Study Protocol and Statistical Analysis Plan

Real-world perspectives on advancements in hearing aid technology

Version 3

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Protocol Title

Real-world perspectives on advancements in hearing aid technology

1 Background

Understanding speech in a noisy environment can be difficult for people with hearing loss even with hearing aids. Hearing aid manufacturers have implanted various methods (i.e., directional microphones, noise reduction, noise cancelers) to try to improve SNR to increase the speech understanding in these difficult listening situations.

One of Phonak's early directional microphone systems used a dual microphone directional microphone in the programmable behind-the-ear (BTE) PiCS Audio-Zoom and improved the SNR by about 8 dB relative to the omnidirectional microphone in a lab setting (Valente et al, 1995).

Stewart et. al, 2019 described various Phonak microphone systems. Real Ear Sound (RES) is a microphone mode in Phonak hearing aids that mimics the directional benefit that is provided naturally by the shape and resonances of the pinna. UltraZoom (UZ) was introduced with Phonak's Spice platform and is a monaural adaptive beamformer. StereoZoom was first introduced in Quest hearing aids as a static binaural beamformer creating a narrow focus. With Venture hearing aids, StereoZoom became an adaptive binaural beamformer that is active in the SPiLN program.

StereoZoom has shown a 1.5 dB improvement over the monaural beamformer, UZ, in noise when speech is in the front in various studies summarized by Stewart et. al, 2019. StereoZoom is beneficial when the dominant speech is located to the front in a noisy environment, however if the dominant speech is located to the sides or back, a narrow beamformer to the front is not ideal. Speech Locator is a feature that is new with Phonak Lumity that determines with the dominant talker is located in the front, back, left or right and steers the beamformer to a different/wider directional setting. StereoZoom 2.0 will also be introduced with Lumity and it allows for activation at a lower noise floor compared to the earlier version. The activation of StereoZoom 2.0 at a lower noise floor level is beneficial because research has indicated that the typical "speech in noise" environment is around 68 dB and typically not with a negative SNR (Smeds et. al, 2015 and Wu et. al, 2018). In addition, the transition into the SPiLN program for Audéo Lumity is smooth and only one ear needs to meet the criteria to switch into this program from AutoSense OS 5.0.

Audéo Lumity with APD 2.0, AutoSense OS 5.0, Speech Locator and StereoZoom 2.0 is expected to require less listening effort in noisy environments compared to previous generations with APD, AutoSense OS 3.0 and StereoZoom but has not been directly compared. In the lab setting, this investigation will focus on making it similar to the "real-world" by using a common level of a speech in noise situation with common SNRs when obtaining data on listening effort for Audéo Lumity vs. a previous generation device. During the home trial, inferences will be made from real-world situations recorded with EMA data regarding microphone mode settings for Lumity and a compartor device.

2 Objectives

Primary Objective:
Evaluate whether Audéo Lumity provides lower perceived listening effort (at least ~1 point on a 10 point rating scale) with speech from the side and from the back in noisy situations compared to a previous generation device with adults who have moderate to moderately severe hearing loss during a lab session using realistic overall noise levels and SNRs.

3 Description of the investigational device

The Audeo Lumity is the latest generation of Audeo RIC hearing aids. There are three form factors: R (Rechargeable), RT (Rechargeable with Telecoil) and RL (Rechargeable lifeproof). This study will use the Audeo Lumity 90-R.
The overall intended purpose of the device is to amplify and transmit sound ot the ear and thereby compensate for impaired hearing.

4 Design of the clinical investigation

This clinical investigation is an interventional study executed at one investigation site with a confirmatory design. The investigation model is single group with a crossover design and is single blinded. In lab, listening effort will be evaluated with speech from the side and from the back in noisy situations with both HIs.

5 Risks and benefits of the investigational device and clinical investigation

Audéo L hearing instruments carry only minimal risks under normal use conditions and are intended to give the user auditory access to speech communication. There are no risks associated with the investigation procedures that are not associated with the use of the device. Participants in this investigation will benefit from the ability to hear and communicate in their daily lives, while experiencing only minimal risk associated with the use of the device.

