Study Protocol and Statistical Analysis Plan

Sound Quality Comparisons with Different Hearing Aid Couplings and Venting Systems

Version 2.0

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Protocol Title

Sound Quality Comparisons with Different Hearing Aid Couplings and Venting Systems

1 Background

When achieving optimal success with a hearing aid client, clinicians often have to manipulate coupling to adapt to patient's complaints. For example, more occluded coupling allows for less direct sound, al-lowing for a heavier balance of the HI's DSP algorithms relative to the environment. However, this occlusion often comes with client com-plaints of an unsatisfactory perception of their own voice. When the ear canal is occluded, it eliminates the ability for sound to transfer out of the ear canal, altering the ear canal acoustics and creating a change in perception of the user's own voice. This change in perception is often described as the user's voice being too loud, "boomy", or "hollow" (Winkler et al. 2016). Commonly, this becomes a process of trial and error for HCPs. A dynamic vent offers a potential solution for these situations. The mechanical operation of a dynamic vent allows for an occluded coupling in situations such as media streaming, but allows for an open coupling in situations where a more open coupling will suffice. The dynamic nature of a dynamic vent allows for the ear canal acoustics to adapt to the environment. For example, when streaming media, a closed position does not allow low frequencies to transfer out of the ear canal as they would with open fittings. Contrarily, in quiet environments, a vent that remains open allows for a more natural perception of the user's own voice.

Research has been conducted at NAL (sponsored by Sonova) as well as internally, to investigate sound quality and occlusion of a dynamic vent compared to other coupling options. However, previous research has investigated custom earmolds with various degrees of venting as comparators to a dynamic venting system. In the United States, it is customary to use universal domes (open, closed, vented, power, etc.), assuming gain is not a limiting factor and domes provide adequate retention. This research intends to identify significant perceptual difference in terms of sound quality, and occlusion, when a dynamic venting system is compared to universal open domes and vented domes.

2 Objectives

The primary objective of this study is to evaluate an active venting system across domains of sound quality and occlusion. More specifically, researchers hypothesize that a dynamic venting system will provide better streaming sound quality than coupling achieved with an open dome. Additionally, researchers hypothesize that a dynamic venting system will provide better quality of their own voice (less occlusion effect) than with coupling achieved with vented domes.

3 Description of the investigational device

The overall intended purpose of the device is to amplify and transmit sound ot the ear and thereby compensate for impaired hearing. The dynamic receiver features a mechanically

switching vent that is seamlessly steered by the automatic operating system of the hearing aid. It combines the hearing performance of the a closed fit with the comfort of an open fit.

4 Design of the clinical investigation

This confirmatory study will have 3 conditions across two tasks. One task will be investigating streaming sound quality and the other will investigate own voice perception (occlusion effect). The sample population will be of 15-20 human subjects. The order of conditions will be counterbalanced and the participants will be blinded to the conditions.

5 Risks and benefits of the investigational device and clinical investigation

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

Primary endpoint: Subjective ratings of the coupling conditions, for both streaming sound quality and own voice perception (occlusion effect). These will be administered via a 100 point scale, from 0 to 100 (0 = least preferred, 100 = most preferred). For streaming sound quality, participants will be presented with a pop song and will be asked to adjust the volume to their most comfortable level before making a rating. For the own voice perception portion, participants will be asked to read the Rainbow Passage prior to making a rating.
Secondary endpoint: Analysis of audio recordings of participants reading the Rainbow Pas-sage (for occlusion investigation). Given the Lombard effect, researchers believe there to be a possibility that subjects will adapt certain qualities of their voice depending on the level of occlusion. This secondary measure may give insight to such phenomenon and supplement further understanding of the primary objective.

7 Inclusion and Exclusion Criteria

Inclusion criteria:

18+ years of age

Hearing loss must be within the recommended fitting range and candidacy guidelines for the study devices and couplings.

Participants must indicate no prior history of problematic tinnitus or pain/discomfort from loud sounds.

