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Development and deployment of a small stereo-hearing testing system: Two manuscripts

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Development and Deployment of a Small Stereo-Hearing Testing System: Two Manuscripts

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Dedication

This dissertation is dedicated to the patients and families who participated in the atresia deployment.

Acknowledgements

To my research subjects and parents, I am so fortunate to have become involved with such dedicated people who are eager to see progress. It was truly inspiring to connect with you all in our common struggles with unilateral hearing loss. Thank you for helping others by participating. To my friends, classmates, faculty, and family members who always cheered for me with each passing milestone, your words were always appreciated and never taken lightly.

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Thank you all.

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Two Studies of a Small Stereo-Hearing Testing System

INTRODUCTION

This dissertation is a combination of two studies: a normative study (a combination of the author's undergraduate honors thesis and a School of Engineering Capstone project), and a study of otology patients (completed as an audiology doctorate research requirement). The first study, *Development of a Deployable Stereo-Hearing System*, investigated the difference between one-eared (unilateral hearing loss) and two-eared (bilateral or "normal" hearing) individuals in tasks of both sound localization and understanding speech in noise using a laboratory-made device. A multidisciplinary team of engineers and auditory scientists developed this small, packaged, deployable system to test sound localization and speech perception in noise. The primary purpose of the first study was to demonstrate the ability of the prototype hearing testing system to correctly identify the difference between unilateral and bilateral subjects based on their performance in these two binaural tasks, thus validating the system for use in the second study. The second study, *Deployment of a Stereo-Hearing System to Postoperative Atresia Patients*, proceeds from the first study with the purpose of investigating two questions. Can the device be shipped domestically to patients for testing and retrieved in a cost-effective and secure manner? How do postoperative repaired atresia patients perform in two binaural listening tasks (sound localization and speech-in-noise understanding) in comparison with their bilateral and unilateral control group counterparts?

The hearing testing system costs about $2000 and can be delivered to most places in the United States for about $50 to $100 (round-trip). Initial testing during system design has demonstrated that the system can be unpacked, set up, and used by lay persons without professional supervision. Figure 1 below shows the prototype with a laptop containing the program for the two tests of sound localization and speech-in-noise comprehension and eight identical speakers placed precisely on a custom table-mat around the laptop. The eight speakers are arranged at 0, 20, 40, 60, 120, 140, 160, and 180 degrees of azimuth. Each speaker is labeled, 1 (at 0 degrees) through 8 (at 180 degrees) respectively.

Figure 1: The Laboratory-Made Stereo-Hearing System

Figure 1: The laboratory-made stereo-hearing device used to test all subjects in the binaural processing tasks of sound localization and understanding speech in noise. The device set-up contains a laptop, custom table-mat with 3-D printed speaker stands, and 8 speakers precisely placed in a 180-degree azimuth.

The system currently evaluates accuracy of horizontal sound localization and understanding of speech with noise presented at different locations. The sound localization test presents 48 trials of 250-ms broadband noises at random speaker locations with an average intensity of 70 dB SPL randomly roved by +/- 10 dB SPL; the subject clicks a button on the laptop to indicate the perceived location of the sound. The speech in noise test adaptively varies broadband noise based on the accuracy of a button click to the Coordinate Response Measure (CRM) Corpus command “Ready [Call-sign] go to [Color] [Number] now” presented at 60 dB SPL at a different location than the noise. This test consists of 4 conditions where the speech and noise are maximally and minimally separated, that is speech and noise from the following 4 speaker pairs: 1 and 8, 8 and 1, 4 and 5, and 5 and 4. We then analyze the difference in threshold between when the speech and noise are ‘flipped’ (that is 1 and 8 minus 8 and 1 and 5 and 4 minus 4 and 5). We expect little difference in normal-hearing (bilateral) subjects because it shouldn’t matter on which side is the speech relative to contralateral noise, but we expect a large difference in unilateral subjects because their head shadow will give a more favorable SNR when the speech is toward their good ear.

LITERATURE REVIEW

Congenital aural atresia defines the anatomical deformity of the outer and middle ear which is present at birth (congenital) and causes a closing or sealed nature (atresia) of the ear (aural) canal, (Kesser, 2016, in press). Aural atresia is the result of abnormal embryological development of the first and second branchial arches, (Wilmington, 1994). Congenital aural atresia is present in 1 in 10,000 to 20,000 live births (Kesser, 2014). Congenital aural atresia occurs most commonly unilaterally than bilaterally (Wilmington, 1994) with a ratio of 3:1, occurs more commonly in the right ear than the left ear (Kesser, 2014), and affects more males than females.

In congenital aural atresia, the cartilaginous portion, bony portion, or the entirety of the external auditory meatus may have never been formed during embryological development. Furthermore, structures of the middle ear may have also failed to develop completely or at all, such as the tympanic membrane, malleus, incus, and/or stapes. Aural atresia is often comorbid with microtia (the malformation/underdevelopment of the pinna) or anotia (total absence of the pinna) on the respective affected side, (Kesser, 2014).

Figure 2: Congenital Aural Atresia: Before and After Surgical Repair

Congenital aural atresia can cause up to a maximum conductive hearing loss (a range of 40-70 dB HL) while retaining normal cochlear function, and is surgically correctable, as seen in Figure A above, (Kesser, 2016, in press). The severity of the malformation of the outer and middle ear structure correlates with the severity of the hearing loss. Consequently, preoperative hearing scores are positively correlated with postoperative hearing scores and status of preoperative ear anatomy, (Nicholas, 2012). Jahrsdoerfer created a standardized grading scale system used to quantify the severity of the anatomical malformation, determine candidacy of the patient for surgical intervention, and determine the outcome prognosis for corrective surgery, (Jahrsdoerfer, 1992). Scoring is determined on the basis of visual observation of the external ear and on the basis of a Computerized Tomography (CT) scan of the temporal bone and primary structures of the affected side(s), (Jahrsdoerfer, 1992, Shonka, 2008). The grading scale is ranked from 1 to 10; the higher the score, the more likely that the patient qualifies as a candidate and that the corrective surgery will successfully restore hearing. A score of 5 out of 10, or lower, disqualifies the patient from surgery due to the low prognosis of surgical success. Approximately 65-75% of isolated atresia (non-syndromic) patients are candidates for surgery, (Kesser, 2014).

The purpose of the aural atresia repair surgery is to restore the mechanism of sound conduction through the outer and middle ear systems, (Shonka, 2008). This procedure is executed by an otolaryngologist: drilling a new canal at the location where it should have developed, mobilizing the three ossicles, replacing any dysfunctional or missing ossicles with Partial Ossicular Replacement Prostheses" (PORPs) or "Total Ossicular Replacement Prostheses" (TORPs) as needed, creating a new tympanic membrane from an underarm fascia skin graft, lining the newly opened canal with the skin graft, filling the canal with absorbent gauze and medicine, and patching the area, (Shonka, 2008). After approximately one month of recovery, the patient returns to have the gauze and packaging removed from the repaired ear. At this appointment, an updated audiogram of pure-tone and speech testing (air- and bone-conduction) is completed on the patient, revealing the improvement of hearing threshold due to surgery, (Gray, 2013). It is routine for the patient to return annually to undergo an audiometric evaluation from this point forward to monitor the hearing of the repaired ear. A successful atresia repair is considered one that returns the speech reception threshold (SRT) of the postoperative atretic ear to 15 to 25 dB HL, (Jahrsdoerfer, 1992). Because the skin graft lining the repaired meatus does not migrate as does the normal skin, the EAM needs to be professionally cleaned (cerumen removed) about once a year.

Individuals with binaural hearing have listening advantages over those with monaural hearing. Having two functioning ears enables the ability to locate a sound source in space without head movement and the ability to understand speech in noisy environments, (Wilmington, 1994, Gray, 2013, Kesser, 2013, Kesser, 2016, in press). These abilities arise from four main binaural advantages: redundancy, head shadow, binaural squelch, binaural summation, localization, (Kesser, 2016, in press). Individuals with unilateral hearing thus experience an array of various deficits, resulting from the lack of these binaural advantages, (Gray, 2013). For unilateral subjects, soft sounds would be 3-6 dB SPL softer, they would have difficulty localizing sounds, and speech in noise could possibly be as much as 14 dB SPL louder. As discussed in the Kesser, 2013 study, unilateral conductive hearing losses in children can have a significant impact on academic performance and these children are more likely to use some sort of intervention resource (FM system, preferential seating, Individualized Education Plan) than their sensorineural unilateral loss counterparts, (Kesser, 2013).

Three studies revealed that after successful atresia repair, the average improvement for pure tone average air conduction in the atretic ear was 35-36 dB HL (Wilmington, 1994, Gray, 2013, Kesser, 2016, in press). A patient can have up to a 50 dB gain in thresholds in the atretic ear, therefore hearing external sounds with a second, new ear for the first time after a successful surgery. Providing access of binaural inputs allows the previously mentioned psychoacoustical binaural phenomena to emerge. Wilmington reported that emergent binaural processing ability improved after surgery in all the following areas: interaural temporal difference limens, alternate and simultaneous loudness balances, localization, detection thresholds, and speech understanding in noise, (Wilmington, 1994). Gray reports that, after successful surgery, “all patients are able to take advantage of a favorable SNR in their newly opened ear,” (Gray et al., 2009). A 3 dB gain is observed immediately after surgery due to binaural summation, (Kesser, in press). It should be understood that binaural ability after surgery is variable, which may indicate significant interactions of early experiences, (Wilmington, 1994). Gray et al. report that an effect of age exists for binaural squelch after surgery, documenting that for each decade that corrective surgery is postponed, “approximately 2 dB of binaural gain is lost;” suggesting a correlation with length of auditory deprivation (as no binaural benefit is evident after 38 years of age), (Gray et al., 2009).

With the proven fact that two ears are better than one, the issue then becomes the lack of evidence and understanding of the learning curve that an individual encounters as they learn how to use their new ear after surgery. Sufficient data exists in the last 30 years documenting audiometric and speech scores of atresia patients before and after operation, however, sufficient evidence of binaural processing improvement does not exist. Current efforts are investigating if and how these patients are able to "integrate signals from their new and old ears," (Kesser, in press). Gray concluded that "longer follow-up is an important next step; the youngest patients may take more time to learn new complex tasks involving the use of signals from two ears," (Gray et al., 2009). How many years after corrective surgery does a patient finally approach binaural skills of a normal bilateral counterpart? Longitudinal data is further necessary to: understand the improvement of binaural hearing over time, understand the critical periods of binaural plasticity, to guide surgeons towards optimal age of operation, and to investigate the importance of real-world binaural hearing, (Gray, 2013, Kesser, in press). These recent studies and conclusions urge the purpose of the current study: to investigate the difference between bilateral subjects and subjects with unilateral hearing loss in the performance of binaural listening tasks (localizing sound and understanding speech in noise), to investigate where atresia patients fall in performance compared to those two populations, and to implement a solution for collecting data on binaural improvement over time. With these investigations, we can begin to study the nature of learning that occurs for emerging binaural listening post-operation.

MANUSCRIPT #1 TITLE

Development of a Deployable Stereo-Hearing System

ABSTRACT

Objective: To investigate the effectiveness and efficiency of a portable stereo-hearing testing system with the intent of deployment for data collection in future studies. We quantify sound localization accuracy and speech-in-noise thresholds comparing unilateral (such as single-sided deafness) and bilateral subjects. We desired to design a small, inexpensive system that would show a large effect size between binaural and monaural subjects in a variety of stereo hearing tasks.

Methods: Subjects were tested on localization accuracy and speech understanding in noise using a laboratory-made stereo-hearing testing device. For the localization task, the subject identifies the location of a 250 ms noise presented randomly at one of 8 speakers in a 180^o array. For the speech-in-noise task, the subject identifies the CRM color/number command presented from a speaker in one hemi-field while an adaptive noise track is presented simultaneously from a speaker in the opposite hemi-field. RMS error quantified accuracy of localization. Analysis of the speech-detection thresholds involved differences between conditions when the speech and noise were each on different sides: a best-to-worst condition compared speech toward the good ear and noise toward the bad ear and vice versa; in a good-to-poor condition both the speech and noise were closer to midline (approaching straight ahead of the subject) but still on opposite hemi-fields. The right ear was considered 'good' for bilaterally-normal control subjects. We expect a large difference between the 'best' and 'worst' conditions for unilateral subjects and no such difference for the bilateral controls.

Results: Differences exist between unilateral and bilateral subjects in both sound localization and understanding speech in noise with ‘extremely large’ effect sizes (Cohen’s d >3 or ‘huge’ for both tests (and 1.6 or twice what Cohen said was a ‘large effect’ for the ‘good-to-poor’ comparison). Bilateral subjects localized and listened in noise better than unilateral subjects (p<.001 by post-hoc LSD tests). A group of ‘plugged subjects’ (bilaterals with an ear plug and earmuff), localized worse than both the true unilateral and bilateral subjects, but they understood speech in noise with thresholds between the true unilateral and bilateral groups.

Conclusions: Our device can distinguish between monaural and binaural subjects and is ready for deployment to investigate patients after otologic surgery, who we expect to perform ‘between’ these unilateral and bilateral subjects. Bilateral subjects localized sounds with near-perfect accuracy while unilateral subjects made many more errors. In unilateral subjects, thresholds detecting signals in noise were highly dependent on which hemi-fields produced the signal and noise (as expected, participants with unilateral hearing heard better when the signal was on the side of their one normal ear with contralateral noise facing the poorer ear) while bilateral subjects were relatively unaffected by the hemi-field of signal and noise. Plugged subjects (bilateral controls with an ear plug and an earmuff) localized worse than true unilateral subjects, suggesting an effect of learning how to localize with monaural cues.

INTRODUCTION

Statement of the Problem

While much documentation exists on the improvement in hearing thresholds and speech scores of these patients, normative data does not exist for how binaural hearing ability improves and is learned over time post-operation. Gray et al. 2003 ended their report of binaural processing following surgical correction of congenital maximal conductive hearing loss saying “longer follow-up is an important next step; the youngest patients may take more time to learn new complex tasks involving use of signals from two ears.” However, there are significant practical and financial problems in obtaining such data. Insurance companies do not reimburse patients to return to the clinic for follow-up appointments. A cost-effective and efficient method of collecting longitudinal data of the binaural processing abilities of repaired atresia patients in the years following their operation is one solution to this problem.

Purpose of the First Study

To investigate validity and reliability of a laboratory-made stereo-hearing testing device in measuring the subjective performance of two binaural listening tasks: localization and understanding speech-in-noise. To investigate the program’s ability to distinguish between bilateral and unilateral subjects. To estimate the binaural performance of preoperative atretic patients by investigating the performance of two experimental groups designed to represent the atresia population (a group of subjects with congenital/long-term unilateral hearing loss and a group of bilateral subjects with hearing temporarily modified by creating an artificial conductive unilateral hearing loss with noise attenuators).

Research Hypotheses

1. The subjects who possess hearing within normal limits (bilateral subjects) will pass the sound localization test with success and high accuracy. The subjects who possess a profound single-sided hearing loss (true unilateral subjects) will fail with low accuracy (scoring at 50% or less).
2. True unilateral subjects will perform significantly higher in localization accuracy than the plugged subjects (bilateral subjects with one ear occluded immediately prior to testing) who have no significant experience in listening with a single-sided hearing loss.
3. Bilateral subjects will perform well in the speech-in-noise test with a low signal-to-noise ratio (SNR) at CRM threshold. Unilateral subjects will score with a high SNR at CRM threshold.

MATERIALS & METHODS

Participants:

A total of 50 subjects participated in this study; 40 of the subjects were bilateral subjects and the remaining 10 subjects had unilateral hearing loss, with one severely or profoundly impaired ear and normal hearing in the contralateral ear. Thirty-nine of the 50 total subjects completed the sound localization task, 33 of which possessed normal hearing, 18 of which completed the test once or twice again while wearing an earplug in one ear or the other ear (to simulate an artificial unilateral hearing loss). The remaining 6 of the 39 subjects had a unilateral hearing loss. Twenty-five of the 50 total subjects completed the speech-in-noise test, twenty with normal hearing and 5 with unilateral hearing loss. Each of these 20 bilateral subjects were tested again with a plug in one ear to simulate an artificial unilateral hearing loss.

The ages of all subjects ranged between 18 and 65 years old. Of the 40 bilateral control subjects, all except 2 had hearing within normal limits in both ears (air and bone-conduction thresholds at or better than 20 dB HL across frequencies of 250-8000 Hz). Of the 2 remaining bilateral subjects, one had bilateral mild sensorineural hearing loss at 2000 Hz and the other had a bilateral sensorineural hearing loss at 4000 Hz (normal and mild) and 8000 Hz (mild and moderate), respectively. Both were accepted into the criteria as they have symmetrical binaural access to auditory input. Subjects participated as volunteers (unpaid) for this study, and all provided informed consent following approved IRB protocol (JMU 13-0058).

The criteria for participation in this study included: providing informed consent, to be in a status of overall health, to be able to independently complete a computer-administered study, and to have either hearing within normal limits or a severe to profound unilateral hearing loss with normal hearing in the opposite ear. Pure tone thresholds were measured by either a certified audiologist, supervised audiology doctoral student, or the lead-student researcher in a soundproof booth or empty laboratory.

Materials & Calibrations:

The portable audiometer “Beltone Audio Scout 109” was used by the student researcher. The subjects tested by doctoral students or certified audiologists were either tested by the audiometer “Madsen Astera” in the JMU Audiology clinic or by an unknown audiometer at an off-campus location, respectively. The prototype portable hearing-testing device was used to test sound localization on every subject. The sound localization test was conducted in a quiet, empty laboratory setting.

Pre-testing Procedures

If the subject did not have a current audiogram, pure tone air conduction thresholds were measured at 250-8000 Hz frequencies. The bilateral control subjects (those with normal hearing) took the localization test up to three times, once using both ears (binaural condition), and once or twice while being plugged with an “artificial” unilateral hearing loss in either ear (selected randomly). The simulated unilateral hearing loss was produced with a disposable foam earplug (Moldex Purafit) combined with a circumaural earmuff (Silencio RBW-71) covering over the earplug. Total attenuation of this artificial conductive HL is estimated to be approximately 56 dB SPL. Order of testing (binaural or plugged unilaterally) and the designated ear to be plugged were randomized. The experimental group (those with a true unilateral hearing loss) was just tested once.

Figure 1: The Laboratory-Made Stereo-Hearing System

Figure 1: The laboratory-made stereo-hearing device used to test all subjects in the binaural processing tasks of sound localization and understanding speech in noise. The device set-up contains a laptop, custom table-mat with 3-D printed speaker stands, and 8 speakers (labeled 1 to 8 from left to right) precisely placed in a 180-degree azimuth.

Sound Localization: (testing procedures)

Unilateral subjects performed the sound localization test once. Bilateral subjects took this test once, performing as the control group, and again as a secondary experimental group testing using the disposable ear plug and ear muff on a randomly selected ear. These conditions were assigned in a random order. When the bilateral subjects tested as the experiment group, the group was referred to as the plugged subjects or plugged group.

The subject sits in a chair in front of the laptop device, with the head located approximately in the center between the first speaker (#1) and the last speaker (#8) endpoints, (see Figure 1). Prior to testing, subjects were instructed to refrain from moving the head during the stimulus. The program randomly activates one speaker with a 250 ms broadband noise at a level ranging between 65 and 75 dB SPL. After each sound stimulus, the subject makes a selection on the laptop screen (see Figure 2 below) indicating the perceived location. There is no time limit and there is no feedback regarding the subject's accuracy. The test continues for 48 trials. Outcome measures were derived and analyzed in the form of: RMS error in degrees, the number of correct trials, the number of trials incorrect (categorized by number of speakers in error), and a percentage of correct speaker identification out of 48 total trials.

Figure 2: Sound Localization Test Screen

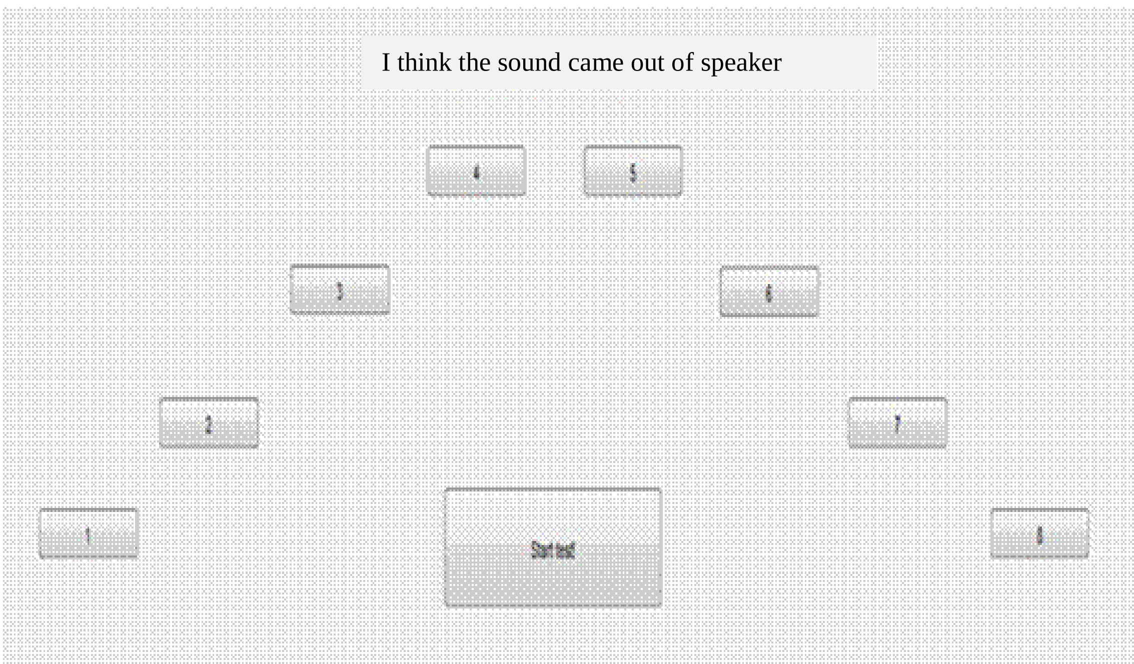


Figure 2: Screenshot of the sound localization testing screen used by the subject to indicate the perceived speaker location of the broadband noise stimulus on an azimuth plot on the computer screen.

Speech-in-Noise: (testing procedures)

The speech-in-noise test used the Coordinate Response Measure (CRM) corpus, (first set, male speaker, “Charlie” call sign), (Bolia, Nelson, Ericson, Simpson, 2000), in which recorded speech is played from a designated speaker in one hemi-field in the following format “Ready (call sign), go to (color)(number) now” while a broadband noise stimulus is simultaneously played from a designated speaker in the opposite hemi-field. The subject then makes a selection on the screen from a grid of numbered and colored buttons, based on the perceived command. For example, if the speech signal from one hemi-field was: “*Ready Charlie go to blue seven now*,” and it was heard correctly, then the subject would select the blue button that is labeled with the number 7, (see Figure 3 below). This test then alters the intensity of the broadband noise stimulus using a 1 down, 1 up adaptive track; (increases and decreases the noise by 6 dB SPL step sizes until the 4^{th} change of direction, then changed by 4 dB step sizes) based on the subject’s correct and incorrect responses (respectively). The level of noise was limited to 80 dB (while the CRM speech stimulus remained stable at 60 dB SPL). The test continues for eight changes in direction, or 25 maximum trials, before a threshold is reached; with threshold defined as the mean dB(A) of the noise at the 5^{th} to 8^{th} change of direction in the adaptive track.

Figure 3: CRM Speech-in-Noise Test Screen

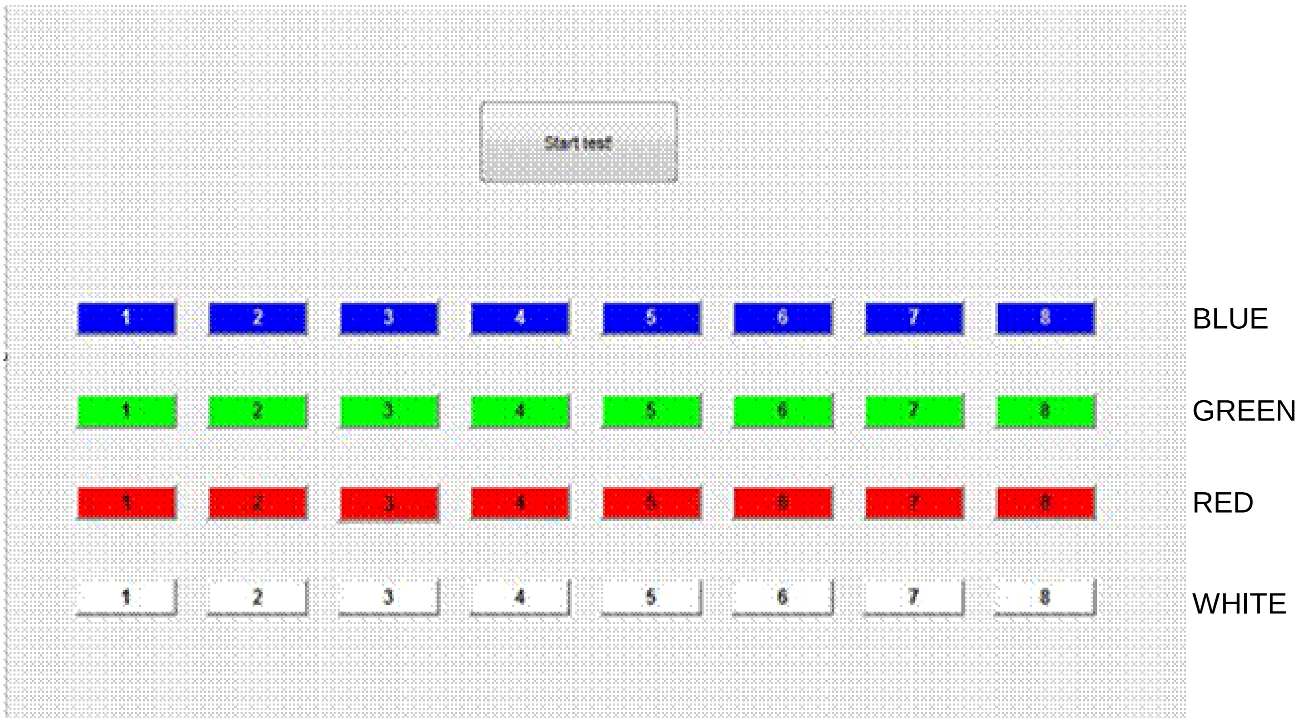


Figure 3: Screenshot of the speech in noise CRM testing screen used by the subject to indicate the perceived number and color presented in the CRM speech stimulus.

The subject completes a brief training portion before beginning the test; the subject must complete 5 consecutive trials correctly before proceeding. This test is repeated in 4 consecutive conditions: condition 1 with the speech from speaker 8 (to the right side of the subject) and the noise from speaker 1 (to the left side of the subject); condition 2 with the speech from speaker 5 and the noise from speaker 4; condition 3 is the reverse of condition 2, presenting the speech from speaker 4 and the noise from speaker 5; and condition 4 is the reverse of condition 1, with the speech from speaker 1 and the noise from speaker 8. Review Figure 1 for speaker orientation.

RESULTS

Bilateral subjects are theorized to have a right-eared bias, congruent with early research (Berlin, Hughes, Lowe-Bell, Berlin, 1973). For the analyses and the presentations of the data below, the right ear is considered the "good ear" for all subjects. Thus, the side of ear impairment for subjects with right-sided hearing loss was adjusted by flipping speech in noise conditions (1 to 8, 4 to 5, etc.) before subtraction to form the best-to-worst and good-to-bad dependent variables, (those subjects with left-sided hearing loss were left as is). Therefore, all data are presented as if hearing losses were on the left for all unilateral or plugged subjects.

Sound Localization

One way ANOVA in RMS errors showed significant differences between the bilateral, true unilateral, and plugged groups ($F_{2,56}$=71; p<0.001). Post-Hoc comparison showed a significant difference between true unilateral and bilateral subjects (p<0.001; effect size 3.0); error bars are $\pm$ 1 standard error, (see Figure 4). Post-Hoc comparison showed a significant difference between plugged and bilateral subjects (p<0.001, ES =10). Post-Hoc comparison showed a significant difference between the plugged group and the true unilateral group, (p<.001; ES=1.6) one-tailed).

Figure 4: Localization Performance Across All Groups

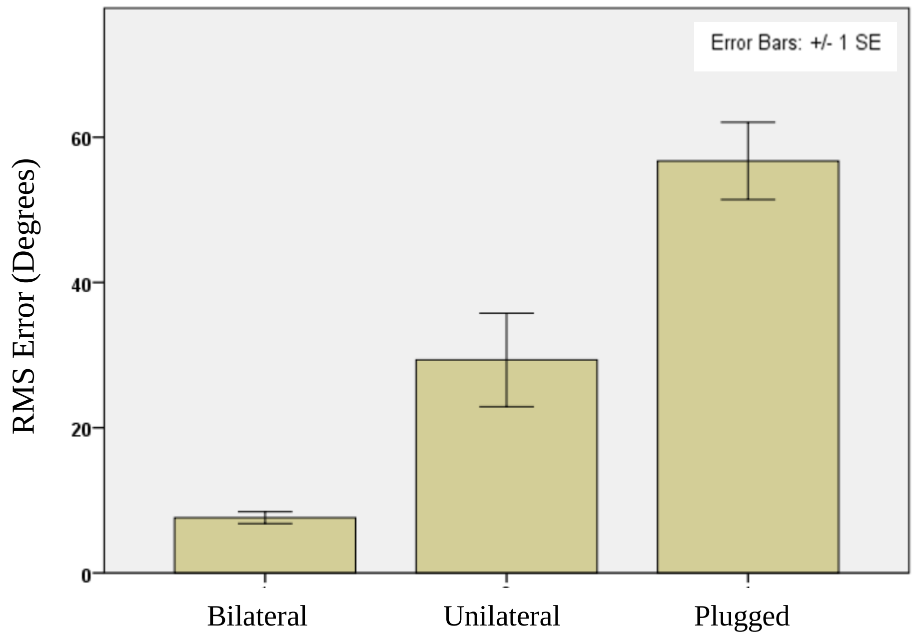


Figure 4: The difference in localization performance of three subject groups. Performance is measured by mean root-mean-square (RMS) error in degrees. The bilateral subjects perform with significantly less degrees of error on average than the unilateral subjects and even less than the plugged bilateral subjects.

Figure 4 is a plot of the RMS errors in degrees that were made by the three subject groups. The bilateral subjects made the least errors on average, (a mean RMS of 7.6 degrees deviating from the correct speaker) of the three groups. The true unilateral group made larger and more frequent errors, (a mean RMS of 29 degrees of deviation). The plugged subjects made the most errors; they were the most severe in deviation from the correct speaker than the bilateral subjects or true unilateral subjects, (a mean RMS of 57 degrees of deviation). The bilateral subjects performed significantly better than the unilateral subjects in the sound localization task.

CRM Speech-in-Noise

The dependent variable of the speech-in-noise test is derived from the intensity level of the noise (dBA) that produced 50% correct detections (CRM threshold) of 60 dB SPL speech signal in the contralateral hemi-field. The amount of noise can be compared to the 60 dB SPL speech level to derive a signal-to-noise ratio (SNR); a smaller SNR equates to a more challenging task, and thus, a higher-performing test-taker. This task was completed in 4 conditions which are named based on the expected performance of the unilateral subjects. Condition 1 is called the "best condition" (speech to normal ear; noise to impaired ear), condition 2 is "good condition" (speech from near front in normal-ear hemi-field; noise from near front in impaired-ear hemi-field), condition 3 is the "bad condition" (reverse of condition 2), and condition 4 is "worst condition" (reverse of condition 1).

Figure 5 below plots the average performance of the unilateral and bilateral groups showing the SNR at CRM threshold across the 4 task conditions. The bilateral group shows a flat, balanced, and high performance (low SNR) across all conditions whereas the unilateral group's performance is high in the "best" condition and slopes steeply upward through the "good" to "poor" to "worst" condition (variable SNR).

Figure 5: Speech-in-Noise Performance Across 4 CRM Conditions

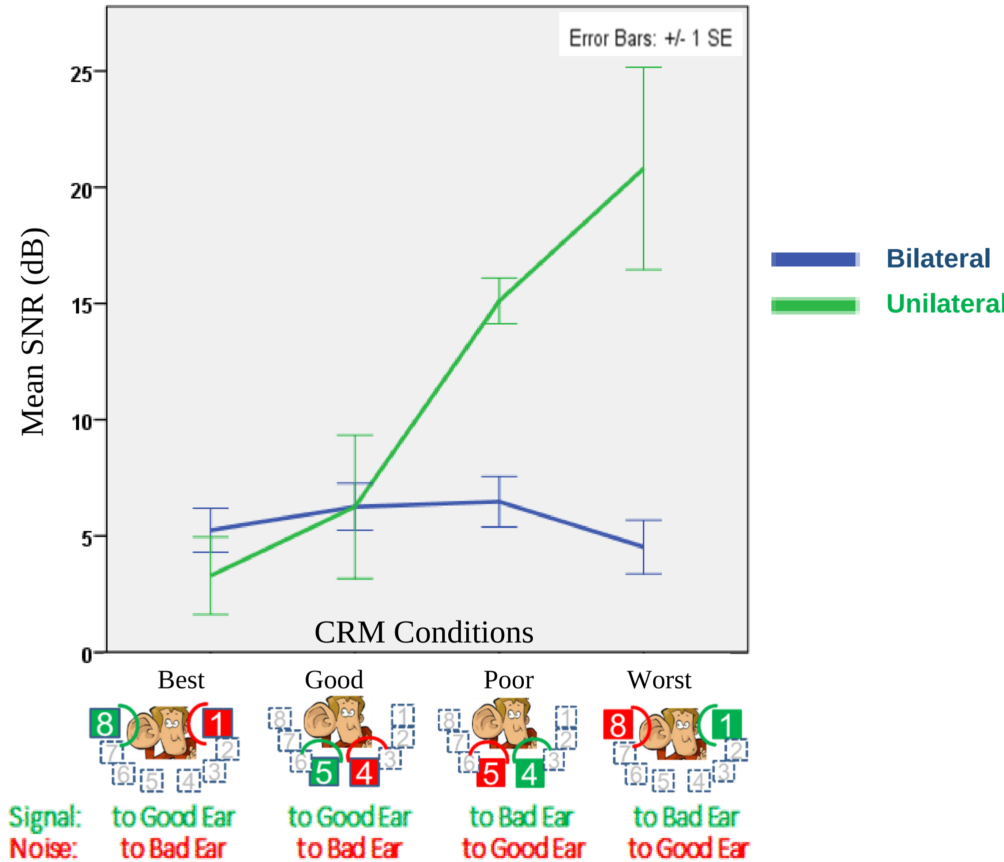


Figure 5: Performance of speech understanding in noise ability measured by average SNR at the threshold of 50% accuracy for each subject group. The performance of unilateral subjects worsens from the 'best' to 'worst' conditions. The bilateral subjects exhibit a flat performance at a low SNR level. The 'plugged' group (not shown) demonstrated intermediate performance.

From the speech-in-noise task measures, two dependent variables were calculated from the CRM thresholds: a best-to-worst difference, which is the noise level at CRM threshold in the 'best' condition minus that in the 'worst' condition; and a good-to-poor difference, which is the noise level at CRM threshold in the 'good' condition minus that in the 'poor' condition.

Figure 6 shows the means and standard errors of the best-to-worst difference. OneWay ANOVA in this difference shows a highly significant effect of group (Bilateral, Unilateral, or Plugged) $F_{2,35}$=15.2, p<.001. Post-hoc LSD tests showed that all groups were significantly different (p=.007 or less). The effect size of the difference between unilateral and bilateral subjects was 3 or 'huge' and the two comparisons with the plugged group had effect sizes > 1.1 or well above what Cohen considered 'large.'

Figure 6: CRM Performance Difference Between Best and Worst Conditions

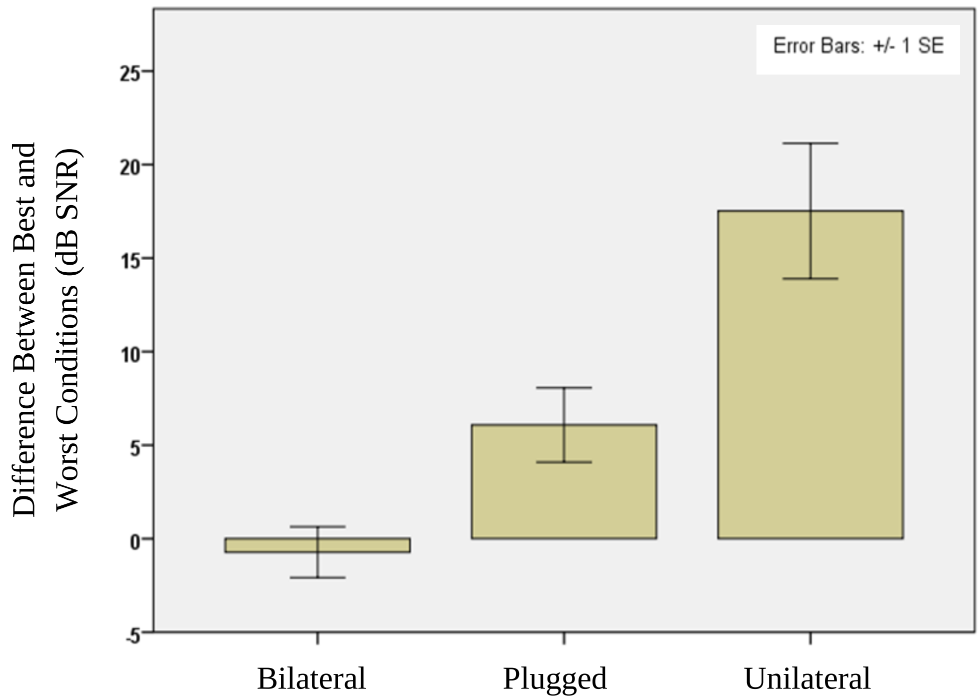


Figure 6: The difference in speech-in-noise comprehension performance, measured by subtracting the mean SNR at CRM threshold in the 'worst' condition from the 'best' condition. The bilateral subjects perform equally in both conditions, the plugged subjects exhibited a difference, and the unilateral subjects performed with the largest difference.

OneWay ANOVA in the difference in noise threshold between the 'good-to-poor' listening conditions shows a significant effect of group (Bilateral, Unilateral, or Plugged) $F_{2,36}$=3.9, p=.03. Post-hoc LSD tests showed that all groups were significantly different (p=.04 or less, except the unilateral compared to the plugged (p=.43). The effect size of the difference between unilateral and bilateral subjects was 1.6 or twice what Cohen said was ‘large’) and the comparisons between the bilateral and plugged group had effect size of 1. The means and standard errors of these data are shown in Figure 7 below.

Figure 7: CRM Performance Difference Between Good and Poor Conditions

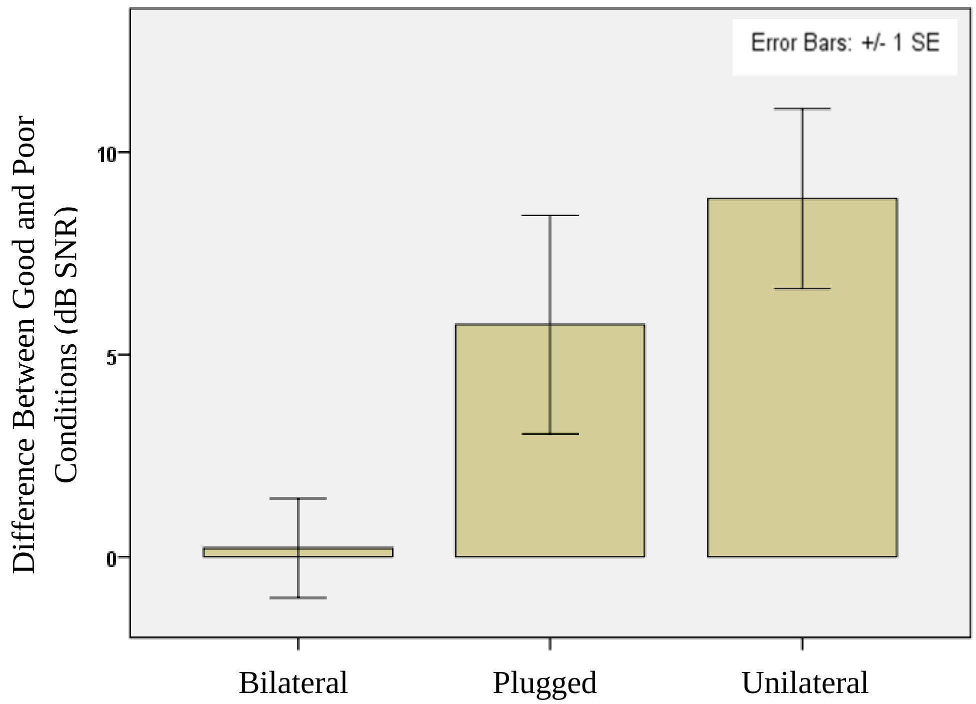


Figure 7: The difference in speech-in-noise comprehension performance, measured by subtracting the mean SNR at CRM threshold in the ‘poor’ condition from the ‘good’ condition. The bilateral subjects perform equally in both conditions, the plugged and unilateral subjects exhibited a significant difference.

DISCUSSION

The stereo-hearing testing system shows a significant difference between bilateral and unilateral subjects in the binaural processing tasks of sound localization and understanding speech-in-noise; it is therefore validated for data collection of experimental groups for binaural processing investigation over time.

The analysis of the bilateral subjects who were plugged in one ear is interesting in that they perform so poorly on the sound localization task (as seen in Figure 4). This low performance suggests the true unilaterals had learned over their years of hearing loss to localize with monaural cues. The plugged group actually had less of a hearing loss (about 56 dB SPL attenuation created by the earplug and ear muff) than the true unilateral group possessed (about 97 dB HL), yet performed worse. This may be attributed to the fact that the plugged subjects did not have any time to learn “how to use” their hearing loss, let alone adjust to it. On the other hand, the majority of the unilateral subjects were born with their hearing loss, if not, had acquired it numerous years prior to this experiment.

The data become increasingly interesting when analyzing the speech-in-noise performance of the plugged subjects to the unilateral subjects. This trend is different in speech in noise testing; the plugged subjects had results that were in between those of the bilateral and unilateral subject groups (as opposed to performing significantly worse than the unilateral group as they did in the localization task). The effect of an ear plug is different (compared to true unilateral subjects) in the speech-in-noise measures. The plugged group did better than the unilateral group as measured by the “best to worst” and the “good to poor” differences, suggesting that a plugged ear was less affected by the location of the signals than a dead/deaf ear in our speech-in-noise tasks. Unlike the localization task, it suggests that the understanding of speech-in-noise task may not be as dependent on learning how to compensate for a hearing loss, as much as the actual degree of the hearing loss (as mentioned before, the plugged group actually had less of a hearing loss created by the earplug and ear muff than the true unilateral group possessed).

Of the four CRM speech and noise conditions, the true unilateral subjects performed the best in the first CRM condition (called the “best condition”) in which the speech is toward the good ear and the competing noise is toward the deaf or impaired ear. This low signal-to-noise threshold is expected for those with single-sided deafness, the head shadow effect is acting in favor for the subject as it allows the speech signal to be heard more easily, (Kesser, in press). Conversely, the true unilateral subjects performed the worst in the reverse condition, the fourth condition, (called the “worst condition”) with the speech toward the deaf/impaired ear and the competing noise toward the normal ear for the same reasoning because head shadow attenuates the speech but not the noise; leading to a lower threshold for noise (a higher SNR). In the second and third conditions, the speech signal and noise originate closer to midline, in front of the subject, one in the center-right hemi-field (speaker 4) and the other in the center-left hemi-field (speaker 5), and the reverse. However, because speakers 4 and 5 are closer to midline we expect these listening tasks to be more similar, yet still slightly favoring the condition when the speech was on the side of the good ear. As expected the unilateral subjects scored higher noise levels at CRM threshold (thus lower SNR) in the “good condition” when the speech signal arrived from the hemi-field of the better ear (speaker 5), and the noise arrived from the hemi-field of the deaf ear (speaker 4), as opposed to the reverse, or “poor condition.” This effect was even more significant between the “best” and “worst” conditions. The bilateral subjects performed consistently well with low SNR thresholds throughout all conditions.

CONCLUSION

The small, inexpensive, deployable, and easy-to-set up stereo-hearing test system described here (Allen et al., 2013, Harwell et al., 2014) produces large differences between bilateral and unilateral subjects. Having binaural access to environmental sound provides an advantage in localization accuracy and in detection of speech in competing noise.

There is a significant difference in the performance of bilateral subjects and true unilateral or plugged subjects in all tests. There is a marginal difference with true unilateral subjects localizing better on average than the plugged subjects. This suggests that there might be some long-term adaptation to unilateral hearing loss and bodes well for the eventual goal of this project, which is to evaluate long-term changes in atresia patients, post-surgery.

In the CRM speech-in-noise task, the true unilateral subjects performed the best when the speech signal was on the side of the normal ear and the noise on the side of the deaf ear. Unilateral subjects have an advantage over the bilateral subjects in this condition due to head shadow effect. The reverse condition is the most challenging for the unilateral subjects. The middle conditions, which present the speech and noise signals closer to midline, though still in opposite hemi-fields, created a trend that transitions in performance from the easiest to the hardest condition. The bilateral subjects performed consistently well with high noise levels (thus low SNRs) at CRM thresholds throughout all conditions.

The prototype proves successful in separating the bilateral and unilateral (both the true unilateral and plugged) subjects. The system is designed to test subjects in distinct intervals over long periods of time for the purpose of recording improvement or change in hearing, localization ability, and speech-in-noise reception. The stereo-hearing testing device is now ready for deployment to investigate patients with surgically corrected congenital aural atresia, who we expect to perform ‘between’ these unilateral and bilateral subjects in both binaural processing tasks.

MANUSCRIPT #2 TITLE

Deployment of a Stereo-Hearing System to Postoperative Atresia Patients

ABSTRACT

Objective: To investigate the performance of atresia patients, postoperatively, in two binaural processing tasks, and to compare that performance to subjects with normal hearing and subjects with a complete unilateral hearing loss. To investigate the reliability, validity, and efficiency of collecting data via transcontinental shipment of the prototype device.

Methods: From their home, subjects were tested on localization accuracy and speech understanding in noise using a laboratory-made stereo-hearing testing device. For the localization task, the subject identified the location of a 250 ms noise burst presented randomly from an 8-speaker array. For the speech-in-noise task, the subject must identify a color/number command presented from a speaker in one hemi-field while an adaptive noise track is presented simultaneously from a speaker in the adjacent hemi-field. The test is repeated with different locations of speech and noise.

