ABSTRACT

EFFICACY OF AUDIOLOGIC AND OTOLOGIC OUTCOME MEASURES TO PREDICT MIDDLE EAR STATUS

by Lindsey Brooke Davis

The purpose of this study was to investigate the most effective diagnostic protocol for health care professionals to determine the middle ear status of the pediatric population. Children ages 0 to 6 years that were seeking medical attention from their primary physician were selected to participate. Data was collected to determine the specificity and sensitivity rates of the following otologic and audiologic measures: 1) pneumatic otoscopy, 2) conventional tympanometry, 3) multifrequency tympanometry, and 4) Ear Check, an acoustic reflectometry screener marketed to parents for at-home use. The diagnoses provided between the physician using pneumatic otoscopy and tympanometry were both similar, agreeing in diagnosis 66.7% to 77.4% of the time. However, the diagnosis from the Ear Check did not correlate well with either pneumatic otoscopy or tympanometry. Therefore, the Ear Check has yet to prove itself as an accurate means for parents to diagnose ear infections. Due to the lack of subjects present with middle ear effusion, further comparisons between pneumatic otoscopy and tympanometry could not be made.
Efficacy of Audiologic and Otologic Outcome Measures
to Predict Middle Ear Status

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The difference between average people and great people can be explained in three words. The three words are: “and then some.” The top people did what was expected, and then some.

---James Byrnes, Gallaudet College, 1996

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CHAPTER I

Introduction

Aside from the common cold, otitis media (OM) is the most prevalent disease in children (Eden, Fireman, & Stool, 1995). Thirty million office visits a year are attributed to OM. Nearly 75% of children before the age of 3 will have one to three episodes and 75% of all children by the age of 5 will have at least one episode (Gravel, 1996).

Otitis media is a general term used to describe the presence of inflammation in the middle ear. Physicians often categorize types of otitis media according to the stage and condition of the inflammation/infection. Acute otitis media (AOM) indicates an active inflammation and/or infection of the middle ear cavity of recent onset. AOM condition is caused by Eustachian tube dysfunction that creates negative pressure in the middle ear cavity (Kavanagh, 1986). When negative pressure in the middle ear cavity is sustained for a period of time, bacteria or a virus that has been trapped within the middle ear triggers the mucosal linings to produce fluid (effusion), which accumulates behind the tympanic membrane. The fluid often becomes infected, resulting in purulent fluid (pus) that applies positive pressure on the tympanic membrane. Otitis media with effusion (OME) is defined by the presence of fluid in the middle ear cavity with the absence of acute infection. OME is often an ensuing condition of AOM, following the resolution of the infection with medical treatment.

Symptoms of AOM in infants or toddlers can include crying, irritability, fever, tugging at the ears, vomiting, and ear drainage. However, these symptoms also accompany many disorders in children that do not involve the ear. Thus, variable symptoms make it difficult for parents to recognize when their child is suffering from
Identification is especially difficult for parents of preverbal children who are unable to express the location of their discomfort. Otitis media with effusion (OME) can be a silent problem—it may or may not be accompanied by any clearly identifiable symptoms because the infection has resolved, leaving behind only an accumulation of fluid. As a result, OME is even more difficult to detect. The primary indicator that middle ear effusion is present is a mild conductive hearing loss; however, this problem may also go unnoticed.

The period when otitis media is most prevalent is also the period during which language acquisition is most critical. To what extent recurrent otitis media with effusion affects a child’s speech and language acquisition remains to be debated. Health care professionals divide between two core standpoints regarding the effects of OME. One perspective suggests that OME has no detrimental effect on speech and language acquisition because the child’s hearing returns to normal immediately following the episode of the effusion (Butler & MacMillan, 2001). The opposing perspective argues that OME adversely affects speech and language acquisition in children due to inconsistent auditory input resulting from the fluctuating hearing loss that often accompanies middle ear effusion (Roberts et al., 1998).

In 2000, Paradise et al. studied the possible effects of early-life otitis media on children’s speech, language, and cognitive abilities. The middle ear status of 6,350 healthy infants was monitored using pneumatic otoscopy and tympanometry throughout their first three years of life. At the three-year mark, children who had developed middle ear effusion for a period of at least 90 days were deemed eligible for the study. A random sample of 241 children was then selected from the group to undergo formal
hearing, speech, and cognitive tests. Paradise et al. found significant negative correlations between the child’s duration of MEE and their scores on the formal tests of receptive vocabulary and verbal cognition. No correlations were found between MEE and expressive vocabulary, speech production, or other cognitive areas. These findings suggest that early-life middle ear effusion can cause impairments in certain areas of speech and cognition later on in the child’s life.

Gravel and Wallace (1992) conducted a similar study on the effects of early otitis media, but found an opposing outcome. The middle ear status of 23 infants was monitored via pneumatic otoscopy during their first year of life. Two groups were identified in the sample: otitis positive subjects and otitis negative subjects. An infant was considered otitis positive if during the baby’s first-year doctor visits, otitis media was detected bilaterally at least 30% of the time. At four years of age, the infants’ expressive and receptive language, cognition, and listening skills were assessed using formalized tests. Results indicated no differences between the groups in regards to receptive and expressive language skills or in cognitive abilities. The only significant difference found between the two groups was in their performance in the listening task. Although all of the children had normal audiograms on the day of testing, the otitis media positive group required a greater signal-to-competing message ratio to maintain a performance of 50% sentence understanding. All of the children were able to identify the stimulus with 100% accuracy in quiet. Gravel and Wallace (1992) concluded that early-life otitis media has no effect on a child’s language acquisition, but could possibly affect listening performance in the presence of background noise. However, they acknowledge that other
factors, such as motivation, attention span, and previous listening experience could also affect a child’s auditory abilities.

The lack of strong correlations and definitive statements in the Gravel and Wallace (1992) study could possibly be contributed to the limitations of the study. The subjects’ middle ear status was only monitored during the first year of life, and therefore, it is unknown how long or if the otitis media continued through the toddler years of each child. In addition, a small sample size of only 23 subjects was used. A greater relationship between language abilities and otitis media may have been found had more subjects been assessed for a longer period of time with shorter assessment intervals.