Hearing loss must be symmetrical below 500 Hz (<= 10 dB) and sensorineural etiology

Exclusion criteria:

Unable or unwilling to have two appointments lasting approximately 2 hours each

Unable or unwilling to wear devices for study appointments

Active middle or outer ear drainage, infection, redness, swelling within 90 days of appointments

8 Measurements and procedures

Participants will be seen for two appointments. The first appointment will consist of updating the audiogram and taking earmold impressions.
The second appointment will last approximately one hour.
Two sets of comparisons will take place investigating streaming sound quality, and own voice tolerance. To compare streaming sound quality, participants will listen to a streamed music signal under the following conditions – dynamic vent receiver using a custom earmold in the closed position, SDS 4.0 receivers coupled with appropriately fitting open domes, as well as SDS 4.0 receivers coupled with vented domes. Conditions will be counterbalanced and randomized. Participants will listen to a 30 second excerpt of a pop song and make an absolute sound quality rating for each condition. To compare own voice tolerance, participants will read the rainbow passage (Fairbanks, 1960) under the following conditions - dynamic receiver in the open position compared to SDS 4.0 receivers coupled with appropriately fitting vented domes and open domes. Participants will be asked to give an absolute rating for both sets of comparisons-streaming sound quality, and quality of own voice.

All analysis of the results will occur at the conclusion of the study. Paper questionnaires will be digitized for statistical analysis. Audio recordings will be anonymized and saved as .wav files to be used for an intensity analysis. These will be stored on a company network drive.

9 Statistical design and analysis

A power analysis was conducted prior to the investigation. For a repeated measures ANOVA, a sample size of 20 participants is deemed adequate to detect a medium effect size (.3) with a power of 80%. This assumes a nonsphericity correction of 1. In the event that the dataset is not normally distributed, a rational arcsine unit transformation will be performed prior to per-forming the statistical analysis.

10 Investigation Duration

Expected participation for each subject is two days. The entire investigation is expected to last 2-4 weeks.

11 Data handling and management

Electronic or paper based CRFs will be used to capture the participant data. If electronic, subjective questionnaires will be available in the EDC system and the participant will be able to read question and choose answer. If paper based subjective questionnaires are used, the participant will answer each question and the results will be transferred to the EDC by the investigator. Objective data will either be entered in directly to the EDC system, or transferred from a paper based CRF into the EDC system.

All CRFs are kept current to reflect the subject's status at each phase during the course of study. Participants cannot be identified in the CRF by name or initials and birth date but an appropriate coded identification is used. All study team members are authorized for the CRF entries and it is assured that any authorized person can be identified both for pCRFs and eCRFs. If pCRFs are used, the investigator's initials and subject ID are documented and data are entered into an electronic file for analysis by the respective investigator and data will be monitored by the assigned monitor. In case of a self-evident corrections, either the subject does it by himself or the investigator undertakes the correction by crossing out the word/sentence with a single horizontal line and by adding the correction including his personal identifier and the date.

The results for the audiometer-based objective measure will be taken from the computer used to complete the test and imported into the EDC system or transferred via an excel or csv file. Real Ear Measurements will be imported from the verification system and stored as an excel file.

The pCRFs/eCRFs are only available to the local study team and to the monitor of the study. In the case of an audit or a serious adverse event, the CRFs may need to be de-anonymized and sent to the governing body (i.e FDA) or insurance company.
Any paper-based data will be stored in a locked filing cabinet at the investigation site. All electronic data will be stored on an access-restricted server owned, operated, and maintained by Sonova USA. Servers used to store data in this investigation are physically located in the US. Permission to access data will be limited to study manager, monitor, PI, and essential research staff, as designated by the principal investigator.
During data collection of the investigation, physical copies of the data will be compiled and digitized by the study manager/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 detailed plan for monitoring arrangements is provided separately from this CIP.

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

Sonova, in its capacity as sponsor, will maintain a log of all investigational devices, including the date of shipment from Sonova to the site, serial number, receiving study site, and date returned to Sonova.

The site will maintain a log of the devices provided by Sonova, including the date of receipt,serial number, date of fitting, participant identification, date of return to site by participant, and date returned to Sonova. Sonova will provide each site a template with which to record such information.

If a device needs to be replaced due to a device deficiency, the PI or sub-investigator will add the new device serial number, date of receipt, and date of return of the defective device on the Device Accountability Log.

In the case of a device deficiency, the Adverse Event-Device Deficiency form will be completed by the study manager and the PI or sub-investigators together.

15 Informed consent process

Informed consent will be obtained from participants prior to any study participation in accord-ance with the IRB guidelines. The participants will be granted sufficient time to read through the consent in full and ask any questions they have before signing. After the participant signs the consent form, the researcher will sign and provide a copy to the participant. This process will take place in a private office located in the Phonak Audiology Research Center (PARC).

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.