

Remote Microphone (RM) Technology in  
Children using Bone Conduction Devices:  
A comparative study

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### 1) **Protocol Title**

Remote Microphone (RM) Technology in Children using Bone Conduction Devices: A comparative study

### 2) **Objectives\***

- Aim 1: To determine the benefits of remote microphone (RM) technology for listening in classroom noise in children using bone conduction hearing devices.
- Aim 2: To determine whether RM wireless audio-streaming accessory results in improved listening in noise performance compared to RM digital adaptive in children using bone conduction hearing devices.

### 3) **Background\***

The purpose of this investigation is to evaluate objective outcomes in pediatric bone conduction hearing device (often termed “BAHA”) users with and without remote microphone (RM) technology. In this study, two remote microphone technologies will be evaluated to determine benefit in speech understanding in noise.

Research shows that intervention with hearing devices alone (i.e. hearing aids, cochlear implants, bone conduction devices) does not alleviate the difficulties children with hearing loss encounter in classroom environments. The effects of noise, distance, and reverberation make classroom listening particularly challenging. Specifically, classrooms often have poor acoustics resulting in negative signal-to-noise ratio (SNR) values (the noise is louder than the speaker of interest). Individuals with hearing loss require the speech signal to be 4-18 dB louder than the background noise in order to obtain speech recognition scores similar to individuals with normal hearing (Moore, 1997). Children spend 45-60% of classroom time engaged in listening (Rosenberg et. al, 1999); therefore, it is essential that they have consistent access to all speech sounds to ensure no delays in academic performance, speech/language development, or social interaction skills.

One of the most common methods of reducing these deleterious effects in children with hearing loss is the use of a personal remote microphone (RM) system. A personal RM system consists of a microphone that is worn by the speaker or teacher and a transmitter that transfers the signal to a receiver that is in the child’s hearing device. Studies have demonstrated that RM systems can reduce SNR values, and result in improved hearing outcomes (Pittman, et. al, 1999; Hawkins, 1984). While this has been shown in conventional amplification (Anderson & Goldstein, 2004) and cochlear implants (Schafer & Thibodeau, 2006; Wolfe et. al, 2009) to date, there are no studies looking at the benefits of RM technology for pediatric bone conduction hearing device users.

In the past several years, remote microphone technology has evolved. Hearing instrument manufacturers have developed and introduced wireless remote microphone accessories in an effort to make RM technology available at a reduced cost and increase access. These RM devices transmit the signal on the globally,

license-free 2.4 GHz industrial, scientific, and medical radio band. These RM devices are commonly referred to as, “*wireless audio-streaming accessories*.” In addition, there has been an emergence of the use of *digital adaptive radio frequency (RF) transmission* to deliver the signal from the transmitter to the radio receiver. When using digital adaptive RF, the transmission switches throughout the 2.4 GHz band on the basis of a communication protocol that is established when the transmitter and receiver are paired. There are studies looking at the benefit of these different type of technologies, yet to date these studies have not been completed in pediatric bone conduction hearing device users.

In hearing aid users, it has been suggested that digital adaptive RM systems outperform wireless audio-streaming accessories in moderate to high levels of competing noise. These differences are likely due to the adaptive increase in receiver gain provided by the adaptive system when in moderate-to high-level noise resulting in poor signal to noise ratios (Wolfe, et. al, 2015). These noise levels, resulting in negative SNRs, represent many classroom settings that children spend their majority of time. In addition, the currently published studies used fixed SNRs which may not be sensitive to the differences in RM technologies. This is an important question as most bone conduction hearing devices offer wireless audio-streaming accessory at minimal to no cost. Understanding how these technologies differ in performance will provide an improved understanding of cost benefit of these accessories and lead to better patient centered and personalized care.

This study will evaluate hearing in noise performance of children with hearing loss using bone conduction hearing device(s) with and without RM technology. The specific aim is to obtain objective data on the benefits of 2 different RM technologies versus standard of care bone conduction hearing device in children with hearing loss. We will also make comparisons between the 2 RM technologies.

