Study Protocol and Statistical Analysis Plan

Benefit of Assistive Listening Device for Lateralization

Version 1.0

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Protocol Title

Benefit of Assistive Listening Device for Lateralization and Spatial Hearing

1 Background

MultiBeam technology available in Roger devices utilizes three directional microphones to form six directional beams. The signal-to-noise ration (SNR) within each beam is calculated simultaneously, and the beam that contains the highest SNR is made the active beam. This allows the user to better understand speech in group settings, especially in the presence of background noise. . Prior to the release of Roger On, the problem of multiple conversations happening at once could be managed using the manual steering functionality in the Roger Select. The drawback of this feature, however, is that it requires constant monitoring and adjusting by the listener. Further, making these manual adjustments to the microphone settings can result in distraction or disruption of conversation within the communication group. Spatializing the sound from a table microphone may provide cues to the listener that helps them to differentiate between two concurrent speech sources without manually steering the microphone beams. The purpose of this study is to evaluate the benefits in lateralization and spatial hearing with the new Roger On, compared to the legacy non-spatial multibeam setting in Roger Select.

2 Objectives

The primary objective of this study is to demonstrate an improvement in ability to discriminate direction of speech with the use of a Phonak Roger On remote microphone compared to the use of a Roger Select remote microphone for a group of adults with moderate to severe hearing loss.

3 Description of the investigational device

Roger On is a versatile wireless microphone dedicated for all conversation where background noise is present or when there is a distance to the talker. It features MultiBeam 2.0 Technology and Pointing mode 2.0. Personalization and remote control of the Roger On is easy with the new myRogerMic app. Roger On is compatible with all hearing devices with RogerDirect™ and all Roger receivers.

Intended Use: The wireless microphone captures the sound of a sound source by its microphones. It transmits the processed sound then wirelessly to a receiver in the hearing instrument.

4 Design of the clinical investigation

This clinical investigation is a single-site, interventional study with a confirmatory design. Neither experimenters nor participants are blinded to the intervention (Audéo P90 + Roger On, Audéo P90 + Roger Select) as each remote microphone must be placed on the table in front of the participant, in easy view. No control group is used for this investigation, as the objective is to quantify the benefit of spatial multibeam technology over non-spatial multibeam technology for individuals with moderate to severe hearing loss. Previous research conducted by Sonova

has revealed that, under certain conditions, Phonak Roger technology may yield a benefit for speech understanding in noise and over distance beyond the performance of listeners with normal hearing.

5 Risks and benefits of the investigational device and clinical investigation

For this clinical investigation, participants will be fit with laboratory hearing aids that have be designated for use in the study. Because the fit of these devices may differ from that of their personal hearing aids, the laboratory hearing aids may cause minor irritation or discomfort to the user when worn over a prolonged time. This may be mitigated with new coupling, and participants will be asked to report discomfort to the investigator immediately. In rare instances, domes and/or wax guards may detach from the device and become lodged in the ear. These items do not pose a significant health risk and can be removed from the ear canal by a licensed hearing care professional and/or physician.

There are minimal risks associated with both the investigational device and participating in the clinical investigation. Identified risks are no greater than those associated with the daily use and wear of approved, available hearing aids. The device used presents non-significant risk per FDA.

The benefits of participating in the investigation include the possibility of hearing sounds that have not been previously heard, such as speech and environmental sounds, which may improve communication in daily life. Subjects may experience the benefit of personal satisfaction for participating in research to improve hearing instrument technology. Subjects will also be compensated for their time in participating in this study.

There are no known or anticipated risks to subject hearing ability associated with participation in this study. All sounds used in this study will be presented at safe listening levels. While using hearing aids, the following are possible occurrences:

- •Cerumen impaction
- •Ear discomfort, pain or soreness
- •Sweat or moisture accumulation in the ear canal or pinna
- •A feeling of pressure or fullness in the ear
- •Itching, blisters, or sores in the ear canal or pinna
- •Headache
- •Redness of tissue

The research personnel will review these risks with the subjects and answer any questions they have. Hearing aids are not a significant risk investigational device as defined in the FDA 21 CFR 812.3(m).

