EFFECTS OF EARPLUG MATERIAL, INSERTION DEPTH, AND MEASUREMENT TECHNIQUE ON HEARING OCCLUSION EFFECT

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ABSTRACT

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Occlusion effects result from amplification of low frequency components of body-transmitted sound when the ear canal is occluded with hearing protection devices, hearing aids, or other canal-sealing inserts. Since the occlusion effect will enhance the hearing of bodily-generated sounds and result in distorted perception of one’s own voice, many people report annoyance with hearing aids and hearing protectors that produce occlusion effects. Previous research has studied the effects of ear device insertion depth and influence of the location of the bone vibrator, which has typically been used as the excitation stimulus. However, the effects of monaural vs. binaural, ear device material, and different excitation stimuli were not investigated.

In this research study, the effect of left/right ear canal on the occlusion effect, which was measured objectively as the sound pressure level difference in dB, was investigated. Also, an experiment to determine the effect of earplug types (differing in material and design), insertion depth, and excitation sources was conducted. Lastly, the noise attenuation capability of medical balloon-based earplugs was tested.

Ten subjects, six male and four female, volunteered for the three separate experiments. They were subjected to the three earplug types (foam earplugs, premolded flanged earplugs, and medical balloon-based earplugs), two earplug insertion depth levels of shallow and deep (only feasible with the foam earplug and the balloon-based earplug), and two levels of excitation
sources, one of which was a forehead-mounted bone vibrator and the other a self vocal utterance of “EE” to 65 decibels A-weighted (dBA). The attenuation capability of the medical balloon-based earplugs were tested via monaural Real-Ear-Attenuation-at-Threshold (REAT) test per ANSI S3.19-1974 and compared to that of a Peltor H10A earmuff.

Experimental results of the first experiment demonstrated that left right ear canal SPL measurements were not statistically different, and therefore subsequent measurements of occlusion effects for the second experiment were conducted via a monaural left ear measurement protocol. The results of the second experiment confirmed significant effects of insertion depth on the occlusion effect. At the shallow insertion, the occlusion effects, on average, were greater by 11.2 dB(linear) (dBZ) then the deep insertion measured at 500 Hz. The effects of earplug type were mixed. At the shallow insertion, earplug type did not influence the occlusion effect. However, the mean occlusion effect, measured at the 1/3-octave band centered at 500 Hz, of deeply inserted balloon-based earplugs was larger than that of foam earplugs by 3.7 dBZ. Excitation sources that were used as the sound energy stimuli to elicit occlusion effects did not show statistically significant differences. The Noise Reduction Rating (NRR), as calculated per ANSI S3.19-1974, of the medical balloon-based earplug was 10 dB while that of a Peltor H10A earmuff was 24 dB. Although the medical balloon-based earplug did not prove to be a high attenuation-hearing protector, it produced a unique flat attenuation across the frequency spectrum, as compared to the typical increasing-with-frequency attenuation, pointing to its potential utility for applications wherein the pitch perception of sound is important.
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INTRODUCTION

When a person wears a hearing protection device, a hearing aid, or other canal-sealing insert they will sense that their own voice sounds different as well as typically reporting that bodily-generated sounds, including heartbeats and respiration, sound more pronounced. Blocking the ear canal causes amplification of particularly the lower frequency components of body-transmitted sound that reaches the ear canal wall, which causes the person to perceive their own voice as sounding “hollow” or “booming”. This amplification is called the occlusion effect\(^1\). While the occlusion effect does not pose a direct threat to a person’s hearing, it can be an indirect cause of one since people may decide not to use a particular earplug or hearing aid due to its occlusion effect. However, the occlusion effects of hearing aid devices are particularly important. One research study showed that out of 4421 participants, 27% of them reported that occlusion effect (as subjectively measured by the naturalness of own voice) to be problematic (Dillon, Birtles, & Lovegrove, 1999). Thus a comprehensive investigation of the occlusion effect characteristic of earplugs and inserts is needed and probably should be performed during product development effort.

Tonndorf (1966) suggested that open ear canal acts as a high pass filter. Occlusion of the ear canal would then remove the high pass filter effect and result in bone conducted sound whose lower frequency components are amplified. Researchers have found that the occlusion effect is the greatest when the occluding device is placed at the entrance (i.e. aperture) of the ear canal and decreases as the occluding device is moved either inward or outward from the entrance (Berger, 2003; Dean & Martin, 2000; Wright & Angelelli, 1991). Researchers have also found that a vent or tube through the occluding device reduces occlusion effects (Kiessling, Brenner,

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\(^1\) A glossary of many technical terms is provided herein on APPENDIX D.
Jespersen, Groth, & Jensen, 2005; Kuk, Keenan, & Lau, 2005, 2009). These findings have helped in the design of new devices with reduced occlusion effects, although the repositioning of the hearing aids inward from the ear canal entrance sometimes reduced user comfort and the introduction of vents often introduced a feedback issue that the amplified sound from the receiver speaker leaks through the vent and gets amplified again by the hearing aid when the external microphone transducers it.

Ideally, hearing protection devices and hearing aids should be designed in a way that decreases occlusion effects without introducing other negative effects such as reduced comfort or feedback issues. Earplugs currently on the market are generally made of foam or polymer. Researchers have proposed a new earplug design that uses medical balloons that are inserted into the ear canal and inflated. A preliminary experiment performed by Dr. Casali, Dr. Keady, and the author indicated that the new design could possibly lower occlusion effects compared to the conventional foam earplugs without sacrificing comfort.

The research objectives of this dissertation were: 1) to compare different objective measurement protocols (1 vs. 2 ears) to measure the occlusion effect of various insert earplugs, 2) to investigate the effect of balloon air pressure and insertion depth of the balloon earplug on the occlusion effect, and 3) to evaluate the noise attenuation capability of the balloon earplug. To accomplish the first objective, an experiment with the objective measurement protocols as the independent variable (IV) and the objectively measured occlusion effect as the dependent variable (DV) was performed. To accomplish the second objective, an experiment with IVs that are consist of earplug type, insertion depth, and excitation source and DVs that are objective and subjective measurement of the occlusion effect were performed. Real Ear Attenuation Threshold (REAT) tests were performed to accomplish the third objective.
It was expected that hearing protection device and hearing aid design engineers will be able to use the results of this study to design products that will minimize occlusion effects, provide better comfort for the user, and increase user acceptance.
The Human Ear: Basic Anatomical Features and Acoustics

Humans can hear sounds in the dynamic amplitude sensitivity range of almost 0 to 120 dB and in the frequency sensitivity bandwidth of approximately 20 to 20,000 Hz (Rossing, Moore, & Wheeler, 2002). Human audition is similar to the sense of touch in that it is always “on.” In order for a person to hear a sound, the energy in the transmission medium must first be transformed into an electrical signal that can be processed by the brain. The human ear is the organ that does this transformation. Figure shows the structure of the human ear, which can be divided into three sections based on structure and function: the outer ear, the middle ear and the inner ear. The outer ear modifies airborne acoustic waves. The modified acoustic waves are then converted into a structural bone vibration in the middle ear. The inner ear transforms the vibration into neural impulses, which are transmitted to the brain for processing, resulting in perception of the sound’s parameters (Henderson & Hamernik, 1995).

The outer ear consists of the pinna (or auricle) and ear canal (also called external auditory meatus). The pinna is the outermost part of the ear and is usually referred to by people as “the ear.” Due to its shape, the pinna amplifies certain frequencies of acoustic waves and attenuates others. Since each person has a different pinna shape, each person’s ear transforms sound differently, which can be regarded as an “imprint” on the sound. The external auditory meatus or ear canal performs another important modification. Due to its shape and dimension, sounds in the 3 kHz region resonate and are greatly amplified. The overall modification effect of outer ear is a 10-15 dB amplification of sound in the 2 – 4 kHz region. These alterations are called as the transfer function of the open ear (TFOE) and a graph of measured data (Casali, Mauney, & Burks, 1995) is shown at Figure 2.
The middle ear consists of the tympanic membrane (eardrum), the ossicles, and the Eustachian tube. The eardrum is a thin, elastic membrane that divides the outer and middle ear. It is cone-shaped with the apex pointed inward. It displaces about one hundred millionth of a cm to voiced pressure waves and it transforms air-borne vibration to structural-borne vibration that is conducted through the ossicles. The ossicles are three small bones called the malleus, incus, and stapes. They form a conductive chain that allows the structural-borne wave to transmit, and also provides impedance matching, as follows. When an acoustic wave enters fluid mediums from air, the typical energy loss is about 30 dB. The ossicles provide gains of about 2.5 dB and 23 dB through a “lever action” and “hydraulic jack or piston,” respectively (Rossing et al., 2002). As a result, the middle ear transfers the acoustic wave to the inner ear with only about a 4.5 dB loss from air conduction to fluid conduction.

Another important function of the middle ear is protection of the inner ear from loud continuous and impulse noises. Two muscles connected to the ossicles: the tensor tympani and the tensor stapedius contract and lock the ossicles together, which stiffens the conductive chain resulting in reduced transmission. However, there are several limitations to this reflex. Since it is a muscle contraction, it takes about 30 milliseconds to initiate the contraction and 200 milliseconds to reach maximal contraction. Therefore, the reflex cannot provide adequate protection from impulse noises such as gunshots. Other limitations are that it only attenuates low frequencies below 500 Hz and that fatigue of the muscles occurs.
Figure 1. Chittka L, Brockmann, 2009 Anatomy of the Human Ear (with labeling modifications by the author), retrieved from http://commons.wikimedia.org/wiki/File:Anatomy_of_the_Human_Ear.svg (Permission provided on web page).

Figure 2. Transfer Function of the Open Ear (TFOE) mean and standard deviation values, collapsed across both ears and 10 subjects. Reproduced from (Casali et al., 1995) with permission from the author.
The Eustachian tube connects the middle ear cavity to the outside of a person’s body via the nasal passage. The Eustachian tube is opened when a person swallows or vocalizes, which equalizes air pressure on both sides of the eardrum.

The inner ear, also called the neural ear, consists of the auditory nerve and the cochlea, which is embedded in the temporal bone. The cochlea is a cone-shaped organ that is coiled like a snail and separated into three sections by two membranes: Reissner’s membrane and the basilar membrane. The basilar membrane, the tectorial membrane, inner/outer hair cells, and stereocilia form the Organ of Corti. The vibration of the stapes, connected to the oval window of the cochlea, is transferred to the perilymph fluid in the cochlea. The fluid motion causes displacement of the basilar membrane and in turn causes deflection of the stereocilia that causes the neurons that are connected to hair cells to generate impulses that are sent to the brain for auditory perception (Goldstein, Humphreys, Shiffrar, & Yost, 2005). While the cochlea transforms sound waves into an electrical signal that will travel via auditory nerve to the brain for cognitive processing, it does so for only the “perceptually relevant features of sound” (Nobili, Mammano, & Ashmore, 1998).

The human ear is the sensory organ that enables a person to hear sound. However the ear is not a simple linear transformer that changes sound waves to electrical signals. Rather it is a specialized organ for human communication via speech as well as other functions such as sound localization and balancing.

**The Bone and Body-Conducted Pathways**

There are two pathways through which acoustic waves travel to reach the cochlea where the transformation to electrical signals, which a person can perceive, occurs. The primary
pathway of audition is the air-conducted (AC) pathway where acoustic wave travels through the external ear, the middle ear, and the inner ear as explained in the previous section. The secondary, much less efficient, pathway of audition is the bone-conducted (BC) pathway. In case of the BC pathway, acoustic waves, regardless of their origin, vibrate the bones of the skull to reach the cochlea, where the acoustic waves turn into electric impulses, either directly or through the ear canal and the eardrum. At the cochlea, both air-conducted waves and bone conducted waves are translated as a neural signal (Lowy, 1942). However, when acoustic waves are incident from the surrounding environment (i.e. in air), the large impedance mismatch between the air and the skull makes the effect of BC nearly negligible when compared to that of AC: the BC pathway is 40 dB less effective than the AC pathway in mid to high frequencies and 70 dB less effective in low frequencies (Blauert, Els, & Schroeter, 1980). Although vibrations applied to any point or the surface of the human body can transmit through bone and tissues to create auditory sensation, vibrators placed at body parts other than head are unlikely to result in auditory sensation due to the large transmission loss that occurs when the wave travels through the human body.

The bone-conducted pathway plays an important role in people’s perception of their own voice. The effect of the BC pathway on a person’s perception of their own voice can be noticed when a person listens to playback of a recording of their speech. A recording is the only way in which a person can hear the portion of their voice that is conducted only through the air-conducted pathway. A person’s recorded voice lacks the lower frequency components of their voice that reaches their ear canal through the body conduction pathway, since a person’s body attenuates more at high frequencies. When a person speaks, the ratio of the sound of their voice reaching their cochlea by the AC pathway to that reaching their cochlea via the BC pathway is
about one to one (Bekesy, 1949). This means that a person normally hears their voice through both the AC pathway and BC pathway equally.

**The Physics of Open and Closed Ducts**

A mechanical system resonates when the frequency of its vibration matches its natural frequency. Acoustic resonance is a part of mechanical resonance that the frequency range is within the audible range. Musical instruments utilize acoustic resonances. For example, string instruments such as pianos, guitars, and harps resonate at their fundamental frequencies and also at their harmonic frequencies. Wind instruments such as flutes, clarinets, and so forth contain a tube of air and the air resonates at particular frequencies depending on the length of the tube, the diameter of the tube, and whether one or both ends of the air tube ends are open or closed.

Tubes can be open at both ends, closed at both ends, or open at one end and closed at the other end. The term “open tube” refers to a tube with either both ends open or both ends closed. The term “closed tube” refers to a tube that has only one open end (Kool, Gwozdz, & Rascher, 1987). Since tubes with both ends open and tubes with both ends closed share the same fundamental and harmonic frequencies, both types are referred to as “open tubes.” Figure 3 shows shapes of the first three resonances and their approximate waveforms for tubes that are open at both ends, closed at both ends, and open at one end and closed at the other end.
Figure 3. Fundamental and harmonic frequencies of tubes whose ends are either open or closed and tubes whose ends are open at one end and closed at the other end. (see text for explanation of these).

The columns (a) and (b) in the Figure 3 show that although waveforms differ between the columns, their frequencies are the same. Hence they are referred as “open tubes”. The first resonance occurs when the wavelength is twice the length of the tube. The fundamental resonance frequency can be calculated with following equation (Kinsler, 2000).

\[ f = \frac{n}{2(L + \frac{8}{3\pi}d)} \]

where  
\( n \) is 1,2,3,..., (integer values)  
\( v \) is the speed of sound in air,  
\( L \) is the length of the tube,  
\( d \) is the diameter of the tube,  
and \( f \) is the fundamental resonance frequency with \( n = 1 \).

The resonant frequencies of the “open” tube are all harmonics of the fundamental frequency.

The column (c) of the Figure 3 shows the shapes of the first three resonances and their approximate waveforms for “closed tubes” referring to tubes that are open at one end and closed
at the other end. The “closed tube” model is similar to the unoccluded ear canal that is blocked at one end with the tympanic membrane and open at the other end.

\[ f = \frac{nv}{4(L + 0.4d)} \]

where \( n = 1, 3, 5, \ldots \), (odd integer values)
\( v \) is the speed of sound in air,
\( L \) is the length of the tube,
\( d \) is the diameter of the tube.
and \( f \) is the fundamental resonance frequency with \( n = 1 \).

“\( n \)” is odd positive integers since the resonant frequencies are odd harmonics of the fundamental frequency.

The human ear canal can be treated as a “closed tube” (a tube with only one open end). Using parameters of average human ear canal length of 25 mm (Yost, 1994) and air sound speed of 340 m/sec, the first resonant frequency is 3400 Hz. The second and third frequencies are 10,200 Hz and 17,000 Hz. An occluded ear canal would be similar to an “open tube” with both ends closed. Using equation 1, the first three resonant frequencies are 6,800 Hz, 13,600 Hz, and 20,400 Hz. This demonstrates that when a person blocks their ear canal, they lose amplification in the 3000 Hz region, because the first resonant frequency of the “closed” tube is lost.

**Air Bubble Model**

Kinsler (2000) developed a model that can predict resonance angular frequency of an air bubble in water. Although occluded air volume of an ear canal is not exactly the same with an air bubble in water, the two shares similarity in that both are air volume surrounded by external
medium. Also part of tissues on the ear canal wall contains large amount of water. Of course the occluding devices, i.e. earplugs, might not contain water at all and even human tissues are not 100% water. Moreover, the occluded volume in the ear canal would be shaped more like a cylinder than a sphere. Even with these limitations, the air bubble model was the only alternative model that was found.

The equation is:

$$\omega_0 = \frac{1}{\alpha} \left( \frac{3 \gamma P_b}{\rho_0} \right)^{1/2}$$

where,
- $\omega_0$: resonance angular frequency
- $\alpha$: radius of the sphere
- $\gamma$: ratio of specific heats, 1.004 for water
- $P_b$: equilibrium pressure within the bubble = 101325 kg/m$^3$/s$^2$ (Pa) = 1 atm
- $\rho_0$: density of water = 998 kg/m$^3$

Assuming the air bubble has the same volume as an occluded ear canal, its radius can be calculated. Since an average human ear canal has a length of 25mm and radius of 3mm (Yost, 1994), an air bubble should have equal volume to a cylinder with 12.5mm length and radius of 3mm assuming the ear canal is blocked at the midpoint. This will predict an air bubble with 4.386 mm radius and predicted resonance frequency of 635 Hz. Changing the ear canal radius to 2.5 mm and 3.5 mm yields the resonance frequencies of 717 Hz and 573 Hz. Similarly, if one assumes blocking at near the entrance with resulting ear canal length of 20mm, the resulting resonance frequency will be 613 Hz, 543 Hz, and 490 Hz for radii of 2.5mm, 3.0mm, and 3.5mm respectively. The model predicts that as the volume increases the resonance frequency decreases.

Based on the above approximation, the predicted resonance frequencies for the human ear canal will be in the range from 490 Hz to 717 Hz. The range agrees with the below 1000 Hz
range for significant occlusion effect reported by other researchers (Fagelson & Martin, 1998; Goldstein & Hayes, 1965; Huizing, 1960; Stenfelt & Reinfeldt, 2007; Sweetow & Pirzanski, 2003; Vogel, Zahnert, Hofmann, & Huettenbrink, 1996).

**Occlusion Effect**

In addition to a person’s own voice, there are many self-generated sounds: such as the heartbeat, teeth colliding, and breathing that are produced inside of a person’s body. Some of the body-conducted sound transmitted through the human head reaches the walls of the ear canal and radiates (Stenfelt & Goode, 2005a). Normally, when the ear canal is open, a person does not feel (hear) the radiation since most of the radiation escapes and sound through the air conduction pathway dominates (Stenfelt, Wild, Hato, & Goode, 2003). However, when a person blocks their ear canal, it effectively limits the efficiency of the air-conducted pathway and the bone-conducted pathway dominates. A person with blocked (occluded) ear canals perceives their own voice as sounding “hollow” or “booming” due to amplification of the low frequency component of body-conducted sound. In most individuals, the voice also sounds louder. This amplification is called the occlusion effect.