#### 4) **Inclusion and Exclusion Criteria\***

##### **Inclusion Criteria:**

English speaking pediatric conduction device users or candidates and will be included for study. We will include pediatric patients 5 years of age to 17 years of age who have a conductive or mixed unilateral or bilateral hearing loss with a minimum of a 30 dB air-bone gap.

**Normal hearing controls** The control group will be limited to adults greater than 18 years of age with hearing thresholds  $\leq 25$  dB 500 – 4,000 Hz

##### **Exclusion Criteria**

Participants will not be specifically excluded unless they do not meet the described inclusion criteria. The study is limited to English speakers, as speech perception measures are only available in English so non-native English speakers do not undergo the standard clinical protocol. The study is also limited to children 5 years

of age and older to ensure adequate language development to complete the described tests of speech perception to determine objective benefit with RM technology.

**5) Number of Participants\***

We expect to enroll a minimum of 10 participants and a maximum of 30 patients for prospective portion of the study.

We expect to review 150 charts for the retrospective portion.

15 normal hearing controls

**6) Study-Wide Recruitment Methods\***

*Retrospective*

We will perform a retrospective chart review of bone conduction hearing device users or candidates seen in our clinic from January 1, 2010 to October 29th, 2019. Demographic and hearing data will be collected retrospectively including, etiology of hearing loss, onset of hearing loss, device use history, and audiograms.

*Prospective*

We will enroll participants who meet the described inclusion criteria for prospective study. We will perform a retrospective chart review of bone conduction hearing device users or candidates seen in our clinic from January 1, 2010 to October 29, 2019. Bone conduction device patients who meet audiometric criteria and their guardian/s will be contacted by phone or email to collect prospective data. Additionally, patients who present to the clinic who are candidates for this study will be approached along with their guardian to see if they are interested in taking part of the study. A study team investigator will inform the potential subject and their guardian about all aspects of the experiment. If the subject expresses interest in the study, a study team member will be contacted. If possible, on that same day, the member of the study will make arrangements for one of the study personnel to meet with the subject to review the informed consent. Where applicable, assent will be obtained. Otherwise, a research appointment will be made for a future time to meet with the potential subject and their guardian.

Participants will be told that their participation in the study is voluntary and that they do not need to participate in the study if they choose not to. If they decide to take part and later change their mind, they are free to withdraw from the project at any stage. Potential research participants will be informed that participation in the study will in no way affect their treatment in the Department of Otolaryngology at the University of Miami. Patients will receive the same treatment by the clinicians in the Department of Otolaryngology if they choose not to participate. Appropriate and understandable language will be used with children and assent will be obtained using age appropriate language where applicable.

7) **Study Timelines\***

It is anticipated that each subject will participate for 1-2 visits depending on proximity to the test site. Each visit will last approximately 1-2 hours.

8) **Study Endpoints**

Study will be completed when we have data on at least 10 participants but no greater than 30 participants. Enrollment is expected to be complete by 4/8/2020.

9) **Procedures Involved\***

Pediatric conductive or mixed hearing loss patients who are between the ages of 5 and 17 years of age and present to the University of Miami Ear Institute hearing rehabilitation by bone conduction technology will be enrolled for study.

Speech perception in noise performance will be measured using sentences presented in noise. Performance will be evaluated in the following conditions:

1. Bone conduction device (BAHA) only
2. Bone conduction device (BAHA) + Wireless Audio-Streaming Accessory (using the Mini Microphone 2+, Cochlear Corporation)
3. BAHA + Digital Adaptive RM System (using Roger™, Sonova)

Conditions will be randomized by subject. Speech will be presented from the front at 0 degrees azimuth and the noise signal will be presented from four loudspeakers located at approximately 30 degrees, 135 degrees, 225 degrees, and 330 degrees.

The remote microphone will be positioned 6 in. away from the center of the cone of the loudspeaker presenting the sentences at 0 degrees azimuth (American Academy of Audiology Remote Microphone Guidelines, 2008).

