Research Protocol

Benefits of Bimodal Streaming for MED-EL Cochlear Implants: Early user experience with the AudioKey Application and Starkey Hearing Aids
Version 1.0

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Benefits of Bimodal Streaming for MED-EL Cochlear Implants: Early user experience with the AudioKey Application and Starkey Hearing Aids

1. Introduction

This study aims to capture early user feedback from bimodal MED-EL cochlear implant (CI) recipients using a novel audio streaming paradigm that allows direct, simultaneous streaming from an iOS or Android device to both their CI audio processor and hearing aid. Streaming audio has become ubiquitous and for many patients it is an important part of daily listening habits. Individuals with hearing loss may rely more heavily on Bluetooth streaming to their hearing devices as background noise disparately affects their ability to understand speech. Until now, direct, simultaneous Bluetooth streaming to a MED-EL cochlear implant audio processor and a hearing aid was possible only for Android users, with iOS users requiring a third-party intermediary device in order to receive sounds to both devices. MED-EL Elektromedizinische Geräte GmbH (Austria) recently partnered with Starkey Laboratories, Inc. to develop a bimodal solution that streamlines Bluetooth pairing and allows audio streaming from an iOS device to both ears for patients using a compatible MED-EL audio processor and Starkey hearing aid. MED-EL CI recipients will be able to configure their audio processor for direct streaming with a compatible Starkey hearing aid in the AudioKey application. Once configured in the application, recipients can stream phone calls and media directly from the iOS device to their CI audio processor and hearing aid for a binaural listening experience. This innovation brings Bluetooth streaming access to bimodal MED-EL recipients using iOS or Android devices which may provide improvements to these users' overall satisfaction with their hearing devices and may ultimately reduce their need for technical support from their audiologist. This study aims to capture feedback from early adopters of this new bimodal streaming paradigm between MED-EL and Starkey devices, and to measure ease of use and overall satisfaction with this technology.

2. Aims and Objectives

2.1. **Specific Aim 1:** To evaluate subjective user satisfaction with and improvement in aspects of hearing with bimodal streaming when compared to their previous streaming setup.

2.2. **Specific Aim 2:** To compare changes in participant streaming behavior and satisfaction with bimodal streaming from Baseline to 1-Week.

3. Study Sites and Investigators

3.1. Up to three (3) sites will participate. Sites will complete study procedures in accordance with the protocol including subject consent, device fitting as applicable survey distribution, and data entry.

3.2. Each site will obtain Investigational Review Board (IRB) approval and/or acknowledgment of exempt status prior to beginning subject enrollment. The Primary Investigator and Co-Investigator(s) for each site will sign Investigator Agreements and will be expected to collect and submit data in accordance with the requirements of this protocol.

4. Device Description(s)

4.1. **AudioKey application:** The MED-EL AudioKey application is a software product which can be used with compatible non-implantable MED-EL products. It is intended to be used on a smartphone with internet connection to remotely control compatible MED-EL audio processors and to provide status information of compatible non-implantable MED-EL products. The AudioKey application is intended to be used by individuals who received at least one of the compatible MED-EL audio processors and caregivers of these individuals. The AudioKey application allows users to customize personal settings, locate lost or misplaced audio processors using the Find My Processor functionality, review device usage statistics of the connected audio processors, and quickly access user manuals. AudioKey can configure devices for Bluetooth streaming including MED-EL audio processors, streaming devices (AudioStream, AudioLink), and compatible Starkey hearing aids. AudioKey is available for free download in Google Play and Apple application stores.

5. Potential Benefits

5.1. Bimodal streaming of audio to both ears may provide the following benefits to the listener:

5.1.1. Improvement in clarity and sound quality of music, calls, and other audio streamed from the cellphone

5.1.2. Increased enjoyment of music when streamed from the cellphone

5.1.3. Reduced listening effort when streaming phone calls from the cellphone

5.1.4. Improvement in overall satisfaction with streaming audio from the cellphone

5.1.5. Improvement in overall satisfaction with hearing devices

6. **Potential Risks**

6.1. The AudioKey application does not perform as expected

6.2. The audio processor does not receive changes initiated by the AudioKey application

6.3. Loud sound sensations are perceived by the listener during audio streaming

7. **Study Population and Sample Size**

7.1. **Study Population:** Adults who have already been implanted with a MED-EL cochlear implant and who are utilizing a Starkey hearing aid that is compatible with the AudioKey application will be recruited for participation.

