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Evaluation of Custom Hearing Protection Fabricated from Digital Ear Scanning and Traditional Methods

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United States Army Aeromedical Research Laboratory

Warfighter Performance Group

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14. ABSTRACT

The purpose of this study was to evaluate the hearing protection of custom earplugs made from six different fabrication methods. Three digital ear scanning methods, traditional physical ear impressions, digital scans of physical impressions, and a 3D printing method was used to create custom earplugs for 20 volunteer subjects. The hearing protection of the custom earplugs was evaluated by standard test methodologies according to the American National Standards Institute (ANSI S12.6-2016). A questionnaire was used to assess subjective comfort for each type of custom earplug. Results indicate traditional physical impressions produced significantly higher attenuating custom earplugs with the least comfort compared to all other custom earplug fabrication methods. Custom earplugs made from digital ear scanning methods were not significantly different from each other in terms of attenuation or comfort but were significantly better than the physical impression method for comfort.

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Summary

Making ear canal impressions is considered by many to be the riskiest procedure conducted by hearing practitioners. The consequences of iatrogenic injuries from these procedures can be catastrophic, ranging from the need for surgical intervention to complete hearing loss in the affected ear. To reduce these risks, several optical ear-canal scanning devices have been introduced. The purpose of this study was to evaluate the hearing protection of custom earplugs made from six different fabrication methods. Three digital ear scanning methods, traditional physical ear impressions, digital scans of physical impressions, and a 3D printing method were used to create custom earplugs for 20 volunteer subjects. The hearing protection of the custom earplugs was evaluated by standard test methodology according to the American National Standards Institute (ANSI S12.6-2016). A questionnaire was used to assess subjective comfort for each type of custom earplug. Results indicate traditional physical impressions created significantly higher attenuating custom earplugs with the least comfort compared to all other custom earplug fabrication methods. Custom earplugs made from digital ear scanning methods were not significantly different from each other in terms of attenuation or comfort but were significantly better than the physical impression method for comfort. In conclusion, it appears that digital ear scanning methods may not be appropriate for fabrication of all custom earplugs but may still be appropriate for hearing protection at moderate noise levels and for ear pieces not intended as hearing protection devices.

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Introduction

Exposure to high levels of noise can cause irreversible injuries to the human auditory system. These often-preventable injuries can affect communication, social abilities, safety, and health (Moos et al., 2018). Furthermore, noise-induced hearing injuries (NIHIs) have detrimental effects on warfighter lethality, survivability, combat readiness, and mission success.

To decrease the risk of hearing injuries, Soldiers routinely exposed to hazardous noise are enrolled in the Army Hearing Program (AHP) (Department of the Army, 2015), which aims to prevent noise-induced hearing loss (NIHL) through implementation of operational and clinical hearing services, hearing readiness, and hearing conservation. Specifically, the hearing readiness component of the AHP ensures “Soldiers have the required hearing capability to perform their job-specific duties, as well as the appropriate and properly-fitted hearing protection devices for their mission” (Department of the Army, 2015, p. 4). In addition to Army regulations, employers in the United States are required to provide hearing protection devices (HPDs) to workers exposed to hazardous occupational noise (Occupational Noise Exposure, 1983).

In many situations, HPDs are the only defense workers have against NIHIs. However, HPDs are only effective if they fit the individual well enough to attenuate sufficient noise for his or her needs and if the individual wears them while exposed to the hazardous noise. According to the Occupational Safety and Health Administration (OSHA), an estimated $242 million is spent annually on workers compensation for hearing loss disability (Occupational Safety and Health Administration, 2018). Hearing injuries (hearing loss and tinnitus) have also been the two most prevalent compensatory disabilities from serving the in the U.S. military (Veterans Administration, 2019). Furthermore, the most prevalent form of acquired hearing loss is caused by noise (Nelson, Nelson, Concha-Barrientos, & Fingerhut, 2005). Thus, it is apparent from the numerous cases of hearing loss caused by noise, in both military and industry, that protecting workers from noise has not been done well to date.

As mentioned, HPDs are only effective if they fit the individual well enough to block hazardous noise from entering the auditory system. Due to the variance in anatomy between persons, a one-size-fits all approach generally does not work. However, numerous HPDs are commercially available in wide ranges of types, styles, sizes, and materials (e.g., polyvinyl chloride, polyurethane foam, silicone). If a commercial off the shelf (COTS) product does not provide an adequate fit, HPDs can also be tailor-made to fit the individual, commonly referred to as custom earplugs or custom-molded HPDs. Thus, custom earplugs, in theory, should ideally fit the intended individual to block hazardous noise while also accommodating their specific anatomy comfortably.

In addition to being specifically made to fit each user, custom earplugs have other potential advantages for protecting workers from noise. Some advantages may include increased comfort and compliance with requirements to wear HPDs since they are often requested by workers. Custom earplugs also usually provide the same level of protection each time they are worn (Du, Homma, & Saunders, 2008), which generally provides a more consistent level of protection between fittings than non-custom earplugs (Tufts, Jahn, & Byram, 2013). This is primarily because non-custom earplugs may be inserted at different depths or positions in the ear canal depending on the user's fitting technique. Furthermore, for traditional foam earplugs, a roll-down technique is usually performed before fitting the earplug. This technique reduces the size of the foam earplug to allow placement in the ear canal and should be done in a uniform manner to prevent folds or creases. Once placed in the ear, the foam earplug expands, conforming to the shape of the ear canal to create an acoustic seal. However, the roll-down technique is not always done correctly or the same way between fittings, which can cause variation in the level of hearing protection provided. Conversely, custom earplugs are donned the same way and to the same depth of the ear canal, providing less variation between fittings. Custom earplugs are also highly attenuating if they are made to fit deep within the ear canal. In fact, Du et al. (2008) reported deep insert custom earplugs—made to fit up to or beyond the second bend of the ear canal—provided hearing protection similar to or greater than standard foam earplugs. Custom earplugs have also shown relatively stable attenuation levels even after performing rigorous physical activities and jaw movements (Du et al., 2008).

