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Effect of noise on transient-evoked otoacoustic emissions and pure-tone screening audiometry

Laura Annette Wade

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EFFECT OF NOISE ON TRANSIENT-EVOKED OTOACOUSTIC EMISSIONS

AND PURE-TONE SCREENING AUDIOMETRY

by

Laura Annette Wade, B.A., M.A.

A Dissertation Presented in Partial Fulfillment
of the Requirements for the Degree
Doctor of Audiology

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We hereby recommend that the dissertation prepared under our supervision
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Screening Audiology
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ABSTRACT

Currently, the American Speech-Language Hearing Association (ASHA) recommends pure-tone audiometry as the preferred audiometric screening method of school-aged children; however, background noise is often present and can result in high referral rate. The current study’s goal was to examine the effect of noise on the pass rate on transient-evoked otoacoustic emissions (TEOAEs) and pure-tone audiometric screening measures. Twenty normal hearing adults ($M = 22.85$), eighteen females and two males, were screened with TEOAEs and pure-tone audiometry in quiet and in different levels of noise (i.e., 40 dB SPL, 50 dB SPL, 60 dB SPL) in a sound-treated booth.

Pure-tone audiometry and TEOAEs were present at 40 dB SPL. At 50 dB SPL, a 90% pass rate was recorded for TEOAEs and 60% pass rate for pure-tone audiometry. In 60 dB SPL noise, a 70% pass rate was found for TEOAE screenings and a 15% pass rate was found for pure-tone screenings. The amplitude was not found to be significantly different for the right or left ear, suggesting participants had similar TEOAE amplitudes in all noise levels. A significant difference for the right ear TEOAE reproducibility was found for the quiet to 60 dB level, but no other noise level was found to be significant. The reproducibility for the left ear TEOAE was found to be significant at the 40 to 60 dB noise levels and the 50 to 60 dB noise conditions.
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CHAPTER I

Introduction

Each year 1 in 6 of every 1000 children are born with a hearing loss, and while some children with a hearing loss can be detected at birth, many are not identified until they begin school (Harlor & Bower, 2009). In an effort to identify hearing loss acquired during early childhood, school hearing screenings are employed and typically consist of behavioral testing done by audiologists or other school personnel with portable audiometers. Although this technique has been used for many years, problems exist due to the nature of subjective testing. A subjective test, like audiometry, requires the child to accurately and willingly respond in a consistent manner, and this is not always possible with younger children. Additional pitfalls of pure-tone screenings are the inability to identify otitis media with effusion accurately and the influences of background noise during the screening.

A transient-evoked otoacoustic emission (TEOAE) test, on the other hand, is a screening measure that is objective in nature and requires no contribution from the child other than remaining still. In cases where children are unable (e.g., developmentally delayed) or unwilling to respond due to poor attention or a young age, an objective measure such as TEOAEs is an effective means of screening the peripheral auditory system. An objective test such as a TEOAE may be more effective than pure-tone audiometry in some ways in that it requires minimum communication between the child and tester; in other words, it can overcome language barriers that can be difficult when
screening children who do not speak the same language as the tester in schools.

Transient-evoked OAEs are also an effective tool in detecting the presence of otitis media due to their sensitivity to middle ear fluid (Georgalas, Xenelis, Davilis, Tzangaroulakis, & Ferekidis, 2008). However, one drawback of TEOAEs is the effect of noise on OAE recordings; a TEOAE can be recorded as reduced or absent, even if hearing is within normal limits (Smith, Kei, McPherson, & Smith, 2001).

While studies show that TEOAEs are a valid objective measure (Yang, Young, & Kuo, 2002; Yin, Bottrell, Clarke, Shacks, & Poulsen, 2009), the American Speech-Language Hearing Association (ASHA, 1997) recommends behavioral testing as the primary method of screening in schools, and currently does not recommend portable hand-held devices as effective measures. The American Speech-Language Hearing Association states that “hand-held devices are not recommended in the school-age population based on the high false positive rate” (1997, p. 44). Universal newborn hearing screenings require an audiological screening be completed before an infant leaves the hospital. Children are also screened in kindergarten and grades one, two, three, seven, and eleven. Screenings can contain behavioral measures, objective measures, or a combination of both screening types. According to the ASHA (1997) guidelines, objective measures such as otoacoustic emissions or auditory brainstem response tests should be used when screening neonates to detect any congenital hearing loss. However, ASHA (1997) has made no definitive statement regarding objective screening tests for school-aged children, although hand-held devices are not recommended (e.g., screening TEOAEs).

However, investigators have examined TEOAEs as a tool for detecting middle ear effusion (Georgalas et al., 2008), revealing that this objective measure can be a practical
addition to screenings in schools. An effective screening method such as OAEs may be sensitive to hearing loss. It was found in studies by Konopka, Zalewski, and Pietkiewicz (2001) and Sisto et al. (2007) that OAEs were more sensitive to noise-induced hearing loss than pure-tone thresholds, and also detect changes in thresholds sooner than pure-tone audiometric threshold shifts. In 2001, Smith et al. studied normal hearing adults using various speech babble intensities and TEOAEs to determine how noise affects the TEOAE results. The investigators found that the higher intensity of the noise decreased the TEOAE signal-to-noise ratio (SNR), but they also discovered that the OAEs appeared as an effective method of detecting hearing loss in noise.

The purpose of the current study was to investigate the validity of TEOAE screening devices when screening normal hearing adults using 40, 50, and 60 dB SPL of cafeteria noise. The objective TEOAE measure was compared to the behavioral pure-tone audiometric screening measure to determine if objective tests were as effective in identifying hearing loss. This investigator examined how noise affects the pass or refer rate of both TEOAEs and pure-tone audiometric screening in various levels of cafeteria noise. The specific research question addressed was: What is the effect of noise levels on TEOAEs and pure-tone screenings?
Audiological Screening Measures

An audiological evaluation is the method used to assess hearing function in both adults and children. However, a complete evaluation is not always necessary; a hearing screening is also a viable option that can quickly determine presence or absence of a possible hearing loss. Subjective screening measures, such as pure-tone audiometry, require a patient’s behavioral response in order to collect data. These tests can be administered in a sound booth with diagnostic audiometers, but more commonly are performed via a portable audiometer in a quiet room. Pure-tone audiometry screening consists of presenting air conduction tones via supra-aural headphones. The patient hears a continuous or pulsed tone that travels through the outer and middle ear system to the inner ear and is then interpreted by the brain. The frequencies tested for each ear are 1000, 2000, and 4000 Hz, and the patient responds by raising his/her hand or pressing a button each time the tone is heard.

Objective measures require no response from the patient. Objective procedures most commonly included in a screening test battery are tympanometry and otoacoustic emissions (OAEs). Tympanometry measures the acoustic immittance in the plane of the tympanic membrane and is made with a probe tip placed in the external auditory meatus (Prieve & Fitzgerald, 2009). Otoacoustic emissions are “sounds that originate in the cochlea and propagate through the middle ear and into the ear canal where they can be
measured using a sensitive microphone” (Prieve & Fitzgerald, 2009, p. 497). Otoacoustic emissions have many advantages as an objective measure; they offer reliably obtained data of cochlear function, are easily measured, and are a non-invasive test (Cunningham, 2011). The presence of an OAE can provide valuable information regarding function of the ear, from the pinna to the outer hair cells within the cochlea. Present OAEs reveal to the hearing professional that there is no occluding cerumen, the tympanic membrane has normal or near normal mobility, and an operational ossicular chain (Cunningham, 2011) in addition to functioning outer hair cells. However, OAEs provide no assessment of central auditory system integrity.

**Otoacoustic Emissions**

Otoacoustic emissions are thought to be produced by hair cell motility and are measured in the ear canal (Cunningham, 2011). A more detailed explanation is discussed by Prieve & Fitzgerald (2009) regarding the theories of OAE generation. They state that the generators of OAEs are believed to be derived from the processes of nonlinear distortion and linear coherent reflection (Prieve & Fitzgerald, 2009). Currently, two hypotheses exploring the outer hair cells and their part in the cochlear amplifier exist. These hypotheses include the outer hair cell’s somatic motion, as well as the active processes of the stereocilia. It is thought that both somatic motility and stereocilia are needed in the development of OAEs, and that these may provide a stimulus that is intensity specific (Prieve & Fitzgerald, 2009).

Otoacoustic emissions typically used by clinicians are spontaneous otoacoustic emissions (SOAEs), distortion product otoacoustic emissions (DPOAEs), and transient-evoked otoacoustic emissions (TEOAEs). Spontaneous otoacoustic emissions are
produced without any external stimulation and are measured with the microphone's recording in the frequency spectrum. In the adult population, SOAEs are typically measured between 1000 and 2000 Hz which are the band-pass frequencies that are most reflective of the middle ear features (Prieve & Fitzgerald, 2009). Spontaneous otoacoustic emissions are most often employed for research purposes and are rarely applied in clinical situations.

Two types of OAEs that are commonly used clinically are TEOAEs and DPOAEs. A DPOAE is measured after two independent pure-tones are presented to the ear simultaneously. The OAE type used in the present study is TEOAEs. Transient-evoked otoacoustic emissions are elicited after a transient, or very brief, presentation of a stimulus such as a click or tone burst is presented to the ear; the click is a broadband signal. It is produced after a short time delay following the stimulus presentation (Prieve & Fitzgerald, 2009).

ASHA Screening Guidelines

The ASHA (1997) guidelines state that the purpose of a school screening is to identify the presence of a hearing impairment and to determine if a referral for further hearing testing is needed. Hearing screenings are essential in detecting hearing impairment in children, especially in young children as the first three years are essential in language and speech development. Unfortunately, children with hearing loss may go undetected until after 12 months of age, and a mild hearing loss may not be identified until much later. Research has shown that early detection and treatment of a hearing impairment gives the child a better chance to avoid or diminish the effects of impairment (Ross, 1992). A hearing screening is recommended by ASHA (1997) periodically...
between birth and age 18 for the purpose of identifying a hearing loss that can be
detrimental to a child’s general welfare, ability to communicate, general development,
and learning ability.