While there is a dispute over the potential long-term effects of OM on language, there is a uniform agreement that a child’s ability to acquire new information is impaired during the period of existing otitis media with effusion. The average hearing threshold (500, 1000, 2000 Hertz) ranges from 15dB Hearing Level (HL) to 40dB Hearing Level (HL) in children with OME. The extent to which a lack of auditory input specifically affects a child’s language abilities remains to be unknown.

Otitis media with effusion left untreated can result in numerous medical complications. Possible sequelae of OME include: perforation of the TM, cholesteatoma, mastoiditis, tympanosclerosis, ossicular discontinuity, labyrinthitis, and facial paralysis (Northern & Downs, 2002).

With such a high prevalence of otitis media with effusion in children, it is obvious that an effective test battery is necessary to detect those affected as soon as possible. Prompt evaluation of these young children is crucial to limit possible medical complications and potential impact on speech and language. Detection of middle ear
effusion is necessary for appropriate diagnosis and management of otitis media in infants and toddlers.

Currently, many physicians diagnose OME solely based on their interpretations of pneumatic otoscopy. However, with the emerging research on multifrequency tympanometry and acoustic reflectometry, it is apparent that the traditional methods of evaluating otitis media in infants and toddlers may not be sufficient. Multifrequency tympanometry is a measure similar to conventional tympanometry, except a higher frequency tone, such as 678Hz or 1000Hz, is used. Researchers believe that using a high frequency stimulus can provide more information on subtle changes of mass and stiffness within the middle ear cavity (Ferekidis et al., 1999). Acoustic reflectometry is a new tool that assesses the middle ear space by measuring the amount of reflectance in the ear canal. Because this measure relies on the principle of reflected sound, an accurate reading can be taken without obtaining a hermatic seal.

Pneumatic otoscopy is the universally recommended method of diagnosing otitis media with effusion within the physician community (Pelton, 1998). While there are audiologic tools available to assist in diagnosing OME, they are not being utilized by the medical field. The following literature review will investigate the various measures available to detect middle ear effusion.
CHAPTER II

Review of Literature

Pneumatic Otoscopy

Pneumatic otoscopy is a primary diagnostic tool used by health care professionals to diagnose otitis media and otitis media with effusion (Pelton, 1998). The procedure involves evaluating the mobility of the tympanic membrane by creating a slight positive and negative pressure in the ear canal through the use of a rubber bulb attached to the otoscope. In order to cause movement of the tympanic membrane successfully, the ear speculum must create an air seal against the ear canal, which is seldom possible with the standard disposable speculum (Pichichero, 2000). Tympanic membrane position, color, and translucency are also evaluated during this procedure. A bulging or retracted tympanic membrane with reduced translucency and a yellowish or reddened appearance may be suggestive of middle ear infection.

In 1987, Mills investigated the presence of middle ear effusion in 44 pediatric patients scheduled to undergo myringotomy. The sensitivity and specificity of pneumatic otoscopy and tympanometry were examined. Pneumatic otoscopy had a sensitivity of 87.7% and a specificity of 91.4%. Tympanometry had a sensitivity of 80.2% and a specificity of 98.8%. In combination, the sensitivity was 92.6% and specificity was 95.1%. The authors concluded that using tympanometry in conjunction with pneumatic otoscopy provided the most effective method of diagnosing MEE.

Pneumatic otoscopy may not be accurate when used solely as a diagnostic tool. Due to the small ear canal size of an infant or toddler, it is often difficult to obtain a clear view of the tympanic membrane, thus, making it impossible to observe its appearance.
and mobility (Northern & Downs, 2002). Also, a diagnosis based solely on the appearance of the tympanic membrane can be misleading. During the examination, it is highly possible that the child will become irritable and will begin to cry, which in turn, causes the tympanic membrane to turn red. A reddened tympanic membrane can be misinterpreted as an indicator of otitis media.

Conventional Tympanometry

Similar to pneumatic otoscopy, tympanometry is a measure of the mobility of the tympanic membrane as air pressure is varied within the ear canal. During tympanometry, a soft probe tip is placed in the child’s ear in order to obtain a hermetic seal. Conventionally, a 226Hz probe tone is presented and the change in reflected energy is measured as pressure is created at +200daPa and at the point of maximum compliance of the middle ear cavity. This objective immittance measure, unlike pneumatic otoscopy, gives a quantitative measure of the tympanic peak pressure, equivalent ear canal volume, and static compliance (Roeser, Valente, & Hosford-Dunn, 2000). Tympanograms are commonly characterized in terms of the shape of the graph generated during the pressure sweep. Jerger (1970) describes 5 shapes, 3 of which are commonly associated with the progression of otitis media: Type A, Type B, or Type C. Refer to Figure 1 for further definition of each tympanogram type. With the presence of middle ear effusion, the mobility of the tympanic membrane is reduced, and thus, a Type B tympanogram (Jerger classification) is produced, characterized by a flat tympanogram shape with normal ear canal volume and abnormal static compliance (Stach, 1998).

According to research conducted by Palmu et al. (1999), the sensitivity and specificity of tympanometry in the diagnosis of OME is 70% and 98%, respectively. One
hundred and twenty-one visits of 58 infants, ages 2-11 months, were evaluated for middle ear effusion. The infants were examined with tympanometry, using a 226Hz probe tone. Only Type B tympanograms were considered indicative of middle ear effusion. The diagnosis of middle ear effusion was verified with pneumatic otoscopy and myringotomy (if necessary). Results found 57/228 ears with middle ear effusion, as detected by pneumatic otoscopy. Overall, the sensitivity rate of tympanometry in this study was fair. Given a closer look at the results, the sensitivity rate of the infants less than 7 months of age proved to be lower. The sensitivity rate in the group of the infants ages 7-11 months was 0.79, whereas the sensitivity rate of the infants 2-7 months was 0.61. Palmu et al. (1999) contributed the decrease in sensitivity to the more compliant ear canal of younger infants. In addition, there are those who argue that a higher rate of false positives and false negatives occur in infants because the 226Hz probe tone is inappropriate for the anatomical makeup of an infant’s ear. An infant’s ear is mass dominated, whereas an adult’s and older child’s ear is stiffness dominated. This physical change in the external and middle ear systems from infancy to adulthood occurs due to an increase in the size of the external ear canal, the formation of the bony ear canal wall, change in bone density, and loss of mesenchyme (Holte, Margolis, & Cavanaugh, 1991; Roeser, Valente, & Hosford-Dunn, 2000). Using a low frequency stimulus, which acts upon the stiffness components of the ear, may produce inaccurate results in an infant, whose ear becomes even more mass dominated with the presence of middle ear effusion. Keefe, Bulen, Arehart, and Burns (1993) measured the impedance in adults and infants over a frequency range of 125-10700Hz. Their data showed that the frequency range from 220-660Hz provided the least clinically valuable tympanograms for infants.
There are some limitations to tympanometry. It is possible that false positives may also result from impacted cerumen, tympanic membrane perforation, or improper placement of the probe tip in the ear canal.