The magnitude of the occlusion effect is dependent on the insertion depth of the occluding device or the occluded volume, which is the trapped air volume between the occluding device and the tympanum. The magnitude is largest when the entrapped volume is largest, i.e., when the occlusion occurs at the entrance of the ear canal either by earplug, ear canal cap, or supra-aural device such as an audiometer headphone (Berger, 2003; Dean & Martin, 2000). The magnitude decreases as the occluded volume either increases (as with a large earmuff) or decreases (as with a deeply-inserted earplug) from the occluded volume at the biggest occlusion.
effect. The occluded volume can be changed either by inserting the earplug further into ear canal or by placing larger volume ear muffs that cover the entire pinna over the outer ear (Berger, 2003). Figure 4 shows the relationship of the relative occlusion effect and the occluded volume, in schematic form. It shows that the occlusion effect is minimized when the occluded volume is either at its minimum with a deeply-inserted earplug or at its maximum with a big volume earmuff. Also, the occlusion effect reaches its maximum value when the occlusion occurs at or near the entrance of the ear canal, as shown at the center of the schematic.

Figure 4. Relative occlusion effect per occluded volume based on the type and fit of hearing protectors (Berger, 2003). Reproduced with permission of the author, E.H. Berger.

*High-pass filter effect*

Tonndorf (1966) presented a more scientific explanation of the occlusion effect: the open ear canal acts as a high frequency pass filter for bone conducted sound (Tonndorf, 1966). When a person’s ear canal is open, the radiated sound that reached the ear canal wall through bone conduction will face a high-pass filter and most of the low frequency components will be
blocked from conduction to middle ear. Thus, when a person blocks his/her ear canal with an earplug or other devices, they are effectively disabling the high frequency pass filter effect. In turn, this will result in relative amplification of the low frequency components of ear canal wall-radiated sound.

**Measuring Occlusion Effects**

*Objective measurement of occlusion effects*

Objective methods include the physical measurement of sound pressure level in the ear canal via miniature microphones, electrophysiological measurement of slow cortical acoustical evoked potentials, and physical measurement of vibrations in the middle ear via laser vibrometry (Goldstein & Hayes, 1965; Huizing, 1960; Stenfelt & Hakansson, 2002; Stenfelt et al., 2003; Vogel et al., 1996).

A probe-tube microphone with the probe-tube placed near the tympanic membrane can be used to measure sound pressure levels (SPL) in a single open and closed ear canal, with the two measurements occurring sequentially in time under the same sound stimulus. The occlusion effect is the difference of the two SPL measurements. An occlusion meter, model ER-33 by Etymotic Research, employs a similar method. While the probe-tube method employs a single microphone with its probe-tube placed near the tympanic membrane for both SPL measurements, ER-33 employs two microphones for simultaneous measurements. One microphone is connected to a probe-tube that is placed near the tympanic membrane while the second microphone is installed to measure SPL at the outside of the ear. This is different from the previously mentioned method. By using a second microphone outside of the ear canal, the ER-33 achieves convenience while losing accuracy. The lost accuracy is due to the fact that the outer ear
transforms sound hence SPL measurements at the outside of the ear are different from SPL measurements near the tympanic membrane. The ER-33 provides a measurement of transmission noise reduction instead of true insertion loss (Killion, 2004). The fundamental difference in the simultaneous measurements required for noise reduction, as compared to the sequential measurements required for insertion loss are detailed in Casali (2005).

Increased sound pressure level in the ear canal will naturally result in increased vibrations of the conductive chain (ossicles) as well as increased electrical signals from the cochlea; thus, this represents the conductive transmission and neurophysiologic transduction of the occlusion effect beyond its origination in the ear canal. Vogel et al. (1996) were able to measure and document a decrease in latency of slow cortical acoustical evoked potentials, which are electrical signals generated and transmitted from cochlea to brain. The authors called this electrophysiological evidence. Another objective method to measure the occlusion effect is to measure the increased structural vibration of the tympanic membrane or ossicles via laser vibrometry (Vogel et al., 1996).

Subjective measurement of occlusion effects

REAT is a psychometric subjective method that requires self-report by subjects (Casali, 2005). A similar method to determine the occlusion effects is the measurement of bone conduction threshold shift (Goldstein & Hayes, 1965). Bone conduction threshold shift measurements showed positive correlation with SPL difference measurements for 250, 500, and 1000 Hz.

Another psychometric subjective method to determine the occlusion effect is the rating scale technique (Kampe & Wynne, 1996; Kuk et al., 2005). Subjects were given a sentence to
read while their ear canals were unoccluded, and asked to judge the naturalness of their voice. The subjects then read the sentence again with their ear canals occluded and determined the naturalness of their own voice. Researchers typically use various rating scale levels such as 1 to 5 and 1 to 10.

**Review of Prior Research on the Occlusion Effects**

Huizing (1960) in his research of bone conduction measured occlusion effect, used the subjective bone conduction threshold shift method and reported occlusion effects of 11 dB at 125 Hz, 15 dB at 500 Hz and 5 dB at 1000 Hz. The author used pure tones at the three frequencies.

Goldstein & Hayes (1965) measured occlusion effects both objectively and subjectively. They used a Radioear B70 bone vibrator to introduce pure tones on the subjects’ mastoid and forehead. The occlusion effects, determined via bone conduction threshold shift measurements and sound pressure level shift measurements, were significantly different with $\alpha = 1\%$ at 250 Hz, 500 Hz, and 1000 Hz with levels between 5 and 25 dB. The subjective measurements (bone conduction threshold shift) of occlusion effects were smaller in magnitude than that of objective measurement (SPL) of occlusion effect. The position of the bone vibrator did not produce occlusion effects whose difference was statistically significant.

Vogel, et al. (1996) researched different methods to measure occlusion effects: slow cortical acoustical evoked potentials, the use of laser vibrometry on the round window and stapes, probe tube microphone in the ear canal, and hydrophone in the inner ear liquid to measure occlusion effect. The authors used cadaver heads. They reported occlusion effects of more than 15 dB at frequencies lower than 2000 Hz. Measurements through laser vibrometry and
hydrophones, as well as the measurement of the slow cortical acoustical evoked potentials, all indicated occlusion effects.

Fagelson & Martin (1998) compared occlusion effects measured both objectively and subjectively. The authors used a Radioear bone conduction vibrator (model #B-71) placed at the mastoid process and the frontal bone to present the stimuli at three frequencies: 250, 500, and 1000 Hz. For the subjective method, the authors used a measure of bone conduction threshold shift. They reported subjective occlusion effects of 19 to 25 dB at 250 Hz, 16 dB at 500 Hz and 5 to 7 dB at 1000 Hz. For the objective method, they used a probe tube microphone placed in the ear canal at or beyond the osseocartilaginous junction to measure the SPL differences. The objective occlusion effects were 18 to 22 dB at 250 Hz, 16 to 18 dB at 500 Hz and 6 to 9 dB at 1000 Hz.

Sweetow & Pirzanski (2003) in their research about occlusion effect and ampclusion effect (Painton, 1993) asked subjects to vocalize “EE” during which they measured the SPL difference at the ear canal and reported occlusion effects of 22~25 dB at the frequency range between 125 Hz and 500 Hz. The authors coined the term “ampclusion” which refers to the possible altered perception of own voice by a hearing aid user due to addition of the occlusion effect and amplification of air-conducted own voice by hearing aid.

Kuk, F., Keenan, D., & Lau, C. C. (2005) investigated how vent diameters affect objective and subjective occlusion effects. For the objective measurements, subjects were asked to vocalize /i/ while the researchers measured the SPL inside the ear canal. Objective occlusion effects were averaged to be 17 dB at 258 Hz without any vent. The value decreased to about 5 dB with 3 mm diameter vents. For subjective occlusion effect measurements, the subjects were asked to repeat the phrase “Baby Jeanny is teeny tiny” and rate their own voice quality while
wearing hearing aids with and without vents of varying diameters on the scale of 1 to 10, with “10” being natural voice quality. The subjective ratings of certain participants increased as vent diameter increased while other participants reported either constant or even degradation of own voice quality. The authors reported that, through post hoc Wilcoxon Signed Rank test, only the subjective ratings at 0 mm vent condition were statistically different from that of other vent conditions.

Stenfelt and his colleagues conducted extensive researches about bone conduction and the occlusion effect (Stenfelt, 2007; Stenfelt & Goode, 2005a, 2005b; Stenfelt & Hakansson, 2002; Stenfelt, Hato, & Goode, 2002; Stenfelt & Reinfeldt, 2007; Stenfelt et al., 2003; Stenfelt & Hakansson, 1999). Stenfelt, Wild, Hato, & Goode (2003) researched the effect of outer ear on the bone conduction. By measuring sound pressure level in the ear canal of five cadaver heads, they found that the SPL in the ear canal was decreased by 5-15 dB when the cartilage part and soft tissues of the ear canal were removed. The measured occlusion effects were about 10 dB below 400Hz, and about 20 dB at 500-800 Hz. Also, they found that bone conduction compared to air conduction has only minimal effect in an open ear, while hearing is dominated by bone conduction for frequencies between 0.4 and 1.2 kHz in an occluded ear.

Stenfelt et al. (2002) investigated inertial effect of the middle ear in relation to the bone conduction hearing. Authors used 26 temporal bone samples extracted from cadaver heads and a laser Doppler vibrometer as well as a probe tube microphone positioned at 2 mm from the tympanic membrane. The SPL differences between the open ear canal and the occluded ear canal were about 5 dB at frequencies below 400 Hz and increased to about 20 dB at the frequencies around 600 Hz.
Stenfelt & Reinfeldt (2007) designed an acoustic model to predict the occlusion effect in humans. The model was built in a way that its structure is based on simplified anatomy so that each part of the model has physical interpretations. To validate their model, the authors measured occlusion effects both objectively and subjectively, via ear canal sound pressure level and bone conduction threshold shift, respectively. “Shallow” insertion of a foam earplug, 7mm into the ear canal, resulted in an occlusion effect measured via sound pressure of about 30 dB at 200 Hz and an occlusion effect measured via the bone conduction threshold shift method of about 22 dB at 200 Hz. Both methods yielded negative occlusion effects at frequencies above 2000 Hz which might be the result of shifted ear canal resonant frequency. One of the effect of the ear canal occlusion is alteration of its first resonance frequency from a quarter wavelength resonance at around 2.7 kHz to a half wavelength at around 5.5 kHz (Khanna, Tonndorf, & Queller, 1976; Stenfelt et al., 2002). “Deep” (23 mm) insertion of a foam earplug produced a similar occlusion effect trend although much smaller in magnitude: SPL measurement of the occlusion effect yielded about 15 dB at 200 Hz while the bone conduction threshold shift measurement yielded about 10 dB at 200 Hz. Above 500 Hz, occlusion effects were negligible with the “deep” insertion. The circumaural earmuff produced occlusion effect of about 25 dB and 15 dB at 200 Hz as measured with the SPL difference and the bone conduction threshold shift, respectively. The authors used a bone transducer with broadband noise. These are summarized at Table 1.
Table 1. Summary of prior research on occlusion effects in hearing.

<table>
<thead>
<tr>
<th>Author</th>
<th>Occlusion effect found</th>
<th>Method</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huizing (1960)</td>
<td>11 dB at 125 Hz, 15 dB at 500 Hz and 5 dB at 1000 Hz</td>
<td>subjective bone conduction threshold shift</td>
<td></td>
</tr>
<tr>
<td>Goldstein &amp; Hayes (1965)</td>
<td>5~25 dB at 250, 500, and 1000 Hz</td>
<td>object SPL and subjective bone conduction threshold shift</td>
<td></td>
</tr>
<tr>
<td>Vogel, et al. (1996)</td>
<td>15 dB at frequencies below 2000 Hz</td>
<td>laser vibrometry, hydrophones, slow cortical acoustical evoked potentials</td>
<td>used cadaver heads</td>
</tr>
<tr>
<td>Fagelson &amp; Martin (1998)</td>
<td>19 to 25 dB at 250 Hz, 16 dB at 500 Hz and 5 to 7 dB at 1000 Hz</td>
<td>subjective bone conduction threshold shift</td>
<td></td>
</tr>
<tr>
<td>Fagelson &amp; Martin (1998)</td>
<td>18 to 22 dB at 250 Hz, 16 to 18 dB at 500 Hz and 6 to 9 dB at 1000 Hz</td>
<td>objective SPL</td>
<td></td>
</tr>
<tr>
<td>Sweetow &amp; Pirzanski (2003)</td>
<td>22~25 dB at 125 ~ 500 Hz</td>
<td>objective SPL</td>
<td>vocal utterance of &quot;EE&quot;</td>
</tr>
<tr>
<td>Kuk, F., Keenan, D., &amp; Lau, C. C. (2005)</td>
<td>17 dB at 258 Hz</td>
<td>objective SPL</td>
<td>studied vent effect</td>
</tr>
<tr>
<td>Kuk, F., Keenan, D., &amp; Lau, C. C. (2005)</td>
<td>statistically different rating only with blocked vent</td>
<td>subjective rating of own voice reading a phrase</td>
<td></td>
</tr>
<tr>
<td>Stenfelt, Wild, Hato, &amp; Goode (2003)</td>
<td>10 dB below 400Hz, and about 20 dB at 500-800 Hz</td>
<td>objective SPL</td>
<td>SPL decreased by 5-15 dB when the cartilage part and soft tissues of the ear canal were removed used cadaver heads</td>
</tr>
<tr>
<td>Stenfelt et al. (2002)</td>
<td>5 dB below 400 Hz, 20 dB around 600 Hz</td>
<td>objective laser doppler vibrometry</td>
<td>used cadaver heads</td>
</tr>
<tr>
<td>Stenfelt &amp; Reinfeldt (2007)</td>
<td>30 dB (objective) and 22 dB (subjective) at 200 Hz</td>
<td>objective SPL, subjective bone conduction threshold shift</td>
<td>shallow insertion 7mm</td>
</tr>
<tr>
<td>Stenfelt &amp; Reinfeldt (2007)</td>
<td>15 dB (objective) and 10 dB (subjective) at 200 Hz</td>
<td>objective SPL, subjective bone conduction threshold shift</td>
<td>deep insertion 23mm</td>
</tr>
</tbody>
</table>
Working Memory and Occlusion Effect

People perceive their surroundings through various sensory inputs such as vision, audition, olfaction, and the tactile sense. Since the occlusion effect can affect the hearing of an otherwise normal person, it is possible that it will result in altered perception of their surroundings. The possibility of situation awareness affected by occlusion effect is explored in this section.

The Multicomponent model of working memory presented by Baddeley and Hitch (1974) is one of the three accepted theories that describe how working memories function. The model consists of two slave systems, the phonological loop and the visuospatial sketchpad, and the central executive. The phonological loop provides a temporary phonological store where auditory memory can be rehearsed to prevent decay. The visuospatial sketchpad provides temporary storage and maintenance of spatial and visual information. The central executive handles cognitive processes.

Two major functions of the phonological loop are temporary store of auditory memory and rehearsal. Experiments that exhibit the phonological similarity effect support the phonological store function of the phonological loop (Baddeley, 1966; Conrad & Hull, 1964). The phonological similarity effect is that sequences of phonologically similar letters are harder to remember accurately. When a sequence of letters is presented, the visual information is transferred to phonological loop through subvocalization. In other experiments, subjects were asked to remember a sequence of short words and a sequence of long words (Baddeley, Thomson, & Buchanan, 1975). Short words were monosyllable words such as wit and sum while long words were polysyllable words such as university and auditorium. It was harder for the subjects to remember longer words since it takes longer to rehearse them.
The visuospatial sketchpad provides similar functions with visual information as the phonological loop does for auditory information. It handles information such as colors, shapes, location or speed of objects in space. A task such as planning a route inside of a complex structure will require use of the visuospatial sketchpad.

Baddeley added the fourth component called the episodic buffer to the model (2000). The episodic buffer is another slave system that can integrate information from several sources as well as links to long-term memory and semantical meaning. Although the buffer is limited, it can be used to model an environment and can be utilized in problem solving.

The model of working memory can be utilized to explain how a person extracts visual, auditory, and other sensory information from his/her environment and integrates them to understand the situation. For example, let’s assume a person is walking while talking on the phone. The person’s attention is likely concentrated on the conversation while part of the attention will be shared with visual information. If he/she hears a shout from behind saying “your left!” his/her attention will temporarily shift from the phone conversation to the shout. Then he/she will start to gather auditory information such as the bicycle sound and/or visual information by turning his/her head to create a quick picture of the situation. The likely result of this cognitive processing will be slight movement of body to the right in preparation of passing bicycle on the left.

Let’s assume another scenario of a soldier performing a reconnaissance mission to survey an enemy post in the night. The soldier will have to pay attention to the surroundings as well as his/her own noise level. The visuospatial sketchpad and phonological loop as well as episodic buffer will have to be utilized to create best possible situation awareness. The occlusion effect caused by a communication system can cause the soldier to perceive a higher level of self-
produced noise such as footsteps, breathing, and whispers. Even if the communication system worn by the soldier does not affect the perceived sound level of surrounding environment, the soldier can be confused when he/she tries to determine the level of self-quietness based on perceived self-produced noise and previous knowledge of such noise levels.

From the above discussions, it is possible that a person experiencing occlusion effects may need to allocate additional attention to maintain similar levels of situation awareness as one who is not experiencing occlusion effects. The additional attention that is required due to occlusion effects means increased mental workload and it can adversely affect performance of the person depending on the level of mental/physical workload.

**Earplug Technologies**

*Conventional Earplugs*

Hearing protection devices can be categorized as passive (non-electronic) and active (electronic) devices (Casali, 2005). Passive hearing protection devices can be further categorized as earplugs, ear canal caps, earmuffs, and helmets based on the location of the sealing (Gerges & Casali, 2007). Most earplugs, which provide sealing by insertion into the ear canal, are “one-size-fits-most” earplugs that are larger in cross-sectional diameter than the ear canal and need to be compressed prior to or upon insertion. Hence, these user-molded products are manufactured with materials such as slow-recovery polyurethane or polyvinyl foams, finely spun fiberglass, various paraffin and beeswax-based products, and malleable putty encapsulated inside a soft plastic sheath. These materials are formable and/or compressible/expandable-recovery. For instance, a user must compress foam earplugs and insert them into the ear canal before they recover to the shape and size of the ear canal itself. Since their original dimension is bigger than the ear canal into which they are inserted, the recovery process creates an acoustic seal. Foam
earplugs such as SparkPlug™ by Moldex and E-A-R Classic PVC foam earplugs are examples of slow-recovery devices. Premolded flanged earplugs such as Ultrafit™ by AEARO-3M and HOWARD LEIGHT Fusion® only require users to push them into ear canal without any premolding. Earplugs made of paraffin or beeswax will require initial premolding by the user and then a forced insertion to deform them to fit the ear canal of the user.