The ASHA (1997) guidelines for screening infants and children for outer and
middle ear disorders are inclusive for birth through 18 years of age, but ASHA does not
offer a position on a universal screening for middle ear disorders. It is necessary to
identify and treat chronic middle ear diseases in young children because, left undetected,
they could affect their development and health. To test for outer and middle ear disorder,
ASHA recommends only one set of guidelines for the entire pediatric age range which
includes case history, otoscopy and tympanometry, with the case history being optional.
Clinical indications stipulated by the ASHA guidelines are to screen for outer and middle
ear disorders in the pediatric population as needed or when children are at risk for the
disorders. The ASHA guidelines do not suggest using OAEs for the screening process of
middle and outer ear disorders, however research (Georgalas et al., 2008; Saleem,
Ramachandran, & Ramamurthy, 2007; Shakeel, Hasan, Hashmi, & Ullah, 2010; Taylor
& Brooks, 2000; Yeo, Park, Park, & Suh, 2002) has since shown that OAEs are an
effective measure. The ASHA guidelines state that “it has also been suggested that such
testing [OAEs] might be useful for identifying those at risk for middle ear disorders as
well” (ASHA, 1997, p. 19-20) but they cite a need for more data.

The neonate and young infant population, birth to 6 months of age, have specific
ASHA (1997) guidelines for hearing impairment screenings. The ASHA guidelines
recommend screening with at least one or two tests, including DPOAE and TEOAE
which are measurements of cochlear function. Specifically the guidelines recommend
that TEOAEs should be performed at 50-80/second at 80 dB pe SPL using a click stimulus. Behavioral measures such as pure-tone hearing testing are described as inappropriate measures for this age range as this population is difficult to condition to a task. According to the ASHA guidelines, behavioral measures may be unreliable in identifying a mild hearing loss in the newborn population.

However, the ASHA (1997) guidelines for infants and toddlers, 7 months through 2 years, include behavioral measures as appropriate forms of testing if the child can be conditioned to the task. Visual reinforcement audiometry (VRA) and play audiometry using headphones can be attempted with children. If any child or infant is unable to respond to behavioral tests due to prematurity or delayed development, objective measures recommended in the birth to 6 month age group may be used. Modifications in testing are acceptable, such as using OAEs if a behavioral response cannot be obtained. Although ASHA recommends primarily behavioral measures for this population, OAEs have been shown to be a reliable measure and are used to screen the birth to 6 month age group. If TEOAEs are effective in screening for hearing loss in infants, this objective test could also be a viable alternative to pure-tone audiometry.

Behavioral tests are also recommended by the ASHA guidelines (1997) to screen for hearing impairment in preschool children, age 3 to 5 years. The child should first be conditioned to respond to tones prior to testing, and two trials should be used to condition the child at a suprathreshold intensity level. The child should be screened with headphones or inserts at an intensity of 20 dB HL at 1000, 2000, and 4000 Hz tones using conditioned play audiometry or traditional audiometry if possible. Inappropriate procedures are cited, such as using stimuli that are not frequency specific.
For the school-age population, 5 years through 18 years, the 1997 ASHA guidelines recommend behavioral pure-tone screening using conditioned play audiometry or traditional audiometry. The pure-tone screening is conducted at 20 dB HL for 1000, 2000, and 4000 Hz tones with headphones or inserts. Procedures considered inappropriate include “transient evoked otoacoustic emissions (TEOAE) or distortion product otoacoustic emissions (DPOAE) testing” (ASHA, 1997, p. 42-43). Even though ASHA recommends OAEs to screen the infant population for hearing impairment, ASHA does not currently recommend this objective measure for school-age children due to “the high false positive rate” (ASHA, 1997, p. 44). However, research on TEOAEs and DPOAEs currently “suggests that these are promising procedures for the future of screening for hearing disorder in this population” (ASHA, 1997, p. 44). ASHA cites a need for further research in TEOAEs and DPOAEs before including these objective measures in current screening guidelines.

**Pure-tone Hearing Screening Versus TEOAE Screening**

Halloran, Hardin, and Wall (2009) examined pure-tone screening measures and their sensitivity and specificity in 1061 children, ages 3 to 19 years old. The children’s parents were asked about participation in the study during well-child calls. In the first stage of the study, pure-tone screenings at 20 dB at 1000, 2000, and 4000 Hz were performed for both ears. The results of the pure-tone audiometric screenings were classified as pass, refer, or could not test. A refer was given if at least one frequency was not heard by the child. Follow-ups were performed by a physician at subsequent well-child appointments. The second stage of the study consisted of an audiological evaluation by an audiologist for children that received a refer after the initial screening,
as well as a random sampling of children that passed the first screening. If after three months a child from the random sample was unable to make the follow-up evaluation, another child was randomly chosen. One hundred and thirty children were referred for an evaluation, including random selection of 102 children and the 28 children that were referred by a physician. A total of four children were identified as having a hearing loss; two of the four failed the initial screening and the remaining two had passed the first pure-tone screening. A total of 21 children that received a referral were never evaluated and were consequently labeled as non-compliant. The children that attended the referred evaluation were tested an average of 128 days after their first hearing screening. The researchers revealed that the pure-tone screening had only 50% sensitivity and 78% specificity. The authors deduced that the poor specificity and sensitivity, as well as other drawbacks such as test time, the examiner’s testing skill, and the necessity of the child’s participation and ability to perform the task, affected pure-tone testing. Due to these factors, it was determined by Halloran et al. (2009) that pure-tone audiometry not be the primary screening method in school screenings, while more effective and objective measures such as OAEs exist.

McClure (2010) compared subjective and objective audiological screening results of 67 school-aged children in a Union Parish elementary school. The children were recruited by a mailed letter to their parents detailing the project’s purpose and requesting consent. All students were screened with the ASHA recommended pure-tone screening guidelines with a portable audiometer, as well as the objective measures of TEOAEs, DPOAEs, and tympanometry. The screenings took place in locations that were previously used for school screenings (i.e., the school’s library and auditorium). The
subjective screenings (i.e., pure-tone screening) were conducted at one table and the objective screenings (i.e., TEOAEs, DPOAEs, and tympanometry) were conducted at a second table within a single room. The pure-tone screening was obtained with a 20 dB HL intensity at the frequencies of 500, 1000, 2000, and 4000 Hz for both ears. A pass was noted for pure tones if the child responded for all frequencies in the right and left ear, and referred if a response was not noted for any frequency for the right or left ear. A pass was provided for TEOAEs if the signal was 6 dB above the noise floor and the wave reproduced at 70% for 1500 through 4000 Hz. The DPOAEs were passed if three out of four frequencies produced a 6 dB SNR. Tympanometry screenings were passed if the peak compliance was present at .2 cm³ to 1.4 cm³, as well as a tympanic pressure between -150 daPa to +100 daPa. Of the 67 students tested, the investigator found that 39 children passed the ASHA recommended behavioral screening (i.e., 1000, 2000, and 4000 Hz), while only 6 children passed the complete pure-tone screening (i.e., 500, 1000, 2000, and 4000 Hz). Only 53 children were tested with tympanometry due to technical difficulty, and 28 of the children passed this measure. All 67 children were screened with DPOAEs and TEOAEs, and a total of 58 children passed DPOAE screening measures and 52 children passed TEOAE measures. Overall, DPOAEs were found to have the highest pass rate, and McClure recommended that, in the future, screening procedures should consist of “TEOAEs, DPOAEs, and screening tympanometry with normal auditory function resulting from a pass from two of the three measures” (2010, p. 41).

Yin and colleagues (2009) used TEOAEs to screen preschoolers who were at risk for hearing loss. The researchers also examined the speed at which TEOAEs could be obtained and compared this to the time it took to obtain a pure-tone audiometric
screening. These screenings were performed by two nurses and a pediatrician at city schools on at-risk preschool children, ages 2 to 6 years. A group of 744 children was screened using TEOAEs only, and a second group called the secondary cohort consisted of 135 children who were screened with both TEOAEs and pure-tones. These children were engaged in the study by the Child Health-Words organization, which is a program that offers different intervention services to those in need. The nurses and pediatrician were trained by an audiologist in the OAE screening procedures. To be included in the study, participants were only required to have a guardian complete a signed consent form for the audiological screening. According to guardian reports, none of the children was known to have a hearing impairment prior to the study. Transient-evoked otoacoustic emissions were screened using the Otodynamics Echo Port ILO 288 at 1000, 1200, 2000, 3000, and 4000 Hz by the Quick screen method which was filtered at 400 Hz to pass the high frequencies. A TEOAE was considered to be present in an ear when a response was detected in at least three frequencies at a 5 dB SNR. If these requirements were not met, a refer was assigned to that ear. Several audiologists from the school system were employed in the study in order to test the reliability of the screening procedures. The audiologists tested the secondary cohort group of 135 children with a pure-tone screening to compare to the TEOAE screenings results in order to ensure reliability. For the secondary cohort of 135 children, TEOAEs were tested at the initial screening, and in a three-month period, these children were rescreened using pure-tone audiometry. Pure-tones were screened at 1000, 2000, and 4000 Hz at 25 dB HL for both ears. A refer was assigned if a response was not determined at any of the frequencies. The pure-tone screening and TEOEA screening measures were evaluated against each other.
Yin et al. (2009) found TEOAEs were present for 644 participants, 41 participants were referred for both ears, and 51 participants were referred for one ear. Follow-up testing was performed by an audiologist. Of the 135 participants from the secondary cohort, 126 children received a pass on both the pure-tone and TEOAE screening tests, eight children received a refer on the TEOAE screening and a pass on the pure-tone testing, and one child was found to have a hearing impairment, receiving a refer on both the pure-tones and TEOAE tests. From the results of this study, the researchers indicated that TEOAEs were an effective measure for a first line screening with 94% specificity and 100% sensitivity.

