

2019-2020 _ Clinical Testing and Results: (Dr. Linda Thibodeau, Audiology)

Figures are numbered for this Section only.

Data collection overview:

The algorithms on the Smartphone (“SHARP-2 app”) were evaluated by persons with normal and impaired hearing. All listeners received the signal via bilateral hearing instruments programmed for either normal hearing or their specific hearing loss. Normal hearing participants also evaluated the algorithms on the Smartphone using standard, wired headphones (e.g., Sennheiser). Three manufacturer hearing aids, Starkey, Oticon, and Phonak were evaluated in various wireless microphone arrangements.

Subject Recruitment:

The online SONA system was used to recruit students with normal hearing. It was designed to assist researchers at the University of Texas at Dallas to recruit participants in IRB approved studies. After the IRB was reappraised, an account was created on SONA containing information about the study and how students can sign-up. Participants with hearing loss were recruited through announcements to persons who attended previous research sessions at UTD or attended a presentation given by Dr. Thibodeau, who often lectures at retirement centers and the support groups such as the local chapter of the Hearing Loss Association of America.

Normal hearing (NH) participants had clear ear canals as verified by otoscopy and passed a hearing screening at 250, 500, 1000, 2000, and 4000Hz at 25dB HL or less as tested with traditional audiometry using insert earphones. NH listeners wore hearing aids that were programmed to 10 dB HL thresholds from 250-2000Hz and 15 dB HL from 3000-8000Hz using the NAL-NL2 fitting formula. The age range for normal hearing participants was 18-65 years of age.

Hearing impaired (HI) participants also had clear ear canals, as verified by otoscopy. For participants with stable hearing thresholds (verbally confirmed), their most recent audiogram was used for programming the hearing aids. For all other participants, a hearing test was completed using traditional audiometry and insert earphones. In order to evaluate the benefit of smartphone algorithms, persons with a range of hearing loss degrees and types were recruited. The hearing thresholds ranged from normal hearing in the low frequencies to profound hearing loss in the high frequencies, asymmetrical hearing loss, and mixed or sensorineural hearing loss. The thresholds of the better ear are shown in Figure 1, according to the protocol used. The hearing aids were programmed accordingly using the NAL-NL2 fitting formula and verified using real-ear measures on the Verifit 1. The age range for hearing impaired participants was 18-85 years of age.

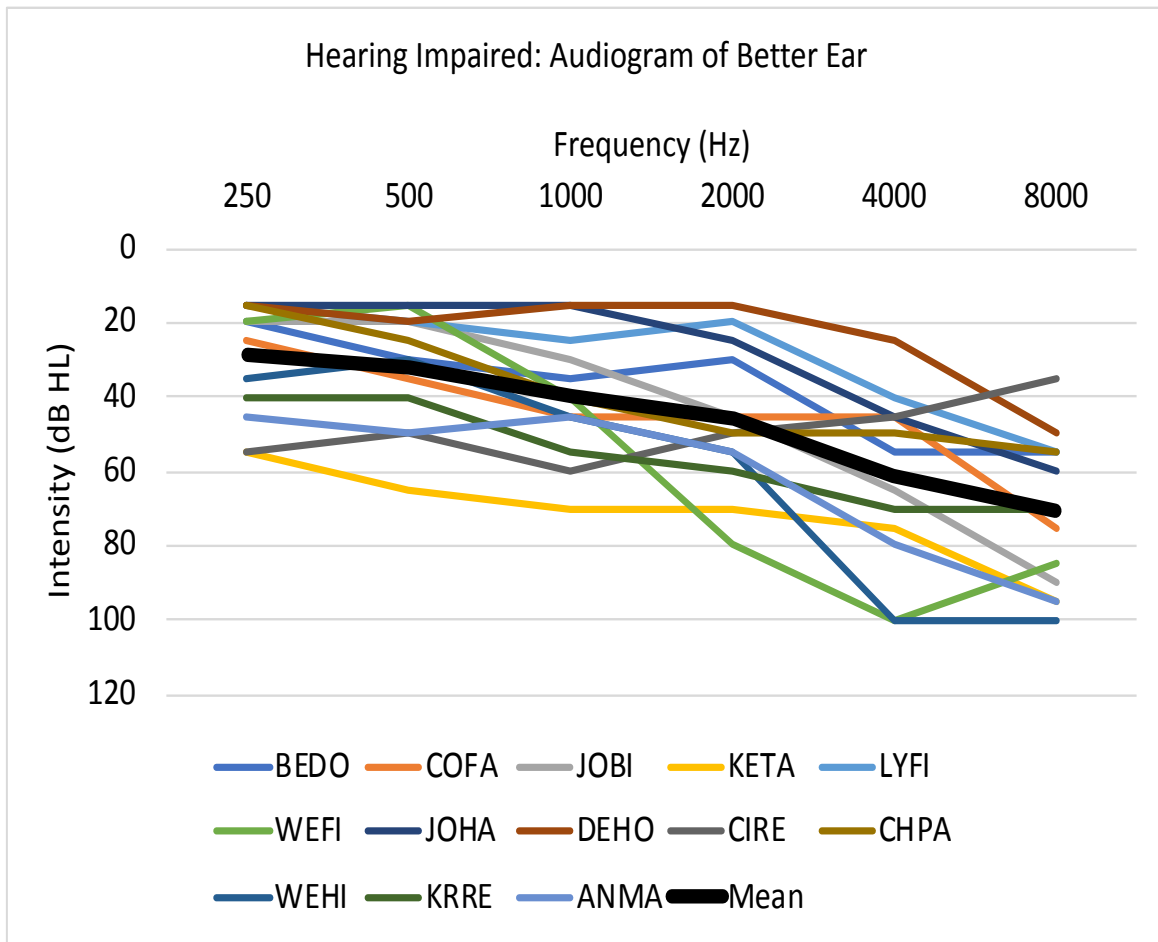


Figure 1. n=13. Better hearing ear of all hearing impaired participants from year 4. The average better ear audiogram is indicated by the thick black line.