Results: Postoperative atresia subjects performed better than unilateral subjects in all tasks, showing the expected improvements in binaural processing following canal-plasty. Atresia patients equaled the bilateral controls in sound localization and the most challenging speech in noise test. Within this initial sample of atresia patients (N=9) only vague trends are evident among the dependent variables and with various covariates. Post-operative audiometric speech reception thresholds correlate with the speech in noise testing. Both localization and speech-in-noise understanding appear to improve over post-

operative time as a general trend, but outlier(s) increase the variance to a point of statistical insignificance.

Conclusions: Repaired atresia subjects perform better than unilateral subjects in localizing sound and understanding speech with a separated noise. The performance of the post-op atresia patients is closer to the bilateral subjects than to unilateral subjects, confirming a benefit of the surgical repair of congenital conductive hearing loss. Our device can be used reliably and efficiently to collect data via transcontinental shipment to residential locations. More follow-up longitudinal data would help investigate any improvement in of binaural listening tasks over time in these patients. One option to continue this research is for medical centers to deploy this device to patients' homes annually for updated testing.

INTRODUCTION

Statement of the Problem:

Patients travel from around the country to meet with Dr. Bradley Kesser, an otolaryngologist at the University of Virginia Medical Center, for atresia-repair operations. These patients undergo the operation, as early as age 5, and wake up hearing air conducted sounds for the first time from their newly opened ear. The patients return approximately one month post-operation to undergo a conventional hearing test to document improvement in hearing sensitivity in the repaired ear. Audiometric measures of hearing generally occur annually. Thus, while much documentation exists on the improvement in hearing thresholds and speech scores of these patients, data do not exist on how binaural hearing improves over time after the surgery, an ability that is only possible with two open inputs of auditory information. Insurance commonly covers the costs associated with traveling back to the medical center for the one month post-op follow-up appointment, and it will not cover any costs to return annually for analysis of binaural hearing ability. We developed and now deploy a small, easily un-packable stereo-hearing test system. See (preceding manuscript: "Development of a Deployable Stereo-Hearing System") for details of this device.

Purpose of the Second Study:

To investigate efficiency and cost-effectiveness of shipping an evidence-based stereo-hearing testing device to the homes of patients for testing and shipping it back for result analysis. To investigate the performance of post-operative patients in tests of sound localization and understanding speech-in-noise considering various parameters such as: age at time of surgery, number of surgeries, age at time of testing, number of years since surgerie(s), and pre/post op PTA and SRT scores.

Research Hypotheses:

1. Transcontinental shipping the device to the residences of patients will be cost-effective (less than $100 to ship round trip), time effective (2 weeks of turnaround), and successful in patient-protected data collection.
2. Reliable results from auditory testing can be obtained in the patients' homes and are comparable to results obtained in the lab setting (at JMU and UVA).
3. Repaired atresia patients will perform better in both binaural listening tasks (sound localization and understanding speech in noise) than the unilateral control

group (representing the pre-op atresia population) and will perform worse than the bilateral control group (both control groups are derived from data in the preceding manuscript).

4. Postoperative atresia subjects will perform better on both tests as a factor of the time passed since the corrective surgery.
5. The postoperative atresia subjects will perform better on both tests as a factor of how young they were at the time of the surgery.
6. The postoperative atresia subjects will perform better on both tests as a factor of their PTA and SRT scores before surgery and the amount of improvement of these scores.

MATERIALS & METHODS

Participants:

A total of 9 postoperative congenital unilateral atresia individuals participated in this study. The ages of the subjects ranged between 5 and 25 years old, (M = 12.9, SD = 5.8). These participants completed the study within a range of 4 months to 11 years after their (most recent) atresia repair a group average of 3.8 years post-operation. Preoperative audiograms of these participants reveal a unilateral conductive hearing loss of a degree ranging from mostly moderate to severe, with hearing within normal limits in their unaffected ear (air and bone-conduction thresholds at or better than 20 dB HL). At the time of the experiment (postoperative), all subjects, except one, had normal hearing to a mild hearing loss in the affected (repaired atretic) ear; the remaining subject possessed a moderate hearing loss in the atretic ear. The mean pure-tone average (PTA) for the atretic ear prior to any operation was 59.2 dB HL (SD = 11.7 dB HL). The mean PTA for the repaired atretic ear after the most recent surgery was 25.9 dB HL (SD = 12.5 dB HL). Thus, there was an average improvement of 33 dB HL. Dr. Bradley Kesser recruited and acquired consent of each subject at the University of Virginia Medical Center before their participation in the study. Patients also provided informed consent to before beginning their tests at home. Audiograms from pre-operation and post-operation were obtained prior to the start of the study. Atresia subjects were paid for their participation and time. Control subjects were recruited on a volunteer (unpaid) participation basis.

Inclusion criteria for the study included: unilateral congenital aural atresia post-operation, within 15 years since most recent repair operation, ability to follow self-administered stereo-hearing testing via deployable device (age of 5 or above), and possessing an address to receive and ship the deployable device. Exclusion criteria for the study included: the patient or the parent/guardian did not want to participate in the study at any time, possessing bilateral congenital aural atresia, or not (cognitively) developed enough to participate independently in the testing.

For the sound localization test, these 9 post-op atresia subjects were compared to a control group of 33 bilateral subjects, a group of 18 bilateral subjects who repeated the test with an artificial unilateral hearing loss (plugged group), and a control group of 6 unilateral subjects from the first study. For the speech-in-noise test, these 9 subjects were compared to a control group of 20 bilateral subjects and the control group of 5 unilateral subjects (from the first study), (each of these 20 bilateral subjects were tested again with an earplug in one ear and an earmuff covering it to simulate an artificial unilateral hearing loss). Audiograms were obtained or completed for each subject in this study prior to testing. Of the bilateral control subjects, all except 2 had hearing within normal limits in both ears (air and bone-conduction thresholds at or better than 20 dB HL across frequencies of 250-8000 Hz). Of the 2 remaining bilateral subjects, one had bilateral mild hearing loss at 2000 Hz and the other had a bilateral normal/mild to moderate sensorineural hearing loss at 6000 and 8000 Hz. Of the 6 unilateral subjects who possessed a sensorineural one-sided hearing loss, 5 had a profound hearing loss and 1 had a moderate hearing loss.

This research study received IRB approval at both James Madison University (#13-0058) and University of Virginia (#12490). Each subject (or subject's parent/guardian if subject was a minor) was contacted by the researcher by phone to discuss the study and the procedure expectations. Then the stereo-hearing testing device package was shipped to the home of each subject. Upon opening the package, each subject must read and follow the provided written instructions for unpacking, set-up, testing, disassembly, packing, and shipping. All testing was conducted in the respective home of each subject, in a room selected by the subject based on the criteria detailed in the instructions packet (see Instructions in the Appendix). Parents/guardians of minor subjects are permitted to assist the subject with assembly and disassembly, however, the parents/guardians must leave the subject to complete the actual testing independently.

The Tests: Sound Localization and Speech in Noise CRM

The subject sits in a chair in front of the laptop device, with the head located approximately in the center between the first speaker (#1) and the last speaker (#8) endpoints, (see Figure 1). Prior to testing, subjects were instructed to refrain from moving the head during the stimulus. The program randomly activates one speaker with a 250 ms broadband noise burst at varying intensity levels between 60 and 80 dB SPL (average intensity level of 70 dB SPL, roved by +/- 10 dB SPL). After each sound stimulus, the subject makes a selection on the laptop screen (see Figure 1 below) indicating the perceived location. There is no time limit and there is no feedback regarding the subject's accuracy. The test continues for 48 trials. Outcome measures were derived and analyzed in the form of: RMS error in degrees, the number of correct trials, the number of trials incorrect (categorized by number of speakers in error), and a percentage of correct speaker identification out of 48 total trials.

Figure 1: Sound Localization Test Screen

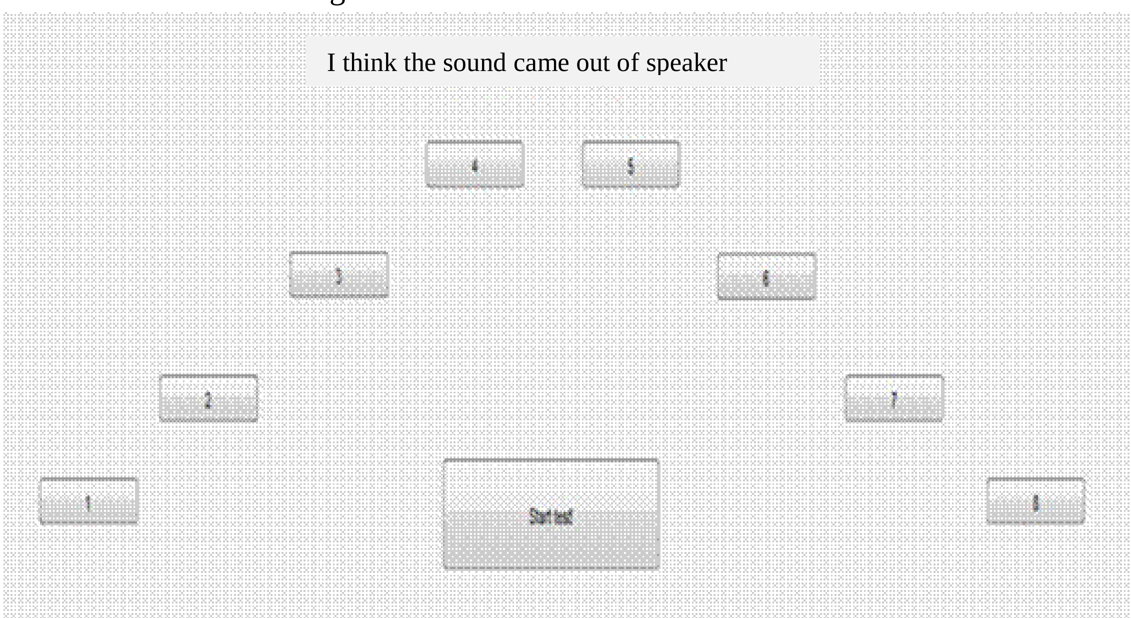


Figure 1: Screenshot of the sound localization testing screen used by the subject to indicate the perceived speaker location of the broadband noise stimulus on an azimuth plot on the computer screen.

The speech-in-noise test used the Corpus Response Measure (CRM), (first set, male speaker, “Charlie” call sign), (Bolia, Nelson, Ericson, Simpson, 2000), in which a speech recording is played from a designated speaker in one hemi-field in the following format “Ready (call sign), go to (color)(number) now” while a broadband noise stimulus is simultaneously played from a designated speaker in the opposite hemi-field. The subject then makes a selection on the screen from a grid of numbered and colored buttons, based on the signal. For example, if the signal presented with: “Ready Charlie go to blue seven now,” and was heard correctly, then the subject would select the blue button that is labeled with the number 7, (see Figure 2 below). With each speech signal presentation from a designated speaker, another designated speaker is programmed to present a broadband noise recording simultaneously (which is the duration of the speech signal). This test alters the intensity of the broadband noise stimulus using a 1 down, 1 up adaptive track; (increases and decreases the noise by 6 dB SPL step sizes until the 4th change of direction, then changed by 4 dB step sizes) based on the subject’s correct and incorrect responses (respectively). The level of noise was limited to 80 dB (while the CRM speech stimulus remained stable at 60 dB SPL). The test continues for eight changes in direction, or 25 maximum trials, before threshold is reached; threshold defined as the mean dB(A) of the noise at the 5th to 8th change of direction in the adaptive track.

This test is repeated in 4 consecutive conditions: condition 1 with the speech from speaker 8 (to the right side of the subject) and the noise from speaker 1 (to the left side of the subject); condition 2 with the speech from speaker 5 and the noise from speaker 4; condition 3 is the reverse of condition 2, presenting the speech from speaker 4 and the noise from speaker 5; and condition 4 is the reverse of condition 1, with the speech from speaker 1 and the noise from speaker 8. Review Figure 1 for speaker orientation.

Figure 2: CRM Speech-in-Noise Test Screen

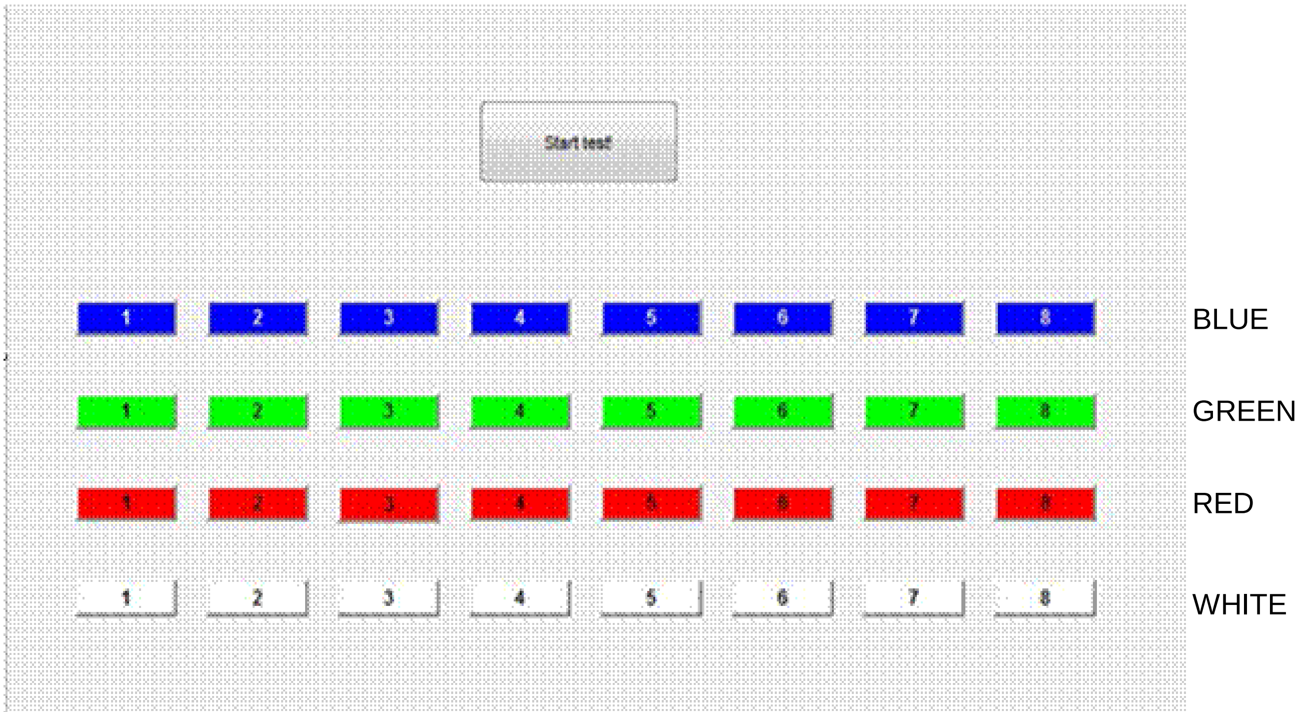


Figure 2: Screenshot of the speech in noise CRM testing screen used by the subject to indicate the perceived number and color presented in the CRM speech stimulus.

Taking the Tests

When launching the laptop device for testing, the subject is prompted to a log-in screen to enter their personal, anonymous username and password. The screen then prompts the subject to silence all electronics before beginning a recording of the background noise in the testing area. Once the recording is completed, the screen will provide instructions for the first test: sound localization. The subject listens for the 250 ms broadband stimulus and then selects the button on the screen that correlates with the exact speaker location the sound was perceived to have been presented from. When the test is concluded, the subject is prompted to begin the CRM test next.

For the CRM test, the screen will provide instructions and then prompt the subject to begin the brief training portion; the subject must complete 5 consecutive trials correctly before proceeding. Finally, the subject is prompted to begin the test, listening for the speech stimulus that is presented from one speaker as the noise is presented simultaneously from another. The subject then selects the button on the screen that correlates with the exact color and number combination that the recorded sentence was perceived to have instructed. The test is repeated 4 times with different speakers emitting the signal and noise (1&8, 4&5, 5&4, 8&1). When all 4 conditions are completed, the screen will prompt the subject to shut down the device. Finally, the subject follows the written instructions to disassemble the device, pack all the materials into its original shipping container, and drop the package off to the designated shipping carrier.

RESULTS

Bilateral subjects are theorized to have a right-eared bias, congruent with early research (Berlin, Hughes, Lowe-Bell, Berlin, 1973). For the analyses and the presentations of the data below, the right ear is considered the “good ear” for all subjects. Thus, the side of ear impairment for subjects with right-sided hearing loss was adjusted by flipping speech in noise conditions (1 to 8, 4 to 5, etc.) before subtraction to form the best-to-worst and good to bad dependent variables, (those subjects with left-sided hearing loss were left as is). Therefore, all data are presented as if hearing losses were on the left for all unilateral or artificially-plugged subjects.

Sound Localization

Oneway analysis of variance showed a significant difference between groups (bilateral, atresia, unilateral, and plugged-bilateral) in root-mean-square (RMS) localization errors in degrees, ($F_{3,64}$=53, p<.001). As seen in Figure 3 below, postoperative atresia subjects performed with higher horizontal localization accuracy (in the form of a lower average root-mean-square error in degrees) than subjects with unilateral sensorineural hearing loss and normal hearing subjects with an artificial unilateral conductive hearing loss (plugged). Post hoc tests (LSD) showed that there was no difference between the atresia patients and the bilateral subjects (p=0.129), and the atresia patients localized significantly better than the true unilateral subjects (p=0.046) with a very large effect size (Cohen's d = 1.6) and localized better than the plugged subjects (p<0.001).

Figure 3: Localization Performance Across All Groups

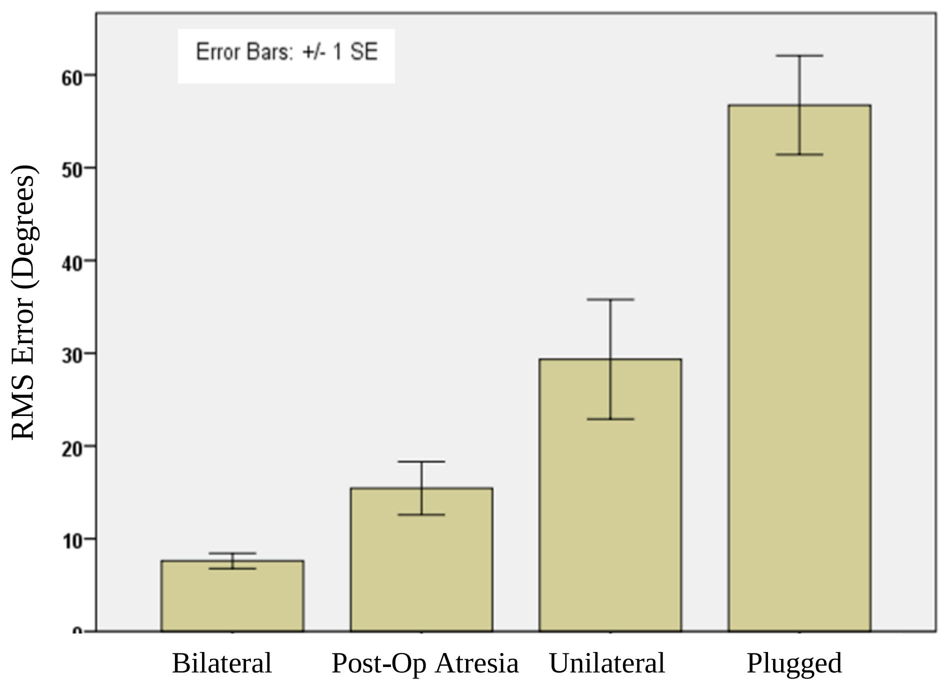


Figure 3: Performance of horizontal localization ability measured by average root mean square of error in degrees for each subject group. The postoperative atresia patients perform with higher accuracy than the unilateral and plugged subjects and similar to the bilateral subjects, on average.

CRM Speech-in-Noise

As seen in Figure 4, the bilateral subjects revealed a high and generally flat performance across all 4 conditions. The subjects with unilateral sensorineural hearing loss performed the best in condition 1, called the “best condition,” (when the speech was directed at the normal ear and the noise was directed at the poorer/deaf ear). The unilateral subjects then performed second-best in condition 2, called the “good condition,” (speech originating from the front of the speaker and the same hemi-field of the normal ear, and noise originating from the front, same hemi-field of the poorer ear). The unilateral group performed the worst in condition 4, called the “worst condition,” (reverse of condition 1), and a similar performance in condition 3, called the “poor condition,” (reverse of condition 2). The plugged subject group exhibited a similar pattern as the unilateral group, with a smaller range of results. The post-op atresia subject group performed higher than the unilateral group in the two conditions that directed speech to the repaired ear and performed nearly identically to them in the first condition. The post-op atresia subject group performed slightly lower than the bilateral group in all conditions except the first condition.

Figure 4: Speech-in-Noise Performance Across 4 CRM Conditions

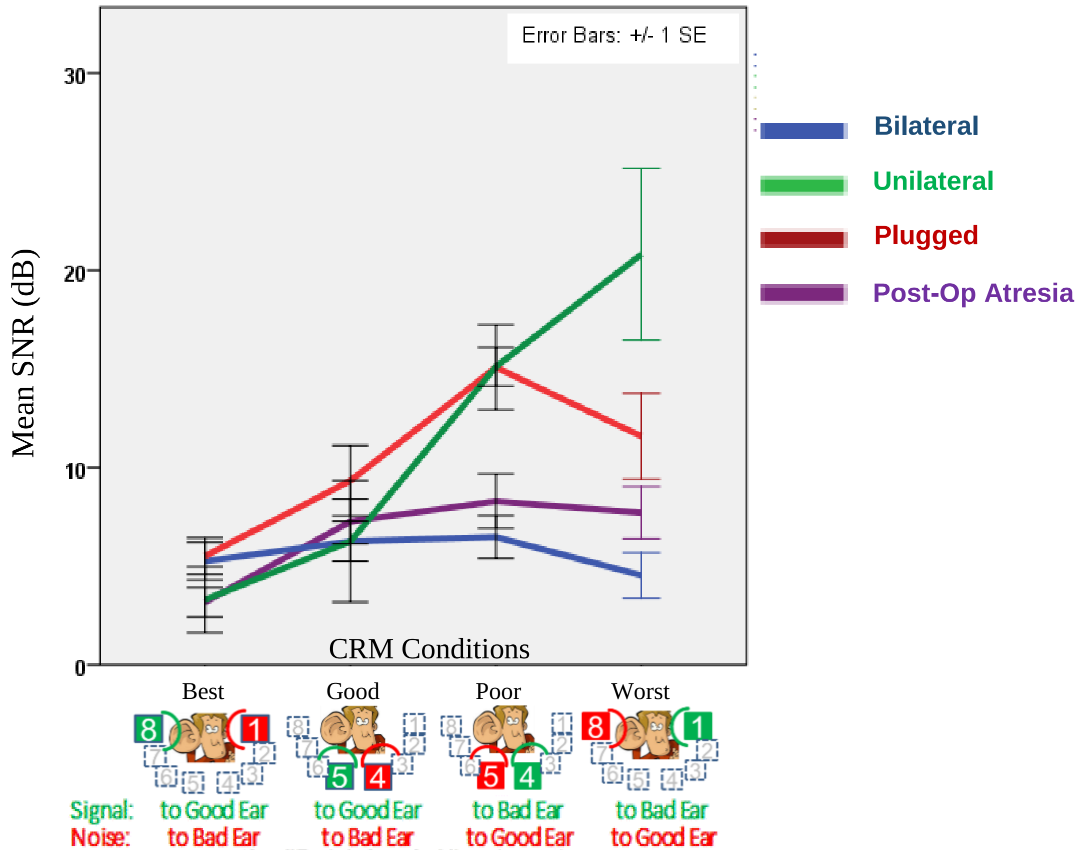


Figure 4: Performance of speech understanding in noise ability measured by average SNR level at the threshold of 50% accuracy for each subject group. The performance of postoperative atresia patients shares similarities with the unilateral and bilateral group performances; performing “like unilateral” in condition 1 and “like bilateral” in conditions 2, 3, and 4.

From the speech-in-noise task measures, two dependent variables were calculated from the CRM thresholds: a best-to-worst difference, which is the noise level at CRM threshold in the ‘best’ condition minus that in the ‘worst’ condition; and a good-to-poor difference, which is the noise level at CRM threshold in the ‘good’ condition minus that in the ‘poor’ condition.

Oneway analysis of variance showed a significant difference between the bilateral group and the post-op atresia, unilateral, and plugged-bilateral in noise intensity level at CRM threshold between the best and worst conditions, ($F_{3,44}$=11.5; p<.001). Post hoc tests

(LSD) showed that there was a marginal difference between the post-op atresia patients and the bilateral subjects ($p=0.047$), and a highly significant difference between the post-op atresia patients and the unilateral subjects ($p=0.001$). There was not a significant difference between the post-op atresia patients and the plugged bilaterals ($p=0.578$). Figure 5 shows the differences in mean noise intensity levels (which is an exact conversion to differences in mean SNR) at CRM threshold of 50% accuracy between the most lateralized speech signal and noise signal in different hemi-fields.

Figure 6 illustrates the same parameters as Figure 5, except now the dependent variable is the difference between the ‘good’ and ‘poor’ condition (the least lateralized signal locations). Here the speech and noise are still in different hemi-fields but the two speakers are closer to midline. Note that the magnitude of this difference is now less (y-axis up to 25dB in Fig 5 and only up to half that in Figure 6. Oneway analysis of variance showed a significant difference between the 4 groups (bilateral, post-op atresia, unilateral, and plugged-bilateral) in noise intensity level at CRM threshold between the more medial “good-to-poor” listening conditions, ($F_{3,44}=3.2$; $p=.033$). Post hoc tests (LSD) showed that there was now no difference between the post-op atresia patients and the bilateral subjects ($p=0.775$), and still a significant difference between the post-op atresia patients and the unilateral subjects ($p=0.05$). There was not a significant difference between the post-op atresia patients and the plugged bilateral subjects ($p=0.122$).

Figure 5: CRM Performance Difference Between Best and Worst Conditions

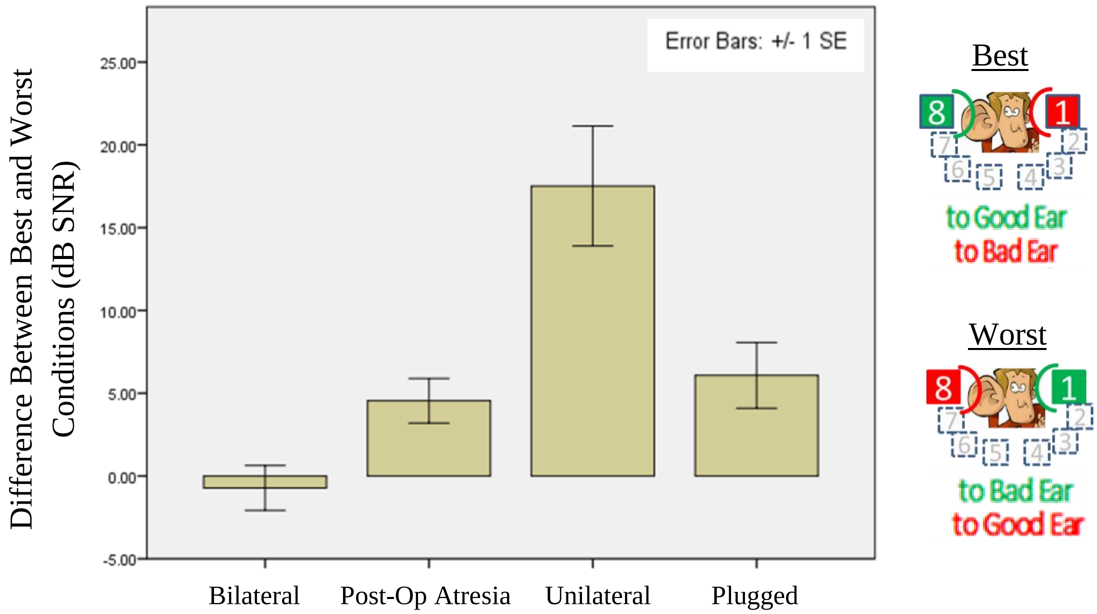


Figure 5: The difference in mean SNR at CRM threshold between the best and worst conditions. The bilateral subjects perform equally in both conditions, whereas the remaining subjects exhibited a significant difference.

Figure 6: CRM Performance Difference Between Good and Poor Conditions

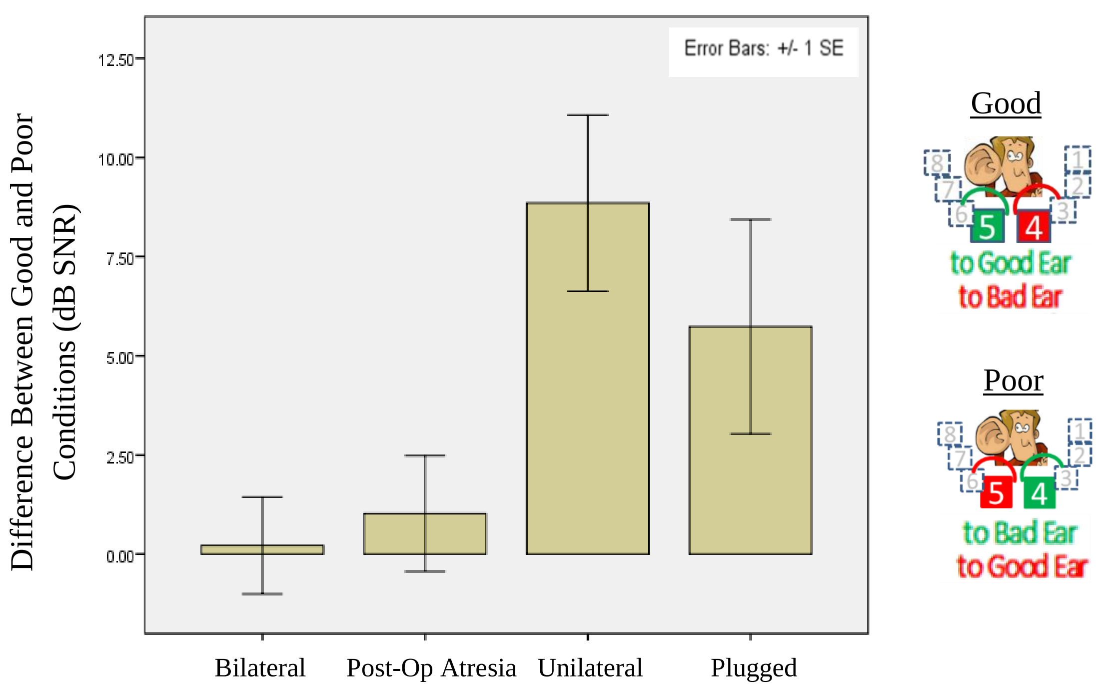


Figure 6: The difference in mean SNR at CRM threshold between the good and poor conditions. The bilateral subjects perform equally in both conditions, whereas the post-op atresia, plugged, and unilateral subjects exhibited a significant difference. The post-op atresia subjects exhibited less of a difference between their performances compared to the best-to-worst results in Figure 5.

Much like other studies, (Wilmington, 1994), there was no strong (significant) correlation between the various measures of binaural processing (in the present paper localization errors are compared to SNR in speech understanding ability). Individual postoperative atresia subjects are plotted on performance in localization accuracy (in RMS error in degrees) compared to the difference in speech-in-noise ability (in dB of noise intensity level at CRM threshold, or otherwise in dB SNR) between the “good’ versus ‘poor’ speaker configurations (condition 2 SNR subtracted by condition 3 SNR). As seen in Figure 7 below, performance trend between these two binaural processing tasks is not a clear linear correlation. This trend suggests that there might be two subsets indicated by the light-yellow lines; the line with the steep slope indicating subjects that are relatively good localizers (relative to their speech-in-noise performance) and the flatter slope indicating a group of poor localizers (high RMS errors).

Figure 7: Localization and CRM Ability for Post-Op Atresia Subjects

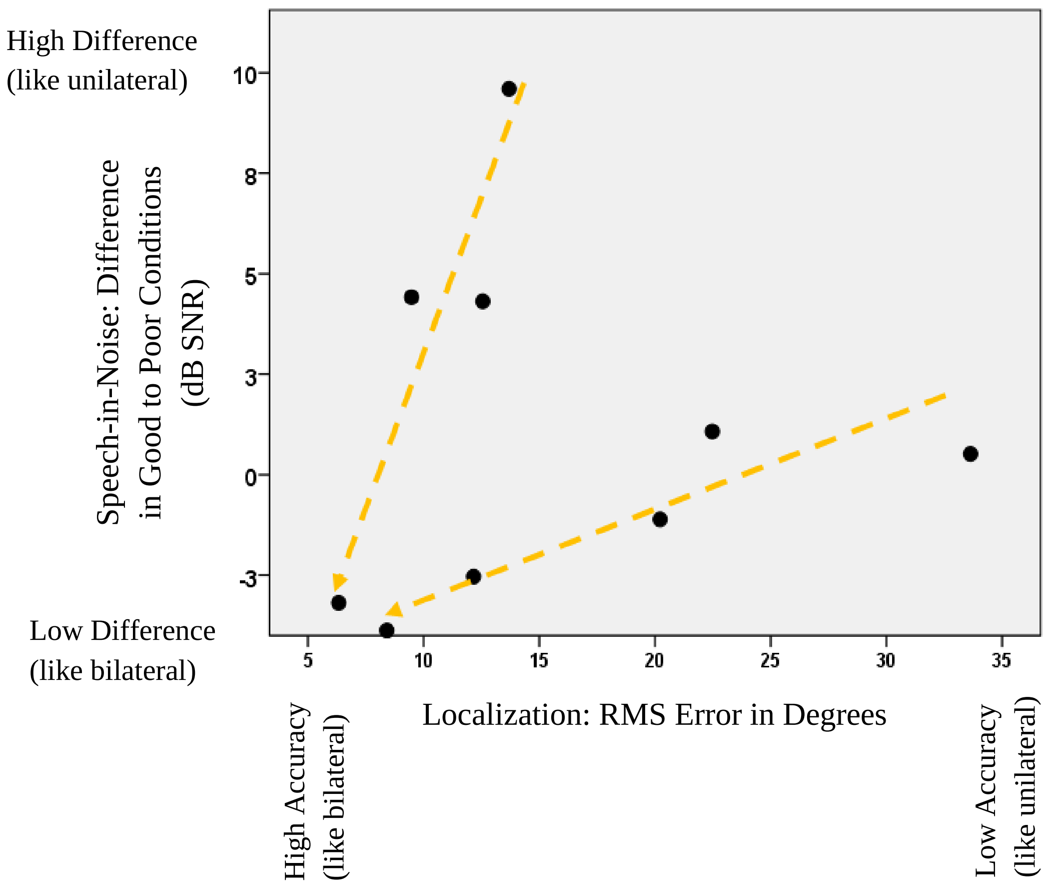


Figure 7: Plots of each individual postoperative atresia subject in localization ability and difference (dB SNR) of performance between the 'good' and 'poor' conditions at CRM threshold. The dashed yellow lines are hand-drawn to represent the observed trends.

The overall goal of the deployable system is to document improvements in performance over time passed since surgery. Thus, an interesting correlation might exist between the amount of time passed since atresia surgery and the performance of the speech-in-noise and localization tasks. As seen in Figure 8 below, individual postoperative atresia subjects are plotted on years passed since the most recent atresia surgery against the difference in speech-in-noise performance between the best and worst conditions (in dB SNR) at CRM threshold. With the exception of a single outlier in the upper right, performance in this task appears to improve with time in a non-linear trend, as expected. It should be noted that the outlier's PTA was 60 dB HL before surgery and improved to 47 dB HL and the SRT was 60 dB HL improved to 45 dB HL.

Figure 8: Years Since Last Surgery and CRM Ability for Post-Op Atresia Subjects

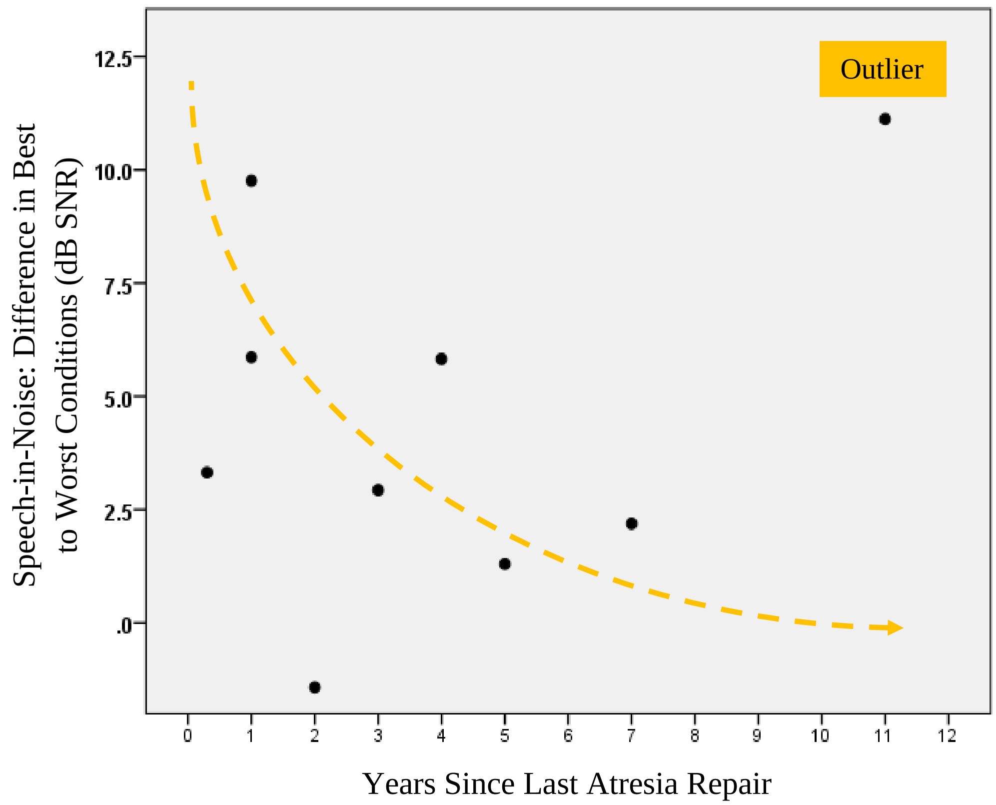


Figure 8: This scatterplot shows that a non-linear correlation exists between the number of years passed since atresia repair surgery and the difference in SNR between the 'best' and 'worst' conditions at CRM threshold. As time passes, the difference in performance between conditions becomes more bilateral in nature to a certain extent and a plateau is reached, with the exception of one outlier. The dashed yellow line is hand-drawn to represent the observed trend.

Figure 9 below shows localization (RMS errors) performance of post-op atresia subjects as a function of how many years have passed since their last (or only) repair operation. It appears that, although there is some variability; localization improves with chronical age of new ear in an expected non-linear trend similar to Figure 8.

Figure 9: Years Since Last Surgery and Localization Ability

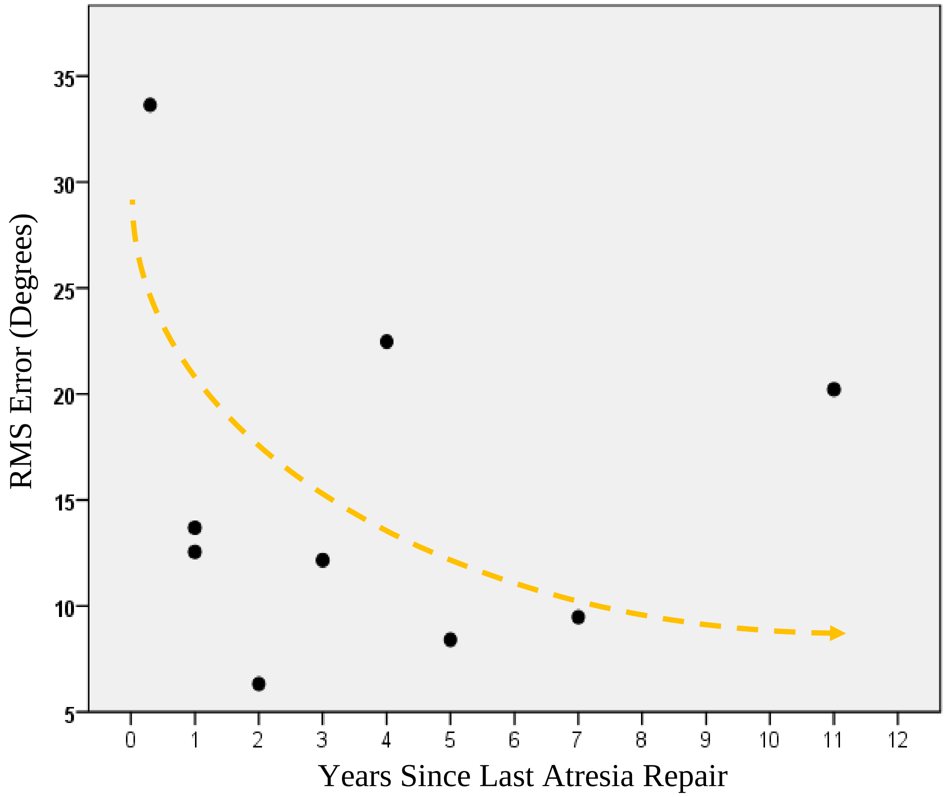


Figure 9: This scatterplot shows that a non-linear correlation exists between the number of years passed since atresia repair surgery and horizontal localization performance. As time passes, the localization ability improves to a certain extent and a plateau is reached. The dashed yellow line is hand-drawn to represent the observed trend.

As a reference, Table 1 is provided below with the demographic and audiometric data of each individual postoperative atresia subject that participated in this study. This table can be used to cross-reference to each dot on the scatterplot of Figure 8 above. The highlighted column in Table 1 is the atresia subject (15 years old) that is marked as the outlier in Figure 8. Compared to the rest of the post-op atresia subjects, especially its age-matched counterpart above it (16 years old), this subject has the worst PTA and SRT audiometric thresholds post-operation (see red arrows), despite having passed the longest duration of time since surgery (11 years).

Table 1: Demographics and Audiometric Data of Post-Op Atresia Subjects

Age	Surgery	Yr1stOP	YrLastOp	post or pre-op	audiogram	Norm PTA AC	Norm PTA BC	Atretic PTA AC	Atretic PTA BC	Norm SRT	Atretic SRT	Norm WRS	Atretic WRS
16	(Dec 2008)	7	7	pre	(Dec 2008)	2	n/a	47	5	0	45	100% @ 40	100% @ 85
				post	(Nov 2014)	2	0	32	3	5	30	100% @ 45	92% @ 70
15	(May 2004)	11	11	pre	(Sept 2003)	12	5	60	13	0	60	n/a	n/a
				post	(Jan 2015)	8	7	47	15	5	45	100% @ 45	100% @ 85
25	1997	8	3	pre/post	(Jan 2011)	0	0	37	2	0	30	100% @ 40	100% @ 70
	2007			pre/post	(June 2012)	5	n/a	32	2	5	30	95% @ 45	100% @ 70
	(Dec 2012)			post	(Feb 2015)	0	0	12	3	0	10	100% @ 40	100% @ 50
9	(June 2011)	4	4	pre	(April 2011)	13	3	77	13	10	70	100% @ 50	88% @ 100
				post	(July 2011)	10	0	28	2	5	25	100% @ 45	80% @ 65
				post	(May 2014)	8	n/a	33	2	5	30	100% @ 45	92% @ 70
				post	(March 2015)	5	2	27	7	0	30	100% @ 40	100% @ 70
9	(June 2013)	2	2	pre	(June 2013)	0	0	58	2	0	50	100% @ 40	98% @ 80
				post	(Dec 2014)	2	0	12	2	5	15	100% @ 45	100% @ 55
				post	(June 2015)	0	n/a	12	0	0	15	100% @ 35	100% @ 50
5 turning 6	(March 2015)	4 mo	4 mo	pre	(March 2015)	7	3	60	3	0	60	n/a	n/a
				post	(April 2015)	3	n/a	20	2	0	15	n/a	n/a
12	(August 2014)	4	1	pre	(May 2014)	0	n/a	62	5	0	55	100% @ 40	96% @ 85
	(Dec 2011)			post	(Sept 2014)	3	0	32	3	0	35	100% @ 40	100% @ 75
				post	(March 2015)	3	2	33	2	5	30	100% @ 45	100% @ 70
10 turning 11	(May 2014)	1	1	pre	(May 2014)	7	7	70	18	5	65	100% @ 45	88% @ 100
				post	(June 2014)	7	7	37	20	5	30	96% @ 45	96% @ 70
15	(Nov 2009)	5	5	pre	(Nov 2009)	2	n/a	62	13	0	55	100% @ 40	96% @ 95
				post	(August 2014)	3	2	15	2	10	20	100% @ 50	100% @ 60
				post	(August 2015)	3	2	13	2	0	15	100% @ 40	96% @ 55

Various clinical covariates were explored to seek explanation of task performance. Table 2 shows all possible correlations between the 'clinical' audiometric data versus the measures from the deployed stereo-hearing test. Interestingly nothing correlates with the localization performance, and several audiometric results correlate with the speech-in-noise tests. Arguably none of these correlations are truly significant given the number of comparisons in this table. However, the most significant correlation (post-op PTA versus best-to-worst condition difference) is plotted in Figure 10 in the Discussion section. Another significant correlation (post-op SRT versus worst condition ability) is plotted in Figure 11 in the Discussion section.

