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Otoscopic and Tympanometric Outcomes in Haitian Children

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OTOSCOPIC AND TYMPANOMETRIC OUTCOMES IN HAITIAN CHILDREN

by

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ABSTRACT

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Outer and middle ear pathologies are common and highly treatable conditions that affect children worldwide. While data on the prevalence of outer and middle ear disorders in children in North America and other developed countries is ample, such data in developing countries is oftentimes scarce. Determining the prevalence of outer and middle ear disorders is vital, as these types of disorders, if left untreated, can have medical, audiological, and educational implications. Both the identification and treatment of outer and middle ear pathologies are especially important in Haiti, a country that has a severe lack of medical resources, and is especially devastated since the earthquake in 2010.

The purpose of this study was to collect otoscopic and tympanometric data on schoolchildren (ages 5 – 8) in a kindergarten and primary school in Port-au-Prince, Haiti. The otoscopic and tympanometric data were collected and statistically analyzed, and recommendations and referrals to proper medical professionals were issued. Issuing referrals is vital; especially since the prevalence of serious middle ear disorders (such as chronic suppurative otitis media) are more prevalent in developing countries, and, if left untreated, more serious middle ear disorders can occur, and have potentially devastating consequences.

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INTRODUCTION

According to the World Health Organization, 32 million children under the age of 15 worldwide have a hearing loss which is considered disabling (WHO, 2013). A disabling hearing loss, according to the World Health Organization, is a hearing loss of 30 dB HL or poorer. The overwhelming majority of children with disabling hearing loss reside in developing countries, and, of these children, only a small fraction (~10%, or fewer than 1 out of 40 people with hearing loss) have access to amplification, or other hearing assistive technology (WHO, 2013). Of the 32 million children worldwide with hearing loss, half of the hearing losses are preventable, with the majority of them caused by ear infections, e.g. otitis media (WHO, 2013).

Though in the grand scheme of public health crises in the developing world, hearing loss may seem minor; its impacts can severely take a toll on an individual's and a family's quality of life. These impacts can be functional, emotional, social, and economic. From a functional standpoint, children with hearing loss can suffer deficits in educational pursuits, speech and language development, and communication (WHO, 2013). This is because a medical condition such as otitis media can often create a mild, temporary (unless left untreated) hearing loss (CDC, 2013). Feelings of social isolation can also occur due to hearing loss, which can be detrimental in children. Additionally, in developing countries oftentimes those with hearing loss will not receive a proper education, which can severely reduce one's employment opportunities (WHO, 2013).

Developing Countries

It is important to understand the differences between developing and developed countries, especially in the public health arena. From a general standpoint, countries are able to classify

themselves as either “developing” or “developed”, with the criteria usually utilized involving gross national income, infrastructure, and general quality of life. Those which are “developing” often are characterized by low gross national income, i.e. <$1,035 per capita (Goulios & Patuzzi, 2008; World Bank, 2012). Certain health conditions which may be eradicated from developed countries may be rampant in the developing world. Additionally, those who reside in developing countries tend to have poor living standards, shorter life expectancies, and may not view non-life threatening conditions such as hearing impairment as a pressing issue (Goulios & Patuzzi, 2008; WHO, 2004). Furthermore, even if those in developing countries wished to pursue professional help for their suspected hearing loss, hearing health professionals in developing countries are few and far between, with an average of 1 audiologist per 0.5 million or 6.25 million (WHO, 1998).

Why Haiti

Though audiological data are starting to be collected and codified more and more in developing countries worldwide, data from Haiti are still far behind. According to a report by the World Health Organization, Haiti is considered one of the poorest countries in the Americas, and its wealth is disproportionally distributed among its inhabitants (Pan American Health Organization, 2010). More than half of the population has little or no access to basic health care and medications, and tuberculosis, tetanus, measles, polio, malaria, and HIV are serious health concerns in the Republic of Haiti (Pan American Health Organization, 2010). Extensive literature reviews have come up with no research studies to date outlining audiological data on residents of Haiti. Goulios and Patuzzi conducted a major study in 2008 to identify the number of hearing health professionals globally, but Haiti was not polled.

90% of global births occur in the developing world, which is often characterized by less than ideal conditions (Olusanya & Okolo, 2006; Olusanya, 2005; Newton, 2001 – as cited in Olusanya & Okolo, 2006). This can often result in women in developing countries such as Haiti not having access to quality perinatal care, which can in turn result in their children acquiring significant hearing losses (Olusanya, 2005). These acquired hearing losses can develop from such conditions as: measles, febrile illness, meningitis, mumps, severe birth asphyxia, ototoxicity, neonatal jaundice, cerebral palsy, cerebral malaria, and congenital rubella syndrome (Dunmade et al., 2007).

Drugs used to treat malaria have been implicated in the cause of profound sensorineural hearing loss in both children and adults (Holborow et al., 1982- as cited in Olusanya & Okolo, 2006; Wright & Leigh, 1995 – as cited in Dunmade et al, 2007).The resulting deafness and hearing loss is thought to be caused by disruptions in the endings of the cochlea, or simply by lowering immunity to disease, which in turn can cause the infections leading to hearing loss (Dunmade et al., 2007). The potential hearing loss that can be caused by malaria is especially concerning in the Republic of Haiti, where its prevalence can fluctuate, based on the decade. Luckily, recent efforts have been taken to eradicate the spread of malaria (Kachur et al., 1998).

Early hearing identification is a vital and pressing issue in developed countries, and has risen considerably in importance since the advent of universal newborn hearing screening. Identifying hearing losses as early as possible is especially important in developing countries, due to the paucity of hearing health professionals in these regions. It is important to identify and treat hearing loss as early as possible to prevent academic, vocational, psychological, and communication deficits (Olusanya, 2001). Additionally, early intervention (starting at 6 months

of age or earlier) is important, to minimize the possibly devastating effects (Yoshinaga-Itano et al., 1998).

Though universal newborn hearing screenings are of course preferable, they are not always feasible or cost-effective to implement in developing countries. When newborn hearing screenings are not possible, there may be some merit to conducting hearing screenings prior to school entrance (Olusanya, 2001).These types of screenings can involve diagnostic audiology such as otoacoustic emissions, auditory brainstem response testing, pure tone audiometry, otoscopy, and tympanometry (Olusanya, 2001).

Otitis Media

The most common forms of preventable hearing loss are those caused by ear infections, i.e. otitis media (WHO, 2013). The two most common forms of otitis media are otitis media with effusion (OME) and acute otitis media (AOM) (Mark et al, 2013). Otitis media with effusion is defined as the presence of fluid in the middle ear without an active infection being present (Stool et al, 1994 – as cited in Mark et al, 2013), while acute otitis media is the presence of an active infection, complete with fever, and other associated symptoms. OME and AOM are common in children under the age of 7 (Gell et al., 1992), can be associated with either temporary or permanent hearing loss, and can sometimes cause developmental delays if the hearing loss goes untreated (Paradise, 1981).

Otitis media with effusion can develop into acute otitis media (active infection) or chronic suppurative otitis media (CSOM), which is prevalent in developing countries (Okafor, 1984; Holborow, 1985 – as cited in Gell et al, 1992; Prasansuk, 1987 – as cited in Gell et al, 1992). Chronic suppurative otitis media is characterized by constant discharge from the middle

ear through a tympanic membrane perforation (WHO, 2004). Chronic suppurative otitis media is considered to be the primary cause of preventable hearing loss in developing countries (Bluestone, 1998), and the dearth of research on the world-wide prevalence caused the World Health Organization to classify it as a vital public health issue (WHO, 1998). Chronic suppurative otitis media is a major cause of hearing loss worldwide (WHO, 2004 – as cited in Jensen, Koch & Homoe, 2013), and affects 65 – 330 million individuals worldwide (Homoe, Christensen & Bretlar, 1996; Koch, Homoe, Pipper et al, 2011 – as cited in Jensen et al, 2013). This type of otitis media is often prevalent in developing countries, while non-infective otitis media is more prevalent in developed countries (Gupta et al., 1985 – as cited in Gell et al, 1992). Chronic suppurative otitis media tends to occur more frequently in those with poor living conditions and hygiene, usually characteristic of developing countries, such as Haiti (WHO, 2004; Casselbrant et al, 1985; Teele et al, 1989 – as cited in Mark et al, 2013). It is also more common in young children (under the age of six) who tend to reside in developing countries, as developing countries tend to have a younger population than developed countries (WHO, 2004). CSOM can be validly diagnosed using pneumatic otoscopy and tympanometric studies (Rosenfeld et al, 2004 – as cited in Mark et al, 2013).

Immittance Testing

Immittance testing is a valuable method of identifying the presence of possible outer and middle ear abnormalities and pathologies. Immittance testing involves measuring both the impedance and the admittance of the ear, i.e. the opposition and the ease of the flow of sound energy into the ear, respectively. When certain pathologies are present, they can change the springiness, mass, or resistance of the ear. A probe tip placed into a test subject's ear introduces

air pressure, which in turn measures the equivalent ear canal volume, tympanometric peak pressure, tympanometric gradient/width, and the static acoustic admittance of the ear. Most tympanograms are measured using a 226 Hz probe tone. The values obtained from each tympanogram are then compared to otoscopic findings and normative values (Gelfand, 2009).