Driscoll, Kei, and McPherson (2000) examined the ranges of TEOAE results for 940 school-age children from Australia. An audiologist measured TEOAEs using an ILO292 Otodynamics Analyser with the Quickscreen method. The TEOAEs were set on default to obtain 260 responses using the Fast Fourier Transform analysis. To make sure the results were reliable, the investigators collected data a second time for 79 of the ears. The number of right and left ears, as well as number of female and male participants, were evenly distributed throughout the sample. A pass was designated for an ear if the SNR was 3 dB or greater, and a fail was designated if this condition was not reached. A total of 20.3% participants received a fail for the TEOAE measurements, and the researchers found a difference in the pass/fail rate with males having a slightly higher fail rate than the female participants. The researchers discovered that the results were significant when a history of middle ear infections, asymmetry of ears, and sex were compared.
Middle Ear Disorders and OAEs

In a study in Turkey involving hearing detection in the preschool population, Nur, Altuntas, Cerrah, Yildirim, and Sumer (2010) performed TEOAEs and tympanometry as a first stage of hearing screening to observe the effectiveness of these objective tests and to determine the hearing loss incidence in the selected population. A cross-sectional design was used between October of 2007 and April of 2008. The 1096 participants included preschool children from 22 government schools, aged 4 to 6. Each child’s parent received information regarding the screening procedures and forms for consent. Parents were also given the option to provide verbal consent for their child’s participation in lieu of returning the consent form by mail. Questionnaires were provided to the parents for completion (e.g., prenatal history, developmental history, hearing status, and general health information). None of the participants’ parents reported a hearing impairment prior to testing.

Otoscopy, tympanometry, and TEOAEs were performed on all children by two trained audiologists in classrooms with environmental noise measured at levels varying between 40 to 53 dBA. Tympanometry was conducted using the MAICO MI 44 Analyzer, and a pass was given only when a Type A tympanogram was produced. The MAICO ERO SCAN Analyzer was used to perform TEOAE recordings, and if the child did not pass the original TEOAE testing, the recording was taken a second time before labeling that ear as a refer. Children who did not pass tympanometry or TEOAE screening measures were termed a fail for the entire screening, and these participants were referred for follow-up appointments at the Cumhuriyet University Ear, Nose, and Throat Clinic.
The majority of the participants, 886 out of 1096, revealed Type A tympanograms, while 180 participants showed Type B tympanograms, 6 participants showed Type C tympanograms, and 23 participants could not be tested due to excess cerumen, the child’s activity level, or other non-specified reasons (e.g., failure to attend appointment). The resulting TEOAE recordings revealed a pass for 883 children, a refer for 180 children, and the remaining 33 children could not be tested for various reasons. A total of 78.4% of the children passed both screening measures, tympanometry and TEOAE testing, while the other 21.6% did not receive a pass for one of the ears for either tympanometry or TEOAE screening procedures. Those individuals that did not pass the screenings attended follow-up assessments; of those individuals, 132 children were labeled as having a hearing impairment or a hearing disorder that needed to be observed or treated. After assessment, it was also discovered that of the hearing losses identified 31 cases had unilateral or bilateral hearing loss (e.g., sensorineural or conductive), 83 had middle ear fluid, and 18 were congested or experienced excess cerumen. For both screening measures, an overall fail of 17.8% resulted; however, the high screening fail rate did not necessarily indicate a hearing loss. The researchers in this study found that the prevalence of hearing loss in the preschool population was higher than expected from previous reports; however, this was thought to be due to the age differences that were observed. Overall, tympanometry and TEOAE were found to be an effective screening measure for the preschool population.

In a cross-sectional study, Georgalas and colleagues (2008) examined how OAEs contributed to screenings on hearing loss and middle-ear effusion in schools. The 196 participants (i.e., 392 ears) were selected through press releases in Argolida, Greece. The
children, age 6 to 12 years old, were screened with OAEs and pure-tones from December 2004 to March 2005, and their parents filled out questionnaires regarding otological history prior to testing at the school. Testing was performed by Ear, Nose, Throat specialists (ENTs) and took place in a semi-soundproofed room. Otoscopy, tympanometry, and pure-tone audiometry were performed on all children; however, otoscopy revealed cerumen impactions in 16 ears. Tympanometry was conducted with an Interacoustics AT–235 immittance bridge using a 226 Hz tone at 85 dB SPL, and pure-tone thresholds were obtained with a Maico MA 40 portable audiometer at 500, 1000, 2000, and 4000 Hz. The TEOAEs were measured using an ILO 92 recorder with the Quickscreen setting with a 83.5 dB nonlinear click, and a response was accepted if the recorded noise in the ear canal was less than 47.3 dB. The measurements were considered a pass if the SNR was 3 dB or greater. Type A tympanograms were revealed for 185 ears, Type B tympanograms were revealed for 49 ears, and Type C tympanograms were revealed for 152 ears. Average thresholds were calculated for the participants in three manners: 1) children with normal hearing with no history of otological difficulties, 2) children that had a history of acute otitis media (AOM), and 3) children with a history of otitis media with effusion (OME). Those with no history of otological problems had an average threshold of 11.9 dB, those with AOM had an average threshold of 14.3 dB, and those with a history of OME had an average threshold of 19.8 dB. Overall, pure-tone thresholds were worse if the participant experienced middle ear problems in the past. Transient-evoked otoacoustic emissions were conducted on all 196 participants; 63 of the participants had no TEOAE in one ear and 39 participants had absent TEOAEs for both ears. The participants’ past ototolitical history
did not seem to affect OAE results. If the child had hearing sensitivity worse than 30 dB HL, TEOAEs were absent, and in cases of hearing sensitivity worse than 25 dB, TEOAEs were absent in 9 out of 10 of the participants. In detecting OME, TEOAEs were absent 2.26 times when otoscopy revealed abnormalities with the ear drum, and an absent TEOAE resulted for 22 of the 32 participants that were classified with Type B tympanograms, indicating that TEOAEs could be a reasonable measure in school screenings.

Yeo et al. (2002) conducted a study in order to determine the effect that the middle ear condition and hearing impairment had on OAEs. The researchers conducted a variety of OAE tests (e.g., TEOAEs, DPOAEs, SOAEs), specifically focusing on DPOAEs. Forty-three participants, ranging in age from 2 to 11 years, who were patients at a pediatric hospital, were included in this study, and testing was performed on 85 ears of the participants. All patients presented with middle ear symptoms that included ear fullness, tinnitus, congestion, and ear pain, and the 43 patients were divided into a control group and experimental group (i.e., OME group). In addition to otoscopy, tympanometry was conducted in order to determine middle ear status prior to the study. The experimental group consisted of 32 ears with middle ear symptoms, including discoloration of the tympanic membrane, fluid in the middle ear, as well as retracted ear drums. All participants within the OME group were classified with Type B tympanograms. The control group was made up of 44 ears with Type A tympanograms and healthy ear drums. Nine ears were left out of the study due to having Type C tympanograms. Bone and air conduction audiometry were conducted on 40 of the participants with the GSI 10 audiometer. Thresholds for air conduction measurements
were found at 125 to 8000 Hz, while thresholds for bone conduction measurements were found at 500 to 4000 Hz. An ILO-92 otodynamic analyser was used to measure OAEs in a room that was soundproof. Spontaneous otoacoustic emissions were measured for up to 2 minutes with a spectrum analyser. The average of signals that were received was converted with an analog-digital converter, and a Fourier transform was used to analyze the data on an IBM computer. In order to be included in the study, the amplitude of the SOAE had to be 3 dB or more than the noise floor. For the TEOAEs, an ILO-88 analyser was used with nonlinear clicks presented at an intensity between 75 and 85 dB SPL. Averages were taken once 260 responses occurred and included in the data if the following criteria were met: responses were 50% or more, stability of the response was 70% or more, and the SNR was 5 dB or greater. Distortion product OAEs were measured at the frequency of 2f1-f2 in two different ways. The DPOAEs were first taken with a 70 dB SPL signal at 1000 to 6000 Hz. Distortion product OAEs were then measured at 1000, 2000, 3000, 4000, and 6000 Hz as an input-output curve with the amplitude raised by 1.5 dB at 35 to 75 dB SPL. For this study, DPOAEs were included if SNR of 5 dB was reached.

Pure-tone measurements for the control group were an average of 11.9 ± 7.9 dB HL at 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz. For the group with OME, the pure-tone thresholds revealed an average of 24.6 ± 7.6 dB HL for the same frequencies measured in the control group. The SOAE results were present for 36 of the 44 ears in the control group. For the experimental group, SOAEs were present in 11 of 32 ears. Transient-evoked OAEs were present in 40 of the control group’s 44 ears and in four of the OME group’s 32 ears. The DPOAEs were present in 15 ears of the OME
group’s 32 ears and were present in all of the ears in the control group. Due to the high association between the different OAE measures, Yeo et al. (2002) revealed in their study that the state of the middle ear, in both healthy and affected middle ears, does have an impact on TEOAE, DPOAE, and SOAE measurements in children. It was found that OAEs show not only the cochlear status, but also the condition of the middle ear. The conclusions of this study support previous research that indicated the value of OAEs as a way to detect and monitor middle ear status, in addition to cochlear function.

A study was conducted on children, ages 2 to 15 years old, by Saleem and fellow investigators (2007) in order to determine the role of OAEs in regards to middle-ear effusion and the presence of grommets. In total, 90 ears were tested of the participants who were having surgical placement of grommets due to effusion of the middle ear. Children having any additional surgery, such as tonsillectomy, were not included in this study. Pure-tone audiometry, tympanometry, and TEOAEs were performed prior to grommet placement and 3 to 6 months post surgery. Otoacoustic emissions were measured using the Otodynamics ILO-88 system using the Quickscreen mode with a nonlinear click. Measurements were obtained by an audiologist in a room that was soundproofed. In order to be accepted as a measurement, the TEOAE recording had to be at least 3 dB or greater than the noise floor and the wave had to be repeatable for 50% of the time. Otoacoustic emission measurements were shown as absent or present, and no classification of amplitude was made for this study.