Likely due to many of the factors mentioned, the use of custom earplugs in the military has been increasing. However, the process to create a custom earplug is neither timely, efficient, nor without a certain amount of risk. For instance, Beyer and Younker (2011) and Shaw (2014) noted taking ear impressions as the riskiest procedure performed by audiologists. While the procedure is usually performed safely, it is an invasive process that can sometimes have unforeseen problems.

To make a custom earplug, the process usually starts with an otoscopic examination to determine suitability of the individual's ears for making an ear impression. If the individual is a suitable candidate, the trained professional places an oto-block in the ear canal. The oto-block is used to prevent impression material from advancing too deep within the ear canal or from contacting the tympanic membrane (TM). Next, the hearing professional (should) examine the ears to verify correct placement and proper sealing of the oto-block to the walls of the ear canal. If there are gaps, the oto-block should be adjusted or a different size may be needed. Once the oto-block is in the correct position, impression material is inserted into the ear canal with an injection gun or syringe. This process takes a certain level of skill and experience to ensure the material is injected in a controlled, smooth fashion to prevent voids while also not applying too much pressure, which can push impression material too deep or even around the oto-block. After the impressions material cures (approximately 5 minutes), the impressions are removed and inspected for voids and proper retention features. The ears should then be inspected again to ensure all material was removed.

However, this procedure is not without risk (Beyer & Younker, 2011; Shaw, 2014). Most of the reports of ear injuries from impressions are case studies from the hearing-aid industry (Algudkar, Maden, Singh, & Tatla, 2013; Holdstein, Mazzawi, Watad, & Shupak, 2013; Kohan, Sorin, Marra, Gottlieb, & Hoffman, 2004; Lee & Cho, 2012; Leong, Banhegyi, & Panarese, 2012; Meyers, Ardeshirpour, Hilton, & Levine, 2013; Wynne, Kahn, Abel, & Allen, 2000). In these case studies, the impression material was forced through the TM into the middle-ear cavity as a result of a failure to use an oto-block, the presence of a perforated TM, or the impression material being forced through a previously-intact TM. When an oto-block is used, impression material can be forced past the oto-block (i.e., sometimes called a “blow-by”). Blow-bys typically result when an oto-block does not sufficiently seal the ear canal (due to incorrect size or subject jaw movement while the oto-block is being inserted), excessive pressure from an impression syringe or impression gun, excessive jaw movement by the subject while the impression material is being introduced into the ear canal, complications from failure to conduct a proper otoscopic inspection, failing to observe impacted cerumen or TM perforations. Fatigue (especially in a one-person shop) and inattention also can result in blow-bys.

When the impression material solidifies against the TM and the impression is removed from the ear canal, the TM or TM and one or more middle-ear ossicles can be removed as well. If the ear impression cannot be removed, frequently due to the excruciating pain experienced by the patient, surgical removal is required (Holdstein et al., 2013). The consequences of these types of injuries can include abrasions, hematoma, trauma, lesions, or destruction of the TM and/or the middle ear ossicles, removal of a pressure equalization tube, perilymph fistula, severe vertigo, and temporary or permanent hearing losses from inner-ear trauma (Beyer & Younker, 2011; Leong et al., 2012; Wynne et al., 2000).

Although relatively rare, these injuries can be catastrophic and devastating. For the Soldier, in the most severe cases, permanent hearing losses including complete loss of hearing in the affected ear, severe vertigo, disarticulation or removal of the middle-ear ossicles, can result. Each of these consequences would negatively affect the readiness of the Soldier. An aviator with vertigo cannot fly. A Soldier with a dead ear, while deployable, will be a danger to himself and his unit due the loss of his binaural hearing ability for localization and signal segregation. For the civilian clinician, consequences can be suspension or revocation of a license to practice, malpractice legal suits, and large cash malpractice settlements.

The objective of this study was to evaluate emerging technologies in digital ear scanning. Digitizing the process to capture ear canal geometries for the production of custom earpieces has potential to create efficiencies while also reducing or eliminating the risk of injuries compared to the current process. Three private companies have developed digital ear scanning technologies that may eliminate the need for making physical ear impressions. These technologies use light capture methods to create 3D models of the ear and ear canal. The digital 3D models can then be modified with computer-aided design (CAD) software to create custom fitting earpieces.

In contrast, traditional fabrication methods require making physical earmold impressions. The physical impressions are then shipped to an earplug manufacturer and either casted to create a negative mold of the ear or scanned by an ear-impression scanner to create a digital model of the physical impression. The earplug manufacturer then models the ear impressions (physically or digitally) to create custom earplugs for the user. Both of these methods are used currently to produce custom earpieces.

To evaluate and compare fabrication methods, custom earplugs were made from six different methods. Both traditional fabrication methods, using physical ear impressions and digital scans of the physical impressions, were used along with three digital ear-scanning methods, and an in-house 3D printing method. The hearing protection of custom earplugs made from each method was evaluated using standard test methodologies. An additional measure, comfort index, was evaluated by questionnaire.