The acoustic reflex is a phenomenon that occurs bilaterally in response to an adequately loud sound. When an individual encounters an intense sound, the ear's conductive mechanism stiffens by contracting the stapedius muscle, which in turn changes (usually decreases) the admittance of the middle ear. Sensory (afferent) and motor (efferent) pathways are involved in causing the acoustic reflex to occur. The afferent pathway begins when the sound from either the right or left cochlea travels to the 8^{th} nerve, which in turn goes to the ipsilateral ventral cochlear nucleus. Following this, the neurons travel to the superior olivary complex on both sides of the brainstem. The afferent pathway ends with both superior olivary complexes sending signals to the ipsilateral facial nerve. The efferent pathway begins when the facial nerves of both the right and left side cause their respective stapedius muscles to contract (Gelfand, 2009).

Clinically, acoustic reflexes are measured ipsilaterally (uncrossed pathway) and contralaterally (crossed pathway) with an immittance device. The lowest level which elicits a measurable reflex is known as the acoustic reflex threshold. Analyzing acoustic reflex results can help with detecting the presence, type, and degree of hearing loss, and can also be a valuable tool for helping to identify possible retrocochlear pathologies (Gelfand, 2009).

Background Information

Many different methods have been employed to identify and treat hearing loss in developing countries, where resources and trained personnel are often in short supply. Many of

the audiological studies conducted across the world involve hearing screenings, usually either at birth, or prior to school entrance. In order for a hearing screening to be successful, it must accurately identify those who need to obtain proper referrals or undergo further testing, be economical, be timely, and involve proper methods and protocols (Sliwa et al, 2011; Ciorba et al, 2008 – as cited in Sliwa et al, 2011).

Hearing screenings can involve both objective and subjective tests, e.g. otoscopy, tympanometry, acoustic reflex testing, transient/distortion product otoacoustic emissions, auditory evoked potentials, pure tone screenings, and standard pure tone audiometry. Specificity and sensitivity rates tend to be higher when (a) more methods are used and (b) the methods used are more sophisticated (Sliwa et al, 2011). Finding a delicate balance between cost-effectiveness and maximizing sensitivity and specificity is oftentimes a challenge for audiological research being conducted in developing countries. Several examples of audiological research in developing countries are outlined below.

Adebola et al (2013) conducted a cross sectional study in Ogbomoso, Nigeria, which involved conducting hearing screenings on 101 schoolchildren aged 3.5 – 6 years. The subjects were selected randomly from six schools (three primary schools and three public schools) in the Ogbomoso area. Otoscopic studies were performed by otolaryngologists, and all results were recorded. Following otoscopic studies, audiometric studies were performed by a licensed audiologist. Before intervention, otoscopy revealed normal outer and middle ear function in 52.4% of the ears examined, impacted cerumen in 21.4% of the ears, otitis media with effusion in 13.9% of the ears, and perforated tympanic membranes in 11.9% of the ears. Prior to intervention, 78.7% of the subjects passed hearing screenings. Post intervention, 88.6% of the ears passed otoscopy, while 93.6% passed hearing screenings. This research study highlights the

fact that otoscopy, tympanometry, and hearing screenings are relatively inexpensive screening tools that can help to determine the prevalence of outer, middle, and inner ear disorders, especially in developing countries, where funds and instrumentation are often unavailable (Adebola et al, 2013). This can be an important consideration in advocating and facilitating proper treatment and rehabilitation for those with outer ear disorders, middle ear disorders, or hearing impairment (Adebola et al, 2013).

Sliwa et al, 2011 compared the performance of 190 school-aged children in Warsaw, Poland on both subjective and objective methods of audiological testing. The four different testing procedures utilized were the following: standard pure tone audiometry, an automated pure tone screening tool (4-frequency), immittance testing (tympanometry and acoustic reflex screening at 100 dB SPL), and automated transient evoked otoacoustic emissions testing. The sensitivity, specificity, and predicted value were calculated for all three screening methods individually, as well as in conjunction with one another. The highest sensitivity and specificity was found with the combination of the 4-frequency screening audiometer and tympanometry. The researchers concluded from their analysis that properly conducted hearing screening programs for school-aged children are vital and effective for identifying hearing loss (Sliwa et al, 2011).

A screening study conducted by Samelli et al (2012) sought to evaluate the efficacy of two types of screening methods for conductive hearing loss on 507 children aged 3 – 6 years in Brazil. The two screening methods used were (a) a battery of testing including otoscopy, tympanometry, and acoustic reflex screening, and (b) a 14 question survey filled out by parents, consisting of parental concerns, child development, and medical history. 507 subjects underwent the immittance screening. 177 subjects failed the screening, while 330 of the subjects passed the

immittance screening. 111 subjects (including those who failed the screening and those who passed the screening) underwent complete audiological evaluations, further immittance testing, and had the questionnaires completed on their behalf. 61.3% of the subjects had normal audiometric outcomes, and 38.7% had abnormal audiometric outcomes (i.e. mild to moderate conductive hearing loss). The sensitivity and specificity of the two forms of screening (immittance and survey) were analyzed individually and collectively. Individually, the two showed high sensitivity and low specificity. However, when the two methods were combined to test the subjects, a sensitivity rate of 95% and a specificity rate of 72% were found. This suggests that a combination of the screening methods utilized and the survey ensured accuracy in identifying conductive hearing loss in children (Samelli et al, 2012).

Olusanya conducted a research study to ascertain the prevalence of different types of hearing loss among children residing in Lagos, Nigeria. Eight primary schools were randomly selected from a pool of 76 schools in the area, out of which 359 children (with the majority stemming from low income households) were chosen for the study. She found that the prevalence of hearing loss was approximately 13.9%, with 36% of the verified hearing losses having conductive components (Olusanya, 2001). Olusanya postulated that the results obtained can be extrapolated to the majority of children in developing countries, and that adequate screening methods are vital (Olusanya, 2001). Without proper screening methods being carried out on children, quality of life for children with hearing loss in developing countries can be greatly compromised (Swanepoel et al., 2004 – as cited in Theunissen & Swanepoel, 2008). However, it may not be viable or feasible for developing countries to utilize the same methods as developed countries, due to the fact that most children are born outside of major hospitals

(Olusanya et al., 2004), and due to limited medical resources and trained professionals (Olusanya & Okolo, 2006).

Jensen, Koch & Hoboe (2013) conducted a longitudinal study of the effects of chronic suppurative otitis media on hearing thresholds in two cohorts of Greenlandic children. The children examined were between 0 and 8 years of age. Low/high frequency hearing loss was found in about 50% of the participants (PTA>15 dB HL and in one or both ears), and 1 in 10 of the participants were found to have a hearing loss of >40 dB HL. The majority of the hearing losses identified among the Greenlandic children was determined to be related to chronic suppurative otitis media. Mixed hearing loss was found even in those who had bouts of chronic suppurative otitis media that had been healed. Overall, the prevalence of hearing loss in the cohort of Greenlandic children was triple the prevalence in the United States, with the vast majority of it a result of chronic suppurative otitis media. The researchers estimated that those who experience chronic suppurative otitis media in childhood have a 91% chance of developing a slight (15 dB HL) or poorer permanent hearing loss (Jensen, Koch & Hoboe, 2013).

In a mass hearing screening research study conducted by Clark (2008), the most common forms of hearing loss in Mozambique (considered to be a developing country) were ototoxicity and chronic otitis media. The percentage of children evaluated who presented with chronic otitis media was 18.6%, while 5% of them presented with both otitis media and accompanying hearing loss (Clark, 2008). Outer-ear conditions found by Clark included external auditory canal abnormalities, abnormal tympanic membrane mobility, and actively draining ears. Raising awareness of both external and middle ear pathologies is vital in developing countries due to the reversible nature of the hearing losses associated with the aforementioned pathologies,

and due to the effect these pathologies can have on educational development and quality of life (Clark, 2008).

Hatcher et al (1995) conducted a study of the prevalence of chronic suppurative otitis media, ear canal abnormalities, tympanic membrane perforations, and cerumen impaction among schoolchildren in Kiambu, Kenya (Hatcher et al., 1995). 5368 children in 57 schools were picked to participate in the study, and those diagnosed with chronic suppurative otitis media were referred to a local health professional or ENT doctor. Results revealed the highest prevalence of impacted cerumen, while chronic suppurative otitis media occurred in 1.1% of the children tested (Hatcher et al., 1995). The connection between cerumen impaction and chronic suppurative otitis media and hearing loss is not definitive (Hatcher et al., 1995).