6 Endpoints

Primary endpoint:
A subjective listening effort questionnaire with a 10-point scale will be used. This questionnaire includes some questions from the Speech, Spatial and Qualities of hearing Scale (SSQ; Gatehouse & Noble, 2004) and was used in a previous study at PARC.

7 Inclusion and Exclusion Criteria

Subjects fulfilling all of the following inclusion criteria are eligible for the investigation:
-N3-N4 sensorineural hearing loss
-18+ years old
-Experienced hearing aid user
-Has a significant other/communication partner that could fill out a questionnaire about hearing aid performance during the home trial

The presence of any of the following exclusion criteria will lead to the exclusion of the subject
-Cognitive impairment
-Unwilling to wear the hearing aid

8 Measurements and procedures

The following measurements and procedures may be used during this investigation: Audiogram, speech intelligibility in noise (AZBio Sentences), RHHI_S, ASHA QCL, Listening effort questionnaire, Significant Other questionnaire, subjective questionnaire for ease of use.

Data will be captured at the time of testing. Data will be stored electronically on a Sonova-owned server and will be analyzed after all participants have completed all investigation tasks and appointments. Any paper-based data will be stored in a locked filing cabinet in which only authorized study personnel have access.

9 Statistical design and analysis

Sample size was estimated using G*Power software for the planned analysis using RMANOVA with within-subjects factor of device. An effect size in partial eta squared was calculated using data from a previous conducted at the site utilizing the same subjective measure of listening effort. The prior study investigated devices from multiple HI manufacturers under similar conditions planned for the current investigation. The effect size calculated from the existing data was then assessed for clinical applicability. The resulting effect size equated to roughly a 1 point difference on the measurement scale, which was judged to be clinically relevant.

This analysis will be conducted on a per protocol population (since the study involves a single group). Subjective listening effort ratings made during a laboratory session with two hearing instruments will be analyzed.

Data supporting the primary objective will be subjected to RM-ANOVA with a within-subjects factor of device. Analysis will be conducted with JASP open source statistical software. JASP will also be used to calculate descriptive statistics and generate visualizations of the data supporting the primary objective.

Adverse events, serious adverse events, and device deficiencies will be reported in a timely manner throughout the investigation. Appropriate action will be taken at the time of the report as outlined in this clinical investigation plan.

10 Investigation Duration

The expected duration for each participant is approximately 2-3 weeks. The total expected duration of the study is 4-6 weeks.

11 Data handling and management

This investigation will utilize paper-based and electronic CRFs. For all CRFs, the participants will be identified only by an anonymous code, which will not include their real names, initials, birthdates or identifying information. The code list will be stored separately on a restricted accesses server maintained by Sonova USA. All investigators and study staff will have address to the CRFs during the course of the investigation. Following the completion of this investigation, CRFs will be locked and maintained in the TMF and filing cabinet.

Any paper-based data will be stored in a locked filing cabinet at the investigation site for 10 years. All electronic data will be stored on an access-restricted server owned, operated, and maintained by Sonova USA for 10 years. Servers used to store data in this investigation are physically located in the US.

Only authorized study personnel will have access. Permission to access data will be limited to study manager, monitor, PI, and essential research staff, as designated by the PI.

All participants will be assigned an alphanumeric code by the study manager. There is no disclosure of personal information to anyone else but the investigation team and only members of the investigation team have access to these documents. Any identifiable information, such as the Subject ID Log, will be kept in a secure location at the investigative site.

Source data is encoded and will be archived encoded as well. Participants and their respective data will be tracked on source data and source documents via their participant ID. The de-identified data will be kept for 10 years after the publication of the results.

12 Amendments to the CIP

If it is necessary to make an amendment to this CIP, the changes to the CIP will be clearly identified with the date the change was made, and the version number will be incremented. Non-substantial amendments (e.g., correcting a typographical error) will be recorded as a minor version incrementation, whereas substantial amendments (e.g., a change to the study procedure or statistical plan) will be recorded as a major version incrementation. In an emergency situation, this CIP will be amended and updated only after participant health and safety have been assured and FDA/WIRB have been notified (as applicable). The amended CIP will go through the approval process and necessary signatures obtained from the study manager/sponsor, PI, and statistician. The amended CIP will be uploaded to the eQMS system as an additional revision.
Any necessary amendments to the CIP will be communicated by the PI, study manager and/or sponsor. Necessary members of the investigation team will be trained on the amendments.