Methods

Sound attenuation testing was performed in accordance with (IAW) the American National Standards Methods for Measuring the Real-Ear Attenuation of Hearing Protectors Method A: Trained-subject fit defined in ANSI/ASA S12.6-2016 (Acoustical Society of America, 2016). The acoustical testing facilities used for this study at the U.S. Army Aeromedical Research Laboratory (USAARL) meet all of the qualifications specified in the standard.

Subjects

Twenty-four volunteer subjects (14 male, 10 female) were recruited from the USAARL Acoustics Branch Volunteer Listening Panel. All volunteers on the listening panel satisfy the subject requirements specified by ANSI/ASA S12.6-2016. Three subjects were not able to participate in the study due to ear anatomy or excessive cerumen preventing ear impressions to be made. One subject was unable to return for testing. Twenty subjects (11 male, 9 female) completed the study.

Procedure

Each subject visited the Laboratory on three separate occasions. On the first visit, subjects were given an informed consent document to read, ask questions, and sign if they agreed to participate in the research study. After the informed consent document was signed, an otoscopic examination was performed by a certified occupational hearing conservationist. After subjects were qualified to be in the study, digital ear scans and physical ear impressions were obtained. Six pairs of custom earplugs were made, each from a different fabrication method. Three pairs were made from three different digital scans of the ear (described below), one from physical ear impressions, one from digital scans of the physical impressions, and one pair was made at USAARL using 3D printing.

After custom earplugs were fabricated, subjects returned to complete real-ear attenuation at threshold (REAT) testing and subjective questionnaires on comfort. Three custom earplugs were evaluated on each of the second and third visits. The order of the REAT tests were counterbalanced between subjects so that the first three earplugs evaluated by the first half of the subjects were evaluated last by the second half of the subjects. After completing a custom earplug REAT test, a questionnaire was completed about the perceived comfort for that particular earplug while the earplugs remained donned. All earplugs were also weighed to the 100th gram for additional comparisons.

Statistical analyses were performed using STATISTICA™ version 13.2 from TIBCO Software Inc., Palo Alto, CA. The probability of a Type I error was set at 0.05 for all analyses.

Equipment

The REAT testing procedure utilized two QSC Audio PLX 3402 power amplifiers, three Electro-Voice T251 speakers, a National Instruments (NI) PXIe-1062Q chassis with digital signal analyzers, data acquisition hardware and control circuit modules (PXle-8360, PXI-6620, PXI-4461), and a personal computer (PC) running Windows 10. The sound field was generated using REATPro software. TRIDENT software was used to measure one-third octave band frequency information, and results were exported to Microsoft Excel. Both REATPro and TRIDENT were developed by VIacoustics. Calibration of the system was checked daily by sound field measurement using a Brüel & Kjær (B&K) Type 4942 1/2-inch microphone, coupled to a B&K Type 2671 preamplifier and a B&K Type 4231 microphone calibrator. Weight of earplugs was obtained using a calibrated compact digital scale model number HL-100 from AND A&D Weighing.

Comfort Index

Immediately after completing attenuation testing for each custom earplug, subjects completed a questionnaire on their perception of comfort while the hearing protector remained donned. The original comfort index was developed by Casali, Lam, and Epps (1987), and modified by Byrne, Davis, Shaw, Specht, and Holland (2011). The modified version described by Byrne et al. (2011) was used in the present study. The questionnaire consisted of 14 word-pairs describing how the earplug felt to the individual. The word pairs were separated on a five-point scale with the word most associated with comfort representing a score of 1 and the word most associated with discomfort representing a 5. By summing the total points for the 14 word pairs, the comfort index ranged from 14 (most comfortable) to 70 (least comfortable).

Otoscopy

Video otoscopy was performed using a Welch-Allyn® Digital MacroView™ otoscope. Otoscopy was used to ensure subjects qualified and to rule out any conditions that may interfere with scanning or impressions (e.g., impacted cerumen, collapsed canal, visible debris, infection, etc.). Ear canal images were retained prior to digital ear scans, after completing all digital ear scans, and after completing physical ear impressions.

Digital Ear Scans

Following acceptable otoscopic examination, digital ear scans were captured for each volunteer (both ears) using three different digital ear scanners. The same manufacturer-trained technician performed all digital ear scans.

1.) AURA™ 3D Ear Scanning System by Lantos™ Technologies

This system is comprised of a hand-held scanner (Figure 1), docking station, disposable membranes, water-based solution cartridges, a PC and software, power supply, and an Ethernet connection to transfer data from the scanner to the laptop computer.

Figure 1. AURA™ 3D ear scanning system by Lantos™ Technologies.

Pre-scan set-up.

Prior to conducting a scan, the operator first loaded the scanner with a solution cartridge and a new disposable membrane. The software, UveroView, was loaded and configured with the subject's information (e.g., identification number). The scanner was then prepped—process by which the membrane is inflated and deflated to check for any issues or possible leaks in the membrane. Next, the operator inflated the membrane partially by pressing the corresponding button on the scanner and extended the scanning probe. After minor adjustments to the membrane and cleaning of the viewing window, if needed, a clear video image was displayed on the PC (the tip of the scanning probe contains a camera, which enables video otoscopy and proper placement of the probe in the ear). If the camera lens becomes foggy or cloudy, a defogging solution may be applied to obtain a clear image. After pressing the select button on the scanner, a yellow circle is viewable on-screen to assist with placing the scanning probe at an appropriate depth in the ear canal. For example, when the TM is approximately lined-up with the yellow circle (viewable on the PC), the scanning probe is approximately 4 millimeters (mm) from the TM.