7.2. **Sample Size:** This study will enroll 10 to 20 subjects with a goal of enrolling at least 10 subjects for analysis of the primary endpoint.

8. **Duration of the Investigation**

8.1. Subject recruitment is expected to take place over a period of 6 months. Data will be collected on each subject for a period of up to 3 weeks.

8.2. Data management and analysis is expected to be completed over the course of 3 months following final subject completion. The total expected duration of the investigation is 10 months.

9. **Study Design**

9.1. Prospective, multicenter study.

9.2. Test Materials and Administration

9.2.1. **Baseline User Survey:** The baseline user survey is intended to be completed by the subject at the baseline interval. Survey questions ask for the subject's experience with Bluetooth streaming and their satisfaction ratings of their

current hearing abilities, hearing devices, and Bluetooth streaming set-up. Subjects who participated in the pairing process of AudioKey application are asked for their rating on ease of use.

9.2.2. **1-Week User Survey:** The 1-week user survey is intended to be completed by the subject after they have completed a trial with AudioKey application. Survey questions ask for the subject's success with maintaining a Bluetooth connection to AudioKey application and their subjective ratings on improvement in clarity, sound quality, enjoyment and ease of listening to different inputs when streaming with AudioKey, as well as improvement in their global satisfaction with their current hearing devices with added use of AudioKey, and likelihood of continued use of AudioKey application.

10. **Test Intervals and Procedures**

10.1. **Baseline Visit (completed after subject is consented)**

10.1.1. The subject's hearing aid and audio processor are verified by the study site to be functioning appropriately prior to study procedures.

10.1.2. The AudioKey application is installed on the subject's cellphone if not already downloaded. The subject's audio processor and hearing aid are paired to AudioKey application. Subject is then trained on application use for bimodal streaming during the 1-week trial.

10.1.3. The Baseline User Survey is completed by the subject.

10.2. **1-Week Visit (1-3 weeks after Baseline)**

10.2.1. Subjects complete the 1-Week User Survey. Subjects who have agreed to receive surveys electronically receive a link to complete the survey via email. Subjects who have not agreed to complete the survey electronically are provided a paper copy of the survey and are asked to return it to their investigative site promptly after completion.

10.2.2. Subject participation in the study is complete once the 1-Week User Survey is received.

11. **Subject Selection and Withdrawal**

11.1. Inclusion Criteria:

11.1.1. Implanted with a MED-EL cochlear implant in one ear

11.1.2. Consistently using a MED-EL audio processor that is compatible with AudioKey (SONNET (EAS), SONNNET 2 (EAS), SONNET 3 (EAS), RONDO 3)

11.1.3. Has access to a MED-EL streaming device if needed (SONNET (EAS)/SONNET2 (EAS)/RONDO 3 users)

11.1.4. Using a Starkey hearing aid in the nonimplanted ear that is compatible with the AudioKey application

11.1.5. Using a smartphone that can support the AudioKey application

11.1.6. Able to complete a survey via cellphone or computer

11.1.7. Prior experience with Bluetooth streaming OR expressed motivation to Bluetooth stream to hearing devices

11.1.8. Ability to complete all study procedures including provide responses to survey questions

11.2. Exclusion Criteria:

11.2.1. Unable to provide reliable feedback

11.2.2. Unable to operate a smartphone with or without assistance

11.3. Subject Withdrawal:

11.3.1. Subjects may choose to withdraw themselves from the study at any point during participation without fear of repercussion.

11.3.2. Investigators should report subject withdrawals, terminations, and subjects who are lost-to-follow up to the Sponsor immediately. Every effort should be made to contact subjects lost-to-follow-up and determine reason for noncompliance.