Prior to surgery, 63 of the participants’ ears had a conductive loss as shown with pure-tone thresholds and 27 ears were defined as having normal hearing. For the ears with conductive hearing losses, tympanometry results revealed normal Type A
tympanograms for 25 ears, Type C tympanograms for 17 ears, and Type B
tympanograms for 21 ears. For TEOAEs, the children with conductive hearing losses
had absent OAEs in 59 cases prior to surgery; the other four ears revealed present
TEOAEs with normal Type A tympanograms. The tympanometry results for the 27
normal hearing ears revealed 21 Type A tympanograms, three Type C tympanograms,
and three Type B tympanograms; all of the ears with normal audiometric hearing
thresholds had present OAEs. Three to 6 months after grommet placement, the
participants with normal hearing continued to have present OAEs. The researchers came
to the conclusion that TEOAEs are valuable and effective in screening children with
middle ear effusion and grommets, particularly in children that are more difficult to test
for behavioral reasons.

Shakeel et al. (2010) investigated the correlation of otoacoustic emission response
and audiometric hearing in 97 ears from 50 participants, ages 3 to 45 years, from an Ear,
Nose and Throat Out-Patient Department (ENT OPD) with middle ear ventilation
disorders. The researchers divided the individuals into groups, with 61 participants in the
experimental group and 36 participants in the control group, based on the results from
otoscopy, tympanometry, and pure-tone testing. The 36 participants placed in the control
group had type A tympanograms and pure-tone audiometric hearing and otoscopy within
normal limits. The 61 participants in the experimental group had symptoms of a middle
ear disorder and were placed into this group when a Type B or Type C tympanogram was
measured. Participants were measured with OAEs, tympanometry, and pure-tone
audiometry pre-treatment (i.e., treatment not specified in study) for their middle ear
disorder and all of the tests were conducted again post-treatment. The OAEs were
conducted in a room that was soundproofed using a Maico Ero-Scan OAE Test System. A TEOAE response was recorded as a pass if a 4 dB SNR was measured at least three of the six frequencies. A DPOAE response was determined to be a pass if a 6 dB SNR was recorded for four of the six frequencies. The pure-tone average for the control group was 12.05 dB, and 24.88 dB for the experimental group. The OAEs were found to be reduced in the group designated pretreatment, and an improvement was discovered when the SNR was increased post-treatment at one and two months. Transient-evoked OAEs were discovered to be the most effective in detecting hearing impairment that was less than 25 dB, while DPOAEs were more likely to detect a hearing loss if the impairment was equal to or greater than 25 dB. An individual with a referral from a DPOAE test was seen to need a more extended treatment that was more aggressive in nature than a referral from a TEOAE test. The investigators determined that the OAEs, both DPs and TEs, are a reliable form of hearing loss assessment, as well as in monitoring any changes that occur in ears with middle ear ventilation disorders.

Taylor and Brooks (2000) screened 152 participants, ages 3 to 8 years, with TEOAEs in order to discover the specificity and sensitivity of the test in identifying middle ear disorders and hearing loss. The researchers also screened the children using pure-tone audiometry and tympanometry screening measures as a comparison to the TEOAE results. The data were stated as individual ears, rather than participants. The participants used in this study were referred from a variety of locations (e.g., center for early intervention services, neighboring speech and hearing clinics, an otolaryngologist, day-care centers, Children's Rehabilitation Services). Sixteen of the ears were known to have hearing loss (e.g., conductive, sensorineural, mixed); however, the specific type of
hearing loss was not known for the 16 ears because those children were referred by a
physician without audiograms. Seven ears could not be included in the study; six ears
were not included due to participant uncooperativeness during testing, and one ear with
atresia was not included.

The children were tested by two audiologists using tympanometry, pure-tone
screening, and TEOAEs, and test measurements were conducted in random order. Pure-
tone testing was conducted with the Grason-Stadler GSI-10 audiometer and TDH-50
supraaural earphones using the ASHA recommendations for pure-tone screening.
Measurements were taken using an air-conduction signal at 1000, 2000, and 4000 Hz at
20 dB HL for the right ear and then repeated for the left ear. If a child did not respond to
a frequency at 20 dB HL, then that ear was labeled a refer and a threshold was
determined for that individual ear. Tympanometry was performed using a Grason-Stadler
GSI-33 immittance bridge that was calibrated according to ANSI S3.39-1987 standards.
A 226 Hz tone was used during tympanometry testing with the pressure at +400 to -600
daPa. The ears were categorized as a pass or as a refer based on ASHA’s 1997
guidelines. In order to be considered a refer, one of the following criteria had to be met:
the admittance was under 0.3 mmho, the canal volume was over 1.0 cm³ with a flat
tympanogram present, or the width of the tympanogram was over 200 daPa. The
TEOAEs were measured with the Otodynamic Analyzer Model IL088 that contained a
filter to cut the low frequencies. Frequencies included were 500 to 5000 Hz at an
intensity of 75 to 85 dB pSLP. Fifty clicks were emitted per second in a nonlinear mode,
and measurements were subaveraged for a total of 260 times in groups of four clicks
before being delivered to two separate buffers. The TEOAE tests automatically stopped
once the 260 subaverages were completed. The rejection level of noise was set to 47 dB SPL and a filter set to 400 was also in place in order to pass the high frequencies. To be considered a pass, the TEOAE measurements had to be 3 dB greater than the noise floor for at least three frequencies. In addition, the TEOAEs also has to obtain a 90 to 95% sensitivity with a specificity equal or higher, and 40% repeatability of the frequency-band and whole wave of the TEOAE wave forms.

Pure-tone and TEOAE screenings were compared by their sensitivity and specificity by Taylor and Brooks (2000). They found the following results: 251 ears passed both TEOAE and pure-tone measures; six ears passed the TEOAE measures but failed pure-tones; 26 ears failed both screening measures (e.g., pure-tones and TEOAEs); and 14 ears passed pure-tones but failed TEOAE measures. Tympanometry and TEOAEs were compared in terms of specificity and sensitivity for disorders of the middle ear. Tympanometry was revealed to be 91%, while TEOAEs were found to be 60% sensitive in terms of detecting middle ear dysfunction. It was found that TEOAEs were 81% sensitive and 95% specific when compared to pure-tone audiometry, and it was determined that TEOAE measures could be effective as a substitution for pure-tone audiometry in screenings.

**Noise and OAEs**

Smith and colleagues (2001) conducted a study testing normal-hearing adults in order to determine the effect of various intensities of speech babble on TEOAEs. Participants included 30 adults with normal hearing between the ages of 18 and 32 years old. The adults consisted of an equal number of males and females, and to be included in the study, both of the participants’ hearing had to be within normal limits, which was
determined by having audiometric thresholds at 500, 1000, 2000, and 4000 Hz equal to or less than 20 dB HL. The participants also had to be free of any past occurrence of disordered hearing, as well as having Type A tympanograms bilaterally. Transient-evoked otoacoustic emissions were performed with an ILO88 Otodynamic Analyzer in a sound booth with the environmental noise under 30 dBA. For testing, the participants were seated at a distance of 1 meter from a Minimus Realistic loudspeaker, with the ear receiving the stimuli oriented towards the speaker. Four-talker speech babble recorded on a cassette tape was used as ambient noise for the duration of the TEOAE measurements. The background noise was calculated with a Bruea and Kjaer sound level meter with the setting on a slow speed. The speech babble's sound pressure levels were measured when no participants were in the room. The sound intensities of the speech babble were 60, 65, 70, and 75 dBA. A nonlinear TEOAE measurement was elicited with clicks for each participant in the Quickscreen and default procedures. The stimulus levels of the peak SPL were kept within 79 to 81 dB for the Quickscreen and default methods. In order to reproduce TEOAE measurements in realistic noise environments, the rejection level of the noise was maintained at 50.2 dB for situations with noise at ≤ 65 dBA and maintained at 54.4 dB for situations with noise at 70 to 75 dBA. Once TEOAE testing started, the clinician monitored the measurements continually and 260 clicks were emitted before the recording was ceased automatically. The testing order, Quickscreen and default method, of the TEOAEs were conducted for 15 of the participants, and for the remaining 15 participants the arrangement of testing was switched in order to control for any variance resulting from testing order. For both the Quickscreen and default method, testing was conducted in quiet and in noise with speech babble set at 60, 65, 70, and 75
dBA. In the quiet testing situation, the background noise originated from a computer and was measured by a sound level meter at 36 dBA. An effort was made to perform the five measurements without disturbing probe placement between the two test methods.

The results of the study by Smith and fellow investigators (2001) for whole-wave reproducibility (WWR) showed a decrease in WWR when the speech babble was amplified, and it was also determined that WWR for each of the various noise levels, including quiet, was significantly dissimilar. For the TEOAE measurement methods, both default and Quickscreen, the mean of the SNR revealed a decrease whenever the levels of speech babble was turned up. The researchers determined that the Quickscreen method was more effective than the default method in measuring TEOAEs in situations with noise. It was discovered that the WWR’s criteria were not useful for testing hearing in noise-filled situations due to this measure’s sensitivity to noise; however, the SNR criteria appeared effective in testing individuals with normal hearing in the presence of noise for the default mode at 65 dBA and for the Quickscreen setting at 70 dBA.

