Study Protocol and Statistical Analysis Plan

Measuring comfort and clarity with low gain feature in pediatric hearing aid users

Version 1

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Protocol Title

Balancing Comfort and Clarity with an Adaptive Situation Gain (ASG) Feature in Pediatric Hearing Aid Users

1 Background

Children with hearing loss have expressed clear preferences regarding the function of their hearing aids in noise and low-level (quiet) listening environments (Scollie et al., 2010). Generally, environmental noise reduces listening comfort while distance from the talker or low-level conversations reduce listening clarity. Both situations can be addressed with noise management features and remote microphones, however management of the full landscape of listening environments is currently beyond the reach of these technologies. For example, neither feature provides auditory access to low-level input from multiple talkers at a distance which is known to be the source of most vocabulary learning in young children.

Among the hearing-aid prescriptions available to audiologists, two prescriptions are used most frequently with children. The Desired Sensation Level (DSL) prescription (Scollie et al., 2005) emphasizes audibility so that children have as much access as possible to the speech around them. The National Acoustic Laboratory NAL-NL2 prescription (Keidser, Dillon, Flax, Ching, & Brewer, 2011) emphasizes listening comfort. The output prescribed by these two approaches can differ as much as 5 to 15 dB, across frequency. In a field study with grade-school children, DSL (more gain) was preferred when listening to soft or distant speech while NAL (less gain) was preferred when listening to loud speech or in a noisy environment (Scollie et al., 2010a). Put simply, NAL was comfortable but not clear while DSL was clear but not comfortable. The results suggest that the hearing devices used at that time could not accommodate the wide range of input levels experienced by the children and therefore allow the fitting prescriptions to provide listening comfort and clarity.

The opportunity exists to extend the auditory field of children with hearing loss with a soft speech enhancer feature. Specifically, this feature has the potential to improve perception of low-level speech in quiet environments while preventing excessive amplification for louder inputs. Previous studies of adults with hearing loss have suggested a benefit of speech enhancement for perception of low-level speech. It is not uncommon for benefits observed in adults to be the same or larger in children. If so, this feature may provide audiologists with an additional tool to balance clarity and comfort for children. This document refers to this feature as ASG (Adaptive Situation Gain).

2 Objectives

The primary objective of this study is to evaluate the contribution of a soft speech enhancer feature (ASG) on auditory perception/memory and listener experience using the amplification strategies that are most common for pediatric fittings (NAL and DSL), in children with mild to moderately-severe sensorineural hearing loss.

There is no secondary objective.

3 Description of the investigational device

The investigational device is a commercially available receiver-in-canal (RIC) hearing aid. Hearing aids are intended to amplify and transmit sound to the ears and to hereby compensate for impaired hearing. The device is worn behind the ear for a duration of up to 16 hours per day, while the receiver is placed in the ear canal up to the ear drum. A qualified hearing care professional programs the device with the aid of Phonak Target to the patient's individual hearing loss.

4 Design of the clinical investigation

This clinical investigation is a single-site, interventional study with a exploratory design. Participants but not experimenters are blinded to the intervention (DSL vs. NAL, ASG on vs. AGS off) as the experimenters are responsible for programming and fitting the study devices. No control group is used for this investigation due to budget limitations.

5 Risks and benefits of the investigational device and clinical investigation

The purpose of this study is to determine if the unique benefits of the NAL and DSL prescriptive algorithms for children with hearing loss can be optimized further with ASG, an adaptive amplification feature designed to improve audibility for speech at low-level input levels.

Previous studies have shown that hearing loss slows the rate of language learning in children, relative to their normal hearing peers (e.g., Blamey et al., 2001). Outcome measures assessing how children with hearing loss perform on tasks involving both familiar and unfamiliar (i.e., new words) were chosen in order to determine if the unique benefits of the NAL (listening comfort) and DSL (speech clarity) prescriptive algorithms can be optimized further with Speech Enhancer for speech at low-level input levels. Optimizing the listening experience of children with hearing loss may support learning by improving audibility for new words as well as familiar ones (particularly when presented at low levels) without exceeding the children's tolerance for high-level input.

Identified risks are no greater than those associated with the participants personal hearing aids.

6 Endpoints

The primary study objective will be assessed by examining listening performance for stimuli presented at low- and high-presentation levels across a broad range of endpoints drawn from three categories of device benefit:

1) Familiar words: Perception (word recognition) and memory (familiar word recall)
2) New words: Non-word detection, identification, learning, and recall
3) User Experience: vocal level, ampclusion, and preferred hearing aid settings

7 Inclusion and Exclusion Criteria

Inclusion criteria are as follows:

1. Hearing impaired children between 8 and 15 years of age [Revised: 12 to 17 years of age]
2. Hearing loss is symmetric (no more than a 15 dB difference between the right and left ears at three contiguous frequencies) and mild to moderately-severe in degree (N2-N4 standard audiogram)
3. Oral mode of communication

4. Good written and spoken English language skills
5. Healthy outer ear (confirmed by otoscopy)
6. Informed assent (child) and consent (parent/guardian) as documented by signature

Exclusionary criteria are as follows:

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

Study tasks and other relevant measures (audiometry, Real Ear measures) will be completed in the following order:

1) Pure-tone audiometry will be completed at the beginning of Session 1, after informed consent/assent has been obtained, in a double-walled, sound-treated booth.
2) Real Ear Measurement (REM): Real-Ear Measurement (REM) is a tool used to objectively measure the hearing instrument's frequency response in a participant's ear. In this clinical investigation, on-ear REM will be completed using the Verifit2. Real ear measurement will be completed after hearing aid fitting and before the administration of study tasks.