In recent years, new research has shown that there are alternative diagnostic/screening tools available that could increase the accuracy of identifying otitis media with effusion in toddlers: multifrequency tympanometry and acoustic reflectometry (Roeser, Valente, & Hosford-Dunn, 2000). Although these diagnostic tools cannot be used in isolation, when used in adjunct with pneumatic otoscopy, they may prove to provide the best sensitivity and specificity in diagnosing OME.

*Multifrequency Tympanometry*

Multifrequency tympanometry involves the same procedure as conventional tympanometry, but uses a higher frequency probe tone. Frequencies such as 678Hz or 1000Hz are used instead of the low frequency 226Hz probe tone. Otitis media with effusion is a pathology that increases the impedance (resistance) of the middle ear. Maximal compliance (least resistance) is achieved when the air pressure in the external ear canal equals the air pressure in the middle ear cavity. As effusion develops in the middle ear space, the compliance of the middle ear system decreases. A Type B tympanogram arises when little or no change in compliance of the middle ear system occurs, as air pressure is varied in the external ear canal. However, in some cases when the effusion is thick, the mass of the middle ear is also increased (Roeser et al., 2000). With this condition, the 226Hz tympanogram may not be flat, but rather resemble a Type A (normal) tympanogram with a rounded peak or notching. Therefore, the presence of OME is likely to be missed using this tool.
Multifrequency tympanometry is based on the fundamental of admittance (the inverse of impedance), which is comprised of the components stiffness, mass susceptance, and conductance (Shlomo & Silverman, 1991). Both susceptance and conductance are affected by mass, stiffness, and friction. With a low frequency probe tone, mass susceptance is small, and the tympanogram is primarily representative of stiffness susceptance. As the probe tone frequency is increased, mass susceptance has a greater contribution to the admittance of the middle ear system. Thus, a higher frequency probe tone is more appropriate in identifying ears with a mass-loaded middle ear system.

Vanhuyse, Creten, and Van Camp (1975) developed a model of tympanogram patterns, showing changes in admittance, for a high frequency probe tone. Each pattern is named according to the number of susceptance peaks (B) and conductance peaks (G). Normal middle ear systems progress through 1B-1G to 3B-1G to 3B-3G to 5B-3G as the probe tone frequency is increased. According to the Vanhuyse et al. model, a flat tympanogram (Type B) or an “abnormal W” tympanogram, with greater than 100daPa between the outermost peaks, is indicative of middle ear effusion. Refer to Figure 2 for a graphic depiction of each tympanogram pattern.

The controversy of using a 226Hz vs. a higher frequency probe tone arose when Paradise, Smith, and Bluestone (1976) observed frequent normal or notched 226Hz tympanograms in infants with cases of surgically-confirmed OME. Researchers attributed these findings to the movement of an infant’s flaccid external auditory canal with changes in pressure. However, Holte, Cavanaugh, and Margolis (1990) have since questioned this explanation. They were able to record canal wall movement during pneumatic otoscopy and discovered the tympanogram shape was unrelated to the canal
wall movement. In 1986, Marchant et al. observed normal or notched 226Hz tympanograms in infants under 2 months of age who had surgically-confirmed OME, similar to Paradise’s findings. However, when using a 660Hz probe tone, flat tympanograms were revealed with an acceptable sensitivity and specificity rate.

In 1999, Ferekidis et al. compared the results of multi-frequency tympanometry to conventional tympanometry in seventy children with acute otitis media (AOM). Tympanometry measurements were taken on the day of diagnosis and at 10-day intervals for one month following antibiotic treatment. Results revealed that although conventional tympanometry presented normal curves one month post AOM episode, multifrequency tympanometry (swept from 250 to 2000Hz) indicated the middle ear systems had not yet returned to a normal state yet. Multifrequency tympanometry seemed to detect changes in the middle ear system following AOM that 226Hz tympanometry was unable to detect, implying persistence of pathology.

Acoustic Reflectometry

Acoustic reflectometry functions on the principle of reflected sound. The acoustic otoscope transmits a “sonar” signal down the external ear canal and the sound is then reflected off the tympanic membrane. The amount of reflected sound is analyzed by the acoustic otoscope and a simple reading of either low, mid, or high risk of effusion is given. In a healthy ear, the reflected signal will be negligible. However, when fluid is present in the middle ear, the increase in the reflected signal amplitude will be directly proportional to the amount of fluid present (Sohn & Davis, 1991). Because acoustic reflectometry measures are based only on the amplitude of reflected sound, a hermatic seal is not required. Also, the cooperation of the patient is not necessary. If the child is
crying, the acoustic otoscope discounts the background noise and waits until the child takes a breath of air before taking an accurate reading of the reflected sound (Sohn & Davis, 1991).