Table 2: Correlations Between Clinical Audiometric Data and Binaural Task Data

Correlations

		RMS	dBAInC#1	dBAInC#2	dBAInC#3	dBAInC#4	dBBtoW	dBGtoP
DeltaPTA	r	.068	-.103	-.057	.255	.390	-.439	-.282
	p	.862	.791	.885	.508	.300	.237	.463
RightEarBad	r	-.411	.089	.209	-.023	-.050	.099	.184
	p	.271	.819	.589	.953	.898	.800	.636
AgeAtSurg	r	-.510	.024	.350	.412	.329	-.308	-.115
	p	.161	.951	.356	.270	.388	.420	.769
YrSinceFirstSurg	r	-.199	-.247	-.309	.088	-.415	.268	-.321
	p	.607	.522	.418	.823	.267	.486	.400
YrSinceLastSurg	r	-.098	-.197	-.429	-.078	-.427	.308	-.258
	p	.801	.611	.249	.841	.252	.421	.502
BetterEarPTAAC	r	.599	.349	-.118	-.342	-.640	.822**	.228
	p	.089	.357	.762	.367	.063	.007	.555
BetterEarPTABC	r	.381	.500	-.138	-.574	-.569	.833**	.429
	p	.312	.171	.723	.106	.112	.005	.249
PreOpPTAAtreticAC	r	.314	-.001	-.196	-.499	-.407	.398	.315
	p	.410	.997	.614	.172	.277	.289	.410
PostOpPTAAtreticAC	r	.218	.115	-.120	-.753*	-.819**	.865**	.611
	p	.572	.769	.759	.019	.007	.003	.081
PreOPSRT	r	.478	.162	-.147	-.505	-.421	.503	.358
	p	.193	.676	.706	.165	.259	.167	.344
PostOPSRT	r	.137	-.099	-.291	-.734*	-.863**	.790*	.460
	p	.726	.800	.447	.024	.003	.011	.212
PreOpPTAAtreticBC	r	-.042	.301	-.194	-.526	-.493	.651	.341
	p	.915	.432	.617	.145	.177	.058	.369
Age	r	-.469	-.134	.050	.334	-.029	-.047	-.274
	p	.203	.732	.898	.379	.942	.905	.476

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

91 Comparisons: expect 0.9 at p<.01 (got 5), and 4.6 at p<.05 (got 8)

0.00055 level of significance required for Bonferroni correction for multiple comparisions

Figure 10

Figure 11

DISCUSSION

This relatively small sample shows that our small test system can be effectively deployed and retrieved with what appear to be interesting data. The post-op atresia patients, as a group, do quite well in these tasks. They do significantly better than the unilateral controls in all measures (localization accuracy and both ways of quantifying speech-understanding-in-noise), and they are no different than bilateral controls in localization and in one of the speech measures (difference between the 'good and poor' CRM conditions). Looking within the group of post-op atresia patients, it appears that the two tasks (localization and understanding speech in noise) are not closely correlated. Rather it appears that individuals do better in either one of these tasks, or the other. The emergence of binaural processing is thus not a unitary process. It is suggested that different aspects of stereo hearing emerge at different rates in different patients after they have two ears with approximately normal air-conduction thresholds.

With this small sample, we fail to find statistically significant relationships between our dependent variable and various clinical covariates (age, time since surgery, pre- or post-op audiometric data, etc.). With the exception of expected outliers in such a population, some general trends might be evident, such as improvement over time since surgery. It appears that the amount of time passed since an aural atresia repair surgery contributes to higher success in binaural processing performance for most of these patients. Nevertheless, results are variable in that some postoperative atresia patients perform more similar to bilateral hearing subjects immediately after surgery, while others might experience a learning interaction over time for approaching normalized results. A more valid indicator of binaural processing success might be attributed to post-op clinical audiometric data, such as puretone averages (PTAs) and speech reception thresholds (SRTs). This is exemplified in Figures 10 and 11 below; the better the SRT or PTA score post-operation, the better the speech-in-noise performance.

Figure 10: PTA of Post-Op Atresia Subjects and CRM Ability

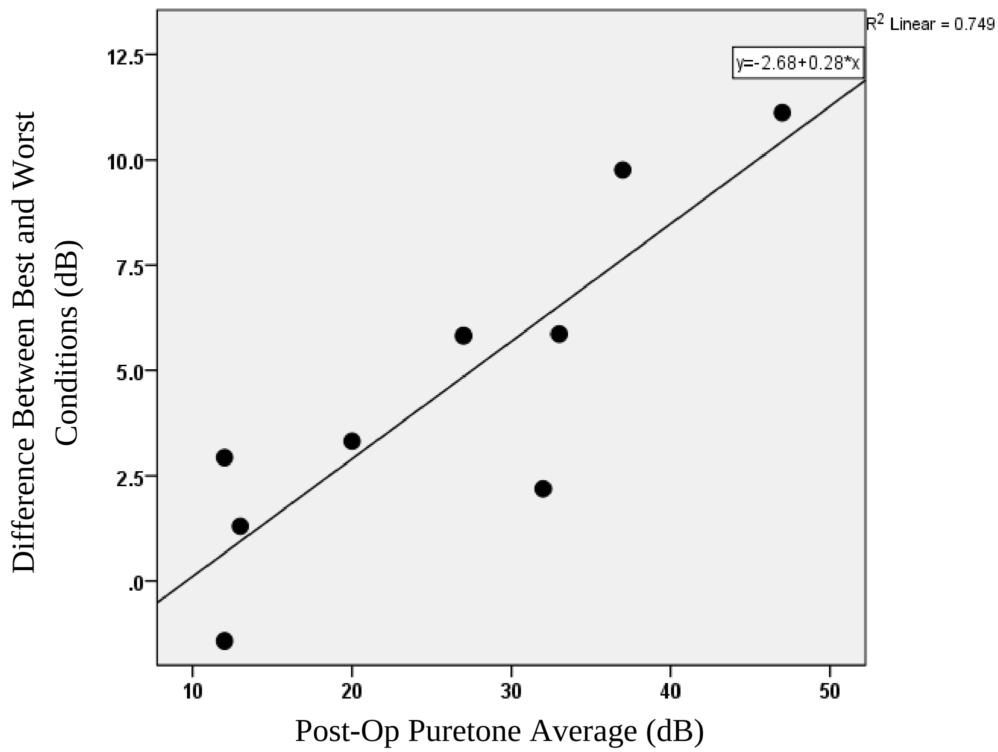


Figure 10: The scatterplot shows a linear correlation exists between the puretone average (PTA) of atresia subjects following reparative surgery and the difference in speech-in-noise performance between the best and worst conditions at CRM threshold.

Figure 11: Post-Op Atresia SRT Scores with Worst CRM Condition

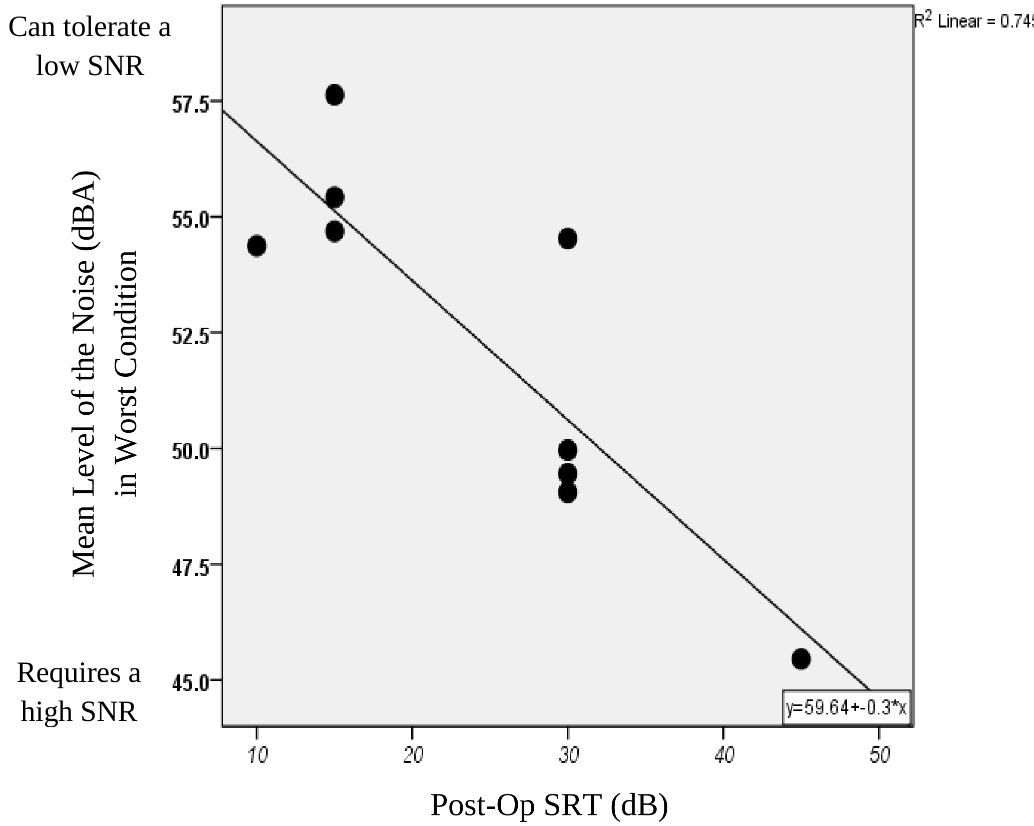


Figure 11: The scatterplot shows a linear and negative correlation exists between the speech reception threshold (SRT) of the post-op atresia subjects following reparative surgery and the mean level of the noise at the CRM threshold for the 'worst' condition. In other words, those who achieved a low SNR at threshold also exhibit a lower (better) post-op SRT.

CRM speech-in-noise test results for the postoperative atresia patients revealed a trend that shared similarities with the bilateral control group and the true unilateral subjects. Figure 4 shows how the post-op atresia group and the unilateral group have excellent performance (better than the bilateral control subjects) in the first CRM condition where the speech signal is facing the normal ear and the competing noise is facing the poorer ear (best condition). In the next two conditions, the speech signal and noise originate from the front of the subject, one in the center-right hemi-field (speaker 4) and the other in the center-left hemi-field (speaker 5), and the reverse (good and poor conditions). The post-op atresia subjects had CRM thresholds at similar noise intensity levels within these two conditions, with a slightly higher performance occurring when the speech signal arrived from the same hemi-field of the normal ear and the noise arrived from the same hemi-field of the repaired atretic ear. In the last condition, with the speech signal facing the repaired atretic ear and the noise facing the normal ear (worst condition), the post-op atresia subjects performed similarly as they did in conditions 2 and 3. They performed between the bilateral control group and the unilateral control group in the last condition. The bilateral subjects performed consistently well with low SNR scores throughout all conditions.

CONCLUSION

Atresia patients who underwent the surgical repair were able to perform better than unilateral subject counterparts and near their bilateral hearing counterparts. Results suggest that a learning curve exists for learning to use the newly repaired ear; years since surgery is one predictor of success in these two binaural tasks, yet clinical measures such as puretone average (PTA) and speech reception threshold (SRT) immediately following surgery might serve as more valid indicators. Binaural processing tasks, specifically horizontal localization of sound and understanding speech-in-noise, may not have the same rate of learning and development as previously thought. Post-operative atresia patients may perform well in one task but not the other. Further follow-up is needed to continue this study for the purpose of tracking the performance of the same patients year after year to create a longitudinal investigation of each subject’s improvement with binaural processing over time as a factor of learning and time passed since surgery. The current deployable stereo-hearing testing prototype can be shipped for testing and returned for analysis in a cost-effective and reliable manner with mild risk.

APPENDIX

Manuscript 1: Further Discussion

A small sample of 5 bilateral subjects, unilateral subjects, and plugged subjects was randomly selected for localization error analysis. The amount of errors and severity of errors were measured for each sample group. When bilateral subjects made errors in the sound localization test, the errors were dissimilar to the unilateral and plugged subjects; they made fewer mistakes and the mistakes were less severe in degrees (errored by one speaker on average). Both the true unilateral and plugged subjects made more errors, which were typically greater than two speakers in error (over 30 degrees). Figures A, B, and C display the nature of these errors. Of all bilateral subjects in the control group, the majority missed the correct speaker by just one speaker to the left or right in **all** their mistakes. In the control group, the highest number of errors made by a subject was 22 (with each of the 22 errors being off by just one speaker). The lowest number of errors was made by a subject was zero.

The true unilateral and plugged subjects expressed much larger and varied distribution of error types than the bilateral subjects. Between the two unilateral groups, the plugged subjects made more errors, which were also more severe in nature, than the true unilateral subjects. This strongly suggests that the prototype is successful in not only separating the localization abilities of one- and two- eared subjects, but furthermore making a distinction between experienced (true) and novice (plugged) one-eared subjects. Due to lack of experience with a hearing loss, plugged subjects made more frequent and more severe errors than the true unilateral subjects, and thus, had the widest distribution of error types among the three groups. For these unilateral groups, the direction of average error is opposite the side of deafness (or hearing loss); those with right-sided deafness tend to make more errors towards the left when selecting speakers and vice versa, as expected. The true unilateral subjects and plugged subjects matched in pattern of average error direction. The differences shown between Figures B and C suggest that there is long-term adaptation involved with having hearing loss (congenital or acquired). In theory, an adult born with unilateral hearing loss would perform significantly higher than an adult who experiences a recent sudden sensorineural hearing loss, when testing for sound localization accuracy on this device. Atresia patients have much more practice and experience in listening with a single ear, (Kesser, in press). This shadows the nature of habilitation that postoperative aural atresia patients encounter over time after the corrective surgery.

Figure A: Distribution of Error Types Among 5 Randomly Selected Bilateral Subjects

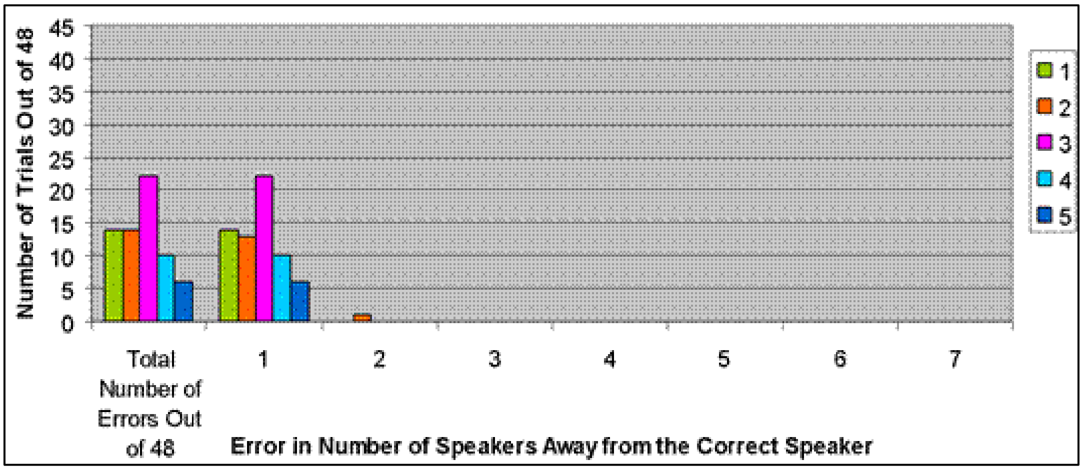


Figure B: Distribution of Error Types Among 5 True Unilateral Subjects

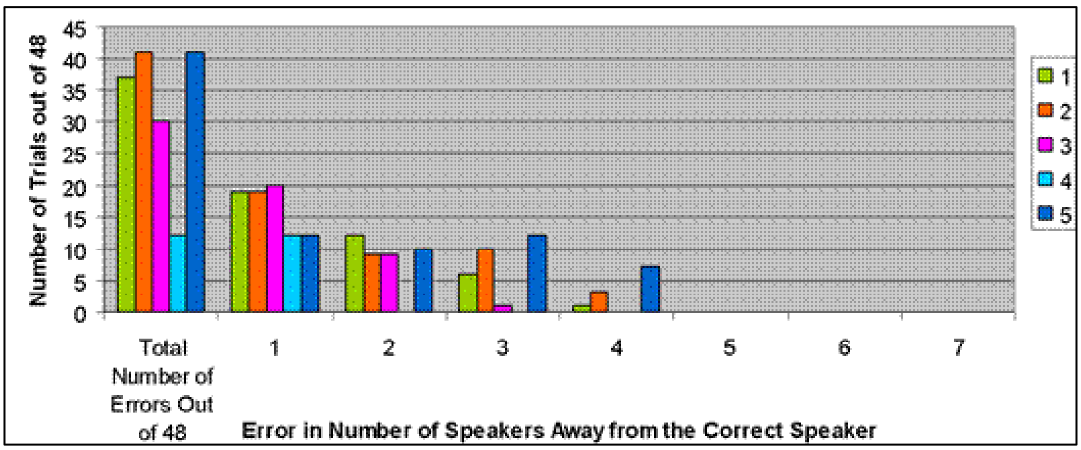
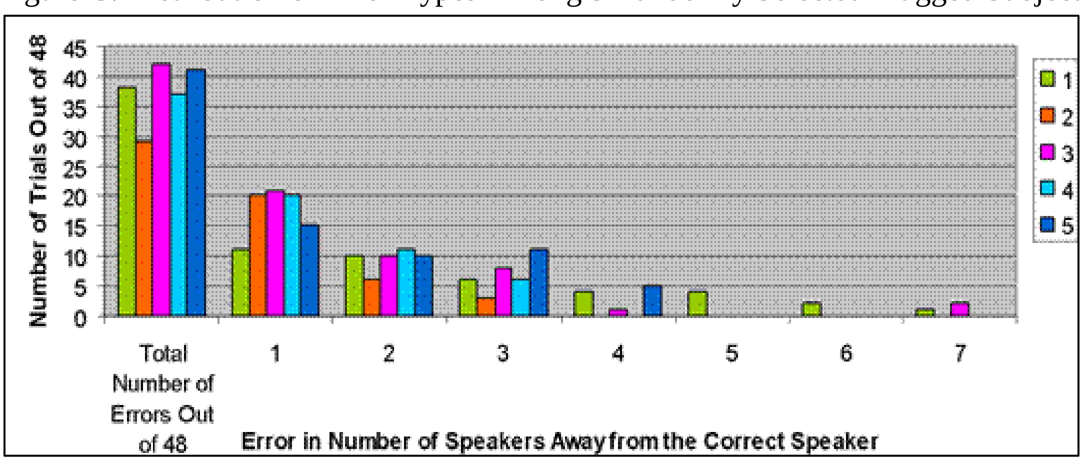


Figure C: Distribution of Error Types Among 5 Randomly Selected Plugged Subjects



For sound localization, the error patterns of the true unilateral subjects matched that of the plugged subjects. They both tended to localize the sound toward their normal ("good") ear (true unilateral subjects) or unplugged ear (plugged subjects). When comparing the average direction of those errors between the two unilateral groups combined, the two samples were practically indistinguishable. This demonstrates that both groups were almost identical in directional pattern of speaker selection during the testing due to the unilateral HL, despite whether it was an artificial or true hearing loss.

Extension Study 1

Purpose: to investigate whether a difference occurs (among only 2-eared participants) when placing the laptop on the mat in front of the speaker array versus behind the speaker array. The original placement of the laptop (in front of the speaker array) has been previously questioned as the laptop screen appears to partially block the view of speakers 4 and 5, which would in theory affect conditions 2 and 3 of the CRM test. We did this pilot experiment to evaluate if the scores of bilateral subjects changed based on this parameter. Figure 1: Y axis = CRM threshold. X axis = CRM speaker condition.

Results: there is no significant difference in results or performance between the 2 laptop locations. On average all subjects performed better with one location in one condition and better with the other location in the other condition

Conclusion: there is no difference, interference, or skew with the laptop placement in front of the speakers than behind them. Confirming appropriate testing placement of all subjects thus far in the current study.

Figure D: CRM Threshold of Normal Controls and Laptop Placement

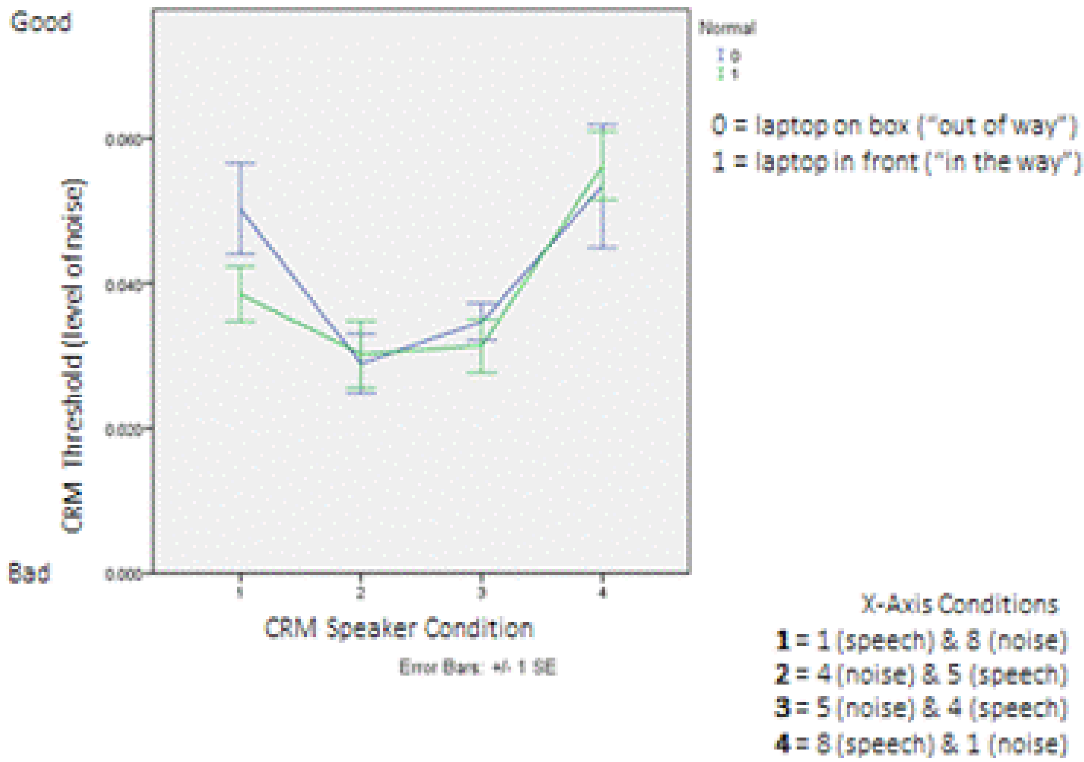
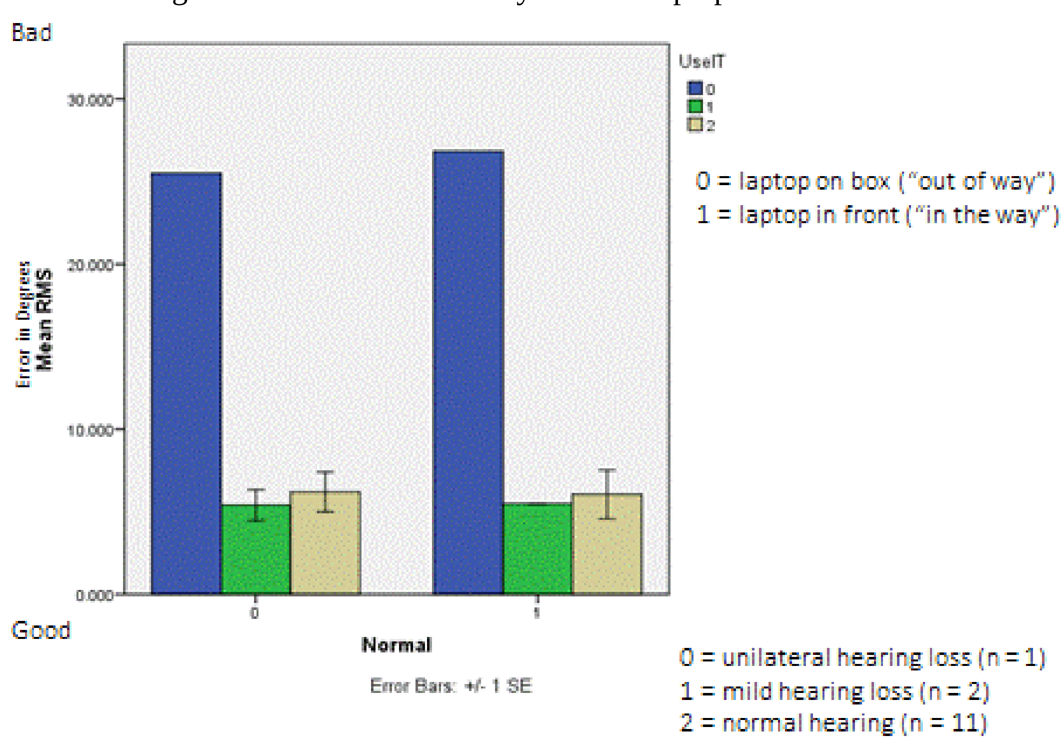


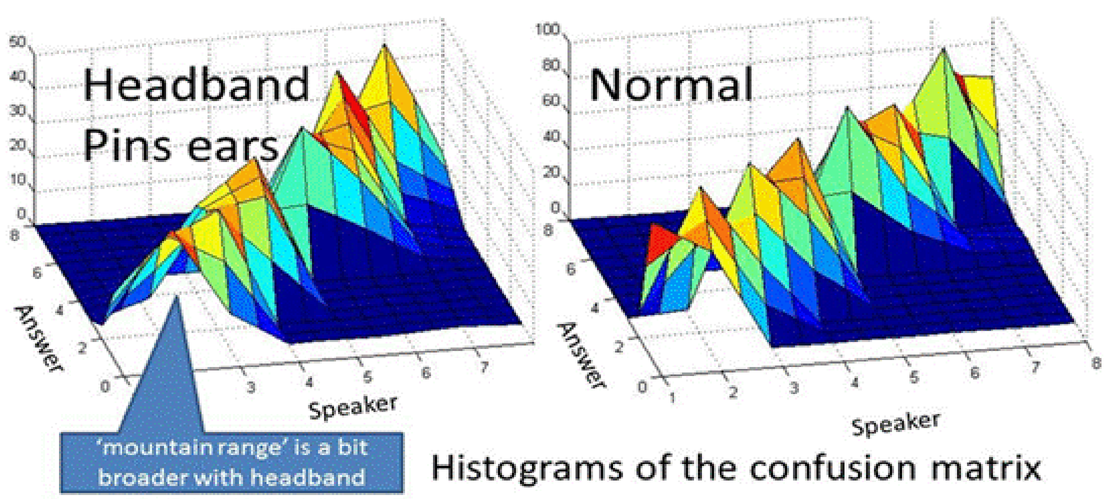
Figure E: Localization Ability in Two Laptop Placements



Extension Study 2

Extension 2 of this experiment investigated the effects of bilateral anatomical pinna position on performance of sound localization using the prototype device. Subjects with normal hearing completed the localization task once while wearing a plastic headband to pin the pinnae back against the mastoid bone, thus removing pinna cues (pinned condition), and once without (normal condition). Results (Cohen's d=1.1, t_{10}=3.7, p=.004) suggested that slight pinna cues provide a significant and beneficial contribution to horizontal sound localization of noise bursts in bilateral subjects. Therefore, removing these pinna cues causes reduced localization accuracy. This information, illustrated in Figure F below, can be considered significant to medical professionals such as the plastic surgeons who construct the new pinnae for atresia patients.

Figure F: Localization Accuracy for Two Pinna Conditions



** Note that y-axis scales of these figures do not match*

Taken Precautions

Parents and children were familiarized with the study and procedures once on the phone and again in the instructions received with the device. The instructions described how to select a room for testing in the residence and how to ensure a quiet testing environment. Instructions described the appropriate posture and positioning for taking the tests without skewing the results. A motion-detecting camera installment is the eventual goal for validating subject head position in the future.

Localization accuracy decreases with increasing reverberant energy, (Kopco and Shinn-Cunningham, 2002). For this reason, all subjects were administered the tests (or instructed to take the tests) from a minimum distance of 5 feet from all walls in the testing room or lab.

Limitations of Current Research

As this device was shipped to the residences of subjects around the country, the rooms of testing selected by each subject/family of the subject are highly variable. Despite sending instructions to the families regarding how to maximally reduce noise disruption (turn off the washing machine, dishwasher, air conditioning, put the family pets in another part of the house, etc.), the psychoacoustical properties of each room selected for testing is unknown. Furthermore, while instructions were clear for keeping the subject’s head in a proper and unmoved position, evidence of obeying these instructions were not documented. It is a future goal of this project to install a motion-detecting camera onto the device for the purpose of ensuring proper head/body position and recording evidence of the subject's position during testing.

Review of Device Deployment Success

Our devices were shipped to 9 different residences across the country, with approximately $1,000 of insurance documented for each; each one was returned to the researcher. The delivery time did not exceed 4 days for the furthest subject (New Mexico, shipped from Virginia). The turnaround time for sending and receiving each device back (after two days of testing) was about 2 weeks. While assembling and setting up the device requires about 20 minutes or less for a layperson who has never seen the prototype before, an hour was set aside for the subjects (the same amount of time applies to disassembly and packing the device back into the shipping box. The tests take about 20 minutes to complete (5 minutes for sound localization and 15 minutes for speech-in-noise); an hour was set aside for subjects to complete the tests. Each of 9 device shipments, except one, returned in a secure and undamaged status. Only one box was received from the subject as "damaged." The extent of this damage was just chipping of the plastic casing around one corner of the laptop, leaving the laptop and program fully functioning. The shipping carrier was informed of this damage and the carrier agreed to replace the cost of the laptop' which was executed successfully in less than one month. The James Madison University Communication Sciences and Disorders Department shipping carrier account was used for shipping the devices to subjects (and reimbursed by the research team). While this allowed for discounted rates, it was chosen in order to replicate rates that are expected to correlate with those shipping accounts used in medical centers and private businesses where these devices may be used in the future.

Implications for Future Research

Further data collection is needed in the form of repeated measures on the post-op atresia subjects. The goal is to ship the device back to those patients annually to investigate any changes in performance in these two tasks of binaural processing. It is theorized that a learning curve exists for binaural listening tasks after aural atresia repair surgery. The hypothesis is that these post-op atresia patients will improve after surgery (one-tailed test), with the variable of time passed since surgery.

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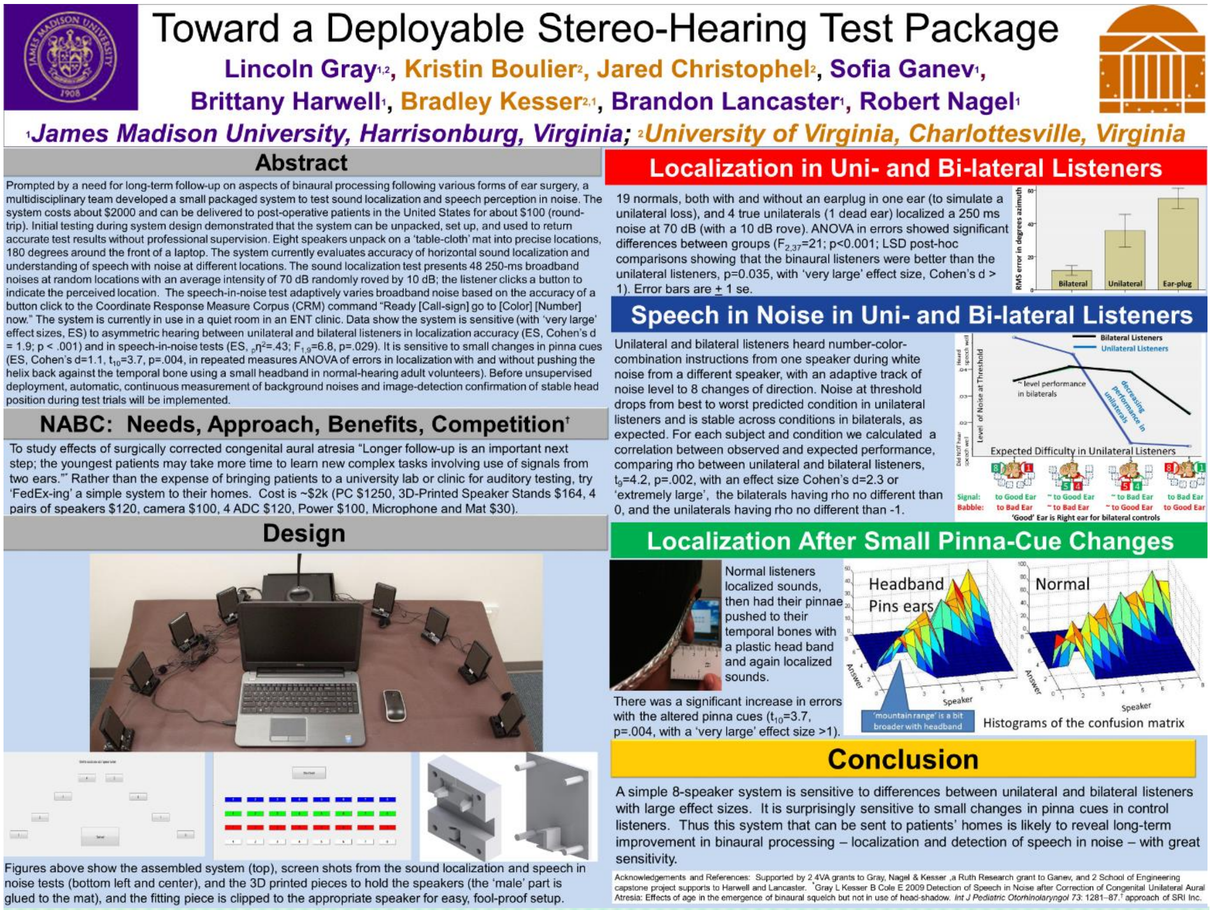
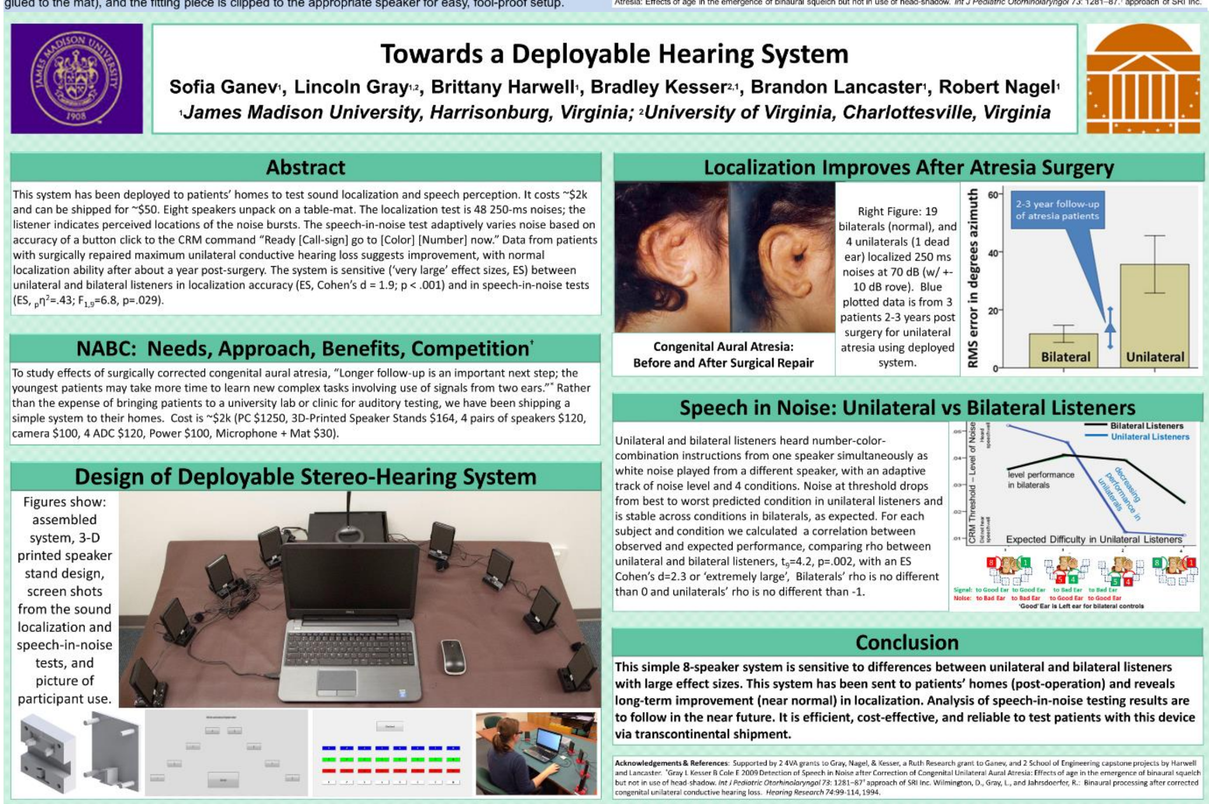
- Adviser: Lincoln Gray, Ph.D. JMU Dept of Communication Sciences and Disorders
- Collaborators: Kristin Boulier B.S., Jared Christophel M.D., Bradley Kesser M.D.: UVA Medical School. Brittany Harwell, B.S., Brandon Lancaster, B.S., Robert Nagel, Ph.D.: JMU School of Engineering

Device Prototype Inventory

- Sherman Prototype → development with LG
- Florida Prototype → retired, JMU ENG Lab
- Bahamas Prototype → retired, JMU ENG Lab
- Ryals Prototype → at UVA
- Rockville Prototype → deployable, slightly damaged
- Rockville 2.0 Prototype → deployable, JMU ENG Lab
- Greenbrier Prototype → deployable, JMU ENG Lab
- Watson Prototype (tablet) → with LG
- Tadlock Prototype → with LG

Presented Posters of the Research



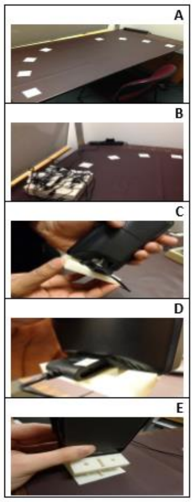


Instructions for the Post-Op Atresia Subjects

Hearing Test Setup Instructions

Setup

1. Lay the mat out on a clean, hard surface. **(Figure A)**
2. Place the hub box in the black outline area "Hub". Plug the box in to Power. **(Figure B)**
3. Separate speakers from each other and connect a speaker box to each plastic stand. **(Figure C)**
    a. Note: Make sure they are plugged in completely **(Figure D)**
    b. Note: Any speaker can be connected to any stand
4. Match each speaker to the stand with the same number.**(Figure E)**



Hearing Test Setup Instructions

5. Place microphone in designated spot on top of hub box **(Figure G)**
6. Place the laptop in the designated box and plug the microphone in to the left side of the laptop **(Figure H)**
7. Plug the USB from the hub box into the right side of the laptop.
    a. Note: The USB marked with a 1 goes on top **(Figure I)**
    b. The 2 goes onto the bottom **(Figure I)**
8. Plug the mouse into any remaining USB port (Do NOT use trackpad)
9. Turn on the computer to log in **(Figure J)**
    c. Choose user: Lincoln
    d. Password: c!satcsd
    e. Wait for the computer to open the program itself
    f. Please be patient

Taking your Tests

Testing Instructions:

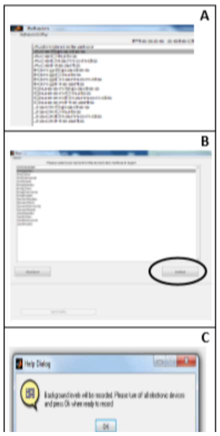
1. Check that your face is in the pop up preview window. Right click "OK" if you see yourself and are completely in the frame. After you press ok, the program will monitor you while you take your tests. The red circle on the webcam will stay lit as you take your test. The video monitoring will stop when you shut down the computer. IT IS VERY IMPORTANT THAT YOU CLICK OK TO BEGIN MONITORING. Otherwise, data will not be used because we cannot verify testing conditions.

Select your "name"

1. On the ID panel choose the appropriate name instructed by the proctor. **(Figure A)**
2. Click continue. **(Figure B)**
3. Type the password (there is no visible cursor & and the password is case sensitive).
4. After typing in the password press enter.

Calibrating background noise

5. A pop up screen will arise, please read



Taking your Tests

6. After clicking ok, the background noise will be recorded. Please remain quiet until it is completed. **(Figure D)**
7. Click Yes unless there was a disturbance
    a. If disturbed click no, recalibrate **(Figure F)**
    b. click Yes when the calibration is valid **(Figure F)**

Sound Localization Test

8. Please read over the test instructions in the dialog box, the dialog box will guide you through the test. **(Figure G)**
9. To begin the test click Start test **(Figure H)**

Hearing in Noise Test

10. Please read over the test instructions in the dialog box, the dialog box will guide you through the test. **(Figure I)**

Taking your Tests

11. To begin the test click Start **(Figure J)**
12. Before beginning the test you must complete a training loop **(Figure K)**
13. You must complete the four trials to finish the test **(Figure L)**
14. After finishing the test leave the computer screen on the main home page

Suggestions:

1. Take a deep breath and relax before beginning the test.
2. Listen closely to the noise from the speakers.
3. After completing the test relax for 1 or 2 minutes before beginning the next test.

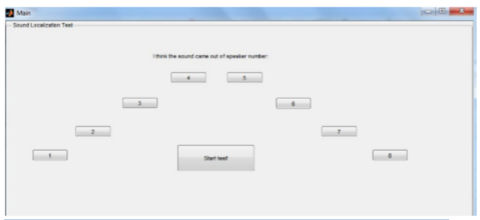
Sound Localization Test

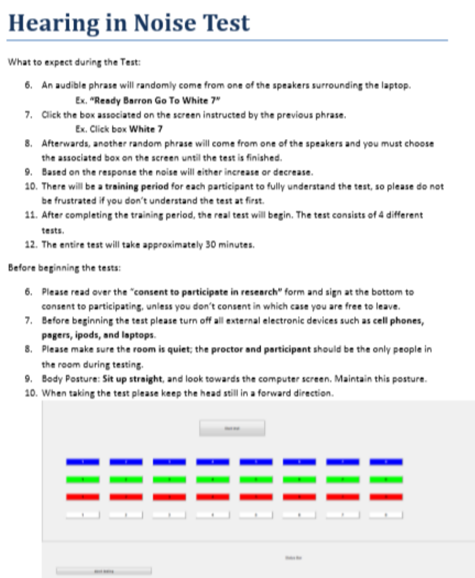
What to expect during the Test:

1. After selecting "Start Test!", a noise will play out of a random speaker at a random level.
2. Select the number on the screen that corresponds to the speaker number that you heard the noise come from.
3. The speaker number is printed in the plastic speaker stands for your convenience.
4. Continue listening and recording your answers until a pop-up says that you are finished with the sound localization test.
5. The entire test will take approximately 10-15 minutes.

Before beginning the test:

1. Please read over the "**consent to participate in research**" form and sign at the bottom to consent to participating, unless you don't consent in which case you are free to leave.
2. Before beginning the test please turn off all external electronic devices such as **cell phones, pagers, ipods, and laptops**.
3. Please make sure the **room is quiet**; the **proctor and participant** should be the only people in the room during testing.
4. Body Posture: **Sit up straight**, and look towards the computer screen. Maintain this posture.
5. When taking the test please keep the head still in a forward direction.





Hearing in Noise Test

What to expect during the Test:

6. An audible phrase will randomly come from one of the speakers surrounding the laptop.
   Ex. **"Ready Barron Go To White 7"**
7. Click the box associated on the screen instructed by the previous phrase.
   Ex. Click box **White 7**
8. Afterwards, another random phrase will come from one of the speakers and you must choose the associated box on the screen until the test is finished.
9. Based on the response the noise will either increase or decrease.
10. There will be a **training period** for each participant to fully understand the test, so please do not be frustrated if you don't understand the test at first.
11. After completing the training period, the real test will begin. The test consists of 4 different tests.
12. The entire test will take approximately 30 minutes.

Before beginning the tests:

6. Please read over the "**consent to participate in research"** form and sign at the bottom to consent to participating, unless you don't consent in which case you are free to leave.
7. Before beginning the test please turn off all external electronic devices such as **cell phones, pagers, ipods, and laptops**.
8. Please make sure the **room is quiet**; the **proctor and participant** should be the only people in the room during testing.
9. Body Posture: **Sit up straight**, and look towards the computer screen. Maintain this posture.
10. When taking the test please keep the head still in a forward direction.

Legend of Coded Subject Groups from SPSS Analysis

Post-op Atresia = 0

Bilateral = 1

True Unilateral = -1

Plugged = 0.5

Development of a Mobile Hearing Assessment

for Aural Atresia Patients

A Project Presented to

the Faculty of the Undergraduate

College of Health and Behavioral Studies

James Madison University

in Partial Fulfillment of the Requirements

for the Degree of Bachelor of Sciences

by Sofia Antonov Ganev

May 2013

Accepted by the faculty of the Department of Communication Sciences and Disorders, James Madison University, in partial fulfillment of the requirements for the Degree of Bachelor of Sciences.

FACULTY COMMITTEE

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Abstract

Twenty-seven participants were tested using a prototype hearing device that assessed sound localization ability. These participants were divided into one control group and two experimental groups based on their status of hearing. These groups are: Normal listeners (hearing within normal limits, at 20 dB or lower at frequencies of 250-8000 Hz), Real Unilateral listeners (subjects with a profound, single-sided, sensorineural hearing loss (HL)), and 'Fake' Unilateral listeners (subjects from the Normal listeners group with an artificially given conductive HL by plugging one ear). RMS localization errors were measured from 19 control listeners with normal hearing in both ears and six experimental listeners with complete unilateral hearing loss. Oneway ANOVA showed a significant difference between the Normals and the Real Unilaterals. ($F_{(2,37)}$ = 21; $p < .001$). Post Hoc comparison showed a significant difference between 'Fake' Unilaterals and Normals; ($p < .001$). Post Hoc comparison showed a marginal difference between Fake and Real Unilaterals, ($p = .04$), one-tailed. There is a significant difference in the performance of Normal subjects and Real or Fake Unilateral subjects. There is a marginal difference between the performance of Real Unilaterals and Fake Unilaterals. Fake Unilateral tended to localize better during the middle of the test and lower at the beginning and end of the test, perhaps from minor adaptation. Normal subjects make minimal errors in localizing sound, while Real and Fake Unilaterals have a much larger distribution of error types. The side of deafness/HL designates the direction of average error. The Real and Fake Unilateral subjects matched in pattern of average error direction. The ultimate goal was being able to demonstrate that the deployable stereo hearing system has been successful in proving a difference between Normal and Unilateral listeners' sound-localizing ability. This goal was achieved with high construct validity.

Introduction

Purpose of Study:

Congenital Aural Atresia

Congenital aural atresia is a condition characterized by the malformation and poor development of the external auditory meatus (ear canal) and the middle ear structures, such as one or more of the ossicles. This disorder, occurring at birth, can vary in degree; for example, the ear canal can be partially closed or completely absent. Some or all of the ossicles may be underdeveloped or absent. In a less severe case, each of the three bones may actually be present but the ossicular chain may not be mobile. Aural atresia is commonly associated with “microtia” otherwise known as a small outer ear (pinna), or sometimes the absence of one altogether (anotia). Depending on severity, aural atresia results in various degrees of conductive hearing loss (conductive hearing loss refers to a dysfunction in the outer or middle ear; sensorineural hearing loss refers to a dysfunction in the inner ear and/or the nerve connecting the inner ear to the brain). This condition occurs three to five times more often unilaterally than bilaterally. Incidence is one in 10,000 to 20,000 births.