Hearing Instruments:

During the fourth year of testing the smartphone algorithms, hearing aids from three manufacturers were tested. Starkey Halo I/II, Oticon Opn 1, and Phonak Audeo Marvel hearing devices were programmed for either normal hearing or individual hearing impairment accordingly using NAL-NL2 fitting formula and verified ± 5 dB using real-ear measures on the Verifit 1 for the HI participants. In all wireless microphone/smartphone conditions, the participants' external/local hearing aid microphones were muted so that only the processed auditory signals by the wireless microphone/smartphone would be available. Further, all participants wore noise-cancellation headphones (except in the hearing aid alone trial) to reduce the contribution of their natural hearing. Finally, to evaluate as much as possible only the effects of using the SHARP-2 app, all advanced signal processing features were turned off ("HA Lite"). In later phases, we began testing with all hearing aid advanced signal features turned on ("HA Max"), but data collection ceased due to COVID-19.

Smartphone:

The iPhone 7, iOS 12.2, and iPhone Xr ("10") iOS 12.2 and 12.4 were used for testing. Previous investigations under this project showed that either microphone (standard or video) for initial smartphone processing did not affect participant performance. All data reported for year 4 utilizes the standard microphone. Further, changes to the SHARP application were made following the closure of year three and the new app was named "SHARP-2".

Stimuli:

Lists of ten HINT sentences were presented at a constant level of 65 dBA (at the listener's head) through KEMAR with a voice simulator at 0 degrees azimuth to the listener. The use of this KEMAR allowed the speech to be radiated across the microphone opening as would naturally happen in real-world settings. Restaurant

noise was delivered at 180 degrees azimuth from a loudspeaker at various signal-to-noise ratios (SNR) ranging from -10 to +15 depending on the participants' performance in either the hearing aid alone or the SHARP app condition. The previous investigation through the project indicated that the noise used might be too heterogeneous, and the smartphone signal processing algorithm could not keep up. Data from phase one and two use more heterogeneous noise ("old noise"). The noise file was altered to equalize RMS across the digital file ("new noise").

General Testing Procedures:

Participants were seated at a desk, as indicated in Figure 2, and utilized a computer to type their responses. A practice list in quiet was always completed first and followed by randomized conditions including hearing aids alone, hearing aids and SHARP-2 app, no technology, or standard headphones and SHARP-2 app. There were ten sentences per list, and the percent words correct was calculated. Further, the previous investigation through the project indicated that participant performance increases after the first list and stabilizes by the third list. Each condition was completed three times, using three different sentence lists. The scores reported were the best score of the three sentence lists in that condition.

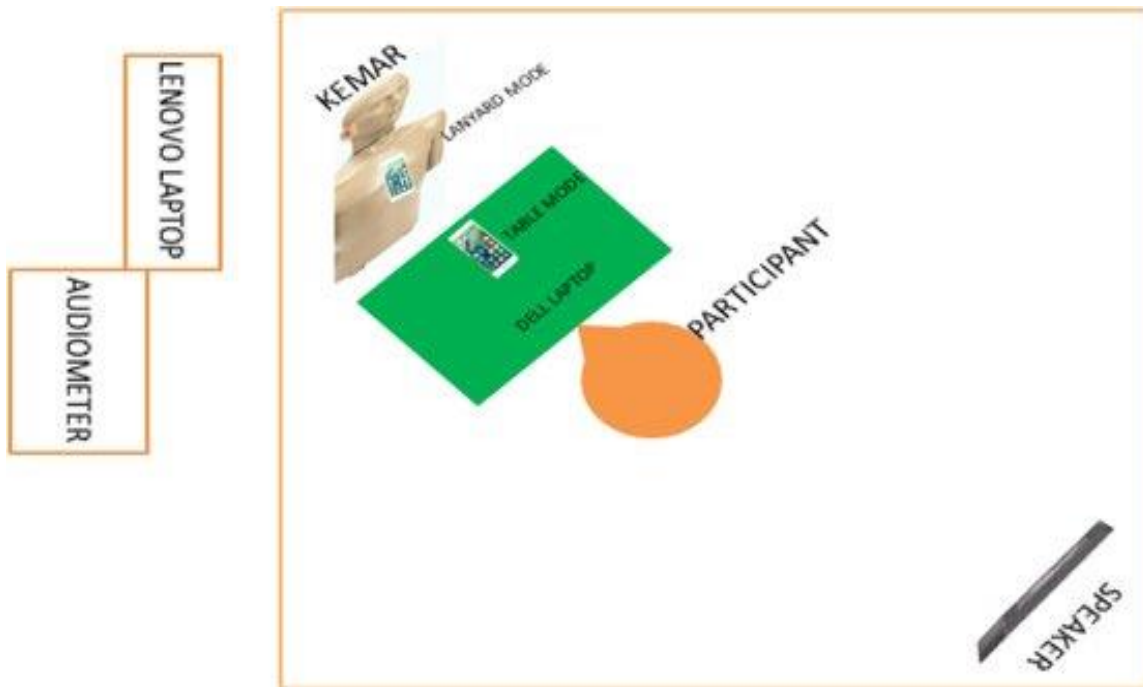


Figure 2. The testing arrangement for table iPhone conditions. The iPhone was placed touchscreen-side-down with the video microphone closest to KEMAR.

Phase 1: Learning Effect of HINT Sentences with Listeners with Normal Hearing.

Following Spring 2019 data collection, there was concern that participants might be exhibiting a learning effect (e.g., showing better performance after each trial/sentence list). To examine this, normal hearing participants were tested using Oticon OPN1 hearing aids connected to live listen through the iPhone. First, participants completed a practice condition in quiet. Second, background noise was added in to create a signal to noise ratio (SNR) of 0 or -5dB. If their sentence list score was less than or equal to 60%, the SNR remained the same. If their score was greater than 61%, the SNR decreased (i.e., more difficult) until they achieved a score of less than or equal to 60%. When that SNR was determined, participants then completed as many trials (sentence lists) as possible in their allotted time slot (e.g., 60 minutes total).

Conclusion: As shown in Figure 3, after three trials (sentence lists), participant scores began to stabilize. Individual patterns of results suggest that participant performance increases from trial one to trial three and begins to level out thereafter. Future results will represent the best score out of 3 trials at each condition.