Konopka and colleagues (2001) studied the effects of hazardous noise from gunfire on the amplitudes of TEOAEs and DPOAEs before and after noise exposure. Participants included 10 soldiers (m = 20 years of age) who did not wear hearing protection during the course of this study. The study took place during their shooting training. The noise included automatic gunfire of 15 single rounds measuring 150 to 165 dB SPL. Ten to 15 minutes prior to and after impulse noise exposure, the OAE measurements were taken in a quiet environment along with pure-tone thresholds and tympanometry. Otoacoustic emissions were measured with an ILO 292 Echoport version 5.0. The TEOAE measurements included a sweep of 260 times for each participant with
a click duration of 80 s. The DPOAEs were recorded with 70 dB SPL and averaged until the point at which the noise floor was constant. Measurements were accepted as a response if a standard deviation of two or more greater than the noise level was achieved. The pure-tone thresholds for participants resulted in an average of 10 to 20 dB HL at both ears for 3000 Hz and 25 to 30 dB HL for 4000 to 8000 Hz for both ears. There were no significant differences between pre-testing and post-testing for pure-tone testing, tympanometry, and acoustic reflexes. Transient-evoked OAE results were found to be significantly reduced in amplitude after noise exposure at 1000, 1500, 2000, 3000, and 4000 Hz in the right ear, and the left ear was found to be significantly reduced at 1000 Hz and 2000 Hz after exposure to the gunfire. The investigators found DPOAEs were decreased in amplitude for 19 out of 20 ears over the entire frequency range tested. The largest decrease in amplitude for DPOAEs was seen at 1000 Hz and 3000 Hz for the left ear from pre- to post-testing. The authors revealed exposure to impulse noise, such as gunfire, can cause a temporary threshold shift. This temporary threshold shift can be detected by the reduced amplitude of both TEOAEs and DPOAEs even when pure-tone audiometric thresholds are not affected. According to Konopka and colleagues, these decreased amplitudes are an early sign of NIHL, indicating that OAEs can be used as an effective method to monitor those individuals who are exposed to hazardous noise.

Sisto and colleagues (2007) investigated the sensitivity of OAEs in identifying hearing loss due to noise at low levels. The sample group of this longitudinal study consisted of 217 employees who worked in various degrees of noise and the researchers used both OAE and pure-tone threshold measurements bilaterally on all participants. Individuals were excluded from the study if they had a history of ototoxic medication or
if any past otologic disorder was reported. Otoscopy as well as tympanometry were
measured prior to the pure-tone and OAE testing in order to determine that the middle
and outer ears were within normal limits. Otoacoustic emissions, TEOAEs and
DPOAEs, and pure-tone audiometry were conducted in a sound booth. Audiometry was
performed in the standard method at 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000
Hz. The TEOAEs were measured using an 80 dB click with the nonlinear method; this
method consisted of two rotating averages from 260 recordings of waveforms. The noise
floor was determined by subtracting the two averages, and the noise level was usually
found to be -12 dB. The DPOAEs were measured at an intensity of 65 – 55 dB primarily
with a -8 to -15 dB noise level, and the greatest amount of noise was found at 1000 Hz,
while the smallest amount was found at 3000 to 4000 Hz. Distortion product OAEs were
measured at other intensities as well, but in this study, the researchers only included the
data from the 160 individual ears measured with DPOAEs at an intensity of 65 – 55 dB.
At the completion of the study, the investigators divided the data into three groups of
NORM (normal; less than 10 dB at all frequencies), MHL (mild hearing loss; less than 20
dB at every frequency with greater than 10 dB at one or more frequencies), and HL
(hearing loss; greater than 20 dB at one or more frequencies). An additional
classification system for pure-tone audiometry was also used for the 1000 to 3000
frequency band: AVN (less than 5 dB as the average), AVM (greater than 5 dB and less
than 10 dB average), and AVH (greater than 10 dB average). The investigators decided
in which category to place the OAE results based on the SNR. The audiometric results
were 20 ears in the HL category, 63 ears in the MHL category, and 77 ears in the NORM
category. Results for the additional classification system were 96 ears in the AVN
category, 42 ears in the AVM category, and 22 ears in the AVH category. Sisto et al. (2007) believed this second classification was a helpful way to evaluate OAE sensitivity levels across frequencies. The researchers found that the average of TEOAEs and DPOAEs across the three main groups (e.g., NORM, MHL, HL) was significantly different when compared. At the end of the study, the investigators confirmed their belief that OAEs are a sensitive and specific test for determining hearing loss, particularly in participants with a mild hearing loss.

Hollowell (2012) examined the effect of background noise on hearing screenings and DPOAEs. Twenty adults with normal hearing were exposed to cafeteria noise levels at 40, 50, and 60 dB SPL while undergoing OAE and pure-tone screening bilaterally. Participants also had no known cognitive, central auditory processing, or neurological deficits. The screenings were conducted at 25 dB HL for the frequencies 500, 1000, 2000, and 4000 Hz for both ears. Data were collected for each ear and determined as a “pass” or “refer” for the behavioral and subjective measures. The researcher found that the participants did not begin to fail the DPOAEs until the background noise reached 60 dB SPL with only two adults failing the DPOAE screening in this noise condition. Four participants failed the pure-tone screening when the cafeteria noise reached 50 dB SPL. When the noise was increased to 60 dB SPL, only six participants passed the pure-tone screening. Overall, the researcher found that the pure-tone screenings were less resistant to background noise than DPOAE screenings.

Yang and fellow researchers (2002) conducted a study on the effect of noise on the pass/fail criteria of TEOAEs. The researchers used varying levels of noise while measuring a single TEOAE, and then examined the correlation of the SNR to the TEOAE
settings. Of the 16 participants, data from 25 normal hearing ears were used to conduct TEOAE measurements in a non-soundproofed laboratory. Transient-evoked OAEs were measured with noise that was synthesized at varying levels, as well as a TEOAE that was absent of noise. The TEOAE was measured with 512 responses that were subaveraged for each individual ear, and then divided into buffer A and buffer B. The TEOAE response was then determined once the 256 responses from the two buffers were averaged together. The researchers found that the decrease of the SNR did increase the TEOAEs, but that the estimated repeatability reduced to 7% from 97%. They further discussed the likelihood that a TEOAE response can be detected when the TEOAE level is corrected, and TEOAE detection is also due to the correlation of the repeatability of a signal across the SNRs.

In 2010, Olusanya reported on the ambient levels of noise in infant screening programs in southwest Nigeria and the effect that these levels had on TEOAEs. A total of two studies in the urban region of Lagos, Nigeria, were performed. For the studies, 4718 and 7179 neonates were screened with TEOAEs, and if a referral was determined, an Automated Auditory Brainstem Response (AABR) screening was conducted. Two TEOAE screening machines were used, Echo-Screen and the Echocheck. The AABR was performed using the ALGO Portable machine. With the Echo-Screen, TEOAEs were conducted in the nonlinear method at 85 dB SPL with 60 clicks at 1500 to 3500 Hz, while the Echocheck used clicks at 84 dB SPL nonlinearly at 1000 through 4000 Hz with 100 clicks each second. The ALGO Portable AABR machine used 1000 clicks at an intensity of 35 dBnHL at 37 clicks each second. Two nurses completed all screening measures each day from 9:00 a.m. to 3:00 p.m., except Sundays. The average noise was
measured at 76.9 dBA SPL and 66.9 dBA SPL for ambient levels. A total of 7.1% infants received a refer for the TEOAE measures in the first study and 19.4% for the second study at 60.3 dBA SPL. The investigators of this study found that noise intensities at these sites were high enough to create higher false positives with most commercial TEOAE machines. However, the ambient noise levels in this study were considerably louder than noise levels found more often in the majority of the developing countries.

Hand-held devices and OAEs have been shown from the research cited above to be as reliable, if not more reliable, than behavioral measures such as pure-tone audiometry, and these objective measures are also effectively used on a routine basis in clinic. Behavioral measures suffer from shortcomings such as an inability to accurately detect effusion and inconsistent responses in the presence of background noise levels. Pure-tone audiometry, in some cases, may not be as reliable as OAEs; audiometry is a subjective measure that requires a truthful and willing response on the individual’s part, while the objective OAE measure requires no participation from the individual other than sitting still. Due to the objective nature of OAEs, they may also overcome language barriers that may pose a problem when testing children in a school setting using pure-tone audiometry, a behavioral measure. Some children may just not be good responders for any number of different reasons, such as developmental delays or poor attention. The purpose of the present study was to examine the reliability and validity of objective measures such as hand-held TEOAE screening devices in a screening of normal hearing adults when different SPL levels of cafeteria noise were introduced. This objective test was then compared to a behavioral test, a pure-tone audiometric screening, in order to
discover if objective measures were also effective in detecting the presence or absence of a hearing loss. This investigator examined the effect of noise on the pass rate of both TEOAEs and pure-tone audiometry in normal hearing adults and compared the two measures. The specific research question to be addressed was: What is the effect of noise levels on TEOAEs and pure-tone screenings?
CHAPTER III

Methods and Procedures

Participants

Twenty normal hearing adults (2 males and 18 females) ranging in age from 18 to 30 years (mean age of 22.85 years) were recruited from students on the campus of Louisiana Tech University. No compensation was given to the participants, aside from a free hearing screening. To be included in this study each participant had to have clear ear canals, behavioral responses to a pure-tone screening at 20 dB HL for 500, 1000, 2000, and 4000 Hz, pass TEOAE screening in quiet, and report no history of auditory processing or cognitive deficits (Appendix A). Any participant who failed to meet this criteria was referred to the Louisiana Tech University Speech and Hearing Center for a complimentary complete audiological evaluation, and appropriate referral or recommendations as indicated. All procedures were conducted in a sound treated booth in Woodard Hall on the campus of Louisiana Tech University.

Instrumentation

All qualification and experimental testing was conducted in an Industrial Acoustics Company (IAC), Model 30 double-wall, double suite sound treated booth lined with acoustical foam meeting ANSI S12.60-2002 standards (American National Standards Institute, 2002) for ambient noise levels. Each participant received a hearing screening, which included otoscopy, audiometric pure-tone screening in quiet, and TEOAE screening in quiet. Otoscopy was performed using a Welch-Allen otoscope, and
if ear canals were clear, TEOAEs were measured using a 2006 Bio-logic Systems Corp. AuDXPro OAE Screener (SN06L8497A), and pure-tone screening was performed with supra-aural headphones (TDH-39) using a Grason Stadler Model GSI-17 portable audiometer (SNAR079374). Professional recorded cafeteria noise from Auditec of St. Louis was presented through the Tascam CD-160 CD player (SN0231289) and routed through the GSI-61 diagnostic audiometer (SN53200082329) which undergoes annual electroacoustical and daily biological checks. Noise levels were verified in dB SPL using a Quest Electronics sound level meter (SLM) Model 1700 (SNHT6040004).

