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Effects of untrained earmold impression taking on custom hearing protector device performance

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EFFECTS OF UNTRAINED EARMOLD IMPRESSION TAKING ON CUSTOM HEARING PROTECTOR DEVICE PERFORMANCE

by

Kelly R. Pack, B.S.

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

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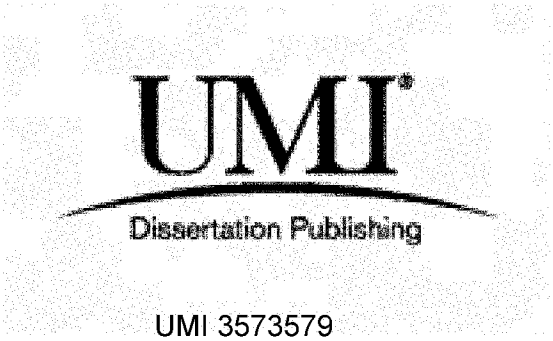

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Effects of Untrained Earmold Impression Taking on Custom Hearing Protector Device Performance

be accepted in partial fulfillment of the requirements for the Degree of Doctor of Audiology

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Abstract

Today's consumer is increasingly turning to the internet for both healthcare information as well as the purchase of custom hearing protection devices (HPDs). These HPDs are often cast from do-it-yourself home ear impression kits that include a syringe and silicone earmold impression material to be injected into the ear canal. Although not required by law, earmold impressions have typically been taken by medical professionals and other individuals formally trained in the procedures and safety measures of effective earmold impression taking. The main purpose of this study was to determine if do-it-yourself earmold impressions produce HPD's with lower attenuation levels than those HPD's made from impressions taken by trained professionals. Custom HPDs cast from both amateur and professionally made impressions were evaluated by recording both real ear measurements and pure tone thresholds and compared for attenuation differences. The results showed that HPDs made from amateur made impressions showed significantly less attenuation than those made from professional made impressions. These results indicate that custom HPDs cast from amateur made impressions may not adequately provide adequate attenuation of noise leaving the wearer vulnerable to the damaging effects of noise.

Keywords: Do-it-yourself impression, custom hearing protector, custom earmold.

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Author Kelly Pack

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CHAPTER I

Introduction

With internet accessibility reaching an all-time high due to wireless devices such as laptop computers and internet capable mobile phones, research shows that 74% of American adults report having access to and using the internet (Rainie, 2010). As many as 58% of American adults report using the internet to research a service or product information online (Jansen, 2010) and 75%-80% of internet users report using the internet to research healthcare information (Fox, 2008). As internet use becomes more prevalent, more and more consumers are turning to the internet to not only research a product or service but also to make their purchases. In 2007 research estimated 49% of American adults had made one or more online purchases, a 27% increase from 2000 (Horrigan, 2008). The U.S. Census bureau reports that in 2007, business to consumer retail purchases accounted for over $127 billion dollars in revenue (U.S. Census Bureau, 2010). With this growth in the market place many industries are clamoring to find their niche in the online retail world. The hearing protection industry is no exception.

Today's consumer can find a wide array of hearing protection devices (HPD) for purchase online including custom HPD's cast from impressions of the wearers ear. Although not required by law, these earmold impressions have typically been taken by medical professionals and other individuals who have been formally trained in the procedures and safety measures in conducting effective earmold impressions. Consumers purchasing custom HPDs online are often sent a "do-it-yourself" home earmold

impression kit that includes a syringe and silicone earmold impression material that is required to be injected into the ear canal. This study will seek to determine if do-it-yourself earmold impressions produce HPD's with lower attenuation levels than those HPD's made from impressions taken by trained professionals. This research is important because a reduction in actual attenuation could leave the user vulnerable to the damaging effects of noise. Specifically this investigation seeks to answer the following research question, "Do custom hearing protection devices made from earmold impressions that were taken by untrained individuals have significantly different frequency attenuations than custom hearing protectors made from earmold impressions that were taken by trained individuals?"

CHAPTER II

Review of Literature

Effects of Noise on Hearing Sensitivity

Continuous noise exposure causes the overstimulation of hair cells and leads to heavy production of metabolic waste at a rate that is faster than the body can safely remove it, this in turn can create a toxic environment for hair cells and ultimately cause hair cell death. Exposure to continuous noise at or above 85 decibels has the capacity to cause hearing loss. The more intense the sound, the shorter the exposure time before hearing loss starts to occur. Sounds softer than 75 decibels are unlikely to cause hearing loss no matter the length of exposure (National Institute on Deafness and Other Communication Disorders [NIDCD], 2008). The Occupational Safety & Health Administration (OSHA), the government body that regulates safety and health legislation in the workplace, recommends hearing protection in noise louder than 85 dB, and no more than 8 hours of exposure in 90 dB continuous or "steady state" noise. For every 5 dB increase in noise, exposure time should be cut in half up to 115 dB at which point no exposure is recommended.

Impulse noise is characterized as an acoustic event with a very short rise time and duration (Environmental Protection Agency [EPA], 1972). There are two types of impulse noise: 1.) Subsonic or "impact" noise and 2.) Supersonic, or "blast" noise. The Occupational Safety and Health Association (OSHA) defines subsonic industrial impact

noise as, "Repetitive bursts of energy 15 dB louder than ambient sound recurring no closer than 1 second apart." Blast noise is a burst of energy traveling faster than the speed of sound. Safe impulse noise levels are limited to 140 dB (Occupational Health and Safety Administration [OSHA], 1970). Flamme, Wong, Liebe, and Lynd (2009) investigated impulse noise from firearms to estimate the auditory risk to outdoor firearm users. To estimate the amount of impulse noise that reaches the ear canal of a firearm user the investigators positioned microphone 150 degrees from the line of fire at a distance that was equal to the length from the muzzle and the shooters left ear when in firing position. Five common sizes of the 3 types of firearms available were chosen for the study, a .30-06 rifle, a .22 caliber rifle, a 12 gauge shotgun, a .357 handgun, and a 9mm handgun. Two different loads were used for each firearm to simulate loads commonly used by recreational hunters and recreational target shooters. The recording took place in an outdoor firing lane that consisted of a concrete pad, metal awning and firing table. The firearm was placed on the firing table and the microphone was moved into position that was calculated to be within 3 cm of the shooters ear. The firearm was discharged remotely and 10 recordings were made in each test condition. This study found that impulse noise from all of the firearms, with the exception of the .22 rifle, reached average peaks between 161 and 164 dB SPL. The .22 rifle showed greater variability in the recordings, but still reached noise peaks of up to 141 dB SPL.

Olszewski, Milonski, Sulkowski, Majak, and Olszewski (2005) researched the effects of impulse noise from a kbk AKMS rifle on temporary threshold shifts (TTS) of soldiers. Eighty healthy male soldiers between the ages of 19-23 were recruited for the study. All participants were given an audiometric exam including pure tone audiometry,

tympanometry, and reflex thresholds testing and were found to have pure tone audiometric thresholds between 10-15 dB HL. Forty of the soldiers were placed in the research group and 40 were placed in the control group. In the research group, transient evoked otoacoustic emissions (TEOAE) testing was performed using a 80 dB SPL 80 μs click presented at a rate of 50/s in nonlinear mode. The responses were calculated using an average of 260 repetitions with a time analysis of 2, 5 and 20ms. TEOAEs were performed at the frequencies of 1, 2, 3, 4 and 5 kHz. TEOAEs were taken 3 to 5 minutes before any firing of firearms occurred. The participant were then asked to fire 5 shots using a kbk AKMS rifle, caliber 7.62 mm, in a recumbent position. These firings were recorded at an average of 156 dB SPL. After firings were complete the participant were placed in a quiet environment and TEOAEs were recorded at 2 minutes, 1, 2 and 3 hours post firing. The control group was placed in a quiet environment and TEOAEs were recorded for an initial baseline and then at 1, 2, and 3 hours. In post firing conditions the research group was found to have a significant reduction in TEOAEs at 1, 2, 3, 4 and 5 kHz frequencies with the most reduction being seen at 4 and 5 kHz. Although TEOAEs are not a measure of TTS, it does show a shift in response from the outer hair cells and has been shown to correlate with TTS, (Vinck, Van Cauwenberge, Corthals, De Vel, 1998). The conclusion of this study indicates that a significant change in outer hair cell emission can occur in a short exposure to impulse noise.

Balatsouras, Homisoglou, and Danielidis (2005) followed 39 Greek soldiers age 18 to 20 years that had been hospitalized for hearing loss and tinnitus following exposure to impulse noise from firearm use. Participants in this study were self-reported to have previously had normal hearing, had no current ear infections, were not being treated with

amino glycoside medication and had no familial history of hearing loss. All injuries were the result of impulse noise from a G3 rifle with an average peak sound pressure of 159 dB SPL with a spectral peak at 1.6 kHz. The number of impulses the participants were exposed to ranged from 4 to 50 impulses with the mean being 11 impulses and no subjects were wearing any form of hearing protection at time of exposure. The mean time of admittance from exposure was 6.2 days. Upon admittance a general otolaryngology examination was performed to rule out any middle ear pathology. Pure tone audiometry using the ascending-descending method was conducted upon admittance to the hospital in the range of .25-8 kHz using standard TDH-49 headphones and Sennheiser HDA200 circumaural headphones for extended high range frequency testing in 9-20 kHz. There was no statistical difference in hearing acuity found when comparing right to left ears, so only left ears were reported for the research group in this study. Participants in the research group were given a regimen of corticosteroid, vasoactive substance and Vitamin E for 10 days or more. The average length of hospital stay for patients in the research group was eight days with a range of 4 to 22 days. Before discharge a repeat audiogram was conducted. A control group was used that consisted of 15 Greek soldier's age 18-21 years with no self-reported history of noise exposure. All participants in the control group were recruits and had therefore not been exposed by the military to impulse noise in training.

The results of this study showed upon admittance to the hospital the research group had significantly lower thresholds in the .25 to 11.2 kHz range with the exception of 1 kHz when compared to the control group that had received no impulse noise exposure. The greatest differences were shown in the 4 to 8 kHz range. At time of

discharge the audiometric results of the research group showed a significant improvement over their initial audiometric results with only a significant decrease shown in the 4 to 9 kHz range, but were still significantly less than the control groups. While hearing acuity did improve with treatment and time, it did not return to normal indicating a permanent loss in hearing acuity in the higher frequency ranges of 4-9 kHz.