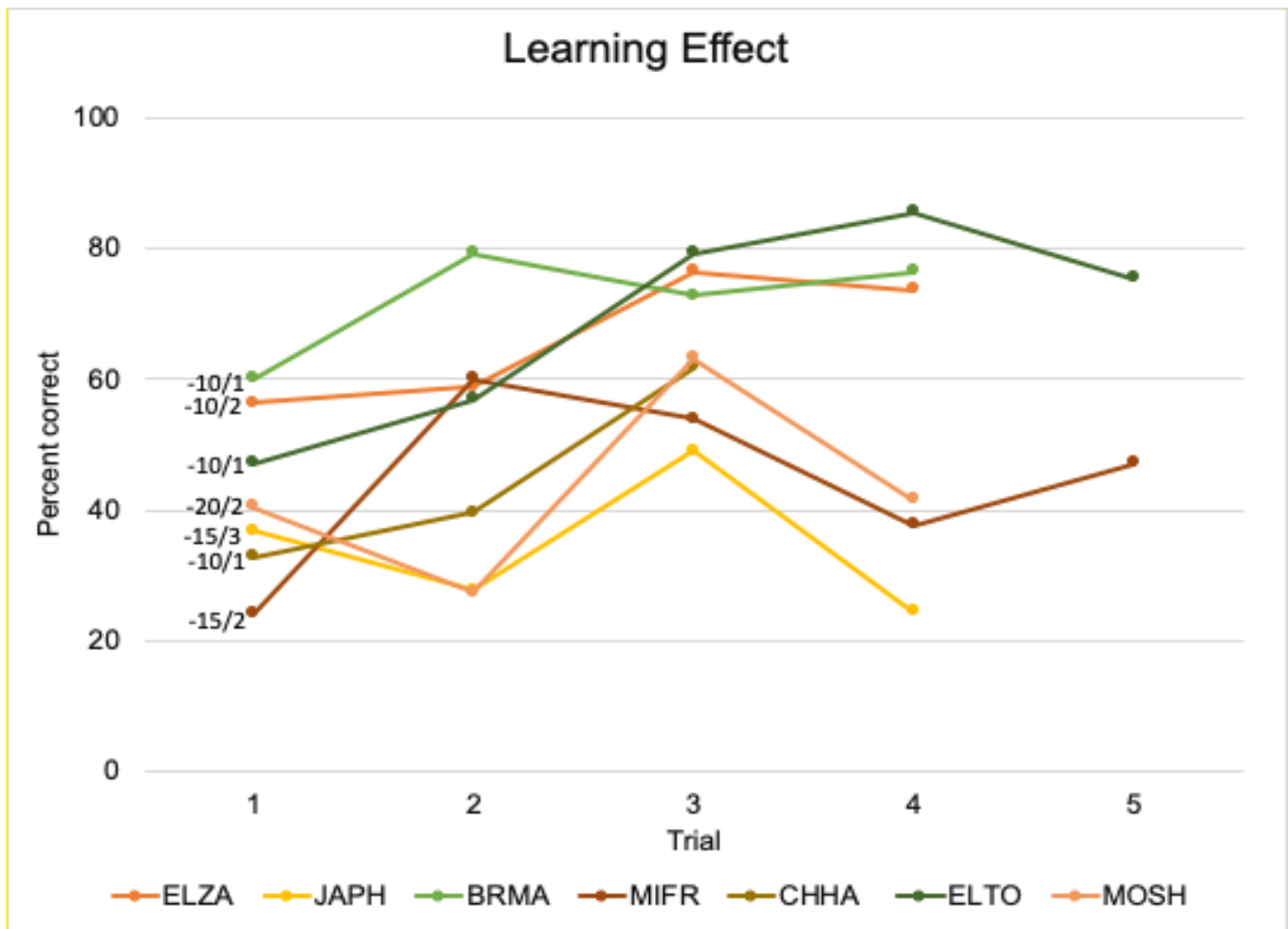


Figure 3. n=7. The learning effect in normal hearing participants. The numbers to the left of each line describe the final SNR tested and how many trials it took to determine the final SNR. SNR=signal-to-noise ratio. Hearing aids=Oticon OPN1. iPhone=7. Application=Live Listen. iPhone Volume=100%. Noise=old noise.

Phase 2: Comparison of SHARP-2 vs. Hearing Aid Alone performance with Oticon OPN1 Hearing aids in Listeners with Normal Hearing.

The purpose of phase 2 was to compare normal hearing participant performance using the Oticon OPN1 hearing aid. Testing was completed for hearing aid alone and the hearing aid with the SHARP-2 app. The scores shown in Figure 4 are the maximum performance (from 3 trials) of that condition. A total of 8 participants with normal hearing were tested at either -5dB or -10 dB SNR.

Conclusion: The results suggest meager benefits (~7% increase) using SHARP-2 at -5dB or -10dB SNR. The average score at -5dB SNR was 85.66% and 93.20% for HA Lite and HA Lite+SHARP-2, respectively. The average score at -10dB SNR was 76.45% and 83.65% for HA Lite and HA Lite+SHARP-2, respectively. One participant (SABH) scored poorer using the SHARP-2 app. Participant performance from -5dB SNR to the -10dB SNR conditions dropped approximately 10% for both HA Lite and HA Lite+SHARP-2. Due to variability in the data and small sample size no statistical analysis was performed.