11.3.3. The principal investigator may terminate subject participation from the study due to noncompliance with the study protocol or health concerns that prevent required participation.

11.3.4. Withdrawn subjects will continue to be seen by their clinical audiologist but no additional data will be collected.

12. **Database and Statistical Analysis**

12.1. MED-EL North American Clinical Research Department, the study sponsor, will complete data entry, database management, and statistical analysis.

13. **Statistics and analysis plan**

13.1. Descriptive statistics will be used to report baseline characteristics (e.g., age, duration of CI use). Quantitative data will be presented as the mean and standard deviation (SD) or median and range (minimum and maximum).

13.2. **Specific Aim 1:** To evaluate subjective user satisfaction with and improvement in aspects of hearing with bimodal streaming when compared to their previous streaming set-up.

13.2.1. Subject responses on the 1-week survey will be reported using descriptive statistics including the percentage response rates for each question/domain.

13.3. **Specific Aim 2:** To compare changes in subject streaming behavior and satisfaction with bimodal streaming from baseline to 1-week.

13.3.1. The change in subject response from the baseline to 1-week survey will be summarized using descriptive statistics for the following questions/domains:

13.3.1.1. Frequency of Bluetooth streaming

13.3.1.2. Satisfaction with bimodal streaming

14. **Monitoring**

14.1. Database entry and associated source data (paper surveys and case report forms) will be monitored periodically by the Sponsor.

15. **Data Management**

15.1. Copies of completed case report forms (CRFs) and surveys will be submitted to the Sponsor through secure email. Surveys completed electronically will be captured and stored in a secure electronic survey application. Personal identifiable information is excluded from CRFs and surveys to ensure protection of subject's personal information. The sponsor will use an unambiguous subject identification code to allow identification of all the data reported for each subject, to ensure confidentiality. Data will be extracted from case report forms and surveys and manually entered into a controlled network database.

16. **Investigator Agreement**

16.1. Prior to commencement of the Clinical Investigation at each Site, the investigators shall have signed the Investigator Agreement, obtained IRB approval or exemption for this Investigational Plan and any associated consent materials to be used, and submitted the documentation required by 21 CFR Part 812 to the Sponsor.

17. **Investigational Review Board (IRB)**

17.1. The protocol and associated materials will be reviewed by a centralized IRB to ensure protection of human subjects during the retrospective review of medical records. In addition, the IRB at each investigational site will review the investigational plan and any consent materials, if required, prior to study start. Sites will provide a copy of IRB approval or institutional IRB acknowledgement of centralized IRB approval to the study sponsor prior to data upload.

18. **Informed Consent**

18.1. The consent form included with the protocol will be provided to each investigative site.

18.2. Written documentation of Subject's consent must be obtained prior to initiating data collection. The Subject must be verbally informed as to the purpose of the study and the potential risks and benefits known, or that can be reasonably predicted or expected. These risks are described in the consent. Subjects shall have sufficient opportunity to consider participation in the study. The investigator will explain the research study to the potential Subject, discuss their rights as research Subjects, and answer any questions that arise.

18.3. Subjects are then invited to sign and date the consent form, indicating their consent for enrollment. The investigator administering the consent will also sign and date the form to indicate the document was sufficiently explained and the Subject signature was witnessed. Only the Investigator or study personnel expressly approved by their ethics committee may administer consent. The Investigator will retain the original copy of the consent form, signed, and dated by the Subject, in the Investigator's study file. A duplicate shall be provided to the Subject, who is now a subject of the trial.

18.4. Subjects may withdraw consent to participate at any time without prejudice. Data collected prior to withdrawal will be included in the analyzed data set.

19. **Study Budget**

19.1. A study budget will be provided to the investigator which will include subject compensation. Subjects will receive reasonable compensation for their time and participation in the study.

20. **Publication**

20.1. Individual centers may use their results for publication and presentation, but the Sponsor has the right to review the material prior to submission for publication/presentation. Additionally, the Sponsor has a right to collaborate with study sites on publications and presentations