Sliwinska-Kowalska and Jedlinska (1998) investigated the physical effects of impulse noise on the cochlea of guinea pigs. Guinea pigs were exposed to 95 dB SPL to 98 dB SPL of steady-state industrial noise for 16 hours per day, 5 days per week for 12 weeks. A control group was kept in an environment in which noise levels never exceeded 60 dB SPL. Data was observed at five, eight, and 12 weeks. Auditory thresholds were estimated using auditory brainstem response (ABR) techniques and a few animals were sacrificed to observe the cochlea directly under light and electron microscopy. After four weeks of exposure the research group showed an average permanent hearing threshold shift of 22.8 dB. Microscopy revealed floppy, disarrayed and missing outer hair cell (OHC) stereocilia predominately in the second and third turns of the cochlea. After eight weeks of exposure, hearing additional threshold shifts were non-significant and appeared asymptotic; however, damage to OHC stereocilia appeared more pronounced and had spread to the fourth turn of the cochlea. Specifically stereocilia appeared broken at the rootlet or torn off completely, the cuticular plate appeared softened and protruded and swelling could be observed in the OHC bodies. At 12 weeks hearing thresholds were still not significantly higher than at the four week exposure level; however floppy and disarrayed OHC stereocilia as well as inner hair cell (IHC) stereocilia could be seen on all turns of the cochlea. The cuticular plates of the

hair cells appeared distorted and were bulging outward into the subtectorial space. In contrast the control group showed no significant hearing threshold shift and only a few missing OHC stereocilia in the apical part of the cochlea. These findings revealed how quickly permanent cochlear damage could happen at a moderate level of steady-state noise in a relatively short amount of time.

Hearing Protection Devices

HPDs are devices worn around, or in, the ear canal to protect the ears from the damaging effects of high levels of steady-state and impulse noises. HPDs commonly come in two forms, the earmuff design and the canal insert design; and are offered in two classifications, passive and active. Passive protection devices are non-electronic devices that attenuate at fixed levels, and active protection devices, such as level dependent amplifying devices and active noise reduction (ANR) devices allow the user to hear normally below a specific decibel (dB) level, then turn off and become passive in nature when unsafe decibel levels are reached. Sound energy in both passive and active HPDs is attenuated by mass. High frequency sound waves are short and easily absorbed by mass, however low frequencies are longer and more easily pass through the HPD (Valente, Hosford-Dunn, Roeser, 2000). In addition to attenuating by mass ANR devices replicate low frequency noise waves 180 degrees out of phase creating a standing wave for low frequency information and essentially cancelling out the low frequency signal (Abel, Tsang and Boyne, 2007).

Noise reduction rating

The amount of attenuation provided by a HPD is expressed by a Noise Reduction Rating (NRR), a single-score rating system of the estimated of the amount of attenuation

provided by the HPD. The NRR of an HPD is determined by testing the HPD in a licensed laboratory according to ANSI standard S12.68-2007 and guidelines set forth by the Environmental Protection Agency's (EPA) Noise Control Act of 1972, 40 C.F.R part 211(EPA, 1972). Many studies have shown that the NRR recorded in the laboratory environment is not a good predictor of the actual attenuation of the HPD in real world use (Franks, Murphy, Johnson, & Harris, 2000; Neitzel, Somers and Seixas, 2006; Toivonen, Paakkonen, Savolainen, & Lehtomaki, 2002).

Franks et al. (2000) evaluated the attenuation of four earplug type HPDs by comparing their manufacturer's reported NRR to both an experimenter fit NRR and a subject fit NRR. Participants were chosen who had no former instruction on the use of HPDs, no reported hearing loss, who did not wear HPDs in a job setting and had not, worn HPDs more than twice in the previous month. Thresholds of each participant were evaluated using automated audiometry in a soundproof booth using the nine center frequencies in the range of 125 Hz to 8,000 Hz. Test subjects were then given an HPD with the manufacturer's instructions only. They were asked to fit themselves with the HPD and two measurements of thresholds were obtained using automated audiometry at the same frequencies. For the final test, subjects were fit again with the same type of HPD, however the experimenter placed the HPD in the subject's ear canal and 3 measurements of thresholds were obtained using automated audiometry at the same frequencies. The results of the study showed the experimenter fit attenuations to be significantly lower than the manufacturers reported NRR. When the data was sorted to find the highest experimenter fit recording, the experimenter fit NRR approximated the manufacturer's NRR but was still less. The attenuations of the subject fit NRRs showed

lower mean attenuations than the experimenter fit attenuations and higher standard deviations as well. These results indicate that the NRR of subject fit HPDs may provide significantly less protection than the NRR that is reported by the manufacturer.

These findings were also confirmed by Neitzel et al. (2006.) One hundred participants working in a corrugated packaging plant were assigned to two groups. Group A was given an expandable foam earplug with an NRR of 29 dB, and Group B was given a custom-molded silicone earplug with an NRR of 24 dB. Both contained a testing vent that could be opened for mic-in-real-ear (MIRE) attenuation measurements of the HPD without degrading the seal of the HPD in the ear canal. Groups A and B received a brief training that included proper use of each type of earplug, instruction on when and where to wear the HPD, and a demonstration of how to properly insert the HPD. Participants were asked to demonstrate to the researcher proper insertion and placement of the HPD and given appropriate feedback. Participants in group B were instructed to apply a small amount of petroleum jelly to the HPD several times per day for the first 5 days of use per manufacturer's instructions. Compliance with instructions was not monitored to best simulate real-world conditions. Participants in each group were instructed to wear their HPD for 5 consecutive days. On the fifth and sixth days attenuation of the participant inserted HPD was measured and recorded multiple times throughout the course of the day.

Participants were placed in a quiet area of the testing facility where background noise had been previously monitored during a pilot study using a SVAN 912AE Type 1 frequency analyzer. During the pilot study the levels of background noise at 2, 4 and 8

kHz were found to be compliant with OSHA requirements for audiometric testing, but levels at 5 and 1 kHz exceeded requirements by approximately 13dB.

Two methods were used to evaluate attenuation, the real ear at threshold (REAT) method and the MIRE method. A FitCheck system consisting of the FitCheck hardware box, a laptop PC, FitCheck software and a set of superaural headphones was used in the REAT evaluation. Unoccluded thresholds were first obtained using automatic audiometric testing with superaural headphones. Bekesy audiometry was used with 1/3 octave band pulsed stimuli delivered at .25, .5, 1, 2, 4, 6.3, and 8 kHz. Three cycles of increasing to decreasing amplitude at each frequency with amplitude changes occurring in steps of 1.5 dB SPL were recorded. Participants were then instructed to insert their assigned HPD into their ear canal and the automatic audiometric threshold test was repeated. The differences at each frequency were recorded as attenuation of the HPD. Thresholds which could not be reached due to exceeding the output limitations of the equipment and inconsistent threshold responses were discarded. The MIRE method was evaluated using a FlashTest system that consisted of a laptop PC connected to a Creative Labs SoundBlaster Model S80300 external sound card and an Altec Lansing VS2121 speaker system. Two Knowles FG-3652-P16 over-molded microphones connected to an amplifier with 20 dB SPL of gain connected to a soundcard were used. One microphone passed through the vent in the HPD and recorded sound levels inside the ear canal. The other microphone was mounted to a machined aluminum cylinder that sat on the same shoulder as the test ear and simultaneously recorded sound levels outside the ear canal. A broadband white noise test stimuli was used that produced approximately 75 dB SPL at

the test subjects position at approximately 2 meters from the speakers. Attenuation was recorded as the difference between the two recordings.

On the first day of data collection each participant received two right-ear FitCheck tests, two right ear FlashTest tests, and one left ear FlashTest tests for each earplug at different interval times throughout the day for a total of ten recordings. On day two each participant received two right-ear FitCheck tests and two Right-ear FlashTest tests for each earplug for a total of eight recordings. Statistical analysis of data was conducted using Intercooled Stata 9.0.

Results of this study showed the custom molded earplug to achieve greater attenuation than the foam earplug. Custom molded earplugs were also shown to have the lowest variability in both the FitCheck and the FlashTest results indicating that there is less variability in attenuation throughout the day and between users than users who used the foam HPD. The results also showed the custom molded earplug to have the largest variability between subjects and no significant within-subject variability. The foam earplug showed significant variability in within-subject and within day variability and less between-subject variability. This large individual-specific variability shown in this study indicates that the NRR of an HPD, foam or custom-molded, can vary between users and may change dynamically throughout the course of a day. The variability and underestimation of an HPD's NRR in real-world situations can expose the user to the damaging of high level noise.

Toivonen et al. (2002) showed subject fit attenuation can be significantly improved with hands on instruction of proper insertion and use of the HPD. The research study consisted of fifty-four Finnish male soldiers ages eighteen to twenty-five who

voluntarily participated in the study. This group was divided into a research group and a control group. The research group contained twenty nine participants who were asked to select a pair of either a Bilsom 303S or Bilsom 303L earplugs. They then received a 30 minute lecture on the proper use and insertion of an earplug. After the lecture the participants were allowed to practice insertion of the earplug under the supervision and guidance of an occupational health nurse. The control group received their choice of either a pair of Bilsom 303S or Bilsom 303L foam earplugs. This group did not receive training or supervised practice of insertion.

The MIRE method and the REAT method were both used to evaluate attenuation levels of the earplugs in both groups. In the MIRE method a small Sennheizer KE4-211-2 microphone (<5x5 mm) was attached to the end of all participants chosen earplug and the participant was asked to insert the plug into his ear canal. Signal from the microphone was transmitted from inside the canal to a measurement amplifier, a sound level meter and a plotter through insulated wire less than .1 mm in diameter. A loudspeaker located 80cm in front of the participant produced pink noise in the frequency range of 63-12500 Hz at an A-weighted noise level of 85 dB for one minute. Measurements with the same stimulus were then taken with the same microphone located 5cm to the side of the canal. Earplug attenuation was determined by subtracting the sound pressure level (SPL) inside the occluded canal from the SPL recorded outside of the canal. These measurements were taken in a normal office room, not an audiometric booth. In the REAT method a screening audiometer was used in an audiometric booth. Hearing thresholds at 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 5000 Hz and 8000 Hz were obtained with earplugs inserted were subtracted from hearing thresholds

obtained at the same frequencies without earplugs inserted. The difference was calculated to be the amount of attenuation provided by the earplug. Each earplug was visually inspected by a physician and graded on quality of insertion. The grading scale was zero for no insertion, one for poor insertion, two for satisfactory insertion and three for good insertion.

In the control group seven of the twenty-five participants (46%) were recorded having less than 15 dB of attenuation. In the research group 4 participants could not insert the earplug and microphone into their canal. Of the remaining twenty-five participants who were able to carry out the experiment, twenty-five (100%) were recorded having more than 15 dB of attenuation. The results of the REAT method showed the average attenuation for the control group was 23.6 dB at the 1000Hz and the average attenuation of the research group was 30.3 at 1000 Hz. The research group showed an improvement in attenuation at all frequencies over the control group by 4 to 7 dB. In visual inspection grading the research group received an average grade of 2.6 and the control group received an average grade of 1.9. Averages of all 3 methods: the REAT, MIRE and visual inspection grading were higher in the research group than in the control group. The research group also showed a lower standard deviation than the control group. These findings indicate that the attenuation of earplugs used in the real-world could be improved by the user receiving proper hands-on training on proper insertion techniques of foam HPDs. Consumers who purchase their HPDs online without the benefit of working with a hearing health professional may be increasing their risk of noise exposure by missing hands on instruction and feedback on proper insertion techniques.