**Experimental Test Procedures**

**Pre-experimental Procedures**

The IAC booth door was sealed during the measurements to eliminate environmental noise. Prior to the initiation of the study, professional recorded cafeteria noise from Auditec of St. Louis was routed through the GSI-61 diagnostic audiometer and presented through the left loudspeaker (see Figure 1 for Diagram of Loudspeaker Array) which was located in position A. The Quest Electronics SLM was held approximately 3 feet from the loudspeaker at 0 degrees azimuth at the approximate height of the participant's head located at Position C on the diagram. The sound level meter was set on slow response A-scale weighting. The cafeteria noise was measured with a sound level meter at different levels to determine what hearing levels were needed to achieve 40, 50, and 60 dB SPL (Hollowell, 2012). The measurements revealed the following conversions: 40 dB SPL (25 dB HL), 50 dB SPL (35 dB HL), and 60 dB SPL (45 dB HL).
Figure 1. Diagram of Loudspeaker Array.

**Qualification Procedures**

Prior to the initiation of this study, the Institutional Review Board at Louisiana Tech University (Appendix B) approved this project. Each participant completed a questionnaire (Appendix A) regarding the status of current hearing, auditory processing ability, and cognition to rule out possible contraindication that might contaminate the experimental portion of the study. In addition, each participant (i) received a verbal description of the study, including the general purpose, nature of participation, and potential risks and benefits, and (ii) a written consent form was read and signed by the individual wishing to participate (Appendix C).

Immediately prior to qualification procedures, the Human Subjects Permission Form (Appendix C) was read by the participant, any questions answered, and the permission form signed. Next, the questionnaire was completed (Appendix A), and the participant was escorted into the sound treated booth and screened. If inclusion criteria were met, then experimental procedures were administered. The audiometric screening
occurred in the sound treated booth and stimuli were delivered through supra-aural headphones (TDH-39) using a Grason Stadler Model GSI-17 portable audiometer. Because portable audiometers are used in school hearing screenings, a portable audiometer was used in this study instead of a diagnostic audiometer. The 1997 ASHA recommended protocol for screening school-aged children was used in this study; however, 500 Hz was added to the protocol (20 dB HL at 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz). Testing began with the right ear, followed by the left ear. The 500 Hz tone was added in order to increase detection of temporarily impaired hearing caused by otitis media with effusion. A pass for the TEOAE screening was determined if a response was detected 2 out of 3 times at a center frequency between 1286 to 3536 Hz with a wave reproducibility of 70% and a SNR of at least 6 dB (ASHA, 2004). A refer for the TEOAE screening was designated for a SNR ratio of 5 dB or less (Bio-logic Systems Corp, 2006). Order of administration of pure-tone and TEOAE screenings was counterbalanced; for example, if one participant received the pure-tone screening first, the next participant was administered the TEOAE screening first, followed by the pure-tone screening.

Participants were seated in a sound treated booth (Position C, see Figure 1) facing the right loudspeaker (Position B, see Figure 1), and 3 feet from the left loudspeaker (see Figure 1 for Diagram) located at 180° azimuth (behind the participant in Position A), and remained seated in that position for the duration of testing. Pure-tone audiometric screening and TEOAE screening were assessed in quiet. Pure-tone testing via supra-aural headphones was administered and the participants were given the following instructions:
Raise your hand every time you hear the tone, or even if you think you hear the tone.

Each participant’s performance was assessed as a “pass” or “refer” for each ear. For pure-tone screening, a “pass” was determined if a response was received at 20 dB HL at all frequencies tested (i.e., 500, 1000, 2000, and 4000 Hz). A “refer” for pure-tone screening was provided if a response was not observed at any of the frequencies at 20 dB HL for either ear and documented on the Questionnaire and Screening Forms (see Appendix A).

The participants were assessed with a TEOAE screening in quiet with a Bio-logic AuDXPro OAE Screener (Bio-logic Systems Corp, 2006). The following instructions were provided to the participants for the TEOAE screening:

You will hear some soft clicks in your ear. You do not need to respond. remain still and quiet while the test is in progress. I will tell you when it is over.

The clinician printed TEOAE data for each ear immediately after the response was detected for that ear and placed on the Questionnaire and Screening Forms (see Appendix A). Total screening time took approximately 10 minutes. Participants not meeting the qualification criteria were dismissed from the study and referred to the Louisiana Tech University Speech and Hearing Center. In order to be included in the study, the participant received a “pass” for both pure-tone audiometric testing and TEOAE screening for both the left ear and right ear in quiet. If only one ear received a “refer” for any screening procedure, that participant was then excluded from the study and appropriate referrals made.
Experimental Testing

If the participant passed both screening measures in quiet, the participant remained seated in the same position for the duration of testing and different levels of cafeteria noise were added (i.e., 40 dB SPL, 50 dB SPL, and 60 dB SPL) via the GSI 61 audiometer routed through the Tascam CD-160 CD player. The noise signal was presented at 40 dB SPL (i.e., GSI-61 audiometer adjusted to 25 dB HL) from the back loudspeaker (located directly behind the participant in Position A-see Figure 1) while the participant received the pure-tone screening via supra-aural headphones on a portable audiometer, followed by a TEOAE screening in that noise condition (or vice versa for counter balancing). The following instructions were provided for pure-tone testing:

*Raise your hand every time you hear the tone, or even if you think you hear the tone.*

The participant was rescreened at 20 dB HL with pure-tone audimetry via supra-aural headphones for both ears while 40 dB SPL of cafeteria noise was produced through the back loudspeaker. Immediately following pure-tone screening in that noise condition, the TEOAE screening was conducted in the presence of 40 dB SPL of cafeteria noise. In each noise condition, results were recorded on the corresponding Questionnaire and Screening Forms (see Appendix A). The following instructions were again provided to the participants for the TEOAE screening:

*You will hear some clicks in your ear. You do not have to respond. Please remain still for this test.*

Transient-evoked otoacoustic emissions were measured if a response was present 2 out of 3 times at the frequency bandwidth of 1286 to 3536 Hz. The above procedures were
repeated for 50 dB SPL (i.e., 35 dB HL) and 60 dB SPL (i.e., 45 dB HL) of noise. Each participant’s performance was assessed as a “pass” or “refer” for each ear. For pure-tone screening, a “pass” was determined if a response was received at 20 dB HL at all frequencies tested (i.e., 500, 1000, 2000, and 4000 Hz). A “refer” for pure-tone screening was provided if a response was not seen at any of the frequencies at an intensity of 20 dB HL. A “pass” for TEOAE testing was automatically designated by the portable screener when an SNR of 6 dB was reached. If an SNR of 6 dB was not reached, a “refer” was assigned for that ear. Both the TEOAE and pure-tone screening procedures were considered standard audiological procedures and did not deviate from routine clinical practice, with the exception of the addition of cafeteria noise. It should be noted that all experimental testing was done at levels no louder than normal conversational speech levels. This procedure took approximately 20 minutes. Therefore, total testing time took approximately 30 minutes.
CHAPTER IV

Results

As mentioned previously, the goal of the present study was to examine the effect of noise on the pass rate of both TEOAEs and pure-tone audiometry screenings in normal hearing adults. The specific research question addressed was: What is the effect of noise levels on TEOAEs and pure-tone audiometry screening?

For statistical analysis, paired $t$ tests were performed to evaluate the TEOAE noise floors for the right and left ear, while a repeated measures analysis of variance (RM-ANOVA) was performed to evaluate TEOAE amplitude and reproducibility for both ears. Bonferroni corrections were used to make adjustments for multiple comparisons for both $t$ tests and RM-ANOVAs.

TEOAE Descriptive Data

The results of the pass rate for the right and left ear TEOAE screenings are shown in Figure 2; as the cafeteria noise level was increased, the TEOAE pass rate began to decrease. Transient-evoked OAEs were recorded if a response was present 2 out of 3 times at the frequency bandwidth of 1286 to 3536 Hz. In the TEOAE screening, a “pass” was automatically selected by the portable screener when an SNR of 6 dB was reached. If an SNR of 6 dB was not reached, than a “refer” was assigned for that ear. The TEOAE screening was performed in quiet and at 40 dB SPL, 50 dB SPL, and 60 dB SPL of cafeteria noise. Each participant’s performance was assessed as a “pass” or “refer” for
each ear. As seen in Figure 2, the greatest decrease in pass rate was seen in the 60 dB SPL noise level.

![Bar graph showing pass rates for TEOAE screening in various noise levels.](image)

**Figure 2.** Total number of participants who passed the TEOAE screening for the right and left ear in the different levels of cafeteria noise.

**Pure-tone Descriptive Data Analysis**

Another research objective of the current study was to establish the intensity level of background noise that began to affect pure-tone results in normal hearing adults. Pure-tone screening measures were performed for each participant at 20 dB HL at 500, 1000, 2000, and 4000 Hz. A “pass” was determined if the participant responded at 20 dB HL for all frequencies tested at that ear. Pure-tone screening measures were performed in quiet and in various noise levels (i.e., 40, 50, and 60 dB SPL). The results for the pure-tone screening pass rates are shown below in Figure 3. As the cafeteria noise level increased in intensity, the pass rate for pure-tone screenings decreased for both ears. At 50 dB SPL, 18 participants passed the right ear screening, while only 13 participants
passed for the left ear. At 60 dB SPL of cafeteria noise, only 5 participants passed for the right ear and 4 participants passed the pure-tone screening for the left ear.