Scanning process.

After the scanner set-up, the scanning probe was carefully placed in the subject's ear canal to the desired depth (viewable on the PC) and the membrane was inflated by pressing the corresponding button on the scanner. The fluid-filled membrane inflated, conforming to the shape of the ear canal, and the scanning probe retracted. The operator then extended the probe, scanning the interior membrane, in a controlled smooth method picking up data points of the membrane (viewable onscreen as red dots that turned to black dots after acquiring the data points). Once the operator scanned all the data points, the stop button on the scanner was pressed. The membrane then deflated and the probe retracted. This process generated a 3D model which was viewable onscreen. The 3D model could be viewed and saved or discarded if not acceptable. Notes may also be inserted into the image to describe characteristics of the ear (e.g., correct anatomical structures noted). The process was repeated for the other ear. The same membrane was used for both ears of the same subject but not between subjects.

It should be mentioned that a quick stop button is located on the scanner that will stop, deflate, and retract the probe if there is a need to do so at any time during the scanning process. Also during scanning, if the operator moves the probe too quickly (not allowing time for the scanner to acquire the data points), the scanner can lose the stitch (3D model being created) and the scan will need to be restarted. No problems or issues occurred with the equipment or the scanning process during this study.

The Lantos 3D scanning system utilized in this study only scanned the ear canal portion of the ear and not the outer ear (concha bowl or pinna). The manufacturer of this scanner has developed a new membrane, and has launched a "full-ear" scanning system. The manufacture states the updated system, the "Lantos L3DS-19" is commercially available and leverages data capture of the outer ear, including upper and lower concha, in addition to the ear canal to within 4 mm of the TM.

2.) 3Shape Phoenix™ Scanner by 3Shape A/S

The 3Shape Phoenix™ scanner by 3Shape A/S system is comprised of a hand-held scanner (Figure 2) with a mirror tip, docking station, a PC and software, power supply, an Ethernet connection to transfer data to the PC, and a calibration device. The scanner tip can be removed and replaced, if needed.

Figure 2. 3Shape Phoenix™ Scanner by 3Shape A/S.

Pre-scan set-up.

Prior to conducting a scan, the system was first connected to the PC and powered on. The software, Ear Scan Studio, was loaded and the mirror tip placed on the scanner. The mirror tip was cleaned with an alcohol prep pad. The included calibration block was placed on a flat surface and the scanner tip inserted into the calibration block. The scanner was calibrated by selecting the calibration tab within the software, which took only a few seconds to complete. After successful calibration, the subject's info was loaded into the software and the system was ready for scanning.

Scanning process.

The operator started by scanning the subject's ear from the base of the crus (top portion of the cymba) and then rotated the mirror tip approximately 90º so the mirror tip faced the top side of the cymba. The tip was then moved slowly along the top of the cymba all the way to the cavum of the concha bowl. After scanning the concha bowl, the scanner tip was pointed at the ear canal with the base of the scanner laid flat to the subject's ear. This allowed for the light to point into the ear canal. The tip was then rotated around the aperture of the canal to capture the geometry of the ear canal up to the first bend. After completing the scan, the operator turned the scanner off by pressing the on/off button located on the scanner. The file was saved and post-processing steps followed. The operator viewed the 3D model on the PC screen and selected three point locations (one below the first bend, one on the outer left side of helix and one at the top of the cymba). The software processed the image and a smoothed 3D model appeared onscreen. The operator again selected the same three point locations and the software processed the model a second time. After the software finalized the 3D model, the onscreen model depicted the actual data collected for the subject's ear and areas that were added by the software via red coloring. The final model was saved and used for the production of custom earplugs. The model may also be discarded and the process repeated if the final 3D model was inaccurate or if it did not contain enough actual data. The process was repeated for the other ear.

This scanner picks up images from the scanning surface (i.e., skin) and constructs a 3D model in real-time. If the operator moves the scanner tip too fast, the scanner will stop acquiring data (i.e., lose stitch), but the operator can slowly move the tip backwards until the scanner recognizes the last known location of the stitch and continue from that point going forward. The system uses a continuous scanning process with an audible clicking noise that keeps the operator informed of data acquisitions. If the audible clicking stops, the operator can back-up the scanner slightly to continue capturing the needed data for that area. However, if the operator moves too fast or too far and cannot regain the last known data acquisition location, the scan will have to be stopped and restarted. No problems or issues occurred with the equipment or the scanning process during this study.

3.) eFit™ Scanner by United Sciences

This system is comprised of a hand-held scanner (Figure 3), docking station (Figure 4), circumaural headset (Figure 5), PC and software, power supply, and a USB connection to power the scanner and transfer data to the laptop computer.

Figure 3. eFit scanner.

Figure 4. eFit scanner and docking station.

Pre-scan set-up.

Prior to conducting a scan, the system was first plugged into the PC and the scanner was turned on by loading the eFit software. The scanner probe tip was cleaned with an alcohol prep pad (tip should be cleaned before and after use). After loading the software and entering a subject's information, the scanner was calibrated while in the docking station/cradle. After successful calibration, the scanner was ready for use as either a video otoscope, with the ability to capture pictures of the ear canal, or as a 3D scanner.