3) After the fitting is complete and while the hearing aids and probe mics are still in the ears (after Real Ear Measures), physical and acoustic occlusion will be measured using the On-Ear Occlusion test option on the Verifit 2.

4) Binaural soundfield audiometric thresholds will be obtained but instead of being presented through headphones or insert earphones, tones will be presented through a loudspeaker positioned 1 m away from the participant at 0° azimuth. This will be completed in the hearing aid program with ASG activated. Additionally, a binaural speech reception threshold (SRT) will be obtained in each hearing aid program.

Nonword Detection Threshold
Speech reception threshold will be obtained. However, instead of only familiar words, participants will be presented with a mix of familiar and unfamiliar two-syllable words and asked to repeat each word they hear. The first words will be presented at a comfortable listening level. If the listener repeats the word correctly, presentation level will be reduced 10 dB and the next word will be presented. If the wrong word is given, presentation level will be increased 5 dB before the next word is presented. This will be continued until the lowest level has been identified corresponding to two out of three correct repetitions. This level is the nonword detection threshold. This task will be completed in each hearing aid program (ASG on, ASG off), and at both test sessions (DSL, NAL).

Word Recognition
Participants will hear lists of 20 monosyllabic words (10 per presentation level [40 dB, 70 dB], randomized) drawn from the Northwestern University word lists, presented one at a time. The listener will be instructed to repeat each word after they hear it. One 20-word list will be presented in each hearing aid program (ASG on, ASG off). A digital audio recorder (Zoom H2n), placed on the desk between the participant and the loudspeaker, will capture participants' verbal responses, which will be scored offline later by independent examiners. Scores will reflect the proportion of words repeated correctly. This task will be completed at both test sessions (DSL, NAL).

Auditory Verbal Learning Task
Participants will be instructed to listen to a list of 14 words (7 per presentation level [40 dB, 70 dB], randomized) and then repeat as many words aloud as they can remember at the end of the list. After each repetition of the list, the experimenter will select the correctly repeated words using the customized computer software. This will be repeated using the same words four more times, for a total of five trials. This task will be completed in each hearing aid program (ASG on, ASG off), and at both test sessions (DSL, NAL).

Nonword Identification
The nonword identification task will involve a mix of monosyllabic familiar and novel (nonsense) words presented together in three-word phrases. Following the presentation of each phrase, participants will indicate which words (if any) in each phrase were nonsense words by selecting the corresponding numbered button(s) on a computer screen. Visual reinforcement will be provided via an interactive computer game for correct responses, but not for incorrect responses. Performance is represented as the proportion of correct responses for whole phrases or individual words. One list of 20 phrases will be presented in each hearing aid program (ASG on, ASG off). Each list contains five phrases containing 3 real words and 0 nonsense words, five phrases containing 2 real words and 1 nonsense word, five phrases containing 1 real word and 2 nonsense words, and five phrases containing 0 real words and 3 nonsense words. Presentation level (40, 70) will be randomized across phrases. This task will be completed at both test sessions (DSL, NAL).

Novel Word Learning
Participants will learn novel words through a process of trial and error using an interactive computer game. Participants will hear five nonsense words, presented randomly one at a time. Each nonsense word is paired with one of five nonsense objects/characters. A picture of each nonsense image is displayed on one of five buttons arranged across the bottom of a computer screen. Listeners select one of the five images after presentation of each nonsense word. Visual reinforcement for correct selections is provided by a computer game located above the response buttons. The game advances following each correct response (e.g., one piece of a puzzle appears), while no reinforcement is provided for incorrect selections. Participants use the reinforcement to associate each nonsense word with the correct image. Each nonsense word will be presented 20 times (10 per presentation level [40 dB, 70 dB], randomized), for a total of 90 randomized trials. Trial-by-trial performance is calculated in 10 trial bins and fitted with an exponential function to determine the number of trials needed to reach 71%. Overall learning speed is calculated as the number of trials required to reach the criterion level of performance. Fewer trials indicate faster learning. This task will be completed in each hearing aid program (ASG on, ASG off), and at both test sessions (DSL, NAL).

Novel Word Learning Posttest
Each participant will complete a post-test 1 day after each word-learning session to determine the number of words retained for each hearing aid condition. This task will be conducted remotely. The child will be shown the 10 images learned the day before and a word bank from which to choose the correct response. The word bank will include links to audio files that the child may listen to as they make their decision. The word bank will contain an equal number of target- and nonsense-words. The images learned in the two hearing-aid conditions for the session will be presented randomly one at a time. No feedback is provided for either correct or incorrect responses. Performance is quantified as the number of words correctly identified in each experimental condition (ASG on, ASG off; DSL, NAL).