**Custom-molded earplugs**

Unlike other conventional earplugs, single custom-molded earplug can be made as either passive or active devices (Casali, 2010a, 2010b). After a custom-molded earplug is produced per a person’s ear canal, it can be used as itself as a passive device that provides relatively good attenuation since the impression is usually made with a deeply-inserted ear dam. However, many companies such as Sonomax creates a pass-through channel or vent that can be fitted with various dampers that can provide different levels of attenuation (Casali, 2005). The channel or vent can also be fitted with blocks that contain electronic circuitry that can provide electronic augmentations such as noise cancellation, electronic filtering, closed-loop attenuation control, hearing assistive circuits, automatic gain control, digital signal recognition/processing, etc (Casali, 2010b).

**Balloon-based earplugs**

Traditionally, medical balloons have been used in angioplasty to expand stents once a physician placed it at the desired position. Improvements in manufacturing technology and balloon design and materials have lead to broader applications of the medical balloon. A new development based on the angioplasty balloon technology entails an ear insert that is dynamically adjustable (Casali, 2010a; Goldstein & Keady, 2009; Keady, 2009). The balloon-
based earplug design is different from the aforementioned conventional earplugs in that its initial dimension is smaller than that of ear canal. Users can insert them without initial compression or premolding. After the insertion, the balloon is then inflated to create an acoustic seal.

Selected earplugs for the experiment

Three earplugs were selected for this dissertation experiments: a PVC foam earplug (AEARO-3M Classic™), a premolded flanged earplug (HOWARD LEIGHT Fusion®), and a medical balloon-based earplug (MEDLINE 100% Silicone foley catheter). The foam earplug was selected as a reference as it was used by previous researchers (Stenfelt & Reinfeldt, 2007). Also, it was selected due to its shape that resulted in easier control of insertion depth. A premolded flanged earplug was selected to investigate whether the shape and/or sealing method of the earplug affects the occlusion effect. A medical balloon-based earplug was selected since it was under development as a hearing aid and had shown possibility of lower occlusion effect. A silicone foley catheter by MEDLINE was used for this dissertation’s experiments since it was commercially available and believed to be safer than hand-made balloons, in view that it was a medically-approved device.
RESEARCH OBJECTIVES

In any research effort concerning the occlusion effect, the first challenge is that a standard protocol to measure occlusion effect does not exist. Therefore, researchers have developed their own protocols and instrumentation, some of which are similar while others seem to be rather different. One popular example of instrumentation is the ER-33 device by Etymotic Research, a commercially available “occlusion effect meter”, which measures what should be regarded as transmission noise reduction (see earlier explanation). Although Vogel, et al. (1996) presented different occlusion effect measurement methods, none compared different measurement protocols and instrumentation. Since the goal of this research was to study the occlusion effect of a newly developed medical balloon-based earplug as compared to popular conventional earplugs, it was worthwhile to compare different protocols that objectively measure the occlusion effect; therefore this comprised the first objective.

The second objective of this research was to ascertain the occlusion effect characteristics of medical balloon-based earplugs as compared to popular conventional, commercially available earplugs. Occlusion effects of the medical balloon-based earplugs under various design variable values, as well as that of conventional earplugs, was measured and compared. The insertion depth of earplugs and the type of excitation sound stimuli were the other two factors whose influences on the occlusion effect were investigated.

The third objective of this research was to investigate the noise-reduction or protective capabilities of the new balloon-based earplug. Because foreseeable applications of the balloon-based device include hearing protection and earphones (for music and communications), it was important to determine its attenuation characteristics. Therefore, spectral attenuation was measured and a Noise Reduction Rating was calculated for the balloon-based earplug. Although
standard REAT test is a binaural test, due to the difficulty of inflating two balloons to same size, monaural REAT was performed. Hence a conventional earmuff was also tested monaurally for comparison.

In summary, the objectives of this research were:

1) **Evaluation of two different objective occlusion effect measurement protocols and instrumentation.**

2) **Investigation of occlusion effects of new medical balloon-based earplugs as compared to conventional passive earplugs as well as influences of the earplug insertion depth and the excitation sound stimuli on the occlusion effect.**

3) **Evaluation of noise attenuation capability of the medical balloon-based earplugs.**
METHODOLOGY

Participants

Six male and four female volunteered for the experiment. Their ages were from 22 to 37 with mean of 27.8 yrs. Before the experiment, participants read and signed an informed consent form that provided a general overview of the experiment. A visual inspection of the participant’s ear canal was conducted with an otoscope to make sure that they did not have ear canal lesions or severe wax buildup. The participants who participated in the REAT test were also screened through a pure tone audiogram and variability testing per ANSI S3.19-1974 (ANSI, 1974); however those who only participated in the occlusion trials were not audiometrically tested since they merely functioned as measurement fixtures. The standard requires minimum dBHL of 10 or better at frequencies 250, 500, and 1000 Hz, and 20 or better at frequencies 125, 2000, 3000, 4000, 6000, and 8000 Hz. A Beltone audiometer model 114 and anechoic chamber in the Auditory Systems Lab at Virginia Tech were used to conduct pure-tone audiogram. REAT tests were conducted at the reverberant room located in the same lab.

Experimental Design for Investigation 1

The goal of investigation 1 was to compare different objective occlusion effect measurement protocols. The experimental design, as shown at Figure 5, was a 3X2 within-subjects design. The first independent variable was comprised of the measurement protocols, with three levels, as described later. The second independent variable was the excitation source and the two levels were forehead-mounted bone vibrator and subject’s own vocal utterance.
Objective measurement of the occlusion effect was operationally defined as the measured SPL difference in dB between open ear and occluded ear using a probe-tube microphone placed near the tympanic membrane in the ear canal. In protocol 1, SPL was measured with one microphone (i.e. an insertion loss technique). It was necessary to perform two measurements: one for the open ear and one for the occluded ear. Hence, it was important to generate exactly the same acoustical input for both trials. When a bone vibrator was used as the excitation source, it was not difficult to generate the same input for both trials since the voltage input to the vibrator was regulated. However, when the subject’s voice was used as the excitation source, it was more difficult to generate the same input for both trials. A technique that used visual feedback was developed to overcome this problem, which is described in the following section.

Because people have two ears, it is possible to measure the SPL in both ears simultaneously with one ear open and the other occluded using two probe-tube microphones. This procedure was protocol 2. During protocol 2, it was important for the bone vibrator to be placed at the exact center of forehead to provide the same level of bone-conducted sound input. Another concern was that no one is perfectly left/right symmetrical with regard to the efficiency of sound conduction. That is, a person’s bone conduction efficiency to the left ear canal could be

<table>
<thead>
<tr>
<th></th>
<th>protocol 1</th>
<th>protocol 2</th>
<th>protocol 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>S₁-S₁₀</td>
<td>S₁-S₁₀</td>
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<tr>
<td>S₁-S₁₀</td>
<td>S₁-S₁₀</td>
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</tr>
<tr>
<td></td>
<td>vocal utterance</td>
<td>bone vibrator</td>
<td></td>
</tr>
</tbody>
</table>
different from that of the right ear canal. These concerns resulted in development of protocol 3, which was performing protocol 2 twice, switching the occluded and unoccluded ears between them. The occlusion effect was then determined as the mean of the two results.

Sound pressure level was measured at the 1/3 octave band with center frequency of 500Hz and at broadband dBZ. The occlusion effects were calculated for both the 500 Hz band as well as the broadband dBZ, in dB.

**Trials**

For the occluded condition, a foam earplug was inserted at 5 mm depth by marking an earplug at 5 mm from one end and inserting it until the mark just disappears. A single trial 4-second $L_{eq}$ was measured when bone vibrator was employed as excitation source while two trials of 2-second $L_{eq}$s were measured when subject’s vocal utterance was employed as excitation source. The measurement of SPL with vocal utterance was divided into two 2-second intervals rather than one 4-second interval for the comfort of the subjects. The two measurements were then averaged. Also, subjects were asked to hold their breath during the bone vibrator occlusion effect measurements, and of course, their breath was being exhaled during the vocal utterance measurement.

**Instrumentation for vocal utterance**

For the vocal utterance, as one of the excitation sources in the above-described protocols, the participants was required to produce the phoneme “EEE” at a constant level of 65 dBA for at least 3 seconds. The phoneme “EEE” is chosen over other phonemes such as “AH” since people can vocalize at higher sound pressure level when measured at the back of the mouth, that is, 116 dB SPL for “AH” versus 142 dB SPL for “EEE” (Killion, Wilber, & Gudmundsen, 1988). An
LD 800-B sound level meter (SLM) assembled with a matched ½-inch measurement microphone and preamplifier was used to provide visual feedback to the participants. The SLM measurement microphone was placed at a distance of 1 foot horizontally from the mouth. During vocalization, participants could view the analogue bar indicator (an LED vertical thermometer style) and adjust their vocal output to match 65 dBA which was marked with a tape on the SLM (see Figure 6). It is well known that a large volume earmuff over the pinna produces a negligible occlusion effect (Stenfelt & Reinfeldt, 2007). Therefore, to prevent air conduction of vocal utterance to ear canal and to the measurement microphone, a large volume earmuff (Peltor H10A) was used to cover the pinna during both open ear canal measurements and occluded ear canal measurements. During measurement trials, the occlusion effect of the earmuff alone was measured and determined to be negligible, as described later.

*Instrumentation for bone vibrator*

A Radioear B70-A (10 ohm) vibrator device with a Huggies™ headband was used as the bone vibrator excitation sound source (see Figure 7). The vibrator was placed at the center of the participant’s forehead and held in place with a Huggies™ headband to provide an approximate holding force of 5 Newton. The input signal to the vibrator was pink noise produced from a laptop and fed through the TAPE input of a Beltone 114 audiometer, then through the audiometer’s BONE output jack to the vibrator. The audiometer was used to produce a calibrated output signal. Again, the large volume Peltor H10A earmuff was used to prevent any air-conducted sound from reaching the measurement microphone. Although measurements and calculations to verify the attenuated air-conducted path was negligible than the bone-conducted path was not conducted for this experiment, the set up was considered to be good based on the similar prior study (Keady & Casali, 2009).
Figure 6. Larson Davis 800B sound level meter with 65 dBA level as marked for subject vocalization control.

Instrumentation for probe tube microphone and spectrum analyzer measurement system

A Knowles model EM3068 microphone with an ER-7 silastic probe tube was used as the probe-tube microphone for the experiment (see Figure 8). The end of the probe tube was placed about 2mm from the subject’s tympanum by pulling it out after it just touched the tympanum as reported by the participant. The outer end of the probe tube along with the microphone was then taped on the cheek area and remained at the same position throughout the measurements. The electrical leads from the microphone were guided toward the front of the participants and taped on the table before being fed into a junction box and then to the direct line input of the LD 3200D spectrum analyzer (See Figure 9). The LD 3200D was configured to measure either a 4-second or 2-second Leq (i.e. integrated) for 1/3 octave bands with dB(Z) weighting and an 1/8-second time constant as explained in previous section. A noise floor measurement of a subject with aforementioned set-up is shown at Table 2. The measured dB levels were lower than open ear canal muff alone with either excitation source at frequencies below 4000 Hz.
Table 2. Sound pressure level as measured with a probe tube placed in the ear canal covered with a Peltor H10A earmuff (noise floor measurement).

<table>
<thead>
<tr>
<th>Frequency</th>
<th>dBZ</th>
<th>125 Hz</th>
<th>160 Hz</th>
<th>200 Hz</th>
<th>250 Hz</th>
<th>315 Hz</th>
<th>400 Hz</th>
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<tbody>
<tr>
<td>Frequency</td>
<td>dB</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td>125 Hz</td>
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<td>28.6</td>
<td>24.2</td>
<td>22.6</td>
<td>21.1</td>
<td>27.3</td>
<td>21.7</td>
</tr>
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</tr>
<tr>
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<td>25.8</td>
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<td>22.0</td>
<td>23.7</td>
<td>22.6</td>
<td>25.1</td>
</tr>
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<tr>
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<td>1.25 kHz</td>
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<td>8.00 kHz</td>
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</tbody>
</table>

Figure 7. Radioear B70-A bone vibrator was used to introduce excitation sound to the forehead of the subjects.

Figure 8. Knowles model EM3068 microphone with an Etymotic ER-7 silastic probe tube, used with LD-3200D (shown in Figure 9) to measure SPL in the ear canal.
Figure 9. Larson Davis real time spectrum analyzer LD-3200D, used with probe tube microphone (shown in Figure 8) to measure SPL in the ear canal.

Experimental Design of Investigation 2

The goal of investigation 2 was to conduct an evaluation of the occlusion effects of a medical balloon-based earplug under different design conditions and compare them to that of currently available earplugs. The experimental design was a 2x3x2, partial factorial, within-subjects design, as shown in Figure 10. A full factorial design was impossible since one of the earplugs (the flanged earplug) by the nature of its design, is nearly impossible to control as to its insertion depth.

The dependent variables were the occlusion effects measured both objectively and subjectively. The objective measurement was the SPL difference (in dB) between the open ear measurement and occluded ear while one of the aforementioned excitation sources was employed to generate sound. Subjective measurement was self-reported values for naturalness of the participant’s own voice. Those are explained in more detail in the Measurements section below. There were three independent variables: depth of insertion, excitation source, and earplug type. The two levels of Insertion Depth were shallow and deep, where shallow was 2mm,
and deep was 11mm as detailed later. The two levels of **Excitation Source** were vocal utterance and bone vibrator at the forehead. The three levels of **Earplug** included a PVC foam earplug, a premolded flanged earplug, and a medical balloon-based earplug, as detailed later.

![Experimental design for evaluation of occlusion effects per earplug design, insertion depth, and excitation source.](image)

**Earplugs**

Figure 10. Experimental design for evaluation of occlusion effects per earplug design, insertion depth, and excitation source.

The first independent variable was the insertion depth of the occluding devices at two levels, shallow and deep. As referenced in the Instrumentation section, it is well known that the occlusion effect of an occluding device is dependent on its insertion depth. Since the human ear canal length is between 23 mm and 30 mm and the outer 1/2 to 1/3 of the ear canal is cartilaginous (Yost, 1994), it can be expected that insertion depth of about 8-15 mm is where a major change in the occlusion effect will occur.

The **shallow insertion depth** was set as 2 mm of insertion from the entrance (aperture) of the ear canal since the shallow insertion depth was intended to simulate the maximum occlusion effect which occurs when ear canal is occluded at the entrance while allowing the earplugs to be held at the fixed location through the measurements (Berger, 2003). Foam earplugs were marked at 2 mm from the end as shown in Figure 11, and inserted until the marking nearly disappears. It
is expected the occlusion occurred at 2 mm toward the tympanic membrane from the aperture. In case of the balloon-based plugs, they were fitted to accomplish an acoustic seal without any insertion into the canal, and instead establishing a seal at the aperture of the canal.

The **deep insertion depth** was set as 11 mm, which should place earplugs nearly into the bony part of ear canal (Figure 1). The deep insertion was expected to produce smaller magnitude occlusion effects, as employed in some custom-fit devices and as found by Stenfelt et al (2003). Foam earplugs were marked at 11 mm from one end as seen in Figure 12, and inserted until the marking nearly disappears. It is expected the occlusion was occurred at 11 mm toward the tympanic membrane from the aperture thus creating smaller entrapped volume than the shallow insertion (2 mm) did.

![Figure 11](image)

**Figure 11.** Classic foam earplug with a marking for shallow insertion at 2 mm from the right end, which was inserted from the right end until the marking just disappears into the ear canal.
Figure 12. A Classic foam earplug with a marking for deep insertion at 11mm from the right end, which was inserted from the right end until the marking just disappears into the ear canal.

For the premolded flanged earplug it was hard to control the depth of insertion while maintaining acoustic seal. Hence the depth of insertion was not controlled for premolded flanged earplugs; rather they were inserted them as deeply as comfortably possible to create a good acoustic seal. Due to different ear canal diameters, the depth of insertion was different across subjects, but at the least the third flange was partially inserted and the occlusion was expected to occur at near the aperture of the ear canal.

The balloon-based earplugs presented an unexpected challenge in determining the depth of insertion as visual confirmation of its deformation and exact location of acoustic seal were not possible once the earplugs are inserted into the ear canal and inflated. Shallow insertion was operationally determined as when a balloon-based earplug was inflated at the ear canal entrance with minimal insertion. Only a minimal part of the balloon was inserted to create an acoustic seal. The deep insertion was operationally decided as full insertion of the balloon-based earplugs where the end of the balloon was just inside of the aperture. Since the longitudinal dimension of an inflated balloon was about 11 mm, 11 mm was selected as the depth of deep insertion so that when the end of the balloon was approximately coplanar with the canal aperture, the plug was at the “deep insertion” point. Pictures of shallowly inserted and deeply inserted balloon-based
earplugs on a subject are shown at Figure 14. The figure also contains pictures of shallow/deeply-inserted foam earplugs.

As stated prior, the three earplugs were: a PVC foam earplug (AEARO-3M Classic™), a premolded flanged earplug (HOWARD LEIGHT Fusion®), and a medical balloon-based earplug (MEDLINE 100% Silicone foley catheter) as shown in Figure 13. The air pressure level of the medical balloon-based earplug was determined to be a pressure level near the minimum usable air pressure at which an acoustic seal occurs with at least 10-15 dB attenuation. The air pressure of 1.38 bar was chosen after testing six subjects. An LPT1 low-pressure hand pump from DRESSER Instrument was used to inflate the foley catheter and a hand help digital RS232 manometer model 82100 from MANNIX™ was used to measure the air pressure. The value of maximum air pressure that was comfortable, as reported by the subjects, ranged from 1.45 bar to 1.7 bar hence the test air pressure needed to be lower than 1.45 bar. Acoustic seal was obtained as long as the balloon was inflated beyond the ear canal diameter. Although it was possible to keep the balloon inflated at air pressures that were lower than 1.35 bar, often times the balloon collapsed. These two measurements produced usable air pressure range of 1.36–1.44 bar, and 1.38 bar was thus chosen for the experiment.