A systematic review by Brouwer et al. (2005) sought to determine the possible link between acute otitis media in children and their reported health related quality of life. This can have implications for those in developing countries (such as Haiti), who are more prone to chronic suppurative otitis media (WHO, 2004). Physical problems that are oftentimes associated with acute otitis media are difficulty sleeping, irritability, lack of appetite, ear pain, high fever, hearing issues, vestibular problems, and social problems (Asmussen et al., 1996 - as cited in Brouwer et al, 2005; Rosenfeld et al., 1997; Rosenfeld et al., 2000; Richards & Giannoni, 2002). Similarly, Arguedas et al. (2010) surveyed 1800 physicians in nine different countries, and acute otitis media in children under the age of 5 (treated with antibiotics) was found to be a significant burden.

To conclude, Haiti was chosen as a site for our research based on the dearth of screening activities and audiological data available, as well as the likely high prevalence and incidence of middle ear disease (due to widespread adverse living conditions and a lack of access to basic

medical care for many inhabitants). Though other developing countries have some data available on the prevalence of possible outer and middle ear disorders among young children, a systematic review of the literature came up short with regards to Haiti. Identifying possible outer and middle ear abnormalities consistent with findings can help to prevent these conditions from worsening, through notifying the parents of the condition, as well as facilitating proper medical referrals to available practitioners. Additionally, the hope is that through properly identifying such disorders, these children's quality of life, social pursuits, and educational advancement will not suffer. Though providing amplification is not within the means of this research project, a more ultimate goal will be to facilitate the provision of affordable amplification to those subjects who need it most.

OBJECTIVES AND RESEARCH QUESTIONS

My research partner and I mounted a mission to Haiti to perform otoscopy, tympanometry, acoustic reflex screenings, audiometric screenings, and complete audiological evaluations on approximately 40 school-aged children attending the *Ecole Presbyterale de St Vincent de Paul*, due to the many reasons outlined above. The goals of our two projects were to determine the prevalence of hearing loss and possible outer and middle ear pathologies of children in Haiti without active ear disease in order to teach healthy hearing practices and to facilitate the ultimate provision of amplification/assistive listening devices if necessary.

The ultimate goal of collecting this audiological data was to use the data to raise awareness of the global impact of hearing loss on children in developing countries such as Haiti. We planned to achieve this goal by distributing the results from this research project (as well as my research partner's, which focuses on the hearing statuses of the same school-aged children),

in order to make the case for further mission trips all around Haiti, both audiological and medical. We also sought to recommend and teach healthy ear practices to parents of the subjects at *Ecole Presbyterale de St Vincent de Paul*.

Research Questions

1. What proportion of pre-school and school age children have fully impacted cerumen based on otoscopic examination?

2. What is the proportion of observed abnormal outer ear structural abnormalities in the population of children undergoing hearing screening and follow-up testing (e.g. microtia, stenosis, atresia)?

3. What proportion of children had normal tympanograms in one or both ears? What proportion of children had abnormal tympanometric and acoustic reflex screening results?

4. What is the relation between acoustic reflex screening outcomes and audiometric test results?

METHODS

Participants

Otoscopic studies, tympanometric testing, ipsilateral acoustic reflex screenings, and audiometric testing took place at the *Ecole Presbyterale de St Vincent de Paul* kindergarten and primary schools in the Thomson 25 section of Port-au-Prince, Haiti.

Several weeks prior to our arrival, a notice was sent home with students (aged 5 -8) at both the kindergarten and primary school regarding the dates that testing would take place, as

well as a short description of what the testing would entail. Permission forms were sent home a couple of weeks later, and the signed and returned forms were collected and organized by age group by the school staff.

On each day of testing, students who had returned with signed permission forms were chosen randomly to participate in testing. Since data was collected over the course of a week, if some subjects appeared to be recovering from colds, draining ears, or communicable diseases (and they possessed signed permission forms), they were included in testing. Otherwise, subjects with actively draining ears, colds, or other communicable diseases were excluded from testing, even if they returned to school with signed permission forms, which was a limitation of the current study. Subjects with asthma and cleft palate were not excluded from testing.

IRB approval was obtained through the City University of New York in April 2013.

Materials

The instrumentation utilized for the tympanometric evaluations, otoscopic evaluations, hearing screenings, and the complete audiological evaluations included the following: a Maico QT-1 Tympanometer, a Firefly video otoscope, a Welch Allyn standard otoscope, and a Maico (MA-41) Audiometer. Disposable probe tips for the tympanometer and otoscope as well as printer paper were also utilized for every test subject. All of the testing equipment (tympanometer and audiometer) was calibrated according to ANSI (2010) standards, and all equipment was disinfected prior to and in between testing. All data obtained from the immittance instrument were printed, and recorded manually as well.

Prior to conducting otoscopic, tympanometric, and audiometric testing, an Extech digital sound level meter (model # 407730) was utilized to measure the sound levels in the testing

environment. All testing environments were found to have ANSI acceptable sound levels between 40 – 42 dB SPL (Frank, 2000).

Procedures

Prior to our arrival, a note was sent out to the parents (translated into both English and Haitian Creole), clearly explaining and outlining the testing that was to occur in the coming weeks (pending parental/guardian written approval). Written permission forms (see Appendix A) were sent home with all of the children ages 5 to 8 prior to our arrival in Port-au-Prince, Haiti. Subjects who did not return to school with signed permission forms by their parent or guardian were excluded from the testing. The teachers and other relevant members of the administration at the *Ecole Presbyterale de St Vincent de Paul* were contacted to ascertain the best time of the school day to perform the screenings and other testing, as well as the various children's demographic information and chronological ages. From those who did return to school with the above completed documents, approximately 40 subjects, aged 5 – 8, were chosen for testing. Prior to testing, verbal assent (see Appendix B) was delivered to the subjects, and those who did not wish to participate were excluded from testing.

Prior to testing the subjects, permission forms were collected. Children were selected randomly, and assent was obtained verbally in Creole by the school principal. Assent was noted, as well as the principal's signature, and then testing began. Otoscopy was performed first on all of the subjects. Video otoscopy was utilized whenever possible, but standard otoscopy was utilized as well. Those ears tested with the video otoscope had the results recorded both manually and electronically (in the form of jpeg images saved on a computer). Those tested with the

standard otoscope had the results recorded manually only. If there was a question regarding the otoscopic findings, my research partner performed it as well on the subject.

The status of the outer ear, external ear canal, and tympanic membrane was noted, as well as the presence of cerumen, scarring, or possible perforations. Following otoscopy, the ear canals were classified as clear, needing cerumen management, or needing referral to a physician (Clark, 2008).

All of the participants underwent tympanometry and ipsilateral acoustic reflex screenings following otoscopy with a portable tympanometer. Notations were made if no seal was able to be obtained. Both investigators performed otoscopy and tympanometry if there was a questionable result upon testing subjects. The tympanograms that were obtained were classified according to the types and norms listed in Tables 1 and 2.

Table 1. Tympanogram Classification (Martin & Clark, 2006)

Type	**Description**
Type A	Normal tympanogram
Type A_D	Indicates high static admittance, usually associated with a flaccid tympanic membrane
Type A_S	Indicates low static admittance, usually associated with stiffening pathologies, e.g. stapes mobilization, otosclerosis
Type B	Indicates a flat tympanogram, usually associated with fluid in the middle ear, tympanic membrane perforations, or cerumen impaction
Type C	Indicates negative middle ear pressure, and is consistent with Eustachian tube dysfunction, or can be associated with head colds

Table 2. Tympanometric Norms for Children (JCIH, 2007; ASHA, 1990; Jerger et al, 1972; ASHA, 1990)

Measure	Normative Value
Peak Pressure	-150 - +50 daPa
Static Acoustic Admittance	0.35 – 1.3 mmhos
Ear Canal Volume	0.3 – 2.0 cm^3

Following tympanometry, ipsilateral acoustic reflex thresholds screenings at 100 dB SPL were conducted with the immittance system. Ipsilateral acoustic reflexes were classified as "yes" or "no", based on the reading from the immittance system. If a seal could not be maintained for acoustic reflex screenings, it was noted.

Statistical Analyses

The otoscopic, tympanometric, and ipsilateral acoustic reflex outcomes were analyzed using Microsoft Excel.

RESULTS

Participants

Forty one subjects, aged 5 – 8, participated in this study. Twenty six of the participants were male, and fifteen were female. The mean subject age was 6.5 years of age. The median subject age was 7 years of age. Any subject with an actively draining ear was excluded from

testing. The otoscopic, tympanometric, and acoustic reflex screening results were collected, and the results are listed below.

A. *What proportion of pre-school and school-aged children have fully impacted cerumen based on otoscopic examination?*

Visual inspections of both ear canals were performed on each subject utilizing either standard or video otoscopy. The presence or absence of cerumen (as well as the amount of cerumen) was recorded for each subject, and is presented in Table 3. Upon inspection, 70 of the participants' ears did not have cerumen noted in the ear canal, 11 ears had cerumen noted (non-impacted), and 1 ear had occluding cerumen that was noted.