Prior to scanning, the manufacturer recommends the subject clean their ears with a cotton swab dipped in alcohol. The alcohol helps remove loose oil and wax from the ear canal, which helps ensure the scanner probe remains clean and allows the camera to view the canal walls more clearly. Next, the subject must don the included headset (Figure 5). The headset has two rings, which fit around the ears. The surface of the rings contain special marking used by the scanner cameras to track where the scanner is located. The scanner cannot operate without the use of the headset or if the rings are blocked (e.g., by hair). The ears should be centered, completely within the rings and not pressing against the ears. Once the headset is in the proper position, the subject is ready to be scanned. However, caution should be used to ensure the headset does not move once the scan has started, as it can affect the accuracy of the 3D model. If the headset is moved or bumped after the scan has commenced, the scan should be restarted. The headset also has small spines located on the head position and around the ears to reduce movement.

Figure 5. eFit headset and training ear.

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Scanning process.

To conduct a 3D scan, the New Scan button is selected from one of three ways—the mouse on the PC, the trigger button on the scanner, or the touchscreen located on the scanner. The first step was to set the depth gauge of the probe by pressing the probe tip gently to the flat part of the concha and pressing the trigger button. This sets the reference point for the depth gauge, which estimates the distance to the TM based on the average adult ear. The depth gauge and video images are visible on both the PC and the scanner screen. Next, the probe tip was inserted slightly into the ear canal and the scanner calibrated the light (approximately 1-2 seconds). The scanner then began acquiring data of the ear canal as the operator carefully maneuvered the scanner tip to the desired depth of the ear canal. Usually, the scanner tip should be directed at scanning either the top or bottom portion of the canal on the first pass and the other portion on the next pass. The operator viewed the construction of the 3D model in real time while scanning the ear canal. If any parts of the ear canal were not acquired (i.e., holes in the 3D model) additional passes were made to acquire the missing data points. Once all the areas were filled, the canal portion of the scan was complete.

The outer ear was scanned next by selecting the line scanner. The outer portion of the ear was scanned by moving the line scanner over the surfaces of the outer ear. Once all the areas were scanned with the line scanner, the ring scanner was used to fill-in any missing data points. The ring scanner was used to acquire data in the helix and concha bowl areas (the non-flat surfaces). Once the 3D model was constructed and all data points were collected (i.e., no gaps or holes in the image), the scan was saved. The process was repeated for the other ear. There were no issues with the equipment or scanning process during this study.

Physical Earmold Impressions

After digital scanning, each subject had earmold impressions made by a technician trained and certified by the custom earplug manufacturer used in this study. The earmold impression process involved placing an oto-block—a small vented piece of foam for blocking impression material from reaching the TM (Figure 6)—in the subject's ear canal using an earlight tip. After ensuring the proper placement of the oto-block, impression material (vinyl polysiloxane) was injected into the ear canal with an impression gun. Once the ear canal and concha were filled properly, the impression material remained in place for approximately five minutes to cure before being removed. After the earmold impression was removed, it was inspected for voids and retention features. An otoscopic inspection followed to ensure no impression material remained in the ear canal. There were no issues with the ear impression process and no remakes were required during this study.

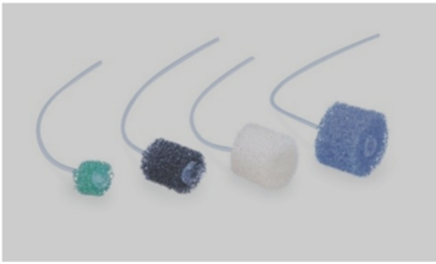

Figure 6. Westone Laboratories Ear Dams (oto-blocks).

Ear Impression Scans

After physical earmold impressions were obtained, they were scanned using a 3Shape A/S Model H600 ear impression scanner. The scans were saved and sent to the custom earplug manufacturer for fabrication of custom earplugs for each volunteer.

Production of Custom Earplugs

All eFit scans, 3Shape scans, physical earmold impressions, and physical ear impression scans were sent to Westone Laboratories for custom earplug fabrication (custom earplug model number AXHPK). Lantos scans were sent to Lantos Technologies for the production of custom earplugs from that system. The model of earplugs made by Lantos were UVERO max. Custom earplugs were also produced at USAARL using 3D printing from each of the scanning methods.

3D Printing

Digital scans were modeled in-house using Cyfex Secret Ear Designer®. An Envisiontec Perfactory® Micro 3D printer and E-Silicone M were used to print custom earplug shells at USAARL. After printing, the shells were washed in a solution of isopropyl alcohol, as instructed by Envisiontec. The alcohol was removed from the shells with pneumatic pressure. The shells were injected with a vulcanizing silicone material—Biopor® AB 40 shore from Dreve America. A pressure polymerization unit—Polymax 1, was used to cure the material in approximately 15 minutes at 5 bar at 60 degrees Celsius. The shells were then removed from the silicone material and the remaining earplug was evaluated.

Each type of digital scan was used for 3D printing as a proof-of-concept. Thus, each volunteer had a single set of 3D-printed custom earplugs made from one of the digital scanning methods. That is, five subjects had custom earplugs 3D printed from impression scans, the next five subjects from eFit scans, five subjects from 3Shape scans, and finally five subjects from Lantos scans. All modeling and printing were completed by the same technician. No formal training on earplug modeling was completed. However, self-training and trial-error was conducted prior to data collection to refine parameters of modeling and 3D printing.