![Figure 13. Three earplugs used in the investigation 2. A picture of inflated a MEDLINE 100% Silicone foley catheter that was used as a balloon-based earplug, a HOWARD LEIGHT Fusion® as a premolded flanged earplug, and a AEARO-3M Classic™ as a foam earplug.](image)
The third independent variable was the excitation source that provided the input sound energy, which aided in the measurement of the occlusion effect. The two levels were subject’s own vocal utterance of “EEE” at a level of 65 dBA as measured 1 foot horizontally from the mouth using the Larson-Davis 800B sound level meter for feedback, and a Radio Ear Bone Vibrator B71 on the participants’ forehead, all as detailed previously. Pink noise was used as input sound to the vibrator. Hence the two-excitation sources were different with regard to location of sound source, that is, internal and on the forehead surface, as well as spectral composition of the signal produced. The sound energy of the vocal utterance of “EEE” will be concentrated at formant frequencies at near 320 Hz and 2500 Hz (Peterson & Barney, 1952) while sound energy transmitted from the bone vibrator will be distributed over a broader spectrum.

The SPLs in the ear canal were measured per all 1/3 OB, with center frequencies from 125 to 8000 Hz, and a summation of frequencies from 20 Hz to 20000 Hz with dBZ (i.e., unweighted). The dBZ filter was chosen over the nonlinear dBC filter for two reasons. One, dBZ filter is a linear filter with uniform weighting of all octave bands. The author tried to minimize any influences introduced by instrumentation, including weighting filter. Two, use of particular filter would not have made any differences since the occlusion effects were defined as the arithmetic differences in SPL measurements between those of the open ear canal and the occluded ear canal.
Figure 14. Picture of deeply-inserted foam earplug and foley catheter as well as shallowly-inserted foam earplug and foley catheter.
**Instrumentation for Investigation 2**

The experimental setup and instrumentation was the same as that of investigation 1. The major changes were the insertion depth of earplugs and type/air pressure of the earplugs. In addition to the objective occlusion effect measurements, a subjective measurement was also conducted. Each subject was asked to read a standard sentence paying close attention to their own voice both with and without earplugs, and to rate the naturalness of their own voices after objective measurement of each earplug conditions, using the rating scale in Appendix C.

**Trials**

Objective measurement of occlusion effects were conducted similarly as they were done during investigation 1. Again, one 4-second $L_{eq}$ was measured when bone vibrator was employed as excitation source while two 2-second $L_{eq}$s were measured when subject’s vocal utterance was employed as excitation source. The measurement of SPL with vocal utterance was divided into two 2-second intervals rather than one 4-second interval for the comfort of the subjects. The two measurements were then averaged. Also, subjects were asked to hold their breath during the bone vibrator occlusion effect measurements, and of course, their breath was being exhaled during the vocal utterance measurement. Subjective measurements of occlusion effects via self-reporting questionnaire were conducted after objective measurements. Subjects were asked to hold their breath during the occlusion effect measurements, which lasted four seconds if bone vibrator was used as an excitation source and two seconds if vocal utterance was used as such action or any internal movement affected SPL at the ear canal.

Before occlusion effect measurements of various experimental conditions, open ear measurements, both objective and subjective, were conducted. The orders of presentation were
randomly selected by pairing each earplug type and insertion depth. For example, foam earplug and deep insertion was designated as form deep. Each pair was given a code, and random number generator was used to create presentation order. The presentation of excitation order, bone vibrator and vocal utterance, was also randomly decided for each earplug/insertion depth presentation.

**Experimental Design of Investigation 3**

Since the medical balloon-based earplug was still in the process of development at the date of data collection, its attenuation capability has not been tested and the objective of investigation 3 was simply to evaluate that capability. When a hearing protection device is designed and produced as a finished product, its protective capability measurement should be conducted using REAT test per ANSI S3.19-1974 (ANSI, 1974). Since usage as a hearing protector is one of the foreseeable major applications of a balloon-based earplug, the REAT test was applied to measure the balloon-based earplug’s noise attenuation capability. The REAT method is one of the standard tests performed at the Auditory Systems Lab at Virginia Tech, and test procedures and subject qualification requirements are stated in the lab manual (Lancaster & Casali, 2002).

REAT tests were conducted using a computer program which incorporated a variant of Bekesy tracking as well as safeguards for validity and reliability of threshold (Casali, Robinson, & Hankins, 2000). Subjects were placed in a reverberant room and asked to respond to 9 1/3-octave bands of filtered pink noise, with center frequencies of 125, 250, 500, 1000, 2000, 3150, 4000, 6300, and 8000 Hz, by pressing the switch whenever they heard the noise band. Furthermore they were asked to hold the switch as long as they could hear the test noise band and let go of the switch when they could no longer hear the test band. The program scored and
recorded the hearing threshold level for the subject at each frequency and then continued to the next frequency.

Each subject performed three pairs of monaural REAT tests for the medical balloon-based earplug and for a Peltor H10A earmuff. The standard REAT test is binaural in nature since both ears of a subject are either open or occluded. However, the balloon-based earplugs used in the experiment, silicone foley catheters, did not inflate to exactly same size under the same air pressure. Hence a decision was made to conduct monaural REAT tests by covering the unused ear with both a Classic foam earplug and a Peltor H10A earmuff. The unused ear was covered with the two devices throughout the open and occluded (with a balloon-based earplug) REAT tests. To compare the monaural REAT test results with, similar monaural REAT test for a Peltor H10A earmuff was also performed.

The balloon-based earplugs, silicone foley catheters, were inflated to 1.42 atm (absolute) pressure at the beginning of the experiment, and the manually pumped up before it dropped below 1.39 atm during the testing. This range was chosen after surveying the subjects for maximum comfortable air pressures that ranged from 1.45 atm to 1.7 atm. Also the balloon became unstable at 1.36 atm at which it collapsed more often than not. Hence feasible, usable air pressure levels during all tests were 1.36 atm to 1.45 atm. However, the comfort of the subjects and to reduce the possibility of accidental deflation, actual levels used in the experiments were the air pressures from 1.38 ~ 1.42 atm.

Ten subjects, six male and four female, were recruited for the test and half of the subjects started with unoccluded condition first while the other half started with the occluded condition. Subsequent tests were performed by alternating occluded and unoccluded conditions.
DATA REDUCTION AND ANALYSIS OF RESULTS

Selection of Metrics for Statistical Analysis

Dependent measure of occlusion effect for analysis although all frequencies from an 1/3 octave band between 125 and 8000 Hz were graphed to illustrate occlusion effects in the subsequent sections, only two metrics were used in the statistical analysis. The two, dBZ and the 1/3 OB centered at 500 Hz were selected for the following reasons. The first metric, dBZ, was selected since it represents the linear measure of broadband occlusion effect influence. The second metric, the 1/3 OB centered at 500 Hz was chosen since it was one of the metrics used by many researchers (Dean & Martin, 2000; Kiessling et al., 2005; Tonndorf, 1966). Another rationale for the selection was the fact that the 1/3 OB at 500 Hz exhibited the maximum occlusion effects across the frequencies and its width of 95% confidence interval of mean was one of the smallest among the metrics with greater occlusion effect; this can be seen in Figures 16-34 to follow.

Subjective measurement of occlusion effect was made through the use of questionnaire. However, the results were not included in the analysis since statistical analysis did not produce any meaningful results.

Investigation 1

The goal of investigation 1 was to compare different objective measurement protocols that were based on either one-ear measurements or two-ear measurements. Also, the fact that a human body is not perfectly left/right symmetrical raises the question of which ear should be used for the measurement if a one ear measurement protocol is employed. The first question that should be answered is whether the SPL of the occluded left ear is equal to that of the right ear. If
the answer to the question is yes, a simple one-ear measurement method would suffice in lieu of two-ear occlusion effect measurements, and the selection of the particular measurement ear should not matter.

The SPL was measured three times per ear, per subject, and per excitation source. Each right ear SPL value was subtracted from the left ear SPL value and 10 was added to move the center value from zero to 10. The data reduction resulted in 120 left/right SPL differences; 30 SPL differences per frequency (500 Hz and dBZ) and per excitation source (bone vibrator and vocal utterance). The $t$-test of means was conducted using JMP for measurements at 500 Hz and over the entire spectrum (dBZ); results are shown in Table 3. Since the data did not pass the Shapiro-Wilk W test, a test to determine whether a data is from the Normal distribution, a non-parametric test (Signed-rank test) was also conducted.

Table 3. Result of mean tests for left/right ear SPL difference using both parametric and non-parametric methods.

<table>
<thead>
<tr>
<th>dBZ</th>
<th>Test Statistic</th>
<th>$t$-test</th>
<th>Signed-Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone vibrator</td>
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<td></td>
</tr>
<tr>
<td>500Hz</td>
<td>Test Statistic</td>
<td>1.342</td>
<td>78.5</td>
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<tr>
<td></td>
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<tr>
<td></td>
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<tr>
<td>Vocal utterance</td>
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</tr>
<tr>
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<td>$p$-value</td>
<td>0.12</td>
<td>0.14</td>
</tr>
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</table>

*p < 0.05 was considered as the level required for statistical significance.
When a bone vibrator was used to produce occlusion effect, the SPL, measured over the entire sound spectrum and summarized with linear weighting (dBZ), did not show statistically significant differences between SPL values of the left ear and that of the right ear at an α-value of 5%. The SPL measured at 1/3 octave band centered at 500 Hz also did not show statistically significant differences at an α-value of 5%. Similarly, SPL measurements over dBZ and 500 Hz did not show statistically significant differences at an α-value of 5% when vocal utterances were used as the excitation source.

**Investigation 2**

*Data reduction*

Objective measurements of the occlusion effect were obtained for the 1/3 octave bands with center frequencies at 125, 160, 200, 250, 315, 400, 500, 630, 800, 1000, 1250, 1600, 2000, 2500, 3150, 4000, 5000, 6300, 8000 Hz, and over entire frequencies with linear weighting (dBZ) by calculating the arithmetic differences between the SPL measured at the open ear canal and at the earplug-occluded ear canal (ear was always covered with an earmuff to prevent contamination from air-conducted noise). The two 2-second Leq measurement trials where vocal utterance was employed as an excitation source were averaged for each subject. This step was not required for the SPL measurements where the bone vibrator was employed as an excitation source since there was only a single measurement of four-seconds Leq. Across 10 subjects, these data reductions yielded 10 occlusion effect measurements per earplug type, per insertion depth, per 1/3 octave band, and per excitation source. Arithmetic means were calculated for each group and 95% confidence intervals based on the *t*-distribution were also calculated.
Data set: Individual subjects occlusion effects and their mean

The means of individual subject occlusion effects per 1/3 octave band per earplug type as well as the 95% confidence interval based on the $t$-distribution are summarized in Table 4. Each subject’s data over the frequencies as well as their means and 95% confidence intervals are plotted in Figure 15-Figure 34. On each page of these figures, at the top is occlusion effect for ten subjects with a type of earplug and either bone vibrator or self vocal utterance stimuli are plotted over all measured frequencies. At the bottom of each page, plot of the mean and 95% confidence intervals for the group of 10 subjects is provided. The first plots of ten pairs depict occlusion effects produced with bone vibrator as the excitation source while the second set of ten plots depicts occlusion effects produced with self-vocal utterance as the excitation source.

First, trends in the data will be described prior to the formal statistical analyses. While each earplug yielded different occlusion effects, the means graphs present some similarities between earplugs. When the bone vibrator was used as an excitation source, the resulting occlusion effects exhibited much smaller variations than with the vocal utterance. The width of confidence intervals of the occlusion effects produced with the bone vibrator was smaller than that of occlusion effects produced with self vocal utterance. Most of the mean occlusion effect plots show steady increases from 125 Hz to the 500/630 Hz region, then a steady decrease until 2500 Hz, and then converging to zero dB at higher frequencies. The maximum occlusion effects were measured to be 24.0 dB at 500 Hz when subjects were wearing shallowly inserted foam earplugs excited with self vocal utterance. The maximum occlusion effects at 400, 500, 630, and 800 Hz were in the range of 19.5-24.0 dB. They declined to 16.5, 13.6, and 7.4 dB as frequency increases to 1000, 1250, and 1600 Hz. At higher frequencies, the occlusion effect entered into the negative range and became negligible. The negative occlusion effect at frequencies around
2500 Hz might be due to the shift of resonant frequency of the ear canal. As explained in the air tube model, the resonant frequency of the ear canal shifts from the 3000 Hz region to the 6000 Hz region as the ear canal changes between open and occluded. Stenfelt (2003) also suggested a similar explanation.

Figures 25, 27, 29, 31, and 33 shows plots of individual subject’s occlusion effects produced with their vocal utterance as the excitation source. These graphs show greater variability at frequencies below 500 Hz than at other frequencies. At least one subject from each of the graphs exhibited a greater occlusion effect than that of entire subjects’ group data at 500 Hz when the 1/3 OB centered at 500 Hz exhibited the greatest occlusion effect as calculated by their means. The greater variability of lower frequency bands was greater when vocal utterance was used as the excitation source as compared to the vibrator. The author found that the occlusion effect varies as one opens mouth vertically. Another factor could have been the distance between the measuring microphone and the subject’s mouth. Although a 12 in ruler was given to each subject and they were asked to use it to maintain correct distances through entire experiments, they were not required to hold it during vocalization. Hence it was possible to move their relative head position between measurements. Since subjects were asked to maintain their vocal utterance at 65 dBA as measured by the SLM, they would typically vocalize at higher SPL as they moved away from the measuring microphone.
Table 4. Mean occlusion effects and 95% confidence intervals based on the t-distribution of earplugs.

|                  | Frequency (Hz) | dBZ | 125 | 160 | 200 | 250 | 315 | 400 | 500 | 630 | 800 | 1000 | 1250 | 1600 | 2000 | 2500 | 3150 | 4000 | 5000 | 6300 | 8000 |
|------------------|----------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| B BALLOON DEEP   | 4.3            | 1.6 | 3.7 | 6.8 | 9.4 | 8.1 | 14.5| 15.1| 14.4| 11.7| 10.1| 8.3 | 3.1 | -3.6| -7.7| -5.0| -2.1| -0.7| -0.4| 0.0 |
|                  | confidence interval | 5.2 | 3.2 | 7.8 | 7.8 | 7.6 | 5.8 | 7.2 | 5.4 | 6.8 | 7.0 | 6.0 | 5.6 | 5.8 | 4.0 | 6.6 | 5.8 | 4.0 | 2.0 | 1.6 | 0.8 |
| B BALLOON SHALLOW | 8.9            | 2.4 | 4.2 | 6.6 | 8.7 | 7.2 | 14.9| 18.7| 20.4| 17.5| 16.5| 13.6| 6.9 | -2.3| -7.6| -5.0| -2.8| -0.9| -0.8| -0.1|
|                  | confidence interval | 7.2 | 10.0| 12.8| 13.8| 10.4| 7.4 | 11.0| 8.6 | 6.2 | 4.4 | 4.2 | 3.8 | 6.4 | 5.0 | 6.0 | 6.0 | 3.0 | 2.0 | 1.2 | 0.4 |
| B FLANGE         | 7.5            | 0.4 | 3.4 | 6.4 | 7.7 | 5.7 | 15.0| 17.6| 17.2| 14.0| 13.6| 12.1| 7.1 | -0.1| -4.5| -2.7| -2.3| -0.4| 0.3 | 0.2 |
|                  | confidence interval | 8.4 | 7.4 | 7.2 | 8.8 | 10.4| 5.6 | 8.8 | 9.0 | 7.2 | 7.0 | 6.6 | 6.2 | 5.4 | 2.8 | 4.8 | 5.2 | 2.6 | 4.0 | 3.8 | 0.8 |
| B FOAM DEEP      | 1.3            | -0.8| 0.7 | 1.3 | 3.4 | 2.7 | 6.6 | 6.4 | 5.7 | 5.1 | 5.5 | 4.4 | 0.1 | -5.4| -7.6| -6.3| -3.5| -1.5| -0.7| -0.2|
|                  | confidence interval | 4.4 | 8.4 | 9.4 | 9.4 | 7.4 | 4.6 | 7.6 | 8.2 | 9.2 | 9.6 | 7.2 | 6.0 | 8.0 | 6.6 | 6.0 | 4.8 | 3.0 | 2.0 | 1.4 | 0.8 |
| B FOAM SHALLOW   | 8.9            | 3.9 | 6.7 | 9.9 | 13.1| 10.5| 18.4| 20.7| 19.6| 16.7| 15.2| 13.3| 6.4 | -2.0| -6.9| -4.9| -2.3| -0.9| -0.6| 0.0 |
|                  | confidence interval | 3.6 | 9.6 | 12.8| 13.8| 10.6| 9.0 | 9.8 | 6.8 | 7.0 | 6.6 | 3.8 | 3.0 | 6.2 | 4.2 | 6.0 | 5.6 | 3.8 | 2.4 | 2.0 | 0.8 |
| V BALLOON DEEP   | 2.6            | 3.7 | -3.7| -1.9| 5.7 | 1.5 | 13.9| 14.6| 9.0 | 7.9 | 8.0 | 8.3 | 2.9 | -3.8| -6.0| -2.7| 0.1 | 0.2 | 0.4 | 0.4 |
|                  | confidence interval | 8.8 | 14.6| 26.4| 23.6| 24.6| 27.8| 26.2| 11.2| 10.0| 10.6| 15.6| 6.5 | 6.0 | 8.2 | 4.8 | 1.0 | 1.0 | 1.0 | 1.4 |
| V BALLOON SHALLOW| 8.3            | 7.4 | 0.8 | -3.6| 13.4| 6.7 | 15.6| 22.8| 13.8| 15.5| 15.2| 13.3| 7.4 | -1.0| -5.3| -3.4| 0.0 | 0.1 | 0.1 | 0.2 |
|                  | confidence interval | 9.0 | 17.2| 19.4| 18.6| 17.2| 18.0| 22.4| 9.0 | 16.0| 7.8 | 8.0 | 7.8 | 7.8 | 8.4 | 9.0 | 4.2 | 0.6 | 0.4 | 0.4 | 1.2 |
| V FLANGE         | 6.3            | 9.3 | -1.9| -1.9| 16.0| 8.2 | 17.5| 20.0| 13.2| 10.5| 8.8 | 9.9 | 5.6 | -0.2| -3.6| -2.5| 0.1 | 0.1 | 0.5 | 0.8 |
|                  | confidence interval | 8.6 | 22.2| 16.6| 20.6| 26.4| 19.8| 22.0| 9.2 | 8.4 | 9.0 | 14.4| 9.2 | 9.0 | 8.4 | 4.8 | 3.4 | 0.6 | 0.6 | 1.0 | 1.4 |
| V FOAM DEEP      | -0.7           | 3.9 | -4.3| -8.1| 1.9 | 2.6 | 5.6 | 5.3 | 0.3 | 2.6 | 5.8 | 5.3 | -0.5| -7.2| -8.9| -3.5| 0.0 | 0.0 | 0.1 | 0.2 |
|                  | confidence interval | 9.8 | 20.0| 13.8| 15.6| 30.8| 19.6| 20.4| 14.0| 12.6| 11.2| 7.6 | 6.4 | 8.8 | 8.8 | 6.8 | 4.8 | 0.6 | 0.4 | 0.4 | 1.4 |
| V FOAM SHALLOW   | 10.7           | 6.2 | 2.1 | 2.8 | 14.4| 11.5| 22.6| 24.0| 16.1| 16.2| 14.8| 12.0| 6.8 | -1.1| -5.5| -3.0| 0.4 | 0.5 | 0.8 | 0.9 |
|                  | confidence interval | 8.4 | 20.8| 12.8| 14.2| 19.8| 15.6| 13.8| 8.4 | 11.0| 8.4 | 9.2 | 5.8 | 5.4 | 7.0 | 7.8 | 5.2 | 1.0 | 1.4 | 2.4 | 2.4 |
| Minimum occlusion effect | -0.7 | -0.8 | -4.3 | -8.1 | 1.9 | 1.5 | 5.6 | 5.3 | 0.3 | 2.6 | 5.5 | 4.4 | -0.5 | -7.2 | -8.9 | -6.3 | -3.5 | -1.5 | -0.8 | -0.2 |
| Maximum occlusion effect | 10.7 | 9.3 | 6.7 | 9.9 | 16.0| 11.5| 22.6| 24.0| 20.4| 19.5| 16.5| 13.6| 7.4 | -0.1| -3.6| -2.5| 0.4 | 0.5 | 0.8 | 0.9 |
Figure 15. Individual participants’ occlusion effects of deeply-inserted balloon-based earplug as produced with the bone vibrator.