6 Endpoints

Lateralization and spatial hearing performance are the primary clinical endpoints of this clinical investigation for the comparison of the intervention conditions Audéo P90-R + Roger On vs. Audéo P90-R + Roger Select.

These clinical endpoints were chosen to obtain clinical data that shows the clinical benefit of the spatial multibeam feature in the Roger On device. The intended purpose of the investigational device (i.e., Roger On) is to pick up the voice of a talker and send it directly to the listener's ears, in order to improve speech understanding in noise and over distance. The measurement of lateralization and spatial hearing performance was selected as primary endpoint because this is one of the primary use cases for spatial multibeam technology. The spatial multibeam feature of the Roger On is designed to provide cues to the listener that helps them to differentiate between

multiple speech sources without manually steering the microphone beams, thus preserving the spatial cues of the auditory scene.

The lateralization and spatial hearing tasks were selected as primary endpoints because these were found in a previous study to be sensitive to the benefit of SMB for detection the direction of sound and separating multiple speech sources falling in different beams of the Roger On.

7 Inclusion and Exclusion Criteria

Inclusion criteria:

1. Hearing impaired adults (minimum age: 18 years) who are experienced hearing aid users
2. Hearing loss is symmetric (no more than a 15 dB difference between the right and left ears at three contiguous frequencies) and moderate to severe in degree (N3-N5 standard audiogram)
3. Good written and spoken English language skills
4. Healthy outer ear (confirmed by otoscopy)

Exclusion criteria:

1. Contraindications to the medical device noted upon otoscopy (e.g., ear canal drainage)
2. Known hypersensitivity or allergy to materials of the investigational device or comparator
3. Inability to produce reliable test results
4. Known psychological problems
5. Reported symptoms of vertigo and dizziness by participant

8 Measurements and procedures

Lateralization and spatial hearing will be measured in two hearing technology conditions:

1. Audéo P 90 + Roger Select

2. Audéo P-90 + Roger On

Participants:

Adults with bilateral moderate to moderate severe sensorineural hearing loss

*10 adults (≥18 years of age)

*Note: More participants may be required if preliminary results reveal higher intersubject variability than observed in previous studies, or if participants withdraw or must be excluded.

PTA = 40 to 69 dB HL

Equipment set-up: Participants will be seated at a table with the Roger microphone centered on the table, 1 meter away from them. Three loudspeakers, used to present speech stimuli, will be positioned around the table at 0°, +60°, and -60° azimuth, relative to the position of the Roger microphone, each at a distance of 1 meter from the device. Consequently, the speaker positioned at 0° azimuth will be 2 meters away from the participant.
Stimuli: For the lateralization task, two lists of 18 sentences from the Hearing in Noise Test (HINT; Nilsson et al., 1994) will be administered to each participant. For the spatial hearing task, two lists of 12 sentence pairs (12 target sentences with 12 competing sentences) will be administered to

each participant. All sentences will be presented at a level of 65 dB SPL, measured at the location of the Roger On microphone.