Researchers Kemaloglu, Sener, Beder, Bayazit, and Goksu (1999) compared the specificity and sensitivity of acoustic reflectometry and conventional tympanometry. A sample group of 150 ears with OME and 150 normal ears of children ages 2-6 was evaluated. In tympanometry, Type B tympanograms were considered indicative of middle ear effusion. With acoustic reflectometry, reflectivity ($\geq 5$) and curve angles (two cut points: $75^\circ$ and $95^\circ$) were used to diagnose MEE. Data using acoustic reflectometry presented a specificity of 99.33% using either a reflectivity cut-off of $\geq 5$ or a curve angle cut-off of $75^\circ$. Tympanometry presented a specificity rate of 92%. When a curve angle cut-off of $90^\circ$ was used, specificity decreased to 85.33%. In the group of OME ears, tympanometry produced a sensitivity rate of 96%. Reflectivity (cut-off $\geq 5$) and a curve angle of $75^\circ$ produced a sensitivity rate of 65.33 and 78%, respectively. The sensitivity of a curve angle of $90^\circ$ (97.33%) was not significantly different that tympanometry. When the results of tympanometry and acoustic reflectometry were combined, specificity and sensitivity rates were found to be 91.33 and 100%, respectively. Kemaloglu et al. found both devices provided complimentary data and suggested they be used together clinically to provide a stronger confirmation of OME.

By reviewing the literature on OME in children, it is apparent that the traditional diagnosis method may not be the most accurate approach. It is plausible that an audiologic measure or combination of otologic and audiologic measures would be a more
effective procedure for OME diagnosis. This current study will attempt to uncover the most appropriate protocol in the detection of middle ear effusion in young children.
CHAPTER III

Methods and Procedures

Subjects

A total of 103 children (50 male, 53 female) ranging in age from 0 to 6 years (M = 18 mos) were selected to participate in this study. Using pneumatic otoscopy as the gold standard, middle ear effusion was detected in 18 subjects (25 ears). However, with 226Hz tympanometry as the gold standard, MEE was detected in only 9 subjects (12 ears). All of the subjects were patients at Oxford Pediatrics and Adolescents, Inc. in Oxford, Ohio. Children who were uncooperative or for whom a complete set of data could not be obtained were excluded.

Informed Consent and Confidentiality

Informed written consent to participate in the study was obtained from each subject’s parent prior to testing (Appendices A & B). The parent(s) received a letter outlining the study’s purpose and the procedures that were used, and the risks involved. The document stated that the parent could withdraw their child from the study at any point without consequences. Only the children of parent(s) who granted permission for their child to participate were included in the study. The consent forms and procedures of this study were approved by the Institutional Review Board for Human Subjects Research at Miami University. To ensure the confidentiality of all participants in this study, the patient numbers assigned by the physician’s office were used to identify each subject.

Research Questions and Hypotheses

The areas of interest in this study:

1. Are the right and left ears independent of one another?
2. Which outcome measure is the most accurate in the detection of MEE?

The primary research hypotheses are as follows:

**Alternate Hypothesis (H₁):** The left and right ears are not independent of one another.

**Null Hypothesis (H₀₁):** The left and right ears are independent of each other.

**Alternate Hypothesis (H₂):** Tympanometry (conventional and multifrequency) and the Ear Check device will be more accurate in detecting middle ear effusion than pneumatic otoscopy.

**Null Hypothesis (H₀₂):** There will be no difference in accuracy of tympanometry, the Ear Check device, and pneumatic otoscopy in detecting middle ear effusion.

This current study may demonstrate that more current audiologic measures are more appropriate and effective for identifying otitis media in the pediatric population. Increased efficacy in the detection of otitis media will allow health care professionals to make accurate diagnoses and to implement appropriate intervention/treatment strategies, thus improving the quality of care given to the pediatric population.

*Data Gathering*

The following audiologic and otologic measures were performed on each subject, bilaterally:

*Pneumatic Otoscopy*

A Welch-Allyn pneumatic otoscope was used by the physician to examine the ear canal and tympanic membrane (TM) of each subject. The physician characterized the ear as having effusion, no effusion, or normal TM, while remaining unaware of the
audiologic results. Refer to Table 1 for further definition of how each diagnosis compares to tympanometry results.

**Tympanometry**

Acoustic immittance data was obtained using the Madsen Middle Ear Analyzer GSI 33. A 226Hz tone is presented using a positive to negative pressure sweep from +200 to -200daPa. The following immittance measures were recorded for each ear: 1) tympanometric peak pressure (daPa) and 2) tympanogram shape. The Jerger classifications were used to characterize the tympanogram shape as either Type A, B, or C. Type A indicates an aerated middle ear, Type B is indicative of middle ear effusion, and Type C indicates Eustachian tube dysfunction. Refer to Table 1 for further qualification of each tympanogram shape in comparison to the physician’s diagnosis.

**Multifrequency Tympanometry**

Multifrequency tympanometry was performed using the Madsen Middle Ear Analyzer GSI 33. A 1000Hz probe tone was presented using a positive to negative pressure sweep from +200 to -200daPa. Similar to conventional tympanometry, both tympanometric peak pressure and tympanogram shape were recorded. Tympanogram shape was determined by the shape classifications determined by Vanhuyse et al. Refer to Figure 2 for the qualifications of each tympanogram shape according to Vanhuyse and to Table 1 for a comparison of each shape to the physician’s diagnosis.

**Ear Check (Acoustic Reflectometry)**

The Ear Check Pro Model PEC-1 was used to estimate the probability of middle ear effusion in each ear. This instrument uses an 80dB sound source that sweeps from 2000Hz to 4000Hz during a 100ms period. The amount of sound reflected within the
canal is recorded and stratified into a scale ranging from 0 to 5. The greater the number that is displayed on the panel of the instrument, the greater the likelihood of middle ear effusion being present. Refer to Table 2 for the stratification of readings given by the Ear Check.

Statistical Analysis

Comparisons were made between the otoscopic diagnosis, tympanometry, and the Ear Check for both ears. From these comparisons the number of agreements and disagreements were computed. An alpha level of .05 served as the accepted standard for all statistical procedures. Contingency tables were produced to facilitate the comparisons of the left and right ear measurements of the two tympanograms and the otoscope. Based on these tables, $\chi^2$ tests of independence was performed for all three variables. In case of the Ear Check, the Pearson correlation coefficient was obtained and measurements for both ears were plotted.