Corrective Surgery

To explain this complex process in a simple fashion, surgical correction involves the reconstruction of a new pinna (the visible part of the ear), drilling of a hole into the area where the canal should be, and reconstruction of a middle-ear sound conduction mechanism. Image 1 on page 10 shows a patient’s ear before and after the drilling of the external auditory meatus. In order to reconstruct a new pinna, costal cartilage is harvested from the contralateral lower ribs. After the new pinna has been formed, the patient can elect otologic surgery. Otologic surgery is not offered to patients without a functional cochlea (tested preoperatively via bone conduction) or without a normal stapes (on high resolution CT). The surgeon begins by drilling into the atretic temporal bone to create a new canal. Once the middle ear is opened, the ossicles must be identified, mobilized, or replaced. A malleus or incus that are found not to move or function properly will be mobilized with “intact native chain reconstruction” (INCR) or replaced with a “partial ossicular replacement prosthesis” (PORP) or “total ossicular replacement prosthesis” (TORP). After ensuring the functionality of the ossicles, the next step is to construct a tympanic membrane (eardrum) from a fascia graft; this graft is typically taken from the postauricular incision (the area posterior to where the reconstructed pinna is located). Once the tympanic membrane is put in place, the newly drilled ear canal is lined with a split-thickness skin graft. This graft is usually harvested from the inner, upper part of the arm. To finish the procedure, small, absorbent sponges (wicks) and an ototopical antibiotic eardrop preparation are placed inside the new canal in order to secure the skin graft and prevent infection.

Image 1: Congenital Aural Atresia Before and After

Kesser, B., Cole, E., Gray, L. (2013). Congenital aural atresia; before and after. [Image]. Retrieved from “Hearing Speech in Noise from a Single Source Before and After Surgical Improvement of Congenital Conductive Hearing Loss” Poster at the Association for Research in Otolaryngology

Project Objectives:

The Capstone Project

The standard follow-up plan after atresia surgery typically involves one visit one week after surgery in which the surgical packing is removed. A second visit is required one month later to clean the new ear canal and obtain the first postoperative audiogram. A simple pure tone audiogram qualifies how the patient's hearing has improved. Because many atresia patients live a distance away from otolaryngologists and audiologists, (over seas for example), it is understandable that traveling every year for follow-up visits can be a hardship for many people. This situation results in few long-term follow-up visits even for audiograms, let alone specialized research hearing tests (not covered by insurance) such as the free-field localization tests in this report.

Dr. Lincoln Gray and Dr. Robert Nagel of the James Madison University Communication Sciences and Disorders Department and the Department of Engineering, respectively, began a capstone project last year with a group of engineering students to address this problem. This capstone group has been working to design a prototype hearing-testing device that can be sent out, by means of a small Fed-Ex package, to distant families of aural atresia patients. The device will be programmed to test pure tone thresholds, sound localization, detection of speech in noise, and potentially other monaural and binaural psychoacoustic tests. This prototype will include several speakers, a programmed laptop, and instructions on how to set up the device and take the tests without on-site audiological supervision. The undergraduate engineering team has the goal of building and calibrating this system to be used by any untrained individual. An eventual goal of this interdisciplinary team is to receive a research grant to mass-produce and deploy this product into a service that can benefit the world of auditory research and treatment.

My Role

I was born with Waardenburg Syndrome, an inherited disorder that resulted in a unilateral hearing loss. I am profoundly deaf in my right ear and have hearing within normal limits in my left ear. My personal disability, or preferably, personal "difference" has led my passion of study in the major of "communication sciences and disorders" (CSD) and furthermore, to my participation in this thesis. Because of my hearing condition, I am coincidentally an excellent control subject for a person with the most severe case of aural atresia "pre-surgery." As the engineering students have progressed with the design and programming of the product, they have administered various versions of the hearing tests on me. I have naturally responded as an aural atresia patient with maximum conductive hearing loss would, meaning I performed poorly, as expected, to the point of failure. Each of these tests is designed to be extremely difficult for any individual without binaural hearing and fairly easy and natural for individuals with binaural hearing. Fortunately, in addition to our already strong and diverse team, we have another fellow CSD student who has agreed to volunteer as a different kind of participant. My colleague was born with congenital aural atresia of her right ear with her left ear within normal hearing limits. After undergoing several successful surgeries throughout her childhood, she has had the majority of her hearing in the right ear restored as well as a newly constructed outer ear. With my colleague's valuable personal experience, we can test her as the "post-surgery aural atresia patient" (as she certainly is one), and we can test myself as the "pre-surgery aural atresia patient" (as my profound sensorineural hearing loss certainly represents the nature of a severe conductive hearing loss).

Methods & Materials

Participants:

A total of 27 subjects participated in this study. Of these subjects, 19 had bilateral hearing within normal limits (hearing at or below 20 dB at 250, 500, 1000, 2000, 4000, and 8000 Hz frequencies). They were used as the control group during testing and 17 of them were also used as an experimental group during a second set of testing (in which artificial conductive hearing losses were given to this group). Six of the 27 subjects possessed some extent of a unilateral hearing loss as the experimental group. Five of these six subjects presented with a *profound*, sensorineural, unilateral HL, and one presented with a *moderate*, sensorineural, unilateral HL. The last two of the 27 subjects presented with *variable* types of hearing loss and were recruited for testing as well. Table 1 is a summary of the categorizations of all 27 subjects.

*Table 1: Table of Participants***Error! Not a valid link.*** These 17 subjects are double counted from the 19 original Bilateral Hearing Group

Subjects were recruited through brochures, emails, personal requests, and referral, either clinical or academic. The criteria for participation included the following: to sign the volunteer research consent form, to have a healthy status, to be able to complete a computerized study, to be able to provide a current audiogram or be willing to have one conducted, and to have either hearing within normal limits or a unilateral hearing loss (preferably profound but not required).

Pure tone thresholds were measured by either a certified audiologist or doctoral student in a soundproof booth or by the student researcher in a soundproof booth or empty laboratory. The sound localization test was conducted in a quiet, empty laboratory (for lack of space and ability to move the prototype to an available soundproof booth).

Materials & Calibrations:

The portable audiometer “Beltone Audio Scout 109” was used by the student researcher. The subjects tested by doctoral students or certified audiologists were either tested by the audiometer “Madsen Astera” in the JMU Audiology clinic or by an unknown audiometer at an off-campus location, respectively. The prototype portable hearing-testing device was used to test sound localization on every subject.

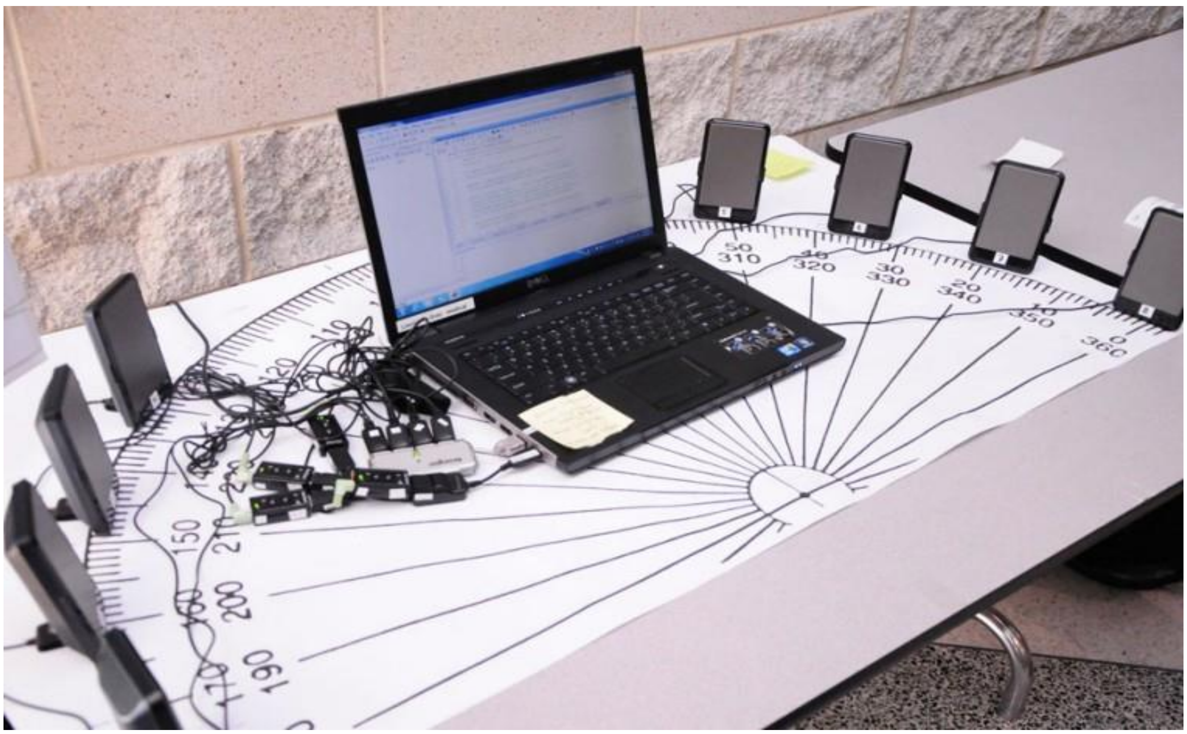
Sound Localization: (pre-testing procedures)

Before testing, each subject signed an IRB-approved informed consent form. If the subject did not have a current audiogram, then pure tone air conduction thresholds (at 250, 500, 1000, 2000, 4000, and 8000 Hz frequencies) were measured. The control subjects (those with normal hearing) were scheduled to take the test twice, once with both ears (binaural condition), and once with a ‘fake’ unilateral hearing loss, produced with a disposable foam earplug (Moldex Purafit) as well as a circumaural earmuff (Silencio RBW-71) covering over the earplug. Total attenuation of this artificial conductive HL is estimated to be approximately 56 dB. Order of testing (binaural or plugged unilaterally) and the ear that was plugged were randomized. The experimental group (with real unilateral hearing loss) was just tested once.

Sound Localization: (prototype and layout)

The prototype consists of a laptop, containing the program for the sound localization test, and eight identical speakers. The eight speakers were arranged along a radius of 24 inches from the subject at horizontal positions of 5, 20, 35, 50, 130, 145, 160, and 175 degrees of azimuth (with the respective degree of position directly in front of each speaker). Each speaker is labeled with a sticker of its respective number. Image 2 and 3 are side view and front view pictures of the prototype and its layout.

Image 2: The Prototype Device Side View



Corey, C. (Producer). (2012). *Senior engineers showcase capstone project*. [Web Photo]. Retrieved from http://www.breezejmu.org/news/image_b4d639fa-8cdf-11e1-95e4-0019bb30f31a.html

Image 3: The Prototype Device Front View

Photo credit: Jonathan Smith (senior engineer). Taken in 2012.

Sound Localization: (testing procedures)

The subject sits in a chair in front of the laptop, close enough to have the head located approximately in the center of the arc of speaker endpoints. Once prompted with instructions, the experimental subjects begin the test. The control subjects (based on their randomly assigned schedule) will either have their designated ear temporarily deafened (plugged and covered by the student researcher), or they will begin the first test with their normal binaural hearing. The test is initiated by a designated button. The program activates one speaker at a time to evoke one second of broadband noise at a level ranging between 60 and 75 dB. After each sound stimulus, the subject records on the laptop the speaker number that s/he guesses to be the one to have made the sound. The next stimulus is not presented until the subject has made such a selection. The test continues for 48 trials. Before testing, subjects were instructed to refrain from moving the head during the stimulus (to prevent any performance bias). After the stimulus has been played, however, the subject is free to move their head to look at the speakers to make an accurate response of predicted speaker by number. The subject must then retract back to the original forward-facing position. If the participant is from the control group, s/he is prepared for the next test by either removing or adding the "fake hearing loss" and then tested again. Experimental subjects completed only a single test. Scores and errors were recorded in the prototype's system.

Outcome measures were derived from various measures of the localization errors. These included RMS error in degrees, number of trials that subjects scored correctly, number of trials that they were incorrect by one, two, or more speakers, the direction of each error (to the left or right of the correct speaker), and whether a subject overall passed or failed, (passing refers to scoring over 50% in correct speaker identification in 48 trials).

Data & Analysis

Parameters:

Subjects were classified as having either unilateral (monaural) or bilateral (binaural) hearing and, if unilateral, they were also classified based on which ear is functional (left or right). The 27 subjects were organized into seven categories for analysis. These categories are: Normal Listeners, Fake Unilateral Listeners, Aural Atresia, Real Unilateral Listeners, Bilateral HL, Asymmetrical HL, and Aided Bilateral HL.

Categories Defined:

** Only a few of the following collected categories were used in data analysis*

- <u>Normal Listeners</u> (n=19): subjects who possess hearing within normal limits.

- <u>Fake Unilateral Listeners</u> (n=17): aka Plugged Normals. Normal subjects who take the test with one ear plugged by a disposable foam earplug and a set of headphones on that ear only, to simulate a fake unilateral HL.

- <u>Atresia</u> (n=1): subjects with an atretic ear, post-operation.
- <u>Real Unilaterals</u> (n=6): subjects with a profound, one-sided HL. One with a moderate one-sided HL.
- <u>Bilateral HL</u> (n=1): subjects who possess a degree of mild to profound HL, which is equal in both ears.
- <u>Asymmetrical HL</u> (n=2): subjects who possess a degree of mild to profound HL, which is different in each ear.
- <u>Aided Bilateral HL</u> (n=2): any subjects with Bilateral or Asymmetrical HL who takes the test again while wearing their hearing aids.

Research Hypotheses:

Hypothesis 1: Performance of Normals vs. Real Unilaterals

The listeners who possess hearing within normal limits (Normal group) will pass the sound localization test with success and ease. The listeners who possess a profound single-sided hearing loss (Real Unilateral group) will encounter difficulty and fail the sound localization test (scoring at 50% or less in correct speaker identification).

Hypothesis 2: Performance of Real Unilaterals vs. Fake Unilaterals

The Real Unilateral subjects have an extensive amount of experience with this type of hearing loss, considering most of them are born with the hearing loss (congenital) or have acquired and lived with it for numerous years of their lives (with our sample of Real Unilaterals ranging from a minimum of 10 years (acquired) to a maximum of 63 years (congenital) of possessing the HL). Due to this amount of experience, Real Unilaterals will perform better than the Fake Unilaterals (Normal subjects with one ear occluded immediately prior to testing). The Real Unilateral subjects have better adaptation to their hearing loss and how to interpret auditory stimuli from various directions using only unilateral (pinna or head-related transfer) cues. The test is difficult in nature for the Real Unilateral subjects, yet it does not differ from the difficulties that they face every day in localizing sound. The Fake Unilateral subjects on the other hand have an even more difficult time in localizing these sounds because they are dealing with a sudden and unnatural change in the balance of their binaural inputs and have never had to complete a task in this condition before.

Hypotheses 3: Adaptation and Learning by Fake Unilaterals

During the test, the Fake Unilateral subjects become more familiar with the new deficit and adapt to it, thus localizing slightly better in the second half of the test than in the first half. This quick adaptation might mimic the pattern of long-term learning and adaptation that a person with unilateral hearing loss (congenital or acquired) encounters in living with a long-term deficit.

Means of Analysis:

- Data were analyzed by means of Root Mean Squared (RMS) and Error Squared calculations to determine the extent of the errors
- Mean Error was used to determine the average direction of errors made away from the activated speaker.

Results and Discussion

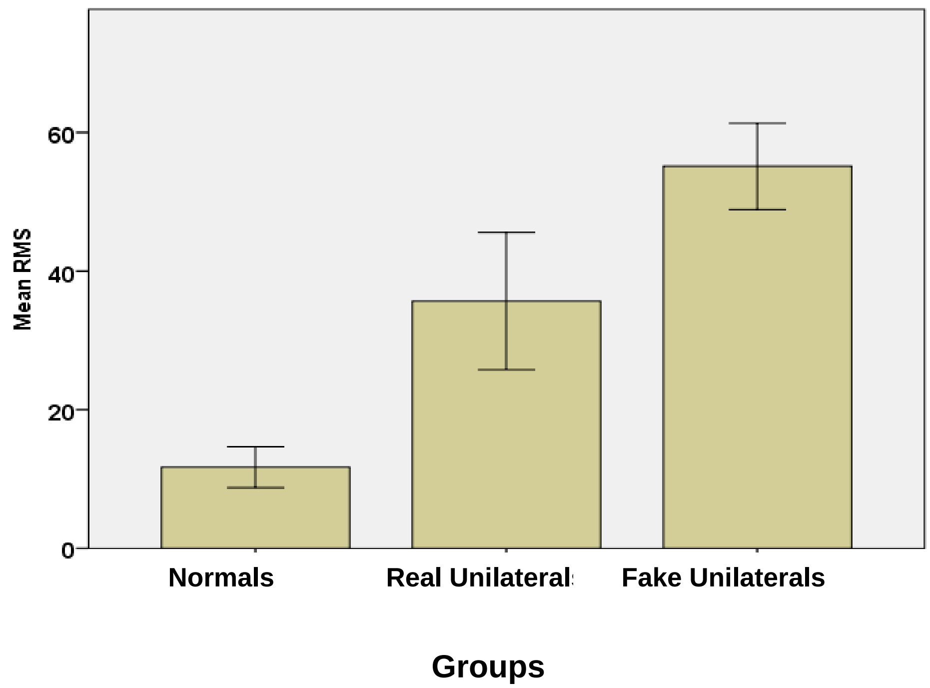
Important Results:

The overall goal of our project was to develop a hearing test that would separate bilateral and unilateral listeners in performance. Results are as follows:

- RMS localization errors were measured from 19 control listeners with normal hearing in both ears and six with complete unilateral hearing loss.
- Oneway ANOVA showed a significant difference between the Normals, Real, and Fake Unilaterals. ($F_{(2,37)} = 21$; $p < .001$).
- Post-Hoc comparison showed a significant difference between Real Unilateral and Normal listeners ($p < .001$; effect size 1.85). This shows the prototype device is a successful evaluation separating the abilities of one- and two-eared listeners, as desired.
- Post-Hoc comparison showed a significant difference between plugged (Fake Unilateral) and unplugged Normals. ($p < .001$).
- Post-Hoc comparison showed a marginal difference between Fake Unilaterals (plugged Normals) and Real Unilaterals. ($p = .04$ one-tailed).

Figure 1 is a plot of the differences in error of degrees that were made by the three subject groups. The Normal listeners made the least amount of errors on average; the errors they made were the least severe (a mean RMS of 12 degrees deviating from the correct speaker) of the three groups. The Real Unilateral group made errors more frequently; these errors were more severe than the Normals (a mean RMS of 38 degrees of deviation). The Fake Unilateral listeners made the most errors; they were the most severe in deviation from the correct speaker than the Normals or Real Unilaterals (a mean RMS of 55 degrees of deviation).

Figure 1: Comparing RMS Error of Normals, Unilaterals, and Fakes



Discussion of Results:

Addressing Initial Hypotheses:

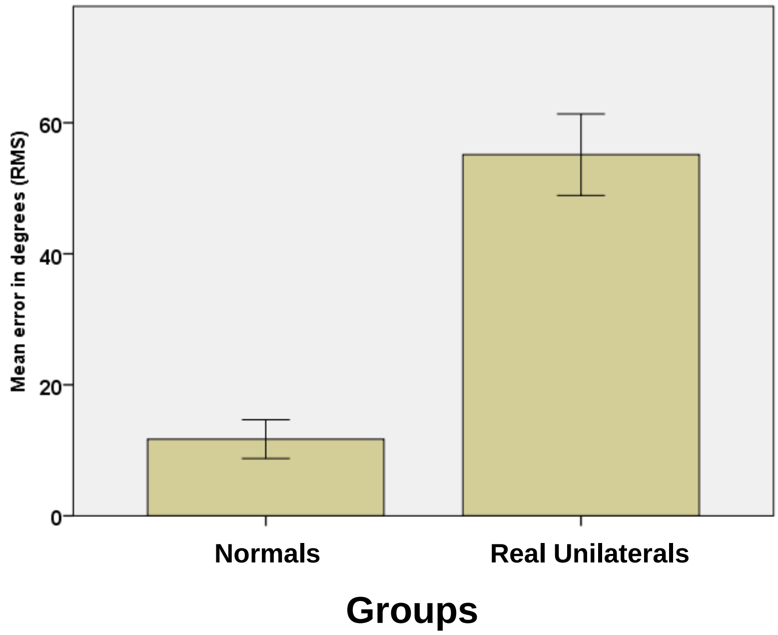
Hypothesis 1: Performance of Normals vs. Real Unilaterals

The listeners who possess hearing within normal limits (Normal group) will pass the sound localization test with success and ease. The listeners who possess a profound single-sided hearing loss (Real Unilateral group) will encounter difficulty and fail the sound localization test (scoring at 50% or less in correct speaker identification).

Normal subjects performed significantly better than the Real Unilaterals (summarized in Figure 2) due to the ability to localize sound with binaural cues; an ability that can only occur with both ears functioning at a level that allows the reception and sensation of auditory stimulus. The Real Unilateral subjects do not possess this capability with one functional ear and thus fail repeatedly at this test.

- 19 of the 19 Normal listeners passed the test with a score of at least 54% or higher.
- 17 of the 19 Normal listeners passed the test with a score of at least 71% or higher.
- 100% of the Real Unilateral listeners failed the test with the highest score being 38% and the lowest score being 15%, with the exception of an outlier who scored 75%.
- This subject (the outlier) possesses a *moderate to severe* (instead of profound) unilateral sensorineural HL (a subgroup of the Real Unilaterals). The unusually high score was due to some auditory information input to both ears (binaural hearing) regardless of the HL.
- With the exception of the outlier’s passing score of 75%, all other Real Unilaterals failed the test by scoring under 50%.

Figure 2: Comparing RMS Error of Real and Fake Unilaterals



*Effect size is large: 1.85. Cohen defines effect size of .5 as medium and .8 as large

Hypothesis 2: Performance of Real Unilaterals vs. Fake Unilaterals

Due to the amount of experience that the Real Unilateral subjects have with this type of hearing loss (most of them are born with the hearing loss or have lived with it for numerous years of their lives), they will perform better than the Fake Unilaterals (Normal subjects with one ear occluded immediately prior to testing). The Real Unilateral subjects have better adaptation to their hearing loss and more experience in how to interpret auditory stimuli from various directions using only unilateral (pinna or head-related transfer) cues. The test is difficult in nature for the Real Unilateral subjects, yet it does not differ from the difficulties that they face every day in localizing sound. The Fake Unilateral subjects on the other hand have an even more difficult time in localizing these sounds because they are dealing with a sudden and unnatural change in the balance of their binaural inputs and have never had to complete a task in this condition before.

- The average correct answer percentage for the Real Unilateral subjects was 33%.

- The average correct answer percentage for the Fake Unilateral subjects was 19%.

The Real Unilateral group performed generally higher than the Fake Unilateral group. Real Unilaterals have more experience with the hearing loss and understand the nature of it, unlike the Fake Unilateral listeners who are not familiar with the sensations of asymmetry caused by the sudden HL. While both groups failed, there was clear evidence of a marginal difference between the two groups. Figures 3 and 4 on page 25 display the marginal difference in failure rate between the Real and Fake Unilateral listeners. The Fake Unilateral listeners consistently made more errors out of 48 trials than the Real Unilateral group.

Figure 3: Failure Rate of Real Unilateral Subjects

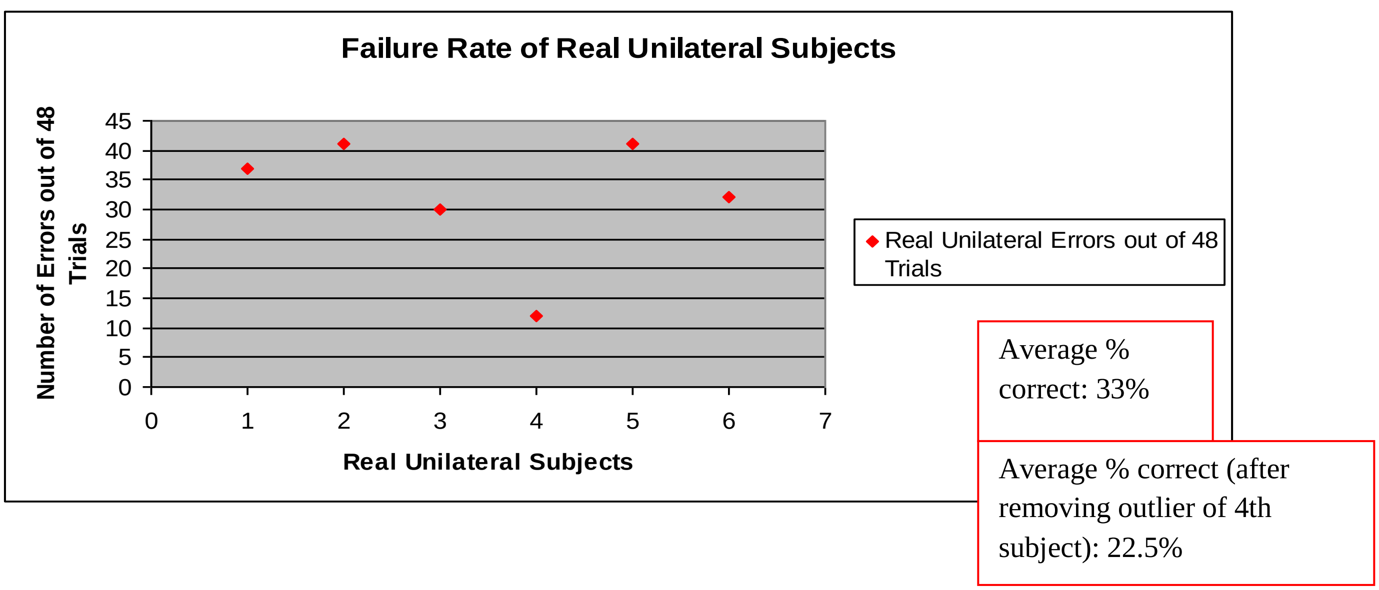
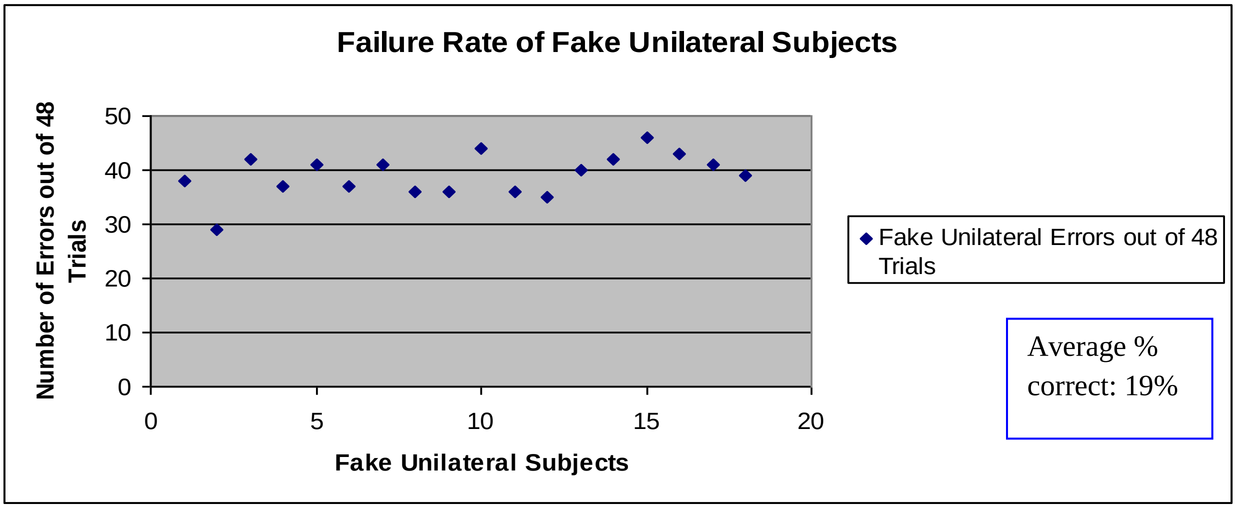


Figure 4: Failure Rate of Fake Unilateral Subjects

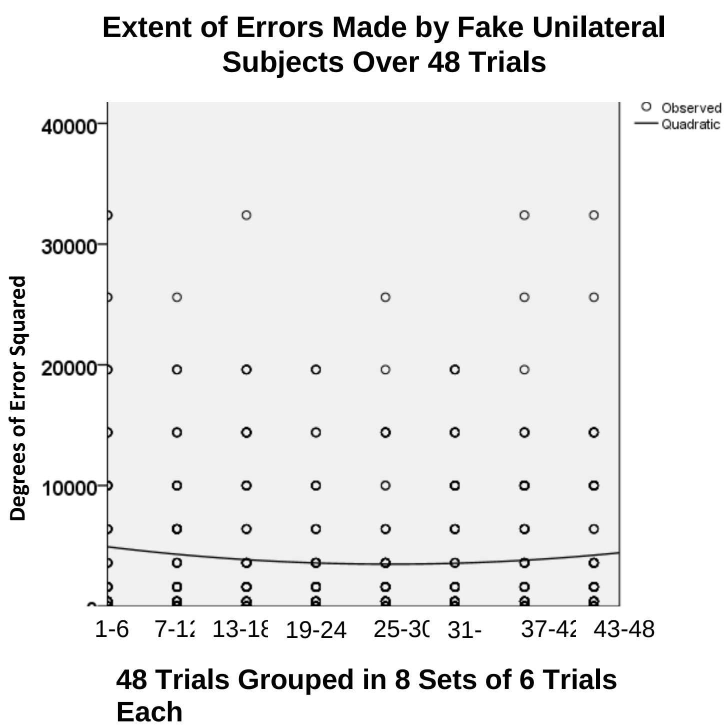


Hypothesis 3: Adaptation and Learning by Fake Unilaterals

> During the test, the Fake Unilateral subjects become more familiar with the new deficit and adapt to it, thus localizing sound slightly better in the second half of the test than in the first half. This quick adaptation might mimic the pattern of long-term learning and adaptation that a person with unilateral hearing (congenital or acquired) encounters in living with a long-term deficit.

There was a very subtle, yet consistent, pattern of improvement during the middle section of the test. Figure 5 on page 27 shows diagramed scores of error which created a slight positive quadratic (smile-like shape; showing a peak of error at the start of the test and a peak again at the end of the test, with a dip (reduction of number/severity of errors made) in the middle of the test). This might suggest that the Fake Unilateral listeners were not able to figure out where the stimuli were coming from in the beginning. While their ability could never technically improve with just one ear, they might have adapted to the nature and sensitivities of the hearing loss and were thus able to better predict the general origin of the sounds over time. It can be predicted that by the end of the test, frustration, mental exhaustion, fatigue, or some other form of stress could have been a factor in the re-peak of errors made, despite possible adaptation. While a slight pattern was found, the data over 48 trials is not significant enough to make a true claim of adaptation.

Figure 5: Extent of Errors Made by Fake Unilateral Subjects Over 48 Trials



Post Hoc Questions and Hypotheses:

Question 1:

When the Normal listeners made errors, were the errors similar to the Real Unilateral and Fake Unilateral listeners? (No)

New Hypothesis: Minimal Errors for Normal Listeners

The Normal group of listeners not only made fewer mistakes during the test, but when mistakes were made, the guesses were almost always off by only one speaker, while both groups of Unilateral listeners made more errors, which were usually greater than two speakers away in error. Out of 19 normal listeners in the control group, 17 missed the correct speaker by just one speaker to the left or right in **all** their mistakes; the remaining two made one error each that was off by more than one speaker (off by six speakers and off by two speakers respectively). In the control group, the highest number of errors made by a subject was 22 (with each of the 22 errors being off by just one speaker). The lowest number of errors was made by a subject was zero. Figures 6 through 8 display the nature of these errors.

Figure 6: Distribution of Error Types Among 5 Randomly Selected Normal Subjects

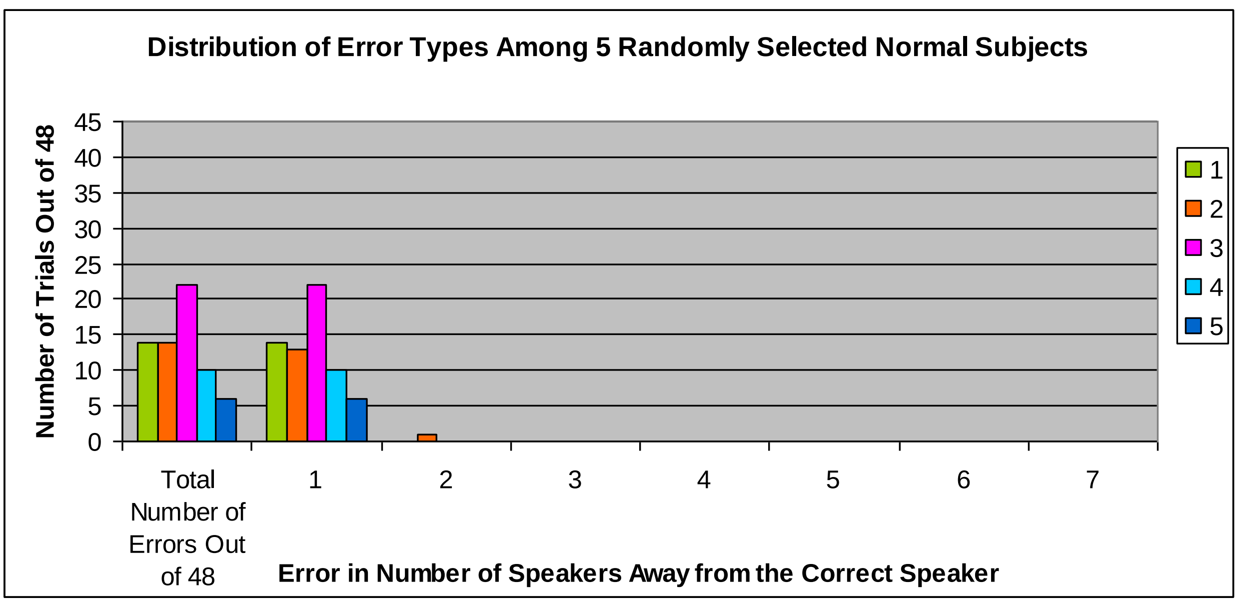


Figure 7: Distribution of Error Types Among the 5 Real Unilateral Subjects

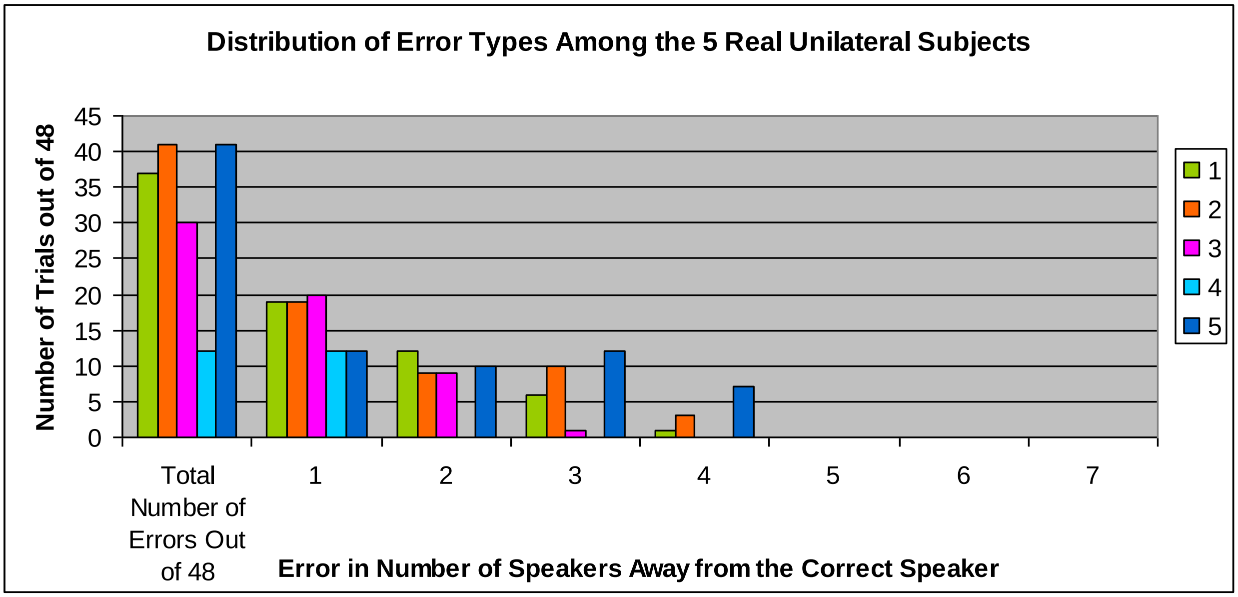
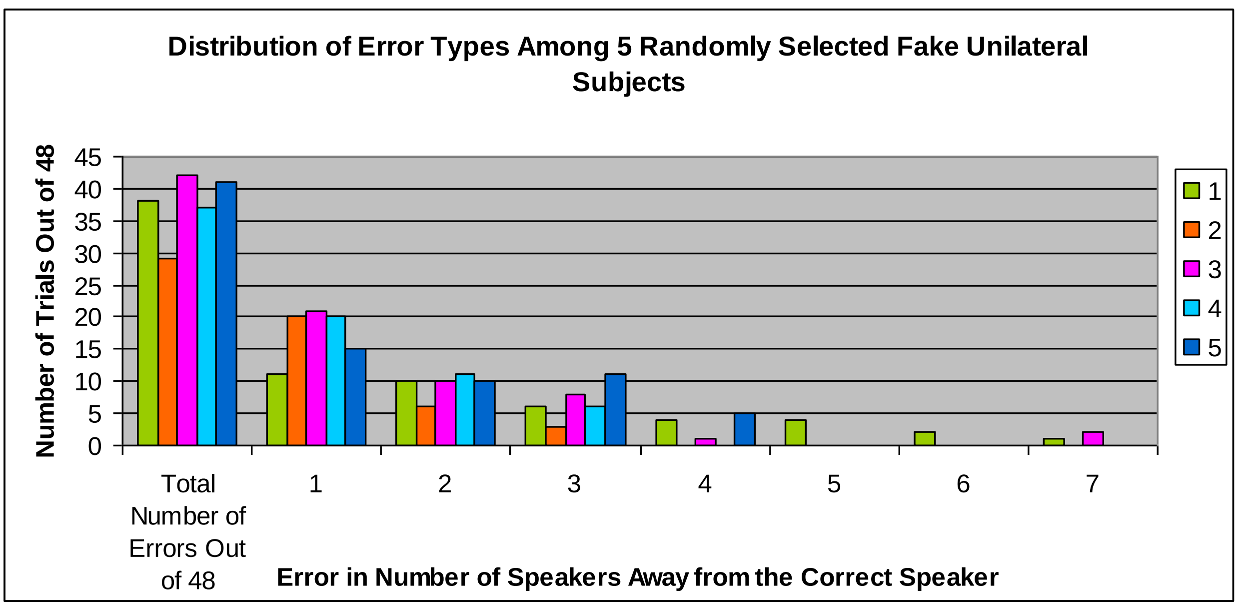


Figure 8: Distribution of Error Types Among 5 Randomly Selected Fake Unilateral Subjects



The Real and Fake Unilateral subjects expressed a much larger range and much more variable distribution of error types than the Normal subjects did. This strongly suggests that the prototype is successful in not only separating the localization abilities of one- and two- eared listeners, but furthermore making a distinction between experienced (Real) and novice (Fake) one-eared listeners. The differences shown between Figures 7 and 8 reveal that there is long-term adaptation involved with having hearing loss (congenital or acquired). This shadows the nature of habilitation that post-operative aural atresia patients encounter over time after the corrective surgery.

Questions 2 and 3:

Do all Real Unilaterals make the same pattern of errors regardless of the side of deafness? (No)

Do the error patterns of the Real Unilaterals match that of the Fake Unilaterals? (Yes)

New Hypothesis: Errors Made in Consistent Directions

When testing, the Real Unilaterals and the Fake Unilaterals did not make equal errors in both directions. They tended to localize the sound toward their ‘good’ or unplugged ear, as expected, and as shown in Table 2. This directional pattern for the Real Unilaterals was found in the Fake Unilateral group as well, as shown in Table 3. When comparing the average error and direction of those errors between the unilateral groups combined, in Table 4, the two samples were practically indistinguishable with positive means of 0.44 and 0.42. This demonstrates that both groups were almost identical in directional pattern of speaker selection during the testing due to the unilateral HL, despite whether it was a fake or real HL.

Table 2: Real Unilateral Subjects: The Deaf Ear and the Mean Direction of Errors

One-Sample Statistics

The Deaf Ear (Right or Left)	Number of Trials	Mean	Std. Deviation	Std. Error Mean
R	48	-14.58	28.506	4.114
R	48	-10.42	55.657	8.033
L	48	23.33	38.776	5.597
L	48	2.50	9.785	1.412
L	48	35.42	62.737	9.055

* Negative mean errors are left-sided errors (of the correct speaker); positive mean errors are right-sided errors.
* Making an error towards the "good" ear means having a positive mean with a left deaf ear or a negative mean with a right deaf ear.

Table 3: Fake Unilateral Subjects: The Temporarily Deafened Ear and the Mean Direction of Errors

One-Sample Statistics

The Plugged Ear (Right or Left)	Number of Trials	Mean	Std. Deviation	Std. Error Mean
R	48	.42	98.455	14.211
L	48	51.67	45.351	6.546
L	48	47.50	67.996	9.814
R	48	-27.08	35.608	5.140
R	48	10.83	45.375	6.549
L	48	27.92	38.202	5.514
R	48	19.17	26.404	3.811
L	48	10.00	54.422	7.855
L	48	10.42	31.145	4.495
L	48	-7.92	23.243	3.355
R	48	-7.92	60.879	8.787
L	48	67.08	56.942	8.219
R	48	-61.25	69.455	10.025
L	48	47.50	46.972	6.780
R	48	-20.00	34.764	5.018
R	48	-38.33	56.993	8.226

* Negative mean errors are left-sided errors (of the correct speaker); positive mean errors are right-sided errors.
* Making an error towards the "unplugged" ear means having a negative mean with a right plugged ear or a positive mean with a left plugged ear.

Table 4: Comparing Real Unilateral and Fake Unilateral Subjects

in Pattern of Directional Mean Error

Group Statistics

	Real	Number of Subjects	Mean	Std. Deviation	Std. Error Mean
dlnPredDirection	0	16	**.44**	.559	.140
	1	5	**.42**	.189	.085

*dlnPredDirection = mean error in degrees is positive if the error was toward the good ear and negative if in the opposite direction. Real=0 are the Fake Unilaterals. Real=1 are the Real Unilaterals.

Discussion Continued:

Our construct validity is likely high. The prototype proves successful in separating the binaural and monaural (both the natural and artificial monaural) listeners. The localization abilities used when testing under the prototype system are expected to reflect localization abilities used in other normal sound situations. We could, however, improve by expanding our experiment to sound field-testing; this would mimic natural sound localizing situations even better. We also plan to explore the option of using additional sound localization tests to further demonstrate the construct validity of our prototype.

Due to the nature of the prototype, our predictive validity is high as well. The system is designed to test subjects in distinct intervals over long periods of time for the purpose of recording improvement or change in hearing and localization ability. Testing a subject repeatedly in various intervals would theoretically attract the same results between any periods of time (assuming their hearing did not change). Subjects will be able to be tested a second time in future experiments in order to reinforce this validity.

Conclusion

Findings:

- There is a significant difference in the performance of Normal subjects and Real or Fake Unilateral subjects, with the Normal subjects consistently passing (more than 50% correct) and the Real and Fake Unilaterals consistently failing (50% or less correct).

- There is a marginal difference with Real Unilateral subjects scoring slightly higher on average than the Fake Unilateral subjects. This indicates that there might be some long-term adaptation to unilateral hearing loss and bodes well for the eventual goal of this project, which is to evaluate long-term changes in atresia patients post-surgery.

- Fake Unilateral subjects may have experienced minor adaptation and tended to perform higher during the middle of the test and lower at the beginning and end of the test. Significance cannot be claimed at this time.

- Normal subjects that do make errors typically make the smallest error in our configuration (mis-localizing the correct speaker by just one speaker to the left or right), while Real and Fake Unilaterals have a much larger distribution of error types (errors of missing one to the max of seven speakers away from the correct speaker).

    - Due to lack of experience with a hearing loss, Fake Unilaterals made more frequent and more severe errors than the Real Unilaterals, and thus, had the widest distribution of error types among the three groups.

- The direction of average error is congruent with the side of deafness (or hearing loss).

  - Those with right sided deafness tend to make more errors to the left when selecting speakers and vice versa, as expected.

- The Real and Fake Unilateral subjects matched in pattern of average error direction.

Implications for Clinical Practice:

The prototype effectively reveals a significant difference between bilateral and unilateral (both natural and artificial) listeners. Because the effect size between these two groups is so large, there is a wide range in between where post-operative atresia patients are expected to fall in localization ability. Over time, their hearing should gradually improve within this range (to a certain extent).

One distinct advantage of this prototype is that the test can be repeated to test aural atresia patients at discrete intervals over long periods of time (every year or so). We can use this to quantify differences in sound localization abilities of aural atresia patients and how they improve over time after corrective surgery. Furthermore, we hope to use this prototype to investigate adaptation rate and learning curve for post-operative atresia patients over time.

Implications for Future Research:

What Might Have Gone Wrong?