Noise: 4-talker babble noise will serve as the competing noise signal. The level of the babble noise will be set to obtain the desired signal-to-noise ratio (SNR), measured at the location of the microphone.
Procedure: For the lateralization task, lists of 18 HINT sentences will be presented from alternating speakers (0°, +60°, -60°) in pseudorandom order using Adobe Audition. Participants will be instructed to keep their head pointed straight forward and indicate from which direction speech was coming by saying 'Left,' 'Center,' or 'Right' following the presentation of each sentence. The first 3 sentences in each list will always came from the left, center, and right speakers respectively and were will be proceeded by a cue from the experimenter (i.e., "this is left," "this is center," "this is right"), as a means of orienting listeners to the differentiation in location of speech in each Roger condition. These first three sentences will be excluded from analysis; thus, performance in each Roger condition will be determined by calculating the proportion of sentences for which direction of speech is correctly indicated, out of 15 sentences. For the spatial hearing task, lists of 12 target sentences from the AzBio sentence test will be presented via Adobe Audition through the left speaker (-60°). AzBio sentences are spoken by 3 different talkers: 2 males and 1 female. Four target sentences will be spoken by each talker in each list, in a pseudorandom order. Interferer sentences will be presented from the right speaker (+60°) by a different talker. Sentences overlap by 0.4-1.0 seconds; order of target vs. interferer sentences (i.e., which is presented first) is counterbalanced within each list. Participants will be instructed to repeat the sentence coming from the left speaker, and ignore the sentence coming from the right speaker. Scores on this task will be determined by calculating the proportion of words correctly repeated. If the participant repeats part or all of the sentence from the right speaker, this will be scored as 0 words correctly repeated.

9 Statistical design and analysis

In a previous internal investigation of spatial multibeam (SMB) technology, significant benefit of SMB (Roger On), compared to non-spatial multibeam (i.e., legacy technology available in Roger Select), was observed in a cohort of 8 adults. Participants in this study will also participate in another study examining benefit of Roger On for speech intelligibility compared to hearing aids alone. Ten participants will be enrolled in this concurrent study, as this replicates a previous study in which a significant benefit of Roger, compared to hearing aids alone, was observed in a cohort of 10 adults (Thibodeau, 2019). Additional participants may be recruited if preliminary results of speech intelligibility reveal higher intersubject variability than observed in previous studies, or if participants withdraw or must be excluded.

Lateralization performance will be recorded in proportion of sentences for which direction of speech is correctly indicated within each intervention condition (Audéo P90 + Roger On, Audéo P90 + Roger Select) for each anonymized participant.

Spatial hearing performance will be recorded in proportion of words correctly repeated from target sentences within each intervention condition (Audéo P90 + Roger On, Audéo P90 + Roger Select) for each anonymized participant.

Primary analysis of study data will be completed at the conclusion of the data collection period by a representative of the sponsor (study manager). The results of the speech intelligibility task will be subjected to multivariate analyses of variance (MANOVA) to examine main and interaction effects of intervention.

All safety related events will be constantly monitored by the investigators and will immediately reported to the Principle Investigator and representative of the study sponsor (study manager). Evaluation of any SAE, SADE, or UADE will be conducted promptly by the study manager using Sonova's standard medical device referral protocol. Confirmed UADEs will be reported to the IRB within 10 days after receiving notice of the event. If it is determined that an event or effect presents an unreasonable risk to subjects, this study, or those parts of the study presenting that risk, will be terminated no later than 5 working days after the determination is made and no later than 15 working days after Sonova USA first received notice of the event.

A safety analysis of the relevant data will be completed at the conclusion of the data collection period.

10 Investigation Duration

The total expected duration of the investigation is estimated to be 2 months. The expected duration of each individual participant is approximately 2 hours.

11 Data handling and management

Clinical investigation data will be recorded both with paper Case Report From (pCRF) and electronic Case Report Form (eCRF). A CRF will be maintained for each enrolled clinical investigation participant. All CRFs will be kept current to reflect the participant's status at each phase during the course of this clinical investigation. Participants will be identified in the CRF by an appropriate coded identification (participant ID). All clinical investigation team members are authorized for the CRF entries and it will be assured that any authorized person can be identified both for pCRFs and eCRFs. If pCRFs will be used, the investigator's identifier as well as the participant ID will be filled in and data are entered into an electronic file for analysis by the respective investigator. Data will be monitored by the assigned monitor. Participants are allowed to self-correct. Investigators do not make any corrections without documentation (i.e., from electronic records from software output).