Impression Techniques

Earmold impressions are silicone casts of the ear canal and concha made for the manufacture of custom fit communication or hearing protection device. A reverse cast of the earmold impression is then made to make a mold for the custom device to be cast. HPDs must make an effective seal in the ear canal to properly attenuate noise. The seal of the custom HPD is inherently dependent upon the accuracy and integrity of the earmold impression.

Pirzanski, Chasin, Klenk, Maye, and Purdy (2000) tested ten participants, five male and five female, with no visible ear tissue or tympanic membrane abnormalities or perforations. Two earmold impressions were made of the participants left ear. The first impression was made using a closed jaw technique and low viscosity silicone impression material administered with a silicone injection gun, this impression was labeled as "CL." The second impression was taken using an open jaw impression using standard viscosity silicone impression material administered through a standard impression syringe. This impression was labeled, "OS." Earmold impressions were then trimmed to 2 mm past the second anatomical bend in the canal portion of the impression. The earmold impressions were coated with three different thicknesses of wax coating with coating A being the thinnest, coating B being thicker than A and thinner than C, and C being the thickest coating. Earmolds were then produced from the impressions using a 30 shore medical grade silicone for the soft molds, and a rigid Ultraviolet resin for the hard earmolds. The earmolds were produced in three styles: canal style that fitted only in the canal and aperture of the canal, a standard style that was a standard full-concha earmold, and a tragal configurations style that had a raised tragal area to provide a better seal in the

tragal area. Impression CL with coating A was used to manufacture standard style earmolds in both hard and soft material. These earmolds are labeled EM-2H and EM-3S respectively. Impression OS with type B coating was used to make a standard style hard earmold, labeled EM-4H, a soft, canal style earmold labeled EM-1S, a soft, standard style earmold labeled EM-5S, and a soft, tragal configuration labeled EM-8S. Impression OS, coated with the type C coating, was then used again to make two standard-style earmolds: EM-6H in hard material and EM-7S in soft material. Each earmold included a channel drilled through the earmold through which a probe tube microphone was inserted. The end of the microphone protruded 1.5 mm past the earmold tip.

Attenuation of the earmolds was then tested in a quiet room with no more than 30 dB SPL ambient noise. All participants were given an otoscopic evaluation and were found to be free of occluding cerumen. A Starkey PFS 6000 real-ear measurement system was used to test real-ear measurements. Real-ear unconcluded response (REUR) measurements were taken using an equal insertion depth and an 80 dB SPL, speech weighted, broadband noise as stimulus. The earmolds with microphones then were inserted into the participant's ear canal by the tester. Real-ear attenuation threshold (REAT) measurements were taken twice with the participants mouth closed and twice with the participant's mouth open and secured with a bite block. Between measurements the probe tube mic and earmold were removed and replaced by the tester. Measurements were taken in a 1/24–octave steps and exported to a desktop computer for storage and analysis. All measures were repeated approximately one week later and averaged to produce a mean response for each earmold.

Findings from this study showed the style of the impression had no significant bearing on the level of attenuation of the earmold indicating that attenuation occurs primarily in the canal rather than in the concha. Earmolds that fit more snugly in the ear canal provided more attenuation than loosely fitting earmolds indicating that proper expansion of the ear canal during impression taking or proper coating of the earmold during manufacture is of importance for proper attenuation. This study also found impressions taken with a closed jaw had significantly lower canal diameters between the first and second anatomical bend than those taken with open jaw method.

These findings are of important significance to this study because it is of concern that the untrained impression taker may not produce an impression that is deep enough or snug enough to provide proper attenuation from the resulting earmold. Furthermore, the untrained impression taker may be unaware that jaw movement during the impression taking may also affect the attenuation of the resulting earmold negatively.

Pirzanski and Berge (2005) found that not only does the impression material need to reach the second bend to create a proper seal, but because this area has a great deal of elasticity, the impression material needs to sufficiently expand the canal in this area to create an effective seal. In this study four impressions of the right ear and four impressions of the left ear were made from 744 participants. A total of 5952 impressions were used for this study. Prior to impression taking the canal cartilage of each participant was evaluated by an audiologist and judged as soft, medium soft, or firm. These perceptions were later cross referenced with impression measurements. Two sets of closed jaw impressions were taken, one using a low-viscosity silicone and the other using a higher-viscosity silicone. Two sets of open jaw impressions were made using high

viscosity silicone. Once the impressions were made the diameter of the canal area was measured at the aperture, mid-section, and second bend. Canal softness was measured as the difference in measurements in the closed jaw impressions taken with a higher-viscosity silicone and the low-viscosity silicone. The magnitude of canal widening with mandibular movements was measured by comparing the difference between the open-jaw and the closed-jaw impressions taken with a low viscosity silicone. The measure of the ear canal maximum expansion was measured as the difference between the open jaw high viscosity impression and the closed-jaw low viscosity impression.

Measurements made from the low viscosity closed jaw impression were used as the baseline measurement because it is understood that these impressions do not stretch the ear canal. Measurements of all other impressions showed the area between the canal's two bends to be the area that was able to be stretched the most with the impression material. This finding suggests that impressions that do not sufficiently expand the ear canal in this area may not produce an effective seal. The findings also show that maximum expansion of the ear canal was found in the open jaw technique using the high viscosity impression material. These findings are significant because they show the majority of the seal occurring near the second bend in the ear canal. They also show how important is for the impression taker to place the otoblock far enough into the canal to allow the impression material to reach this bend. Placing the otoblock this far into the canal can often be uncomfortable for both the impression taker and the patient, possibly causing the untrained impression taker to place the impression material too conservatively in the ear canal to make a proper seal. Furthermore, expanding the

impression material properly in this sensitive area may also be uncomfortable for both the impression taker and the patient causing the earmold to have an ineffective seal.

Kimball (2008) investigated earmold impressions taken by untrained impression takers. Subjects were asked to take earmold impressions on another subject's ear using a replica of an earmold impression kit received from an online retailer of custom hearing aid devices. The earmold impressions were then sent to two different earmold laboratories to evaluate and grade the impressions based on criteria that the labs have evaluated as important for effective hearing aid earmolds. One point was given for each criteria met. Criteria included: 1. smoothness, 2. canal length showing the second bend of the external canal 3. clearly defined helix 4. clearly defined tragus and 5. complete concha. Earmold impressions were also taken by trained professionals using materials that would normally be used in a hearing professional office. The grades of the untrained earmold impressions were then compared to grades of the trained earmold impressions in a blind study. Impressions made by the trained group were found to be significantly better than the untrained group. Approximately 50% of the untrained group's scores were a two or less and 80% of the scores in this group fell below a three. In the trained group 93% scored a four or better with 25% scoring a perfect five. Although no data exists on how high a score needs to be to make an effective earmold, these scores can be used to estimate earmold performance.

Custom hearing devices made from earmold impressions taken by untrained earmold impression takers may not be able to provide the necessary attributes needed to create an effective HPD. Given the severity of damage to hair cells, and subsequent loss of hearing that can occur in a relatively short exposure to high levels of noise, it is

paramount that HPDs perform at the NRR levels reported to protect the user. Given the already known factors that can contribute to the reduction of NRR in a custom HPD such as HPD fit, HPD seal, impression techniques and user insertion errors it is important to know if do-it-yourself earmold impression kits are likely to further degrade the NRR of the HPD.

CHAPTER III

Methods

Subjects

The research group consisted of 10 individuals. Participants in this group were recruited by emails sent through the Louisiana Tech University email system (Appendix A). Criteria for candidacy included: 1) age 18 years or older and 2) had no prior training in methods of taking earmold impressions. Criteria were evaluated through a self-report survey. The control group consisted of three licensed audiologists recruited from local area audiology clinics. The criteria for candidacy included 1) age 18 or older, 2) had previous formal training in creating earmold impressions, and 3) is an active, licensed audiologist. Criteria were verified through state licensing.

An email was drafted by the researcher requesting volunteer participants in an audiological study to be held on Louisiana Tech University's campus. The email stated the purpose of the research, detailed the procedures, stated any risks of participating in the research, and gave directions on how to volunteer to participate (see Appendix A). As an incentive, participants were told they would receive a free hearing evaluation and be able to keep one set of HPDs from the study if they participated.

Instruments

Upon arrival participants were asked to complete a human subjects consent form (Appendix B) and a self-report survey (Appendix C) designed by the researcher. The survey included the following demographic information: 1) age 2) gender, and

3) education level. It also sought to determine if the participant had ever: 1) been trained on making earmold impressions, 2) had any experience making earmold impressions, or 3) had ever had earmold impression made on themselves. Volunteers for the research group who reported being under the age of 18, and/or answered, "yes they have received prior instruction on the procedures of making of earmold impressions" were dismissed from the study. Volunteers who reported being over the age of 18 and answered, "No, they have not received prior instruction on the procedures of making of earmold impressions" were asked to become participants in the study. Conversely, volunteers for the control group who are identified as under the age of 18, not having training in earmold impression techniques and/or are not active licensed audiologists were also dismissed from the study. Volunteers who reported being over the age of 18, having had training in earmold impression techniques and were active licensed audiologists were asked to participate in the control group.

To ensure participant safety this study was approved by the Louisiana Tech University IRB board (Appendix D). In addition the administrator gave an otoscopic examination to all participants in the research group prior to earmold impressions being made. Participants were evaluated for contraindications such as excessive cerumen in the external canal, abrasions or unhealthy appearing tympanic membranes. Participants that were found to have one or more contraindications were excused from the study.

To replicate a consumer's online search to purchase a mail order custom HPD, a Google® search engine search was used with the keywords "Buy custom earplug". The company that appeared as the first listing in the organic search results was used for the purpose of this study (Appendix E). The first organic listing was for, "Earplug

Superstore." Their URL is located at http://earplugstore.stores.yahoo.net. The search was conducted October 1, 2010 at 6:36 p.m. on www.Google.com.

Do-it-yourself impression kit.

A "Do-it-yourself impression kit for custom HPDs, product number, "plcustkit2-1-1" was purchased from Earplug Superstore on October 5, 2010 and was replicated for use in this study (Earplug Superstore, 2010). The kit included materials to make three ear impressions. Included in this kit were 1) one Covidien brand blunt tipped plastic Monoject ™ 35 mL syringe, 2) three double tipped cotton swabs, 3) three blue, medium sized, foam ear dams with cotton removal strings, 4) three small, black foam ear dams with cotton removal strings, 5) three containers of pre-measured one-to-one silicone earmold impression materials, and 6) one set of directions for making earmold impressions using the provided kit (Appendix F). A representative with the Earplug Superstore confirmed the earmold impression material to be silicone earmold impression material; however viscosity, shore hardness and manufacturer information was not available (Customer service representative for the Earplug Superstore, personal communication, November 3, 2010). For the purposes of this study Westone brand "Silicone Singles®" pre-measured one-to-one earmold impression material packets were used. This material is a high viscosity silicone earmold impression material with a shore A hardness of 32 when cured (Westone, 2010). The Earplug Store directions also called for earmold impressions to be sent back to the company in the box in which the earmold impression kit came in; for the purposes of this study earmold impressions were placed in a Westone brand earmold impression shipping box to be shipped directly to Westone.