The results were analyzed by age group, and are displayed graphically in Figure 1. Upon examination of the otoscopic results based on age group, the 5 year old age group had the greatest amount of ears (20) without cerumen. The 8 year old age group had the greatest amount of ears with cerumen noted in the ear canal (7 ears). The one subject (1% of 82 ears) with impacted cerumen noted was in the 8 year old age group.

Table 3. Ear Canal Status

Amount of Cerumen Impaction	Number and Percent (%) of Ears
None	70 (85%)
Cerumen Noted (Non-impacting)	11 (13%)
Impacted Cerumen	1 (1%)

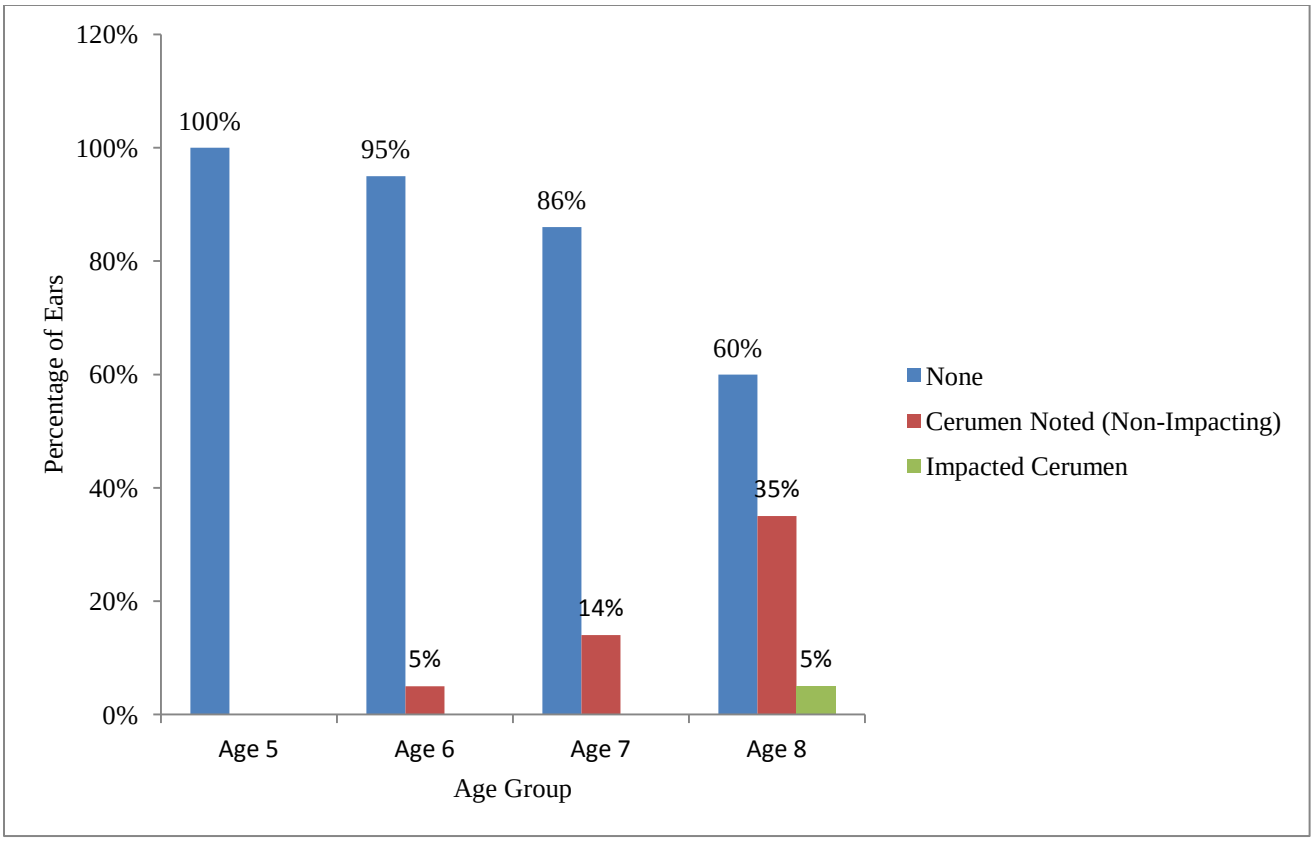

Figure 1. Results of Visual Inspection of Ear Canal by Age Group

B. *What is the proportion of observed abnormal outer ear structural abnormalities in the population of children undergoing hearing screening and follow-up testing (e.g. microtia, stenosis, atresia)?*

Visual inspection revealed that none of the participants had any visible outer ear structural abnormalities.

C. What proportion of children had normal tympanograms in one or both ears? What proportion of children had abnormal tympanometric and acoustic reflex screening results?

The tympanograms for each of the 82 ears tested were classified by their respective tympanogram types, and are displayed in Table 4. The majority of the participants' ears (~49%) presented with Type A tympanograms.

Table 4. Overall Tympanometric Outcomes

Tympanogram Type	Number and Percentage (%) of Ears
Type A	40 (49%)
Type A_S	26 (32%)
Type A_D	2 (2%)
Type B	2 (2%)
Type C	0 (0%)
Could Not Maintain Seal	12 (15%)

The tympanometric results for the 82 ears were also divided by age group. The 8 year old age group had the greatest amount of normal (Type A) tympanograms, as well as the 2 Type B tympanograms. The 5 year old age group had the greatest amount of Type A_S (low static admittance) tympanograms. Type A_D (high static admittance) tympanograms were found only in the 6 year old age group. The 7 year old age group had the greatest amount of ears that were unable to be sealed for immittance testing. These results are presented graphically in Figure 2.

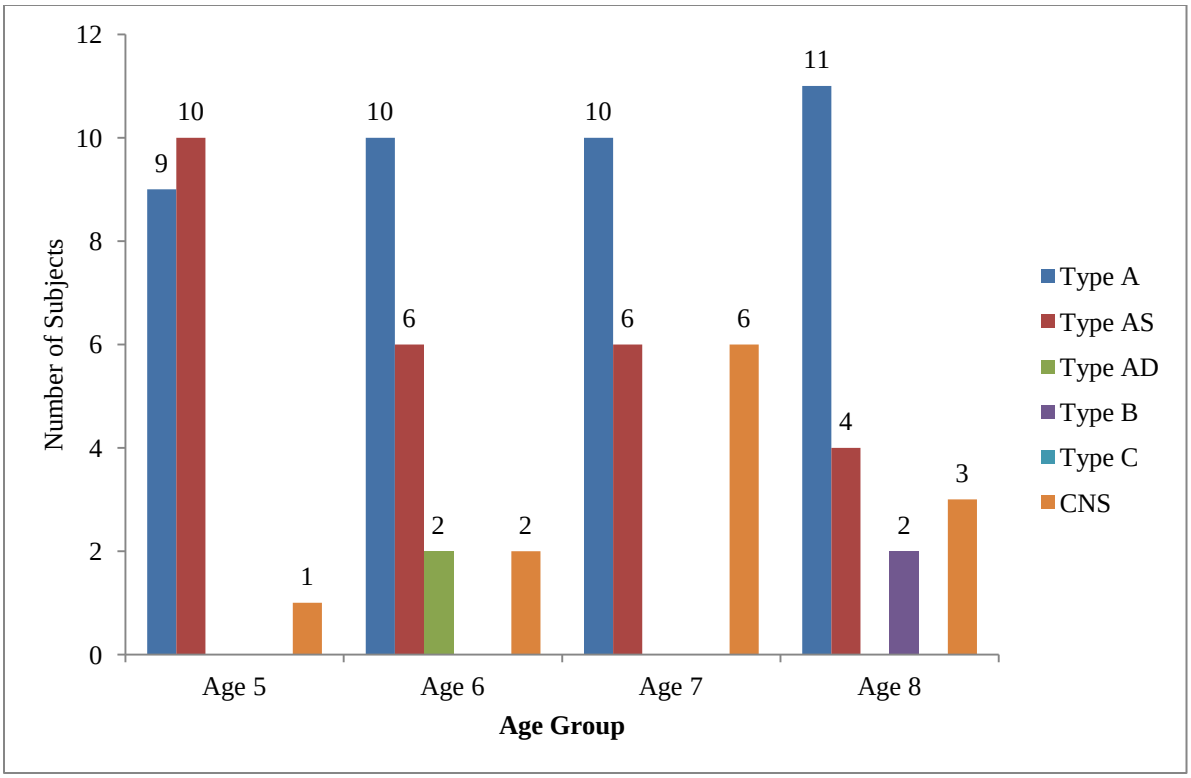

Figure 2. Tympanometric Outcomes by Age Group

The proportion of children with normal tympanograms in one or both ears was divided by age group. Table 5 displays the proportion of children with normal tympanograms in one ear and both ears, divided by age group. Figure 3 displays the subjects with normal tympanograms in either one or both ears graphically.