Any hard copies of the source documentation will be stored in a locked cabinet and kept for a minimum of 3 years after regular or premature termination of the clinical investigation. Electronic data files will reside on a network drive or secure server that is accessible to the clinical investigation team. Servers are located in US. Hence, only encoded data will be stored on servers, which will not include personal data in any means. No third party will be able tracing back the encoded data to personal information of the participants.

During data collection of the investigation, physical copies of the data will be compiled and digitized by an on-site investigator on a daily basis. Data will be reviewed for mis-entries or inaccuracies as each data set is entered.

The extent and nature of monitoring appropriate for the clinical investigation including the strategy for source data verification (SDV) are based on considerations such as the objective, design, complexity, size critical data points and endpoints of the clinical investigation. A de-tailed plan for monitoring arrangements is provided separately from this CIP.

The Sponsor and Principal investigator affirm and uphold the principle of the participant's right to privacy and that they shall comply with applicable privacy laws. Especially, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals.

Individual participant medical information obtained as a result of this clinical investigation is considered confidential and disclosure to third parties is prohibited. Participant confidentiality will

be further ensured by utilizing participant identification code numbers to correspond to treatment data in the computer files as below described further. For data verification purposes, authorized representatives of the Sponsor or the study site Institutional Review Board (IRB) may require direct access to parts of the data records relevant to the investigation.

Actions taken to guarantee participant privacy:

- In general, Sonova follows the requirements from General Data Protection Regulation (GDPR).
- Participant names and details, accessible by the study monitor, appropriate investigators and Principle Investigator, are documented in the Participant Identification Log. There is no disclosure of personal information to anyone else aside from the investigation team.
- Participant paper-based files will be locked in cabinets at the study site; keys to the cabinet are placed in a location to which only the investigators have access.
- Electronical data is uploaded in project files on SharePoint; access is permitted to monitor, principal investigator, and investigators only.

12 Amendments to the CIP

Any necessary amendments to the CIP will be communicated to the study manager/sponsor. A new version of the CIP will be written, with the necessary changes and justification, and the PI will be trained on the amendments. 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.

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

As there is no home trial component to the study, investigational devices and compatible devices will be kept at the investigation site for the duration of the study and will be returned to the sponsor upon conclusion of the study. Tracking information will be shared between the study site and sponsor.

However, compatible device serial numbers will be saved in the fitting software, allowing for traceability during lab testing sessions (i.e., which devices were worn by each participant during each session).

If an investigational device must be replaced due to a device deficiency, record of the new serial number, device identifier, date of receiving the replacement, date of return of the defect investigational device, etc. will be maintained by the Study Manager.

Representatives of the sponsor (Study Manager) will maintain records of shipment/receipt of investigational devices and related study supplies between the sponsor and study site, including the return of devices to the sponsor once the clinical investigation has been finalized.

15 Informed consent process

The investigators will explain to each participant the nature of the study, its purpose, and the procedures, involving the expected duration, the potential risks and benefits and any discomfort it may entail. Each participant will be informed that the participation in the study is voluntary and that they may withdraw from the study at any time, and that withdrawal of consent will not lead to consequences for the participant. The participant must be informed that their medical records may be examined by authorized individuals.

The formal consent of a participant, using the approved consent form, must be obtained before the participant is submitted to any clinical investigation procedure. The participant should be given the opportunity to read and consider the statement before signing and dating the informed consent form and should be offered a copy of the signed document. The consent form must also be signed and dated by the investigator (or their designee) and it will be retained as part of the study records.

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 clinical investigation will be suspended or prematurely terminated if the feature and/or investigative device malfunctions or if the participants or researchers are exposed to safety risks other than those outlined in this document. These events may include but are not limited to – natural disaster, widespread outbreak of illness, compromised structure of the investigation site, etc. The trial will be suspended within 5 days of determination that the study or device puts subjects at an unreasonable risk (per 21 CFR 812).

19 Publication policy

The clinical investigation will be registered in clinicaltrials.gov, a publicly accessible database, as required by US law.

The results of the clinical investigation will be documented internally in a study report, authored by the study manager.