The control group used the same earmold impression material and foam ear dams, but was allowed to use common items typically found in a hearing professional clinic including an otoscope, a variety of polyethylene syringes, various sized foam ear dams, and earlites.

Instructions.

To simulate real-world conditions and to standardize test conditions directions, a real-world scenario script where the participant was called on to create an earmold impression was read to all participants at the beginning of the study (Appendix G). It introduced the participants to the materials available for their use in the research task and outlined the task of making the earmold impressions. The participants were given a copy of the script after it had been read to them for their reference throughout the study. Also, to increase similarities in how the participant might react in an actual home environment, the participants were allowed to use an internet equipped computer and a telephone to ask for assistance from the manufacturer, the earmold impression kit supplier, or an acquaintance.

Hearing protection.

Two full-shell Westone brand model 40 custom-fit high noise multi-purpose ear plugs with an NRR of 29 was used for the study. This HPD is a multipurpose ear plug made of Silicone OtoBlast ™ material. This model was chosen because it is marketed by the Earplug Superstore as "an excellent choice for any high noise environment" that is "very popular with shooting enthusiasts, heavy equipment operators, construction workers." This population of HPD users may be the most at risk if attenuation does not meet the reported NRR. This HPD was offered through the Earplug Superstore at retail

price; however, in the interest of conserving expenses, the Westone brand model 40 custom-fit high noise multi-purpose ear plug were ordered directly from Westone at dealer price through the Louisiana Tech University Speech and Hearing Center.

To record attenuation of the HPD the real-ear-at-threshold (REAT) method and the mic-in-real-ear (MIRE) method were used. These methods have been used in previous studies by Neitzel et al. (2006) and Toivonen et al. (2002) to record attenuation of HPDs. An Audioscan RM500 was used in a soundproof booth to record MIRE unoccluded gain and MIRE insertion loss measurements. Recordings were taken at .25, .5, 1, 2, 4, 6 and 8 kHz. A Grayson-Stradler GSI-61 audiometer and a soundproof booth with a two speaker array were used to evaluate attenuation at .25, .5, 1, 2, 4, 6 and 8 kHz. Hearing thresholds and functional loss thresholds were used to determine attenuation. All equipment was calibrated yearly, and daily biological checks were performed on the equipment to ensure it was in good working order.

Procedures

Participants were tested in groups consisting of two research participants and one control participant in the Louisiana Tech University Speech and Hearing Center. Upon arrival participants of both groups were asked to complete a human subject consent form (Appendix B) and a brief self-report survey developed by the researcher (Appendix C) to collect demographic information and determine their experience and training level with earmold impression taking. All collected information was held confidential and only viewed by the researchers. Participants for the research group received an otoscopic evaluation by a licensed audiologist to ensure they had no contraindications for earmold impressions. Furthermore, volunteers who report being over the age of 18, answered

"No, they have not received prior instruction on the procedures of making earmold impressions," and had no contraindications for earmold impressions were asked to become participants in the research group. Volunteers who reported being over the age of 18, had training in earmold impression techniques and were licensed audiologists were asked to participate in the control group (see Appendix C for survey).

At the beginning of the task, participants were labeled as Participant A (Research Group), B (Research Group), or C (Control Group). Participants A and B were brought into the test room where the researcher had all items needed for the research prepared and readily available for their use. The researcher then read aloud directions to the research group and the scenario script (Appendix F). The directions and scenario script for the research group stated,

> I'm going to read you the instructions for the task. After I am finished reading you may ask any questions that you may have. I will leave these instructions with you for your reference and will be observing you while you complete the task; however, you will not be able to ask questions from me once the task has begun so listen to the instructions closely and ask any questions before we get started?

A pause was allowed for questions from the participant. After questions were answered the researcher continued with the script, "Here is the scenario for the research: Participants A and B have recently decided to purchase a pair of these custom hearing protector devices from an online website." At this point the participant was shown a picture of the pair of passive custom HPDs used in this study for visual reference and then the researcher continued with the script,

> Because they are custom fit, meaning custom made for the wearer's ears, they need to be made from an impression of the wearer's ears. The company has sent an impression kit with all the materials that he will need to make the impressions yourselves.

The researcher pointed to the research group impression kit materials in the Westone earmold impression shipping box. The researcher continued with the script,

> Because it is hard for persons to make impressions on themselves, participants A and B will make the impressions of each other's ears. The company has sent these instructions along with the materials for your guidance. Please be sure to complete steps 1-10.

The researcher then handed the participant the instructions for taking earmold impressions. The researcher continued with the script, "Using the materials you have here you will be making impressions of both ears of the other participant. You are allowed to use this computer equipped with internet service as well as the telephone freely." The researcher introduced a computer and the telephone to the participant for their use. Continuing with the script the researcher stated, "There is a hand cleaning station in the back of the room and a restroom in the hallway for your use" and then showed the participant where each was located. The researcher then resumed the script, "You may also use any of these hand towels" and pointed to the paper products available for use. Returning to the script the researcher stated,

> You may leave the room if necessary. You will have as much time as you need to complete the task. Once you have completed all 10 steps please announce to the research administrator that you are done to signify the

completion of your task. Once the earmold impressions have been completed on both participants A and B, participant C will make a pair of ear impressions for each of you for control purposes. Do you have any questions before we begin?

The researcher then answered any questions the participant had with exclusion to questions about the execution of the earmold impressions. Participants were allowed as much time as needed to complete the task, but were not allowed to ask the researcher questions pertaining to the task once the task had been started.

Once participant A and B had completed earmold impressions on each other, participant C in the control group was asked to enter the room. Participant C was read the control group script and was given the control group earmold impression kit. The researcher began the script stating,

I'm going to read you the instructions for the task. After I am finished reading you may ask any questions that you may have. I will leave these instructions with you for your reference and will be observing you while you complete the task; however you will not be able to ask questions from me once the task has begun so listen to the instructions closely and ask any questions before we get started.

A pause was allowed for questions from the participant. After questions were answered the researcher continued with the script,

Two clients, participant A and Participant B, have requested to purchase a pair of Westone brand model 40 custom-fit high noise multi-purpose ear plugs using the materials you have here you will be making impressions of

> both ears of each client. You will be using Westone brand 'Silicone Singles® pre-measured one-to-one earmold impression material packets for impression material. You may use any of the equipment here in the audiology clinic. Once you are finished with the earmolds please pack them and prepare them to be shipped to the earmold laboratory in this earmold impression shipping box.

The researcher then pointed to the referenced materials, which were available on the workspace table. The researcher continued with the script, "You are allowed to use computer equipped with Internet service as well as the telephone freely" then showed computer and telephone. The researcher then stated from the script, "There is a hand cleaning station in the back of the room and a restroom in the hallway for your use. You may leave the room if necessary." At this point the researcher showed the participant the location of both the hand washing station and the restroom. Continuing with the script the researcher stated, "You will have as much time as you need to complete the task. Do you have any questions before we begin?" The researcher answered any questions the participants might have with exclusion to questions about the execution of the earmold impressions. Participant C was allowed as much time as needed to complete the task. Once the task has been completed, all participants were released.

Once the earmold impressions were completed by the participants, the researcher prepared an order form for the HPD devices. At this time the researcher assigned participants a randomized number drawn from a hat containing numbers 1-100. The number was used in place of the participants name in order to protect the participant's privacy. The order form, along with the impressions, was sent to Westone laboratories to

create a pair of full shell Westone brand model 40 custom-fit high noise multi-purpose ear plugs from the impression material.

Upon receipt of all the HPDs from Westone laboratories, data collection began. Participants in the research group were asked to return to the Louisiana Tech University Speech and Hearing Center for evaluation of the research HPD and the control group HPD.

Real ear measurements.

Research group participants were placed in a soundproof booth for testing. A probe tube microphone from an Audioscan RM500 was placed in each of the participants ear canals and real ear unoccluded gain testing was measured twice to determine sound pressure levels in the ear canal near the tympanic membrane at .25, .5, 1, 2, 4, 6 and 8 kHz. Next the first set of custom HPD devices for that participant was placed in the participant's ear by the administrator with the probe tube microphone still placed in the ear canal. Measurements were taken using a real ear occluded response method to determine sound pressure levels in the ear canal near the tympanic membrane at .25, .5, 1, 2, 4, 6 and 8 kHz. The test was repeated twice using the same HPD with the administrator removing and replacing the HPD between measurements. Then, the first set of HPDs were removed from the participants ear and the second set of HPD's were inserted into the participants near canals by the administrator and occluded MIRE measurements were run a total of three times with the administrator removing and reinserting the HPDs between measurements.

Threshold testing.

Next, the participant was placed approximately 1 meter from the loudspeaker in an audiometric booth. Unoccluded audiometric threshold testing was performed twice in soundfield at .25, .5, 1, 2, 4, 6 and 8 kHz using a pulsed, warbled tone in an ascending/descending method. The first set of HPDs were then placed by the administrator into the participant's ear and the test was repeated three times with the administrator removing and reinserting them in between measurements. The first set of HPDs were removed and the second set of HPD's were placed in the participant's ear by the administrator and the test was repeated for a total of three measurements with the administrator removing and reinserting them in between measurements. Once the data had been collected the researcher will evaluate statistical significances between the research group and the control group using SPSS software analysis.

CHAPTER IV

Results

The purpose of this research was to evaluate attenuation differences between custom order HPDs cast from do-it-yourself home impression kits and HPDs made from professionally made impressions. Two sets of earmold impressions were taken on a group of 10 participants. One set was taken by an amateur participant using a replica of a do-it-yourself home impression kit while the other set was taken by a professional, defined as an actively dispensing licensed audiologist. Full-shell Westone brand model 40 custom-fit high noise multi-purpose ear plugs with an NRR of 29 were cast from each set of impressions made. HPDs were evaluated in three ways: probe microphone measurements were to determine sound pressure levels in the ear canal near the tympanic membrane in unoccluded and occluded ear canals; behavioral thresholds were recorded with unoccluded and occluded ear canals; and earmold impressions were evaluated visually and graded by a third party HPD manufacturer.