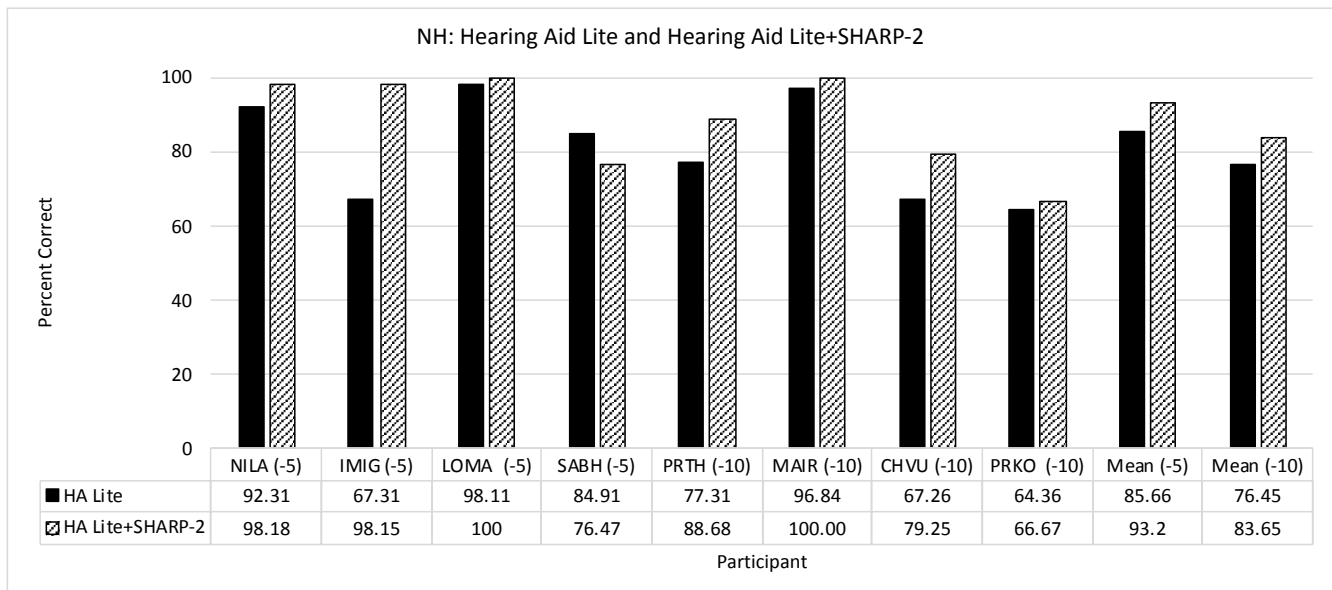


Figure 4. n=8. Oticon OPN1 hearing aid. Normal hearing. The best performance for 3 trials at each condition at -5dB SNR and -10dB SNR (shown in participant parentheses). iPhone=7. iPhone volume=100%. Noise=old noise (less homogenous).

- Lite: the signal processing of device is OFF.
- n: the number of participants.
- iPhone 7 is used.

Phase 3: Comparison of SHARP-2 vs. Hearing Aid Alone performance with Starkey Halo II Hearing aids in Listeners with Hearing Loss.

The purpose of phase 3 was to compare hearing impaired participant performance using the Starkey Halo II hearing aid with the SHARP-2 app. Testing was completed for hearing aid alone and the hearing aid with the SHARP-2 app. The scores shown in Figure 5 are the maximum performance (from 3 trials) of that condition. A total of 5 participants with hearing loss completed this phase.

Conclusion: The results suggest increased performance at the more difficult SNR (-10dB), but average performance does not increase by more than 10% using SHARP-2. At -10dB SNR, for HA Lite, the average score is 81.71%, and for HA Lite+SHARP-2 is 90.74. Interestingly, performance decreases using SHARP-2 at -5dB SNR where the average performance for HA Lite is 83.64%, and for HA Lite+SHARP-2 is 66.04%. Due to variability in the data and small sample size no statistical analysis was performed.

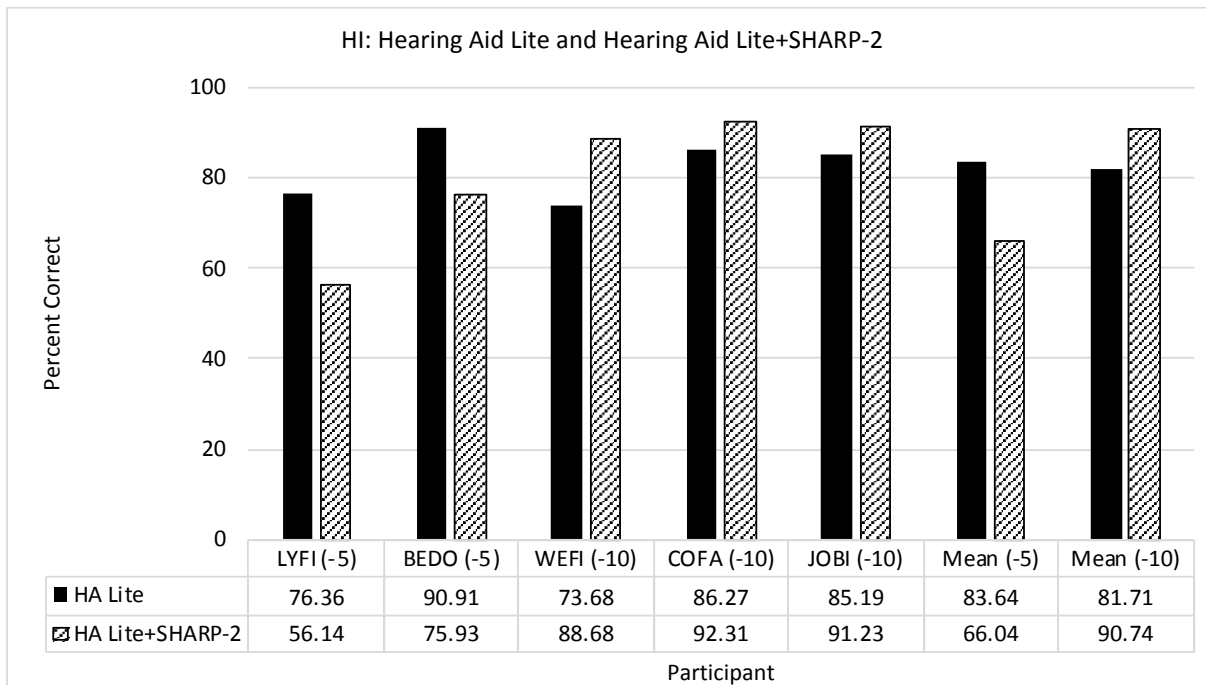


Figure 5. n=5. Starkey Halo II hearing aid. Hearing impaired. The best performance for 3 trials at each condition -5dB SNR and -10dB SNR (shown in participant parentheses). iPhone=7. iPhone volume=variable. Noise=old noise (less homogenous).

- Lite: the signal processing of device is OFF.
- n: the number of participants.
- iPhone 7 is used.

Phase 4: Comparison of SHARP-2 vs. Hearing Aid Alone performance with Phonak Audeo Marvel Hearing aids in Listeners with Normal Hearing.

The purpose of phase 4 was to compare normal hearing participant performance using the Phonak Audeo Marvel hearing aid with the SHARP-2 app. Testing was completed for hearing aid alone and hearing aid with the SHARP-2 app at a -10 to -20dB SNR. Further, testing was completed using HA Lite and HA Max for a total of 13 participants. The scores shown in Figure 6 and Figure 7 are the maximum performance (from 3 trials) of that condition. Further, a statistical analysis was only completed on the HA Lite and HA Lite+SHARP-2 data. An analysis was not completed on the HA Max conditions due to small sample size. The data collection for HA Max conditions was discontinued due to COVID-19.