Figure 16. Mean and 95% confidence interval of occlusion effects of deeply-inserted balloon-based earplugs as produced with the bone vibrator.
Figure 17. Individual participants’ occlusion effects of deeply-inserted foam earplug as produced with the bone vibrator.

Figure 18. Mean and 95% confidence interval of occlusion effects of deeply-inserted foam earplugs as produced with bone vibrator.
Figure 19. Individual participants’ occlusion effects of flanged earplugs as produced with the bone vibrator.

Figure 20. Mean and 95% confidence interval of occlusion effects of flanged earplugs as produced with bone vibrator.
Figure 21. Individual participants’ occlusion effects of shallowly-inserted balloon-based earplugs as produced with the bone vibrator.

Figure 22. Mean and 95% confidence interval of occlusion effects of shallowly-inserted balloon-based earplugs as produced with bone vibrator.
Figure 23. Individual participants’ occlusion effects of shallowly-inserted foam earplugs as produced with the bone vibrator.

Figure 24. Mean and 95% confidence interval of occlusion effects of shallowly-inserted foam earplugs as produced with bone vibrator.
Figure 25. Individual participants' occlusion effects of deeply-inserted balloon-based earplugs as produced with the vocal utterance.

Figure 26. Mean and 95% confidence interval of occlusion effects of deeply-inserted balloon-based earplugs as produced with vocal utterance.
Figure 27. Individual participants’ occlusion effects of deeply-inserted foam earplugs as produced with vocal utterance.

Figure 28. Mean and 95% confidence interval of occlusion effects of deeply-inserted foam earplugs as produced with vocal utterance.
Figure 29. Individual participants’ occlusion effects of flanged earplugs as produced with the vocal utterance.

Figure 30. Mean and 95% confidence interval of occlusion effects of flanged earplugs as produced with vocal utterance.
Figure 31. Individual participants’ occlusion effects of shallowly-inserted balloon-based earplugs as produced with the vocal utterance.

Figure 32. Mean and 95% confidence interval of occlusion effects of shallowly-inserted balloon-based earplugs as produced with vocal utterance.
Figure 33. Individual participants’ occlusion effects of shallowly-inserted foam earplugs as produced with vocal utterance.

Figure 34. Mean and 95% confidence interval of occlusion effects of shallowly-inserted foam earplugs as produced with vocal utterance.
Test of 3-way Factorial Experimental Design

ANOVA on dBZ data. Since the original experimental design of investigation 2 was not a full factorial design, it was not possible to directly test for main effects. Since the single insertion depth of the flanged earplug was not comparable to that of either other earplugs (which both had shallow and deep positions), direct comparison of occlusion effect produced with flanged earplugs and that of the other earplugs was not possible. Exclusion of the flanged earplug data produced a full factorial design of 2X2X2: two levels of earplug, two levels of excitation source, and two levels of insertion depth. With this data set, an ANOVA test was performed on the factorial followed by Tukey’s HSD post hoc test to break down any 2-way interactions. This procedure was first done on the occlusion effect calculated over the broadband metric, dBZ, and the results are summarized in Table 3. ANOVA test showed a significant main effect of insertion depth on occlusion effect (F= 49.1, p < 0.0001), as shown in Table 3. The mean occlusion effect of deeply-inserted earplug was 2.3 dB while that of shallowly-inserted earplug was 9.8 dB (Figure 35). Larger occlusion effect at shallow insertion agreed with prior research results.
Table 5. ANOVA test of broadband occlusion effect: Excitation sources-bone vibrator and self vocal utterance; earplug-foam earplug and balloon-based earplug; insertion depth-deep and shallow.

<table>
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<th>MS</th>
<th>F</th>
<th>p-value</th>
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<td></td>
<td></td>
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</tr>
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<td>insertion depth (ID)</td>
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<td>49.1482</td>
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<tr>
<td>error</td>
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<td>0.7399</td>
<td>0.3926</td>
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<td>3.5157</td>
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*significant effect at $p < 0.05$
Figure 35. The effect of insertion depth of occlusion device on the occlusion effect measured over broadband. Different letters represent significant differences due to insertion depth at $p < 0.05$. Vertical bars indicate 95% confidence intervals about the means.

ANOVA on 1/3 OB at 500 Hz data. When occlusion effects, measured at the 1/3 octave band centered at 500 Hz, were tested via ANOVA among the three independent variables, both earplug ($F = 6.55, p = 0.0126$) and insertion depth ($F = 59.4, p < 0.0001$) showed significant effects at $p < 0.05$ as summarized in Table 6. The mean occlusion effect of balloon-based earplug was 17.8 dB while that of foam earplug was 14.1 dB as graphed at Figure 36. The mean occlusion effect of deeply-inserted balloon-based earplug was not as low as that of deeply-inserted foam earplug and caused its combined mean (shallow and deep) to become larger than the mean occlusion effect of foam earplug (shallow and deep). The mean occlusion effects of deeply-inserted earplugs and shallowly-inserted earplugs were 10.4 and 21.6 dB, respectively. Both Figures 35 and 37 showed the same trend of lower occlusion effect at deeper insertion depth.
Table 6. ANOVA test of 500 Hz occlusion effect: Excitation-bone vibrator and self vocal utterance, earplug-foam earplug and balloon-based earplug, insertion-deep and shallow.

<table>
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<th>F</th>
<th>p-value</th>
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</table>

*significant result at $p < 0.05$
Figure 36. The effect of earplug types on the occlusion effect measured in the 1/3 OB centered at 500 Hz. Different letters represent significant differences due to insertion depth at \( p < 0.05 \). Vertical bars indicate 95% confidence intervals about the means.

Figure 37. The effect of insertion depth of occlusion device on the occlusion effect measured in the 1/3 OB centered at 500 Hz. Different letters represent significant differences due to insertion depth at \( p < 0.05 \). Vertical bars indicate 95% confidence intervals about the means.

The ANOVA test also revealed a significant interaction effect between earplug and insertion depth \( (F = 13.2, p = 0.0005) \). Post-hoc Tukey’s HSD (honestly significant difference)
test, which tested all pairs simultaneously, was conducted. Figure 38 contains the test result along with mean occlusion effects of each sub-group. Although the mean occlusion effect of shallowly-inserted balloon-based earplug (20.8 dB) was numerically smaller than that of shallowly inserted foam earplug (22.3 dB), the two were not statistically different. The occlusion effects of both deeply-inserted earplugs, 5.9 dB for foam earplug and 14.9 dB for balloon-based earplug, were significantly different from each other as well as different from the occlusion effects of both shallowly-inserted earplugs.

![Figure 38](image)

**Figure 38.** The effect of insertion depth on the occlusion effect for both earplug types. Different letters represent significant differences at $p < 0.5$ using Tukey’s HSD test.

**Occlusion effect per excitation source across all frequencies**

The following two graphs, Figure 39 and Figure 40, are plots of the mean occlusion effects along with 95% confidence intervals grouped by excitation sources. Again, the two graphs show very similar overall trends but the self-vocal utterance graph (Figure 39) shows much wider confidence intervals. Each line on either graph represents the mean occlusion effect
of one of the five earplug types. It is important to note that the order of the magnitude of the five mean occlusion effects is the same for both excitation sources from the lowest to the largest magnitude: foam deep, balloon deep, flange, balloon shallow, and foam shallow. The occlusion effect due to the deeply-inserted foam earplug under the bone vibrator is clearly separable from the other graphed lines, exhibiting the lowest occlusion effect. The occlusion effect of the deeply-inserted foam earplug under vocal utterance is clearly less than that of others in the frequency range between 400 Hz and 1000 Hz.

The occlusion effects at frequencies lower than 400 Hz produced with vocal utterances contain considerable variation and the confidence intervals overlap each other in all cases. When subjects vocalize “EE”, there can be several factors that can cause these variations. One major factor that was discovered during preliminary experiments was that a subject can vocalize “EE” at the same SPL but at different pitches. For example, a subject can vocalize “EE” at 65 dBA across trials but certain trials can be at a higher pitch than other trials. Subjects reported that it was easier to produce same sound level when they vocalize at higher pitch. All subjects were asked to decide on the most comfortable pitch during initial practice trials and stick to the same pitch for the rest of the experiment, especially the pitch whether occluded or unoccluded. Another factor that affected SPL measurements was breathing. When subjects breathe, there was a huge jump in the measured occlusion effect SPLs below 500 Hz. Again, subjects were asked to hold their breath during the occlusion effect measurements, which lasted four seconds if the bone vibrator was used as an excitation source and two seconds if vocal utterance was used, i.e., they were asked to not take a breath while uttering “EE”. However, there were probably other unknown factors that caused relatively larger variations for the measurements below 500 Hz when the vocal utterance was used as an excitation source.
A series of one-way t-tests was performed to determine if the excitation source affects occlusion effect. The tests were separately performed for each of the five earplug types at each of the 1/3 octave bands as well as the broadband, dBZ. The results are summarized in Table 7.

The following five graphs (Figures 41-45) contain plots of the mean occlusion effects produced by each earplug with both excitation sources to determine if occlusion effects are influenced or otherwise affected by the excitation sources. The apparent visual similarities of the mean occlusion effects as a function of excitation source are confirmed with the one-way statistical analysis (t-test) results in Table 7. While occlusion effects of all five earplugs were statistically different at 4000 Hz, traditionally, it is believed that occlusion effects do not affect higher frequency sounds (Elpern, 1963). The statistically significant difference can be explained from the fact that all five occlusion effects produced with self vocal utterance were between 0 and 0.4 dB at 4000 Hz while all five occlusion effects produced with a bone vibrator were between -2.1 and -3.5 dB. The near zero dB occlusion effects produced with vocal utterances might be due to the fact that most sound energy of the vocal utterance of “EEE” would be distributed in the frequency spectrum below 4000 Hz as both first and second formant frequencies of the vowel “EEE” are less than 4000 Hz (Hillenbrand, Getty, Clark, & Wheeler, 1995). Hence it could be just that there was not enough sound energy at high frequency when vocal utterances were used as the excitation source to produce occlusion effects.

Another statistical difference was at 200 Hz with deeply-inserted foam earplugs. This difference may have been caused by one subject’s occlusion effect of -27.4 dB with vocal utterance as excitation source. An outlier test, Dixon’s Q test, of the value resulted with a Q value of 0.29 where a value of 0.41 or greater can indicate a data point as an outlier with 90% confidence (Dean & Dixon, 1951). Hence the -27.4 dB data point cannot be excluded as an
outlier. However, a t-test performed without that subject’s data, resulted in statistically insignificant differences between the two excitation sources at 95% confidence. As previously mentioned there were variations in the SPL measurements while subjects vocalize and this subject’s was one of the worst cases, especially at 200 Hz.

Figure 39. Means and their 95% confidence interval of occlusion effects of various earplugs as produced with vocal utterance.
Figure 40. Means and their 95% confidence intervals of occlusion effects of various earplugs as produced with bone vibrator.
Table 7. One-way t-test results for the effect of excitation source by earplug type, with effects which are significant at $p < 0.05$ highlighted.

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<th>250</th>
<th>315</th>
<th>400</th>
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<td>-1.58</td>
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<td>2.02</td>
<td>1.64</td>
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<td>p value</td>
<td>0.36</td>
<td>0.66</td>
<td>0.26</td>
<td>0.12</td>
<td>0.79</td>
<td>0.80</td>
<td>0.28</td>
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<td>0.23</td>
<td>0.85</td>
<td>0.86</td>
<td>0.39</td>
<td>0.82</td>
<td>0.65</td>
<td>0.51</td>
<td>0.27</td>
<td>0.00</td>
<td>0.04</td>
<td>0.06</td>
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Figure 41. Means and their 95% confidence intervals of occlusion effects of deeply-inserted foam earplugs as produced with each excitation source. (B-bone vibrator, V-vocal utterance). Statistically-significant effects from Table 8 are denoted by rectangular boxes.

Figure 42. Means and their 95% confidence intervals of occlusion effects of shallowly-inserted foam earplugs with each excitation source. (B-bone vibrator, V-vocal utterance). Statistically-significant effects from Table 8 are denoted by rectangular boxes.
Figure 43. Means and their 95% confidence intervals of occlusion effects of deeply-inserted balloon-based earplugs as produced with each excitation source. (B-bone vibrator, V-vocal utterance). Statistically-significant effects from Table 8 are denoted by rectangular boxes.

Figure 44. Mean and 95% confidence intervals of occlusion effects of shallowly-inserted balloon-based earplugs as produced with each excitation source. (B-bone vibrator, V-vocal utterance). Statistically-significant effects from Table 8 are denoted by rectangular boxes.
Figure 45. Means and their 95% confidence intervals of occlusion effects of flanged earplugs as produced with each excitation source. (B-bone vibrator, V-vocal utterance). Statistically-significant effects from Table 8 are denoted by rectangular boxes.

Occlusion effect per insertion depth across all frequencies

Figure 46 and Figure 47 are the graphs of mean occlusion effects grouped by the insertion depths. Since their values are listed at Table 2, it was not reproduced here. The four lines of deeply-inserted earplugs diverge into two in the frequency range from about 400 Hz to 1600 Hz. The occlusion effects produced with a bone vibrater and vocal utterance with deeply-inserted balloon-based earplugs group together while those of deeply-inserted foam earplugs group together in the same frequency range. The insertion depth of an earplug has been operationally defined herein as how far an earplug is inserted into the ear canal. It was expected that acoustic sealing would start from the inner most part of the earplug. In case of the foam
earplug, which expands to fill up the ear canal and acoustically seal throughout the entire contact area rather than at a single point, it is reasonable to expect the depth of insertion to be similar to the depth of inner most acoustic sealing point. The balloon-based earplugs presented an unexpected challenge in determining the insertion depth. There was simply not a clear method to determine precise depth of an insertion for the balloon earplugs since they deform as expanded and exact location/area of acoustic seal was unknown. In case of shallow insertion, the balloon-based earplug was inserted so that most the balloon was outside of the ear canal and less than half of the balloon was inserted past the aperture to create an acoustic seal. For the deep insertion, the entire balloon was inserted into the ear canal, so that the entire balloon was past the aperture. Since the inflated balloon was about 11mm in length, the insertion could have resulted in the occlusion at the 11mm point or deeper although the author could not determine the exact location of acoustic seal reliably, as the author could not see inside the occluded canal. The foam earplug was inserted until the markings made at 2mm and 11mm from the end of the earplug just disappear, for shallow insertion and deep insertion, respectively.

The graphs of mean occlusion effects produced with shallowly-inserted earplugs tended to group together more. The flanged earplug data were plotted with shallowly-inserted earplug since the occlusion or seal of the ear canal is believed to occur with the biggest flange which was positioned near the entrance of the ear canal.
Figure 46. Means and 95% confidence intervals of occlusion effects of various deeply-inserted earplugs as produced with each excitation source. (B-bone vibrator, V-vocal utterance).

Figure 47. Means and 95% confidence intervals of occlusion effects of various shallowly-inserted earplugs as produced with each excitation source. (B-bone vibrator, V-vocal utterance).
The results of \( t \)-tests that compare occlusion effects per insertion depth are shown in Table 8. The next two graphs (Figure 48 and 49) show the mean occlusion effects of deeply-inserted and shallowly-inserted balloon-based earplugs. Both graphs show similar visual trends that occlusion effects are different in the 500 Hz - 1600 Hz range as a function of insertion depth. Occlusion effects produced with shallowly-inserted balloon-based earplugs were larger than that of deeply-inserted balloon-based earplugs. The numerical differences of the occlusion effects ranged from the maximum of 6.4 dB at 1000 Hz to the minimum of 3.6 dB at 500 Hz when a bone vibrator was used. The differences ranged from the maximum of 11.6 dB at 800 Hz to the minimum of 4.0 dB at 1250 Hz when a vocal utterance was used as the excitation source. At the frequencies below 500 Hz and above 1600 Hz, both deeply-inserted and shallowly-inserted balloon earplugs produced similar occlusion effects.
Table 8. *t*-test of occlusion effects across different 1/3 octave bands and at broadband dBZ as produced with shallowly-inserted and deeply-inserted earplugs performed for balloon-based earplug and foam earplug.

<table>
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<th>Frequency (Hz)</th>
<th>dBZ</th>
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<th>160</th>
<th>200</th>
<th>250</th>
<th>315</th>
<th>400</th>
<th>500</th>
<th>630</th>
<th>800</th>
<th>1000</th>
<th>1250</th>
<th>1600</th>
<th>2000</th>
<th>2500</th>
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<td>-0.59</td>
<td>-0.46</td>
<td>-1.18</td>
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<td>0.035</td>
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<td>0.000</td>
<td>0.001</td>
<td>0.004</td>
<td>0.130</td>
<td>0.809</td>
<td>0.772</td>
<td>0.562</td>
<td>0.648</td>
<td>0.244</td>
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<td>1.03</td>
<td>2.27</td>
<td>3.05</td>
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<td>2.87</td>
<td>4.81</td>
<td>7.67</td>
<td>6.46</td>
<td>6.34</td>
<td>6.04</td>
<td>6.56</td>
<td>4.39</td>
<td>3.17</td>
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<td>0.012</td>
<td>0.007</td>
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<td>&lt;.0001</td>
<td>&lt;.0001</td>
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<td>0.223</td>
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Figure 48. Means and 95% confidence intervals of occlusion effects of deeply and shallowly-inserted balloon-based earplugs as produced with a bone vibrator as excitation source.