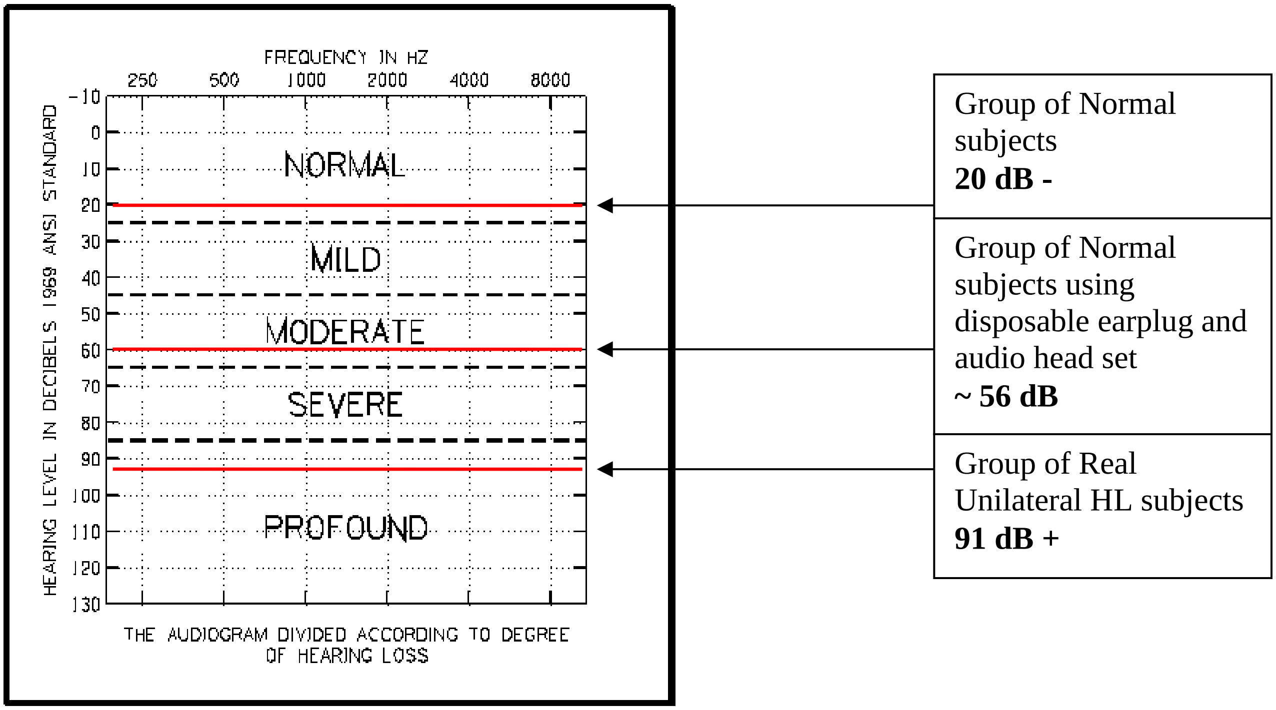
The lab in which testing was conducted was not soundproof. While testing was always conducted in a quiet room with only the tester and participant present, the ventilation system in the back of the room was loud enough to be noticeable. The background noise level in the room was measured (by B&K Sound Level Meter) to be 45 dB (A), (this is primarily low frequency sound). It also measured at 66 dB (C) and 74 dB (linear). This could have had an effect on the subject by means of distraction or interference in localizing the stimuli of the test. Unfortunately, due to the nature of the device's parts and set-up, it was not possible for us to move the testing area from the lab where it was originally constructed. Furthermore, we did not have access to the functionality of the ventilation system for means of adjusting it during testing, and we did not have consistent access to a large enough soundproof booth to for relocation. However, we cannot realistically expect that the houses we deploy the device to will be soundproof. Therefore, it bodes well for us that even with the background noise during the testing, we still found a large effect size in the difference between our control and experimental groups. Furthermore, we can expect that the device will achieve its purpose despite the presence of everyday noise in the average "quiet" family home.

The instructions may not have always been clear to the subjects. There were a couple instances when the subjects (specifically normal listeners who were plugged) finished the test and were surprised to learn that stimuli was played from every speaker at least once. These few subjects (the first 2-3 Fake Unilaterals tested) assumed that since they were plugged for this trial, the behavior of the program and speakers would change by playing only to a certain side of their head rather than randomly playing all of the speakers. It quickly became a standard part of the initial instructions to mention that all eight speakers will randomly play a sound at one point or another regardless of their hearing condition at the time of the test. This way, vagueness of what to expect from the speakers was reduced and the subjects could focus more on what they are hearing and where they are hearing it from, instead of guessing how the system is behaving.

Comparing conductive hearing losses to sensorineural hearing losses may have been a confounding variable in this study. While the method we used to temporarily deafen the Normal subjects was effective (proven by the data), we did not produce a profound conductive HL, and thus, did not perfectly mimic the natural severity of the sensorineural HL of the Real Unilaterals.

We estimate the range of HL caused by the noise reduction rate (NRR) of the disposable foam earplug (NRR of 33 dB) and the audio head set (NRR of 25 dB) used together on a subject's ear was an NRR of about 36 dB. As shown in Figure 9, a Normal subject is defined as having thresholds of at least 20 dB (if not lower) at most standard frequencies, meaning that the average HL simulated on these Normals during their Fake Unilateral testing with the earplug and head set was about 56 dB (defined as a *moderate* HL). Profound HL begins at the inability to hear auditory information at 91 dB and higher. Because of this realization, it is confirmed that the Fake Unilaterals actually had better hearing at 56 dB than the Real Unilaterals did at 91 dB, and yet they still performed worse. Therefore, it can be assumed that if these Fake Unilateral subjects were artificially given a *truly* profound HL, the hypotheses regarding group differences between the Real and Fake Unilaterals would be *even more* significant in that experienced one-eared listeners perform higher in localizing sound than novice one-eared listeners.

Figure 9: The Audiogram Divided According to Degree of Hearing Loss



Enhanced Hearing Center. (n d). Audiogram [Chart]. Retrieved March 27, 2013 from http://www.enhancedhearingcenter.com/links/und_hl1.gif

Possible Future Improvement?

To conduct this experimentation in the future, several improvements can be made to further increase the quality and reliability of the research. First, it would be ideal to have a designated soundproof booth or space to conduct testing so as to not have background noise or any other form of distracting sound interfere with the testing.

Secondly, a typed and printed set of instructions would be beneficial in reducing the chance that the scientist accidentally leaves out anything important and that the subject does not miss any information due to the nature of their hearing or attention. With a printed set of instructions, consistency of experimentation will increase, and therefore, validity and reliability will increase as well. This device is meant for home deployment and independent test taking, so a set of printed instructions will need to be made and developed regardless.

Thirdly, while our data was significant enough with the sample size we had, it may be wise to have a larger sample size for each of the control and experimental groups in the future. Furthermore, the diversity of the samples should be increased for future experimentation to include a wider range of ages and an equal amount of representation of each age.

Lastly, we can improve by conducting pure tone thresholds on the Fake Unilateral subjects while they are wearing an earplug and headphones on one ear. This will serve the purpose of knowing exactly what the level of their hearing loss is, instead of estimating the attenuation by using product labels and logarithmic calculations as we have done.

Where Do We Plan to Go With This?

As we move forward, the next step in this project is to be able to finalize the prototype, package it in a convenient package, and send it off to a post-operative atresia patient. We can expect that the patient will be able to open the package, set-up the device, read the instructions, take the necessary tests, and repackage it to send back to us. At this point, we can gradually move forward towards our ultimate goal of completing additional research and applying for a research grant in order to fund our production of this prototype as a standard medical testing device for atretic audiological evaluations.

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Design of a Distributable Stereo Hearing Test Package

Engr 432 Engineering design VI
May 1, 2013

Project Team Names and Signatures

Team Member 1: Michael Kessler

Team Member 2: Jonathan Smith

Team Member 3: Brandon Lancaster

Team Member 4: Brian Allen

Abstract
The localization and identification of sounds in background noise are such important auditory processing skills that any amount of incompetency may lead to various confusions and learning delays. Through a partnership with James Madison University (JMU) and the University of Virginia (UVA), a unique opportunity exists to test patients before and after a corrected maximal conductive hearing loss in one ear. Patients with congenital aural atresia come to UVA for surgery that will give them normal hearing. Insurance pays for a pure tone threshold hearing test one month after surgery, but due to cost restrictions, longitudinal follow-up testing is often not performed. However, longitudinal data from follow-up studies is essential for understanding the effectiveness of the surgery.

This project is about the design, construction, and testing of a shippable hearing test system for patient testing. The system will test two binaural hearing abilities—the ability to isolate a spatially separated signal from noise and the ability to localize the source of a sound.

Validation testing of the prototype testing system was performed with listeners with both normal hearing and with unilateral hearing loss. In initial testing, the RMS localization errors were measured from 19 control listeners with normal hearing and 4 with complete unilateral hearing loss. There was a significant difference between those listeners with one good ear versus those with two good ears ($p=.01$, $d > 1$ or 'large' effect size). These results provide promise as to the effectiveness of the designed testing package.

1 INTRODUCTION

This project lends itself well to an engineering solution. It has the potential for some meaningful broader impacts, as discussed below.

1.1 Problem Statement

Our stakeholders are Dr. Bradley Kesser and Dr. Lincoln Gray. Dr. Gray is a professor in the School of Communication Science and Disorders (CSD) at James Madison University (JMU). Dr. Kesser is an otolaryngologist at the University of Virginia (UVA). Both want to use a portable hearing testing system to evaluate whether or not corrective surgery for unilateral congenital aural atresia is effective. Most patients who receive this surgery are located a great distance from the Charlottesville area, where the surgeries take place. The patients' insurance only pays for a follow-up audio test, one month after surgery. Money and travel time interfere with the patient's ability to receive checkups. This makes it difficult to understand whether the procedure administered improves the quality of hearing of patients over an extended period of time. In the simplest terms, effectiveness can be defined by how well the atretic ear performs in pure town threshold tests in the long term.

Our machine will help determine the effectiveness through long-term data collection in the comfort of the patients' homes. Currently, we are able to distribute these portable hearing systems for patients to use, to gather data to find out if the atresia surgery helps patients. A speech in noise and a sound localization test for the portable hearing evaluation system have been programmed to successfully test patients. The speech in noise is a test that determines whether a patient can understand speech while white noise is playing in the background. The Sound localization test determines if the patient can locate noise played- from one of the eight speakers that are incorporated into the system.

1.2 Broader Impacts

The project will serve as a resource to acquire data to expand upon current knowledge in the fields pertaining to audiology and neurology. A broad goal of the data obtained by the system will be to help answer how the brain learns how to use the input from two ears. People with hearing in both ears learn to use them in such a way that cannot be done with one ear.[1] Stereo hearing enables the listener to have two specific abilities that people with unilateral hearing do not have. The first is the ability to better isolate a signal from noise. This is similar to the fact that one can only view 3D movies using two eyes. The second is the ability to locate a sound source with a higher degree of accuracy that an individual who can only hear out of one ear. Investigating these effects and abilities are valuable for the academic community, because it will increase our understanding of the brain's relationship to the ear.

While understanding critical period for binaural hearing is an interesting academic venture in and of itself, knowledge in this area can also answer more practical questions. For example, armed with this new information about critical periods, pediatricians could provide better diagnosis to children with ear infections which may cause the child to suffer temporary hearing loss. Some doctors wait and see if the child gets better while others recommend immediate treatment. Is it necessary to treat infections urgently? If a critical period exists, then aggressive treatment might be prescribed to allow the children to hear again during the critical stage of hearing development. However, if no such period exists then a less invasive treatment could be prescribed without side effects.

2 LITERATURE REVIEW

The portable hearing evaluation system will serve as a tool for the continued research of Dr. Bradley Kesser and Dr. Lincoln Gray. To gain a better understanding of the work Dr. Kesser and Dr. Gray do, the following literary discussion provides insight into the field of audiology; the study of hearing and hearing disorders.[1]

> The discipline of audiology essentially evolved during World War II. During and following this war, many military personnel returned from combat with significant hearing impairment resulting from exposure to the many and varied types of warfare noises. Interestingly, it was a prominent speech pathologist, Robert West who called for his profession to expand their discipline to include the area of audition.[2]

Other fields of study have disciplinary overlaps in the science of audiology and speech pathology, such as neurology. The capstone group's faculty advisor, Dr. Gray, is trained in the field of neurology and has approached the study of hearing from this perspective. The other primary client's work, Dr. Kesser, has a stronger base in the field of otology. Otology is concerned with the diagnosis and treatment of individuals who have an ear disease or a disorder of the peripheral mechanism of hearing.[1]

Both Dr. Gray and Dr. Kesser, professionals in the fields of hearing-related sciences, have expressed particular interest in the capability to remotely evaluate patients' ability to localize sound signals, as well as hear speech in noise. Binaural hearing or the processing of sound by two ears is a key factor in the task of sound localization. The significance of the ability to localize sound is expressed in the following passage:

> Under natural conditions animals do orient to certain sounds that may represent prey, predator, or mate. Their ability to localize and identify the source may well be one of their most important adaptations. The accuracy with which they do so may be a complex function of acoustic signal structure, environmental conditions, the availability of input from other sensory modalities, and so on.[3]

The passage from Berlin provides some context into how an individual makes use of sound signals in his or her environment. The discussion on sound localization by Berlin addresses some of the qualitative behavioral significance that develops from binaural hearing. The following passage presented by Bess explains the benefits of binaural hearing from a quantitative approach, through prescribing a methodology for calculating the rate of change in time delayed signal processing. The time delay is seen to be a function of a prescribed sound decibel and azimuth orientation of the patient.

> The localization of sound in space, for instance, is largely a binaural phenomenon. A sound originating on the right side of a listener, for example will arrive at the right ear because it is closer to the sound source. A short time later, the sound will reach the more distant left ear. This produces an interaural (between-ear) difference in the time of arrival of the sound at the two ears. The ear being simulated first will signal the direction from which the sound arose. As might be expected, the magnitude of this interaural time difference will increase as the location of the sound source changes from straight ahead (called 0^0 azimuth) to straight out to the side (90^0 or 270^0 azimuth). When the sound originates directly in front of the listener, the length of the path to both ears is the same, and there is no interaural difference in time of arrival of the sound. At the extreme right or left, however the path to the far ear is greatest (and corresponds to the width of the head). This then will produce the maximum interaural time difference….For frequencies below approximately 1500Hz, the interaural time difference could also be encoded meaningfully into an interaural phase difference.[2]

The model pertaining to the concept of binaural hearing and sound localization will be fundamental in the functionality of the evaluative hearing system. A large reason for the interest in the sound localization hearing phenomenon is its direct relationship to people capable of hearing from two ears. The need to establish metrics associated with the functionality of binaural hearing is essential for developing a means of testing to help the work of Dr. Kesser.

Dr. Kesser specializes in a surgery that is used as a corrective measure for a condition known as congenital unilateral aural atresia. The atresia, or closure of the ear beginning at birth, impacts a person's hearing abilities associated with Binaural hearing. Dr. Gray has been working with Dr. Kesser to develop a means for data collection to evaluate improvement of hearing in patients who have undergone the corrective surgery.

This passage taken from a recently published work by Dr. Gray indicates a variety of tests and results being generated by his research. The published work also indicates recent test data was collected prior to surgery and one month following surgery. The intention for the hearing system will be to extend the data collection period to months or even years following the atresia surgery.

> Unilateral hearing loss causes difficulty hearing in noise (the ‘‘cocktail party effect’’) due to absence of redundancy, head-shadow, and binaural squelch. Methods: Patients with unilateral congenital aural atresia were tested for their ability to understand speech in noise before and again one month after surgery to repair their atresia. In a sound-attenuating booth participants faced a speaker that produced speech signals with noise 90 degrees to the side of the normal (non-atretic) ear and again to the side of the atretic ear. The Hearing in Noise Test (HINT for adults or HINT-C for children) was used to estimate the patients' speech reception thresholds. The speech-in noise test (SPIN) or the Pediatric Speech Intelligibility (PSI) Test was used in the previous study.[1]

During a needs conversation with Dr. Kesser, it was noted that free-field sound localization testing has not been previously conducted in research methodology.

> We have never done free-field sound localization testing.… It would be very worthwhile to setup five or six speakers in an azimuth around the patient and have the patient do the test. Having not already done that this will be a good test of free-field sound localization.[4]

In addition to the free-field sound localization test, the system now includes a speech-in-noise test using the Coordinate Response Measure (CRM) corpus. The CRM was created for use at Air Force Research Laboratory, Wright-Patterson Air Force Base, Ohio, circa 1999. The Coordinate Response Measure (CRM) command statements simulate a multi-talker environment by generating several audio signals where the user is to decipher from the intended signal from the distraction signal. The following passage explains the structure of a CRM signal.

> The phrases in the CRM consist of a call sign and a color–number combination, all embedded within a carrier phrase. Hence a typical sentence would be ‘‘Ready baron, go the blue five now,’’ where baron is the call sign, and blue five is the color–number combination. In the performance of the task, each listener is assigned a call sign, and responds by indicating the color–number combination spoken by the talker who uttered his or her call sign. If the listener does not hear his or her call sign spoken, he or she does not respond or, equivalently, reports the absence of his or her target call sign. Possible dependent measures thus include the percentage of correct call sign detections and the percentage of correctly identified color–number combinations, as well as their associated reaction times.[5]

Given the significance binaural hearing provides in the quality of hearing perceived by Dr. Kesser's patients, the sound localization and CRM based tests clearly will aid in comparing hearing capabilities of people able to hear from one ear and people able to hear from two. The repeatable differences in quality of hearing under these two control environments (one vs. two ears) will be the basis for many of the tests the hearing system prototype will perform.

3 PROJECT STATUS AND PROJECT MANAGEMENT

In order to manage the seven students on the team effectively, strong organization was needed.

3.1 Team Management

The team is cross-disciplinary. It consists of four senior engineering students, two junior engineering students, a Communications Science Disorders student (Sofia Ganev), a Communications Science Disorders department professor (Dr. Lincoln Gray), and an engineering department professor (Dr. Robert Nagel). Our team has one external sponsor, Dr. Bradely Kesser who is a surgeon at University of Virginia specializing in corrective atresia surgery. He refers patients to Dr. Gray for hearing evaluations and will thus provide the patients that will use our machine.

Brandon Lancaster runs the team meetings and also the team manager for the senior engineers. He maintains consistent time slots every week (for this semester it is Tuesday Thursday from 2:00-3:00 pm and Fridays 3:30-5:00 pm) where other team members may come in and ask questions about their tasks. Mike Kessler is the treasurer for the capstone team. Task completion is tracked by sending status updates to the engineering advisor. These status updates are then compiled by Dr. Nagel and archived online.

Meetings take place every week at the same time. Every group member is expected to be present during meetings unless they tell Brandon otherwise. These meetings follow the Defense Acquisition University (DAU) program manager's toolkit for effective meetings (see outline below)[6]. The team's weekly meetings can be categorized as informational, planning/strategizing, or decision types as shown in bullet A of the outline. The meeting is from 1:30-2:30 pm on Wednesdays although it usually ends early if run efficiently. At the beginning of the meeting, each person has two minutes to give his/her status update as to what was completed the past week. Questions are held during this part of the meeting. If someone has completed a task, he/she is then assigned a new one as necessary after status updates are complete. If there are any purchasing or major team decisions to be made, they are made at this time. This has unlimited time. Announcements are then made by various team members. Finally, people are allowed to break into small groups and schedule the necessary meetings with each other for that week. Often times, these meetings occur immediately after the main meeting for scheduling convenience. The overarching goal of the schedule just discussed is to keep the information covered relevant to everyone, this way the team remains efficient. Items pertaining to only a fraction of the group can be discussed later.

DAU PROGRAM MANAGERS TOOL KIT

EFFECTIVE MEETINGS

PRE-MEETING

A. Establish type of meeting
   1. Information (quick, crisp)
   2. Planning/Strategizing (slow, deliberate)
   3. Problem solving (divergent/convergent)
   4. Decision (deliberate)
   5. Staff/Conference (repetitive, short)
   6. Feedback/Evaluation (slow, contemplative)
   7. Training (smooth, flowing)
   8. Social (rambling)

B. Select participants
   1. Based on purpose; relevant; decision auth.
   2. Size: 4-7 ideal; 10-12 tolerable; >13 unsat.

C. Circulate agenda (3-5 days in advance)
   1. Type, purpose, date, place, start/finish times
   2. Topics, time allocated (minutes), speakers
   3. Assign recorder

CONDUCTING MEETING

A. Opening
   1. Start on time
   2. Repeat type and purpose of meeting

B. During
   1. Facilitate the meeting
   2. Encourage openness and communication
   3. Develop cohesion
   4. Use active listening
   5. Stick to agenda

C. Closing
   1. Set time and date of next meeting
   2. Summarize agreements, actions, decisions
   3. Close on time or before

AFTER MEETING

A. Review minutes with recorder

B. Publish minutes

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3.2 Project Management

It is important to determine from the beginning of the work which parts of the project are going to take priority. The time, cost, performance trade-off assessment in Table 1 was determined taking into account that most of this project is planned to be supported by grant money and also that there is a set two year time limit to work on the project.

Table 1: Trade-off Assessment

	Time	Cost	Scope
Constrain	X		
Enhance			X
Accept		X	

Due to changing requirements and new information, it was difficult to maintain traditional project management artifacts (e.g. using a Gantt Chart, work break down structure, etc.). Instead, intrinsic motivation in combination with weekly status updates keeps the team moving forward. This approach to management also allows the team to adapt to changes very quickly. Instead of a Gantt Chart, a list of tasks which need to be completed is maintained on a white board in the project room, Each team member is responsible for a task and all know what they are responsible for.

The team also has milestones that each member is aware of and strives to reach. These milestones are revised at the beginning of each semester. Throughout the project, the team has completed many milestones and should feel proud of its accomplishments. Some achievements completed over the course of the two years include programming the first and second audio tests and finalizing a selection on speakers. We have preformed a speaker positioning pilot study to determine the optimal positioning of the speakers (discussed in section 4.3). The team was successful in its goal to create a second prototype this semester and now maintains two complete working sets of hardware. The first prototype, called the Florida prototype (named after where one of the students went over spring break and where our advisor would have liked to have gone), has the ability to run the matlab code without compiling. It incorporates the most up-to date hardware and software. Any improvement the team wants to test out is done on this prototype. The second prototype called the Bahamas prototype only runs compiled matlab code and is designed for shipping out to patients. Some other milestones that have been completed this semester were shipping the Bahamas prototype out to an atresia patient, prototyping the speaker stands, finalizing the selection of a microphone, validating the design of the setup with data, and fixing speaker accessing problem (discussed later in section 4.3)

Some future milestones include validation testing of the speech in noise test, monitoring background noise during the program, programming in an auto calibrating routine that sets the levels of the speakers, and developing a logistics plan for long-term use. A format for data saving has been established and code must be updated to reflect this standard. The code must also be updated to comply with the programming style guide to ensure the program is well documented. These tasks are left up to the two junior engineering students who will work on the project another year.

The team treasurer, Mike Kessler has kept a sheet with the team purchases made since the beginning of the project. It can be seen in Table 2.

Table 2: Project Expenses

Category	Description	Cost	Total Cost	Vendor	Date
documentation	Sample Audio Recordings of Tests	$1.00	$2.00	JMU Library	01/09/12
testing	Compass Maps for Speaker Setup	$8.00	$16.00	JMU Copy Center	01/12/12
hardware	Pair of Cyber Acoustic Speakers	$22.04	$22.04	K-Mart	02/26/12
hardware	Phantom Power Supply	$49.00	$49.00	Amazon.com	02/08/12
hardware	Pair of Cyber Acoustic Speakers	$22.04	$66.12	K-Mart	04/04/12
hardware	Dynex USB Hub	$41.99	$41.99	Best Buy	05/17/12
hardware	Belkin USB Hub	$41.99	$41.99	Best Buy	05/17/12
hardware	8G USB Flash Drive	$10.49	$10.49	Best Buy	05/17/12
hardware	Pair of Cyber Acoustic Speakers	$22.04	$88.16	K-Mart	N/A
documentation	Copies of Reports	$5.90	$5.90	JMU Copy Center	N/A
presentation	Reprint Poster	$50.40	$50.40	JMU Copy Center	N/A
hardware	Startech USB DAC	$22.38	$89.50	Compbargins.com	N/A
hardware	Layout mat for beta prototype	$10.45	$10.45	Ragtime Fabrics	11/19/12
	Total Expenses 2011-2012		**$494.04**		

4 APPROACH AND METHODS

4.1 Requirements Analysis

In order to compile our customer needs, constraints, requirements, and target specifications, the team first consulted with the stakeholders of the project, Dr. Lincoln Gray and Dr. Bradley Kesser. The team also consulted with two students, a Amy Byers (an alumnus) and Sofia Ganev (current student) who are in CSD program. Each engineer met with one of the stakeholders or students and asked them various questions that would help the team develop possible ideas for designing the system. Some of these questions asked included, “What test should the system be able to run?” and “How will this system need to be shipped?” These questions were compiled into a list that can be seen in appendix 1. Some of the needs were to keep the cost of the testing system lower than the cost of traveling, system must be able to run sound localization and speech in noise test. Another customer need which was incorporated into the design of the system was that the system should be able to set up by patients as young as six years of age. Some of the target specifications were to have twenty to thirty units made that would cost less than $1,000, a test of at least 100 people on a 6 month cycle, and easily accessible data. These target specifications were created from customer needs. Refer to the appendix 1 for a complete list of customer needs and target specifications.

4.2 Conceptual Design

The overall design process consisted of hardware and software aspect which will be further explained in section 4.4 and 4.5 of the Prototyping and Software, respectively. These aspects required the team to stick closely to the engineering design process shown in Figure 1.

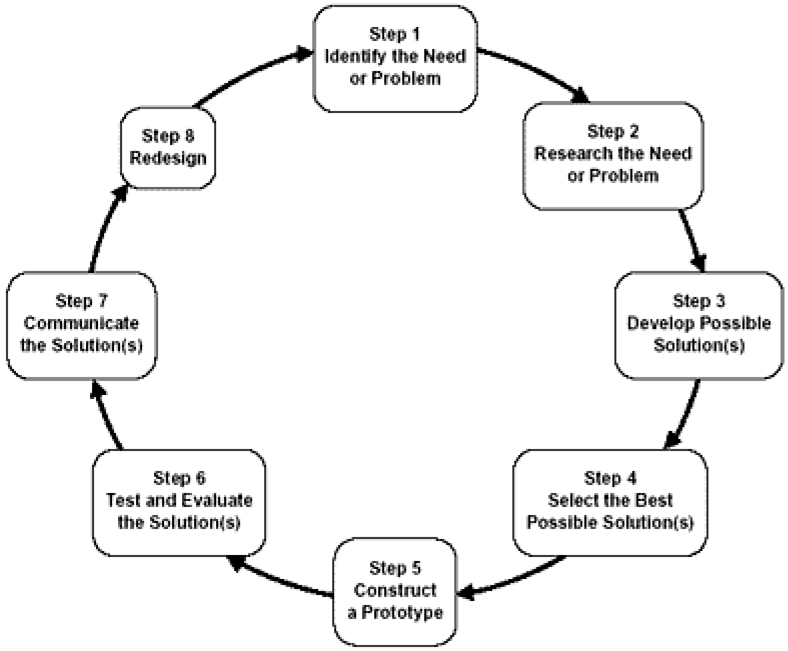

Figure 1. Engineering Design Process.

After identifying the customer needs and specifications for the system, first the team began the process selecting a set of eight speakers that would suit the system. In terms of selecting the speakers, the team needed a set of speakers that were fairly linear at different decibel levels at several frequencies using a Fast Fourier Transform. Four different speakers were tested, with those brands being Motorola, Eddie Bauer, Cyber Acoustics, and Harmon Kardon speakers. This analysis allowed the group to determine the Cyber Acoustics speakers as the best fit for the system. Figure 2 displays the Fast Fourier Transform of the Cyber Acoustics model CA2988.

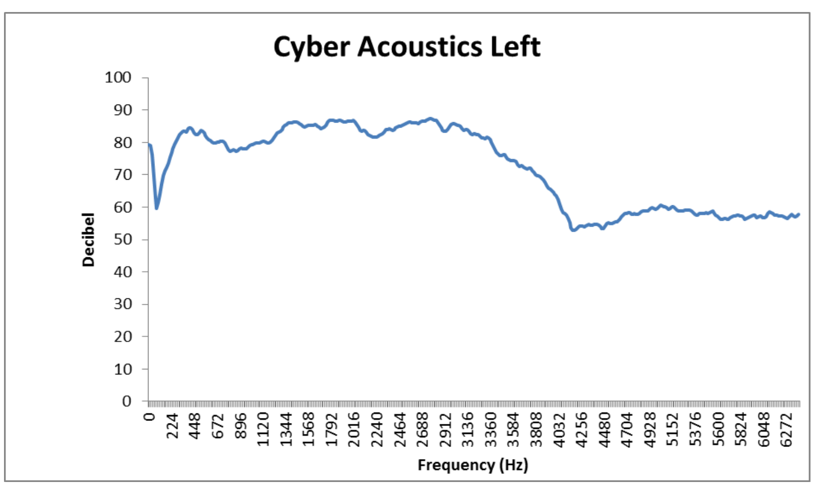

Figure 2. FFT of the selected speaker model.

In addition to its linear FFT, this set of speakers also was portable, simple for disassembly, and protection during. The model allowed the front of two speakers to magnetically attach during shipment. Next, the team had to select a microphone for the system. This analysis involved determining the dB constant at different frequency levels and making sure they didn't clip at different frequencies. The dB constant is the decibel level response and a measure of how persistent relative to an amount of power. Six different microphones were tested and allowed the team to determine the Audio-Technica microphone as the best fit for the system due to its linear dB constant relation and its wavelength at different periods. It also is a dynamic microphone which means it did not require a bulky phantom power supply as the previous condenser microphone die. A figure of this analysis can be seen in appendix 2 of the report. The choice of the USB hub was decided because it had the right spacing for the USB powered speakers and DACs that were chosen. The USB hub was also very small. It's important to state that each of the three selections were also cost effective because the team was working on a tight budget.

The audio test of the system was designed for the user to be able to abort the test anytime necessary. Each test displays instructions before the user begins testing. The use of pictures will also be incorporated for future work so that the user can have a tutorial of how to take the test. A diagram of the process can be seen in Figure 3 below.

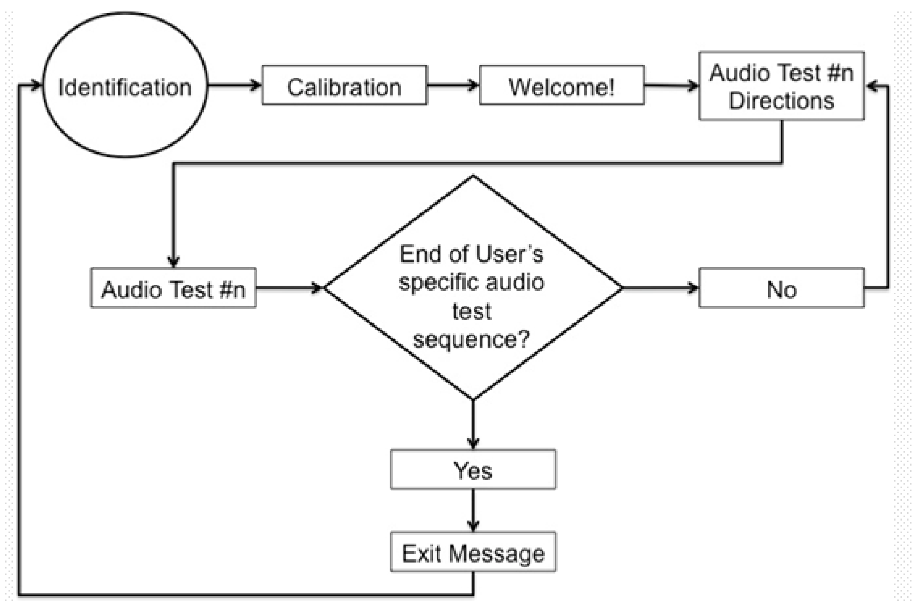

Figure 3. Conceptual process for taking of audio test.

4.3 Engineering Analysis

In working with the system, it was realized that the program would fail to play sound out of the correct speaker if the hardware was not plugged into the exact same USB ports on the hub. It would also not play sound out of the correct speakers if the USB hub was not plugged into the exact same port on the computer. To fix this issues the hardware team permanently used solvent cement to attach the speaker jacks to part of the speaker stands thus making sure the speakers location is recognized the same by the program.

From the software side, it was also discovered that the program would also play the incorrect speaker even if the hardware remained the same. No pattern could be found for this occurrence. To identify each DAC, the program was using a parameter called the device

ID. Each DAC would have a unique number but as stated earlier these numbers were found to change randomly. Obviously, to solve this problem a new method of identifying each DAC connected to the system was needed. The output of the command that creates the DAC objects in the program was found to contain a unique string of text for each DAC. An algorithm was written that instantiates every DAC on the system and then sorts them based on this string of text, thus solving the problem

Clinical tests were performed with assistance from a College of Communications Science's and Disorders undergraduate student Sofia Ganev. The first of these clinical tests aimed to determine the ability of the system to meaningfully test patient's ability to localize sound. Results of the localization test are described in the following paragraph.

Initial tests were performed to determine the angle in degrees from a 180° azimuth about the user. A total of four configurations were tested. The four configurations are depicted in Figure 4.

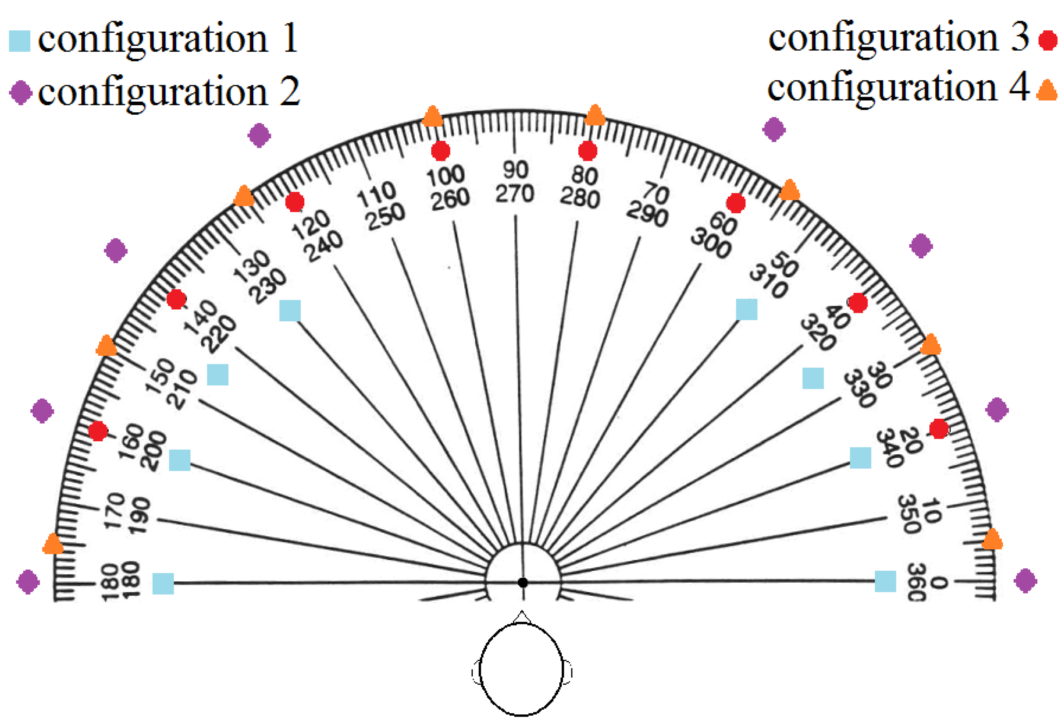

Figure 4. The four speaker arrangements tested initially using sound localization as basis.

Root means squared analysis for error in degrees was then used. This analysis is modeled by the equation:

$$RootMeansSquaredError = |Actual\,Speaker\,Location(degrees) - Chosen\,Speaker\,Location(degrees)|$$

The results of the error in degrees of the user localizing a signal during the sound localization test, given a representative from each of three populations: binaural listener, monaural listener, and a recipient of the atresia surgery is shown in figure 5.

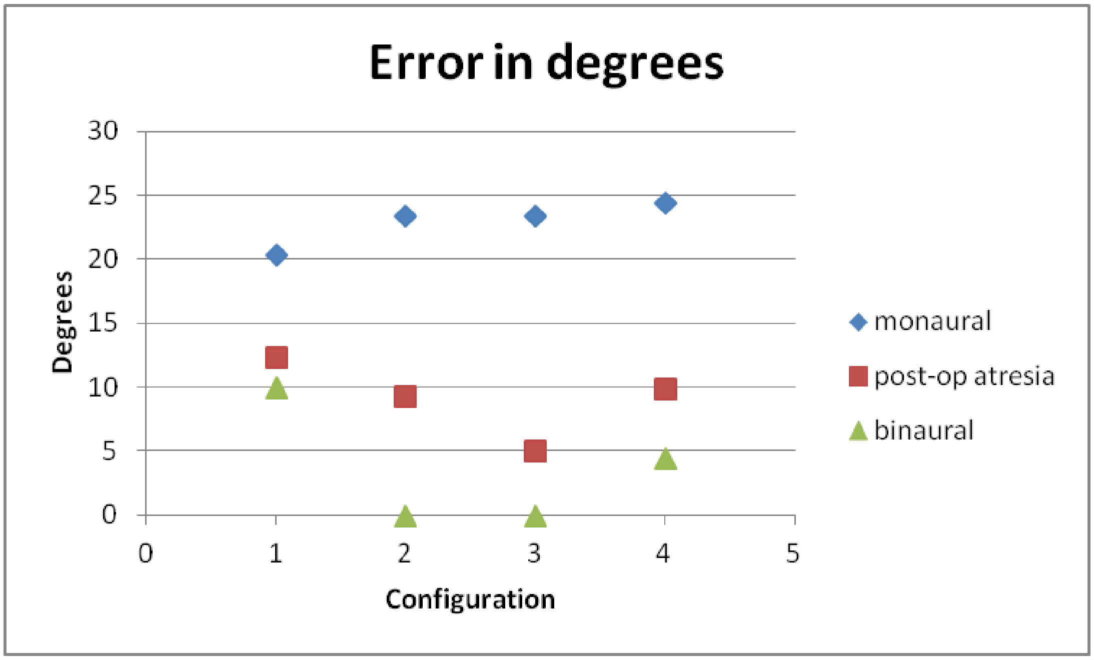

Figure 5. Error in degrees from speaker picked by user compared to true sound source.

The largest variance in the three populations under study could be seen using configuration 2. Configuration 2 was then selected as the current specification for the system design. Additional clinical sound localization tests were then conducted using configuration 2.

4.4 Prototyping

The team needed a way to ensure that the speakers were setup in the property position and with the right angle towards the user. When designing speaker stands the ease of assembly and disassembly as well as labeling was kept in mind. The original speaker stands were bulky and used a male piece with prongs that fit into a female piece located on the mat. They were hard to assemble and disassemble and used a large amount of material. Rapid prototyping was then used to create another six different speaker stand prototypes with the final speaker stand seen in Figure 6.

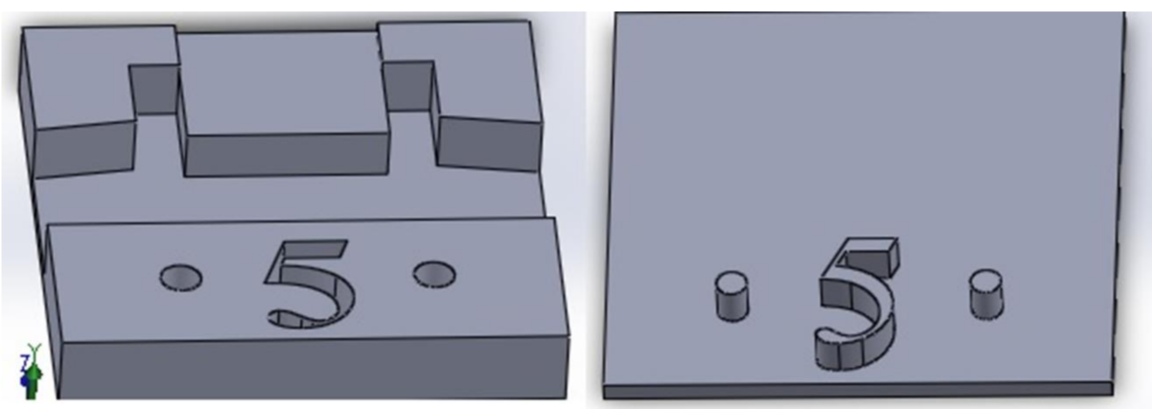

Figure 6. The final design of the speaker stand and mating assembly

Another problem that hardware was used to solve was that the speaker USB connecters needed to remain in the USB HUB untouched and that there were large quantities of extra cords which caused assembly to take large amounts of time. To solve this issue a HUB box was made using the 3D printer which allowed room to house the HUB as wells as extra cords. The top was made very secure so that it would be difficult to remove, but if the team did need to remove it for any reason that would be possible.

4.5 Software

The most important requirements identified through stakeholder interviews for the software application include: ease of use, run on different hardware setups, display different screens of information, authenticate different patients, record data in a useful manner, and send data back to the researchers. An additional requirement for the software on the engineering side is that the code needs to be modular enough to allow multiple programmers to write code at once without interfering with each other.

A Graphical User Interface (GUI) was designed to be user friendly. The software is written in MATLAB to ensure hardware independence and also to ensure continued use in the future by the CSD department; which uses MATLAB for other projects. The code is compiled into an .exe file using MATLAB's Deployment Tool. It can then be run on any computer with the proper MATLAB Compiler Runtime (MCR) installed.

The behavior of the GUI was drawn out. See figure 7 for this diagram. This drawing also shows the type of graphics object each component is. In MATLAB, graphics objects can be one of fourteen different types depending on the behavior desired from the programmer. These are push button, slider, radio button, check box, edit text, static text, pop-up menu, list box, toggle button, table, axes, uipanel, button group and active X control. Uipanel objects are very useful for containing other graphics objects. As seen in the sketch, each new screen full of information is contained on its own uipanel object. Each audio test is preceded by a directions uipanel which explains how to complete the test properly.

It was decided to segment the program up by uipanels. Every uipanel object in the GUI has a unique tag value. A unique .m file exists corresponding to that unique tag value. All the callbacks for every graphical object contained within a specific panel reside in the corresponding .m file. In addition to callbacks, each .m file has a function called runBeforeDisplay, runAfterDisplay and cleanup. These functions give the programmer a chance to run code before the panel is displayed; after it has been displayed; and also in the event the user pushes the cancel button. Figure 7 is a graphical expression of this description. The uipanel displayed at any given time is determined by a controller object. The most important method in control is the next function. Its job is to determine what panel to display next and is called when the programmer is done with whatever screen they were displaying and would like the next screen to come up. The next method makes its decision based on the current user and any error that may have taken place. It is also responsible for executing the current panel's runBeforeDisplay, runAfterDisplay and cleanup functions at the appropriate time.

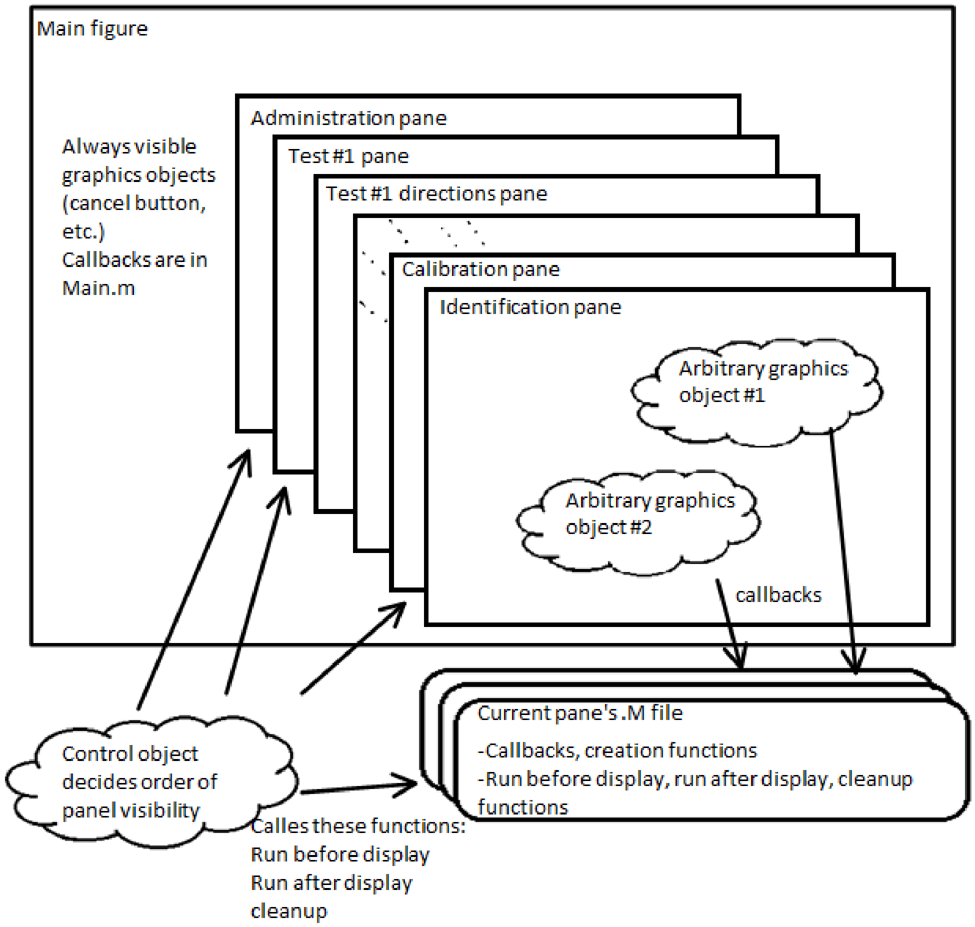

Figure 7. Framework used in the GUI. Any number of uipanels can be added to allow addition of another audio test, more instructions, etc.

In addition to the controller object, several other common tasks the program needs to complete were written into objects. This keeps code duplication to a minimum and also ensures standard behavior (when playing sounds, for instance). The program has a utility object which contains miscellaneous functions that perform such tasks as prompting the user for his/her password and reading the excel sheet containing information about the current user. There is also a sound utility object which is called when a sound needs to be played. It is responsible for ensuring that the sound plays at the proper level and from the correct speaker. The device ID problem discussed in section 4.3 is solved in this object. It ensures the right hardware is associated with the right speaker number in the program. Global variables are also used to pass information (such as the current user's name) between the many callbacks and functions in the program. The control object mentioned above also performs the common task of choosing which panel to display next. Refer to Figure 8 for a visual representation of the various objects in the program.

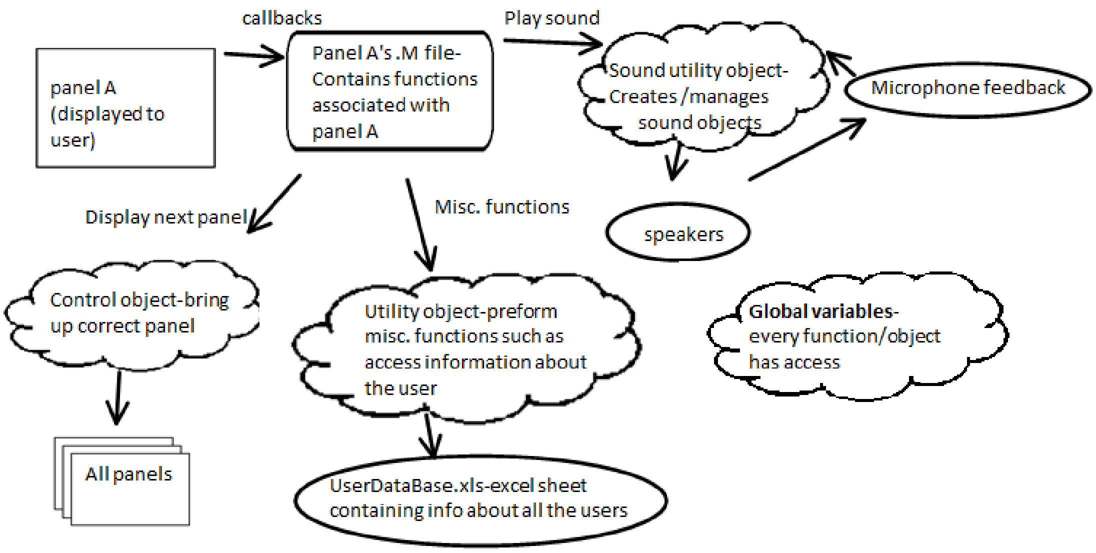

Figure 8. Other Standardized Methods in the Program

The software opens with a list of pseudonyms and the option to log in, allowing for multiple anonymous users. The data is saved separately for each user in the .xls file format. It has not yet been determined how the data will be sent back to the researchers. Current options under consideration are shipping the encrypted data back via a memory card, shipping back the entire system, and sending the encrypted data over the Internet.