Hearing aid program preference
At the end of the second lab session, the participant will listen to a continuous audio file presented in the sound field while toggling between the hearing aid programs at their own pace. The audio file will contain speech samples (sentences) containing real and nonsense words in common environmental noise backgrounds. This will be repeated with the hearing

aids used during the hearing aids used by the participant during Session 1. After the child has had an adequate amount of time to listen to the sound scene in each program, they will be asked to indicate which of the hearing aid programs they most prefer. The experimenter will note which fitting formula was preferred and whether ASG was on or off. Overall results are quantified as the proportion of children who prefer each hearing aid condition.

9 Statistical design and analysis

Datasets to be analyzed, analysis population:

Outcome Measures	Fitting Formulas	Hearing Aid Programs	Presentation Levels
• Ampclusion • Word Recognition • Vocal Level • Familiar Word Recall • Non-word Detection Threshold • Non-word Identification • Rapid Word Learning • Learned Word Recall • Listener Preference	• DSL v5a Pediatric • NAL-NL2	• Speech Enhancer on at default • Speech Enhancer disabled	• 40 dBA • 70 dBA

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Primary analysis will compare results of study tasks completed with ASG on compared to ASG off, and with hearing aids programmed using DSL compared to NAL. Where applicable, separate analyses will be completed for each presentation level. The principal investigator (PI) will complete this analysis.

All safety related events will be constantly monitored by the investigators and will immediately reported to the Principal Investigator. Evaluation of any SAE, SADE, or UADE will be conducted promptly 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 done after the data collection is finished.

10 Investigation Duration

The investigation is expected to last 4-6 months. Each participant is scheduled for two appointments, each lasting approximately 2 hours.

11 Data Handling and Management

Study data is recorded both with paper and with electronic Case Report Forms (p/eCRF). For each enrolled study participant, a CRF is maintained. 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 identifier as well as the subject ID is filled in and data are entered into an electronic file for analysis by the respective investigator and data get monitored by the assigned monitor. Participants are allowed to self-correct. Investigators do not make any corrections without documentation (i.e., from vocal recordings and electronic records from software output).

All paper data will be stored in a binder in a locked lab. All electronic data files will be encrypted and stored on secure network server. All identifying data will be stored at the study site.

The identifiable data kept at the study site is secured indefinitely. The de-identified data will be kept indefinitely after the publication of results. When the data are destroyed, paper records will be shredded by services provided at the study site. Electronic data will be encrypted as de-identified. Digital records of anonymized data will be stored on a secured university network drive.

12 Amendments to the CIP

Amendments to the CIP, if necessary, will be updated with justification in this document.

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

The PI or authorized designee keep records documenting the following:
• Names of participants who received, used, returned, or disposed of device
• Date of receipt, identification, and quantity of each investigational device (batch/serial number or unique code)
• Expiry date (if applicable)
• Date(s) of use
• Participant identification

The PI or authorized designee keep records documenting the following:
• Date on which the device was returned (if applicable)
• Date of return of unused, expired, or malfunctioning investigational devices (if applicable)
• Date and documentation of disposal of devices as per sponsor instructions (if applicable)

15 Informed consent process

Because the participants in this study are minors (<18 years of age), written consent for study participation will be obtained from a parent or legal guardian. Written assent for study participation will be obtained from the participants.

At the beginning of the first appointment, investigators will describe the content of the written assent form to the participant in a private setting, with the consenting parent or guardian present.

The assent form contains detailed information about general study procedures and tasks, potential risks and benefits of study participation, reimbursement, confidentiality, and withdrawal procedures. Any questions will be answered and the participant will be given sufficient time to decide whether or not they want to participate in the study. After assent is obtained, investigators will describe the content of the written consent form to the participant's parent or guardian in a private setting. The consent form contains the same information as the assent form, with the addition of information regarding how to contact the principal investigator and the Investigational Review Board (Ethics Committee). Any questions will be answered and the participant's parent or guardian will be given sufficient time to decide whether or not they want their child to participate in the study.

After the assent and consent forms have been signed by the participant and their parent/ guardian, the investigator will sign both forms and will provide copies to the participant's parent/guardian.

In case of changes to the procedures described in the consent form, the participant and their parent/guardian will be informed at the beginning of an appointment.

Informed assent/consent will only be obtained by investigation participants who can provide informed assent/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 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).

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

Clinical investigation includes minors (i.e., children under the age of 18). See section 15 for the specific informed consent process for this population. The Ethics Committee approves

the assent/consent process and monitors any adverse events. No medical care will be provided for participants after the clinical investigation has been completed.

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).

There are no criteria for access to and breaking the blinding code because the investigation does not involve a blinding or masking technique.

According to the FDA, follow-up is required for participants who experience serious adverse events. Follow-up will be conducted by the study manager 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 US law.
The results of the clinical investigation will be documented internally in a study report, authored by the PI and study manager.
The results of the clinical investigation will be submitted for publication in a peer-reviewed journal by the PI (planned date of submission: January 2022). Results will also be presented at professional conferences by the PI.