Conclusion: The results suggest an average performance increase of more than 30% for both HA Lite and HA Lite+SHARP-2 and HA Max and HA Max+SHARP-2 for the -10dB SNR. However, at -15dB SNR the SHARP-2 performance only increased 15% and at -20dB, SHARP-2 performance actually decreased by 15%. For future testing, we will not exceed -15dB SNR. As expected, the HA Max conditions also showed increased performance compared to the HA Lite conditions due to advanced signal processing features of the hearing aids turned on. For the HA Lite conditions, a statistical analysis was completed. The data were arcsine transformed, and a Student’s T-test for paired two sample means was performed. A significant difference ($p<.01$) was found between HA Lite and HA Lite+SHARP-2.

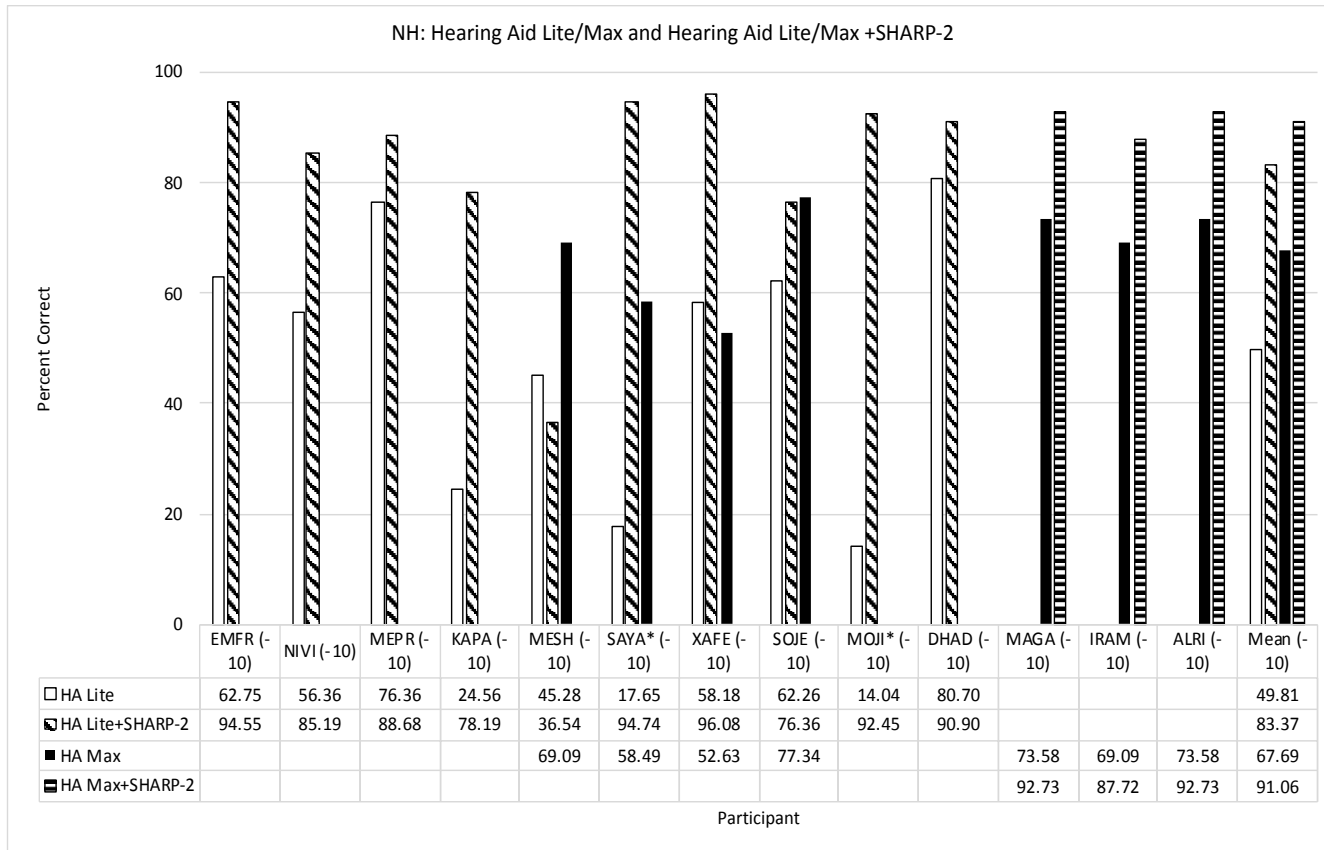


Figure 6. n=13. Phonak Audeo Marvel hearing aid. Normal Hearing. Mean performance for each condition at -10dB SNR (shown in participant parentheses). iPhone=10, *iPhone=7. iPhone volume=100. Noise=new noise (more homogenous).

- Lite: the signal processing of device is OFF.
- n: the number of participants.
- iPhone 7, 10 are used.