13 Deviations from clinical investigation plan

Deviations from the CIP to protect the rights, safety and well-being of human participants under emergency circumstances may proceed without prior approval of the sponsor and the EC – such deviations will be documented and reported to the sponsor representative (Study Manager) and the EC as soon as possible. Apart from that the investigator is not allowed to deviate from this CIP unless that deviation does not influence the investigation data.

14 Device accountability

Each investigational device will have its own unique serial number. The PI or authorized designee will keep records on the Device Accountability Log (TPL-157) in chapter 7 of the TMF_ISF for SRF-285. Details include:

· Device Identifier

· Serial Number

· Date received from Sponsor

· Date(s) of use

· Participant ID

· If a Device Deficiency was experienced

· Date returned to Sponsor

This log will be actively maintained throughout the trial and will be stored in the TMF following the completion of the investigation.

15 Informed consent process

Prior to the beginning of the investigation, all participants will be provided with a written copy of an IRB-approved consent statement. The investigator will explain the consent document to the participant and answer any questions. Participants will be told explicitly that agreement to the consent document and their participation in the investigation is entirely voluntary and may be revoked at any time for any reason or no reason.
Participants will be incentivized with a monetary stipend of 30 USD per hour spent at the investigation site, plus mileage reimbursement for round-trip travel between the investigation site and their home address. Mileage reimbursement will be calculated based on the shortest driving distance in miles multiplied by the Internal Revenue Service’s (IRS) standard mileage rate at the time the study concludes.

Informed Consent will only be obtained by investigation participants who can provide informed consent themselves before enrollment.

16 Adverse events, adverse device effects and device deficiencies

Device deficiencies and all **adverse events (AE)** including all **serious adverse events (SAE)** are collected, fully investigated and documented in the source document and appropriate case report form (CRF) during the entire investigation period, i.e. from participant's informed con-sent until the last protocol-specific procedure, including a safety follow-up period (ISO-14155, 2020). Documentation includes dates of event, treatment, resolution, assessment of serious-ness and causal relationship to device and/or investigation procedure.
Information on AEs is systematically collected during the regular investigation visits, and phone calls (if applicable).
The investigator(s) will follow-up on a biweekly basis with any participant experiencing an AE until either a) the participant reports resolution of the AE or b) 8 weeks have passed since the participant's final visit. If, however, the participant's condition worsens throughout the 8 week follow-up period, the investigator will continue to follow-up biweekly until the AE is resolved or the participant's condition stabilizes over an 8 week period.
The reporting of Serious Adverse Events and Device Deficiencies follows the Regulation (EU) 2017/745 and the MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.
The causality assessment of the SAE will be conducted according to MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.

17 Vulnerable populations

This investigation will not include any vulnerable populations.

18 Suspension or premature termination of the clinical investigation

The study will be terminated if the majority of the participants are not able to wear the devices for the study visit.
The study will be terminated if the participants or researchers are exposed to safety risks other than those outlined in this document.
The study may be terminated in the event natural disasters, widespread outbreak of illness, compromised structure of the investigation site, etc. that would make continuation of the study impossible or impractical. The study will be suspended within 5 days of determination that the study or device put participants at an unreasonable risk.
If a participant is suspended, terminated, or withdraws from the study, their data can be traced with their unique study identification number.
According to the FDA, follow-up is required for participants who experience Serious Adverse Events. Follow up will be conducted by the study manager and/or the PI until the nature of the event is resolved.

19 Publication policy

The clinical investigation will be registered in clinicaltrials.gov, a publicly accessible database, as required by U.S. regulations.
The results of the clinical investigation will be published on clinicaltrials.gov no later than one calendar year following the final participant appointment.
An internal report of the results of this investigation will be completed and uploaded to eQMS.