All test measures are non-experimental and commercially available.

Bone conduction devices will be programmed according to bone conduction thresholds through the device prior to testing.

Normal hearing controls

Hearing loss will be simulated in the normal hearing controls using ear plugs. Speech perception in noise performance will be measured using sentences presented in noise. Performance will be evaluated in the following conditions:

1. Unaided
2. Unilateral hearing aid with contralateral plug.

3. Unilateral hearing aid + Digital Adaptive RM System (using Roger™, Sonova)
4. BAHA with bilateral plugs
5. BAHA + Wireless Audio-Streaming Accessory (using the Mini Microphone 2+, Cochlear Corporation)
6. BAHA + Digital Adaptive RM System (using Roger™, Sonova)

Speech will be presented from the front at 0 degrees azimuth and RM will be positioned 6 in. away from the center of the cone of the loudspeaker presenting the sentences at 0 degrees azimuth, then spatially separated from the noise. The noise signal will be presented from four loudspeakers located at approximately 30 degrees, 135 degrees, 225 degrees, and 330 degrees.

Unilateral hearing aid and BAHA will be programmed to mild gain appropriate for testing in normal hearing controls.

Demographic and audiometric data will be maintained under a unique identifier code linked to the consented study participant for reference to study outcome data.

#### 10) **Data and Specimen Banking\***

All the previously described data will be stored on the PI's HIPAA compliant OneDrive provided by the University of Miami. It will be password protected, and unique identifiers used for subject protection. Paper copies of the data and consent form will be stored in a locked file cabinet in room 825 of the clinical research building at the University of Miami Medical Center, located at 1120 NW 14th Street, 8th Floor, Miami FL, 33136. Data will not be distributed, except in the form of peer-reviewed publication or oral presentation and will maintain the confidentiality of the participants.

*A HIPAA waiver has been requested for retrospective data.*

#### 11) **Data Management\***

All the previously described data will be stored on the PI's HIPAA compliant OneDrive provided by the University of Miami. It will be password protected, and unique identifiers used for subject protection. Paper copies of the data and consent form will be stored in a locked file cabinet 825 of the clinical research building at the University of Miami Medical Center, located at 1120 NW 14th Street, 8th Floor, Miami FL, 33136. Descriptive statistics will be used to report demographic (e.g. age and gender) data. Quantitative data will be presented as mean, standard deviation (SD) and range (minimum and maximum); qualitative data will be presented as frequencies and percentages. Comparisons between unaided to aided conditions will be analyzed using parametric or non-parametric measures as appropriate. Statistical significance will be set to  $p < 0.05$ .

#### 12) **Withdrawal of Participants\***

We do not anticipate voluntary or involuntary withdrawal from the study as participant data is collected acutely in a single test session. Should a participant or their guardian wish to discontinue during the data collection, they will be offered an opportunity to return at another time to complete data collection. Should the participant request to be withdrawn, no further data collection will take place and they will be withdrawn. Collected data will be maintained in the study database.

**13) Risks to Participants\***

The risks to the participants will be minimal. At most, a breach of confidentiality composes the majority of the risk. We will take extensive measures to protect confidentiality and to ensure data security.

**14) Potential Benefits to Participants\***

Participating participants may potentially benefit by identifying the need for remote microphone technology in the school and home setting. Additionally, future patients with hearing loss may benefit from the investigation and findings contained within. The data generated from this study will help determine the aided benefit of remote microphone technology in pediatric bone conduction device users.

**15) Vulnerable Populations\***

The study will include children.

**16) Setting**

The study will take place in the Department of Otolaryngology at University of Miami for pediatric patients seen in the Department of Otolaryngology for bone conduction hearing device services.

**17) Resources Available**

The PI and Co-investigators are well qualified to perform the described study protocol. We have an established clinic with a long history of evaluation and management of individuals with hearing loss, including those using bone conduction devices. The Department of Otolaryngology has a research team to assist in management of study procedures.

