done BEFORE cochlear implantation. The research team must review the CT to see if it can be used in this study. If the CT scan was done at Vanderbilt, the research team may have access to the scan. If the CT scan was done at another facility, the patient will need to obtain a copy of the scan for the research team to review in order to go on to the next steps. When a copy of the scan is requested, the radiology department where the scan was performed will need the following information: The CT scan must be on a CD in the standard DICOM 3D image file format.
- Have 6 months or more use of the CI with stable hearing performance.
- Have any standard multi-channel cochlear implant produced by Advanced Bionics, Med-El or a Nucleus 24 or later device produced by Cochlear Americas.
- Have the ability to understand and repeat complex sentences administered orally.
- Have documentation of audiology history (e.g. audiology clinic note) to include:
 - o Current hearing test results with the implant
 - o Brand and model of implant- internal and external
 - o Mode of communication
- Travel to Vanderbilt University Medical Center, up to three times for one ear and up to five or six times for both ears (see Study Design for details).
- Have a temporal bone CT scan done AFTER cochlear implantation.
 - o For patients who have already had a CT done after implantation:
 - If the CT scan was done at Vanderbilt, the research team may have access to the scan. If the CT scan was done at another facility, the patient will need to obtain a copy of the scan on a CD for the research team to review. When a copy of the scan is requested, the radiology department where the scan was performed will need the following information: The CT scan must be on a CD in the standard DICOM 3D image file format.
 - If no previous scans can be used for the study, a new CT scan can be done as part of the study and will be paid for by research funds.
 - o For patients who have not had a CT scan done after implantation, a CT scan can be done as part of the study and will be paid for by research funds.
 - Females of childbearing potential will undergo testing to document they are not pregnant.

***Please note: CDs and audiology documents will not be returned.**

D. Cost

There is no cost for tests and scans done only for research.

E. Contact

If you would like to take part in this research and you meet the requirements outlined in Section C, or if you have other questions about this research, please contact:

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