4.6 Testing and Refinement

Following final selection of the speaker positioning a larger population statistical analysis was performed. The statistical analysis is explained in the following paragraph.

Data were collected from 19 normal-hearing listeners both with and without an earplug in one ear (to simulate a unilateral loss) and from four people with hearing in only one ear (called 'real' unilateral listeners, or 1 dead ear). A one-way ANOVA showed significant differences between groups ($F_{2, 37} = 21$; $p<0.001$), with LSD post-hoc comparisons showing that the binaural listeners were better than either the real ($p=0.035$) or the plugged ($p<0.001$) unilateral listeners, and a marginally significant difference between the real and plugged unilateral listeners ($p=0.04$, one-tailed). Figure 9 depicts this data graphically.

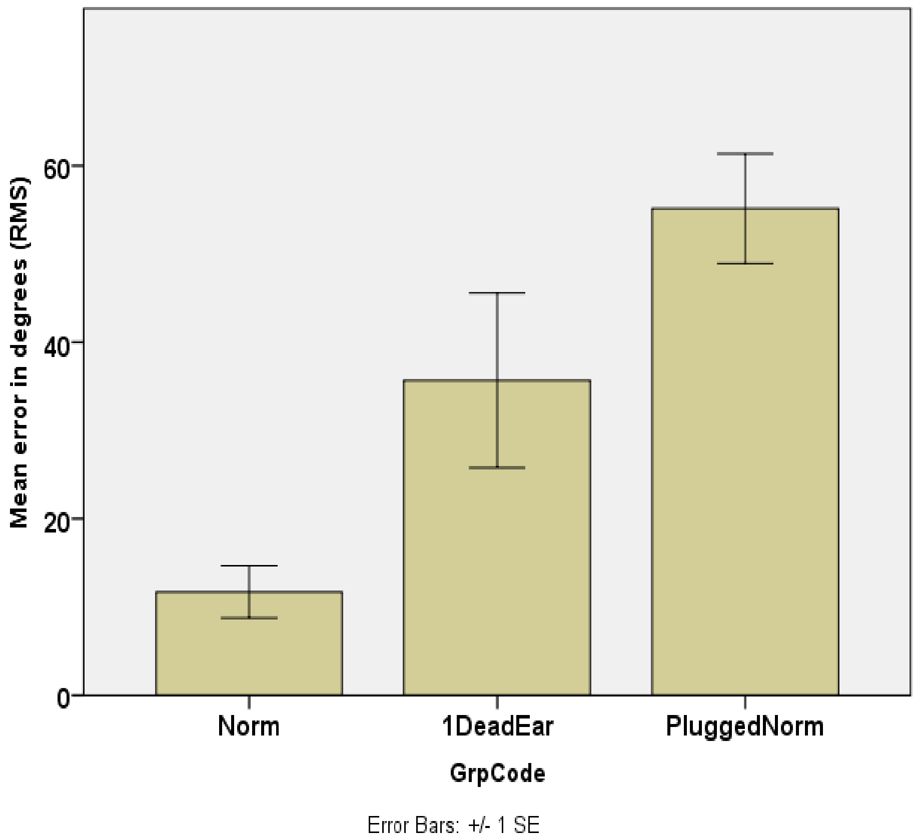

Figure 9. Results of the study. The error on Y axis is the Root Mean Squared (RMS) of the difference (in degrees) of the selected speaker and the actual speaker that was played.

Upon completing the sound localization proof on concept a naïve student unfamiliar with our project from the college of Communication Sciences and Disorders was brought into the lab and instructed to setup the system with only a hard copy of the instructions the team provided. No direction outside of the written instructions was provided to the user to simulate if they had received the system at his or her residence. The student was videotaped during the process to allow for later review by the team.

The video depicted challenges in speaker setup and assembly. Some of the following images will show some simple assembly short comings.

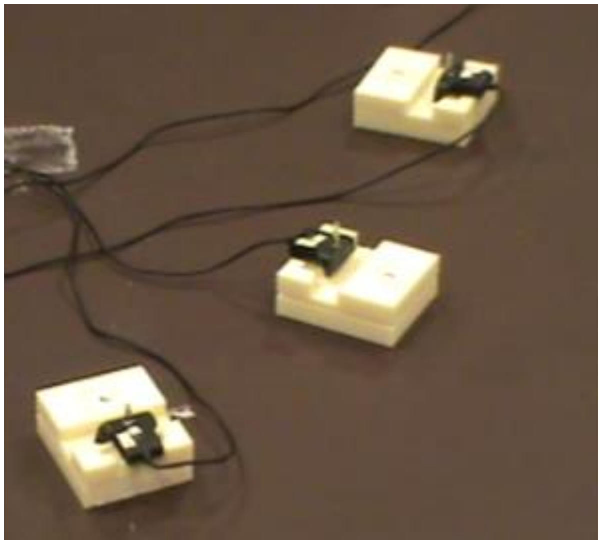

Figure 10. The user can be seen aleternating the speaker stand placements position. The image was taken when the stands still refelected the beta stand prototype, leading to the design of the omega stand prototype seem in Figure 6.

Figure 11. The user is seen trying to attach two speakers which are magnetically joined. A simple edit to the instructions resolved this issue for future users.

Following the onsite naïve test and in the field naïve test was conducted. The system was shipped in its entirety to a JMU Alumni in the Northern Virginia area who had received the corrective surgery for atresia. A written document of suggestions was generated based on a follow up conversation with the alumni after receipt of the original shipment. The recommendations of the last shipment and evaluation should serve as guidelines for the work of the junior team entering their senior design project.

5 DETAILED DESIGN REVIEW

The final set up for our system remains to be the configuration we selected in the very beginning of our project. The hardware includes the speaker stands which can be seen in the previous section noted by Figure 10. The system has successfully been shipped out to a user and the data was received. The packaging of the system was then deemed successful with no necessary needed changes at this time. The two team members left after this semester will continue shipping the system to users and modify the design as needed.

6 DISCUSSION

After having people attempt to set up the hearing system from the box it was clear that some of the instructions need to be more clear. There were also still excess wires. The two hearing tests, sound localization and the CRM test, was recording the proper data and were observed to be operating properly. With these two tests finalized there is room to add more tests to the system if need be or further gather data. The logistics of shipping the system worked out as expected however due to the users schedule it may take a long time to receive the system back. This means that two or three more systems should be developed depending on the amount of users.

7 CONCLUSIONS AND FUTURE WORK

The team has successfully completed a full prototype of the system that has few modifications needed. It meets the needs of testing the users hearing with sound localization and finding their hearing in noise threshold. The system has been shipped out with no issues and construction on a second system has been started. The two team members staying with the project will have the option to continue to test the Sound Localization and CRM programs, add new tests to the system, and increase the total number of systems available for use. There are also plans to incorporate a microphone to assess background noises during the tests to assist in validating the data.

Acknowledgements

Sofie Ganev- CSD student- Facilitated the testing for the localization and CRM tests.

Dr. Lincoln Gray- Faculty advisor that assisted in most areas of the project, including but not limited to: Matlab coding, FFT analysis, and overall knowledge of acoustics

Dr. Robert Nagel- Faculty advisor that assisted in the overall design approach to our system and subsystems

Amy Byers- Graduated CSD student- Helped for the team's first two semesters of work by allowing us to test her with our system since she has had the surgery our system is being made for

JMU students and other volunteers- Names have been kept anonymous however they took part in testing to allow the team to acquire testing data.

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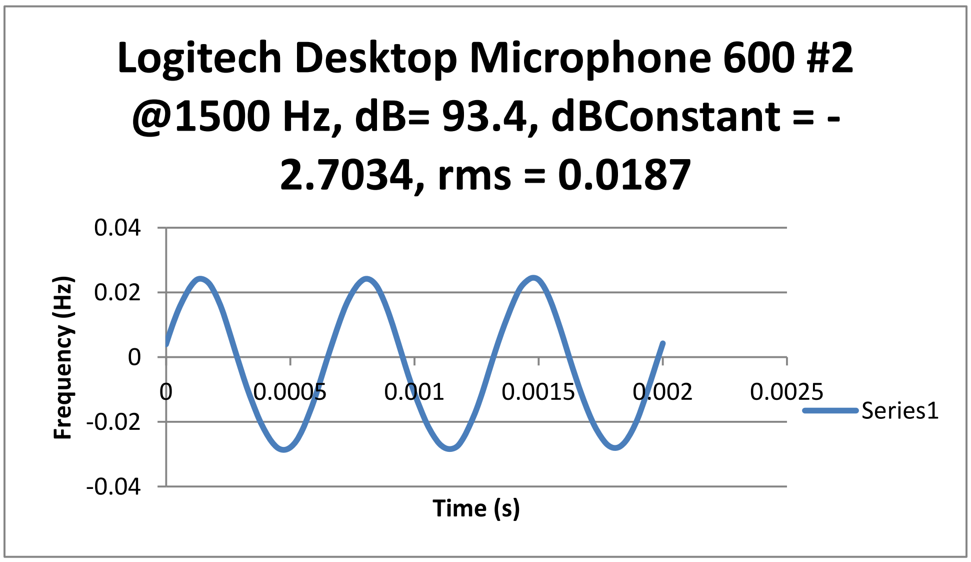
Appendices

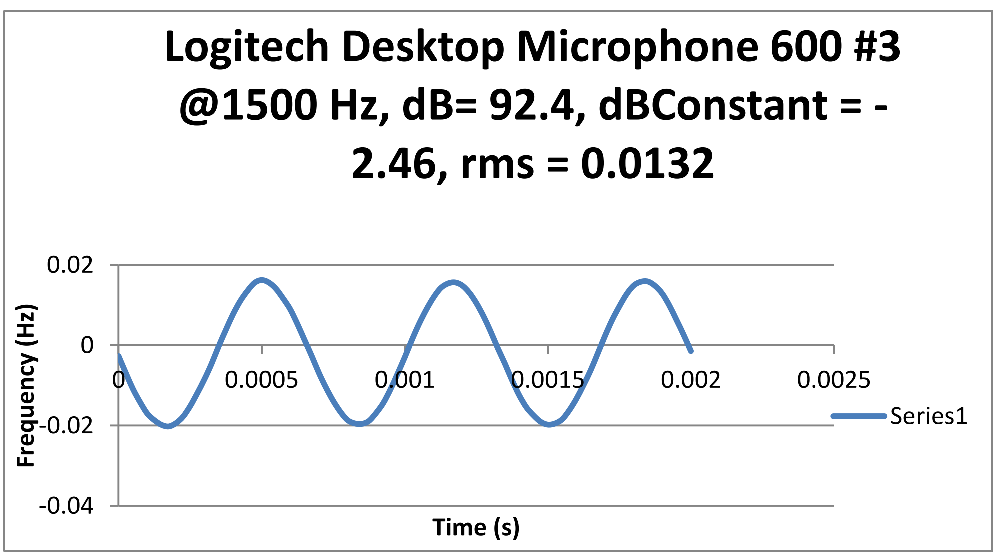
Appendix 1: Customer Needs and Target Specifications

Table 1: Customer Needs and Target Specifications

Dr. Lincoln Gray
1. Portable Hearing Evaluation System must have Instruction Manual 2. Data must be consistent in relation to hearing capabilities 3. Device must be less than traveling cost 4. Must incorporate a microphone 5. Performance levels should be better on test subjects with two ears as opposed to test subjects who have unilateral hearing loss 6. Integration of images into testing procedures to ensure user is correctly position to take test
Dr. Bradley Kesser
1. Portable Hearing Evaluation System must test 100 patients 2. Portable Hearing Evaluation System must run once a year on each patient 3. Must be able to run wide range of audio tests 4. System must return data in real time 5. Must have the ability to connect to live test administrator 6. Must be able to test sound localization 7. Approval must be granted from the University of Virginia for IRB testing
Ms. Sofia Ganev
1. Data must be received electronically and in hardcopy form 2. System must include tutorials, visual aiding helps, and manuals 3. Portable Hearing Evaluation System must be less than $500
Ms. Amy Byers
1. Portable Hearing Evaluation System must be easy to navigate 2. Equipment must be user-friendly

Appendix 2: Analysis for Microphone





Distributable Stereo Hearing Test

4/28/14
Spring 2014
ENGR 432: Engineering Design VI

Student Team Names

By signing, students consent to have reviewed the contents of this report and to agreeing with the content presented.

Brittany Harwell ____________________________

Tony Battu ____________________________

Capstone Advisor Names

Dr. Robert Nagel

Dr. Lincoln Gray

EXECUTIVE SUMMARY

The following report outlines the Distributable Hearing capstone project that was begun on September 12, 2011. The capstone project ends on May 2, 2014. The goal of the project is to provide a way to collect long-term data on patients who have unilateral hearing loss. To date, insurance companies have inhibited the collection of this data because they only cover one hearing test one month after surgery. This system will collect more hearing tests and encourage the collection of long-term data. The system will be shipped to the patient, saving them time and money that would have been spent on travel.

This report focuses on the current capstone team. In addition to preparing the system for deployment, the team developed the speech-in-noise hearing test. A paid audiologist typically performs this hearing test manually, so no standard exists for an automated speech-in-noise hearing test. Therefore, the team has had to design the test themselves. The test is, however, based on standardized tests in that it adaptively responds to the user's input. This report will define the system requirements, explore possible concepts, and then select a concept for the hearing test. The design of the test was conceptualized, implemented, and debugged. Then, the test was used to test the hearing of volunteers. The results were analyzed and proved that the test can distinguish between unilateral and bilateral listeners. Next the speakers used in the test were analyzed using an artificial head and head related transfer functions. In tandem, the system was prepared for deployment. Specifically the speaker stands were redesigned from concept to detailed design. This report demonstrates the application of the design process using the 2011-2013 team's system as a starting point.

1 INTRODUCTION

This interdisciplinary project began in September 2011. A capstone team that graduated last year completed their portion of the project in May 2013. The current team joined them from September 2012 until May 2013 and will continue to work on the project until May 2014. The project works closely with the Communications Sciences and Disorder department to create a hearing test system that the department can eventually use to collect long-term data on patients. This project is also intercollegiate in that the stakeholder is Dr. Kesser from the University of Virginia. Due to this collaboration, the team was eligible for a grant from 4-VA. The team applied in May 2013 and was awarded a grant of $4673. The team has used the grant to buy more supplies. The team will construct at least two testing systems for deployment to UVA and to patients' home. The grant allows the team to accomplish its goal of deploying a hearing test system to a patient's home.

1.1 Problem Statement

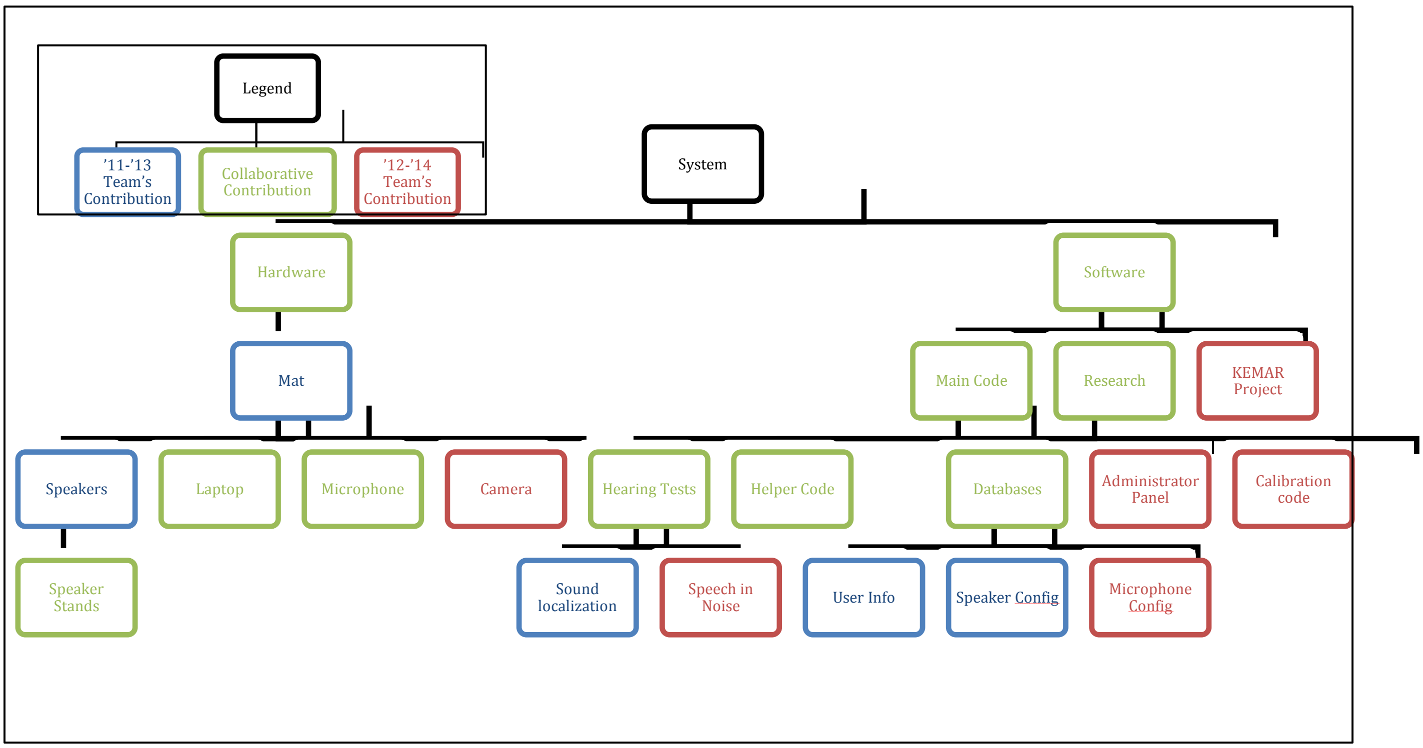
The localization and identification of sounds in background noise are such important auditory processing skills that any amount of incompetency may lead to various confusions and learning delays. Through a partnership with James Madison University (JMU) and the University of Virginia (UVA), a unique opportunity exists to test patients before and after a corrected maximal conductive hearing loss in one ear. Patients with congenital aural atresia come to UVA for surgery that will give them normal hearing. Insurance pays for a pure tone threshold hearing test one month after surgery, but due to cost restrictions, longitudinal follow-up testing is often not performed. However, longitudinal data from follow-up studies is essential for understanding the effectiveness of the surgery. This project is about the design, construction, and testing of a shippable hearing test system for patient testing. The system will test two binaural hearing abilities—the ability to isolate a spatially separated signal from noise and the ability to localize the source of a sound.

1.2 System Breakdown Based on Capstone Team Contribution

This capstone project is unique in that it collaborated with a capstone team its first year. The 2011-2013 team (henceforth referred to as '13 team) designed and created the basic framework of the project and also designed the sound localization hearing test. This team, the 2012-2014 team (henceforth referred to as '14 or current team), has focused on the second hearing test: speech in noise. This test is much more involved because it is adaptive based on user input. Additionally, this team has worked to improve and ready the entire system for deployment.

The system can be broken down into the hardware and the software components (Figure 1). The hardware consists of a mat on which speakers, speaker stands, a laptop, a microphone, and a camera are placed when the patient receives the package. The code to use the speakers was collaborated on between the two teams. The '13 team wrote the methods for playing both stereo and mono sound out of the speaker. The speaker stands were initially created by the '13 team. They printed prototypes on the Stratasys 3D printer, but the '14 team came up with refinements that would eventually make the system easier to set up by employing design for assembly techniques. The refined speaker stands will be covered in more detail later in the report. The software components of the project mainly focus on facilitating the two hearing tests: the sound localization test and the speech in noise test. The ’13 designed and validated the sound localization hearing test. The test plays broadband noise from a random speaker at a random intensity and the user has to answer which speaker it played out of. They collected data using their test and validated that the test could discriminate between unilateral and bilateral listeners. This team, the ‘14 team, is designing the speech in noise hearing test based off the Coordinate Response Measure (CRM). The ’13 team designed the graphical user interface layout and the control code for the software. The ‘14 team used this software to create their hearing test. The ’13 team provided a system that acts as a constraint for our project. More information is in the appendix binder.

Figure 1: System Breakdown Based on Contributions of the Two Capstone Teams



1.3 Broader Impacts

Socially, the new found research and studies will advance the understanding of the brain’s response to a new, surgically corrected ear. The audiology community will benefit from the collection of long-term data on congenital aural atresia patients because they provide a unique opportunity to study binaural processing. The audiology community has the potential to gain more knowledge on how the brain adapts to new hearing abilities. The additional information will help to answer if a critical period exists for developing binaural hearing abilities. After the critical period the brain may not be able to recognize the auditory inputs so it is important for pediatricians to diagnose the patients before this critical period. The research may provide justification to perform the surgery immediately after diagnosing a patient. In addition, some further implications of the new research may eventually be able to explain why males are more likely affected than females with aural atresia.

Environmentally, the project reduces the energy needed to obtain hearing test data given transporting a laptop to a patient consumes significantly less energy than transporting the patient to a testing facility. Furthermore, the system will be shipped to the patients and back, so there is a reusability aspect to the project.

Technically, the platform on a laptop enables the user to be familiar with the system due to standardized mappings. The program is divided into modules to facilitate addition of new audio tests and displays.

Economically, the project will save money for the patients mainly by drastically cutting commuting costs. The price of shipping this testing package was compared to the alternative of having patients travel to a sound proof room and have an audiologist administer these binaural hearing tests. In order to do so, a scenario was created to estimate the cost to ship the system to 40 patients twice a year for five years. This scenario assumes that the system is being shipped to and from San Diego, California because it will probably not be sent out of country so this represents the furthest distance the system will possibly travel. A comparison of cost to receive packing within 5 days between companies was performed and the cheapest company was chosen: UPS, assuming the package weighs less than 20 lbs. The total shipping cost was calculated using equation 1.

$$Total\ Shipping\ Cost = t * n * y * r \tag{1}$$

where t is number of shipments in a year, n is number of patients the system will be shipped to, y is number of years, and r is shipping rate of cheapest company. As stated before, the package will be shipped twice a year over five years. Here it is assumed that 40 patients will participate. The total theoretical cost of the shipping method is $35,000.

This cost was then compared to a scenario where the patient must travel for the same testing. The trip was assumed to be for a family of four traveling from San Diego to Harrisonburg over two days. Some of the other assumptions include:

- Cost of Gas: $3.50
- Cost of a meal: $5.00
- Doctor Fees: $25.00
- Audiologist Fees: $25.00
- Parking at hospital: $20.00
- Hotel cost for 1 room for 1 night: $100.00
- Miles from San Diego to Harrisonburg: 2556
- Car driving receives 25 miles/gallon
- Every individual on trip eats 2 meals per day

Next, the total cost of driving (includes there and back) is determined using equation 2.

$$Cost\ of\ driving\ = \left(\frac{Cost\ of\ gas}{\frac{mil}{gallon} of\ car} * miles\ of\ travel\right) * 2 \tag{2}$$

The total cost of meals was calculated by multiplying the number of people traveling, the cost of one meal, the number of meals per day, and the total days traveling. The total cost for one trip was calculated by summing the cost of driving, total cost of meals, cost of hotel for one room and one night, parking fees, doctor fees, and audiologist fees. The total cost for one of the trips under the assumptions stated is $965.68. The patient would be required to take 2 trips yearly for five years. For 40 patients the total cost was $386,000. The portable hearing system resulted in $35,000. This means that this portable hearing test system would result in over $350,000 saved over 5 years.

Another comparison of the shipping and travel cost was computed to compare the short-term cost of the system. Figure 2 compares the shipping cost and travel cost of one patient using the system.

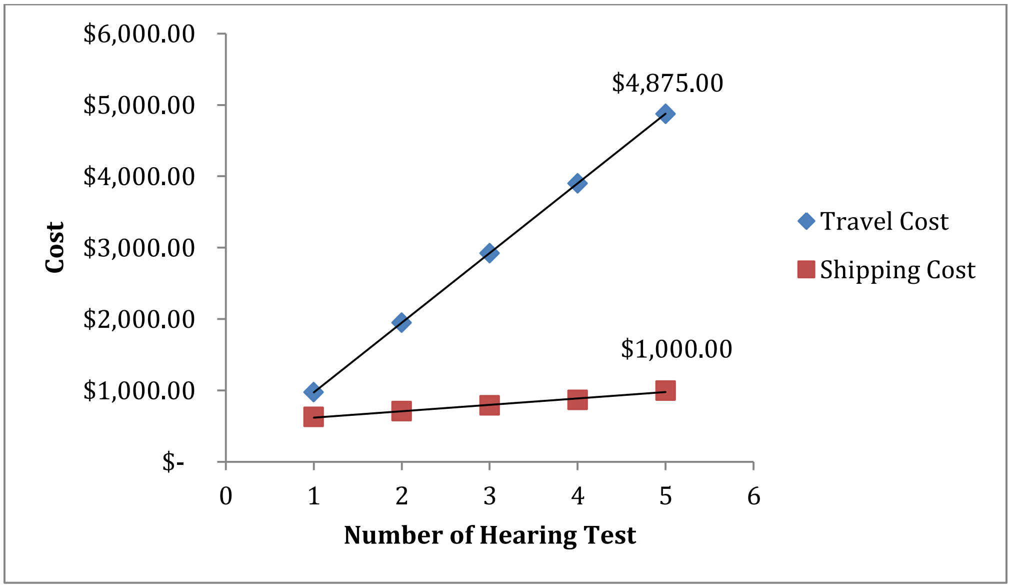


Figure 2: Comparison of Cost to Travel vs. Ship Our System

The shipping cost consists of the cost to build the system ($550) and the shipping cost to send the package. The travel cost consist of all the travel expensive previously stated before. After one use of the hearing system package the patients would save over $400.

Additionally, the time and stress saved from less travel for these patients is as substantial but much more difficult to quantify. It could be assumed that the patients' and their families would lose two weekends a year for five years and this time could affect the children's performance in school. The excel spreadsheet, including assumptions and calculations, and full analysis are attached in the appendix binder.

1.4 Report Overview

The following report will outline the design process followed since September 2012. The literature review will explain the subject group and the existing hearing tests and concepts. Then the system requirements will be investigated and articulated. The concepts found in the literature review will be evaluated and a final concept for the speech in noise hearing test will be selected. The report will then outline the preliminary design, describe testing and refinement and resulting detailed design and analysis. Finally, the project management will be described in terms of team, project management, and future work. All appendix material is located in the team's binder. The binder is organized in the same order as the paper (each tab is a section) and includes the paper within each section. This way, a person can choose to read the report by paging through the binder, appendix material providing a deeper look at the process.

2 LITERATURE REVIEW

Congenital aural atresia is a condition present at birth where an area of the ear is deformed due to failure in the overall development and structure of the auditory canal (De La Cruz 2003). Some of the abnormalities include malformation of the middle ear, but most of the deformities occur in the outer ear (Jahsdoerfer 1978). Still, the inner ear can develop normally. Congenital aural atresia may occur bilaterally, but in most cases patients typically have unilateral atresia. Aural atresia occurs in 0.01% – 0.02% of births (Teufert 2004). In addition, aural atresia is more prevalent in a patient's right ear rather than left ear, and is found in more male than female patients (Jahsdoerfer 1978). The surgery to repair congenital aural atresia involves drilling a new external auditory canal and the construction of a new tympanic membrane (Wilmington 1994). The goal of surgery is normal or near normal hearing. Within one month most patients then appreciate air-conducted sounds in their ear for the first time (Jahsdoerfer 1978).

Subjects with this condition are of special interest to the audiology community because they transition from unilateral to bilateral hearing. How does the brain adapt to the new ear and is there a critical period for auditory development? Patients with corrected unilateral conductive hearing losses provide an opportunity to examine the roles of abnormal early experience on multiple aspects of binaural processing (Wilmington 1994). There may be distinct levels of binaural processing which are affected differently by a long-term asymmetry between the two ears (Wilmington 1994). Longer follow up is likely critical for understanding patients' binaural processing ability (Gray 2009). A new ear may be challenging for the youngest and oldest subjects (Gray 2009). However, longitudinal data is needed. Patients need to be evaluated at times longer than four to five weeks post-surgery. Perhaps binaural performance simply means that teens and young adults adapt more quickly to their repaired ear, and the young children and older adults take longer to adapt (Cole 2009). Future testing should be conducted under more controlled conditions than those used in Wilmington et al (Cole 2009). Cole suggests that, "an array of small, high quality speakers could be mounted in an arc within a typical audiometric sound booth. Then the testing conditions would be somewhat symmetric and replicable" (Cole 2009). The use of an audiometric sound booth was ruled out because of monetary limitations. Insurance pays for a pure tone threshold hearing test one month after surgery, but due to cost restrictions, longitudinal follow up testing is often not performed (Allen 2013). However, longitudinal data from follow up studies are essential for understanding the patients' binaural hearing ability and improvement (Allen 2013).

2.1 The Hearing Tests

Children studied had significantly more difficulty understanding and localizing speech, especially in the presence of background noise (Kesser 2013). There are two advantages of binaural hearing: 1) the ability to localize sounds in space and 2) the ability to detect sounds in background noise (Wilmington 1994). Therefore, this project has focused on creating hearing tests that test these. The 2011-2013 team tackled the sound localization hearing test whilst designing the framework software and hardware. This team, the 2012-2014 team, using the other team's system as a constraint is tackling the test of the ability to detect sounds in background noise. There is no systematic evaluation of how congenital hearing losses affect binaural processing (Wilmington 1994).

The 2011-2013 team designed the sound localization hearing test. The current system conducts a sound localization test that determines whether the patient can locate noise in a normal reverberant space (Allen 2013). Twenty-seven participants were tested using the system and the sound localization hearing test. The participants were grouped into Normal listeners (hearing within normal limits), Real Unilateral listeners (subjects with profound, single-sided sensorineural hearing loss), and 'Fake' Unilateral listeners (subjects from Normal listeners group with a plugged ear to simulate hearing loss) (Ganev 2013). Comparison showed a significant difference between the performance of Normal subjects and Real or Fake Unilateral subjects ($p<0.001$) (Ganev 2013). These results provide promise as to the effectiveness of the designed testing package (Allen 2013).

Before the patient undergoes surgery, Dr. Kesser performs a test on the patient's hearing abilities using an audiogram. Typically the pre-test results in a mean pure tone average for the atretic ear of 64 dB and the mean asymmetry of 56 dB between the two ears (Besing 1995). Post-surgery provides a mean pure-tone average for the atretic ear of 34 dB, which proves that the surgery provided significant results (Besing 1995). However, testing using an audiogram only proves that the patient can hear out of the new ear. Patients have the ability to do simple binaural detection tasks soon after surgery, but have difficulty in more complex processing such as localization and speech comprehension (Wilmington 1994). Audiograms do not predict binaural abilities and abnormal binaural performance can be seen in patients with normal audiometric thresholds (Wilmington 1994).

2.2 The Head Shadow Effect

This team has been developing the hearing test that will test the ability to distinguish speech from noise. Unilateral hearing loss results in difficulty hearing in background noise, referred to as the "cocktail party effect" (Gray 2009). Bilateral hearing can improve understanding due to simple redundancy and due to the physical head shadow effect (Gray 2009). Before surgery the only ear able to hear receives the signal with a poor signal to noise ratio. After surgery the noise to the newly opened ear is attenuated by head shadow (Gray 2009). Improvement in this condition would suggest that patients are able to understand signals in their new ear, now with a favorable signal to noise ratio. A separate phenomenon, binaural squelch, can also significantly improve speech understanding in noise (Gray 2009). Binaural squelch is “a centrally mediated segregation of a signal from noise when that signal and noise are at different locations producing temporal and intensity differences at the two ears” (Gray 2009). Essentially, it is the lack of the head shadow effect. Before surgery, hearing is easier when distracting noise is on the side of the atretic ear. After surgery, this condition is more challenging because there is suddenly a new noise that must be ignored, allowing binaural processing for the first time (Gray 2009). This condition is a test of binaural squelch. Therefore, our speech in noise hearing test must test for these conditions. Additionally, it is common practice to include a practice test. Wilmington et al. gave a practice test before their actual test where the subjects set the babble to an initial barely audible level, ensuring the sentences were easily understood at the start of practice. Then, in the real test, the level of the babble was adaptively varied (Wilmington 1994).

2.3 Existing Speech in Noise Tests

There are many speech in noise tests that already exist. These tests provide use with concepts from which to choose for use as or as a part of our hearing tests. The Hearing in Noise Test (HINT) is a commercialized test where participants are tested in double walled sound attenuating chambers (Gray 2009). Two speakers are mounted at ear level, ninety degrees apart in adjacent corners of a testing booth. Subjects always face the speaker that presents the speech signal (Gray 2009). The subjects were tested in two conditions: one with noise towards the atretic ear and another towards the non-atretic ear. The intensity of the noise was adaptively varied to find a threshold for understanding speech in noise (Gray 2009). The subject must repeat the whole sentence exactly. Therefore, the HINT requires a licensed audiologist to administer and is not automatable.

Another speech in noise test is the SPIN and the Pediatric Speech Intelligibility test, which is the version used for children. The Revised SPIN has two speakers: one plays the sentence and faces the subject and the other plays babble (twelve people reading at one) at ninety degrees to the subject’s gaze (Wilmington 1994). Subjects are tested once with atretic ear closest to the babble (‘easy’ condition) and once with the normal ear closest to the babble (‘hard’ condition). The test operator documents whether subject correctly repeats the final word. No feedback is given (Wilmington 1994).

The standard QuickSIN and the BKB-SIN are two similar tests in that a CD is played through headphones or in a sound field where the babble is located ±45° from each ear and the main speaker is located both 0° and 180° from the listener (QuickSIN™ Etymotic, n.d.). The listener must repeat the sentence that the main speaker says despite the babble (background talkers). The background talkers gradually become louder. The subject uses a microphone to communicate his response to the tester (QuickSIN™ Etymotic, n.d.). Scoring is done by tester and is too difficult; additionally, some normal subjects could not obtain 50% correct score because the sentences are too difficult.

Finally, the Coordinate Response Measure (CRM) is a speech corpus for multitalker communications research. The speech corpus was collected in order to precisely control the talkers as speech stimuli. In order to do so, digital recordings of talkers was determined to be preferable to live talkers (Bolia 1999). The CRM is a nonstandardized communication performance task adapted from similar tasks by Moore (1981) as a measure of speech intelligibility (Bolia 1999). It is simply a free compact disc of phrases useful for an audiological test. The phrases of the CRM consist of a call sign and a color-number combination all embedded within a carrier phrase. A typical sentence: "Ready baron go the blue five now" where baron is the call sign and blue five is the color number combination (Bolia 1999). Each listener is assigned a call sign and must indicate the color number combination spoken by the same speaker who said the listener's call sign. Possible measures of the CRM include percentage of correct call sign detections, percentage of correctly identified color number combinations, and the reaction times (Bolia 1999). The corpus is versatile and easy to use and implement.

3 SYSTEM REQUIREMENTS AND ANALYSIS

The goals of this team have been to develop and design a speech in noise hearing test, finalize the software for use, and prepare a system for ship to UVA Otolaryngology for data collection. Then, the goal is to prepare a system for shipment to a patient's home. The two systems have different requirements: the system that will be shipped to UVA will be called the Alpha Prototype. The system that will be shipped to patients' homes will be called the Beta Prototype. The two will have similar requirements, but the Beta will need to be more automated in terms of checking for correct set up and monitoring the user during testing. There will be an administrator (a person familiar with the system but not an expert) who will be available to help with set up of the Alpha Prototype. Both prototypes require the two hearing tests: speech in noise and sound localization. The sound localization test is completed. This team is focused on the speech in noise test. From literature review, the head shadow effect is an area of interest. Therefore, the hearing test should evaluate speech in noise abilities when head shadow is greatest and when it is least. These prototypes were developed under the following constraints: the existing distributable hearing test system, MATLAB, computer processing abilities, and testing time should not exceed 2 hours in order to avoid subject fatigue.

3.1 Alpha Prototype

The Alpha Prototype is an entire system that was sent to UVA for clinical testing. The system includes a laptop, mouse, eight speakers, speaker placement indicators, microphone, power supply, and instruction manual. The instruction manual is located in the appendix binder. This system will be set up by someone familiar with the system, so this administrator can check that configuration is correct manually. It guides the user through the software and allows for the user to quit if necessary. It tests the user's ability to localize and distinguish sounds from noise. The speech in noise tests the user's ability to use the head shadow effect for binaural processing. Table 1 shows the system requirements, target specifications, ranking, and completion status of the alpha prototype.

Table 1: System Requirements for Alpha Prototype (Rank: 1 is most important, 5 least)

Requirement	Technical Specification	Rank	Completed	✓
Speech in Noise Test	A test of how well a subject can use the head shadow effect to distinguish speech in noise	1	Our CRM test: A test that plays noise and CRM at same time, waits for a response from user, then uses users response to guide the next iteration	✓
Sound localization test	A test of how well subject can localize a sound	1	'13 Team completed this. '14 Team adjusted the volume levels to a more appropriate one.	✓
Save data in a useable form	Data is easily accessible and analyzable	1	A single Excel file that saves all the data from each test, calibration run, and information about aborted tests in different sheets	✓
Practice Loop for speech in noise	A series of runs where data is not saved and there is no adaptive procedure, the user is simply getting used to the test.	1	The training loop is just like the rest of the test except the user has to get 5 in a row correct and the noise level does not change in response to user input	✓
Working set of hardware	The system works when it arrives at destination	1	Used existing, working set of hardware	✓
Set up is intuitive and repeatable (assuming instructions are given)	Way to guide speaker placement to fit testing standard	1	Mat with speaker stands attached whose mate lays out the wires correctly	✓
Requirement	**Technical Specification**	**Rank**	**Completed**	✓
Sent to UVA Otolaryngology	Arrives at UVA	1	Successfully sent to UVA on January 28, 2014	✓
Verify Set up using administrator (familiar with system but not expert)	Interface for admin to check that configuration is correct and working properly	2	Speaker configuration option on administrator panel	✓
Communicate with user about progress	Way to guide user through test so they always know what is going on	2	Dialog boxes that explain what will happen, when parts of the tests are completed	✓
Test head shadow effect during speech in noise test	Run test out of speakers that create the greatest and the least head shadow effect	2	KEMAR testing to find optimal speaker combinations	✓
Instruction manual	A list of instructions for how to set up system and how to use software	2	A set of instructional steps to guide user through set up and software use	✓
User can quit testing anytime	Way to quit testing	2	Abort button	✓
Control volume - max	The signal is quiet enough that the user does not get so many right that the noise becomes too loud and invokes pain	2	Set the level of the signal very low	✓
Control volume - min	Some way to make sure the user can hear the signal before adaptive procedure	3	During training loop, set so that if user gets more than 2 in a row incorrect, the signal level is increased. The software automatically sets their minimum signal volume	✓
Calibration	Records background noise	4	Calibration pane records background noise and root mean squared	✓
Encourage user with positive feedback	Positive words come up at the end of sections and tests	5	Add positive words to dialog boxes that instruct and guide user	✓

The Alpha prototype was completed and shipped to Dr. Kesser at UVA on February 4th 2014. Then the Alpha was analyzed to determine failure modes. The high criticality failures identified in the failure modes and effects analysis (FMEA) are shown in table 2. The full analysis is shown in the appendix binder.

Table 2: Excerpt from Failure Modes and Effects Analysis

Failure	Mode	Effect	Criticality	Action
No sound	Speaker plug broken	Test cannot proceed	high	Minimize possibility of speaker breaking
Lost system	System never sent back	Loss of a system and cost to replace	high	Discourage user from keeping laptop and system
Allows user to cheat	Someone else takes test in place of patient and/or patient gets very close to speaker in order to hear it	Invalid data	high	Monitor the user while taking the tests
Speakers play at different dB levels	Hardware volume levels changed	Biased test	high	Automate to verify set up of speakers (volume)

These failure modes informed the design of the improved prototype by creating additional system requirements.

3.2 Beta Prototype

The FMEA informed the improvements on the Alpha prototype. The Beta prototype will meet the requirements listed in Table 3 in addition to the requirements for the Alpha prototype. It will improve the speaker stands so that they minimize the possibility of the speaker plug (the more expensive part) breaking. The speaker stand should be able to withstand some acceptable amount of fatigue. If the speaker stand breaks, the person may not be able to test. However, if the speaker breaks, then the user will definitely not be able to complete testing. It will also have to automatically verify correct set up by recording the volume of the speakers. To verify correct locations of speakers, the system could play and record sound from each then ask the user to verify that it is the correct speaker in the correct location. Since the system will be sent to patients' homes, there should be some secure way to send their data. It may help discourage them from keeping the laptop if they have to send it back in order for their data to be processed. Since we do not record their real names on the machine, this means their data is secure and this would be a secure solution.

Table 3: System Requirements for Beta Prototype (in addition to those for Alpha)

Requirement	Technical Specification	Rank	Completed	✓
Minimize possibility of speaker breaking	Stand allows speaker to pop out if too much force is applied	2	Analyzed speaker and designed a stand that will break or release speaker before speaker breaks	✓
Discourage user from keeping laptop	Set up laptop so that it only has necessary applications and cannot access internet	2	Collaborated with Ms. Rothgeb for assistance in setting up new laptops	✓

Monitor that the user is taking the test correctly and that user actually took test	Video and audio monitoring	2	Will integrate video and audio monitoring either into the matlab program or into the instruction manual	✓
Automate set up verification - speaker volume	Records levels of each speaker for verification later	3	Level check that plays each speaker and records output into data file	✓
Automate set up verification - speaker location	Verifies that speakers are numbered correctly and in the correct position	3	Administrator checks the hub box is set up correctly before shipping using speaker configuration panel.	✓
Ensure speaker stands will last	Speaker stands will fatigue after 10 cycles	3	Will fatigue test speaker stand design	X
Send data	Provide a secure way to send data back for analysis	4	Forcing them to send back laptop in order for data to be processed will discourage them from keeping it	X

The speaker location set up verification was not completed because the numbers will be clearly marked and tested before shipping the system. The speaker configuration panel can be accessed by an administrator to check that set up will be correct after set up. It was decided to not provide a secure way to send data back and forth except by sending the entire system. This is because we want to incentivize the user to return the $550 system, especially the laptop. The user will spend about two hours setting up, taking the tests, and disassembling the system. He must want results; so making him return the system to us in order to get those results will ensure we retrieve the system.

4 CONCEPTUAL DESIGN AND ANALYSIS

In this phase, concepts were benchmarked and developed. The team has focused on designing the speech in noise hearing test and readying the system for deployment to two locations: 1) UVA Otolaryngology clinic and 2) patients' homes. When readying the system for patients' home, it is necessary to consider the implications of the speakers breaking. If the patient is able to break components during set up, then he will be unable to complete testing.

4.1 Concept Generation

Concepts were developed for the Speech in Noise Hearing Test and for the design of the speaker stands. The Alpha Prototype required the hearing test, because the prototype that was sent to UVA needed to be able to administer both hearing tests and this one was still in development. Since acceptable speaker stands were available thanks to the previous team, they were used for the Alpha Prototype. The team is working on improving the speaker stands in order to meet the Beta Prototype requirement that the possibility of the speaker plug breaking is minimized.

4.1.1 Speech in Noise Hearing Test

Concepts were generated based on literature review. The possible concepts were determined through researching existing speech in noise tests. An overview of these tests is shown in Table 4. The Hearing in Noise Test (HINT) is a commercialized speech in noise test where a signal is played at the same time noise is played. The signal is a sentence and the participant must repeat the whole sentence exactly. The signal is varied based on the participant’s response. The HINT-C is similar but it is a version specifically for children. The sentences are at a child’s understanding level. The Speech in Noise (SPIN) is a speech in noise test where babble is varied which the target is held constant. The target for the SPIN is a sentence where the participant has to repeat the last word of the sentence. The equivalent test for children is the Pediatric Speech Intelligibility (PSI) where the only difference is that the child responds by pointing to an icon on a card. The Coordinate Response Measure (CRM) is a non-standardized corpus of sentences available for use. The corpus suggests that the sentence be played along with twelve other competing sentences. The listener has one call sign and must listen for his call sign and the color-number combination that speaker says. The QuickSIN and BKBSIN are very similar to each other except that the BKBSIN can be used by children and the sentences are different. Both increase the background talkers based on the subject’s answer. The subject must repeat each sentence.

Table 4: Existing Speech in Noise Tests

Age (year)	Test	What is varied	What is constant	The participant's task was to
≥ 13	HINT	Signal	Noise at 65 dB (A)	Repeat whole sentence exactly
≤ 11	HINT-C			
> 9	SPIN	Babble	Target at 30 dB SL	Repeat last word of sentence
≤ 8	PSI			Point to icon on card
Undefined	CRM	Call sign and Color/number combination	Subject's assigned call sign	Identify the color/number combination spoken by the same speaker who said his assigned call sign
Undefined	QuickSIN	Background talkers	Signal	Repeat each sentence
All	BKBSIN	Background talkers	Signal	Repeat the sentence

This team’s task was to use the concepts to develop a test that would work within our constraints.

4.1.2 Speaker Stands

Concepts were generated to help redesign the given speaker stands. The current stands risk speaker breakage because the speaker base it attached securely with glue to the stand. This secure attachment means that the speaker rod runs the risk of breaking in transit or during set up. Therefore, adjustments will be made to the speaker attachment area. The extruded pieces and corresponding matching pieces are not extensive enough. Currently, the speakers wobble when the male and female pieces are matched. The previous speaker design can be seen in Figure 3 where the speaker is glued to the base (circled area) using super glue.