Table 5. Proportion of Children with Normal Tympanograms in One or Both Ears

Age In Years (N)	**Normal Tympanogram in One Ear**	**Percentage (%)**	**Normal Tympanogram in Both Ears**	**Percentage (%)**
N= 5	3	7%	3	7%
N=6	8	20%	1	2%
N=7	6	15%	2	5%
N=8	3	7%	3	7%
TOTAL	20	49%	9	22%

As is evident from Table 5 (which displays the proportion of children with normal tympanograms in one or both ears), the greatest amount of participants with normal tympanograms in one ear came from the 6 year old age group. The greatest amount of participants with normal tympanograms in both ears came from both the 5 and 8 year old age groups. Overall, 49% of the participants presented with normal tympanograms in one ear, while 22% of the participants presented with normal tympanograms in both ears.

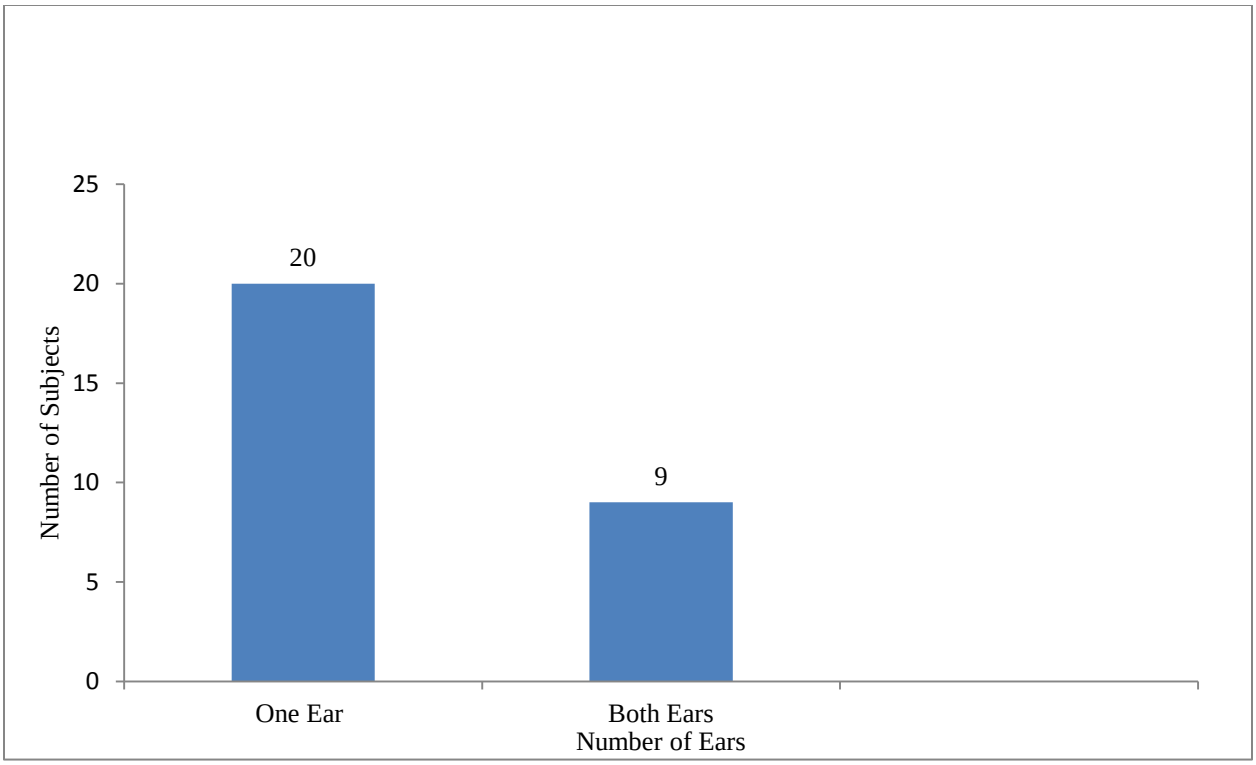

Figure 3. Subjects with Normal Tympanometric Outcomes

As is shown in Figure 3, 20 participants presented with normal tympanometric results in one ear, while only 9 participants presented with normal tympanograms in both ears. The remainder of the participants' tympanometric types could not be evaluated due to the inability to maintain a seal for testing.

Ipsilateral Acoustic Reflex Screening Outcomes

Following tympanometry, all of the 41 participants underwent ipsilateral acoustic reflex screenings at 100 dB SPL with the immittance device. The instrumentation recorded the acoustic reflex responses as "yes" (present) or "no" (absent). The outcomes are divided into categories in Table 6.

Table 6. Overall Ipsilateral Acoustic Reflex Screening Results

Reflex Outcome	Number of Subjects	Percentage
Present in Both Ears	4	10%
Present In One Ear; Absent in One Ear	7	17%
Absent In One Ear; Could Not Seal One Ear	4	10%
Absent Both Ears	22	54%
Absent in One Ear; Could Not Seal One Ear	1	2%
Could Not Seal Both Ears	3	7%

As is evident from Table 6, 22 (54%) of the participants did not pass the ipsilateral acoustic reflex screening at 100 dB SPL for both ears. Upon examination of the remainder of the results, 7 subjects (17%) had reflexes present in one ear and absent in the other ear, 4 subjects (10%) had present acoustic reflexes in both ears, 4 subjects (10%) had a reflex absent in one ear with a seal not being able to be maintained in the other, 3 (7%) of the participants' results could not be analyzed due the inability to maintain a seal in either ear, and 1 subject (2%) had an absent acoustic reflex in one ear with a seal not being able to be maintained for testing for the other ear.

The results of the acoustic reflex screenings for all of the participants were then compared to their respective tympanometric results. Upon comparison, of the 41 subjects tested, 18 (44%) subjects had abnormal tympanometric results (i.e. anything other than a Type A tympanogram) along with a fail on the acoustic reflex screening in one ear. Approximately 17% of the subjects tested presented with abnormal tympanometric results, with failed acoustic reflex screenings in both ears.

Table 7 displays the proportion of subjects with abnormal tympanometric results and failed acoustic reflex screenings, divided by age group.

Table 7. Proportion of Subjects with Abnormal Tympanometric Results and Failed Acoustic Reflex Screening by Age Group

Age in Years (N)	Abnormal Tympanometric Results + Failed AR Screening in One Ear	Percentage (%)	Abnormal Tympanometric Results and Failed AR Screening in Both Ears	Percentage (%)
5 years	4 subjects	10%	3 subjects	7%
6 years	6 subjects	15%	1 subject	2%
7 years	4 subjects	10%	1 subject	2%
8 years	4 subjects`	10%	2 subjects	5%
Total	18 subjects	44%	7 subjects	17%

Upon comparison of the proportion of subjects with abnormal tympanometric results and a failed acoustic reflex screening, the majority of the participants (44%) tested presented with abnormal tympanometric results, along with a failed reflex screening in one ear. Abnormal tympanometric results with failed screening results in both ears was found as an outcome in 17% of the participants. The 6 year old age group presented with the greatest amount of participants (15%) with abnormal tympanometric results coupled with a failed acoustic reflex screening in one ear. The 5 year old age group presented with the greatest amount of participants (7%) with abnormal tympanometric results and a failed acoustic reflex screening in both ears. Figure 4

displays graphically the amount of participants with abnormal tympanometric outcomes and failed acoustic reflex screenings in one or both ears.

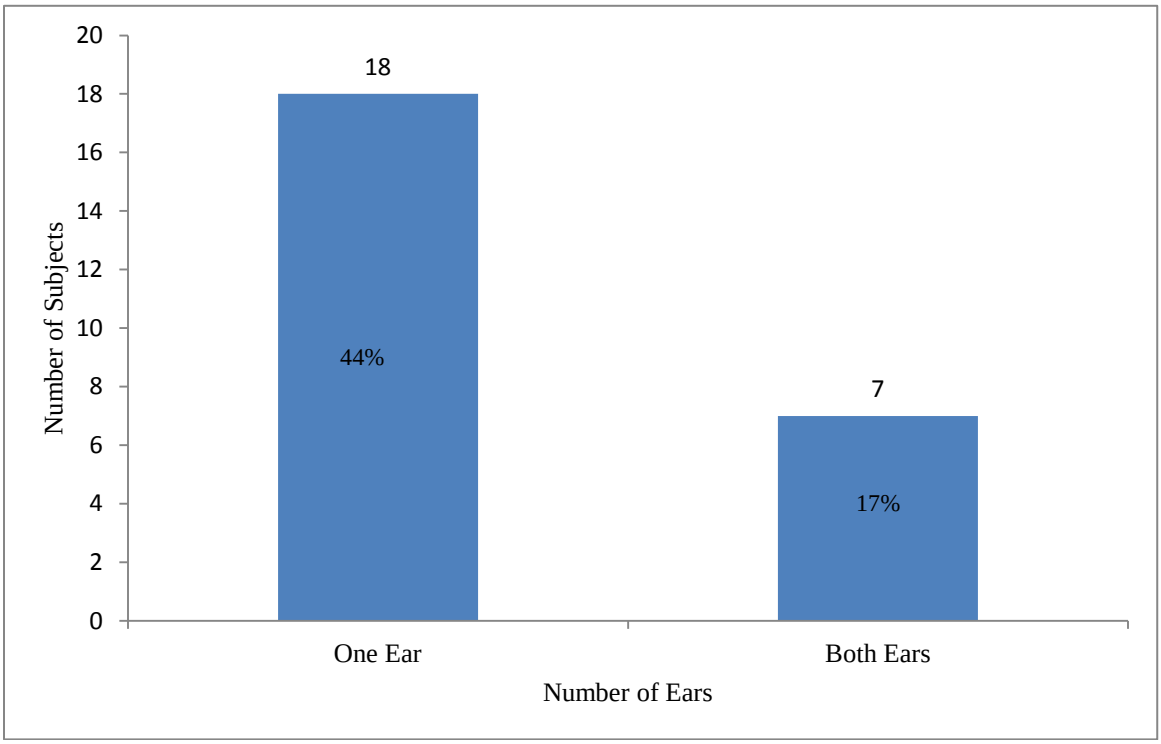

Figure 4. Participants with Abnormal Tympanometric Outcomes with Failed Acoustic Reflex Screenings in One or Both Ears