Figure 49. Means and their 95% confidence intervals of occlusion effects of deeply and shallowly-inserted balloon-based earplugs as produced with vocal utterance as excitation source.
The next two graphs (Figure 50 and 51) show the mean occlusion effects of deeply-inserted and shallowly-inserted foam earplugs. Both graphs show similar visual trends that occlusion effects are different at frequencies in the spectral range below 2500 Hz range. Again, occlusion effects produced with shallowly-inserted foam earplugs were larger than occlusion effects produced with deeply-inserted foam earplug. The numerical differences between the occlusion effects produced with deeply- and shallowly-inserted foam earplugs ranged from 14.3 dB at 500 Hz to 3.4 dB at 2000 Hz when a bone vibrator was used as the excitation source. The difference ranged from 18.7 dB at 500 Hz to 6.1 dB at 2000 Hz when a vocal utterance was used as the excitation source to produce occlusion effects.

The results of $t$-tests at Table 8, confirms the analysis based on visual inspection. The foam earplugs produced statistically different occlusion effects at frequencies below 2500 Hz except 125 Hz. The balloon earplugs produced statistically different occlusion effects at 500 Hz ~ 1600 Hz.

The occlusion effects calculated over the entire acoustic spectrum (dBZ) were statistically different at $p < 0.05$ for both balloon earplugs and foam earplugs. The occlusion effects calculated over dBZ produced with shallowly-inserted earplugs were larger than that produced with deeply-inserted earplugs. In case of the balloon-based earplug, the occlusion effect of shallow insertion was 4.6 dB higher than that of deep insertion when a bone vibrator was used as an excitation source. The difference was 5.7 dB when a vocal utterance was used instead. The numerical differences of mean occlusion effects of foam earplugs were 7.6 dB and 11.4 dB when they were produced with either the bone vibrator or the vocal utterance, respectively.
Figure 50. Means and 95% confidence intervals of occlusion effects of deeply and shallowly-inserted foam earplugs as produced with bone vibrator as excitation source.

Figure 51. Means and 95% confidence interval of occlusion effects of deeply and shallowly-inserted foam earplugs as produced with vocal utterance as excitation source.
Occlusion effect per earplug type at shallow insertion depth

The means of occlusion effects produced with different earplugs were compared and the results are summarized in Table 9. For this comparison, the shallowly-inserted foam earplug and balloon earplugs were selected because the shallow insertions of the two earplugs were more consistent in insertion depth than that of the deeply-inserted earplugs. The means test concluded that there is not a significant difference at $p < 0.05$ in the means of occlusion effect due to earplug type with either excitation source. These data are depicted in prior Figure 42 and 44.
Table 9. *t*-test of occlusion effects across different 1/3 octave bands and at broadband dBZ as produced with balloon-based earplugs and foam earplugs, both earplugs are inserted shallowly, performed for both excitation sources.

| Frequency (Hz) | dBZ | 125 | 160 | 200 | 250 | 315 | 400 | 500 | 630 | 800 | 1000 | 1250 | 1600 | 2000 | 2500 | 3150 | 4000 | 5000 | 6300 | 8000 |
|---------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|------|------|------|------|------|
| **Bone vibrator** | | | | | | | | | | | | | | | | | | | | | | |
| t Ratio       | -0.01 | 0.52 | 0.63 | 0.75 | 1.33 | 1.28 | 1.08 | 0.79 | -0.36 | -0.46 | -0.99 | -0.29 | -0.26 | 0.19 | 0.36 | 0.04 | 0.46 | -0.01 | 0.38 | 0.32 |
| df           | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  |
| p-value      | 0.99 | 0.61 | 0.54 | 0.46 | 0.20 | 0.22 | 0.29 | 0.44 | 0.72 | 0.65 | 0.34 | 0.77 | 0.80 | 0.85 | 0.72 | 0.97 | 0.65 | 0.99 | 0.71 | 0.75 |
| **Vocal utterance** | | | | | | | | | | | | | | | | | | | | | | |
| t Ratio       | 0.90 | -0.20 | 0.25 | 1.23 | 0.18 | 0.92 | 1.19 | 0.45 | 0.55 | -1.30 | -0.23 | -0.12 | -0.26 | -0.05 | -0.07 | 0.32 | 1.75 | 1.31 | 1.25 | 1.15 |
| df           | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  | 18  |
| p-value      | 0.38 | 0.84 | 0.80 | 0.23 | 0.86 | 0.37 | 0.25 | 0.66 | 0.59 | 0.21 | 0.82 | 0.90 | 0.79 | 0.96 | 0.94 | 0.76 | 0.10 | 0.21 | 0.23 | 0.26 |
ANOVA test of occlusion effect per combined earplug types and frequencies

By combining each insertion depth with each of the foam and balloon-based earplug and considering them as a single variable “earplug&depth” effectively changed the experimental design from a partial factorial design to a full factorial design. This change leads to a series of ANOVA test on the entire data set. The new earplug&depth variable had these levels: balloon-deep, balloon-shallow, foam-deep, foam-shallow and flange. Bone vibrator and vocal utterance were the two levels of excitation sources.

Table 10 lists all the p-values of main effects of excitation source and earplug&depth as well as their interactions. Means of occlusion effects per each level of excitation sources and each level of earplug&depth are listed in Table 11 where bold numbers indicate the statistically-significant differences between levels. The main effect of earplug&depth was significant at the frequencies between 400 Hz and 2000 Hz. The main effect of excitation source was significant at low frequencies below 250 Hz and at frequencies higher than 2500 Hz. Moreover, earplug&depth, which was created by combining earplug and insertion depth, confounded their effects as well. Hence, further analysis was not performed.
Table 10. ANOVA test results per each 1/3 octave band frequencies between 125 Hz and 8000 Hz, and over entire spectrum.

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<th>excitation sources</th>
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<th>&lt;.0001*</th>
<th>0.789</th>
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<tr>
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<td>315 Hz</td>
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<td>0.633</td>
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<td>630 Hz</td>
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<td>0.957</td>
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<td>&lt;.0001*</td>
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<td>1.00kHz</td>
<td>0.179</td>
<td>&lt;.0001*</td>
<td>0.676</td>
<td></td>
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<tr>
<td>1.25kHz</td>
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<td>&lt;.0001*</td>
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<tr>
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<td>0.770</td>
<td>&lt;.0001*</td>
<td>0.964</td>
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<tr>
<td>2.00kHz</td>
<td>0.995</td>
<td>0.000*</td>
<td>0.842</td>
<td></td>
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<tr>
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<td>0.297</td>
<td>0.090</td>
<td>0.772</td>
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<tr>
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<td>0.353</td>
<td>0.825</td>
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<tr>
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<td>&lt;.0001*</td>
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<tr>
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<td>0.000*</td>
<td>0.632</td>
<td>0.797</td>
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<tr>
<td>8.00kHz</td>
<td>0.005*</td>
<td>0.356</td>
<td>0.795</td>
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*statistically significant at $p < 0.05$
Table 11. Mean occlusion effects of each level of excitation sources and each level of earplug&depth. Bold numbers denote statistically-significant differences listed at Table 10.

<table>
<thead>
<tr>
<th>excitation sources</th>
<th>earplug&amp;depth</th>
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<tr>
<td>dBZ</td>
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<tr>
<td>1.5</td>
<td>6.1</td>
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<tr>
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<tr>
<td>6.2</td>
<td>-2.5</td>
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<td>6.8</td>
<td>6.1</td>
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</table>

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Investigation 3

REAT tests per ANSI S3.19-1974 were conducted to determine Noise Reduction Ratings (NRR) of both the Peltor H10A earmuff and balloon-based earplug. This was the current prevailing test requirement at the time of this study, as required by the United States Environmental Protection agency (EPA). One deviation from the standard was that the tests were conducted monaurally, meaning only the left ear was tested both open and occluded. The right ear was occluded at all times with a Classic foam earplug and a Peltor H10A earmuff, which provided more attenuation than the single earplug or muff under test in the left ear. The decision to use monaural testing was arrived at due to the fact that balloon-based earplugs did not inflate to same sizes under the same pressure. The balloon-based earplug yielded an NRR of 10 while the Peltor H10A muff yielded an NRR of 24. Obviously with this result of an NRR of 24 for the Peltor muff by itself, the combination of it with the foam earplugs in the non-test ear was more than sufficient to well exceed the attenuation of the single earplug (or single muff) under test in the opposite ear.

From the REAT test results, Figure 52 depicts the mean attenuations and their standard deviations for the 10 subjects for both Peltor H10A and balloon-based earplug tested monaurally. As the spectral means indicate, the attenuation of the balloon-based earplug is much weaker than that of the Peltor H10A at all frequencies except 125 Hz and 250 Hz. One interesting fact is that the attenuation plot of the balloon-based earplug is relatively flat across the frequencies. So-called Musician’s Earplugs™ such as ER•9, ER•15, ER•20 and ER•25 from Etymotic Research, Inc., also provide relatively flat attenuations across frequencies, but these devices have special passive acoustical fitting networks, unlike the balloon-based earplug. Among these earplugs, ER•20 is a mass production product while the others are custom made earplugs for each
individuals. Hence the attenuation means and their standard deviation data are graphed in the Figure 52 for comparison. The ETY•Plugs™ ER•20 high-fidelity earplugs by Etymotic Research Inc. shows somewhat linear attenuations across the frequencies as shown in Figure 52. The published NRR of ER•20 earplugs is 12 dB which is comparable to the 10 dB NRR of the balloon-based earplug.

Figure 52. Attenuation means and standard deviation per 1/3 octave bands for monaural Peltor H10A muff and monaural balloon earplug; testing per ANSI S3.19-1974 REAT protocol, except monaurally. The attenuation means and their standard deviation of ETY•Plugs™ is also plotted.
CONCLUSIONS

Investigation 1

The first question in this research on occlusion effects of ear inserts was to decide on the measurement protocol of monaural measurement vs. binaural measurement. Since a human body is not perfectly left/right symmetrical, the question of left ear vs. right ear can arise if a monaural measurement protocol is selected without knowledge of bilateral symmetry. Investigation 1 was conducted for these reasons and it concluded that the SPL measured in the left ear canal is not statistically different from that of the right ear canal at a $p < 0.05$. The $t$-test results, i.e. no left-right ear differences, were the same for both excitation sources of bone vibrator and self vocal utterance. The SPL was measured over both broadband (dBZ) and 1/3 octave band centered at 500 Hz. Both $t$-tests, conducted with each of the two SPL measurements, resulted in the same conclusions. Hence the bottom-line conclusion from investigation 1 was that a simple one-ear measurement method would suffice in lieu of two-ear occlusion effect measurements, and the selection of the particular measurement ear should not matter. Investigation 2 experiments were subsequently conducted with left ear only measurements.

Investigation 2

The second research objective of this study was the investigation of occlusion effects of new medical balloon-based earplugs as compared to conventional passive earplugs as well as influences of the earplug insertion depth and the excitation sound stimuli on the occlusion effect. Exclusion of the flanged earplug data set changed the experimental design of investigation 2 to a full factorial design of 2 (two levels of insertion depth of the earplugs) X 2 (two levels of excitation sources) X 2 (two levels of earplugs). The two levels of earplugs were then foam
earplug and balloon-based earplug. The two levels of excitation sources were forehead-mounted bone vibrator and self-vocal utterance of “EEE”. The two levels of insertion depth were shallow at 2mm and deep at 11mm from the aperture.

Conclusions from dBZ data

The ANOVA test of occlusion effects measured over broadband (dBZ) revealed that only insertion depth had a significant main effect at $p < 0.05$. The mean occlusion effect of shallowly-inserted earplugs was higher than that of deeply-inserted earplugs by 7.5 dB. Since the SPL measured over dBZ is a linear summation of entire frequency spectrum, the occlusion effect measured over dBZ includes both positive occlusion effects at low frequency spectrum and negative or near-zero occlusion effects at high frequency spectrums. Although the dBZ data did show overall occlusion effect of entire frequency spectrum, it is important to investigate occlusion effects measured at narrow frequency bands, because the general consensus about the occlusion effect is that amplification of low frequency components is most prominent.

Conclusions from 1/3 OB centered at 500 Hz data

The ANOVA test of occlusion effects measured over a 1/3 octave band centered at 500 Hz showed that both insertion depth and earplug type had a significant effect at $p < 0.05$. The effect of the insertion depth was larger at “shallow” insertion as was found in the ANOVA on dBZ data. The mean occlusion effect of shallowly-inserted earplugs was 21.6 dB while that of deeply-inserted earplug was 10.4 dB. Both the magnitudes of individual occlusion effects and their differences are greater than those of dBZ data. This result is somewhat expected since dBZ data represent average of entire frequency spectrum which includes high frequency bands where occlusion effects were either zero or even negative. The significant effect of earplug type was
both expected and unexpected. It was expected that the magnitude of the occlusion effect would be different for each earplug type. However, the expectation was that the balloon-based earplug would produce a lower occlusion effect than the foam earplug would, based on the prior study (Keady & Casali, 2009). The mean occlusion effect of the foam earplug was 14.1 dB while the balloon-based earplug produced a mean occlusion effect of 17.8 dB. This difference of 3.7 dB is mostly due to the differences of the mean occlusion effects of the two types of earplugs when deeply inserted, as explained further below.

Also, the ANOVA test showed a significant interaction effect between insertion depth and earplug type \( p < 0.05 \). Subsequent post-hoc Tukey’s HSD test among the four groups showed three statistically different groups: deeply-inserted foam earplug, deeply-inserted balloon-based earplug, and both shallowly-inserted earplugs, in the order of the smallest occlusion effect to the largest. Shallowly-inserted foam earplugs and balloon-based earplugs produced the largest level of occlusion effects (22.3 dB and 20.8 dB, respectively), and these were statistically not significant from each other. Deeply-inserted balloon-based earplugs produced a higher mean occlusion effect of 14.9 dB while deeply-inserted foam earplugs produced a mean occlusion effect of 5.9 dB. Even though the insertion depth of balloon-based earplugs might not have been as consistent across trials as that of foam earplugs, this statistically-significant difference suggests that earplug material and/or construction can influence the occlusion effect. The contact area of a balloon-based earplug will change as the insertion depth of the earplug changes. At the “shallow” insertion in this study, the contact area would have been closer to a narrow-width circle; at the “deep” insertion, the contact area would have been closer to a cylinder. This difference might have resulted in smaller dB differences between occlusion effects of different insertion depth of the balloon-based earplugs.
Although the excitation source, a forehead-mounted bone vibrator and self vocal utterance, did not have a significant influence on the occlusion effect, the measured occlusion effects as produced with the bone vibrator showed smaller confidence intervals as shown in Table 2. For example, the 95% confidence interval based on the $t$-distribution of occlusion effects of deeply-inserted foam earplug as produced with the bone vibrator was 4.4 dB while that of self vocal utterance was 9.8 dB. Since the means of occlusion effects produced with both excitation sources were not different, the use of the bone vibrator would be preferable in a future study, as it would be more comfortable for the subject who would just be sitting still for the measurement and the resulting data would contain less variation due to unknown factors.

Occlusion effect per excitation source across all frequencies

A series of $t$-tests to compare the two excitation sources was conducted for each earplug at each insertion depth across all frequencies. All five earplug and insertion depth combinations showed statistical differences at 4000 Hz and some of them showed statistical differences at 5000 Hz and 6300 Hz as well. However, it is very likely that these differences are not practically significant. The mean occlusion effects measured at 1/3 OB centered at 4000 Hz was 0.1 dB when vocal utterances was used as the excitation source and the mean was -2.6 dB when the bone vibrator was used instead. The author suspects that vocal utterance of “EEE” did not have enough sound energy at the frequency region of 4000 Hz and higher, and thus resulted in near zero dB occlusion effects. The fact that the first and second formant frequencies of the vowel “EEE” are about 400 Hz and 2500 Hz (Hillenbrand et al. 1995), respectively, supports the author’s suspicion.

The $t$-test of the occlusion effects produced with deeply-inserted foam earplugs measured over the 1/3 OB centered at 200 Hz showed a statistical difference. The other $t$-tests at 200 Hz
did not show statistical differences. Also, the statistical difference was caused by a single subject’s data which exhibited one of the worst variations, as previously discussed. Moreover, both $t$-tests on the mean occlusion effects, across all earplugs and insertion depths, measured over dBZ and 1/3 OB centered at 500 Hz did not show significant effects.

*Occlusion effect per insertion depth across all frequencies*

Since the flanged earplugs were not inserted at two insertion depths, their data was excluded from this analysis. The shallowly- and deeply-inserted foam earplugs produced occlusion effects that were statistically different at the frequencies between 125 Hz and 2500 Hz. However, the occlusion effects produced with either shallowly- or deeply-inserted balloon-based earplugs were statistically different at the frequencies between 400 Hz and 2000 Hz. Since the insertion depth was a well-known factor that impacts the occlusion effect, statistical differences were expected. The unexpected result was that balloon-based earplugs did not produce statistically significant occlusion effects at low frequencies below 500 Hz regardless of the insertion depth. It might be possible that the vibration of soft tissues of the ear canal conducted through bone conduction is transmitted via the balloon membrane and gets radiated into the cavity between the earplug and the tympanic membrane. The same vibration would be damped and disappear if a foam earplug was deeply inserted. However, further research and experiment should be conducted to clearly answer this question.

*Occlusion effects per open-vent balloon vs. closed-vent balloon*

Post-experiment, it was realized that the balloon earplug configuration, as used for *Investigation 2*, the occlusion effect study, contained an open vent. During the experiment the author did not notice that there were two vents that needed to be blocked: one vent for the air
passage to the balloon and another pass-thru vent that runs along the stem. The author was only concerned with the vent that allowed air passage to the balloon. Hence all the occlusion effect measurements were conducted with balloon earplugs that had an open vent. To determine if the unintended open vent affected the occlusion effect measurements, an additional experiment was conducted. The occlusion effects were measured from each of the three subjects while they vocalized “EE” at 65 dBA measured 1 foot from their mouth. The experimental apparatus was the same as the one used in Investigation 2 for vocal utterance. Both open-vent and close-vent balloons were inflated to 1.4 bar (absolute). The results were 18 SPL measurements per 1/3 OB with center frequencies from 125 Hz to 8000 Hz (nine SPL with open-vent balloons and nine with close vent balloons). Since the purpose of the experiment was to determine if the open vent of a balloon earplug affected its measured occlusion effects or not and the fact that each subject produced three pairs of occlusion effects (open vent and close vent), a paired t-test rather than regular t-test was selected to analyze the data. Matched pair analysis (JMP version of paired t-test) did not produce any statistically significant differences except at 4000 Hz and 5000 Hz. However, the mean differences were 0.7 dB at 4000 Hz and 0.2 dB at 5000 Hz. These differences are not practically significant. Hence, the author concludes that the open vent of the balloons did not appreciably affect the measured occlusion effects. One possible explanation is that the vent might have been collapsing as air pressure built up, resulting in effectively closed vent balloon.