Results

The mean attenuation results are shown graphically in Figure 6 and tabulated in Table 1. Analysis of Variance (ANOVA) with repeated measures on two factors (earplug fabrication method and octave-band center frequency) showed statistically significant differences between custom earplugs made from the different fabrication methods $F(30, 684) = 3.04$, $p < .001$. Post-hoc analysis using the Duncan multiple range test showed statistically significant differences for each earplug fabrication method compared to the standard physical impression method at all test frequencies except for one method, at only one frequency (Lantos at 2000Hz). No statistically significant differences were found between any of the other five groups of fabrication methods at any test frequency. Thus, the physical impression fabrication method produced significantly higher attenuating custom earplugs than the other five fabrication methods Attenuation results for each subject are presented in the appendix, Tables A-1 through A-5.

The comfort scores are shown graphically in Figure 7 and tabulated in Table 3. Lower scores represent more comfort, with eFit earplugs showing the lowest score (i.e., highest comfort) on average and earplugs made from physical impression showing the highest score (i.e., least comfort) on average. An ANOVA showed statistically significant differences between the comfort scores of custom earplugs $F(5, 114) = 4.13$, $p = .001739$. Tukey Honest Significant Difference (HSD) post-hoc analysis revealed statistically significant ($p < .05$) differences for earplugs made from physical impressions compared to 3Shape, Lantos, and eFit fabrication methods. No statistically significant differences were found between comfort scores of earplugs made from physical impressions compared to earplugs made from scanned impressions or 3D printed methods. There were no statistically significant differences found between any other comfort scores.

The weight of custom earplugs are presented in Figure 8 and Table 4. The average weight of earplugs made by Lantos were less than 2 grams each, with all other earplugs weighing, on average, more than double the Lantos earplugs. An ANOVA showed statistically significant differences between the weight of earplugs made from the different methods $F(5, 114) = 43.012$, $p < .001$ and $F(5, 114) = 39.692$, $p < .001$ for left and right earplugs, respectively. Post-hoc Tukey HSD analysis showed statistically significant ($p < .05$) differences for all earplugs compared to Lantos earplugs. Statistically significant differences were also apparent for earplugs made from physical impressions compared to earplugs made from 3D printing. The differences between weights of all other earplugs were not significantly different.

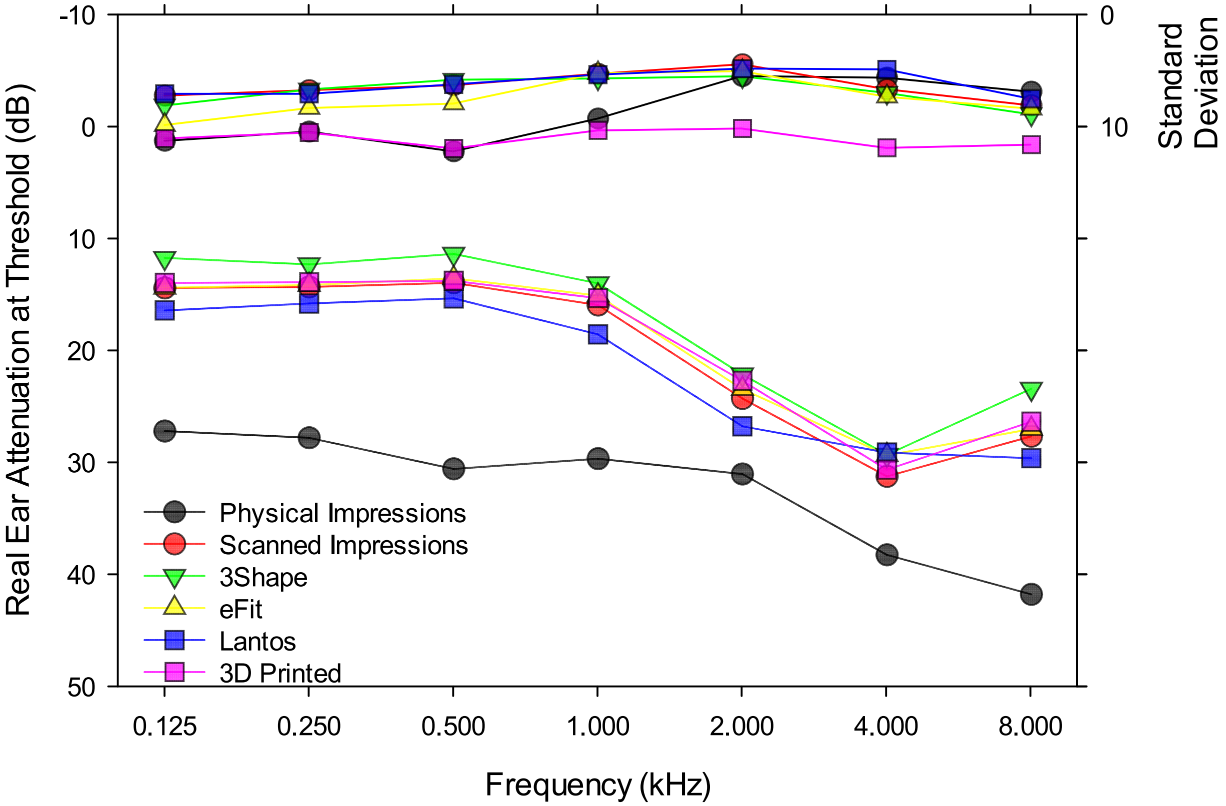

Figure 6. Mean real-ear attenuation at threshold and standard deviations.

Table 1. The mean ($n = 20$) real-ear attenuation at threshold for custom earplugs made from each fabrication method.