D. *What is the relation between acoustic reflex screening outcomes and audiometric test results*?

The acoustic reflex screening results of all of the participants were compared to the presence or absence of significant air bone gaps (ABGs) in the audiometric test results. A significant air bone gap is defined as a gap of 10 dB HL or more between the air and bone conduction

thresholds. A gap of this kind suggests a possible issue with the conductive mechanism of hearing, i.e. the outer and middle ear. This is important in reference to ipsilateral acoustic reflex testing because, when significant air bone gaps (and conductive hearing losses) are present, the stimulus levels of the reflex that can reach the cochlea are diminished, and, even if an immittance change is present, it cannot be observed during testing (Gelfand, 2009).

Upon analysis of the 41 subjects tested, 3 presented with present acoustic reflexes in both ears without significant air-bone gaps.15 of the subjects presented with absent acoustic reflexes in one ear, without significant air-bone gaps. 18 of the subjects did not pass the acoustic reflex screening in both ears, yet did not have significant air-bone gaps present in either ear. From the 41 participants, 2 subjects had present acoustic reflexes in one ear with some hearing loss noted (with no significant air-bone gaps present), while an additional 2 subjects did not pass acoustic reflex screenings in both ears, yet had abnormal audiometric results without air-bone gaps.

Table 8 illustrates the relationship between the presence or absence of significant air-bone gaps and a pass or fail on the acoustic reflex screening in the subjects tested, divided into age groups, while Figure 5 displays those results graphically.

Table 8. Relationship between Air-Bone Gaps and Acoustic Reflex Screening Outcomes

Age in Years (N)	Present AR in Both Ears w/o ABGs	Failed AR in One Ear w/o ABGs	Failed AR in Both Ears w/o ABGs	Abnormal Audiometric Results (w/o ABGs) and Present AR in One Ear	Abnormal Audiometric Results (w/o ABGs) with Failed AR in Both Ears
5 years	0 subjects (0%)	4 subjects (10%)	6 subjects (15%)	0 subjects (0%)	0 subjects (0%)
6 years	1 subject (2%)	4 subjects (10%)	5 subjects (12%)	0 subjects (0%)	0 subjects (0%)
7 years	2 subjects (5%)	4 subjects (10%)	2 subjects (5%)	1 subject (2%)	1 subject (2%)
8 years	0 subjects (0%)	3 subjects (7%)	5 subjects (12%)	1 subject (2%)	1 subject (2%)
Total	3 subjects (7%)	15 subjects (~37%)	18 subjects (~44%)	2 subjects (~5%)	2 subjects (~5%)

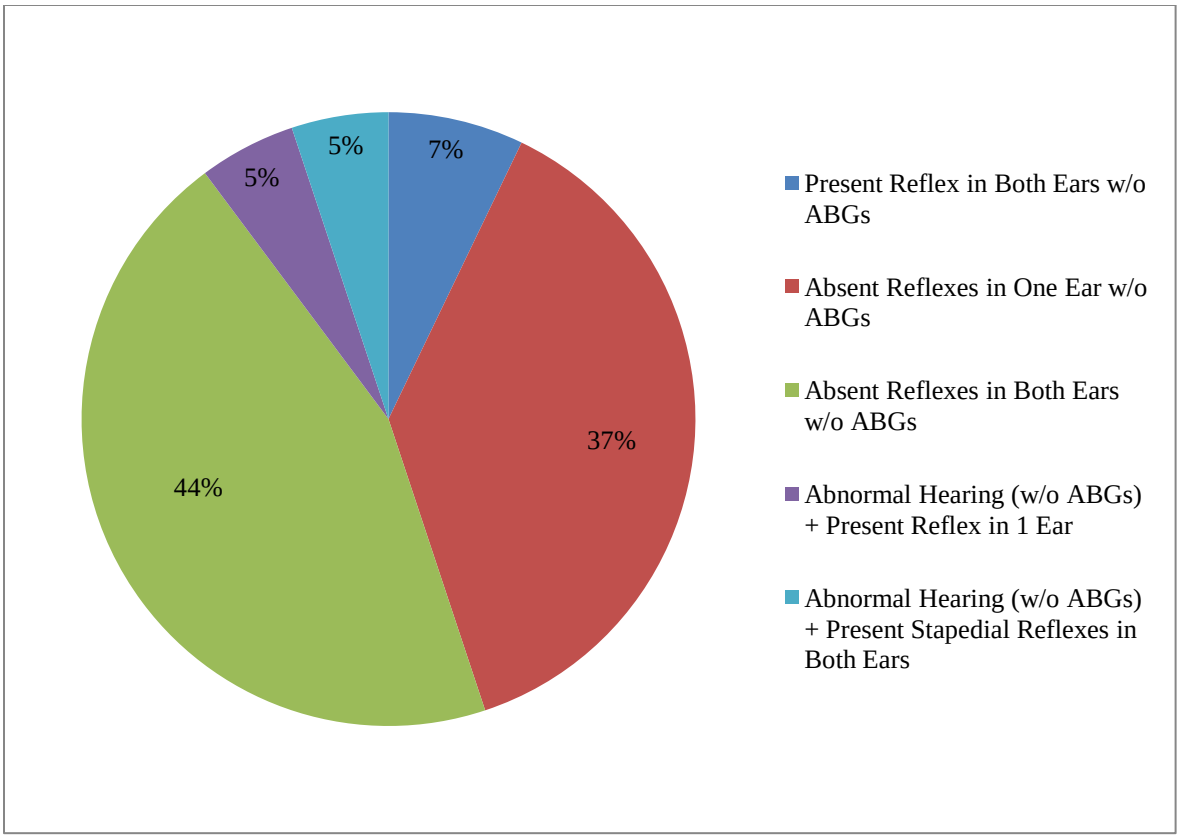

Figure 5. Relationship between Acoustic Reflex Screening Outcomes and Air-Bone Gaps

Both Table 8 and Figure 5 show that the majority of participants (44%) did not pass the acoustic reflex screening at 100 dB SPL, yet audiometric testing did not reveal significant air-bone gaps for any of the subjects tested. 2 subjects presented with abnormal audiometric results (without air bone gaps) along with a present acoustic reflex screening in one ear, and 2 subjects presented with abnormal audiometric results (without air bone gaps) along with failed acoustic reflex screening results in both ears. The results outlined above suggest that the acoustic reflex screenings utilized in this study were not an accurate predictor of the presence or absence of air bone gaps in the subjects tested.

DISCUSSION

The purpose of this research study was to collect otoscopic, tympanometric, and acoustic reflex screening data on school-aged children in a kindergarten and primary school in Port-au-Prince, Haiti. The various sets of data were analyzed to determine the proportion of subjects with both normal and abnormal outcomes in all three categories. Following audiometric testing performed by my research partner, the acoustic reflex screening outcomes were compared to the presence or absence of significant air-bone gaps (>10 dB HL).

For this study, a total of 41 subjects (82 ears) aged 5 -8 underwent otoscopic, tympanometric, and ipsilateral acoustic reflex screening testing. The mean subject age was 6.5 years of age. The median subject age was 7 years of age.

Otoscopic studies (including visual inspection of the outer ear) were performed on 41 subjects, or 82 ears. Upon visual inspection, none of the test subjects were found to have any visible structural abnormalities. The overall otoscopic data revealed that 70 (85%) of the ear canals were considered clear of cerumen, 11 (13%) were classified as having visible, yet non-occluding cerumen, while 1 ear (1%) was classified as having occluding cerumen in the ear canal. The overwhelming majority of participants had normal otoscopic results.

When examining the data based on the age groups tested, 100% of the 5 year old subjects tested (24% of the total ears tested) had clear ear canals based on visual inspection. Of the 10 subjects tested in the 6 year old age group, 19 (95%) ears were classified as clear of cerumen, while 1 ear (5%) was classified as having non-occluding cerumen. 11 7 year old subjects were tested, and 19 (86%) of the ears were classified as being free of cerumen, while 3 (14%) were classified as having non-occluding cerumen. 10 8 year old subjects were tested. 12 ears (60%)

were found to be clear of cerumen, 7 ears (35%) had non-occluding cerumen, and 1 ear (5%) had occluding cerumen noted in the ear canal.