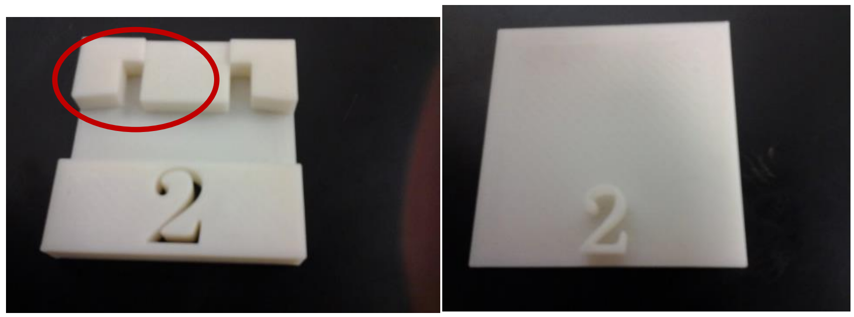


Figure 3: Female piece (Left), Male piece (Right)

Other preexisting designs were benchmarked to find a solution to help redesign the speakers' attachment point. Figure 4 is an attachment of a commercial flashlight that is used to clip the flashlight onto a person's belt. This design uses a clip attachment to easily allow this piece to be added and taken apart. To remove the clip attachment a person would apply a downward force onto a peg to allow the clip attachment to slide off. The clip attachment can easily be added onto the flashlight by sliding the appropriate piece back onto the flashlight.

Figure 4: Flashlight clip

The clip attachment on the flashlight can easily be added and removed unlike the glued speaker stands on the previous design. The flashlight holder has grooves that are pointed outward that help to hold the clip attachment in place. This gives a snug fit for the clip attachment in the flashlight holder.

After benchmarking, a morphological matrix was used to generate multiple solutions. The main parameter for the matrix was to have a design that would allow for a quick release (preferably) or break when a substantial force is applied to the speaker stand rod. Some of the concepts that were brainstormed include: rubber bands, Velcro, press fit, and snap fit. The morphological matrix can be found in the appendix binder.

Concept 1: Rubber bands

In the first concept the speaker stands would be attached and removed using rubber bands as seen in Figure 5. Multiple small rubber bands would be wrapped around the speaker holder and speaker stand. The rubber bands would allow the speaker holder to be easily removed and attached.

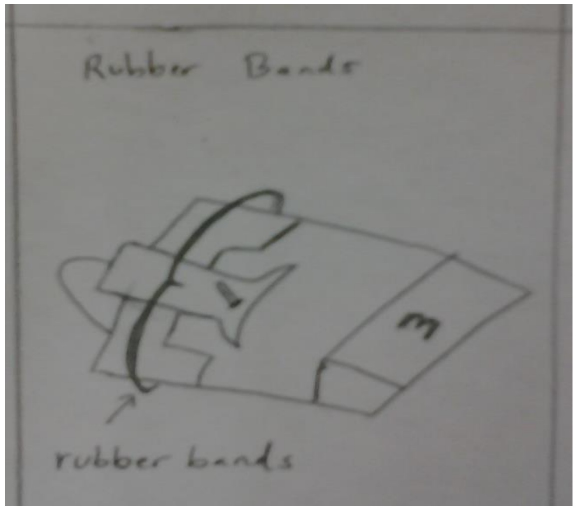


Figure 5: Rubber band conceptual design

Concept 2: Velcro

The second concept included using Velcro to attach the speaker stands to the speaker holder. The bottom side of the Velcro would be super glued onto the bottom of the speaker stand and on the bottom of the speaker holder (Figure 6).

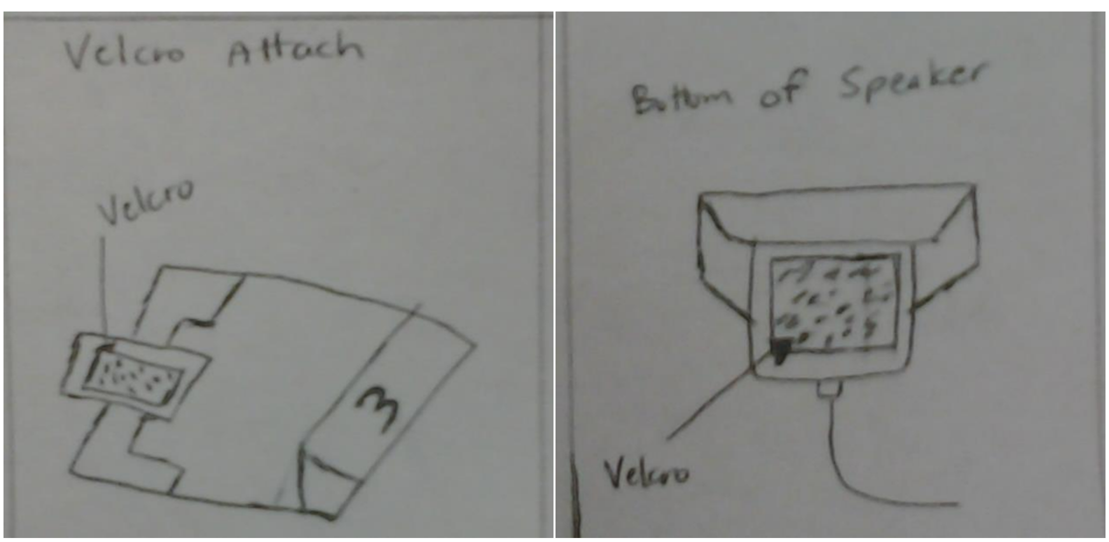


Figure 6: Velcro conceptual design

Concept 3: Press fit

The third concept includes press fitting the speaker stand holder to the speaker stand. In press fitting the two parts would have tight enough tolerances to create a press fit between the stand and the speaker (Figure 7).

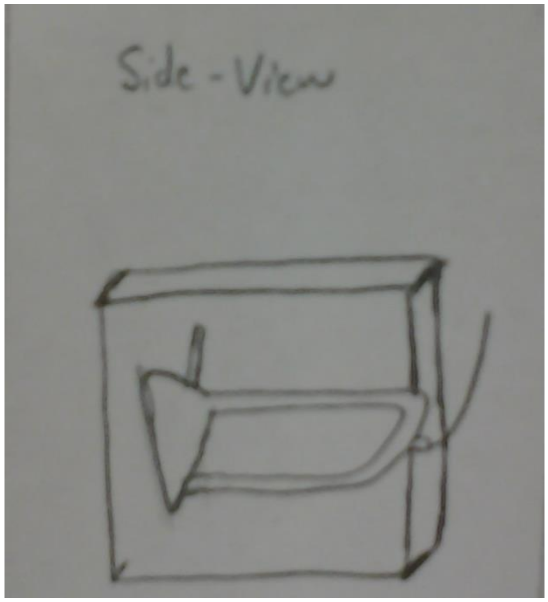


Figure 7: Press Fit conceptual design

Concept 4: Snap fit
The fourth concept includes adding clip attachments onto the speaker stand to hold the speaker holders in place. These pegs would barely hold the speaker in place. They could have a curved triangular top that would allow the user to comfortably remove or re-attach the speaker, if necessary (Figure 8).

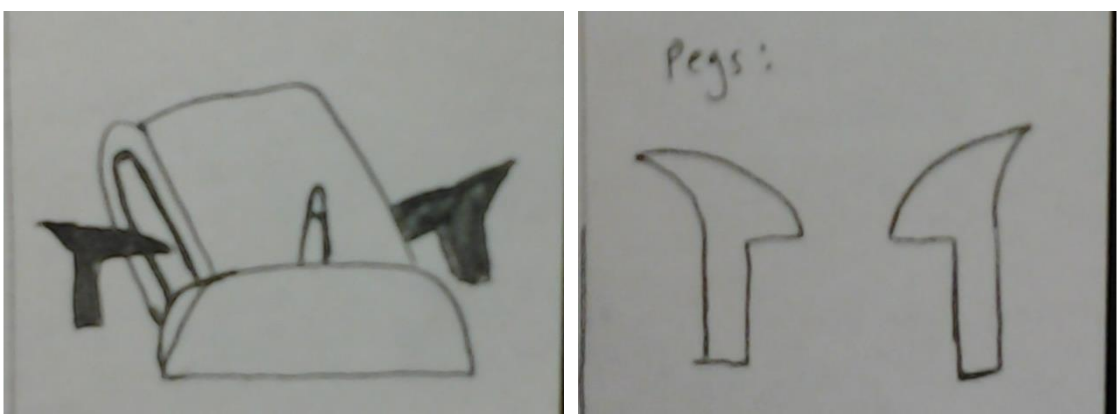


Figure 8: Clip attachments conceptual design

4.2 Concept Evaluation
This section discusses how the concepts were evaluated. The evaluations made in this section guide the process of selecting a concept. For the speech in noise hearing test, the

concepts turned out to be useful for different aspects of the project. For the speaker stands design, the concepts were evaluated using a decision matrix.

4.2.1 Speech in Noise Hearing Test

All of these concepts will provide a speech in noise threshold that can be used to quantify a person's binaural hearing. The problem with the HINT/HINT-C, SPIN, PSI, QuickSIN, and BKBSIN is that they require a test proctor. The next sentence depends on the subject's response. The CRM is the only concept that is automatable. It is a readily available corpus of .wav files that can be used with the given constraints: the existing system including MATLAB. However, the CRM does not describe a test, only a corpus. It can be used for multiple different experiments. Therefore, we must use adapt the corpus and use the other concepts to develop a full speech in noise test.

4.2.2 Speaker Stands

Next a decision matrix was created to compare the different criteria of the new speaker stand designs (Table 5). The speaker stands were redesigned to meet the system requirement that the speaker will not get broken during assembly. The stands must hold the speaker. In addition, the stands must be safe for children and low cost because these are requirements of the system.

Table 5: Decision Matrix for Speaker Stand Concept Selection

Criteria	Weight	Concept 1	Concept 2	Concept 3	Concept 4
Safe for children	5	2	3	4	5
Hold speaker stand securely	3	1	4	5	4
Allow speaker holder to pop off	4	4	2	1	4
Cost	4	5	3	2	5
Ease of Implementation	3	3	2	2	3
	Total	58	53	53	82

The overall goal of the speaker stands is to help simplify the assembly process and to insure that the speakers are set up correctly. New requirements were added onto the previous requirements for the speaker stands.

Concept 1: Rubber bands

Although the rubber bands could be a solution to the problem, it also imposes new challenges. The rubber bands could easily become unattached during the shipping process and be lost within the entire process. In addition, the rubber bands would not prevent the speaker holder from wobbling. The rubber bands would be a very inexpensive solution and would be easy to implement but it would not be a viable solution. Furthermore, rubber bands can easily become unattached and can be digested by young children.

Concept 2: Velcro

Although Velcro can be used to fasten the speaker stands and speaker holder it would be too easy for children to remove and attach. In addition, the material used to make Velcro is particularly noisy when pulled apart. The excess noise could potential affect the validity of the hearing tests. Furthermore, some Velcro products are not strong enough to permanently connect two surfaces. As a result the Velcro would constantly have to be repositioned which causes more excess noise. The Velcro would not allow the speaker to pop off when a downward force is applied. Therefore the nickel chromium rod could potentially break.

Concept 3: Press fit
When the speaker holder would be press fit into the plastic abs material both the plastic abs material and speaker holder would be slightly deformed. In addition, if the speaker holder would come out of the press fit, the participants would have a difficult time to put the part together. With the speaker holder press fit, the nickel chromium rod could potentially break when a participant attaches the speaker to the speaker holder.

Concept 4: Clip attachments
The dimensions of the clip attachment could be adjusted to allow the speaker holder to pop out if large downward force is applied to the nickel chromium rod. It can also be design to have a snug fit for the speaker holder and prevent the speaker holder from wobbling or moving. The clip attachments do not impose a safety concern to young children and can be easily designed in SolidWorks and attached onto the previous speaker stand design.

4.3 Concept Selection
Concept evaluation allowed the team to select the best concept. The best concept is one that meets the requirements defined. Sometimes the best concept exceeded the defined requirements and sometimes multiple concepts were combined to create one final concept.

4.3.1 Speech in Noise Hearing Test
Unlike the CRM suggests, twelve different sentences cannot be played at once due to the limitations of our system (8 speakers). MATLAB can only play sound out of two speakers at one time. Therefore, the corpus will be used but the subject will not have to recognize a call sign out of a variety of other sentences. The subject will just have to recognize a color and number combination while noise is competing in the background. A color and number combination is easier to identify than a call sign. The test will adapt in difficulty based on the subject's response, so the stimulus does not need to be difficult. The stimulus will be paired with noise, similar to the current localization hearing test. The level of the noise will be varied based on the user's response. To simulate the subjects in a loud environment it was decided to change the level of noise. The alternative would simulate that the signal would speak louder, which is less realistic because it would mean that the signal was accommodating for the hearing difficulty of the subject. Additionally, keeping the signal constant was typical of most of the hearing tests we benchmarked; QuickSIN, BKBSIN, SPIN, and PSI all kept the signal constant, so it was also chosen because of similarity to most existing tests. The concept developed uses the CRM as the signal, adapting competing noise based on the user's response. This will work with MATLAB because it involves .wav files and noise playing algorithms that already exist in the system. It will automatically determine the subject's ability to distinguish speech despite the noise because it will be adaptive to the user's response, honing in on their threshold.

4.3.2 Speaker Stands

The clip attachments ranked the highest in the decision matrix. Therefore, the concept that was selected was the clip attachments because it will hold the speaker securely but still allow it to quickly release if a certain maximum force is applied. Also it is safe for children and easy to implement into the existing design.

5 PRELIMINARY DESIGN AND ANALYSIS

The preliminary design for our part of the project included designing the speech in noise hearing test and refining the existing speaker stands. The design was based on analysis of the software platform, Matlab. The speaker stand design was based on the existing design, but they have been refined to take into account possibility of breaking the speaker. In this way, the two elements have been designed to address the system requirements for the two prototypes.

5.1 Speech in Noise Hearing Test

To begin developing the hearing test, research was done on the capabilities of Matlab. Pilot code was written to understand how Matlab interfaces with the speakers. The iterations of code revealed that Matlab requires that the speakers be a pair in order to play different sounds of two speakers. In the system's initial stages of our work, the speaker pairs were all next to each other. So, speaker 1 and 2 would have played sound and noise together. This would have created an impossible situation. Mainly, it would negate the system requirement that the hearing test would use the absence and presence of the head shadow effect to study the patient's binaural hearing. This constraint meant that the system had to be reorganized so that the speaker pairs were separated spatially: 1&8, 2&7, 3&6, and 4&5 became the new speaker pairs.

It is common to have a practice test preceding the actual hearing test to familiarize subjects with the test and to set the initial levels. Additionally, there was concern that the CRM could be confusing at first. There is a lot for the user to analyze, so the initial data may become skewed if there is not a practice time. Therefore, a sub-system of this hearing test is the training loop. The training loop requires that the user answer correctly a certain arbitrary number of times in a row. The number chosen was five because it meant that the user definitely understood the process, was not guessing luckily, and that the user could hear the signal. Since the noise has been capped so that it does not become too loud but the same range was still needed in order to acquire a threshold, the signal had to be softened significantly. Therefore, the training loop also incorporates an adjustment of the signal. If the user gets two in a row incorrect (to ensure it is due to the softness of the signal), then the signal increases by 1.5 dB. As they continue to answer incorrectly, the signal continues to increase until they get an answer correct. Once they get five in a row correct, the actual test begins.

The hearing test was conceptualized using the flow chart in Figure 9. In order to determine a threshold of hearing, the program needed to play sound and noise at the same time, then wait for the user to respond, then use their response to decide how loud to play the noise the next time. The code was written to accomplish this process using for and while loops.

Then the program needed to analyze the data in real time and save that to some excel file. A change of direction (COD) occurs when a user gets an answer correct then the next trial gets it incorrect or vice versa. These CODs are counted and the test ends when there have been eight CODs. It was decided based on benchmarking to calculate the threshold by taking the mean of the intensity level at the fourth through the eighth change of direction (Gray 2009). This way, the test would analyze so that it hones in on the threshold.

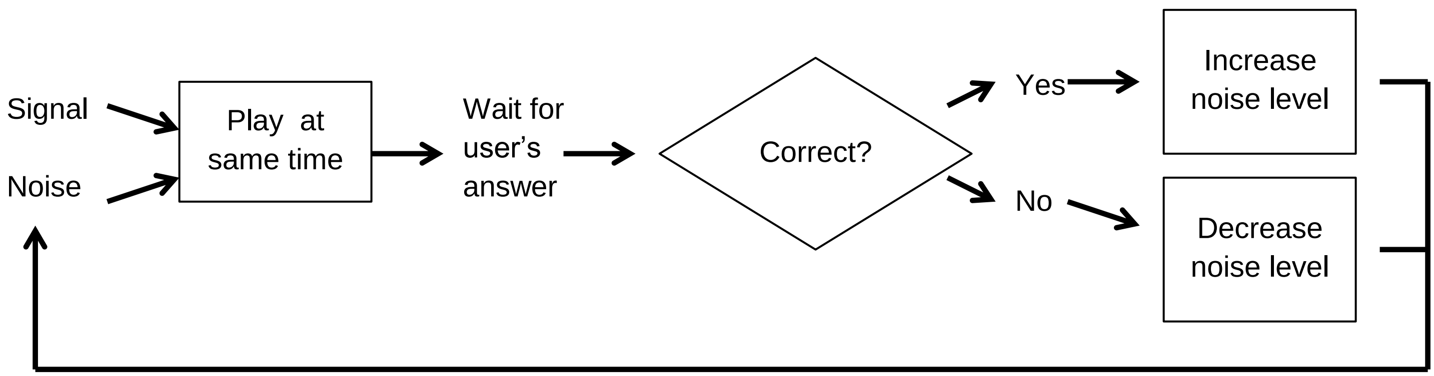


Figure 9: Design of Speech in Noise Hearing Test (excludes Training Loop)

Because the decibel scale is logarithmic, the noise level was increased and decreased using a logarithmic scale. The noise level was created as a vector of random numbers. This vector is then divided by some variable, dBDown. This variable is what changes the level of noise. Additionally, there is a variable, step, which is 6 until the fifth change of direction, and then it is 4. This is also based on benchmarking where the step was decreased in order to hone in more precisely on the threshold (Gray 2009). Therefore, if the user gets the answer correct the noise is divided by dBDown where:

$$dBDown = \frac{dBDown\_Old}{10^{\left(\frac{step}{20}\right)}} \tag{3}$$

Where dBDown_Old is the dBDown used in the previous run. In contrast, when the user gets the answer incorrect the noise is divided by dBDown where:

$$dBDown = dBDown_{Old} * \ 10^{\left(\frac{step}{20}\right)} \tag{4}$$

Therefore, the noise is divided by a larger number if the user gets the answer incorrect while it is divided by a smaller number if the user gets the answer correct. The equations result in about a 2 dB change when the step size is 6 and about a 1.5 dB change when the step size is 4. This preliminary code was run and the data was used to determine the dB, direction, threshold, and step size. Everything was running correctly except the step size was off at the beginning of the test. There was a minor error in the code that was easily fixed. Figure 10 shows example data that helps demonstrate the adaptive nature of the test. Note that the graph simply shows how the level changes over each trial, there are no measurements described on the y axis. This is simply a proof of concept: the level increases logarithmically until the answer is incorrect then it oscillates around the user's threshold. The R and W represent when the user was right or wrong the trial before and the COD demonstrates how the changes of direction (COD) are counted.

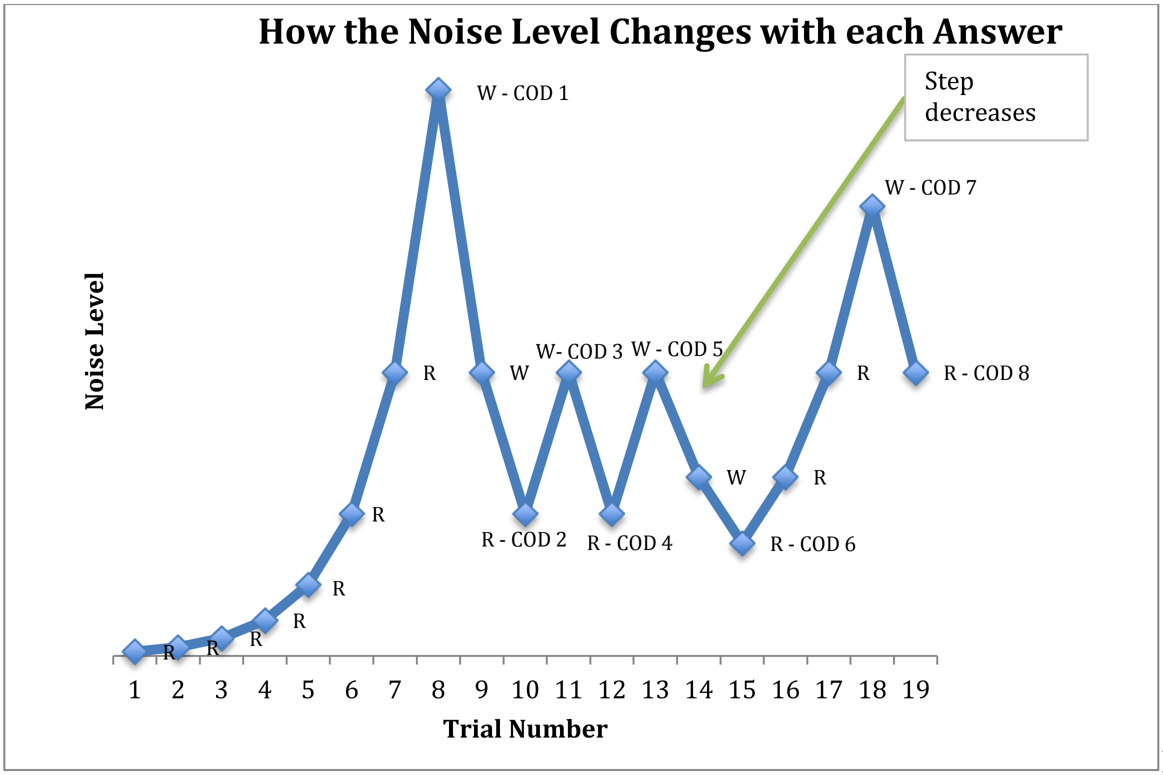


Figure 10: Proof of Concept of CRM Change of Noise Level Based on Correctness (Right or Wrong)

Next the actual level of the noise needed to be determined. Matlab does not record decibel levels, but if we know the initial decibel level of the noise and how much it is being divided by, then we can figure out the actual decibel level. This is based on the assumption that the code described above and the decibel level are linearly related. This linear relationship was verified to be true before continuing with the spectrum analyzer experiment. The noise decibel level was determined by comparing the output in Matlab to that from a spectral analyzer. A linear regression (r^2 = 0.996) was performed on the data where the actual decibel level (from the spectrum analyzer) was compared to the variable that is control the noise level, dBDown (Y):

$$dB(SPL) = 19.8 * log_{10}(Y) + 83.2 \tag{5}$$

where SPL is the sound pressure level and Y represents the variable dBDown. Therefore, with the data the CRM exports, we can calculate the actual decibel level of the noise.

5.2 Speaker Stands

In order to meet the requirement that the setup is correct and repeatable, the speakers need to be setup in the correct position on the mat and angle from user. The solution needed to allow simple assembly and disassembly of the system. To solve this problem, eight speaker stands were developed that included a male piece, which was bonded to a mat, and a female piece, which was bonded to a specific speaker. The initial concept included only a simple, asymmetric shape that the user could easily identify. This concept was refined to incorporate a stand for the speaker. The asymmetric shape worked, but it was difficult to design eight very unique asymmetric shapes, so a peg design was implemented. The second concept was printed as prototypes for all the speakers. These intermediate concepts for the speaker stand mates and a demonstration of how they work are shown in the appendix binder. Volunteers unrelated and unfamiliar with the project were brought in to test the prototypes. From this testing feedback, the designs were refined to improve functionality, usability, and to minimize cost and material. The issue with the first prototypes was that the pegs became very complicated since the pattern of pegs had to be unique for each speaker. The user had to extensively handle the male piece and match it to the female piece. This involved picking up the piece, turning it over, and then mirroring the image in the brain to find the correct female mate, thus extending handling time. Another flaw was that the stands could be installed multidirectional. The current speaker stands incorporate a number on both male and female pieces that allow the user to easily identify the proper mate. The number also serves a dual purpose of identifying the speaker during testing. The male is the one that is bonded to the mat so that vision is not restricted during assembly. One of the final speaker stands is shown in Figure 11.

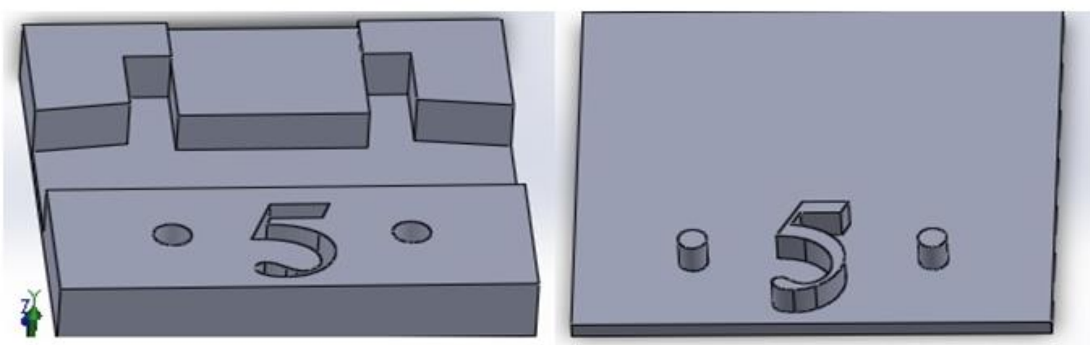


Figure 11: The Given Prototype from Other Team for the Speaker Stand Mates

Figure 12 shows how the stand connects to the speaker wire and how the wire connects to the USB hub inside the box.

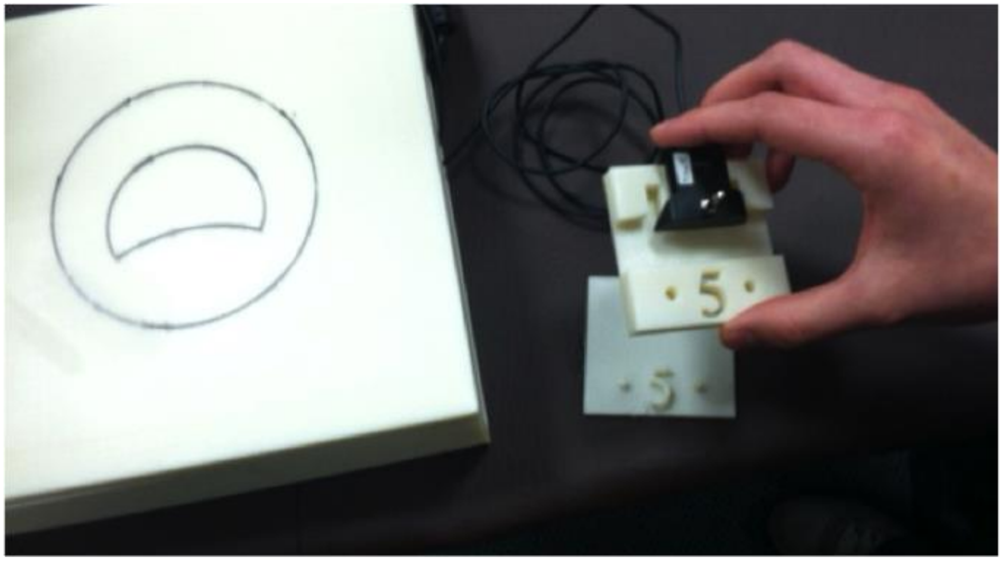


Figure 12: Demonstration of Assembly using Speaker Stand, Mat, and USB Hub Box

This design incorporates the following Design for Assembly principles:

- Parts are easy to align and insert
- Both access and vision are not restricted
- Mistake-proof the design and assembly
- Minimize handling in assembly
- Maximize compliance in assembly
- Minimize assembly directions
- Parts are designed so that are easy to grasp with one hand

The main benefit to the design is that vision is not restricted because the male piece is bonded to the mat. The parts are easy to align and insert and they have minimized assembly directions. These principles minimize handling in assembly and maximize compliance in assembly. Accuracy in assembly is required for accuracy in the data, so the application of these principles helps ensure accurate data.

To meet the system requirement for the Beta Prototype to minimize possibility of breaking the speaker, an analysis was performed on the speaker to guide design of the speaker stands. The speaker stands provide the opportunity for accomplishing the requirement because they work well with the system and they are involved in the assembly of the system, which is the most probably time for breakage to occur. The team investigated whether the client could break the nickel-chromium rod sticking out of speaker holder during the setup process. The speaker holder that will be analyzed is shown in Figure 13.

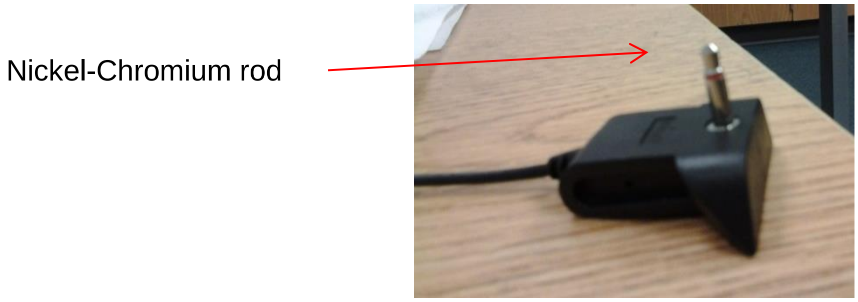


Figure 13: Speaker holder

In the design of the speaker stands provided from the '13 team, the speaker holder is glued onto the male plastic abs piece, which can be seen in Figure 14. In the current design the client would place the speaker onto the speaker holder and apply a downward force onto the speaker stand. The client could possibly apply a strong enough force to break the nickel-chromium rod. A mechanical analysis was completed to determine maximum downward force that can be applied before it breaks the nickel-chromium rod. Once the maximum force was determined the speaker stands would be redesigned to have the plastic abs material break before the nickel-chromium rod broke. This is because the plastic abs material is easier to acquire than a specific pair of speakers.

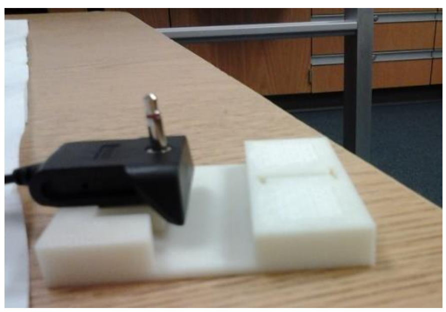


Figure 14: Completed Speaker Stand

To begin the analysis, a system boundary was developed around the nickel chromium rod as seen in Figure 15.

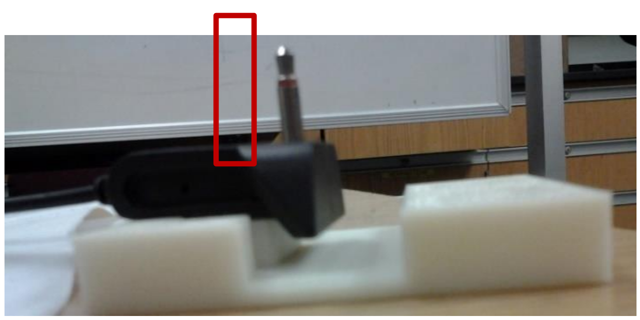


Figure 15: System Boundary

The system was then redrawn, and reoriented to represent a cantilever beam as seen in Figure 16 below: where F_1 is the force applied by the user, and F_2 is the normal force acting in response. The dotted line shows the deflection that will occur and the neutral axis is the line across the centroid of the rod.

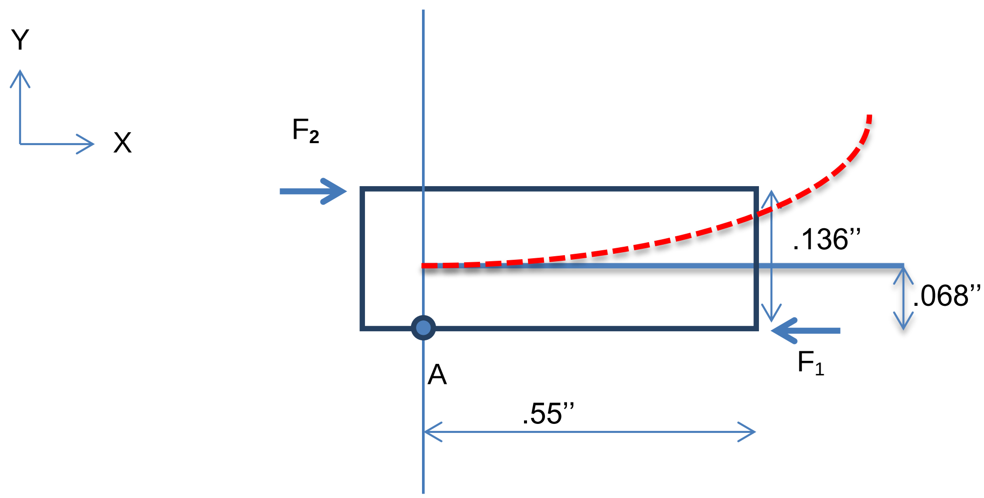


Figure 16: Representation Nickel-Chromium Rod

The forces in the y direction were summed below in equation 6 and it was determined that $F_1 = F_2$.

$$\Sigma F_y: -F_1 + F_2 = 0 \tag{6}$$

$$F_1 = F_2$$

The sum of the moments in the y direction is shown in equation 7.

$$\Sigma M_A = -M_A + F_{load}\,(.55'') = 0 \tag{7}$$

$$M_A = F_{Load}\,(.55'')$$

The moment of inertia for a hollow cylindrical tube was calculated using equation 8. Where D_0 is the outer diameter: 0.00345 m, and D_i is the inner diameter: 0.0013 m.

$$I = \frac{\pi(D_0^4 - D_i^4)}{64} \tag{8}$$

The maximum moment for the beam is calculated using equation 9 where σ is yield stress of the nickel-chromium which is 3.10 Pa, c is the maximum distance from the neutral axis: 0.00172 m, I is the moment of inertia calculated in the equation before: 6.862*10^{-12} m^4.

$$M_A = \frac{\sigma I}{c} \tag{9}$$

The applied moment (M_A) calculated is 1.23 N*m. Equation 10 was then used to determine the force load required to break the beam.

$$F_{Load} = \frac{M_A}{0.01397m} \tag{10}$$

The F_{Load} calculated is 88.16 N, which is the force required to break the beam. Next, the speaker stands were redesigned to allow the speaker holder to snap off before the nickel-chromium rod breaks. A basic design was created from the benchmarking research on the flashlight clip attachment. Figure 17 is a design that allows the speaker holder to be clipped onto the speaker stand instead of attached with a strong adhesive.

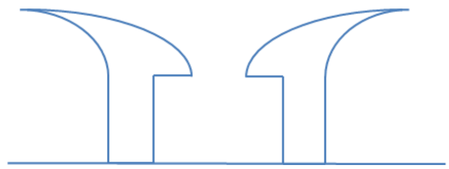


Figure 17: Clip Attachment

The speakers were then analyzed to determine the height and thickness of the clip attachment. To begin the analysis, one side of the snap design was analyzed in Figure 18.

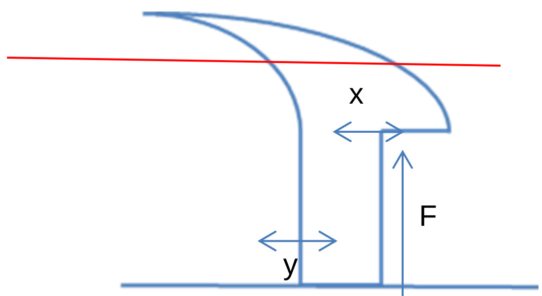


Figure 18: Clip Attachment Diagram

The top part (above the horizontal line) of the snap concept is for comfort, so it is negligible in this analysis (Figure 19). Ideally the snap design will allow the speaker holder to pop out from the female piece if the force applied is greater than 88.16 N.

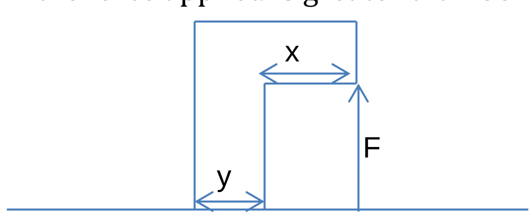


Figure 19: Simplified Model

The model was even further simplified to represent a beam:

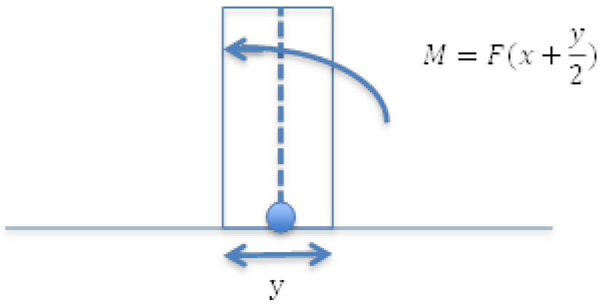


Figure 20: re-simplified model of clip attachments

Equation 11 was used to determine the stress applied to the clip attachment.

$$\sigma = \frac{MC}{I} = \frac{F(x+\frac{y}{2})(\frac{y}{2})}{\frac{by^3}{12}} \tag{11}$$

Where σ is the yield strength of the plastic abs, C is the maximum distance from the neutral axis $[\frac{y}{2}]$, M is the applied moment $[F\left(x+\frac{y}{2}\right)]$ and I is the moment of inertia $[\frac{by^3}{12}]$. The equation was then rearranged to solve for the F in equation 12.

$$F = \frac{\sigma * b * y^2}{6x+3y} \tag{12}$$

In order to determine the free variables of x, b, and y, the force to remove the speaker stand needs to be less than the force required to break the nickel chromium rod $[F < F_b]$.

6 TESTING AND REFINEMENT

The team needs to validate that the speech in noise hearing test can distinguish between uni- and bilateral listeners. Also, the team must validate that the system can be set up before the team can send out a system. The immediate goal is to create a prototype that requires a proctor that can be sent to UVA. The prototype will then be refined so that it does not require a proctor so that it can be sent out to patients' homes.

6.1 Validation Testing

The participants were given instructions to set up the system that initially had all parts placed in a packaging box. The first set of instructions to set up the hardware of the system can be seen in the appendix binder. These instructions were also given to participants and the participants had trouble following the instructions. It was concluded through observation that college participants typically do not read instructions, and therefore the initial set of instructions were refined and the new set can be seen in the appendix binder. The new set of instructions incorporates more pictures and fewer words to simplify the setup process. Since the new instructions have been given to the participants there has been a 100% success in the hardware setup. A total of 11 participants have been tested which includes 4 unilaterals and 7 bilaterals.

6.1.1 Validation of Hardware

Data was collected from 12 naïve participants in order to validate our speech in noise hearing test. To validate the speech in noise test, it would need to show a statistical difference between bilateral and unilateral listeners. Before the system was tested the participants were given a form to consent to participate in research, in accordance with the IRB (IRB # 13-0058). The form was read over by the participants and any participants unwilling to agree to the terms of the form were asked to leave the testing site. The form can be seen in the appendix binder. The subject was then given a box full of components and instructions and asked to set up the system. Once finished, the administrator used the speaker configuration panel to verify the noise was properly coming out of each speaker. Figure 21 shows the speaker configuration panel that we created for this purpose.

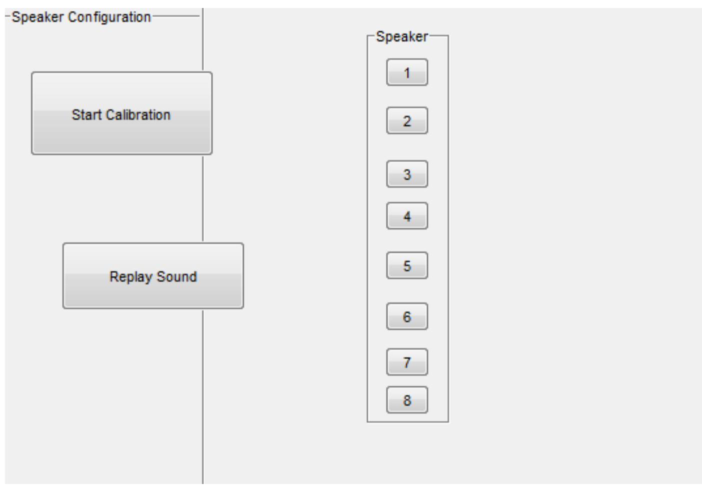


Figure 21: Speaker configuration panel

The administrator first clicked start calibration then a signal came out of speaker 1. The administrator then chose a number based on the speaker from which the signal played. If the speakers chosen by the administrator matched the software's identification of the speakers then "verify setup" was shown in the status bar to indicate that the user properly set up the speakers.

The participants were randomly assigned a screen name from the Identify panel seen in Figure 22. The participants were randomly assigned a screen name using a random generator, repeated for the four different trials. The numbers output from the random generator were associated with the names on the panel, for example, 1 represents AceSpades and 2 represent AceClubs.

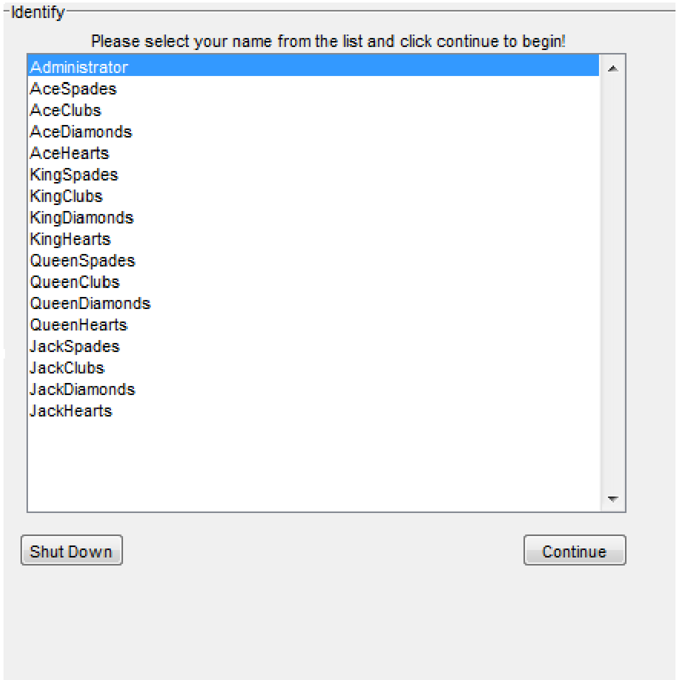


Figure 22: Identification Panel

After the screen name was selected, the auto calibration panel recorded the background noise in the room in Figure 23. If there was a disturbance during this process the recalibration button could be pressed to record the background noise again. The background noise was then collected and written to an Excel document.

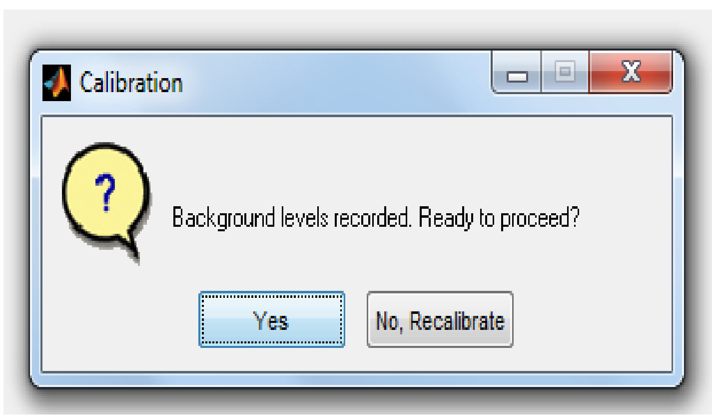


Figure 23: Auto calibration Panel

The participants then read the instructions before proceeding to begin the test. Figure 24 displays the newly formed instructions for the participants to read.

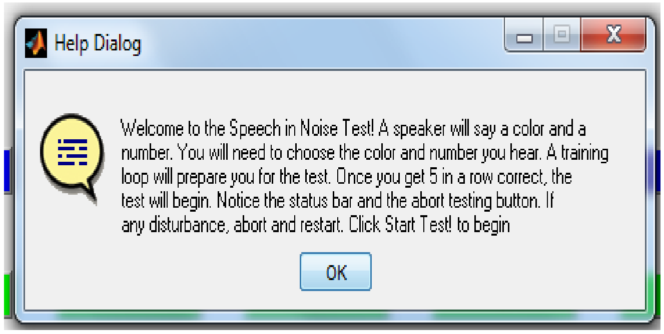


Figure 24: Testing Instructions and Procedures

The participants then began the test. First, the participants had to pass the training loop by answering correctly five times in a row. The training loop, as mentioned before, prepares the user for the test. It also adjusts the signal level in the event that the subject cannot hear it all. In the combined first test all the bilateral participants took the test without any ear plugs or head phones. Next, the excel function =RANDBETWEEN(1,2) was used to determine which ear would be plugged with an earplug and headphones. 1 represented that the right ear would be plugged first, and 2 represented that the left ear would be plugged first. Moldex pura-fit ear plugs were used, and the noise reduction rating is 33 dB according to the box specifications. Next, Silencio RBW-71 headphones were placed on top of the ear with the earplug with a noise reduction rating is 50 dB. Equation 13 calculates the estimated exposure (dBA) using dual protection according to the Noise and Hearing conservation under the department of labor.

$$Estimated\ Exposure\ (dB) = TWA(dB) - (NRR_h + 5) \tag{13}$$

$TWA\ = Time\ weight\ average, Assuming\ 40\ dB\ for\ the\ hearing\ system$
$NRR_H = 50\ dB$

According to OSHA, a standard conversation is about 50 dB to 60 dB (OSHA 2013). The system's noise level is then estimated to be below a standard conversation. More research and testing needs to be done to verify the maximum dB output for the system.

Then the participant took a 1-2 minute break before beginning the next test. Once that test was finished the same procedure was repeated with the other ear to gather a total of 3 tests and 12 trials. All the data was written to 12 excel files and stored onto a folder on the desktop. The data was not placed into a Dropbox folder to protect the participant's confidentiality. The unilateral participants only took 1 test which included 4 trials, but otherwise repeated the same testing procedure as the bilateral participants. The bilateral participants took 3 tests including 12 trials because control (no ear plugs) needed to be established and the participant needed to be simulated as a unilateral listener by plugging one of the ears. All the rata data can be seen in the appendix binder.