	Test frequency (kHz)						
	0.125	0.250	0.500	1.000	2.000	4.000	8.000
Physical Impression Fabrication Method							
$\overline{X}$	27.22	27.83	30.60	29.69	31.07	38.28	41.81
s	11.26	10.45	12.22	9.28	5.49	5.63	6.88
Lantos Scan Fabrication Method							
$\overline{X}$	16.43	15.81	15.35	18.57	26.80	29.15	29.64
s	7.07	7.08	6.23	5.36	4.82	4.89	7.52
Scanned Impression Fabrication Method							
$\overline{X}$	14.43	14.33	13.95	15.95	24.31	31.27	27.70
s	7.23	6.74	6.29	5.30	4.43	6.66	8.09
eFit Scan Fabrication Method							
$\overline{X}$	14.41	14.17	13.57	15.11	23.45	29.39	27.04
s	9.86	8.33	7.94	5.23	5.05	7.33	8.42
3Shape Scan Fabrication Method							
$\overline{X}$	11.73	12.32	11.36	14.01	22.15	29.33	23.41
s	8.12	6.69	5.82	5.7	5.51	6.99	8.9
3D Printed Fabrication Method							
$\overline{X}$	13.98	13.90	13.79	15.33	22.71	30.67	26.39
s	11.06	10.54	11.96	10.35	10.18	11.91	11.61

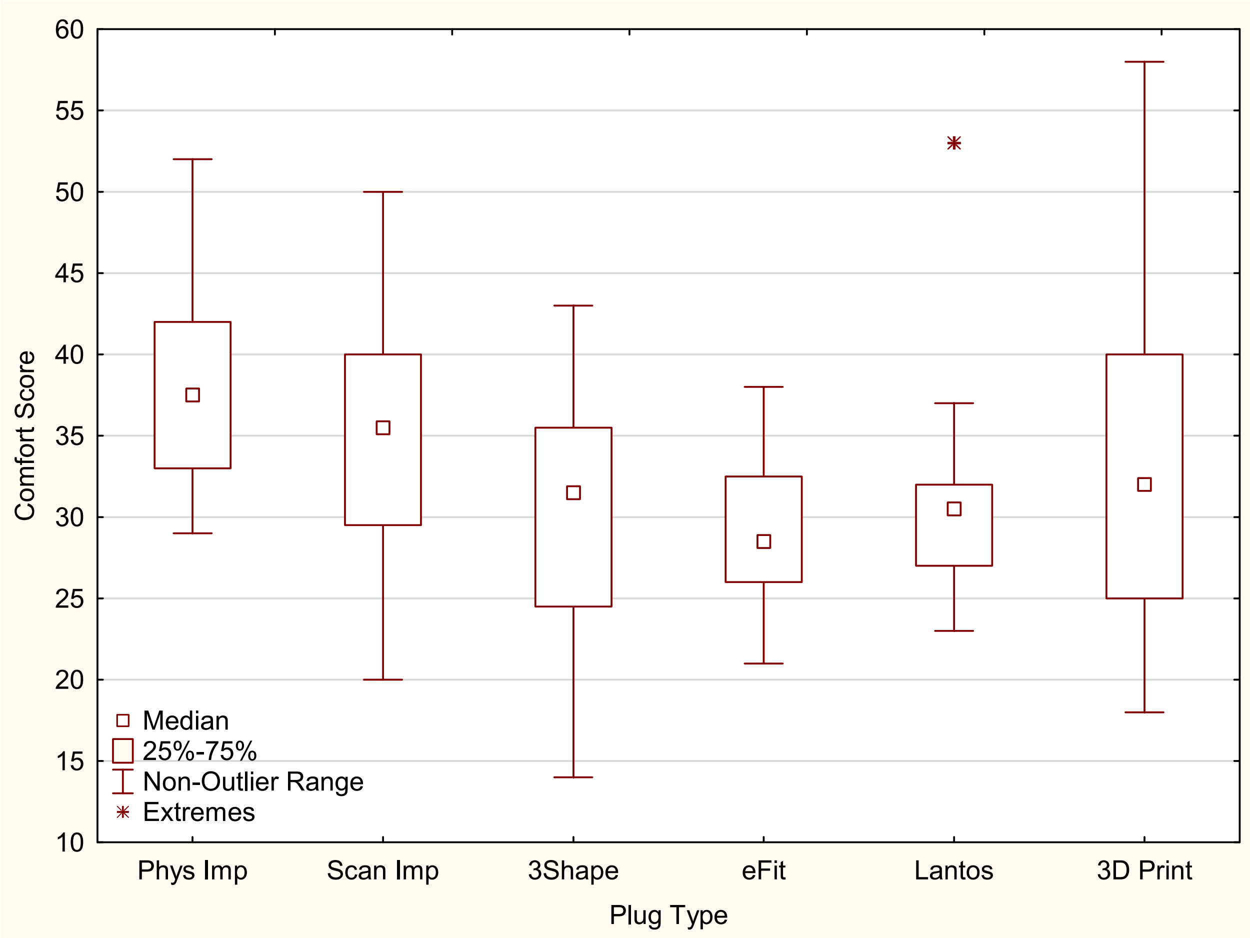

Figure 7. Comfort Scores by type of fabrication method.

Table 2. Mean Comfort Scores by Earplug Fabrication Method.

Comfort Score		
Plug Type	Mean	Std. Dev.
Physical Impressions	38.5	7.21
Scanned Impressions	34.8	8.47
3D Print	33.4	10.59
Lantos	30.9	6.28
3Shape	30.0	7.88
eFit	29.2	4.67

Note. Lower scores reflect more comfort and higher scores reflect less comfort. Highest possible score is 70, lowest possible is 14, and middle scores would be 42.