![Bar chart](image)

**Cafeteria Noise Level**

*Figure 3.* Participant pass rate for the pure-tone screening in different levels of cafeteria noise for the right and left ear.

**TEOAE Versus Pure-tone Screening Pass Rates**

Also compared in the present research project was the pass rate of the TEOAE screening versus the pure-tone audiometry screening. The TEOAE measures were not affected until the cafeteria noise level reached 50 dB SPL with 90% passing the TEOAE screening and 60% passing the pure-tone screening in the same level. As shown in Figure 4, 70% of participants passed the TEOAE screening in the 60 dB noise level, while only 15% participants passed the pure-tone screening in the same 60 dB SPL noise environment. In the present study, the TEOAE screenings appear to be more resistant to cafeteria noise, overall, than the pure-tone screening behavioral measure when cafeteria noise was presented at 60 dB SPL.
Figure 4. Total number of participants who passed the TEOAE screening and pure-tone screening in the different levels of background noise.

TEOAE Inferential Data Analysis

One measure of the TEOAE screening used the noise floors (TE-NF) for both ears. The analysis of the TE-NF data is the recordable difference between the TEOAE (TE) and the noise floor (NF) of the response. This measure was examined in order to determine the effect of noise on the TEOAE response. The means and standard deviations of the OAE noise floors for the right and left ear are reported in Tables 1 and 2.
Table 1  
**Mean of RE OAE Noise Floors**

<table>
<thead>
<tr>
<th>Noise Level</th>
<th>M (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quiet</td>
<td>11.35 (3.453)</td>
</tr>
<tr>
<td>40 dB</td>
<td>11.80 (4.467)</td>
</tr>
<tr>
<td>50 dB</td>
<td>11.15 (5.254)</td>
</tr>
<tr>
<td>60 dB</td>
<td>8.60 (4.210)</td>
</tr>
</tbody>
</table>

Table 2  
**Mean of LE OAE Noise Floors**

<table>
<thead>
<tr>
<th>Noise Level</th>
<th>M (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quiet</td>
<td>10.65 (3.646)</td>
</tr>
<tr>
<td>40 dB</td>
<td>11.40 (4.235)</td>
</tr>
<tr>
<td>50 dB</td>
<td>10.80 (3.861)</td>
</tr>
<tr>
<td>60 dB</td>
<td>8.65 (3.937)</td>
</tr>
</tbody>
</table>

A paired *t* test was used to compare the TEOAE (TE-NF) in the different levels of noise for each ear. Because of the risk of a type I error, a Bonferroni correction of .008 was used (.05 divided by 6 = .008, where 6 is the number of *t* test used). A significant difference was identified on the paired *t* test for the right ear for the quiet to 60 dB SPL level, *t*(19) = 3.406, *p* = .003 and for the 40 dB SPL to 60 dB SPL level, *t*(19) = 3.397, *p* = .003 (see Table 3). This suggests that as noise increased the TEOAE response decreased for the right ear.

As shown in Figure 2, participants had present TEOAEs in all levels for the left ear except when the noise level was increased to 60 dB SPL (i.e., the loudest noise setting for the present study). Paired *t* test for the TE-NF for the left ear were found to be significant for the 40 dB SPL to 60 dB SPL level, *t*(19) = 2.961, *p* = .008 and the 50 dB SPL to 60 dB SPL noise levels, *t*(19) = 3.486, *p* = .002 (see Table 4), also suggesting that as the noise increased, the TEOAE response began to decrease for the left ear.
In addition, the amplitude and reproducibility of the TEOAEs were analyzed using a one-way RM-ANOVA with the levels of noise serving as the within subjects factor. Both amplitude and reproducibility serve as stable, reliable measures of the presence of an OAE, and these measures have been used in previous studies (Konopka et
al., 2001; Smith et al., 2001). When comparing the different noise levels to each other, the amplitudes were not found to be significantly different for the right ear, $F(1.05, 19.95) = .838, p = .376$, Partial $\eta^2 = .042$, or for the left ear, $F(1.952, 37.087) = .300, p = .737$, Partial $\eta^2 = .016$. This suggested that participants had similar TEOAE amplitudes in all noise levels.

When analyzing the reproducibility of the right ear, results were found to be approaching significance, $F(1.738, 33.028) = 3.198, p = .060$. Partial $\eta^2 = .144$. Therefore, an RM-ANOVA pairwise comparison was used to identify if any of the noise levels were significantly different for reproducibility. A significant difference for reproducibility was found for the quiet to 60 dB level ($p = .038$); however, no other levels were found to be significant (see Table 5). The reproducibility for the left ear TEOAE was found to be significant, $F(1.756, 33.368) = 8.170, p = .002$. Partial $\eta^2 = .301$. Specifically, RM-ANOVA pairwise comparison identified the 40 to 60 dB noise levels ($p = .015$) and the 50 to 60 dB noise levels ($p = .015$) to be significantly different (see Table 6). This indicates that reproducibility of the left ear decreased as the noise levels increased.
Table 5  
*Significance of RE OAE Reproducibility*  
<table>
<thead>
<tr>
<th>Noise Level</th>
<th>Significance</th>
</tr>
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<tbody>
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<td>Quiet - 40 dB</td>
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<tr>
<td>Quiet - 60 dB</td>
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<tr>
<td>40 - 50 dB</td>
<td>1.000</td>
</tr>
<tr>
<td>40 - 60 dB</td>
<td>.109</td>
</tr>
<tr>
<td>50 - 60 dB</td>
<td>1.000</td>
</tr>
</tbody>
</table>

*Significance: \( p < .05 \) with Bonferroni correction.

Table 6  
*Significance of LE OAE Reproducibility*  
<table>
<thead>
<tr>
<th>Noise Level</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
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<td>Quiet - 40 dB</td>
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<td>1.000</td>
</tr>
<tr>
<td>40 - 60 dB</td>
<td>.015*</td>
</tr>
<tr>
<td>50 - 60 dB</td>
<td>.015*</td>
</tr>
</tbody>
</table>

*Significance: \( p < .05 \) with Bonferroni correction.
Purpose

To identify hearing impairment in young children, screenings are conducted in schools using pure-tone screenings with portable audiometers. However, difficulties arise due to the subjective nature of behavioral tests. Pure-tone audiometric screening is a subjective test which requires the patient to respond in a time-locked and consistent way; however, this may be difficult for very young children for a variety of reasons. Problems with pure-tone screening include: 1) poor performance in background noise, 2) poor performance identifying effusion because of the interaction between ambient background noise and low frequencies, and 3) communication barriers or difficulty understanding instructions.

A TEOAE screening measure is an objective measure requiring no behavioral response from the patient other than remaining quiet and still for the duration of testing. In circumstances in which a child is unable to perform a behavioral test due to developmental delay, poor attention, or a young age, the TEOAE measure is an effective screening method that can quickly and easily be performed to screen auditory function. The ASHA guidelines (1997) continue to recommend pure-tone audiometric screening as a primary screening method in school screenings, even though research has shown the validity and clinical usefulness of TEOAEs as an objective screening method (Yang et
al., 2002; Yin et al., 2009). The ASHA guidelines (1997) recommended additional research to be conducted on the usefulness of these measures in school screenings. In the 16 years since the ASHA guidelines were written, the research has shown OAEs to be a reliable screening tool with the present study supporting the body of evidence.

The purpose of the present study was to examine the effect of background noise on both an objective measure (i.e., TEOAEs) and a subjective measure (i.e., pure-tone screening) in the screening of normal hearing adults when different SPL levels of cafeteria noise were introduced. Objective test (i.e., TEOAE) results were then compared to behavioral test (i.e., pure-tone audiometric screening) results, in order to discover if objective measures are as effective in detecting the presence or absence of a hearing loss. This investigator examined the effect of noise on the pass rate of both TEOAEs and pure-tone audiometric screening in normal-hearing adults and then compare the two measures. The specific research question addressed was: What is the effect of noise levels on TEOAEs and pure-tone screenings? Adults were used first to determine if a stable protocol could be designed. The present study also used an ideal setting (i.e., sound-treated booth) to control extraneous variables.

In 50 dB SPL of noise, a total of 18 out of 20 participants passed the TEOAE screening in the right ear and 20 out of 20 passed in the left ear. On the other hand, only 18 passed the pure-tone screening for the right ear and 13 passed the left ear in the same condition (50 dB SPL). In the loudest noise level (i.e., 60 dB SPL), 17 participants passed the TEOAE screenings for the right ear, and 17 passed the left ear TEOAE screening. In the same noise level (i.e., 60 dB SPL), only 5 out of 20 participants passed
the pure-tone screening for the right ear and 4 out of 20 participants passed the pure-tone screening for the left ear.

This investigator found that overall participants received a pass in cafeteria noise for the TEOAE screening until the noise was increased to louder levels of 50 and 60 dB SPL. Taken as a whole, pure-tone screening for both ears resulted in a pass for the quiet conditions and in the 40 dB SPL noise condition; however, participants began to fail the pure-tone screening once 50 dB SPL of noise was introduced. The manufacturer’s TEOAE transducer supplied with the screener and used in the present study was an insert, which provides some degree of attenuation and may have allowed for more attenuation of noise compared to the headphones on the audiometer.

Amplitude and reproducibility of the TEOAEs were also analyzed as a constant, dependable measure of the presence of an OAE response. The amplitude was not found to be significantly different for the right or left ear, suggesting participants had similar TEOAE amplitudes in all noise levels. A significant difference for the right ear TEOAE reproducibility was found for the quiet to 60 dB level, but no other noise level was found to be significant. The reproducibility for the left ear TEOAE was found to be significant at the 40 to 60 dB noise levels and the 50 to 60 dB noise conditions. This indicates that reproducibility of the left ear decreased as the noise levels increased.