**18) Prior Approvals**

N/A

**19) Recruitment Methods**

Potential participants will be established patients of the department of Otolaryngology. The clinician will speak with the potential subject and guardian about the research study during a routine visit at the Ear Institute clinic. The PI or co-investigator will inform the potential subject about all

aspects of the evaluation process. If the subject and guardian express interest in the study, the research coordinator will be contacted. If possible, on that same day, the research coordinator will make arrangements for one of the study personnel to meet with the patient to review the informed consent. Otherwise, an appointment will be made for a future time to meet with the potential subject.

Participants will be told that their participation in the study is voluntary and that they do not need to participate in the study if they choose not to. If they decide to take part and later change their mind they are free to withdraw from the project at any stage. They will be told that they will receive the same treatment by the clinicians if they choose not to participate.

Participants identified by retrospective chart review will be contacted via telephone or email (see attached documents).

Children over the age of seven will assent participation. We will provide information about the study in a language understandable to the participant, answer all questions in terms understandable to the child, use written and verbal explanations, and obtain voluntary agreement to participate. The assent document will be written in language at an appropriate level of readability.

Participants will also be recruited by flyer or email advertisement. Flyers will be posted at the following locations:

University of Miami at the Clinical Research Building, UHealth Plantation, UHealth Boca, UHealth Palm Beach, UHealth Lennar and Miami Children's Hospital Division of Audiology.

Participants will be compensated \$12.50/hour and parking fees will be reimbursed.



A minimum of 10 participants will be enrolled for study. We will not enroll more than 30 participants for prospective portion of the study.

**20) Confidentiality**

To ensure confidentiality of the information shared with the investigative team, all information pertaining to a subject will be given a coded number. All data will be stored under this code number and not the subject's name. Records which link participants' identification with their code number will be kept in a locked file on a password protected computer that only the PI has access to and stored separately from the subject data. All computer files that include study data will be stored on a computer with password security and only IRB approved individuals will have access to these codes. The investigator and her co-investigators will consider these records confidential to the extent permitted by law. Identifiable records and results will not be included in any publication, and collected data will not be used in any other studies without a subject's expressed permission.

**21) Provisions to Protect the Privacy Interests of Participants**

N/A

**22) Consent Process**

Due to COVID 19, we also will be consenting remotely. When consenting remotely, we will follow the recommendations provided by both University of Miami and the FDA. Potential subjects will be called and/or emailed for recruitment and if agreed to participate, a zoom meeting will be arranged for the consenting process; a witness will be present in the call. All steps will be documented in the format attached.

The informed consent process will be conducted in English by one of the study personnel. Consent will be performed at visit 1 of the study prior to the performance of any study-related activities. The prospective subject will be informed about study expectations as outlined in the IRB approved consent form. The prospective subject will be given a copy of the informed consent to read and will have the opportunity to ask questions about the study prior to signing the document. The prospective subject can take the document home to review and come back at a later date to ask questions and sign the document if he/she decides to enroll in the study.

It is possible that while our study is limited to English speaking patients, the parents of some patients included may be non-English speakers. Because only a maximum of 30 participants will be enrolled it is anticipated that only a small number of participants may be enrolled whose guardians will not understand English. Based on population data for Miami-Dade, we expect this to be limited to Spanish speakers. For those participants all required documents will be translated into Spanish. Further a native Spanish speaker and certified medical translator will be present for consent and all test sessions.

When determining whether a child is capable of assenting, the ages, maturity, and psychological state of the child will be taken into account. The PI will consider the child's experience and level of understanding, ensure the child is cooperative and agreeable to participation, and ensure the child's rights are maintained. As with adult consents, assent will be conducted in a manner and location that ensures participant privacy, Giving adequate information about the study in a language understandable to the participant, Providing adequate opportunity for the participant to consider all options, Responding to the participant's questions, Ensuring the participant has understood the information provided, Obtaining the participant's voluntary agreement to participate, and Continuing to provide information as the participant or research requires.

**23) Process to Document Consent in Writing**  
**N/A**