The correlation was examined by plotting the measurements of the Ear Check and the measurements for each tympanogram for both the right and left ears and both ears together. Comparisons were made between the level of the Ear Check and the tympanogram diagnosis for both right and left ears at both tympanogram frequencies.

Comparisons were made between the otoscopic diagnosis and the tympanogram diagnosis for both the right and left ears at both tympanogram frequencies. From these comparisons the number of agreements and disagreements were computed and the percent of agreement was calculated. The analysis was duplicated and stratified by physician.
In order to compare the readings between a physician using an otoscope and the Ear Check, side-by-side boxplots were created for each ear. A boxplot is a diagram used to summarize data by graphically displaying the median and range of data. The boxplots display the values from the Ear Check, and are separated by the possible readings given by the physician. If the physician and the Ear Check give similar results, this should be evident from the side-by-side boxplots. For each ear, 95% confidence intervals for the average Ear Check reading were also created. Similar to the boxplots, separate confidence intervals were created for each of the possible diagnosis by a physician. A similar analysis was also performed for each of the physicians separately, to determine whether there was a difference between physicians as to giving similar diagnosis as the Ear Check.
CHAPTER IV

Results

Association between Left and Right Ears

Contingency tables were produced to facilitate the comparisons of the left and right ear measurements of the two tympanograms and the otoscope (Tables 3-5). Based on the $\chi^2$ tests of independence, none of these three variables are independent for the two ears.

In case of the Ear Check, subjects with PE tubes and subjects for whom the Ear Check was unable to give a reading were omitted. More than 30% of the cases were omitted: thus caution must be taken when drawing any conclusions. However, the Pearson correlation coefficient (0.321, P-value=0.006) suggests positive linear relationship between the values of the left and the right ears. Based on Figure 4, the scatter plot of the measurements on the two ears, whether the two ears are not independent for the Ear Check was unable to be determined. More observations with low Ear Check value would be needed to determine this. Note that the Ear Check tends to give slightly larger values for the left ear: on the average, the difference is 7.5. Thus the values for the two ears are dependent for all examined variables.

Association between Ear Check device and the Tympanogram

The results of analyzing the correlation between the Ear Check device and the tympanograms can be seen in Figures 5-8. Figure 5 suggests that Ear Check readings for the left ear decreases with infection readings of the 226Hz tympanogram, but not as quickly as was expected. Most of the observations for infection are in the Low or Low/Moderate risk of disease when the tympanogram already diagnoses an infection.
Figure 6 also shows that the Ear Check gives a low/moderate risk of disease for someone who already has an infection according to the 1000 Hz tympanogram. Figures 7 and 8 show only a few observations where the Ear Check actually shows a reading of Moderate/High risk of disease when the tympanogram shows an infection. The Ear Check's readings tend to be too high, and often suggest there is no infection when in fact there is an infection. Thus, the plots suggest that the Ear Check does not correlate with either of the tympanograms at 226Hz or 1000Hz.

Association between Tympanogram and Otoscopic Diagnosis

Contingency tables were produced to facilitate the comparison of the physician’s otoscopic diagnosis and the tympanogram diagnosis. These tables can be found in Tables 6-9. The contingency tables show that the percent of agreement between the physicians’ diagnoses and the tympanogram diagnoses range from 66.7% to 77.4%. In each situation, there are 2 subjects (2.4% of subjects) where either the tympanogram or the physician was unable to make a decision due to an uninterpretable measurement.

Association between Ear Check and Otoscopic Diagnosis

There is little correlation between the physician's diagnosis and the reading from the Ear Check. From the boxplots shown in Figures 9 and 10, one can see that the majority of readings from the Ear Check all fall within the Low to Low-Moderate risk range, regardless of the physician’s diagnosis. In fact, the medians for each group all fall within the Low to Low-Moderate risk range.

Confidence intervals comparing the average Ear Check readings were also created and are displayed in Tables 10 and 11. The confidence intervals show similar results as
the boxplots. From these confidence intervals one can see the average Ear Check readings are not significantly different between the levels of the physician’s diagnosis.

It is interesting to note that there is a decreasing trend in median Ear Check readings from a normal diagnosis of a physician to an infected diagnosis. Even though the differences here are not significant, one would expect this decreasing trend if the Ear Check and the physician’s diagnosis were completely correlated.

It is also interesting that there is more variability present in the infectious groups (as grouped by physician) as compared to the normal group. This is true for both the left and right ears, and can be seen from both the boxplots and from the wider confidence intervals.
Figure Caption

*Figure 1.* Jerger (1970) Classifications of Tympanogram Shapes.

*Figure 2.* Vanhuyse et al. (1975) Classifications of High-frequency Tympanogram Shapes—Susceptance (B).

*Figure 3.* Examples of Uninterpretable 1000Hz Tympanograms.

*Figure 4.* Scatter Plot for the Left and Right Ears.

*Figure 5.* Plot of Ear Check Measurements vs. the 226Hz Tympanogram for the Left Ear.

*Figure 6.* Plot of Ear Check Measurements vs. the 1000Hz Tympanogram for the Left Ear.

*Figure 7.* Plot of Ear Check Measurements vs. the 226Hz Tympanogram for the Right Ear.

*Figure 8.* Plot of Ear Check Measurements vs. the 1000Hz Tympanogram for the Right Ear.

*Figure 9.* Comparison of Ear Check Reading by Physician’s Diagnosis in Left Ear.