Passing TEOAE results was an unexpected finding in the louder noise levels (i.e., 60 dB SPL) due to the increased noise floor. From the previous research of Smith et al. (2001), it was expected that higher levels of noise would cause the TEOAEs to be decreased in amplitude and to receive a “refer” for the louder noise conditions. However, the majority of the participants received a pass for TEOAE screenings in quiet, 40 dB
SPL, 50 dB SPL, and 60 dB SPL. This could be partially due to the type of transducer used in the study; insert transducers have greater attenuation than headphones, therefore increasing the pass rate of TEOAEs. Conversely, pure-tone audiometric screening resulted in more “refer” responses as the cafeteria noise was increased.

In 2012, Hollowell examined the effect of background noise on hearing screenings and DPOAEs. The study examined the effect of cafeteria noise (40, 50, 60 dB SPL) on twenty adults with normal hearing while the participants underwent both a pure-tone and DPOAE screening. The investigator found that the participants passed DPOAE screenings in all levels of cafeteria noise until 60 dB SPL with only two adults failing the DPOAE screening in this noise condition. When the noise was increased to 60 dB SPL, only six participants passed the pure-tone screening. Overall, the investigator found that the pure-tone screenings were less resistant to background noise than DPOAE screenings. In comparison to the present study, DPOAEs appear to be more resistant to noise than TEOAEs due to the higher DPOAE pass rate found by Hollowell.

Hand-held devices such as TEOAEs have been shown to be as reliable as pure-tone screenings, and are also effectively used on a routine basis in clinic as well as in newborn hearing screenings. Behavioral measures such as pure-tone screenings suffer from limitations such as inconsistent responses in the presence of background noise and an inability to accurately identify effusion. In some instances, pure-tone audiometric screenings may not be as reliable as OAEs. Audiometry is a subjective measure requiring a truthful and willing response from the child, while the objective OAE measure requires no participation from the child other than remaining still and quiet.
Some young children may not be accurate responders for any number of different reasons, such as developmental delays or poor attention.

**Future Research**

Based on the findings from this study, future investigation should include school-aged children tested in a sound-treated booth in comparing the effect of background noise levels on the pass rate of TEOAEs and pure-tone audiometric screenings. Future research should include screenings in the school settings, as well as an evaluative process at the conclusion of the screening to determine if the screening(s) were accurate. In addition, a larger pool of participants should also be tested.

**Summary**

When compared to pure-tone screening methods, TEOAEs were more accurate and received a “pass” result, even when various levels of noise were present during the testing. In the current study, the objective measures of TEOAE screenings were seen to be more resistant to cafeteria noise than the pure-tone audiometry screening measures when cafeteria noise was increased to 60 dB SPL.

Objective measures such as TEOAEs have many advantages over behavioral measures (i.e., pure-tone audiometric screening). For example, an objective TEOAE measure requires no interpretation from the tester during the screening (i.e., results shown as “pass” or “refer”) and does not rely on the listener to understand the instructions. In addition, the objective TEOAE is quicker than the administration of a pure-tone screening. An objective measure using an insert or probe is also more resistant to noise than a behavioral measure using standard headphones. As can be seen from the present study, as well as from previous research, objective screening measures are found to be
reliable, or even more reliable, than behavioral screening measures in determining auditory status when used outside the confines of a sound-treated booth.
APPENDIX A

Questionnaire and Screening Forms
Participant: ___________________
Date: _______________________

Questionnaire

Instructions: Please answer the following questions.

Is your hearing normal today?

________________________________________________________________________

Have you ever been diagnosed with a processing or cognitive problem?

________________________________________________________________________

Inclusive Screening Measures

Pure-Tone Screening in Quiet

<table>
<thead>
<tr>
<th>20 dB</th>
<th>500 Hz</th>
<th>1000 Hz</th>
<th>2000 Hz</th>
<th>4000 Hz</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Ear</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LE OAE Screening in Quiet

Place OAE printout here.

RE OAE Screening in Quiet

Place OAE printout here.
Participant: ____________________
Date: ________________________

Experimental Screening Measures

<p>| Pure-Tone Screening in 40 dB SPL Noise |</p>
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<th>1000 Hz</th>
<th>2000 Hz</th>
<th>4000 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Ear</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Left Ear</td>
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</table>

<table>
<thead>
<tr>
<th>LE OAE Screening in 40 dB SPL</th>
<th>RE OAE Screening in 40 dB SPL</th>
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</thead>
<tbody>
<tr>
<td>Place OAE printout here.</td>
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</tr>
</tbody>
</table>

<p>| Pure-Tone Screening in 50 dB SPL Noise |</p>
<table>
<thead>
<tr>
<th>20 dB</th>
<th>500 Hz</th>
<th>1000 Hz</th>
<th>2000 Hz</th>
<th>4000 Hz</th>
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<tbody>
<tr>
<td>Right Ear</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Left Ear</td>
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</table>

<table>
<thead>
<tr>
<th>LE OAE Screening in 50 dB SPL</th>
<th>RE OAE Screening in 50 dB SPL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Place OAE printout here.</td>
<td>Place OAE printout here.</td>
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</tbody>
</table>
Participant: __________________
Date: __________________

### Pure-Tone Screening in 60 dB SPL Noise

<table>
<thead>
<tr>
<th></th>
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<th>500 Hz</th>
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<th>4000 Hz</th>
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<tr>
<td>Right Ear</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Left Ear</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### LE OAE Screening in 60 dB SPL

Place OAE printout here.

### RE OAE Screening in 60 dB SPL

Place OAE printout here.
APPENDIX B

Approval Memo for HUC
TO: Ms. Laura Wade and Dr. Sheryl Shoemaker
FROM: Barbara Talbot, University Research
SUBJECT: HUMAN USE COMMITTEE REVIEW
DATE: June 1, 2012

In order to facilitate your project, an EXPEDITED REVIEW has been done for your proposed study entitled:

"Effect of Noise of Transient-Evoked Otoacoustic Emissions and Pure-tone Screening Audiometry"

HUC 977

The proposed study's revised procedures were found to provide reasonable and adequate safeguards against possible risks involving human subjects. The information to be collected may be personal in nature or implication. Therefore, diligent care needs to be taken to protect the privacy of the participants and to assure that the data are kept confidential. Informed consent is a critical part of the research process. The subjects must be informed that their participation is voluntary. It is important that consent materials be presented in a language understandable to every participant. If you have participants in your study whose first language is not English, be sure that informed consent materials are adequately explained or translated. Since your reviewed project appears to do no damage to the participants, the Human Use Committee grants approval of the involvement of human subjects as outlined.

Projects should be renewed annually. This approval was finalized on June 1, 2012 and this project will need to receive a continuation review by the IRB if the project, including data analysis, continues beyond June 1, 2013. Any discrepancies in procedure or changes that have been made including approved changes should be noted in the review application. Projects involving NIH funds require annual education training to be documented. For more information regarding this, contact the Office of University Research.

You are requested to maintain written records of your procedures, data collected, and subjects involved. These records will need to be available upon request during the conduct of the study and retained by the university for three years after the conclusion of the study. If changes occur in recruiting of subjects, informed consent process or in your research protocol, or if unanticipated problems should arise it is the Researchers responsibility to notify the Office of Research or IRB in writing. The project should be discontinued until modifications can be reviewed and approved.

If you have any questions, please contact Dr. Mary Livingston at 257-4315.
HUMAN SUBJECTS CONSENT FORM
Experimental Group/Control Group A

The following is a brief summary of the project in which you have been asked to participate. Please read this information before signing below:

TITLE:
Effect of Noise on Transient-Evoked Otoacoustic Emissions and Pure-tone Screening Audiometry

PURPOSE OF STUDY/PROJECT:
To observe the effects of various levels of background noise on transient evoked otoacoustic emissions (TEOAEs) and pure-tone screening audiometry in young normal hearing adults.

PROCEDURE: Prior to inclusion in this study, each participant will be asked to complete a questionnaire to ensure that no known cognitive, auditory processing, or permanent hearing loss are present. Each participant must then pass an otoscopic examination, tympanometry, standard pure tone screening, and transient-evoked otoacoustic emission screening in quiet conditions in order to be included in this study. Cafeteria noise will then be transmitted to the sound booth via a loudspeaker at 40 dB SPL, 50 dB SPL, and 60 dB SPL, and in each noise condition, the participant will receive a standard pure-tone screening on a portable audiometer and a transient-evoked otoacoustic emissions screener.

INSTRUMENTS: The subject's identity will not be used in any form in the analysis or representation of the data. Only numerical data such as percent correct will be used in the presentation of the results.

RISKS/ALTERNATIVE TREATMENTS: There are no known risks to subjects. These procedures do not vary from routine audiometric measures. Participation is voluntary with written consent. The participant understands that Louisiana Tech is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.

BENEFITS/COMPENSATION: None.

I, __________________________________________________, attest with my signature that I have read and understood the following description of the study, “Effect of Noise on Transient-Evoked Otoacoustic Emissions and Pure-tone Screening Audiometry”, and its purposes and methods. I understand that my participation in this research is strictly voluntary and my participation or refusal to participate in this study will not affect my relationship with Louisiana Tech University or the Louisiana Tech University Speech and Hearing Center. Upon completion of the study, I understand that the results will be freely available to me upon request. I understand that the results will be confidential, accessible only to the project director, principal experimenters, myself, or a legally appointed representative. I
have not been requested to waive nor do I waive any of my rights related to participating in this study.
I hereby give my permission for, _________________________________, to participate in the above mentioned study.

_____________________________  ____________________________
Signature of Participant      Date

CONTACT INFORMATION: The principal experimenter listed below may be reached to answer questions about the research, subject's rights, or related matters.

Laura A. Wade, M.A.          Louisiana Tech University (318) 245-1026
Sheryl S. Shoemaker, Ph.D., Au.D. Department of Speech (318) 257-4764

Members of the Human Use Committee of Louisiana Tech University may also be contacted if a problem cannot be discussed with the experimenters:
    Dr. Les Guice (257-3056);    Dr. Mary Livingston (257-2292 or 257-4315)
References