Real Ear Results

To determine objectively how each HPD performed in the ear canal, real ear data was collected using a probe tube microphone system. Participants were placed in a soundproof booth 1 meter from a soundfield speaker. A 50 dB HL white noise signal was emitted through a soundfield speaker and the long term average speech spectrum [LTASS] frequency response curve for 1/12 octave frequencies from 200 to 8,000 Hz

were recorded in each ear. Two measurements were taken for each ear canal unoccluded, 3 measurements for each ear canal occluded with the amateur HPD, and 3 measurements for each ear canal occluded with the professional HPD. The LTASS consists of the peaks, averages, and valleys of speech and displays a 30 dB range of speech to include +12 dB for the peaks of speech and a -18 dB for the valleys of speech; both in comparison to the average frequency response curve (RMSL500SL Users Guide, 2012). The average measurements of each LTASS response recorded were averaged to produce a single frequency response curve for the unoccluded, occluded amateur, and occluded professional recordings for each participant (see Figure 1). As shown in Figure 1, significant attenuation was provided by HPDs manufactured from earmold impressions made by professionals when compared to those made by amateur earmold impression takers. Both HPDs made from earmold impressions obtained from both amateur and professionals showed significantly more attenuation when compared to the unoccluded ear canal.

Then, each participant's averaged unoccluded, occluded amateur, and occluded professional measurements were combined and averaged to produce a single mean left and right ear measurement for each condition, and a two-way repeated measures ANOVA was performed to determine the effect of training on impression taking for HPDs on real ear measures. The within subjects variable was condition with three levels (unoccluded ear canals, ear canals occluded with amateur HPDs, and ear canals occluded with professional HPDs). The between subjects variable was ear with two levels (right and left). The results showed a significant main effect for condition ($F[2,18] = 233.272$, $p < 0.001$) with a large effect size (partial eta squared = 0.963), indicating that

significantly different attenuations were shown when comparing unoccluded ear canals, amateur HPD occluded ear canals and professional HPD occluded ear canals. Furthermore, there was no significant main effect for ear ($F[1,9] = 3.084$, $p = 0.113$) or the condition by ear interaction ($F[2,18] = 2.883$, $p = 0.082$), indicating that the right and left ears showed similar attenuation results for each condition. To further examine the condition (i.e., unoccluded ear canals, ear canals occluded with amateur HPDs, and ear canals occluded with professional HPDs) main effect, pairwise comparisons were completed. A Bonferroni adjustment was completed for multiple comparisons. The results showed that unoccluded measures ($M = 69.14$) showed significantly more sound pressure in the ear canal than occluded amateur measures ($M = 54.47$), which showed significantly more sound pressure in the canal than occluded professional measures ($M = 49.63$). These results indicate that while the amateur HPD attenuates some sound from entering the ear canal, it was significantly less than the attenuation of a professionally made HPD.

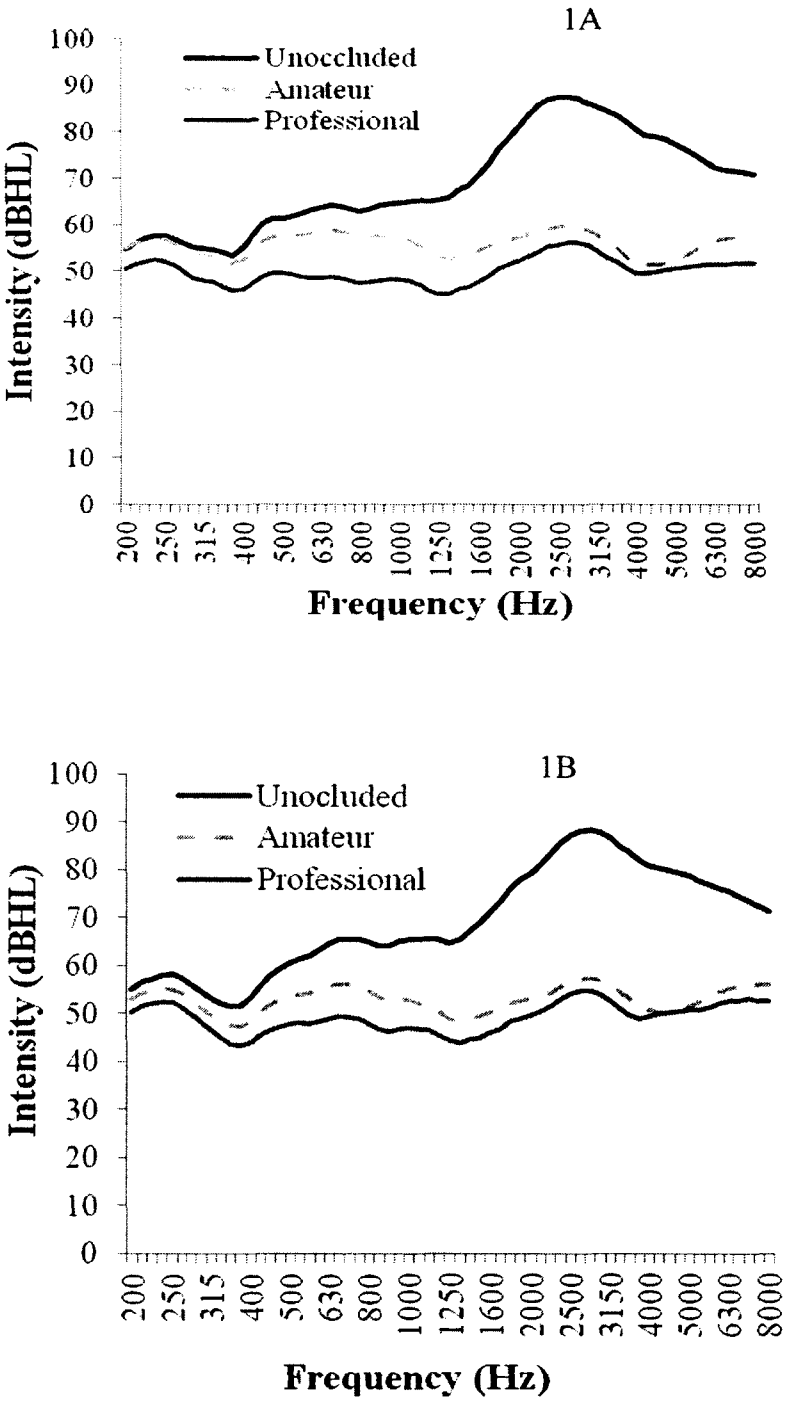


Figure 1. Mean real ear data for right (1A) and left (1B) unoccluded ears and ears using HPDs taken from impressions made by amateur and professional earmold impression takers.

Pure Tone Results

To determine subjectively how HPDs would perform in real-world type scenarios, behavioral thresholds were recorded in a soundproof booth with participants placed 1 meter from a soundfield speaker. Pure tone thresholds were obtained at 250, 500, 1000, 2000, 4000, 6000 and 8000 Hz using an ascending/descending method with 1 dB increments and a pulsed, warble pure tone stimulus. Thresholds were recorded with both ears unoccluded; both ears occluded with amateur HPDs, and both ears occluded with professional HPDs. HPDs were placed in the ear canal by the administrator and removed and replaced by the administrator between each series of thresholds obtained (i.e., thresholds were obtained at all frequencies 250 – 8000 Hz, then the HPDs were removed and thresholds from 250 – 8000 Hz were re-obtained). Thresholds were obtained at least twice under each condition. A third threshold was obtained for those conditions were obtained thresholds showed a difference of more than 2 dB, and the median of the three obtained thresholds was used for analysis purposes. If the threshold was within 2 dB, the mean threshold was used for analysis purposes. The median threshold was used a total of 44 times out of a total of 210 thresholds recorded. The mean or median threshold for each participant was then averaged across participants at each frequency for each condition: unoccluded, amateur occluded and professional occluded. Mean data for all participants is shown in Figure 3.

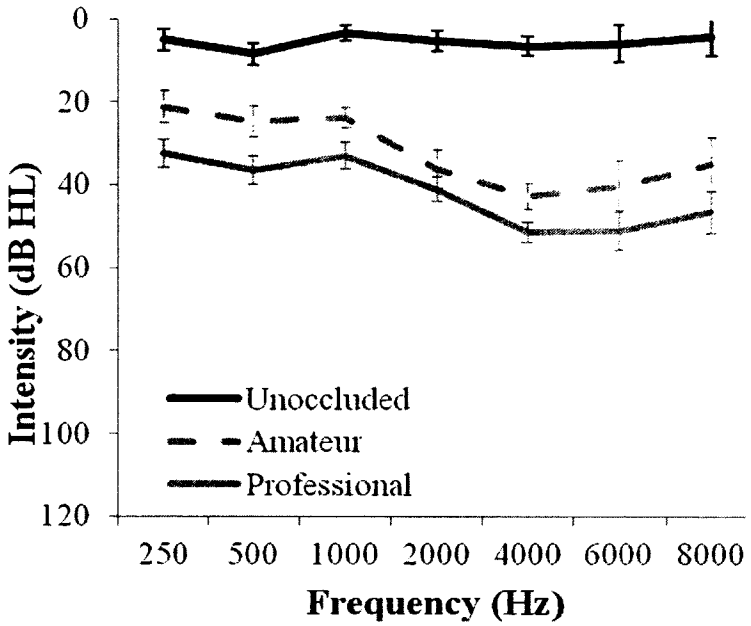


Figure 2. Means and standard deviations pure tone data for unoccluded ears and ears using HPDs taken from impressions made by amateur and professional earmold impression takers.

A one-way repeated measures analyses of variance (ANOVA) was completed to determine if training of the impression taker had a significant effect on attenuation of HPD performance. The grouping variables were threshold with seven levels (250, 500, 1,000, 2,000, 4,000, 6,000 and 8,000 Hz) and condition with three levels (unoccluded ear canals, ear canals occluded with amateur HPDs, and ear canals occluded with professional HPDs). Please note within this ANOVA 21 comparisons were completed (i.e., seven thresholds under 3 conditions); a Bonferroni adjustment for multiple comparisons was completed. The results showed a significant difference in thresholds for unoccluded, occluded amateur, and occluded professional conditions at each frequency tested ($F(14,26) = 13.05$, $p < 0.01$; see Table 1).

Table 1. Univariate tests displaying significance at each threshold tested.

Frequency	dF	F	Significance	Partial eta Squared
250	2	259.359	< 0.001	0.966*
500	2	157.167	< 0.001	0.946*
1000	2	474.929	< 0.001	0.981*
2000	2	320.158	< 0.001	0.973*
4000	2	481.936	< 0.001	0.982*
6000	2	226.082	<0.0001	0.962*
8000	2	152.418	< 0.001	0.944*

*large effect size

Because three conditions (unoccluded ear canals, ear canals occluded with amateur HPDs, and ear canals occluded with professional HPDs) were measured at each frequency, pairwise comparisons were completed to determine what measures were significantly different from others. All pairwise comparisons were significant. Specifically, HPDs made from amateur impressions showed significantly more attenuation from the unoccluded condition at each frequency. Furthermore HPDs made from the professional impressions showed significantly more attenuation than amateur impression HPDs at each frequency. These results indicate that pairs of custom HPDs made from casts of earmold impressions made by amateur impression takers have a significantly lower attenuation levels than those HPDs cast from earmold impressions taken by professionals who have been trained in earmold impression taking techniques. Furthermore, as a part of this ANOVA, partial eta squared (partial η^2) values were calculated to determine effect sizes of clinical significance. Ranges for effect sizes of clinical significance for partial eta squared are evaluated as follows: (1) large effect size ≥

0.138, (2) medium effect size ranged from 0.059 to 0.137, and (3) a small effect size ranged from 0.01 to 0.058 (Nolan and Heinzen, 2007). Statistical analysis showed that there was a clinically significant large effect size at all frequencies tested (see Table 1). These results indicate that the pure tone statistical differences noted in ear canals unoccluded, occluded with amateur HPDs, and occluded with professional HPDs also showed a large clinical significance at all frequencies.