Investigation 3

A monaural REAT test of the balloon-based earplug per ANSI 3.19-1974 produced an NRR of 10 dB while a Peltor H10A earmuff produced an NRR of 24 dB. Clearly, the balloon-based earplug did not prove to be a particularly high attenuation device. However, one
interesting finding was that the attenuation level of the balloon-based earplug was rather flat across the frequencies, much similar to that of a musicians earplug™ (Killion, Stewart, Falco, & Berger, 1992). This finding points to its potential utility for applications wherein the pitch perception of sound is important.

**Implications**

When measuring the occlusion effect via the SPL difference in the ear canal, use of a bone vibrator over self vocal utterance will be preferable since the two excitation sources produced occlusion effects which were statistically nonsignificant in this dissertation study, and the occlusion effects produced with the bone vibrator showed smaller variations across different subjects. Also, if a researcher is trying to measure occlusion effects across all frequencies, white noise could be a better choice than pink noise since white noise contains more energy at higher frequency octave bands where greater attenuation occurs when sound travels via bone/body-conduction pathway.

Earplug materials and/or structures might cause frequency dependent occlusion effects that are different from those of a foam earplug since the occlusion effects of balloon-based earplugs was greater by 3.7 dB than that of foam earplugs at 500 Hz. The difference could have been due to the transmission of the canal-radiated sound wave by the balloon-based earplug membrane, while a foam earplug could have absorbed the wave. Another possible explanation could be that a foam earplug, inserted and expanded inside the ear canal, exerts constant radial pressure on the ear canal surface and stiffens the whole system while a balloon-based earplug, since it is a variable volume balloon, would expand further and exert less pressure to the ear canal and result in less stiff system. Further research to investigate underlying principles is discussed in detail at the Recommendations section.
The balloon-based earplugs exhibited flat attenuations across frequencies unlike conventional earplugs, which exhibit relatively lower attenuations at lower frequency bands than does at higher frequency bands. The only other commercial earplugs that exhibit similar flat attenuation are Musician’s Earplugs™ from Etymotic Research Inc. that are built with specially designed mechanical filters. It would be interesting to compare how this relatively simple uniform-structure balloon-based earplug (compared to the complex structure of the Musician’s Earplug), performs against the Musician’s Earplugs™ in both attenuation and art.

Unlike most conventional earplugs, a user will typically use a technique of inserting a balloon-based earplug into the ear canal while it is deflated and s/he will inflate it after it’s placed in the ear canal. The ease of insertion combined with comfort of balloon-based earplugs can result in higher acceptance rate by the users and possibly more users will wear them properly. Since higher acceptance rate and proper fitting of a hearing device are the two most important factors in proper hearing protection, balloon-based earplugs might provide better hearing protection.
RECOMMENDATIONS FOR FURTHER RESEARCH

While insertion depth was confirmed as a factor with a significant effect, the insertion depth of balloon-based earplugs was not possible to control as was the case of foam earplugs. Development of protocols/instrumentation that can clearly determine insertion depth of a balloon-based earplug will be a great help for any future research on this subject. Use of a stopper device, such as a flange, on the stem of a balloon-based earplug could be one solution to better estimate the insertion depth. Reliable determination of insertion depth will enable researchers to separate the effect of insertion depth from that of the earplug type and will lead to more informed conclusions.

Balloon-based earplugs did not produce occlusion effects that were significantly lower than what foam earplugs produced, as was expected from a preliminary study. The major change from the preliminary study to this study was change of balloon material and its construction. Since the data came from two separate experiments with different protocols (albeit very similar ones), it is not be possible to directly compare the results. Hence, the natural next stage of research could be a comparison of balloon materials’ effects. Medical balloon-based earplugs can be made with many different materials such as silicone, nylon, nylon elastomers, polyurethane, and polyethylene terephthalate (PET). Balloon thickness could be another variable that might affect the occlusion effect. Another extension would be the shape of balloon-based earplugs. Unlike the foam earplugs, balloon-based earplugs can also be made as non-compliant balloons. The shapes can be sphere, cylinder, concave, and convex. While foam earplugs can be shaped as a sphere when compressed and inserted into the ear canal, it is not possible to control its shape after expansion in the ear canal. The non-compliant medical balloon-based earplugs will maintain its shape even after its insertion into the ear canal and subsequent inflation. With
different shaped balloon-based earplugs, it will be possible to determine if the shape has any effect on the occlusion effect. The pressure of a balloon-based earplug is another possible variable to consider. Balloons can be either constant volume or variable volume. A constant volume balloon will not expand beyond predetermined dimension and additional air injection will mostly result in increased pressure. A variable volume balloon will continue to expand beyond initial inflation and it will deform to comply with the ear canal shape. Additional air injected into a variable volume balloon will result in increased volume and/or pressure. Hence, the effect of air pressure on the occlusion effect can be different depending on the type of balloon-based earplug.

The possibility of occlusion effect’s interference with one’s situation awareness was touched on in the background section. However, the author did not conduct any experiment to investigate that application further as it is well beyond the scope of this dissertation. However, human factors research that investigates the relation of occlusion effect of occluding device and the user’s performance level could be very interesting and important for certain groups of people such as soldiers. For instance, soldiers in a reconnaissance mission will need to maintain clear situation awareness however the occlusion effect can interfere with their perception and degrade the level of situation awareness. The soldiers will need to be aware of their voice level when they whisper to each other; however, this could be difficult when their ears are occluded with earplugs or a communication headset since the occlusion will alter their perception of own voices. The occlusion will also enhance the bodily-generated sounds (heart beat etc) and can interfere with situation awareness. All these interferences will likely increase the mental workload of the soldiers whose performance level might deteriorate. One possible research objective can be aimed at determining the relationship between the level of occlusion effect and the level of
mental workload or performance. Another possible research topic can be to determine the effects on one’s own voice modulation of output, e.g. whispering, under the different ear canal occlusion settings.

Subjective rating is another important future topic. Since the subjective rating of occlusion effect is not generally performed, there is not a standard or generally agreed upon methodology. It might be necessary to produce a new methodology to screen subjects prior to the actual experiment. Another possible challenge could be remembering how his/her own voice sounded under various occlusions. The native language of each subject might also affect how he or she perceives a test sentence that will likely be in English.

In a study that compares subjective ratings and objective measurements, these issues should be considered. Since most subjects would not likely have “consciously” compared their natural voice and occluded voice, it will be necessary to have them rehearse several times both occluded and unoccluded conditions and ask them to remember how their voices sound like under each condition. Also, the questionnaire should contain several questions that are redundant in nature but posed differently. The entire experiment should be designed so that it can be done while the subjects retain initial references, which were created with several practice readings with and without earplugs.

Objective measures such as formant frequencies of each subject can be used to better predict individual subjective rating of the occlusion effects. Occlusion effects measured at the formant frequencies of each subject might be better predictors of each subject’s subjective ratings since it will be the frequency that affects the subject the most. Another seemingly important variable that has not been investigated is degree of jaw opening or jaw stiffness. Since the resonant frequency of the lower jaw of a person is about 200 Hz and it changes as a subject
either opens or closes his/her mouth, it will be interesting to investigate occlusion effects as a function of jaw opening. Both of these objective measurements can be used to better predict subjective ratings of each subject. While only the 1/3 octave band centered at 500 Hz was analyzed for occlusion effects, the other 1/3 octave bands might provide different explanations and should be investigated in any future studies.
REFERENCES


APPENDIX A

APPENDIX A - PRE-EXPERIMENTAL SETUP AND CALIBRATION
Pre-Experimental Setup and Calibration (in the lab):

1. The sound system is setup such that the laptop audio output (pink noise source) is connected to the audiometer TAPE INPUT JACK and the BONE OUTPUT JACK connected to the Vibrator.
2. The laptop audio output (pink noise source) is split and also connected to the amplified loudspeaker such that the pink noise stimulus is available for acoustical output.
3. The #1 channel, preamp input, of the LD 3200 analyzer is connected to the ½-inch LD 2559 measurement mic.
4. The Quest calibrator is set to 94 dB output, 1000 Hz is placed over the ½-inch LD 2559 mic and turned on. The analyzer’s #1 channel is then set for calibration to 94 dB at 1000Hz via SYSTEM/UNITS/LEVEL being set to read 94.0 dB.
5. A 3068 probe mic with probe tube is then connected to the #2 channel direct line input of the LD analyzer via the junction box for the leads from the 3068 mic. The probe mic’s tube is then aligned in a plane with the O-ring stop flange inside the Quest calibrator and the index finger is used to firmly seal the chamber at the top, taking care not to compress the probe tube. Then, for the probe tube mic, the #2 channel of the LD analyzer via SYSTEM/UNITS/LEVEL is set to read 94.0 dB, in like fashion to the ½-inch measurement mic setting on #1 channel.
6. The LD 800B SLM with its ½-inch microphone is set to the calibration settings specified on the housing of the SLM. Then, it is calibrated by placing the Quest calibrator over the mic and the SLM adjusted to readout 93.8 dB. The LD 800B is then set to RANGE=90, FAST, A-scale, CONT.
7. The laptop-produced pink noise is controlled through the system volume control 3 units lower from the max output.
8. Calibration of the Radioear B70-A vibrator normally requires an artificial mastoid. As an alternative method, the pink noise from the laptop, as input to the Beltone Audiometer (TAPE INPUT), and then output from the audiometer (which can then be controlled in dB steps on the audiometer) will be input to the Radioear vibrator that is held on the experimenter’s forehead tightly by the Huggies headband. Then, the audiometer’s output control (and speech gain if necessary) are adjusted such that the LD reads out 75 dBLinear from the probe tube as mounted in the subject’s ear. This is comfortable but clearly audible for the listener. This gain/attenuation setting combination will then be used as the starting point for each subject, and readjusted as necessary to produce 75 dBLinear for each subject.
9. The audiometer will have the Vibrator connected to the BONE OUTPUT with TAPE INPUT, while the R and L channels of the audiometer will be connected to the earphones so that a brief hearing test can be conducted at 1000 Hz.
10. The audiometer’s attenuator setting for the Vibrator output will be noted and recorded, and then the ATTENUATOR will be set to 0 dBHL, the FREQUENCY set to 1000 Hz, the INPUT set to TONE, NORMALLY OFF, and the OUTPUT set to EARPHONE.
11. For REAT testing, equalize the loudspeakers in the reverberation chamber at 1000 Hz using the Norwegian Electronics 828 HPD testing system, Equalization menu under Level equalization menu. Following the instructions on the screen, sound level measurements should done as a 30 seconds Leq at 1/3 octave band centered at 1000Hz.
Detailed Experimental Steps

Practice for Vocal Utterance and Ratings; Vibrator Fitting (in the lab):

1. Analyzer is setup to do Vibrator calibration as follows: NORMAL, #2 channel direct input, dotted cursor at 1000 Hz, 1/8-sec response, SUM (dBllinear), Range=100dB, SUBJ#, data cleared via RESET button.


3. EXP states: “Next, I will fit this Vibrator device on your forehead, using a headband. This device will be used a few times during the experiment to emit a small vibration that you can hear, and it is completely safe and made for this purpose. Let me know if you experience any discomfort at any time.” SUBJ is shown and then fit with the Radioear vibrator using the headband, with the transducer foot placed centrally on the forehead.

4. SUBJ is shown the “thermometer” dB scale of the vertical indicator on the LD 800B sound level meter. EXP states: “Now, it is most important that I show you how to speak the sound ‘EEE’ consistently, holding it for at least 3 seconds each time, such that the loudness of your voice comes up to the line on this scale. It is very important that you look at the scale and hold your voice to the line consistently, because I will ask you to do it many times during the experiment.” EXP speaks to demonstrate how to vocalize “EEE” to a level of 65 dBA consistently, as shown by the peak value reached on the indicator.

5. With both ears open, SUBJ is asked to vocalize “EEE” to a level of 65 dBA as indicated on the “thermometer” dB scale, until he can do this consistently (+/- 1.5 dB) 3 times. The 65 dBA is indicated by a line of tape adhered to the SLM so that the subject can easily see the desired level. This is to provide the subject the experience of vocalizing while unoccluded in the test ear.

6. SUBJ is then briefly shown the 2 rating scales that will be used: #1) to compare his/her perceived voice level w/o the insert to w/ the earpiece; #2) to rate the subjective impressions of each earpiece immediately after being tested with it.

7. EXP states: “We want you to be familiar with these two rating scales, because we will be asking you to provide ratings after each short test. In each case, we want you to provide your first impression, based upon the ear insert that you just experienced.”

Probe Tube Fitting and Vibrator Calibration (in the lab):

8. EXP ensures probe tube is firmly attached to 3068 microphone that has already been calibrated and checks connection to junction box and LD 3200 analyzer direct line input, #2 channel.

9. EXP states: “I am going to now place this flexible tube into your ear, and when it just touches your eardrum, tell me and I will then back it out slightly so that it is comfortable. It may tickle a little, but it is
designed for this purpose and will not hurt your ear. Of course, please tell me if there is any discomfort at any time.”

10. Once probe tube touches eardrum, EXP pulls it about 2mm back out, runs the leads through the tragal notch, and tapes the microphone leads to the skin below the ear so that it will not slide when the earpieces are inserted.

11. EXP states: “Next, I will turn on the Vibrator to test it. You should hear and feel the sound. Pink noise is turned on, analyzer is set on NORMAL and is R/S; readout should be 75 dBlinear; if not, adjust output on audiometer to readout 75 dBlinear. DO NOT RECORD LEVEL--for calibration only.

12. Analyzer is reconfigured to do actual measurements as follows: Leq, #2 channel direct input, dotted cursor at 1000 Hz, 1/8-sec response, SUM (dBlinear), Range=100dB, SUBJ#, data cleared via RESET button.

13. EXP types in code for trial as identifier: SUBJ#gender, O=open, M=muff only, CVpressure, BF, CP, CF, trial#, U or V (utterance or vibrator)

Initial Open Ear (with Muff) Measurement

14. EXP then states: “Now, I am going to place just an earmuff over your ears again. Let me know if you feel any movement of the microphone tube in your ear.” EXP carefully places earmuff over ears and over leads.

15. EXP states: “Now, when I give you this hand signal (thumb up), vocalize the sound “EEE”, trying to make the light on the meter hit the line at 65 as I showed you before and keeping your voice at that level for 3 seconds.”

16. On hand signal from EXP, SUBJ utters EEE, and EXP observes LD 800B reading to determine subject’s voice level and EXP starts and stops analyzer to obtain 2-sec (approx) Leq. Repeat until 65 dBA +/- 1.5 dB is achieved, then EXP STORES and PRINTS this trial. (OPEN TRIAL 1) SUBJ#gender, O=open, trial#, U

17. On hand signal from EXP, SUBJ utters EEE, and EXP observes LD 800B reading to determine subject’s voice level and EXP starts and stops analyzer to obtain 2-sec (approx) Leq. Repeat until 65 dBA +/- 1.5 dB is achieved, then EXP STORES and PRINTS this trial. (OPEN TRIAL 2)

18. EXP then states: “Now, I am going to very briefly turn on the forehead vibrator and take a measurement. Do not be startled by the vibration, which will not be loud.”

19. EXP then turns ON the pink noise source and the Vibrator, with the audiometer set to SPEECH GAIN=marker, ATTENUATOR=55 dBH, FREQUENCY=OFF, INPUT=TAPE, NORMALLY OFF, OUTPUT=BONE. Vibrator is left on, via audiometer control, for not more than 4 seconds while next step (measurement) is performed.

20. EXP then starts and stops analyzer to obtain 4-sec (approx) Leq. EXP STORES and PRINTS this trial. SUBJ#gender, O=open, trial#, V. (Only 1 occluded ear Vibrator trial per earpiece is obtained.)

21. EXP then turns OFF the pink noise and the Vibrator.

22. EXP then states: “Now, please say the following sentence, paying particular attention to how your own voice sounds in your ears right now while your ears are open.” “My full name is [say your name] and I live
in the town of [say the town]. I am participating in an experiment about how wearing earphones makes my own voice sound.” EXP hands SUBJ the index card with this sentence printed on it for referral.

23. EXP then gives the SUBJ the **Subject’s Own Voice Perception Rating Scale** (attachment) for voice perception.

**Occluded Earpiece Measurement**

24. EXP then states: “Now, please allow me to gently insert the test earpiece in your test ear. Please tell me if there is any discomfort at any time.”

25. EXP then inserts the test earpiece, taking care not to dislodge the probe tube mic. (For balloon, the pressure tube is taped in the approximate position he/she thinks the earpiece will be when inflation tests are run.) Probe tube mic function and position is re-checked at this point for each earpiece under test. FOR classic foam earplug and premolded tri-flange earplug, GO TO STEP 30.

26. FOR balloon ONLY: EXP then states: “Now, we are going to make sure the earpiece is sealed, to do that we will need to inflate the system. We are going to play noise out of a loudspeaker and we will increase the pressure until we have determined that the earpiece has sealed, then take the seal pressure value. During the procedure if at any time you feel pain or discomfort raise your hand and let us know. You should know that during this entire experiment we will not be exceeding design safety pressure values.”

27. FOR balloon ONLY: EXP changes analyzer (on #2 channel) to NORMAL. EXP turns on the pink noise through the loudspeaker and EXP starts analyzer to determine seal point, as EXP increases pressure. DATA IS NOT RECORDED -- simply used to confirm seal. EXP changes analyzer (on #2 channel) back to Leq.

28. EXP states: “Now, I am going to place an earmuff over your ears. Let me know if you feel any movement of the devices in your ear.” EXP carefully places earmuff over ears and over leads and pressure tube.

29. EXP changes analyzer to Leq. EXP states: “Now, when I give you this hand signal (thumb up), vocalize the sound “EEE”, trying to make the light on the meter hit the line at 65 as I showed you before and keeping your voice at that level for 3 seconds.”

30. On hand signal from EXP, SUBJ utters EEE, and EXP observes LD 800B reading to determine subject’s voice level and EXP starts and stops analyzer to obtain 2-sec (approx) Leq. Repeat until 65 dBA +/- 1.5 dB is achieved, then EXP STORES and PRINTS this trial.

31. On hand signal from EXP, SUBJ utters EEE, and EXP observes LD 800B reading to determine subject’s voice level and EXP starts and stops analyzer to obtain 2-sec (approx) Leq. Repeat until 65 dBA +/- 1.5 dB is achieved, then EXP STORES and PRINTS this trial. (EARPIECE TRIAL 2)

32. EXP then states: “Now, I am going to very briefly turn on the forehead vibrator and take a measurement. Do not be startled by the vibration, which will not be loud.”

33. EXP then turns ON the pink noise source and the Vibrator, with the audiometer set to **SPEECH GAIN=marker, ATTENUATOR=55 dBHL, FREQUENCY=OFF, INPUT=TAPE, NORMALLY**
OFF, OUTPUT=BONE. Vibrator is left on, via audiometer control, for not more than 4 seconds while next step (measurement) is performed.