*Figure 10.* Comparison of Ear Check Reading by Physician’s Diagnosis for Right Ear.
Figure 1

Type A Tympanogram

Type B Tympanogram

Type C Tympanogram
Figure 2

**1B Tympanogram**

![1B Tympanogram](image)

Air Pressure in daPa

**3B Tympanogram**

![3B Tympanogram](image)

Air Pressure in daPa

**5B Tympanogram**

![5B Tympanogram](image)

Air Pressure in daPa

**Abnormal W Tympanogram**

![Abnormal W Tympanogram](image)

Air Pressure in daPa

>100daPa
Figure 3

Uninterpretable Tympanogram
Subject #62

Air Pressure in daPa

Uninterpretable Tympanogram
Subject #77

Air Pressure in daPa

Uninterpretable Tympanogram
Subject #83

Air Pressure in daPa
Figure 4

![Figure 4 Diagram](image-url)
Figure 5
Figure 6

![Graph showing Ear Check Left vs. 1000Hz Tymp Left with categories No infection, Infection, and Uninterpretable.]
Figure 7

226Hz Tymp Right

Ear Check Right

No infection  Infection  Uninterpretable
Figure 8
Comparison of Ear Check Reading by Physician's Diagnosis for Left Ear
Table 1

Tympanogram Readings and Diagnosis: 226Hz and 1000Hz

<table>
<thead>
<tr>
<th>Tympanogram Result</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>No Fluid</td>
</tr>
<tr>
<td>Type B</td>
<td>Fluid</td>
</tr>
<tr>
<td>Type C (&gt;200daPa)</td>
<td>Fluid</td>
</tr>
<tr>
<td>Normal W</td>
<td>No Fluid</td>
</tr>
<tr>
<td>Abnormal W</td>
<td>Fluid</td>
</tr>
<tr>
<td>Uninterpretable</td>
<td>Uninterpretable</td>
</tr>
</tbody>
</table>
Table 2

Ear Check Range and Risk of Infection

<table>
<thead>
<tr>
<th>Ear Check Range</th>
<th>Risk of Ear Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 49</td>
<td>High</td>
</tr>
<tr>
<td>49 – 59</td>
<td>Moderate/High</td>
</tr>
<tr>
<td>60-69</td>
<td>Moderate</td>
</tr>
<tr>
<td>70-95</td>
<td>Low/Moderate</td>
</tr>
<tr>
<td>greater than 95</td>
<td>Low</td>
</tr>
</tbody>
</table>
Table 3

Contingency Table and Test of Independence for the Measurements of Tympanometry (226 Hz) in the Left and Right Ear *(In Parentheses: the Expected Values under Independence)*

<table>
<thead>
<tr>
<th>Left Ear</th>
<th>Normal</th>
<th>Infected</th>
<th>Uninterpretable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>60 (51)</td>
<td>8 (14.8)</td>
<td>0 (2.2)</td>
</tr>
<tr>
<td>Infected</td>
<td>6 (12.8)</td>
<td>11 (3.7)</td>
<td>0 (0.6)</td>
</tr>
<tr>
<td>Uninterpretable</td>
<td>3 (5.3)</td>
<td>1 (1.5)</td>
<td>3 (0.2)</td>
</tr>
</tbody>
</table>

P-value < .0005 \( (\chi^2 = 59.9) \)
Table 4

Contingency Table and Test of Independence for the Measurements of Tympanometry (1000 Hz) in the Left and Right Ear (In Parentheses: the Expected Values under Independence)

<table>
<thead>
<tr>
<th>Left Ear</th>
<th>Normal (50.7)</th>
<th>Infected (13.8)</th>
<th>Uninterpretable (7.7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>57</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Infected</td>
<td>6 (11.6)</td>
<td>10 (3.2)</td>
<td>0 (1.8)</td>
</tr>
<tr>
<td>Uninterpretable</td>
<td>3 (5.8)</td>
<td>2 (1.6)</td>
<td>3 (0.9)</td>
</tr>
</tbody>
</table>

**P-value** < .0005 ($\chi^2$ = 31.1)
Table 5

Contingency Table and Test of Independence for the Measurements of Otoscopy in the Left and Right Ear

<table>
<thead>
<tr>
<th>Left Ear</th>
<th>Normal</th>
<th>Infected</th>
<th>Uninterpretable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>72</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Infected</td>
<td>5</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Uninterpretable</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

P-value $<.0005 \ (\chi^2=52.0)$
Table 6

Number of Agreements Between Otoscopy and Tympanometry (226 Hz) in Left Ear

<table>
<thead>
<tr>
<th>Tympanogram Diagnosis</th>
<th>Otoscopy Diagnosis</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal</td>
<td>Infected</td>
<td>Uninterpretable</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>55</td>
<td>8</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Infected</td>
<td>7</td>
<td>6</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Uninterpretable</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Total Number of Agreements: 61  Percent Agreement: 72.6%
Total Number of Disagreements: 23  Percent Disagreement: 27.4 %
Table 7

Number of Agreements Between Otoscopy and Tympanometry (1000 Hz) in Left Ear

<table>
<thead>
<tr>
<th>Otoscopy Diagnosis</th>
<th>Normal</th>
<th>Infected</th>
<th>Uninterpretable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>58</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Infected</td>
<td>7</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Uninterpretable</td>
<td>2</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>

Total Number of Agreements: 65  Percent Agreement: 77.4%
Total Number of Disagreements: 19  Percent Disagreement: 22.6%
Table 8

Number of Agreements Between Otoscopy and Tympanometry (226 Hz) in Right Ear

<table>
<thead>
<tr>
<th>Tympanogram Diagnosis</th>
<th>Normal</th>
<th>Infected</th>
<th>Uninterpretable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>56</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Infected</td>
<td>7</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Uninterpretable</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Total Number of Agreements: 63  Percent Agreement: 75.0%

Total Number of Disagreements: 21  Percent Disagreement: 25.0%
Table 9

Number of Agreements Between Otoscopy and Tympanometry (1000 Hz) in Right Ear

<table>
<thead>
<tr>
<th>Tympanogram Diagnosis</th>
<th>Normal</th>
<th>Infected</th>
<th>Uninterpretable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>50</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Infected</td>
<td>9</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Uninterpretable</td>
<td>7</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Total Number of Agreements: 56  Percent Agreement: 66.7%

Total Number of Disagreements: 28  Percent Disagreement: 33.3%
Table 10

Confidence Intervals for Average Ear Check Reading in Left Ear

<table>
<thead>
<tr>
<th>Otoscope Level</th>
<th>Observations</th>
<th>Mean</th>
<th>Lower CI</th>
<th>Upper CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>49</td>
<td>108.4</td>
<td>102.5</td>
<td>114.3</td>
</tr>
<tr>
<td>Inflamed</td>
<td>4</td>
<td>109.0</td>
<td>85.7</td>
<td>132.3</td>
</tr>
<tr>
<td>Fluid</td>
<td>12</td>
<td>99.3</td>
<td>83.8</td>
<td>114.8</td>
</tr>
</tbody>
</table>
Table 11
Confidence Intervals for Average Ear Check Readings in Right Ear