Grading of HPDs

All earmold impressions were sent to Westone®, a leading manufacturer of HPDs to cast the HPDs used for this research. Experts at Westone photographed all impressions from 5 different viewing angles. The views are described as follows: (1) impressions mounted so that interior canals are pointing up/camera angle from inferior; (2) impressions mounted canals pointing up; (3) from inferior, impressions rotated slightly from View 1, to see anti-tragus portion of the impression/impressions mounted canals pointing up, view from anterior; (4) impressions mounted canals pointing inward/view from posterior; and (5) Impressions mounted with canals and helix area at top of view/view from interior. From these photographs the earmold impressions were reviewed by 3 earmold impression experts and evaluated on their acceptability for manufacture. Attributes evaluated were (1) sufficient canal length, (2) sufficient amount of material in the canal, (3) sufficient fill of concha, helix and anti-helix areas, and (4) evidence that the impression material having been pressed into the ear while curing as this has the ability to distort the ear anatomy, which could ultimately result in discomfort and/or sealing issues in the final HPD product. Impressions were also graded as either (1) acceptable for manufacture, (2) unacceptable and rejected for manufacture, or (3)

acceptable for manufacture but remakes due to insufficient fit would require a remake of impressions.

It is important to note that any impressions marked as rejected would not have been manufactured by Westone as to ensure proper safety of the devices; however, for the purpose of this study all impressions were made for evaluation. Of the 20 amateur impressions made, all 20 exhibited insufficient material in the canal, 18 exhibited insufficient canal length, and 13 exhibited insufficient material in the concha, helix and anti helix portions. All 20 impressions exhibited signs of being pressed into the ear while curing. Please note that directions for the amateur made impressions contained a direction to press the material into the canal. Of the 20 amateur made impressions 15 would have been rejected per Westone's standards, three would have been accepted and manufactured, and two were borderline but would have been accepted. Of the five impressions that would possibly be accepted, all five would require new impressions for remakes due to insufficient fit. Furthermore, in one subject a mole in the right ear canal was unmarked as a canal anomaly. Failing to note the mole, could lead the lab to potentially fill the indentation, which would cause significant discomfort when wearing a custom earpiece and possibly erode the seal of the HPD.

Of the 20 professionally made impressions, all 20 exhibited sufficient canal length, sufficient material in the canal, and all 20 would have been accepted for manufacture. Furthermore, six impressions exhibited small voids in the helix or antihelix portions that did not warrant rejection, but would require a new impression to be taken in the event a remake (see Figure 3 for a typical professional earmold impression).

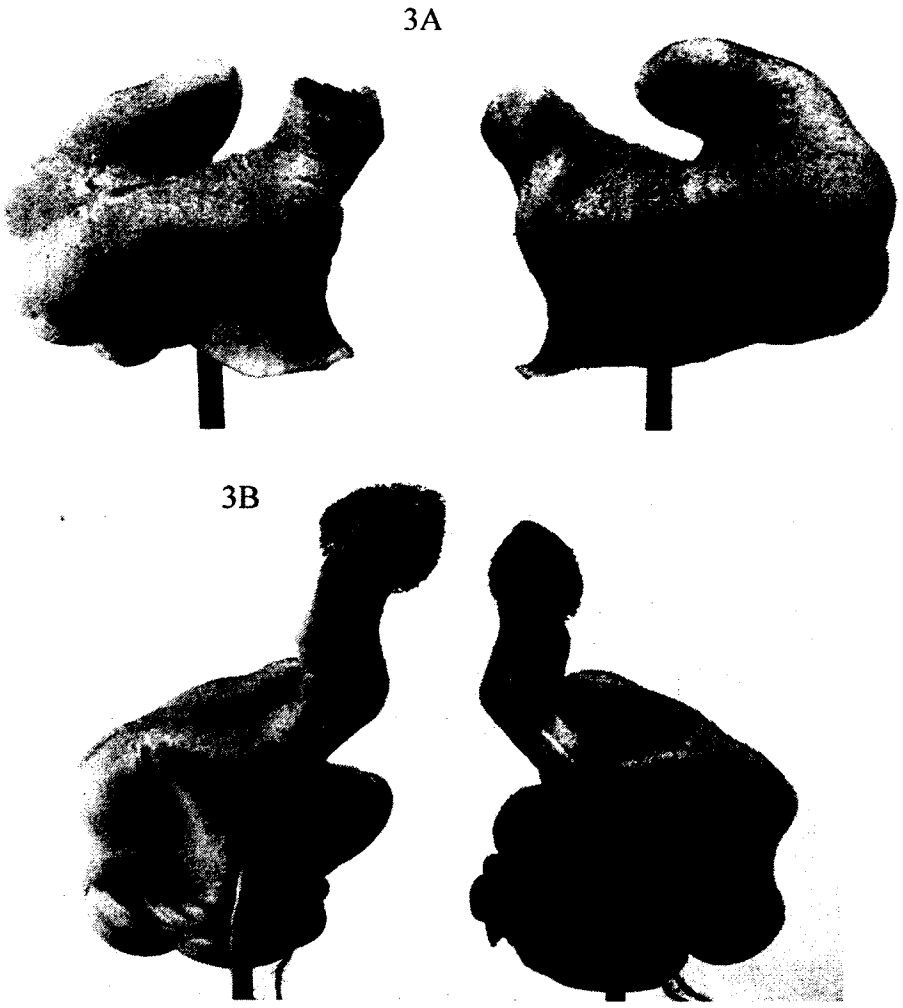


Figure 3. Picture of typical amateur (3A) and professional (3B) impression using data from the same subject.

CHAPTER V

Discussion

The overall purpose of this research was to evaluate the attenuation differences between custom order HPDs cast from do-it-yourself home impression kits and from those cast from professionally made impressions. Two sets of earmold impressions were taken on a group of 10 participants. One set was taken by an amateur participant using a replica of a do-it-yourself home impression kit while the other set was taken by a professional. Full-shell Westone brand model 40 custom-fit high noise multi-purpose ear plugs with an NRR of 29 were cast from each set of impressions. HPDs were evaluated in 3 ways: probe microphone measurements determined sound pressure levels in the ear canal near the tympanic membrane in unoccluded and occluded ear canals; behavioral thresholds were recorded with unoccluded and occluded ear canals; and earmold impressions were evaluated visually and graded by Westone, a third party HPD manufacturer.

Real Ear Results

In the present study sound pressure inside the ear canal was evaluated using real ear measurements. Real ear results showed HPDs made by professionals to have significantly more attenuation than those made by amateurs (see Figure 1). These results were expected as Pirzanski and Berge (2005) found that the impression material needed to reach the second bend of the ear canal and create a proper seal in order to effectively attenuate noise. In this study visual grading revealed 18 of 20 amateur impressions to

have insufficient canal length and all 20 professional impressions to have sufficient canal length. In order for the impression material to reach the second bend of the ear canal, the otoblock must be placed deep into the canal. This method may be uncomfortable for both the impression taker as well as the patient, possibly causing the amateur impression taker to place the otoblock and impression material too conservatively in the ear canal to reach the second bend. Furthermore, Pirzanski et al. (2000) found that jaw position during impression taking had a significant impact on attenuation. Impressions taken with a closed jaw had significantly lower canal diameters between the first and second anatomical bend than those taken with open jaw method. The amateur impression taker may be unaware that jaw movement during impression taking may reduce how snugly the HPD fits inside the canal resulting in a decrease of attenuations.

It is important to note real ear measures for the present study were completed in the conventional manner used in clinical audiology. In other words, the probe tube was inserted into the subject's ear, and then the HPD was placed in the ear on top of the tube. In order to make sure that the probe tube was not being closed off by placement of the HPD, real ear measurements were visualized prior to recording. The portion of the probe tube distal to the HPD was pinched closed by the administrator and real ear measurements were visualized to fall indicating a drop in recorded sound pressure. As the tube was released, the measurements were observed to increase, and the measurements were then recorded. As noted in Figure 1, similar attenuation results are shown for the low frequencies, namely 200 – 400 Hz, of the real ear curves when comparing the occluded and unoccluded results. This is most likely due to the fact that real ear measures were completed using a silicone probe tube, which likely degraded the

seal of the HPD in the ear canal. Attenuation in a sealed canal should show a 20-30 dB separation in low frequency attenuation between occluded and unoccluded conditions. This low frequency attenuation was shown in the pure tone results which were recorded with no degradation to the seal in the canal.

Pure Tone Results

The present study also evaluated insertion loss of amateur and professional HPDs. Results of puretone thresholds revealed amateur HPDs to have significantly less attenuation than professional HPDs at each frequency. These results indicate that pairs of custom HPDs made from casts of earmold impressions made by amateur impression takers have significantly lower attenuation levels than those HPDs cast from earmold impressions taken by professionals. These results were expected based on previous research. For example, Franks et al. (2000) as well as Toivonen et al. (2002) showed a significant correlation between a deep and snug fit of the HPD in the ear canal and higher attenuation levels. Furthermore, studies by Pirzanski et al. (2000) and Pirzanski and Berge (2005) found that attenuation occurs primarily in the canal rather than in the concha. Specifically, earmolds that fit more snugly in the ear canal and reach the second bend of the canal provided more attenuation than loosely fitting earmolds that do not reach the second bend of the ear. In summary, the pure tone results showed that amateur HPDs do not provide adequate attenuation to protect the wearer from environmental noise and increase the likelihood of noise induced hearing damage and subsequent permanent hearing loss.

Grading of HPDs

In the present study a visual grading of each impression was carried out by a leading HPD manufacturer. Specifically, HPDs were graded on four attributes that could result in a poor fit or degraded attenuation,(1) sufficient canal length, (2) sufficient amount of material in the canal, (3) sufficient fill of concha, helix and anti-helix areas, and (4) evidence that the impression material having been pressed into the ear while curing. Results of these measurements indicated each of the amateur made impressions exhibited 1 or more attribute that could result in poor HPD performance, and that 15 of the 20 impressions would have been completely rejected for manufacture. One important aspect is that 18 of 20 amateur made impressions exhibited insufficient canal length. This aspect is important as previous studies by Pirzanski et al. (2000) and Pirzanski and Berge (2005) have shown that sufficient canal length is necessary for proper attenuation. All professionally made impressions were sufficient in all four attributes and all would be accepted for manufacture.