34. EXP then starts and stops analyzer to obtain 4-sec (approx) Leq. EXP STORES and PRINTS this trial. (Only 1 occluded ear Vibrator trial per earpiece is obtained.)

35. EXP turns OFF the pink noise and the Vibrator.

36. EXP then states: “Now, please say the following sentence, paying particular attention to how your own voice sounds in your ears right now while wearing the earpiece.” “My full name is [say your name] and I live in the town of [say the town]. I am participating in an experiment about how wearing earphones makes my own voice sound.” EXP hands SUBJ the index card with this sentence printed on it for referral.

37. EXP then gives the SUBJ the Subject’s Own Voice Perception Rating Scale (attachment) for voice perception.

38. EXP then removes earmuff and test earpiece, taking care not to dislodge the probe tube mic. Vibrator will remain on forehead throughout remainder of trials.

39. With the SUBJ having open ears now, EXP states: “Now, please say the following sentence, paying particular attention to how your own voice sounds in your open ears.” “My full name is [say your name] and I live in the town of [say the town]. I am participating in an experiment about how wearing earphones makes my own voice sound.” EXP hands SUBJ the index card with this sentence printed on it for referral.

2nd OCCLUDED EARPIECE MEASUREMENT

40. EXP then repeats STEPS 24-39, for the 2nd EARPIECE in the pre-determined order.

3rd OCCLUDED EARPIECE MEASUREMENT

41. EXP then repeats STEPS 24-39, for the 3rd EARPIECE in the pre-determined order.

4th OCCLUDED EARPIECE MEASUREMENT

42. EXP then repeats STEPS 24-39, for the 4th EARPIECE in the pre-determined order.

5th OCCLUDED EARPIECE MEASUREMENT

43. EXP then repeats STEPS 24-39, for the 5th EARPIECE in the pre-determined order.

44. EXP then removes earmuff.

45. EXP then pays and dismisses SUBJ.

NOTE for investigation 1 experiment.
The steps designed to subjectively measure occlusion effect will be excluded as they were meant for investigation 2.

For protocol 1, STEPS 24-39 was used without any modification.

For protocol 2, STEPS 24-39 was used with following modification. A second probe tube microphone will be placed at the other ear canal per calibration steps as defined. A large volume earmuff will be placed to cover both ears. The sound levels of both occluded ear canal and unoccluded ear canal will be measured simultaneously.

For protocol 3, data from protocol 2 steps was combined with additional measurements as protocol 2 steps after the occluding device is placed at the unoccluded ear.
NOTE for investigation 2 experiment.
The presentation order of bone vibrator and vocal utterance was randomly selected for each earplug/insertion depth condition.
Steps 26 and 27 were conducted with 6 subjects prior to actual experiment and the data was used to determine test air pressure. These steps were only conducted during actual experiment only when the experimenter suspected a broken acoustic seal.
APPENDIX C

APPENDIX C - QUESTIONNAIRE FOR SUBJECTIVE IMPRESSION OF OWN VOICE
Subject's Own Voice Perception Rating Scale

1) With this EARPIECE as compared to the OPEN EAR condition, in terms of LOUDNESS, my own voice sounded: (circle ONE number)

<table>
<thead>
<tr>
<th>-3</th>
<th>-2</th>
<th>-1</th>
<th>0</th>
<th>+1</th>
<th>+2</th>
<th>+3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely</td>
<td>SAME</td>
<td>Extremely</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QUIETER</td>
<td>LOUDNESS</td>
<td>LOUDER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>with</td>
<td>for</td>
<td>with</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>this earpiece</td>
<td>both</td>
<td>this earpiece</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2) With this EARPIECE as compared to the OPEN EAR condition, in terms of PITCH (highness or lowness), my own voice sounded: (circle ONE number)

<table>
<thead>
<tr>
<th>-3</th>
<th>-2</th>
<th>-1</th>
<th>0</th>
<th>+1</th>
<th>+2</th>
<th>+3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely</td>
<td>SAME</td>
<td>Extremely</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOWER in</td>
<td>pitch</td>
<td>HIGHER in</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PITCH with</td>
<td>for</td>
<td>PITCH with</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>this earpiece</td>
<td>both</td>
<td>this earpiece</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX D

APPENDIX D - GLOSSARY
**Ampclusion**- Mixed effect of occlusion effect and possible gain of air-conducted own voice by hearing aid worn by the person.

**Attenuation**- The decrease in amplitude of a signal.

**dB(A)**- SPL with an A-weighting filter to simulate the human-ear response.

**dB HL**- dB hearing level whose reference level varies per frequency. Thus the reference “zero” level is different for different frequencies and defined at ANSI. It shows deviations from ‘normal’ hearing.

**Insertion loss**- The difference in sound pressure levels measured sequentially at the same point before and after insertion of the device. Possible measurements can be made at the ear canal unoccluded and occluded with external noise.

**Laser vibrometry**- A technique that uses laser and Doppler effect to make a non-contact measurement of vibration.

**Noise reduction**- The difference in sound pressure levels measured simultaneously at any two points along the path of sound propagation, i.e. inside the ear canal and outside of the ear canal for an external noise blocked by an earplug.

**Noise Reduction Rating (NRR)**- shows how well a hearing protector reduces noise in decibel as specified by the Environmental Protection Agency. The higher NRR provides better protection.

**Occlusion effect**- Amplification of low frequency components of bone conducted sound in an occluded ear. Usually results in distorted perception of self voice.

**Open/Closed tube**- A term used to represent a tube who’s both ends are either open or closed unlike a “closed” tube which has one open end and one closed end. The occluded ear canal can be modeled as an “open” tube. The unoccluded ear canal (open ear without hearing protector or aid) can be modeled as a “closed” tube.

**Pure tone**- A tone with no harmonics. All energy is concentrated at a single frequency.
**Resonant frequency** - A frequency that a system resonates.

**Sound pressure level (SPL)** - A logarithmic measure of the effective sound pressure of a sound relative to a reference value, usually measured in dB

**Spectrum analyzer** - An instrument for measuring, and usually recording, the spectral component of a signal; the measurement is typically in x-y graphical form, with frequency in Hz on the x-axis and dB on the y-axis.
Title of Project: Hearing Protector Attenuation Test

Principal Investigator: Dr. J. G. Casali, Grado Professor, ISE

Experimenter: Kichol Lee

I. THE PURPOSE OF THIS RESEARCH

You are invited to participate in a research study aimed at determining the noise reduction characteristics of a hearing protection device (HPD). In order to measure the passive performance of the device, it will be necessary to measure your hearing ability (auditory threshold) in two conditions: 1) while wearing the HPD, and 2) while your ears are uncovered. If the device being tested is an active noise reduction (ANR) design, an additional session will be required in which miniature microphones will be placed in your ears to directly measure the sound levels reaching your ears in the same two conditions (while wearing the device and while your ears are uncovered). A total of 10 to 30 individuals (both males and females) are being recruited for this study with separate experimental sessions scheduled for each participant.

II. PROCEDURES

The procedures to be used in this research are as follows. If you wish to become a participant after reading the description of the study, then sign this form. First, you will be screened to determine if you qualify for the experiment. Screening will consist of a hearing test and several assessment tests. To begin with, you will be asked several questions to assess the general health and condition of your ears. Then you will be given an examination in which the experimenter will look into your ears using an otoscope to determine the condition of your ears. Next, your right and left ear hearing will be tested with very quiet tones played through a set of headphones. You will have to be very attentive and listen carefully for these tones. Depress the button on the hand-held switch and hold it down whenever you hear the pulsed-tones and release it when you do not hear the tones. The tones will be very faint and you will have to listen carefully to hear them. No loud or harmful sounds will be presented over the headphones.

It may also be necessary to obtain a bone-conduction threshold in addition to the air-conduction threshold described above. The procedures and your responses will be identical to those described above. The only difference between the two tests are that instead of wearing headphones, you will be wearing a small vibration transducer placed against the mastoid bone...
behind your ear or against your forehead. You will hear the same tones you heard during the air-conduction audiogram and you are asked to respond in exactly the same manner. Again, the tones will be very faint and you will have to listen carefully to hear them; no loud or harmful sounds will be presented during this test.

Next, the variability of your open-ear threshold will be determined. For this test, the test signals will be third-octave bands of noise rather than tones and they will be presented over loudspeakers located in the test booth instead of over headphones. Again, you will have to be very attentive and listen carefully for the test signals. **Depress the button on the hand-held switch and hold it down whenever you hear the pulsed test signals and release it when you do not hear the signals.** The test signals will be very faint and you will have to listen carefully to hear them. No loud or harmful sounds will be presented. As many as 10 trials may be conducted with each trial taking from three to five minutes. You may request a break at any time between trials.

If you qualify and choose to continue, you will be asked to participate in one or more experimental sessions. If the device to be tested is of the passive variety, the procedures for the experimental sessions will be similar to those used in the second part of the screening session. You will be asked to listen for the pulsing sounds presented over the loudspeakers located in the test booth. However, in these sessions, half of the threshold measurements will be made while you are wearing the HPD. Remember, you will have to be very attentive and listen carefully for the test signals. **Depress the button on the hand-held switch and hold it down whenever you hear the pulsed test signals and release it when you do not hear the signals.** The test signals will be very faint and you will have to listen carefully to hear them. No loud or harmful sounds will be presented. As before, you will have the opportunity to take rest breaks between trials.

The purpose of this experiment is to test the noise reduction capabilities of hearing protection devices (HPDs). You will be fit with an HPD in one of the following manners:

[ ] The HPDs will be fit and adjusted by the experimenter.

[ ] You will be asked to fit the device yourself, but the experimenter will provide instruction and guidance (both verbal and physical) in properly fitting the device.

[ ] You will be asked to fit the device yourself following the written instructions provided by the device manufacturer, but the experimenter cannot provide you with any assistance.

If the test method is one using miniature microphones for measurement, then we will be testing either an HPD of the electronic active noise reduction (ANR) variety, or perhaps just a standard passive HPD. For these tests, the protocol will be as follows. The first session will be conducted exactly as described above. For this session, the device's ANR electronics will be turned off so that its passive attenuation characteristics can be determined (or in the case of a passive HPD, the passive attenuation test will be done as described above). The second experimental session will involve direct measurement of the noise levels reaching your ears using miniature microphones. For MIRE measurements, there are three techniques for positioning and placement of a miniature microphone: 1) in the concha (hereafter, “concha”), 2)
at the entrance of the ear canal, (hereafter, “canal entrance”) and 3) in the ear canal using probe
tube microphone (hereafter, “canal probe”). For concha microphone positioning and placement,
the experimenter will first fit a foam or other soft earplug in your ear canals and then secure a
miniature microphone) to the floor of the concha using double-sided foam tape. For the canal
entrance position and placement, the experimenter will insert a small soft earplug, which holds a
miniature microphone, into the outer portion of your ear canals. For the canal probe position
and placement, the experimenter will connect a miniature microphone to a length of soft, flexible,
hearing aid tubing, the end of which will be placed into your ear canal but not touching the
tympanic membrane (eardrum). The insertion of the probe tube in this method is similar to
deeply fitting an earplug into your ear, and does not pose a known risk to you. The microphone
of the probe tube is located at the outer end of the tube (i.e., outside your ear canal), and only the
hearing aid tubing will be in your ear canal. For all three MIRE positions, after microphone
placement, a small piece of paper first-aid tape will be used to secure the thin wire leads of the
microphone to your cheeks and/or shoulders. This will prevent normal head and body movement
from loosening the microphone during the course of the experiment. After you enter the test
booth, the experimenter will attach the microphone leads to the appropriate cables. In all 3 MIRE
techniques, your skin will not be in contact with any bare wires or terminals, as these are
insulated with plastic sheathing.

The procedures for this part of the experiment differ from those in the previous session
in that you are not required to respond to any signals. Since the microphones will directly
measure the sound levels reaching your outer ears, you need only be as still and as quiet as
possible while sitting in the test booth. Nine noise level measurements will be made during this
session. In the case of testing an ANR headset, three of these measurements will be made while
the ANR headset is not worn (the unoccluded condition); the other six measurements will be
made while the ANR headset is worn (the occluded conditions). Of the six occluded
measurements, three will be made with the ANR electronics turned off (the passive state) and
three will be made with the ANR electronics turned on (the active state). The test signal for
these measurements will be a broadband pink or white noise at a level of 100 dBA. Each of the
nine measurements will take no more than 60 seconds. As before, you will be able to take rest
breaks between measurements.

Occasionally, the need arises to test custom-molded earplugs. Unlike standard HPDs,
which are designed to fit a wide range of people, custom-molded earplugs are made to fit one
specific individual. Therefore, when testing such devices it is necessary to obtain an impression
of each of your ears so that the devices can be manufactured prior to testing. The materials used
to obtain these ear impressions are non-toxic and approved by the FDA for use on human skin.
A description of the product and the material safety data sheets are available for your inspection
if so desired. The materials will not harm you in any way. The general procedures used in
obtaining these impressions are as follows.

Before making the ear impressions, your sensitivity to the molding material will be
ascertained by placing a small amount of the material on your wrist. If a reaction is evident, you
will be paid for your time and no earmold will be made. If no reaction is evident, you will be asked to lay your head on the foam pad or pillow on the table so that your head is roughly horizontal. A small piece of foam or cotton, with a string attached, will then be inserted into your ear canal with the string extending out of the ear. This foam dam will prevent any of the material used to form the impression from reaching your eardrum. After the eardam has been inserted, the molding compound will be mixed and injected into your outer ear canal and concha using a large syringe. Once the material has hardened sufficiently, you will be asked to lift your head from the table. After allowing sufficient time for the molding compound to cure completely, the impression will be carefully removed from your ear by the experimenter. The procedure is then repeated for the other ear. These procedures will not harm you in any way. Similar materials and procedures are routinely used by audiologists and hearing-aid manufacturers to obtain impressions of patients' ears preparatory to the manufacture of custom-molded hearing aids and earplugs.

For some part of the experiment, you will be asked to vocalize “EE” for three to five seconds at a level of 65 dBA. You will be able to monitor your voice level with a sound level meter placed in front of you. You will be asked to complete questionnaires asking the comfortness of the device and naturalness of your voice after testing of certain earplugs.

III. RISKS

The Occupational Safety and Health Administration (OSHA) allows industrial workers in the U.S. to be exposed to continuous 100 dBA noise for two hours every day without wearing hearing protectors. The maximum total exposure time to the noise in this experiment without hearing protectors will be less than 10 minutes (that is, less than 10% of the exposure time allowed per day by OSHA), and 100 dBA is the maximum noise level that will be used.

All of the tests described above will be conducted in a soundproof booth with the experimenter sitting outside. The door to the booth will be shut but not locked; either you may open it from the inside or the experimenter may open it from the outside. There is also an intercom system through which you may communicate with the experimenter by simply talking. (There are no buttons to push.)

There is no known risk to your well-being posed by the hearing tests involved in this research or health assessments. Also, realize that they are not designed to assess or diagnose any physiological or anatomical hearing disorders. The assessments and tests will only be used to determine your ability to participate in the experiment.

The purpose of this experiment is to test the noise reduction capabilities of hearing protection devices (HPDs). Unless the experiment calls for a subject-fit condition, the HPDs will be fit by the experimenter. If you are asked to fit the device yourself, the experimenter will provide instruction and guidance in properly fitting the device. HPDs are intended to provide a snug fit so that noise will be blocked. Therefore, they may seem tight in or around your ears. Some minor discomfort may result from the tight fit, but the protectors will not harm you in any way. If earmolds are obtained for the manufacture of custom-molded devices, your ears may
feel "full" and the material may feel "rubbery", but the material will not harm your ears or hearing.

Several physical measurements may also be obtained as part of the study. These will include dimensional measurements such as ear and head width, obtained with simple rulers, calipers and an ear gauge. None of the previously mentioned health tests and measurements pose any risk to your well-being or cause any pain. (You should also know that the instruments are sanitized prior to each new participant.) You may ask to see and examine these instruments, the test system, or the safety literature for the molding material at this time if you wish.

IV. BENEFITS OF THIS RESEARCH

Your participation in this experiment will provide information that will be used to develop a rating of how well noise is blocked by the particular hearing protection device tested. No guarantee of benefits has been made to encourage you to participate. You may also receive a summary of the results of this research when completed. Please leave or send a self-addressed envelope if you are interested in the summary. To avoid biasing other potential participants, you are requested not to discuss the study with anyone until six months from now.

V. EXTENT OF ANONYMITY AND CONFIDENTIALITY

The results of this study will be kept strictly confidential. At no time will the researchers release the results of the study to anyone other than the individuals working on the project without your written consent. The information you provide will have your name removed and only a participant number will identify you during analyses and any written reports of the research.

VI. COMPENSATION

For participation in this experiment, you will receive a minimum of $10.00 for each hour that you participate.

VII. FREEDOM TO WITHDRAW

You are free to withdraw from this study at any time without penalty. If you choose to withdraw, you will be compensated for the portion of time you have spent in the study. There may also be certain circumstances under which the investigator may determine that you should not continue as a participant of this project. These include, but are not limited to, unforeseen health-related difficulties, inability to perform the task, and unforeseen danger to the participant, experimenter, or equipment.
VIII. APPROVAL OF RESEARCH

This research project has been approved, as required, by the Institutional Review Board for projects involving human participants at Virginia Polytechnic Institute and State University, and by the Department of Industrial and Systems Engineering.

IX. PARTICIPANT’S RESPONSIBILITIES

I know of no reason why I cannot participate in this study. I have the following responsibilities:

- To listen attentively to the sounds during the hearing tests and to press and release the button with relative accuracy and to follow instructions to the best of my ability.

- To notify the experimenter at any time about discomfort or desire to discontinue participation.

________________________________________

Signature of Participant
X. PARTICIPANT'S PERMISSION

Before you sign the signature page of this form, please make sure that you understand, to your complete satisfaction, the nature of the study and your rights as a participant. If you have any questions, please ask the experimenter at this time. Then if you decide to participate, please sign your name on this page and the following pages.

I have read a description of this study and understand the nature of the research and my rights as a participant. I hereby consent to participate, with the understanding that I may discontinue participation at any time if I choose to do so, being paid only for the portion of the time that I spend in the study.

Signature

Printed Name

Date

The experimenter for this experiment is ________________, who is supervised by Dr. John G. Casali, Director of the Auditory Systems Laboratory. He may be contacted at the following addresses and phone numbers:

Office: Room 519G Whittemore Hall
Virginia Tech
Blacksburg, VA  24061
(540) 231-5073
Email: jcasali@vt.edu

In addition, if you have detailed questions regarding your rights as a participant in University research, you may contact the following individual:

Dr. David Moore
CVM Phase II (0442)
Virginia Tech
Blacksburg, VA  24061
(540) 231-4991