Study Protocol

A Study to Examine the Performance of a Hearing Aid Transducer During Typical, In-field Use

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In Field Performance of a Hearing Aid Transducer

1 Background

Hearing aid vents serve three primary purposes. The first purpose of a vent is to allow low-frequency sounds to pass directly into the ear, taking advantage of any residual low-frequency hearing ability. Vents also provide a level of comfort to the wearer by maintaining equal pressure with the space outside the ear. Finally, because vents allow for the escape of amplified sound out of the ear, they reduce the perception of occlusion for the wearer. However, while vents can provide improved sound quality and comfort, there are certain conditions in which a more closed fit would result in better sound quality and hearing performance, such as in noise and with streaming. This study will evaluate the sound quality in these situations with a prototype receiver which houses a dynamic venting system. Because this prototype is a new concept, this study serves to investigate topics such as overall reliability and end user perception.

2 Objectives

The purpose of this study is to evaluate the sound quality and reliability of a prototype receiver for RIC hearing aids.

3 Description of the investigational device

This study will use commercially available Phonak Marvel RIC hearing aids with a prototype dynamic receiver transducer. As the receiver is a prototype, no detailed description will be shared in a publicly viewed database.

4 Design of the clinical investigation

This a single-site, single group prospective, interventional study using commercially available Receiver-In-Canal hearing aids with a prototype receiver. Participants will be asked to participate in a three month long home trial. Following the three month trial, new participants will be recruited to participate in a six month home trial.

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 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. Additionally, participation in this study will help to inform future developments and improvements in hearing device technology.

Subjects experience the benefit of personal satisfaction for participating in research to improve hearing instrument technology, which has the potential to make future hearing aid use more beneficial and convenient. 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 the study. All sounds used in this study will be presented at safe listening levels.
While using the study hearing aid, the following are possible occurrences:
• Cerumen impaction
• Discomfort, pain, or soreness
• Sweat or moisture accumulation in the ear canal or pinna
• A feeling of pressure or fullness in the ear
• Blisters, itching, sores, or rashes in the ear canal or pinna
• Headache
• Redness of tissue

The research personnel will review all of these risks with the subjects and answer any questions they have.
This is a non-significant risk study following the abbreviated IDE requirements set forth in 21
C.F.R. § 812.2 (b)(1). [Hearing Aid] is not a significant risk investigational device as defined in 21C.F.R. § 812.3 (m).

6 Endpoints

Subjective ratings of sound quality in noise will be collected from the participants at the end of the three month trial, and from participants at the end of the six month trial. Reliability of the prototype receivers will also be recorded.

7 Inclusion and Exclusion Criteria

Inclusion criteria are as follows:

-Individuals over the age of 18 with mild to moderate symmetric hearing loss
-Experienced hearing aid users
-Willing to wear hearing aids for 12-16 hours per day for 3 to 6 months
-Able and willing to use smartphone (or other device) to stream media and phone calls to hearing aids.

Exclusion criteria are as follows:

-Anyone self reporting ear-related pathology, including otorrhea within 90 days, dizziness, sudden onset or worsening of hearing loss within 90 days, visible deformity of the ear, or otalgia
-Hearing loss that is too severe or too mild to be included in the recommended fitting range of the hearing devices
-New/inexperienced users
-Unable or unwilling to wear devices for specified period of time
-Recent history of middle e

8 Measurements and procedures

Participants will be given a hearing test if the most recent test on file is greater than 12 months.

Hearing aids will be fit and programmed according to best practices and adjusted for patient comfort, if necessary.

Participants will wear devices for either a 3 month period or a 6 month period, and will use the hearing aids as they would in daily life. Researcher will check in on a regular basis with each participant to ensure that device appears to be functioning and working properly. Additionally, participants will return to the lab on a regular basis for hearing aid checks.

At the end of the three or six month period, participants will be given a questionnaire asking them to rate their satisfaction with the performance of the devices. Additionally, participants may be asked if they would purchase devices and what they would expect a purchase price to be.

Researcher will record any deficiencies found with the prototype receivers and transmit information to the study requestors and product engineers.

9 Statistical design and analysis

There will be no statistical analysis of results. The average satisfaction ratings for sound quality in noise will be reported to the product manager. The reliability of the prototypes will also be recorded, and information will be sent to the engineers in the Research & Development department. Survival rate of the prototypes may be calculated by the R&D personnel in order to inform the future development of the prototype.

10 Investigation Duration

Participants will be expected to participate for either 3 months or 6 months. The entire investigation will take approximately 12 months to complete.

11 Data Handling and Management

Electronic or paper based CRFs will be used to capture the participants' answers to the subjective questions. If electronic, the questionnaire will be available in the EDC system and the participant will be able to read the question and choose the answer. If

paper based, the participant will answer each question and the results will be transferred to the EDC by the investigator.
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 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.

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. Specifically, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing 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.

All participants will be assigned an alphanumeric code by the PI and/or sub-investigators. Data shared with the study manager or monitor will be anonymized. The de-identified data will be kept for 10 years after the publication of the results. Any identifiable information, such as the Subject ID Log, will be kept in a secure location at the investigative site. In the case of external studies, the sponsor/study manager, and monitor will not have permission to save, store, record, retain, or share any identifiable information. The monitor will only view the informed consents in the presence of the study investigator (either via screen share if remote, or in person) for purposes of fulfilling ethical obligation to participant rights and safety.

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 HQ to the site, serial number, receiving study site, and date returned to Sonova.

15 Informed consent process

Informed consent will be obtained from participants prior to any study participation in accordance 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.

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 consent until the last protocol-specific procedure, including a safety follow-up period (ISO-14155, 2020). Documentation includes dates of event, treatment, resolution, assessment of seriousness 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) until the nature of the event is resolved.

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.

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.

17 Vulnerable Populations

There are no vulnerable populations included in this study.

18 Suspension or premature termination of the clinical investigation

The study will be suspended or terminated if the majority of the participants are not able to wear the devices on a daily basis.

The study will be suspended or 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.
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 (per 212 CFR 812).

19 Publication policy

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

The results of the clinical investigation will be published as an internal study report.