Similarly, Kimball (2008) compared amateur and professional earmold impressions by evaluating visual grading scores of earmold impressions based on five criteria known to have an impact on HPD effectiveness. HPDs were evaluated by two different HPD manufacturing labs on the following criteria: (1) smoothness, (2) canal length showing the second bend of the external canal, (3) clearly defined helix, (4) clearly defined tragus, and (5) complete concha. Kimball (2008) found impressions made by professionals had significantly higher and more consistent visual grading scores than amateur made impressions. The results of these findings indicate that amateurs are unlikely to make impressions deep enough to reach the second bend of the ear thus

greatly reducing the attenuation of the HPD and increasing the risk of hearing damage from noise exposure. Similarly, this study found that impressions made by professionals scored significantly higher and more consistent visual grading scores than amateur made impressions. Both studies indicate that impressions made by professionals are more likely to produce an effective HPD based on criteria known to produce effective HPDs.

Clinical Implications and Future Research

Implications of this study strongly support the removal of do-it-yourself earmold impression kits from the market. First, there are significant safety concerns when using do-it-yourself impression kits such as the possibility of tympanic membrane perforations and failure to screen for contraindications. This study controlled for participant safety by: (1) screening for contraindications through taking a brief otologic history; (2) completing an otoscopic exam by a licensed audiologist; and (3) having the otoblock placement checked prior to the execution of the amateur impression. In fact, four participants were asked to replace the otoblock before continuing; in a real-world environment where these participants were performing ear impression at home, these four participants would have been at higher risk for tympanic membrane perforation and other middle ear damage. Even with administrator intervention for safety reasons, it is important to note that all amateur made HPDs still showed lower attenuation than professionally made HPDs and most would have been rejected by the manufacturer and not produced into HPDs.

Furthermore, all data collected in this study (i.e., probe microphone measures and pure tone measures) indicate that HPDs made from amateur impressions have significantly lower attenuation levels than HPDs made by licensed, dispensing

audiologists. Lower attenuation levels leave wearers exposed to the damaging effects of noise exposure. This may be especially important for wearers who believe their HPDs are attenuating the full labeled NRR of the device and are unknowingly overexposing themselves to noise. Therefore, earmold impressions should always be taken by a hearing healthcare provider such as a licensed audiologist, even in the case of mail order HPDs because licensed audiologists either have a masters or a doctorate degree in audiology and are trained to safely take effective earmold impressions. One way that internet HPD companies could facilitate the process of consumers having earmold impressions taken by an audiologist is to include a list of local licensed audiologists in the area. Another way to facilitate this would be for the HPD provider to contract with local, licensed audiologists to make the impressions and include the cost of the impression in the cost of the HPD.

One limitation to the current study includes the fact that this experiment was completed in a highly controlled environment, thus potentially lacking a real world experience for amateur impression taking. Specifically, professional audiologists were asked to evaluate ear canal health for contraindications such as abrasions, tympanic membrane perforations, diabetes or other contraindications that would degrade the integrity of the earmold impression or put the participant at risk for safety concerns. Furthermore, otoblock placement was examined before amateur participants were allowed to proceed with earmold impression taking. The audiologist evaluated the placement of the otoblock to ensure that otoblock provided a sufficient barrier between the impression material and the tympanic membrane. The audiologist had the participant remove and replace the otoblock every time that the placement appeared unsafe. As

noted before, even in this best case environment for amateur impression taking, all amateur made impressions still produced less attenuation than professionally made HPDs. Another limitation for the current study is that only one type of HPD was evaluated; however, many types are available on the market. Furthermore, this study sought to evaluate the relative attenuation difference between amateur and professionally made HPDs. Future research could evaluate the actual NRR of amateur made HPDs to determine if they actually meet the NRR rating under which they are sold. HPDs with lower attenuation than the labeled NRR could result in the wearer believing that they are protected from the effects of noise when they are actually being overexposed.

APPENDIX A

Volunteer Request Email

Volunteers are being sought to participate in a study entitled, "Effects of Untrained Earmold Impression Taking on Custom Hearing Protector Device Performance." This research sees to evaluate the properties of hearing protectors made from earmold impressions taken by persons without formal training and is designed to simulate an online purchase of a custom passive hearing protector device that is commonly fulfilled with the use of "do-it-yourself" home earmold impression kits.

In phase one, participants will be given earmold impression materials and written instructions and asked to create an ear impression on their participant partner. Participants will be asked to return to the clinic in approximately two weeks to further evaluate the custom hearing protector device. Participants will complete audiometric testing in a sound proof booth both with and without the hearing protector placed in the ear.

This study will take place in the Louisiana Tech University Speech & Hearing Center and will take approximately 60 minutes to complete phase one and 60 minutes to complete phase two. There are no known risks to subjects. Participation is voluntary and may be stopped at any time without penalty. Louisiana Tech is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.

If you are interested in participating please contact the Louisiana Tech University Speech & Hearing Center at 318-257-4766 to schedule an appointment. If you have any questions or concerns please feel free to contact the primary experimenter, Kelly Pack, at 38-257-4766.

APPENDIX B

Human Subjects Consent Form

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

TITLE OF PROJECT: Effects of Untrained Earmold Impression Taking on Custom Hearing Protector Device Performance.

PURPOSE OF STUDY/PROJECT: To evaluate the properties of hearing protectors made from earmold impressions taken by untrained and trained persons. This study is designed to simulate an online purchase of a custom passive hearing protector device that is commonly fulfilled with the use of "do-it-yourself" home earmold impression kit.

PROCEDURE: Materials will be provided to the participant and they will be asked to create two earmold impressions on another participant as well as have one set of earmold impressions taken by an untrained earmold impression taker on their ears. An additional set of earmold impressions will be taken on each participant administered by a licensed audiologist.

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

RISKS/ALTERNATIVE TREATMENTS: The participant understands that Louisiana Tech is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.

BENEFITS/COMPENSATION: I, _____, attest with my signature that I have read and understood the following description of the study, "Effects of Untrained Earmold Impression Taking on Custom Hearing Protector Device Performance", and its purposes and methods. I understand that my participation in this research is strictly voluntary and my participation or refusal to participate in this study will not affect my relationship with Louisiana Tech University. Further, I understand that I may withdraw at any time or refuse to answer any questions without penalty. Upon completion of the study, I understand that the results will be freely available to me upon request. I understand that the results of my participation will be confidential, accessible only to the principal investigators, myself, or a legally appointed representative. I have not been requested to waive nor do I waive any of my rights related to participating in this study.

_____ _____

Signature of Participant Date

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

Researcher: Kelly Pack: krp014@latech.edu or Melinda Bryan: Melinda@latech.edu
Members of the Human Use Committee of Louisiana Tech University may also be contacted if a problem cannot be discussed with the experimenters:
Dr. Les Guice (257-3056) Dr. Mary M. Livingston (257-2292 or 257-4315)

APPENDIX C

Participant Survey

1. Name: _____
2. Gender: Male_____ Female_____
3. Age _____
4. Education level: High School or Equivalent _____ College_____

   Post Graduate _____

Circle YES or NO

5. Have you ever received training on earmold impression taking?	Yes	No
6. Have you ever had an earmold impression taken of your ear?	Yes	No
7. Have you ever performed an earmold impression your own ear?	Yes	No
8. Have you ever performed an earmold impression on another person's ear?	Yes	No
9. Have you ever performed an earmold impression on an animal ear?	Yes	No
10. Have you ever worn a custom hearing protection device?	Yes	No
11. Do you currently wear a custom hearing aid device?	Yes	No
12. Do you have diabetes or HIV?	Yes	No
13. Do you currently have any ear pain, tenderness or drainage?	Yes	No
14. Have you ever had any ear surgeries?	Yes	No

APPENDIX D

APPROVAL LETTER FROM IRB BOARD

LOUISIANA TECH
UNIVERSITY

MEMORANDUM

OFFICE OF UNIVERSITY RESEARCH

TO: Ms. Kelly Pack and Dr. Melinda Bryan

FROM: Barbara Talbot, University Research

SUBJECT: HUMAN USE COMMITTEE REVIEW

DATE: February 13, 2012

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

"Effects of Untrained Ear Mold Impression Taking on Custom Hearing Protector Device Performance"

HUC 943

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

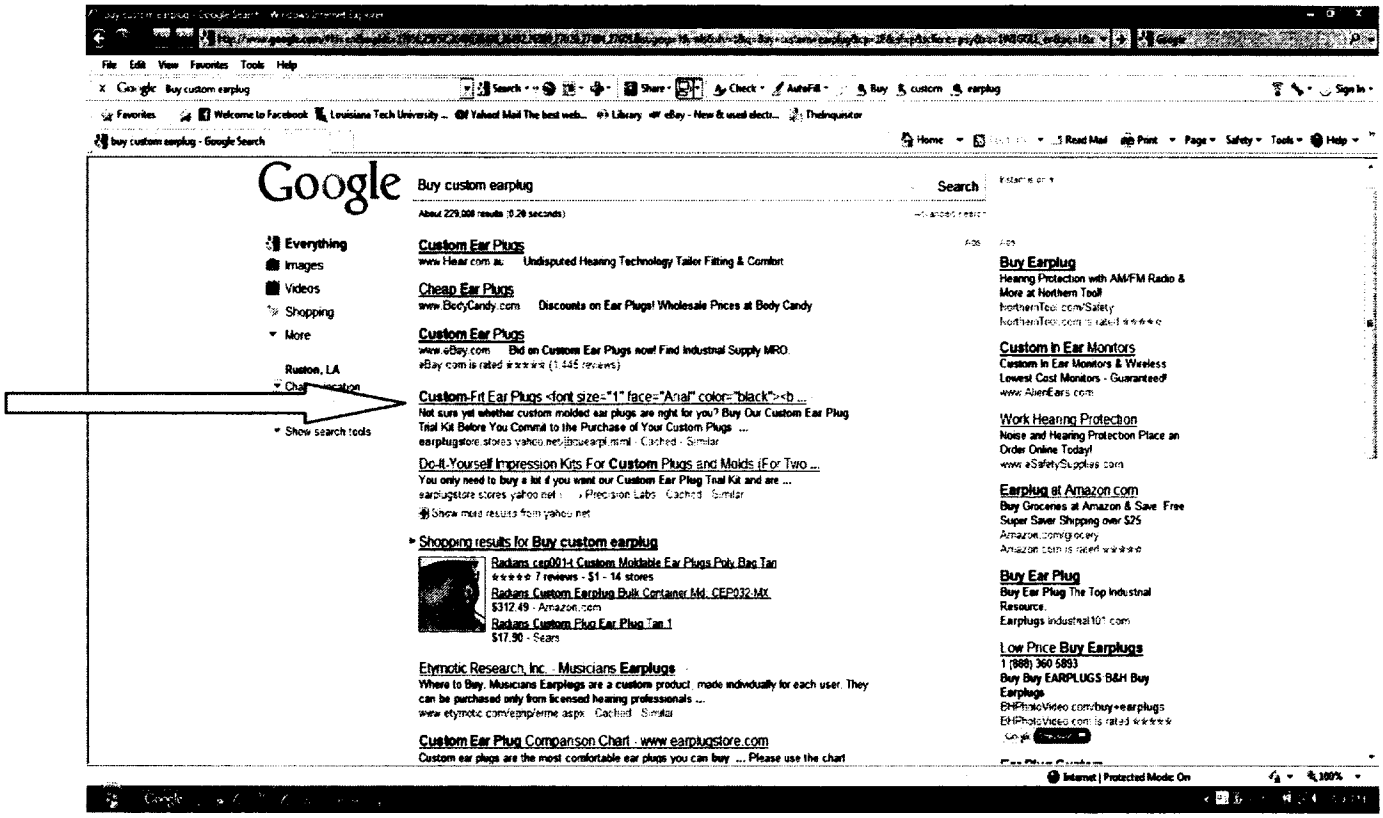
Projects should be renewed annually. ***This approval was finalized on February 13, 2012 and this project will need to receive a continuation review by the IRB if the project, including data analysis, continues beyond February 13, 2013.*** Any discrepancies in procedure or changes that have been made including approved changes should be noted in the review application. Projects involving NIH funds require annual education training to be documented. For more information regarding this, contact the Office of University Research.