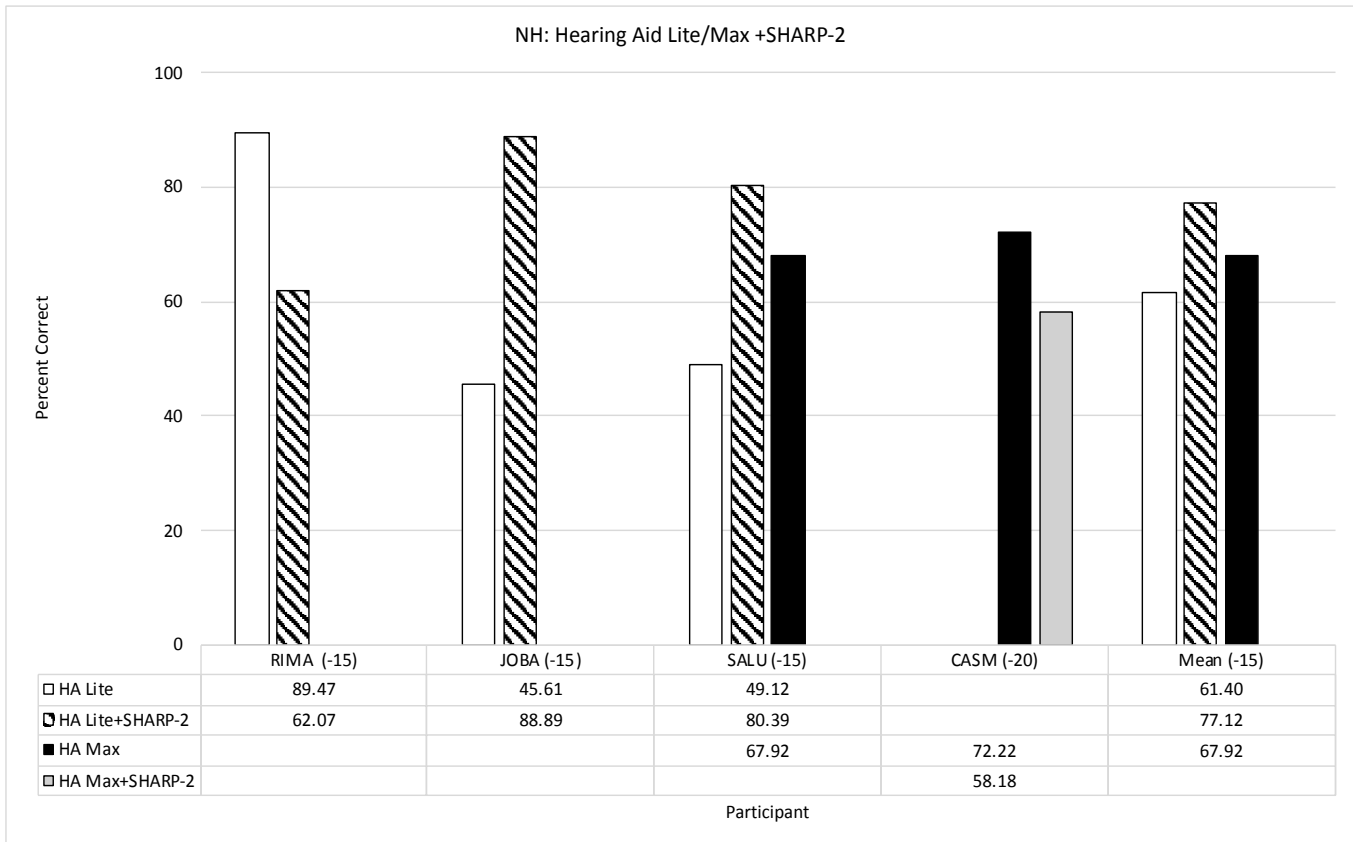


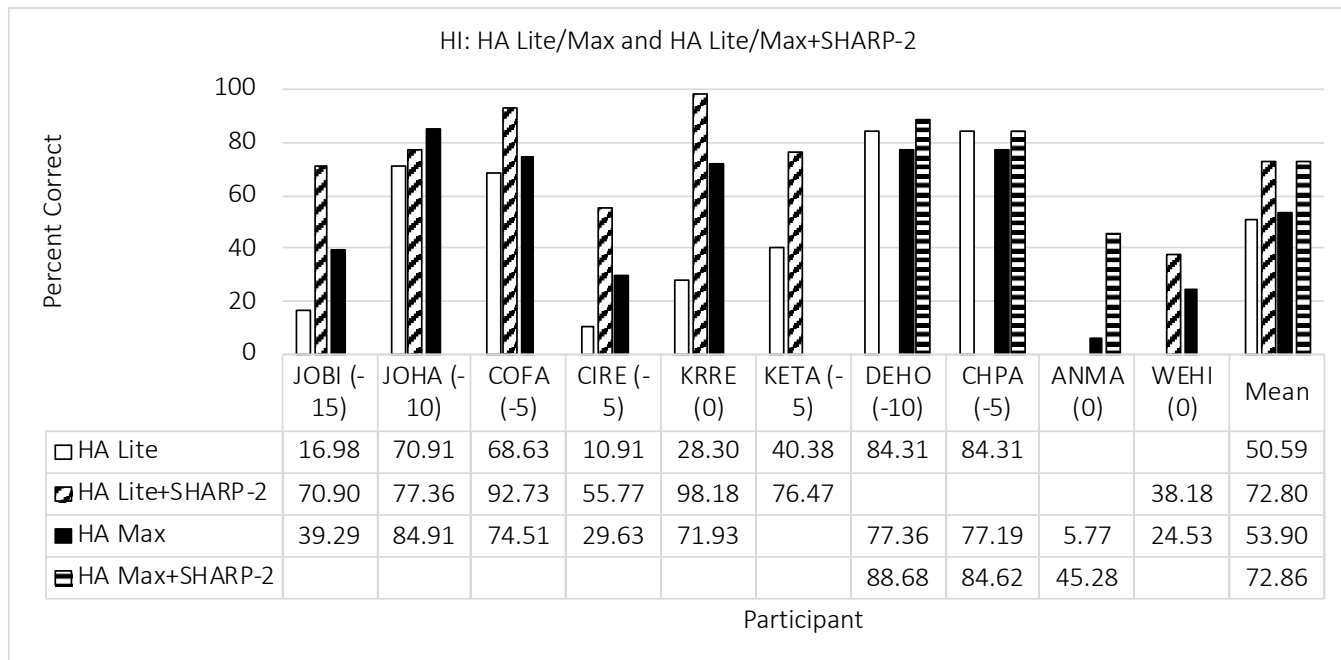
Figure 7. n=4. Phonak Audeo Marvel hearing aid. Normal Hearing. Mean performance for each condition at -10dB and -15dB SNR (shown in participant parentheses). iPhone=10. iPhone volume=100%. Noise=new noise (more homogenous).

- Lite: the signal processing of device is OFF.
- n: the number of participants.
- iPhone 10 is used.

Phase 5: Comparison of SHARP-2 vs. Hearing Aid Alone performance with Phonak Audeo Marvel Hearing aids in Listeners with Hearing Loss.

The purpose of phase 5 was to compare hearing impaired participant performance using the Phonak Audeo Marvel hearing aid with the SHARP-2 app. Testing was completed for hearing aid alone with all noise reduction features turned off (HA Lite) and hearing aid with the SHARP-2 app at 0 to -15dB SNR. To determine the best performance with the hearing aid alone, the Phonak Marvel was also programmed to the MAXIMUM noise reduction features (HAmx). Testing was completed using HA Lite and HA Max for a total of 10 participants. The scores shown in Figure 8 are the maximum performance (from 3 trials) of that condition. Due to the limited number of sentences and fatigue, all participants did not complete all four of the possible conditions, 1) HA Lite, 2) HA Lite+SHARP-2, 3) HA Max, 4) HA Max+SHARP-2. A statistical analysis was completed for the HA Lite conditions only.