6.1.2 Validation of Speech in Noise Hearing Test

In order to validate that the speech in noise hearing test could distinguish between unilateral and bilateral listeners, eleven subjects were tested on the system. Four of them were true unilateral listeners. The remaining seven were bilateral listeners. The bilateral listeners were tested three times: normally and with either ear plugged. Each subject took four tests where the signal and noise location varied each time. The first test played distracting noise from the right speaker 180 degrees from the subject (speaker 8). The second test played noise from the left speaker 60 degrees from the subject (speaker 4). The third test played noise from the right speaker 120 degrees from the subject (speaker 5). The fourth and final test played noise from the speaker 0 degrees from the subject (speaker 1). The average results for the real/fake unilaterals and bilaterals are shown in Figure 25. The plot shows that there is not a statistical difference between the two, even at 50% confidence.

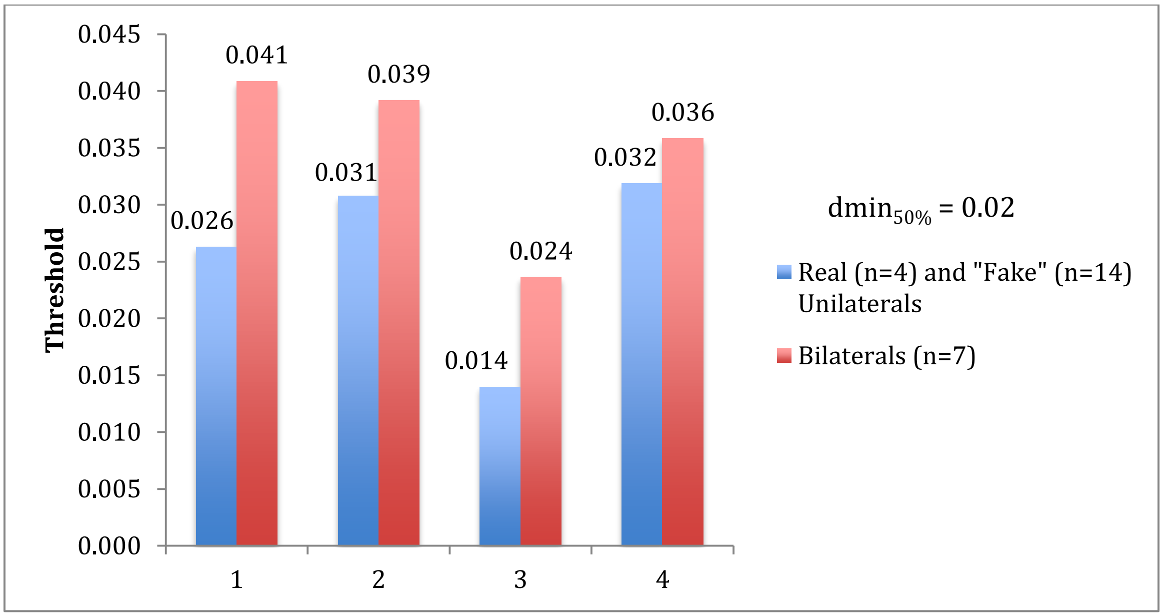


Figure 25: Comparison Between Unilaterals' and Bilaterals' Performance

However, the purpose of this system is to increase sample size, so it follows that a statistical analysis would have a sample size problem. To account for this problem, we compare unilaterals to bilaterals when the unilaterals are at a disadvantage and when they are at an advantage. A unilateral is at an advantage when his bad ear is facing the distracting noise. He is at a disadvantage when his good ear is facing the distracting noise. This represents what is referred to as binaural squelch in the literature. Unilaterals with a good right ear are at a disadvantage during tests 1 and 3, while unilaterals with a good left ear are at a disadvantage during tests 2 and 4. When an analysis of variance one way (ANOVA) is performed using Excel software, $p < 0.2$ when the unilaterals are at a disadvantage. On the other hand, when the unilaterals are at an advantage, there is no statistical difference between those unilaterals the bilaterals. Therefore, we can conclude that our test distinguishes between unilateral and bilateral listeners at 80% confidence when the unilateral listeners have their good ear closest to the distracting noise. More testing should be done to increase the sample size and conclude validity of the test with more confidence. More advance statistical analysis was performed and can be found in the appendix.

6.1.3 Pilot Testing

The Alpha prototype was sent to Dr. Kesser who tested it on himself and his wife, daughter, and son. His detailed comments are provided in the appendix binder. Overall, his comments informed the design. The instructions were refined to be more exact and inclusive. For example, plugging in the mouse was left out of the instructions sent, so that was added to the refined instructions. The instructions were revised to include differentiation between left and right clicks. Also instructions for shut down were added. The new hub box was designed so that the speaker wires would come out on their respective sides (speakers 1-4 wires come out to the left of the hub box and speakers 5-8 wires come out to the right of the hub box now). He expected noises to play during the calibration routine, but it was only recording background noise at that time. Now a sound plays out of each speaker and the output is recorded. From the pilot testing, it became clear that the most important part of sending this system to patients is communication. Even someone who is very familiar with the system and hearing tests had difficulty knowing what to expect and how to execute everything. This informs us that it is vital to communicate with the user effectively. This can be accomplished by refining the instructions and adding a frequently asked questions section. It must be acknowledged that there is a trade off in this respect: both too much and too little information will overwhelm the user. The final instructions can be found in the appendix binder.

6.2 Speaker Stand Testing

The FMEA suggested that there is a possibility that the speaker plug will break. The speaker stands can be designed so that this possibility is minimized. In order to do so, the stands were designed so that it requires less force to remove the speaker stand than the it requires to break the speaker. First, the force required to break the speaker will be calculated. Then, the speaker stand will be designed so that the force required to remove the speaker will be less than the force required to break it. This way, the speaker will eject from the stand before it is broken.

6.2.1 Speaker Plug Testing

A mechanical test was designed to confirm the theoretical calculation of the speaker rod. The rod is assumed to be made from nickel chromium material. The yield strength of the material is assumed to be 3.10E8 PA but the actual yield strength is unknown. An experiment was created to determine the yield strength of the unknown material.

Before beginning the experiment a LCHD-25 strain gage load cell was calibrate by applying a excited voltage of 10 V. Next, incremental 2.5 weights were added to the load cell and the voltage output was measured using a Fluke 155 meter. After the data was collected a voltage output [V] vs force [N] was created in order to determine the calibration equation, which can be seen in Figure 26 below.

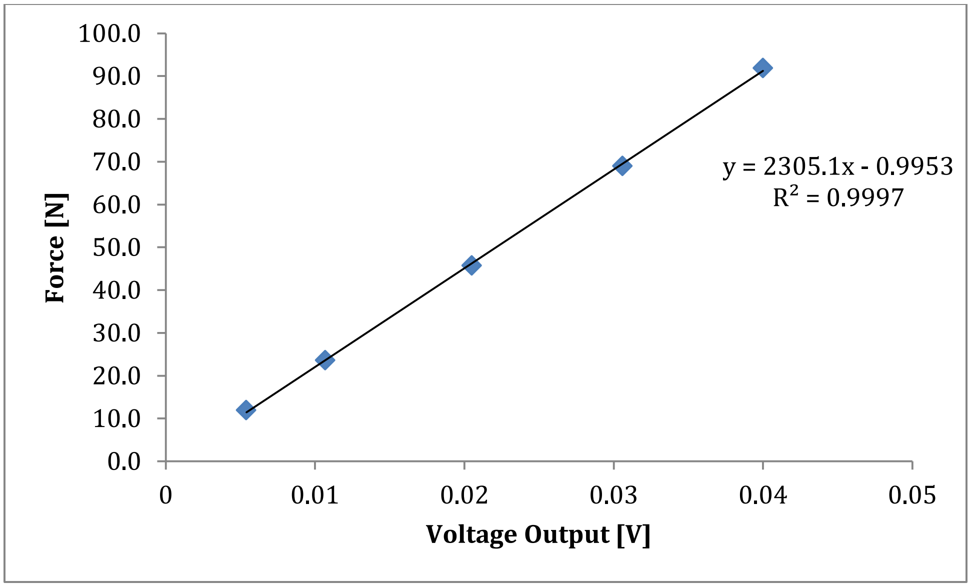


Figure 26: The Calibration Equation for the Load Cell

Next, an experiment was designed to determine the yield strength of the material. In the designed experiment, the speaker rod was placed within a hole in a steel frame. The steel frame was attached to an SLA frame. A load cell was attached to the speaker rod using an S hook, and weights were loaded on the bottom of the load cell using J hooks. The experimental setup can be seen in Figure 27.

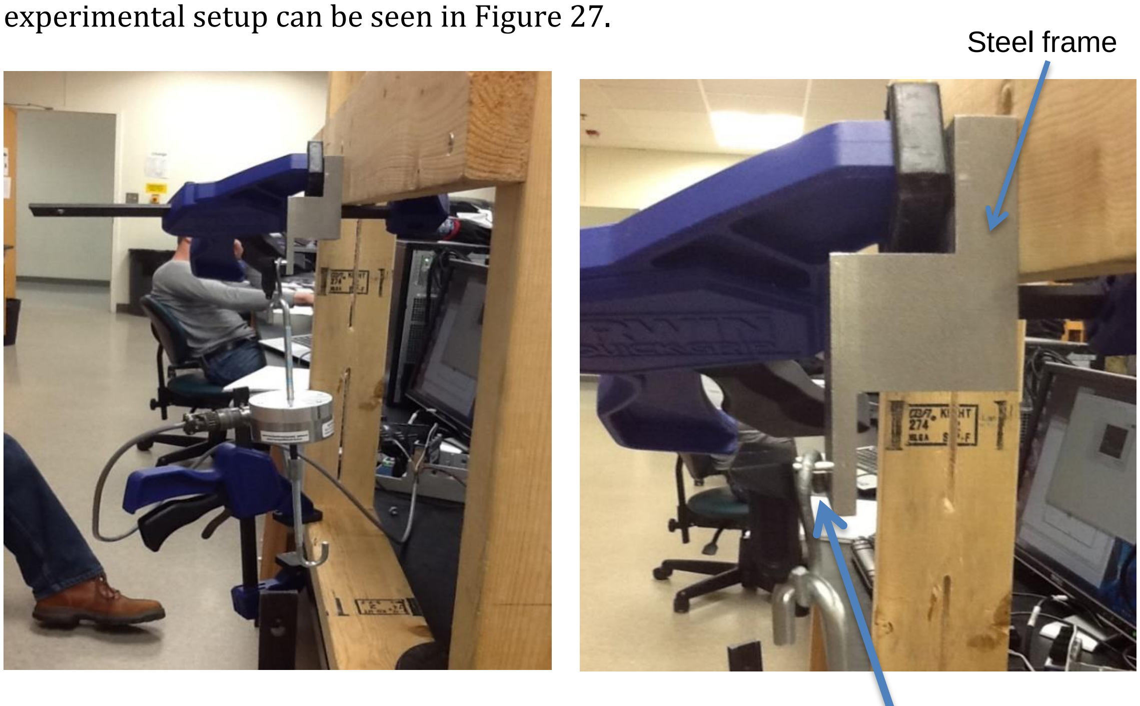


Figure 27: Experimental Setup

Weights were added to the J hook in 2.5 pound increments until the speaker rod broke from the plastic piece. LabView was used to record the voltage output of the load cell and the calibration equation was used to convert the voltage output to a force. Figure 23 is a graph of the force applied to the load cell.

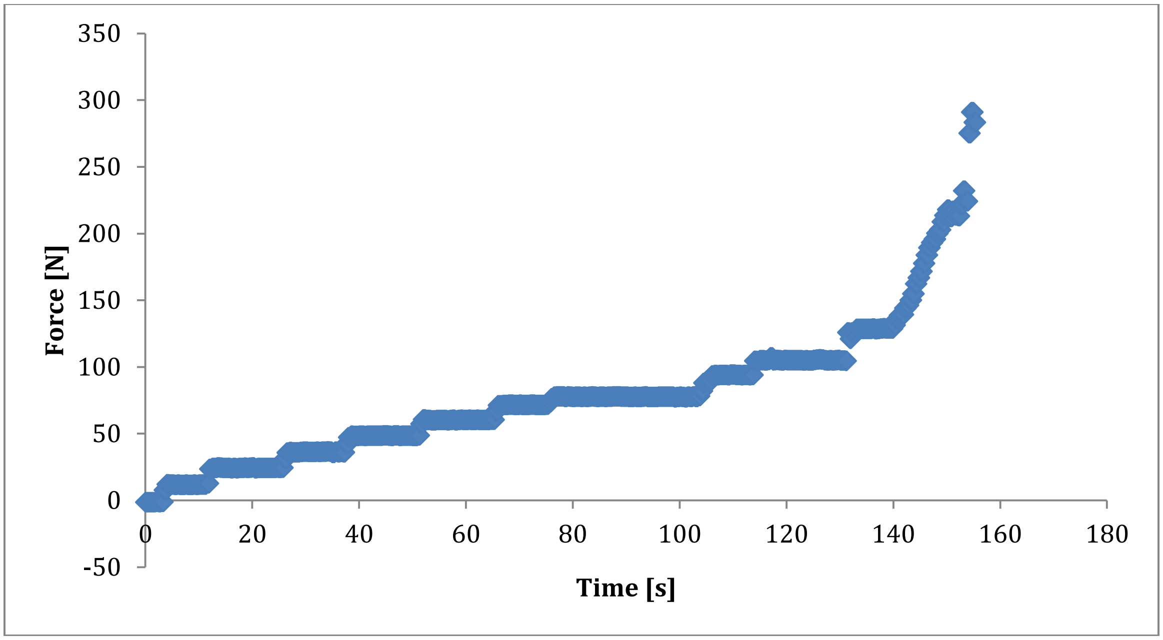


Figure 23: Applied Force [N] vs. Time [s]

A maximum force of 290N was required to break the speaker rod. Next, the maximum force was used to determine the yield strength of the material.

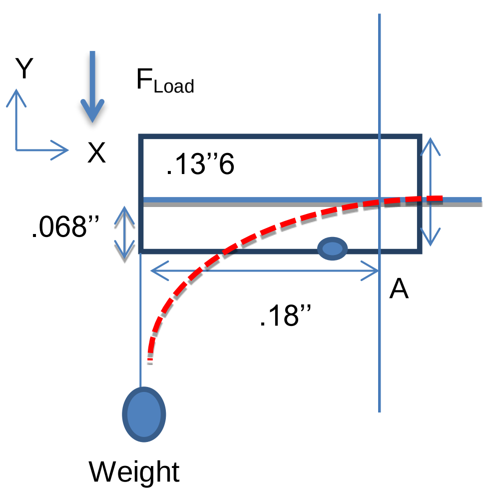


Figure 24: Representation of speaker rod.

The sum of the moments in the y direction is shown in Equation 14.

$$\Sigma M_A = -M_A + F_{load}\,(.18'') = 0 \tag{14}$$

$$M_A = F_{Load}\,(.18'')$$

The yield strength of the rod is determined using equation X. C is the maximum distance from the neutral axis of .00172 m, I is the moment of Inertia which is 6.862*10^{-12} m^4.

$$\sigma = \frac{(F_{Load})(c)(.18)}{I} \tag{15}$$

The yield strength of the material is approximately 3.32E8 PA.

Next the force required to break the rod is calculated.

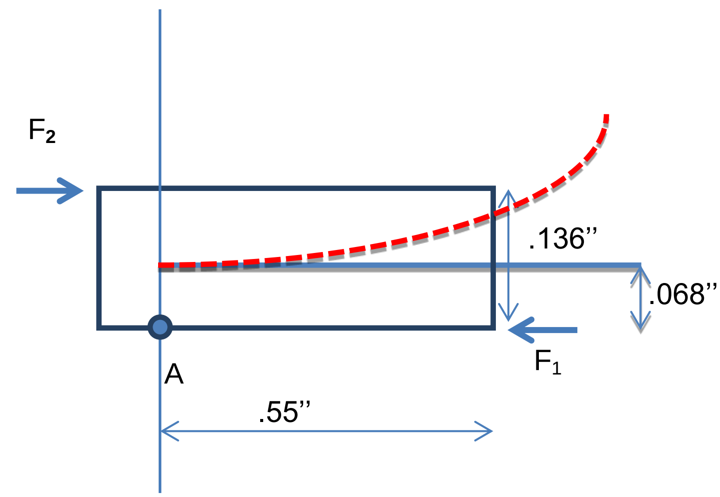


Figure 30: Representation of speaker rod

Using the now known yield strength, the maximum moment of the rod was calculated using equation 16 where σ is yield stress of the nickel-chromium which is 3.32 Pa, c is the maximum distance from the neutral axis of .00172 m, I is the moment of inertia calculated in the equation before: 6.862*10^{-12} m^4.

$$M_A = \frac{\sigma I}{c} \tag{16}$$

The applied moment (M_A) calculated is 1.319 N*m. Equation 17 was then used to determine the force load required to break the beam.

$$F_{Load} = \frac{M_A}{0.01397m} \tag{17}$$

The F_{Load} calculated is 94.41 N, which is the force required to break the speaker rod.

6.2.2 Speaker Stands Testing

In order to design the clip attachments, the yield strength of the plastic ABS material needed to be determined. Literature exists on this value, but it should be confirmed because the 3D printing method results in highly anisotropic material. In addition, the strongest orientation to print the plastic abs material needs to be determined. A tensile test was performed on 15 dog-bone shaped specimens following the ASTM D638-10 standard. According to the standard IV specimens should be used when comparing the material with different rigidity. The dimensions of the dog–bone shaped specimen can be seen in Figure 31 below.

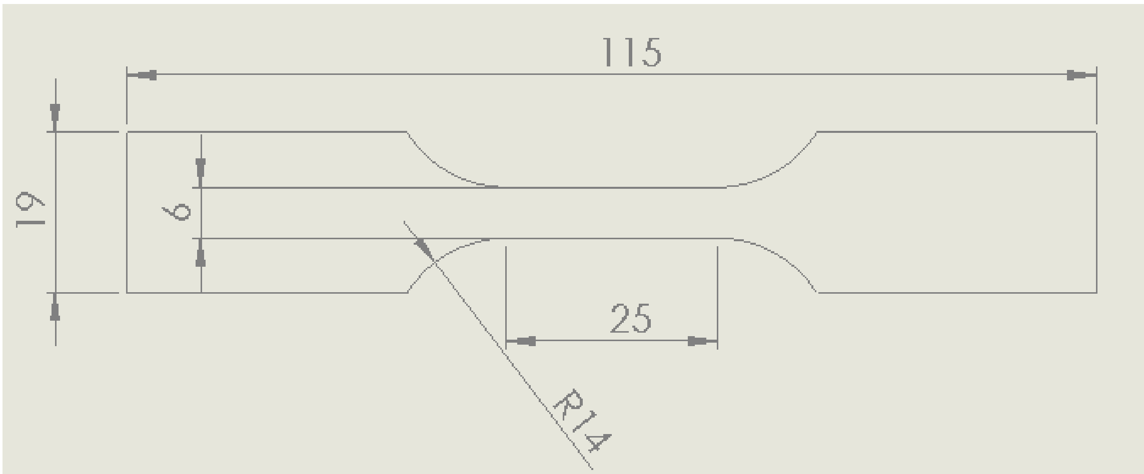


Figure 31: Drawing of the IV specimen (All dimensions in mm).

The specimens were designed in SolidWorks and printed in three different orientations (x,y,z) using the Stratasys printer. The orientation of the specimens can be seen in Figure 32 below. A tensile test was performed on each specimen on the Instron. Following the ASTM standard, the initial length, width, thickness of each specimen was recorded. Next, a wax crayon was used to mark the distance at which the grips were to be attached to the specimen. The speed of testing was set to 5 mm/min.

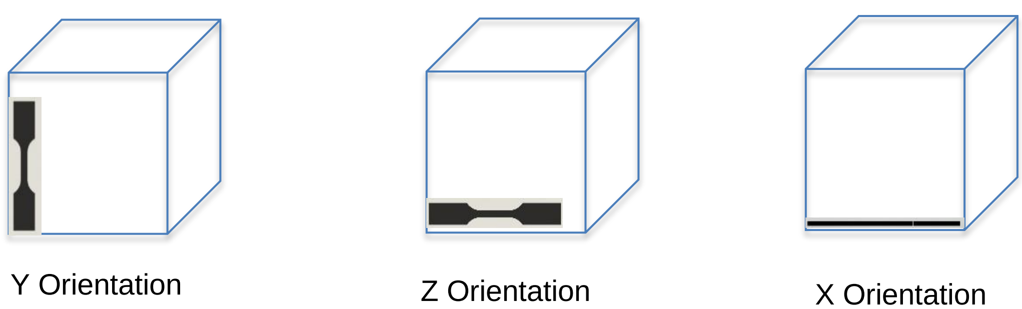


Figure 32: Orientation of Specimens

The next steps deviated from the ASTM standard. According to the standard, a biaxial extensometer should have been used to center the specimen within the gage clips. Instead a caliber was used to measure the distance between the gage clips to ensure the specimen was centered within the Instron. Furthermore, the ASTM standard requires for a small preload force of less than 5N to be applied to the specimen. The specimen was tightened and a small extension was applied until the preload force was approximately 5 N force each specimen. The average tensile strength, yield strength, and modulus were calculated and can be seen in Table 6.

Table 6: Data of Test Specimens

	Average Tensile Strength [MPa]	Average Tensile Strength at Yield [MPa]	Average Modulus [MPa]
X specimen	9.48	9.48	1280
Y specimen	7.18	5.39	1130
Z specimen	10.44	10.6	1470

The z orientation produced the specimen with the highest yield strength. The dimensions of the specimen and overall procedure and results can be found in the appendix.

7 DETAILED DESIGN AND ANALYSIS

This section describes the process of deciding which speakers to use for the speech in noise hearing test. To do so, an experiment was performed using and artificial head and torso. This section also describes the process of defining dimensions of the speaker stands.

7.1 Speech in Noise Hearing Test

The hearing in noise test that the team developed tests a subject's ability to distinguish speech from background noise. The conditions are more realistic and extensive than the pre-existing pure tone threshold tests. When a subject can hear out of both ears, he or she can use the different input (in terms of timing and magnitude) from each ear to locate and focus on the stimulus, blocking out the noise. This team has designed a test for subjects who have or will have corrective surgery, giving them the ability to hear from both ears for the first time. The test is interested in the headshadow effect, which is due to the head separating the magnitude of the input to one ear from that to the other and affecting the timing of the input. Therefore, to determine how the subject learns to use the headshadow effect, the hearing test should stimulate the ears when headshadow is at its greatest and when it is at its smallest effect. In order to test for these conditions, the team used a standard audiology tool, a realistic head and torso equipped with a microphone in his right "ear" called KEMAR. Since KEMAR has a microphone in only one ear, it is expected that the he will hear the stimuli on the right side at a greater magnitude and shorter timing than those on the left side. This test will address the hypothesis that the most headshadow effect is prevalent in speaker pair: 1 & 8, while the least headshadow effect is prevalent in the speaker pair: 4 & 5.

7.1.1 Methods

Fall semester 2013, the team attempted data collection using KEMAR, but the team reached the limitations of the software and hardware available. The issue was the timing of the computer. The computer processed the transition between speakers with different time intervals. Thus, when it came time to compare the timing of the speakers, the data was unreliable and inconclusive. To fix this problem, the team used equipment in CSD2 Lab in

HHS 0209. To test that the setup was effective, the output was directly wired to the input. In this case, it was expected for the output to match the input completely. Figure 33 is a comparison of the input signal to the output signal. It proves that the output matches the input when they are directly connected, which was expected. This implies that the set up would not have any timing issues and that we could proceed with the experiment.

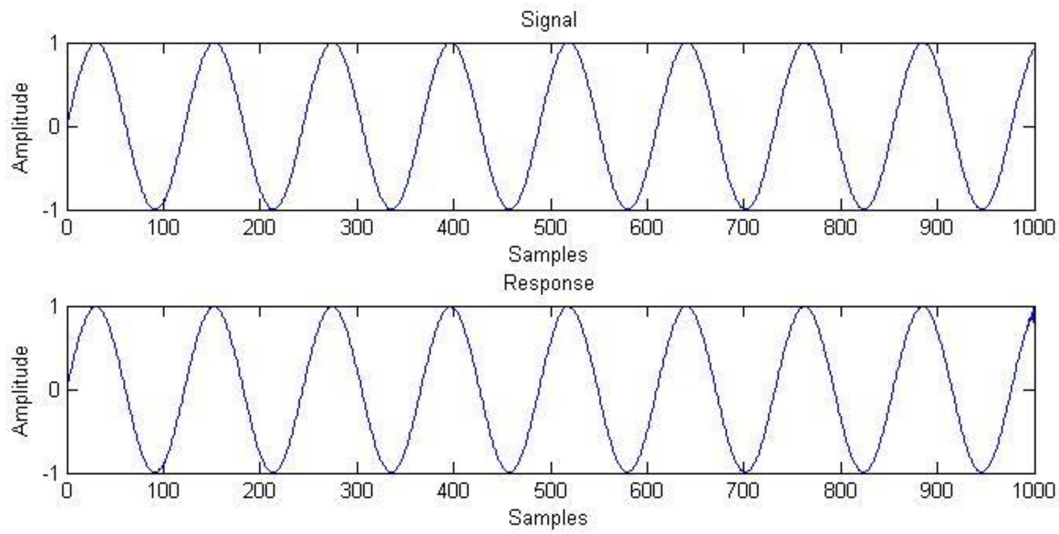


Figure 33: Proof of Successful Experimental Set Up

Next, the output was connected to a single speaker. The speaker was placed in a sound proof booth with KEMAR. The protractor was laid out on a table in the sound proof room and KEMAR was placed in a location mimicking where a subject would sit. The speaker was moved to each location of those in the existing system: 0, 20, 40, 60, 120, 140, 160, 180 degrees corresponding to speakers 1-8, respectively (Figure 34). This representation just shows the locations of each speaker, the numbering begins on the left with speaker 1 and continues clockwise ending with speaker 8.

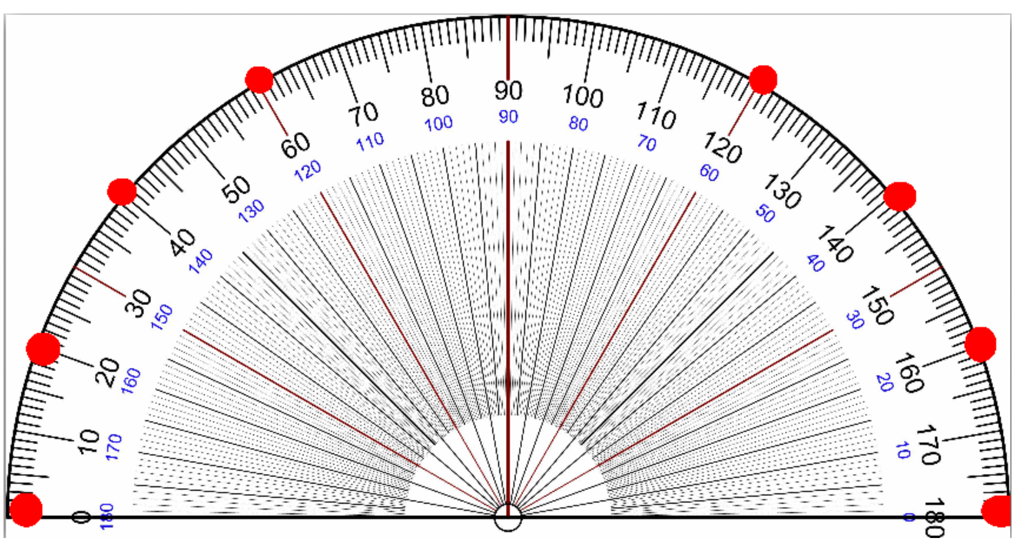


Figure 34: Speaker Locations Denoted by Circle

The speaker was moved in order to keep the output consistent and to avoid timing issues of using multiple speakers. The stimulus was a 25 kHz sample of a 100 sample long click. A click is an excellent stimulus for this experiment because it is broadband and composed of many different frequencies. It does, however, have very little energy. This is why we played twenty-five clicks in a row. The output for each click was averaged, thus averaging out any background activity. Figure 35 shows the experimental set up when the speaker is in the same location as speaker 5.


Figure 35: KEMAR Experimental Set Up

7.1.2 Results

With this set-up, the average output for each speaker was analyzed for comparison to the input in a bode plot. The transfer function was calculated by using equation 18.

$$T(j\omega) = a \pm bj = \frac{FFT(output)}{FFT(input)} \tag{18}$$

The magnitude ($|T(j\omega)|$) and phase shift (θ) were calculated using the following equations:

$$|T(j\omega)| = \sqrt{a^2 + b^2} \tag{19}$$

$$\theta = \tan^{-1}\left(\frac{b}{a}\right) \tag{20}$$

$$gain = 20 * log_{10}(|T(j\omega)|) \tag{21}$$

Next, the speakers were paired off based on the pairing in the system: 1 & 8, 2 & 7, 3 & 6, and 4 & 5. The difference between the speakers in the pairs was calculated for the gain and the phase (for example the difference between the gain of speaker 8 and speaker 1). The results are shown in Figure 36. This shows the magnitude and phase difference between the speaker pairs. It only shows the greatest and least magnitude speaker pairs. Data for all speaker pairs can be found in appendix binder.

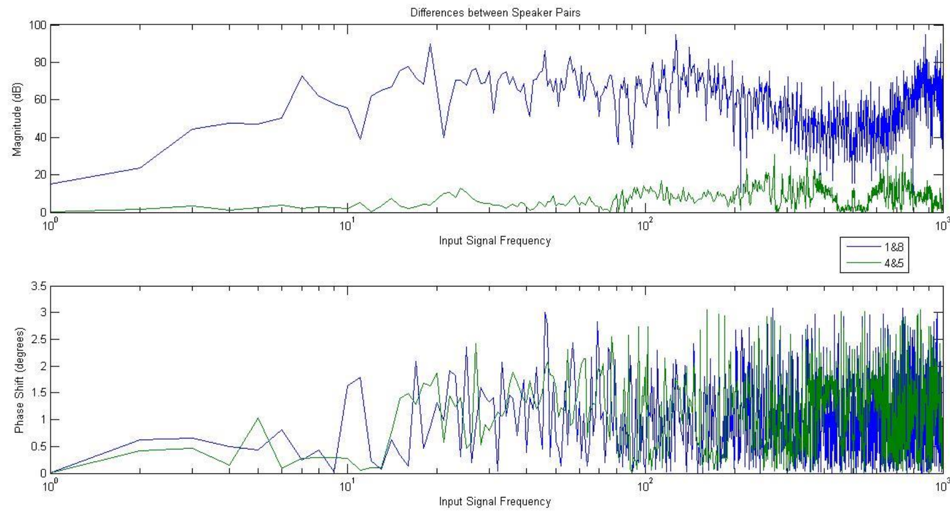


Figure 36: The Difference between Speaker Pairs 1&8 and 4&5 in terms of Magnitude and Phase Shift

Therefore, the results imply that speakers 1 & 8 have the greatest difference in magnitude while speakers 4 & 5 have the least difference in magnitude. The speakers clearly show that they are out of phase with one another, suggesting timing differences as expected.

7.1.3 Discussion

From the results, we can conclude that since speakers 1 & 8 have the overall greatest difference in magnitude, they are the speakers that create the greatest headshadow effect. Since speakers 4 & 5 have the overall least difference in magnitude, they are the speakers that create the least headshadow effect. This makes sense and supports our hypothesis. Therefore, speakers 1 & 8 and 4 & 5 fit the requirements of our hearing test that they test the greatest and the least headshadow effect. The headshadow effect is an audiological technique that the brain uses to hear effectively. The brain processes these inputs automatically and it is truly amazing the amount of computation we are able to process when we have two working ears. From this experiment, the team concluded that the decision to use speakers 1 & 8 and 4 & 5 for the speech in noise test was a valid decision. The team will switch the signal and noise between the two speakers, thus resulting in four tests. To preserve data integrity, the order of speaker pair use will vary and seem random to the subject.

7.2 Improvements to Software

Feedback was provided from the design panel and Dr. Kesser and their inputs shaped the development of the alpha prototype. Dialog boxes that guide the user through the test were incorporated so that the user will know his or her progress. Additionally, positive reinforcement was included in the text of the dialog boxes. In order to keep the user interface consistent, this was done for not only the CRM, but also the calibration pane and the other team's localization hearing test. The data for the tests were being saved in different files. Noting the disorganization and opportunity for confusion, the team programmed the all the operations (CRM, sound localization, and calibration) to save to a single file. Each operation receives its own sheet and allows for multiple sheets in the same operation. The file does not overwrite itself because the file is saved as the user's screen name and the current date. If the user has already signed in and created a file, the program adds *_001 and increments as necessary. If the user has created a file, but then decides to abort, the program records 'invalid' under the heading 'valid?'. This way when the data analyzers receive the data, they will understand exactly what happened during testing.

Additionally, the calibration pane was further developed to record background noises and to record a non-naturally occurring sound from each speaker. In this way, after testing the analyzer can determine whether the levels were set at similar levels for each speaker. This check is due to hardware issues where the analog to digital converters could have been altered so that their volume is changed.

7.3 Speaker Stands

The dimensions of the snap hook needed to be finalized before printing. Some of the dimensions of the snap hooks were identified by recording the measurements of the speaker holder. Minimum and maximum constraints were created for each of the x, y, and b dimensions from knowledge from previous iterations of the printed speaker stands.

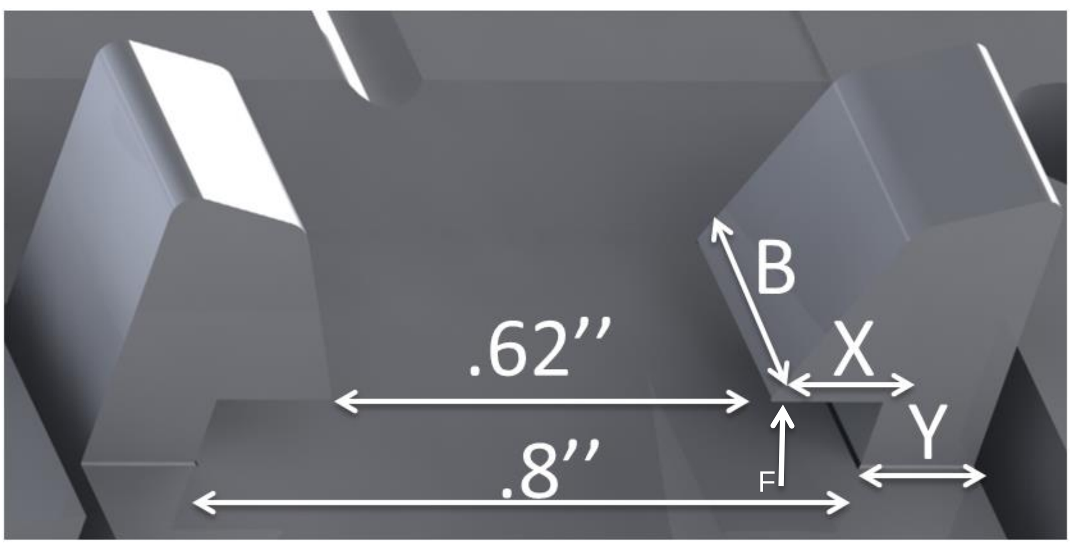


Figure 37: Dimensions of Speaker Hooks

The force to release the speaker stand from speaker hook needed to be less than the minimum force required to break the rod, as calculated before. Lingo, optimization software, was used to minimize the force required to remove the speaker from the speaker stand. This determined the dimensions of b, x, and y. The lingo coding can be found in the appendix. The result can be seen in Table 7 below.

Table 7: Dimensions of the Speaker Hooks

B	X	Y	Force Applied
0.2''	0.10''	0.12''	4.41 N

4.41 N is the force required to remove the speaker holder from the speaker stands.

Next, a static simulation was completed on Solidworks to determine the Von Mises Stress. There are three principle stresses that can be calculated at any point acting in the x, y, z direction. The Von Mises Stress combines the three stresses into an equivalent stress, which can be compared to the yield strength of a material. Therefore, if the calculated Von Mises Stress is greater than the yield strength of the material, then the material is considered the failure mode of the design. The Von Mises stress calculated in SolidWorks was compared to the yield strength of the plastic ABS material determine through the Instron testing to understand if the snap hooks would break. A force of 4.41N was applied onto the snap hooks to simulate the speaker holder being removed from the female speaker stand. In figure 48 the purple arrows represent the 4.41N force applied, and the green arrows represent the fixtures around the snap hooks.

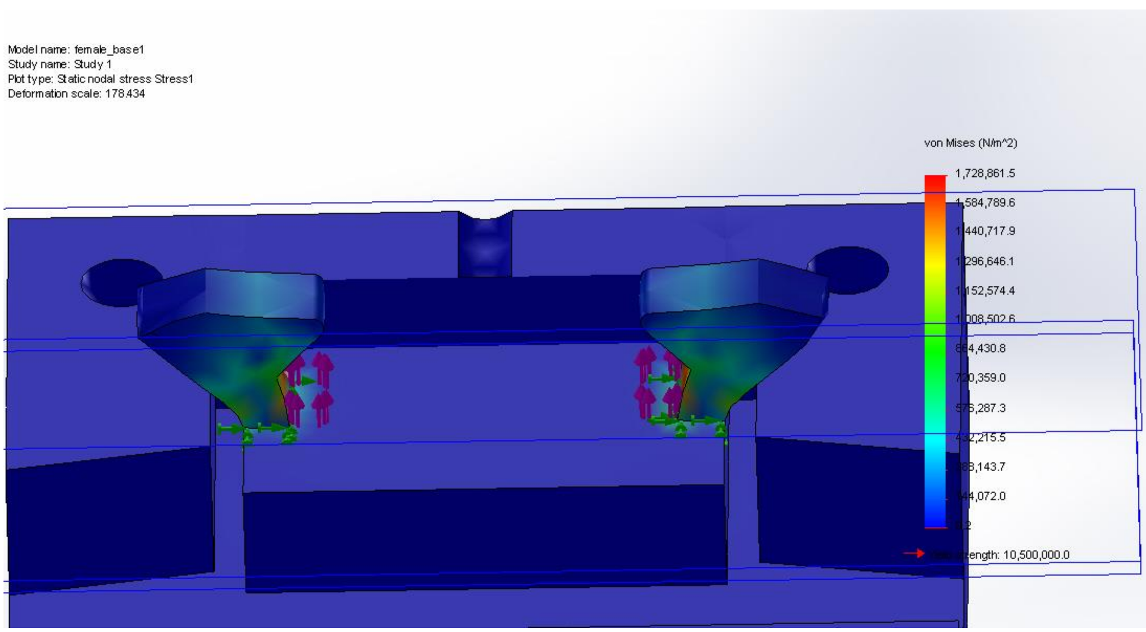


Figure 38: Static Simulation in Solidworks

The maximum Von Mises Stress calculated during the simulation is 1.72 MPa. The yield strength of the material in the Z orientation is 10.4 MPa. As a result, the snap hooks should not break if the speaker holder is removed from the snap hooks. The full static simulation can be found in the appendix.

Using the dimensions determined from the Lingo software the speaker hooks were designed and added onto the female speaker stand piece. The speaker stands were oriented in the Stratasys to allow the speaker hooks to be printed in the z orientation. Figure 39 below is one pair of the male and female speaker stands.

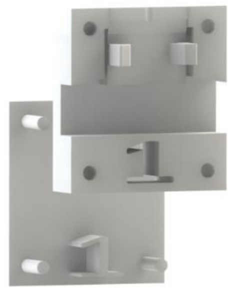


Figure 39: Male and Female Speaker Stands

8 PROJECT MANAGEMENT

The project manager this year is Brittany Harwell. She is leading Tony Battu on the capstone project, which is assisted by Sofie Ganev, Dr. Lincoln Gray, and Dr. Robert Nagel. The following subsections describe how the team and project have been managed and will be managed this school year. The project plan, progress to date, future tasks, and deliverables expected will be outlined in this section.

8.1 Team Management

This capstone team has inherited the graduated capstone team's project. This team has taken on an additional hearing test, will ready the system for shipping, and will create and ship two hearing test systems. Brittany Harwell, project manager, is in charge of delegating tasks and ensuring the project stays on schedule. She is also the lead programmer. Tony Battu, treasurer, is in charge of testing the system on subjects, testing both their hearing and ability to set up the system. He is also the lead hardware designer, analyzing and designing speaker stands for our system. Dr. Kesser, a surgeon at University of Virginia specializing in corrective atresia surgery is an external stakeholder in the project; the advisory team for the project includes: Dr. Gray, a professor in CSD at JMU; and Dr. Nagel, an assistant professor at JMU in the engineering department. Dr. Gray handles communications with Dr. Kesser. The main technical skill required for this project is the ability to program in MATLAB. Brittany Harwell has acquired this skill from participation in a related internship. Tony Battu is learning the basics of programming such as algorithm development and structure. Tony has also taken the required courses for IRB approval so that he can test human subjects. The written code is being stored in a single folder in Dropbox. Deliverables are also being stored in the Dropbox folder. When documents are being worked on in parts, they will be emailed back and forth between Tony, Brittany, Dr. Nagel, and anyone else collaborating on it. Once the parts are done, the compiled version will be stored in the team Dropbox folder. Email is the primary source of communication to plan meetings, organize deliverables, and communicate instructions and deadlines. Text messaging will be a secondary but more frequent mode of communication being used to communicate reminders, upcoming deadlines, meeting times, and meeting locations. This past semester, the entire team has met on Monday at 10:00 AM in Health and Human Services Building, Room 2007. Any other meetings will be communicated at least 24 hours beforehand. A violation of this rule is allowed if all parties agree that the short notice is not inconvenient for them. All meetings use the following structure: determination of meeting end time; status updates from each person; discussion of items on agenda; and then distribution of tasks for the week. For more information on the team contract, see the appendix binder.

8.2 Project Management

The team is small and easier to manage, so the overall project plan is simple. For a more in depth project plan of the last semester (Spring 2014), see the appendix binder. The team has completed the software development (Speech in Noise Hearing Test (SINHT)) and validation. Validation falls into two categories: hearing test validation and hardware validation. Hearing test validation is the process of testing people and analyzing their data. If the person is bilateral, an earplug is placed in one ear and reinforced with a noise-cancelling headphone. Then another trial is completed with the earplug in the other ear. We found a significant difference between unilateral and bilateral hearing. Hardware validation is the process of testing that people can set up the system. We found a repeatable, intuitive set up. Next, the test system components were purchased and test systems will be constructed once the laptops arrive. The existing system was deployed to UVA where patients can use it with a proctor. The hope is that patients will learn how to use it at UVA before and after surgery. Then, they can more easily use it when it is delivered to their house in the future. The data will be analyzed as received and finally the team submitted to Systems and Information Engineering Design Symposium (SIEDS'14) and will present at the conference in April. The entire project plan is shown in Table 8.

Table 8: The Project Plan for the Junior Capstone Team

Semester:	Fall 2012	Fall 2012	Spring 2013	Fall 2013	Spring 2014
Dates:	October 1 - October 26	October 29 - December 3	January 14 - May 1	August 29 - December 1	January 19 - May 1
Milestone:	Planning	Programming SINHT	System Level Design (software), Testing and Refinement (hardware)	Detail Level Design, Production Ramp up	Testing and Refinement (entire system)
Budget:	$0	$0	$500: SIEDS conference fees	$450+grant money: more hardware	$50+grant money: shipping costs and hardware purchases and SIEDs fees
Tasks:	Develop project plan	Design software flow chart concepts	Test design of set up and speaker stands	Handle errors in code	Ship system to UVA to test ease of set up, ease of use, and hearing

	Write mission statement	Program SINHT	Refine speaker stands based on feedback	Create beta prototype	Use feedback to refine designs
	Research topic	Collect customer needs, functions, and target specifications	Ship entire system to Amy for design and hearing testing	Test and refine design of beta prototype	Construct new systems
	Research MATLAB functions	Debug and test SINHT (code)	Calibrate decibel levels	Create more systems	Ship system to a patient
	Acquire technical skills	Test HINT on volunteers	HINT data analysis	Incorporate microphone	Video monitoring
		Hardware concept development	Apply for 4-VA grant		

The timeline for spring semester 2014 is shown in Table 9.

Table 9: Remaining Project Tasks and Timeline (Nagel 2013)

Task Description	08/13	09/13	10/13	11/13	12/13	01/14	02/14	03/14	04/14	05/14
Complete Software Development										
Hearing Test Validation										
Hardware Validation										
Purchase Test System Components										
Construct Test Systems										
Deployment of Test Systems										
Analysis of Data										
Submit SIEDS'14 Conference Paper										

8.3 Future Work

A system was sent to Dr. Kesser at UVA who provided feedback and initial data. From the feedback, the instruction manual was refined. A Frequently Asked Questions sheet was added to the instruction manual based on the Failure Modes and Effects Analysis. On-screen instructions were improved to be dialog boxes so that the testing screen is visible while reading instructions. Since a system that requires a proctor was sent to UVA, the team since automated the system so that it does not require a proctor. This more autonomous system will be sent out to patients in May 2014. The final prototype was presented at the SIEDS'14 conference at UVA April 25, 2014 and it was presented at the MADE xChange on April 26, 2014. Future work includes adding more hearing tests. Since the software is modular, the addition of more hearing tests is facilitated. Research should be done to determine applicable binaural tests or the customer scope could be expanded to other tests.

9 CONCLUSIONS AND RECOMMENDATIONS

It has been determined that the CRM can distinguish bilateral and unilateral listeners. The customers, Dr. Gray and Dr. Kesser, are encouraged by the progress made thus far and excited to start acquiring data with our system at UVA. Once the laptops arrive, we will be able to set them up and begin constructing new test systems. The new test systems will be the Beta Prototype. They will be sent to patients' homes once the Beta Prototype is fully refined and ready.

The Distributable Stereo Hearing Test project has been created to solve Dr. Kesser's problem of having a miniscule amount of post-surgery data. This post-surgery data is necessary to understand how the patients use their new eardrums and to understand how they learn to use binaural processing or whether they learn it all. The capstone team's main goal has been to provide a portable case that contains eight speakers, a microphone, a laptop, and other accessories. The portable case will be deployed to patient's households. After compiling and analyzing the data, Dr. Kesser will become more informed about his operations and be able to advise his patients with more knowledge about what to expect after the atresia operation. In addition, Dr. Kesser may be able to improve his techniques of the surgery to provide his patients with better results. With the additional data, the atresia community will become more educated about the lasting effects of the surgery. Providing this information to doctors may help patients eventually have a higher quality of hearing in life.

Acknowledgements

At this point, we would like to acknowledge 4-VA and JMU Engineering Department for their financial contributions and educational support. Also, we would like to thank Dr. Lincoln Gray for lab support and his assistance with analyzing the hearing test data. We would also like to thank Dr. Robert Nagel for his advice and revision of this paper. We would like to give a special thank you to Dr. Bernstein We would also like to acknowledge the graduated capstone team and their hard work that has made our project possible.

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