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

If you have any questions, please contact Dr. Mary Livingston at 257-4315.

APPENDIX E

Internet Search Engine Results



APPENDIX F

Impression Kit Instructions

Step 1: Check your supplies.

Before handling any materials in the kit make sure your hands are clean.

Your impression kit should contain all of the following:

- From two to five packets of two-part impression material; one packet for each mold or plug you intend to have made, plus one extra packet in case you botch one. Each impression material packet should also contain two foam stops (a large one and a small one) and a Q-tip.
- One plastic tipped syringe.
- The box in which this kit was shipped to you, which you can use to return the impressions.
- A return shipping label.

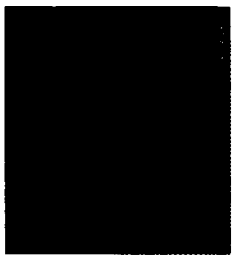
If anything is missing, please contact Ear Plug Superstore® for assistance: help@earplugstore.com or (918) 478-5500.

Step 2: Read all the instructions.

Before doing anything else, read all of the instructions so that you can move quickly through the steps. Once you mix the two-part impression material, it will immediately begin to set up, so time is of the essence.

Speaking of time, the temperature of the material dictates the setup time. The warmer the temperature of the material, the faster it sets up, so if the material is above 70 degrees Fahrenheit, put it into the refrigerator for an hour or more to cool it and thereby retard the speed at which the material will set up, giving you time to work with it. You can leave the material in the refrigerator indefinitely without harm

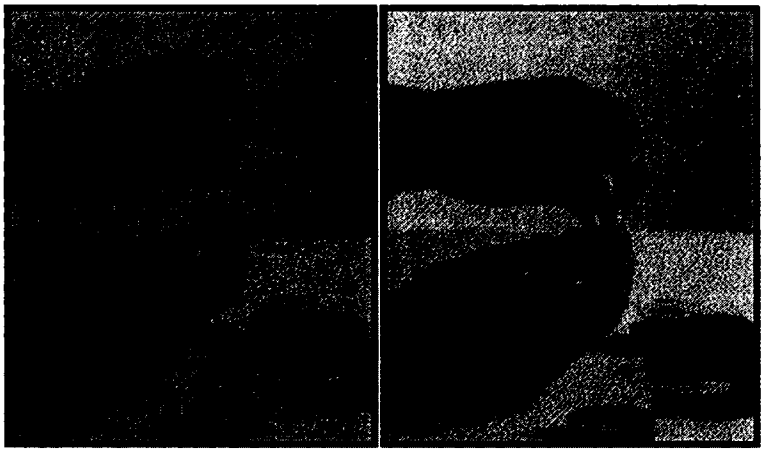
Step 3: Insert the Foam Stops



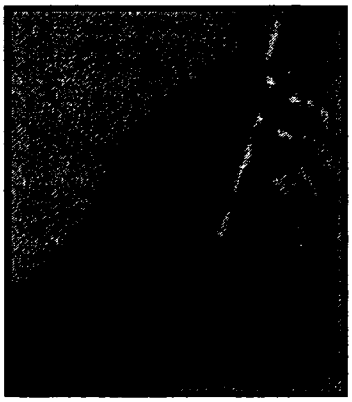
Put the larger foam stop into the ear canal, checking to make sure it fits properly. The foam should fill the ear canal, but should not be difficult to insert. If the foam piece is too large, try the smaller one, or simply trim a bit off to make it smaller. Be sure not to dislodge the string from the foam. The string might be needed later to help remove the foam stop from the ear canal.

(Do this next part yourself so that you can feel how deeply you are inserting the Q-tip) Use a Q-tip to gently nudge the foam stop down past the second bend in the ear canal. Have your helper look into your ear. When properly inserted, the foam stop should not be visible, or should be just barely visible, when your helper is looking directly into the ear canal. Be sure to leave the string hanging out of the ear. If needed, the string can later be used to remove the foam stop.

Step 4: Mix the Material



With the foam stop in the ear, prepare the two-part impression material for one ear. Using clean hands, remove all of the base (green) material from its container, and remove all of the hardener (white) from its container. knead the two blobs of material together in your fingers, working quickly, until the mass is a uniform color. Stop working the material after 15-20 seconds even if there are a few light streaks remaining. As long as the two parts are mostly combined the finished impressions will usually be fine, and continuing to work the material beyond 20 seconds could give you too little time to inject the material into the ear before it sets up.



Step 5: Put Mixed Material Into the Syringe

Remove the plunger from the syringe, place the kneaded material into the syringe and, using the plunger, push the material down into the tip until it is within 1/8" or so of the end. This will remove the air pockets from the material

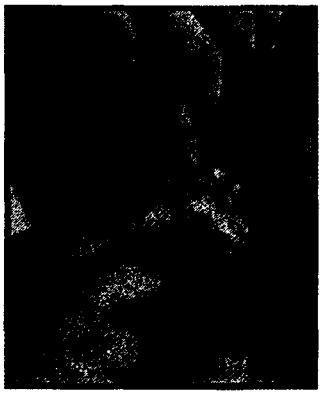
Step 6: Fill the Ear Canal and the Outer Ear
(This step is easier if done by a helper) Carefully place the tip of the syringe just inside the opening to the ear canal and using the plunger, force the material into the ear canal. The tip of the syringe should not touch the sides of the ear canal. As the material fills the ear canal, slowly withdraw the syringe and continue filling the helix, bowl, and tragus areas of the outer ear



Step 7: Firm the Impression Material with the canal, helix, bowl, and tragus areas filled, lightly firm the material into the ear with your finger to eliminate lines and air pockets. Be careful not to press so hard as to distort the ear.

Step 8: Let the Impressions Cure.
Now just relax, keeping your mouth closed and your jaw still, and wait 5-10 minutes for the material to set up. When ready, the material will be firm to the touch with no give at all when pressed on by your finger. Allowing ample time to cure will insure that your impressions will retain their shape after removal from the ear.
Allow the material to set up completely before removing it from the ear. If you are not sure, wait a little longer. The material should not yield to a firm touch. If you remove the material too early, you may distort the impression, especially the canal portion, which will potentially result in discomfort or a poor seal against water and/or noise when you get your finished custom ear plugs, custom earmolds or custom earphones. While you are waiting for the first impression to set up, repeat steps 2 through 7 for the other ear if you are making impressions of both.

Note: With both impressions in place at the same time, and before removing either of the impressions, you should experience approximately the same noise reduction that you will get with your finished ear plugs, depending on the exact model you are buying.



Note: If you are a singer buying custom earmolds or custom earphones for use during performances, you should hold your mouth wide open during the time the impression material is setting up. Mouth-open impressions will produce molds that fit more tightly and that will be less likely to come unsealed during loud singing parts that call for opening the mouth widely. Mouth-closed impressions will produce a more comfortable custom mold or plug to wear for extended periods such as during sleep, all day at work or while riding a motorcycle.

Step 9: Carefully Remove the Impressions
When you are sure the impressions are fully cured, remove each impression by working your fingers under the edges of the impression and gently prying it out. If the foam stop does not come out with the plug, use the string to carefully and gently pull it out.

APPENDIX G

Directions and Scenario Script

Research Group

"I'm going to read you the instructions for the task. After I am finished reading you may ask any questions that you may have. I will leave these instructions with you for your reference and will be observing you while you complete the task; however you will not be able to ask questions from me once the task has begun so listen to the instructions closely and ask any questions before we get started?

Here is the scenario for the research: A friend has recently decided to purchase a pair of these custom hearing protector devices from an online website. (Show picture of the pair of passive custom HPDs for visual reference.) Because they are custom fit, meaning custom made for his ears, they need to be made from an impression of his ear. The company has sent an impression kit with all the materials that he will need to make the impression himself (Show impression kit materials in the Westone earmold impression shipping box). Because it is hard for persons to make impressions on themselves, he has asked you to come over to help him make the impressions of his ears. The company has sent these instructions along with the materials for your guidance. Please be sure to complete steps 1-10" (Show instructions). You will each be performing earmold impressions on your partner. Once you are a finished a set of impressions will be taken on each of you by a licensed Audiologist.

You are allowed to use this computer equipped with internet service as well as the telephone freely, (Show computer and telephone). There is a hand cleaning station in the back of the room and a restroom in the hallway for your use, (Show station and restroom). You may also use any of these napkins, Kleenex or newspapers that you might need. (Show paper products). You may leave the room if necessary. You will have as much time as you need to complete the task. Once you have completed all 10 steps please announce to the research administrator that you are done to signify the completion of your task. Do you have any questions before we begin?"

Control Group

"I'm going to read you the instructions for the task. After I am finished reading you may ask any questions that you may have. I will leave these instructions with you for your reference and will be observing you while you complete the task; however you will not be able to ask questions from me once the task has begun so listen to the instructions closely and ask any questions before we get started?

Two clients have come in and want to purchase a pair of Westone brand model 40 custom-fit high noise multi-purpose ear plugs. Using the materials you have here you will be making one set of impressions on each participant. You will be using these Westone brand "Silicone Singles®" pre-measured one-to-one earmold impression material packets for impression material (Show impression material). You may use any of the equipment here in the audiology clinic including the otoscope, any of the polyethylene syringes, any of the foam ear dams in various sizes and/or the earlites. Once you are finished with the earmolds please pack them and prepare them to be

shipped to earmold laboratory in this earmold impression shipping box, (Show Westone earmold impression shipping box). You are allowed to use computer equipped with internet service as well as the telephone freely, (Show computer and telephone). There is a hand cleaning station in the back of the room and a restroom in the hallway for your use, (Show station and restroom). You may leave the room if necessary. You will have as much time as you need to complete the task. Do you have any questions before we begin?"

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