Conclusion: The results suggest an average performance increase of more than 20-22% for both HA Lite and HA Lite+SHARP-2 and HA Max and HA Max+SHARP-2 across all SNRs. The HA Max conditions also showed increased performance compared to HA Lite condition, but the increase was much smaller (~3%). For the HA Lite conditions across all SNRs, a statistical analysis was completed. The data were arcsine transformed, and a Student's T-test for paired two sample means was performed. A significant difference ($p < .01$) was found between HA Lite and HA Lite+SHARP-2 for hearing impaired listeners.



- **Figure 8. n=10. Phonak Audeo Marvel hearing aid. Hearing impaired. Mean performance for each condition at 0dB and -15dB SNR (shown in participant parentheses). iPhone=10. iPhone volume=variable. Noise=new noise (more homogenous).**
- **Lite: the signal processing of device is OFF.**
- **n: the number of participants.**
- **iPhone 10 is used.**

Phase 6: Comparison of SHARP-2 vs. Cochlear Implant performance with Listeners with severe-profound Hearing Loss who use Bilateral Cochlear Implants.

The purpose of phase 6 was to compare hearing impaired participant performance using their personal cochlear implant (CI) and the SHARP-2 app. Testing was completed for CI alone and CI with the SHARP-2 app at a 0dB SNR. No programming changes were made to the cochlear implants. Only one CI participant could be tested due to the COVID-19 pandemic when data collection was discontinued.

Conclusion: The SHARP-2 app resulted in a performance increase (14%) for the CI participant. At a 0dB SNR, the participant scored 74.51% in the CI alone condition and 88.98% while using the SHARP-2 app.

Phase 7: Comparison of No technology, HA Lite, and a Wired Connection+SHARP-2 Lite with the SHARP-2 app on listeners with Normal Hearing.

The purpose of phase 7 was to compare normal hearing participant performance using No Technology, HA Lite, or a Wired-Connection with the SHARP-2 app. No technology means they are listening with their natural, normal hearing without the use of a device. HA Lite was the Phonak Audeo Marvel hearing aid with all advanced features turned off. The Wired Connection+SHARP-2 condition used the Sennheiser wired ear buds connected to the SHARP-2 app with the noise reduction turned off ("SHARP-2 Lite"). Participants were tested at a -10dB SNR. Figure 9 shows the results of the 11 participants.

Conclusion: The results suggest similar scores across conditions. The average scores for no technology were 85.65%, HA Lite was 88.75%, and the Wired Connection+SHARP-2 app was 87.21%. After the data were arcsine transformed, a one-way analysis of variance (ANOVA) was completed. The ANOVA revealed no significant difference among the three conditions.

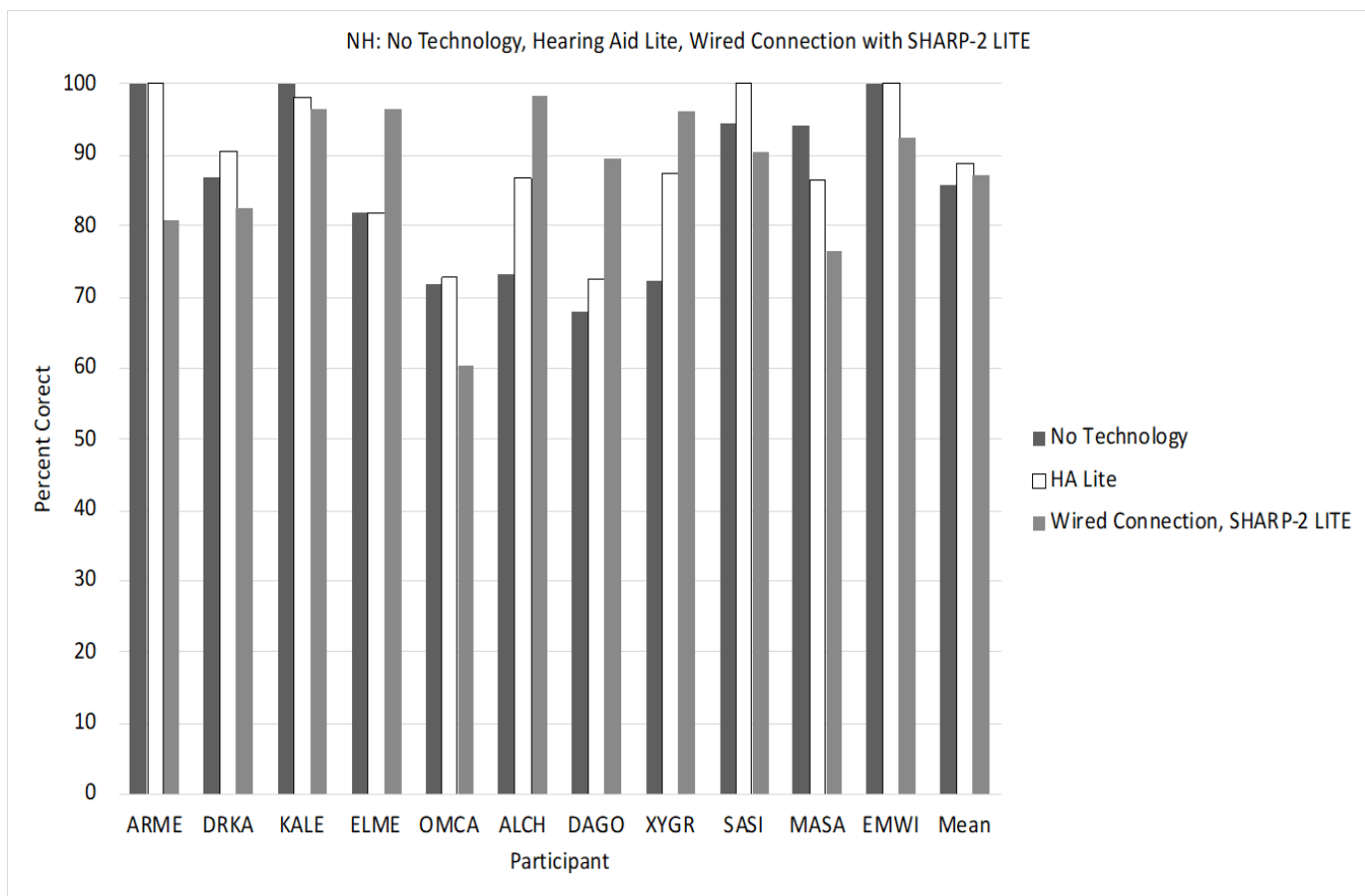


Figure 9. n=11. HA Lite=Phonak Audeo Marvel hearing aid. Wired Connection SHARP-2 Lite=Sennheiser earbuds with SHARP-2 app and noise reduction turned off. Normal hearing. Best performance on 3 trials for each condition at -10dB SNR. iPhone=10. iPhone volume=variable. Noise=new noise (more homogenous).