The tympanometric data collected on the 41 subjects varied from the otoscopic data in that more test subjects had findings that were considered abnormal. Tympanometric testing was performed on 82 ears. The tympanometric values were analyzed based upon norms for children (JCIH, 2007; ASHA, 1990; Jerger et al, 1972; ASHA, 1990), and a tympanogram type was assigned accordingly to each of the ears tested (Martin & Clark, 2006). Upon analysis of the tympanograms, 40 (49%) ears had Type A (normal) tympanograms, 26 (32%) ears had Type A_S (low static admittance) tympanograms, 2 (2%) ears had Type A_D (high static admittance) tympanograms, and 2 (2%) ears had Type B (flat) tympanograms. A seal could not be maintained during testing for 12 (15%) ears, so therefore tympanometric data could not be obtained for those subjects. Interestingly, none of the participants who presented with abnormal tympanograms were found to have significant air-bone gaps in the affected ear upon audiometric testing.

The tympanometric results were analyzed by age group as well. 10 5 year old subjects were tested, and 9 ears (45%) were found to have Type A tympanograms, 10 ears (50%) had Type A_S tympanograms, and 1 ear (5%) could not be classified due to the inability to maintain a seal. Of the 10 6 year old subjects tested, 10 ears (50%) were classified as Type A, 6 ears (30%) were classified as Type A_S, 2 ears (10%) were classified as Type A_D, and 2 ears (10%) could not be classified due to the inability to maintain a seal. Of the 11 7 year old subjects tested, 10 ears (45%) were classified as Type A, 6 ears (27%) were classified as Type A_S, and 6 ears (27%) could not be classified due to the inability to maintain a seal. Of the 10 8 year old subjects tested, 11 ears (55%) were classified as Type A, 4 ears (20%) were classified as Type A_S, 2 ears (10%)

were classified as Type B, and 3 ears (15%) were unable to be classified due to an inability to maintain a seal.

It should be of note that classifying tympanograms purely based on type is sometimes risky, as there is considerable overlap between what is considered normal and what is considered pathologic, particularly with static acoustic admittance values (Silman & Silverman, 1991). It is therefore prudent to analyze otoscopic results, tympanometric results (including ear canal volume, static acoustic admittance, and tympanometric peak pressure), acoustic reflex test results, and audiometric data together, in order to help determine accurate audiological diagnoses, as well as to facilitate referrals to the proper medical professionals for further evaluation, if necessary.

Following the collection of tympanometric data, ipsilateral acoustic reflex screenings at 100 dB SPL were conducted on all of the test subjects. The screenings were performed on 82 ears, and the immittance device recorded the responses as either a "yes" or a "no". The data revealed that 22 (54%) of the subjects had absent ipsilateral acoustic reflexes in both ears, 7 subjects (17%) had reflexes present in one ear and absent in the other ear, 4 subjects (10%) had present acoustic reflexes in both ears, 4 subjects (10%) had a reflex absent in one ear with a seal not being able to be maintained in the other, 3 (7%) of the participants' results could not be analyzed due the inability to maintain a seal in either ear, and 1 subject (2%) had an absent acoustic reflex in one ear with a seal not being able to be maintained for testing for the other ear.

Following testing, the acoustic reflex screening results were compared to the audiometric test results, paying particular attention to the presence or absence of significant air-bone gaps (>10 dB HL) in each ear. Though many subjects did not pass the acoustic reflex screening at 100 dB SPL, no significant air-bone gaps were noted during audiometric testing for those subjects.

Ipsilateral acoustic reflex thresholds for normal hearing subjects usually occur between 85 – 100 dB SPL (Gelfand, 1984 – as cited in Gelfand, 2009). Standard immittance devices give the clinician the ability to choose either "screening" or "diagnostic mode" for ipsilateral acoustic reflex testing. However, many portable or screening immittance devices only have the ability to run the ipsilateral acoustic reflexes using "screening mode". This is important to note because inconsistencies have been noted with performing ipsilateral acoustic reflex screenings in "screening mode", as opposed to utilizing diagnostic mode. For example, Sells et al (1997) found that using the screening mode for ipsilateral acoustic reflex screenings yielded a 31% false positive rate for correctly identifying middle ear effusion. This is because when utilizing the screening mode, a higher artifact is likely, and the criteria necessary to elicit a reflex on the instrumentation is larger than in diagnostic mode (Sells et al, 1997 – as cited in Gelfand, 2009). Only having the ability to perform a "screening mode" for acoustic reflex testing may explain some of the inconsistencies noted between failed acoustic reflex screenings and the absence of significant air-bone gaps in some participants. Furthermore, the possibility remains that some subjects who had failed the ipsilateral acoustic reflex screenings at 100 dB SPL would have had present thresholds at a higher decibel level (e.g. 105 dB SPL), had diagnostic mode been an available mode to utilize.

The findings from the subjects in Haiti were compared to similar research studies conducted in developing countries. In other studies in developing countries, cerumen impaction in the outer ear was found to be one of the most common otoscopic abnormalities among school-aged children subjects (Hatcher et al, 1995; McPherson & Holborow, 1985, White, 1988 – as cited in Hatcher et al, 1995; Godinho et al, 2001; Adebola et al, 2013). Similarly, in Olusanya's mass screening study in Lagos, Nigeria, 40% of the test subjects presented with otoscopic

abnormalities (Olusanya, 2001). The otoscopic data from this study, however, revealed only one subject with an otoscopic abnormality, i.e. occluding cerumen noted in the ear canal.

The otoscopic results and the tympanometric results were compared to one another. Upon comparison of the otoscopic data to the tympanometric results, some disagreement was found to be present. This is similar to Olusanya's study in Lagos, Nigeria. In her study, agreement between otoscopic abnormalities and abnormal tympanograms was only found to be present in 45 out of 144 (31.3%) of test subjects (Olusanya, 2001).

The tympanometric data acquired is similar to the Mark et al (2013) study in that the majority (49%) of participants' tympanograms were classified as Type A (Mark et al, 2013), which is considered to be within normal limits. In the present study, 36% of the 82 ears tested were found to have abnormal tympanograms, similar to the various studies cited in Olusanya (2001), which indicated that the prevalence of middle ear disorders in developing countries varied from 7.3 – 36.2% (Elango et al, 1991, Jacob et al, 1997, Mourad et al, 1993, Seely et al, 1995, Olusanya et al, 2000, Hatcher et al, 1995, Prescott & Kilbel, 1991, Prasansuk, 2000 – as cited in Olusanya, 2001).

The ipsilateral acoustic reflex results were compared to the presence or absence of significant air-bone gaps (>10 dB HL). None of the subjects tested were found to have significant air-bone gaps, despite having abnormal tympanometric outcomes, or not passing the acoustic reflex screening at 100 dB SPL. These inconsistencies could be due to screening mode being the only available method of conducting acoustic reflex testing.

The various resulted collected in this study suggest that despite lack of access to basic medical care, the majority of children tested at the *Ecole Presbyterale de St Vincent de Paul* did

not have abnormal otoscopic or tympanometric outcomes. Additionally, no subjects were found to have significant air-bone gaps present in audiometric testing.

Screening Model

For a screening protocol to be successful, it must identify accurately those who need to obtain proper referrals and undergo further testing. It must also be economical, timely, and involve proper methods and protocols (Sliwa et al, 2011; Ciorba et al, 2008 – as cited in Sliwa et al, 2011). Our research in Haiti was a relatively low-cost trip, which yielded valuable information, collected over the course of only a few short days of testing. We were able to conduct otoscopic, immittance, and audiometric testing on 41 subjects, aged 5 - 8, from both the kindergarten and primary schools at the *Ecole Presbyterale de St Vincent de Paul* . Our testing model included the following:

1. We measured ambient noise levels in the testing environment to ensure they met ANSI (2010) standards.
2. We performed otoscopy, and visually inspected all of the participants' ear canals for structural abnormalities.
3. We performed tympanometry and acoustic reflex testing on all participants utilizing a portable tympanometer.
4. We conducted pure tone air conduction screening at 4 frequencies (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz).

5. We performed complete audiological evaluations, including pure tone air and bone conduction testing, as well as the assessment of word recognition.
6. The parents of those with abnormal test results were notified, and referrals were given, whenever possible.

Our testing model may be a useful screening method for audiology students or graduates to conduct in other developing countries, where necessary resources and medical professionals are oftentimes in short supply.

CONCLUSIONS

The goals of this research study were to determine the following: the proportion of subjects with observed abnormal outer ear structural abnormalities, the proportion of children with normal and abnormal tympanometric and acoustic reflex screening findings, the relation between audiometric thresholds (most importantly the presence of significant air-bone gaps) and acoustic reflex screening findings, and to determine the proportion of subjects with fully impacted cerumen.