<table>
<thead>
<tr>
<th>Otoscope Level</th>
<th>Observations</th>
<th>Mean</th>
<th>Lower CI</th>
<th>Upper CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>51</td>
<td>104.3</td>
<td>99.5</td>
<td>109.1</td>
</tr>
<tr>
<td>Inflamed</td>
<td>7</td>
<td>100.3</td>
<td>81.0</td>
<td>119.6</td>
</tr>
<tr>
<td>Fluid</td>
<td>9</td>
<td>84.4</td>
<td>60.0</td>
<td>108.9</td>
</tr>
<tr>
<td>Wax</td>
<td>1</td>
<td>99.0</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>
CHAPTER V

Discussion

A re-evaluation of the current “gold standard” of diagnosing otitis media is necessary to ensure that physicians and audiologists are providing the utmost quality of care to the infant and toddler population. Pneumatic otoscopy has continued to serve as the primary method of evaluating the middle ear status of a child in the medical setting (Pelton, 1998). However, emerging research has shown that audiologic measures, such as acoustic reflectometry and multifrequency tympanometry may serve as a more effective diagnostic tool in the determination of middle ear status. The purpose of this study was to determine if the Ear Check device and tympanometry (226Hz and 1000Hz) correlated with the physician’s diagnosis, in order to determine the most appropriate protocol for identifying MEE.

Out of a possible 91 observations (after those children with PE tubes were removed from the data set) the Ear Check device was not able to take a reading in the left ear of 27 patients. Likewise, the Ear Check device was unable to take a reading in the right ear of 23 patients. The Ear Check device has been marketed for use with children ages 6 months to young adulthood. Of the 50 ears in which a reading could not be obtained, 25 were attempted in children older than 6 months of age. The Ear Check is packaged with only one standard probe tip size. This size was obviously too large for the small infants. However, it is unclear whether probe tip size or another variable contributed to inability to take measures in these older children. The raw data indicated no patterns in the missing observations compared to the otoscopic diagnosis.
The Ear Check did not provide readings that correlated well with either the otoscopic diagnoses or with the tympanogram. This finding is not in agreement with previous research. In 1999, Kemaloglu et al. found acoustic reflectometry to have a specificity rate of 99.33%. In contrast to the current study, researchers utilized a diagnostic acoustic reflectometer rather than a screener, such as the Ear Check. By using a diagnostic machine, the reflectivity cut-offs and curve angles were able to be manipulated to obtain the most accurate results. The Ear Check allows for no such manipulation and in consequence, did not correlate well with the other measures. In fact, regardless of the diagnosis by the either the physician or the tympanogram, the Ear Check tended to diagnose the children with either a Low or Low-Moderate risk of ear infection. In short, the Ear Check does not appear to be an accurate method of detecting ear infections in children according to the data gathered.

In the data there seemed to be a lack of abnormal readings from any of the possible three techniques of diagnosis. That is, there were not many children included in the study that were diagnosed with an ear infection. Only 25 ears were present with middle ear effusion when pneumatic otoscopy was used as the gold standard. With 226Hz tympanometry as the gold standard, MEE was detected in only 12 ears. In order to further compare the three diagnostic techniques it is necessary to gather more abnormal data.

Otitis media is the second most prevalent disease in children (Eden, Fireman, & Stool, 1995). One would expect with a sample size of 206 ears, OME would be present in more than 12% of the sample. In a study by Nozza, Bluestone, Kardatzke, and Bachman (1994), middle ear effusion was confirmed by myringotomy in 137(55%) of the
249 ears tested. Palmu et al. (1999) confirmed MEE by pneumatic otoscopy and myringotomy in 57(25%) of 228 ears tested. It is unclear as to why the present study found the rate of OME to be much less frequent. Otitis media occurs more frequently in males than females (Eden, Fireman, & Stool, 1995). There is also a greater incidence in Caucasians than in African Americans. Other factors that predispose a child to otitis media include exposure to secondary smoke, family history of recurrent otitis media, lower socioeconomic status, and day care attendance (Montville & White, 1998). It is conceivable that the demographic characteristics of the sample pooled may not have been representative of the population.

Several of the analyses were stratified by physician. This was done to investigate whether a certain physician was able to diagnose ear infections more accurately than other physicians, compared to both the tympanograms and the Ear Check. This analysis was not feasible due to lack of data for several physicians. In fact, only two of the five physicians contributed enough data to make comparisons feasible. The other physicians contributed only a handful of observations. Again, more data is necessary.

Although no statistical significant data could be computed for tympanometry due to lack of abnormal subjects, examination of the raw data shows some points of clinical importance. Conventional tympanometry revealed a notched tympanogram for 10 ears. Of these 10 ears, 1000Hz tympanometry revealed a Type B (indicating fluid) tympanogram for 2 ears and a Type A or Normal W for 8 ears. In addition, conventional tympanometry revealed Type A tympanograms, whereas, the 1000Hz tympanogram revealed an Abnormal W (indicating fluid) in 2 ears. If more children with OME had been included in the study, it is possible a trend of notched or normal 226Hz
tympanograms in the presence of MEE would have been detected. This trend would be similar to the findings of Marchant et al. (1986) and Paradise, Smith, and Bluestone (1976).