- Lite: the signal processing of device is OFF.
- n: the number of participants.
- iPhone 10 is used.

Phase 8. The purpose of phase 8 was to compare the hearing threshold test app developed to run on the smartphone to the thresholds obtained with standard clinical procedures in both normal and hearing impaired listener (N=40 ears). In randomized order, thresholds were obtained with either the smartphone app on the iPhone 7 or 10 with Sennheiser cs 3.0 earbuds or the clinical protocol with a GSI 61 Audiometer and 3R Insert Earphones. There were two versions of the app that were evaluated and the differences between the app and the clinical protocol testing for normal and hearing impaired listeners are shown in Figures 10 and 11, respectively. If the smartphone app agreed perfectly with clinical testing, the difference values on these figures would be 0.

Conclusion: The comparison of the median value for each testing method suggests that using V2 of the smartphone app agrees with clinical testing + or – 10 dB. There is a slight disagreement in the low-frequency threshold where the smartphone app overestimated the hearing level and a 10 dB disagreement in the higher frequencies where the smartphone app underestimates the hearing level.

Differences in Thresholds for Normal Hearing

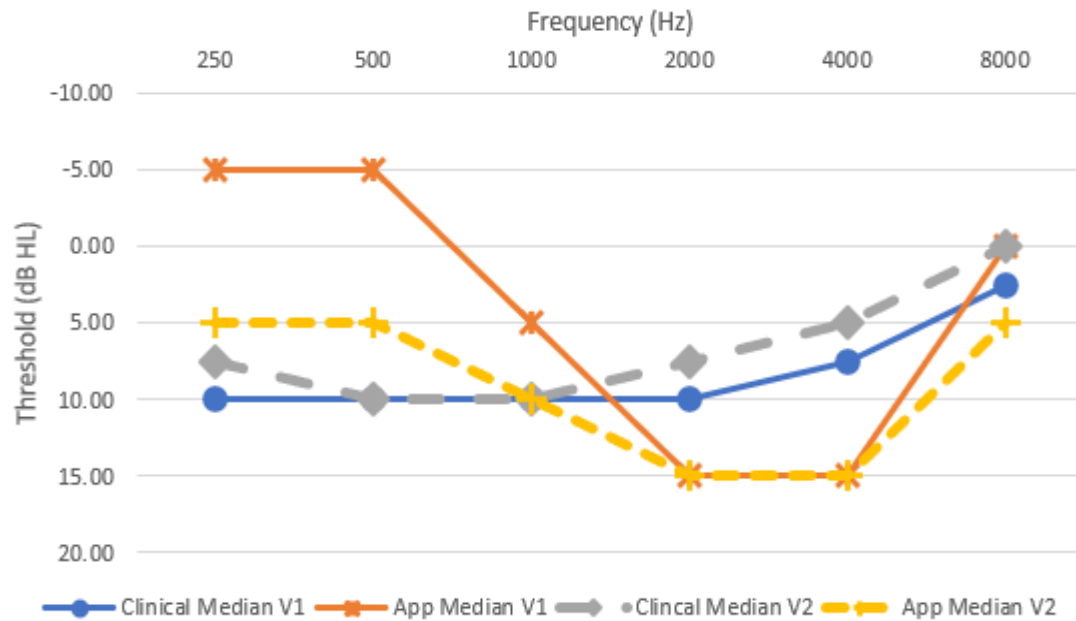


Figure 10. n=40 ears. Comparison of median differences between the 2 versions of the smartphone app and clinically determined thresholds.

- n: the number of participants. iPhone 7, 10 are used.

Hearing Impaired Difference

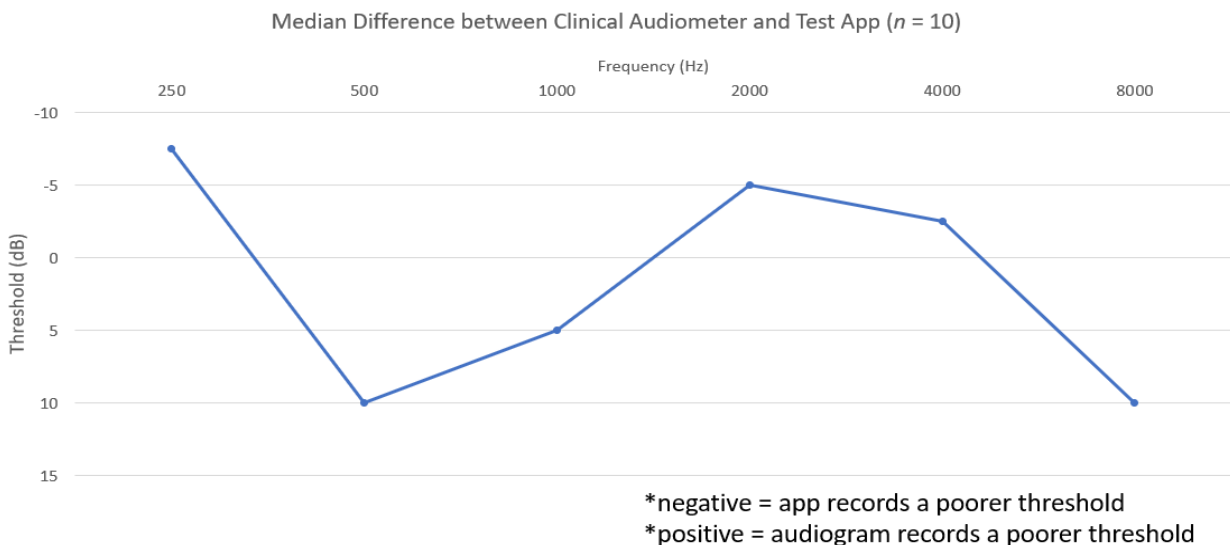


Figure 11. n=10 ears. Comparison of median differences between the smartphone app V2 and clinically determined thresholds.

- n: the number of participants. iPhone 10 is used.