Findings

The majority of children tested had normal otoscopic and tympanometric outcomes. Based on examination, no subjects exhibited any outer ear abnormalities, and only one ear was found to have impacted cerumen with otoscopy. Almost 50% of those tested had normal tympanometric results. Many children who had normal audiometric results did not pass the ipsilateral acoustic reflex screening at 100 dB SPL, but that is perhaps because the instrumentation utilized did not have the ability to conduct a threshold search for reflexes.

Significance of Results

Though to date no other published research studies have collected data on the outer and middle ear status of schoolchildren in Haiti, comparing the data to similar studies showed both similarities and differences. Upon visual inspection, no subjects tested presented with any suspected outer ear abnormalities. The majority of subjects tested had normal otoscopic results, and the majority of tympanograms were found to be normal. Ipsilateral acoustic reflex screenings were not present at a screening level of 100 dB SPL for several participants, but it is possible these results would have been present, had the tympanometer had the ability to perform a threshold search for reflexes.

The expectations prior to testing (and based on examining other similar studies in developing countries) were that there would be more abnormal otoscopic and tympanometric results than were ultimately found, based on the lack of medical professionals, and adverse living conditions that are rampant in Haiti. However, upon analysis of the results, the majority of findings were considered normal. This suggests that despite the adverse living conditions and lack of access of medical care, there was not a significant prevalence of abnormal otoscopic or tympanometric results among the 5 -8 year old subjects utilized in this study. It is of course possible that the prevalence of abnormal otoscopic and tympanometric results could be higher in both younger and older children in Haiti, but testing on other age groups was unfortunately beyond the scope of this present study.

Despite the majority of participants presenting with normal otoscopic and tympanometric results, our research was beneficial in that it helped to generate referrals for a few subjects who presented with abnormal otoscopic and tympanometric results. Additionally, the

research was valuable in that it provided data for a developing country that has a dearth of audiological data available. Beginning to collect data in a country where very little has been studied is necessary as well in that it will hopefully spearhead future research studies in other parts of Haiti, in order to collect audiological results on a wider scale (and on more subjects), to compare the results to our data, and to ultimately provide amplification if any hearing losses are identified.

Limitations of Research and Future Research Needs

This research study was limited in that only 41 subjects from one kindergarten and primary school in Haiti were tested. Testing more subjects in additional schools and comparing the results would have strengthened the research study.

Another potential limitation was that any children with actively draining ears were excluded from the study. In this study, however, no participants were found to have actively draining ears based on visual inspection or otoscopy, so this limitation was not relevant to the data collected in this project. Had any drainage been visible based on visual inspection or otoscopy among the participants, it would have been noted, and the proper individuals would have been notified (i.e. the nurse and school principal), and a referral to be referred to a proper medical professional would have been provided. Excluding any participants with actively draining ears from testing can affect the ability to generalize to other similar aged subjects, within Haiti, other developing countries, and globally.

A further limitation was that the immittance device utilized for this study was only capable of performing ipsilateral acoustic reflexes utilizing “screening mode”, which have been

shown to be somewhat inconsistent, and to have a high false-positive rate for identifying possible middle ear disorders (Sells et al, 1997 – as cited in Gelfand, 2009).

Lastly, during both tympanometric and acoustic reflex screening testing some ears (12 and 11 respectively) could not be sealed for testing. This limited the amount of data able to be used for analysis.

Future research studies would be strengthened by utilizing a tympanometer with the ability to test both ipsilateral and contralateral acoustic reflex thresholds, testing otoacoustic emissions, using more test subjects, comparing results from subjects in different schools, and by including all subjects in testing, regardless of the outer or middle ear status. Since the research was conducted without licensed medical professionals, diagnoses were unable to be made regarding middle ear abnormalities that may have been present in the subjects. Additionally, collaborating with other medical professionals in order to provide on-site medical and audiological care (such as cerumen management and the provision of amplification) would be beneficial for future research studies.

Appendix A

CITY UNIVERSITY OF NEW YORK
Graduate Center
Audiology

PARENTAL/LEGAL GUARDIAN PERMISSION FORM AND AUTHORIZATION FOR CHILD'S PARTICIPATION IN RESEARCH

Project Title: *Otoscopic and Tympanometric Outcomes in Haitian Children*

Principal Investigator: *Ellen May*
Graduate Student
Graduate Center
365 5th Avenue
New York, NY 10016
(412) 779-8847

Faculty Advisor: *Dr. Barbara Weinstein*
Professor
Graduate Center
365 5th Avenue, New York, NY 10016
212-817-7980

Site where study is to be conducted: Ecole Presbyterale de St Vincent *Thomson 25, Haiti*

Note: IRB approval is not needed to conduct research in Haiti, therefore expedited IRB approval is requested.

Introduction/Purpose: Your child is invited to participate in a research study. The study is conducted under the direction of *Ellen May.* The purpose of this research study is to *determine the prevalence of outer or middle ear abnormalities in Haitian children.* The results of this study may *aid in future research, as well as the proper referrals and possible aid for those who need it.*

Procedures: Approximately *50* individuals are expected to participate in this study. Each child will participate in *a screening of their outer/middle ears.* The time commitment of each participant is expected to be *30 minutes.* Each session will take place at *Ecole Presbyterale de St Vincent de Paul.* If time is permitting, your child will be tested twice (once at the beginning and once at the end of the study).

Does your child have asthma or other breathing problems? Y N
Does your child have chronic ear infections? Y N
Do you suspect your child has hearing loss? Y N

Possible Discomforts and Risks: Your child's participation in this study may involve some physical discomfort. To minimize these risks *we will have a translator explain to the child what is to happen.* If your child is *bothered* as a result of this study the child will be allowed to not participate in the study.

Benefits: There are *direct benefits, i.e. we will be collecting research to justify future humanitarian missions, as well as proper referrals for those who need it.*

Alternatives: N/A

Voluntary Participation: Your child's participation in this study is voluntary, and you may decide to withdraw your child from participation without prejudice, penalty, or loss of benefits to which you are otherwise entitled. If you decide to remove your child from the study, please contact Ellen May to inform them of your decision.

Financial Considerations: *N/A*

Confidentiality: The information obtained from your child will be collected via *written documentation.* The collected records will be accessible to *the principal investigator and her partner*. The researcher will protect your child's confidentiality by *securing the data, and ensuring that there is no identifying information on the documents, as well as coded.* The collected information will be stored *on a computer as well as in print.*

Contact Questions/Persons: If you or your child have any questions about the research now or in the future, you should contact the Principal Investigator, *Ellen May, 412-779-8847, emay@gc.cuny.edu.* If you or your child have any questions concerning your child's rights as a participant in this study, you may contact:
Kay Powell
Room 8309
Kpowell@gc.cuny.edu
(212) 817-7525

Dr. Barbara Weinstein
bweinstein@gc.cuny.edu

Statement of Consent:

"I have read the above description of this research and I understand it. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions that I may have will also be answered by the principal investigator of the research study. I voluntary agree to allow my child to participate in this study.

By signing this form I have not waived any of my legal rights to which my child would otherwise be entitled.

I will be given a copy of this statement."

_____	_____	_____
Printed Name of Subject's Legal Guardian	Signature of Subject's Legal Guardian	Date Signed
_____	_____	_____
Printed Name of Person Explaining Form	Signature of Person Explaining Form	Date Signed
_____	_____	_____
Printed Name of Signed Investigator	Signature of Investigator	Date

Appendix B

CITY UNIVERSITY OF NEW YORK
Graduate Center
Department of Audiology

ASSENT TO PARTICPATE IN A RESEARCH PROJECT

Project Title: Otoscopic and Tympanometric Outcomes in Haitian Children

Principal Investigator: *Ellen May*

Faculty Advisor: *Dr. Barbara Weinstein*

Child's Name: _____

You are invited to participate in *my* research study.

What will happen to me in this study?
I'm going to be taking a picture of your ears. Please try to sit still and be quiet while I do this. You'll feel a little bit of funny air in your ears (like being in an airplane), followed by the sound of some birdies chirping.

Will I get hurt?
You may experience a little bit of a feeling of pressure, and the beeps might need to be a little loud. To minimize these risks, please try to sit still. If you are uncomfortable as a result of this study you should tell me right away.

What if I do not want to do this?
No one will be mad at you if you don't want to do this. If you don't want to be in this study, just tell us. If you want to be in this study, just tell us. Remember, it is ok to say yes now and change your mind later. Nothing will happen to you if you decide to stop.

Will anyone know I was involved?
I will not tell anyone that you participated.

Who can I talk to about this study?
You can ask questions any time. You can ask now. You can ask later. You can talk to me or someone else, like your teacher.

Do you want to participate in this study?

YES NO

PERSON CONDUCTING ASSENT

I have explained the study to _____ (*name of child*) in language he/she understands, and he/she has agreed to be in the study.

_____	_____	_____
Name of Person Conducting Assent (*print*)	Signature Person Conducting Assent	Date Signed
_____	_____	_____
Name of Investigator (*print*)	Signature Person Investigator	Date Signed

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