With the 1000Hz tympanometry, 22 of the tympanograms were uninterpretable. That is, the shape of these tympanograms did not follow the patterns described by Vanhuyse et al. (1975). Refer to Figure 3 for examples of these tympanograms. Similar results were found in a study of developmental changes in tympanograms by Holte, Margolis, and Cavanaugh (1991). Researchers obtained tympanograms, using a probe tone from 226-900Hz, on 23 infants, birth to 4 months of age. With the 900Hz probe tone, no tympanograms during the first week of life could be classified by the Vanhuyse et al. patterns. It wasn’t until 4 months of age that the majority of the tympanograms (85%) could be categorized as a Vanhuyse pattern. Researchers developed a new pattern type to describe these uninterpretable tympanograms: 0B1G. This pattern indicates no peak on the susceptance tympanogram and one peak on the conductance tympanogram. In the present study, only a susceptance tympanogram was obtained. Therefore, it is possible the 22 uninterpretable tympanograms could also be labeled as a 0B1G pattern. In contrast to the findings of Holte, Margolis, and Cavanaugh (1991), the age of the subjects with uninterpretable tympanograms in the present study ranged from 1 month to 62 months. Only 3 of the subjects were under the age of 4 months.

Limitations of Study

A proposed limitation of this study is the lack of statistical power due to small sample size of abnormal subjects. Because this study is examining the accuracy of multiple diagnostic procedures, a large sample size is necessary to determine statistical
significance. More children present with OME were needed in order to make a
determination of the accuracy of tympanometry vs. pneumatic otoscopy. Depending on
whether pneumatic otoscopy or tympanometry was used as the gold standard, middle ear
effusion was detected in a maximum of 25 out of 206 ears. A physician could have given
a diagnosis of “normal” without even examining the child’s ears, and been correct more
than 75% of the time.

Another limitation of this study involves the physician’s diagnosis. It is unknown
exactly how the physician concludes that middle ear effusion is present or absent. Is this
decision based solely on the physical examination or are other variables factored in, such
as history of repeated ear infections, parental report, or the presence of symptoms? In
this study, diagnoses were made by five different physicians. It is possible that the skill
of the physician and whether the physician took a conservative approach in diagnosing
OME could have affected the results.

Future Research

The findings of this study suggest that further research is needed in the area of
detecting otitis media with effusion in infants and young children. Although the Ear
Check device was found to be inaccurate, it does not negate the notion of using acoustic
reflectometry in the detection of middle ear effusion. Further research using a diagnostic
acoustic reflectometer, rather than a screener is needed.

Additional studies in which myringotomy is used as the gold standard, rather than
pneumatic otoscopy or tympanometry, would be most valuable. Myringotomy is the only
objective diagnostic tool in which middle ear effusion can be physically confirmed.
While it is not a practical procedure that should be incorporated into the OME diagnostic
protocol, it should be utilized as a gold standard to which all other measures are compared to for research purposes.

Another area of research concerns not only the diagnosis of OME, but also the treatment of the disorder. Although a physician may diagnose a child with otitis media with effusion, the child may or may not be given antibiotics. It would be of importance to determine how the physician determines what stage of otitis media with effusion warrants antibiotic treatment and how that decision corresponds with the audiologic outcome measures.

Implications for Clinical Use

Research has suggested that the traditional method of evaluating a child’s middle ear status may not be the most sensitive measure available. The findings of the current study demonstrated that the Ear Check is an inappropriate audiologic measure in the detection of middle ear effusion. Furthermore, this study contributed to the mounting research that more current audiologic measures, such as multifrequency tympanometry and acoustic reflectometry, may be more effective in identifying otitis media with effusion in the pediatric population. Continued research of this topic will serve to refine the established OME diagnosis protocol. Increased efficacy in the detection of otitis media will allow health care professionals to make accurate diagnoses and to implement appropriate intervention/treatment strategies, thus improving the quality of care given to the infant and toddler population.
References


Appendix A

Information to the Parents

Dear Parent,

As a graduate student in audiology at Miami University, I am conducting a research project regarding the detection of middle ear infections. The purpose of this study is to discover the most effective method of determining the middle ear status in young children. I am conducting this study under the direction of Kathleen Hutchinson, Ph.D., professor of audiology at Miami University and Ellen Buerk, M.D.

Middle ear infections are the perpetrator behind more than 30 million pediatric office visits per year. This inflammation of the middle ear causes fluid to accumulate behind the eardrum, and in turn, can result in a temporary hearing loss. Prompt evaluation of these children is crucial to ensure that the occurrence of hearing loss is avoided so they have ample opportunity to acquire speech and language and that further medical complications may be avoided.

The findings of this study may demonstrate that more current audiologic tests are more appropriate and effective for identifying middle ear infections. An improved accuracy in the detection of middle ear infections will allow physicians to make accurate diagnoses and to provide appropriate intervention and treatment, thus improving the quality of care given to the infant and toddler population.

With your consent, the following audiologic procedures will be performed on both ears of your child:

1) **Tympanometry:** Tests the mobility of the eardrum to determine if fluid is present.
2) **Acoustic Reflectometry:** Detects the presence of fluid.
3) **Otoacoustic Emissions:** A test of hearing.
4) The physician will examine the eardrums and make a diagnosis.

All of the procedures are routine tests used by audiologists and cause little to no discomfort to the child. Each test is performed by placing a soft probe tip in the child’s ear canal. A tone is then presented to the ear and the reflected sound is measured by the probe tip. Participation will require no more than 15 minutes. These audiological tests will be performed free of charge.

Your child’s participation would be greatly appreciated. Participation is completely voluntary, and you may decide at any time to discontinue your involvement in the research at no loss or consequence. Confidentiality will be assured by giving each child a number code and the child’s name will not be used in the reporting of the data. Your child’s results will be explained in the office in conjunction with the attending physician. If you have questions about your child’s
rights as a research subject, please feel free to contact the Office for Advancement of Scholarship and Teaching at Miami University (513.529.3734).

Sincerely,

Brooke Davis, B.S.  
Miami University  
513.523.1195  
davislb@muohio.edu  

Kathleen Hutchinson, Ph.D.  
Miami University  
513.529.2509
Appendix B

Consent Form

Signing below will indicate that you consent for your child’s participation in a research study conducted by a graduate student at Miami University. Your child will undergo the following audiologic tests: tympanometry, acoustic reflectometry, and otoacoustic emissions. The physician will then examine your child’s ears and give the diagnosis. You understand that your child’s personal identity will be protected and kept confidential by numbered codes used to store data. You understand that you may withdraw your child from the study at any time without consequence.

_____________________________________________
Signature of Parent of Legal Guardian