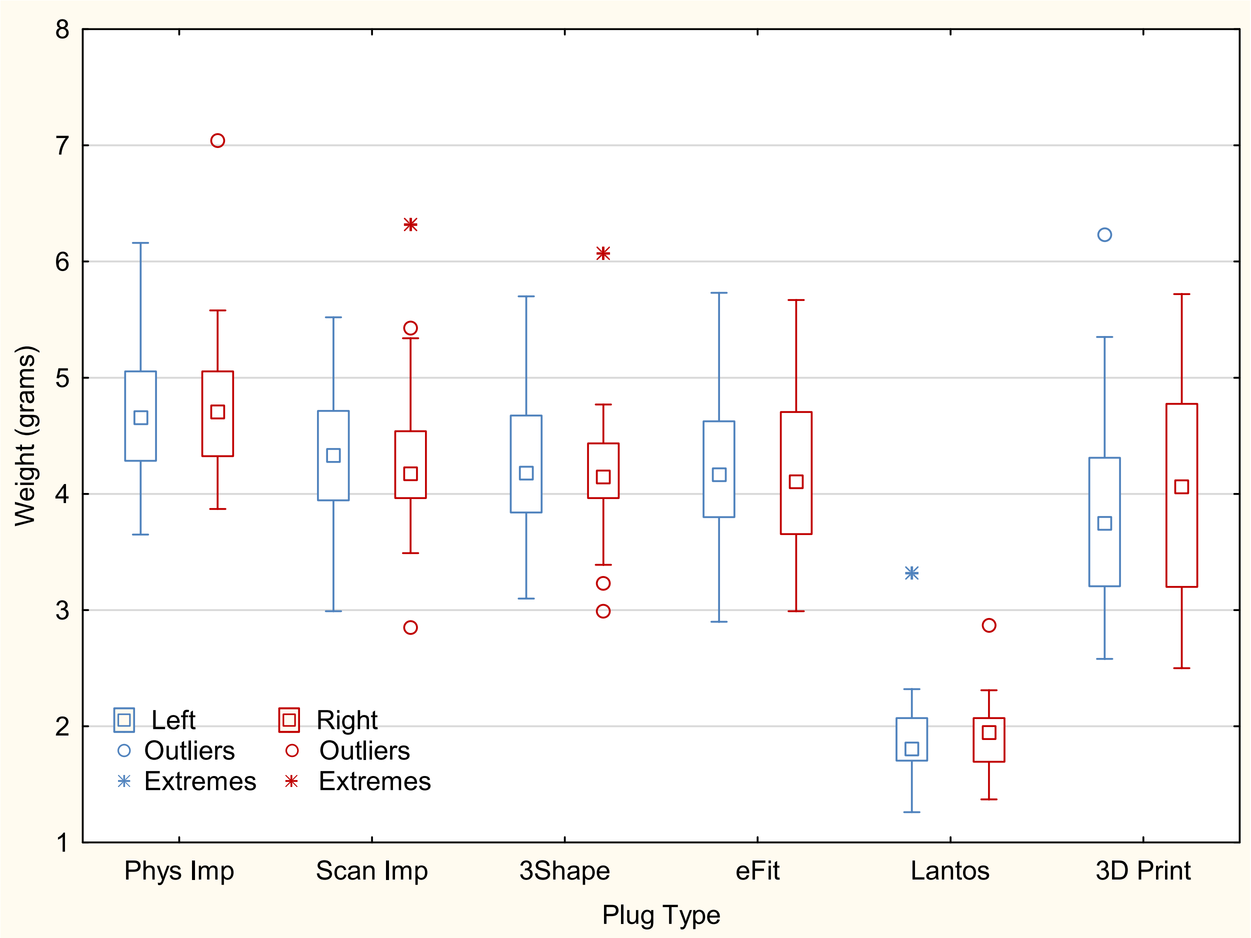

Figure 8. Box plot of left and right custom earplug weights in grams. The lower box boundary represents the 25th percentile, while the top box boundary represents the 75th percentile. Data points in the box represent the median. The vertical lines represent the largest and smallest data points outside of the box. Outliers are marked and extreme outliers are denoted by an asterisk.

Table 3. Custom earplug weight in grams by fabrication method.

Earplug Fabrication Method	Left Earplug		Right Earplug	
	Mean	Std. Dev.	Mean	Std. Dev.
Physical Impressions	4.66	0.590	4.80	0.721
Scanned Impressions	4.34	0.623	4.34	0.765
3Shape	4.25	0.681	4.20	0.634
Lantos	1.91	0.421	1.93	0.327
3D Print	3.89	0.887	4.00	0.948
eFit	4.23	0.782	4.17	0.740

Discussion

The results of this study indicate custom earplugs made from physical ear impressions were, on average, significantly higher attenuating than earplugs made from all other fabrication methods. The results also indicate perceived comfort of earplugs made from physical impressions were the lowest of all the fabrication methods evaluated in this study. This result is not surprising since other studies have indicated an inverse relationship between comfort and attenuation (Byrne et al., 2011).

All earplugs, excluding those made from physical impressions, were not significantly different from each other in terms of attenuation and comfort. While earplugs made by eFit scans had the best mean comfort index (29.2), they were slightly less attenuating on average than earplugs made by Lantos, scanned impression, and physical impression methods. Thus, as attenuation decreased slightly, comfort slightly increased on average for these sets of earplugs. Earplugs made by 3Shape scans were less attenuating than all other earplugs and had a mean comfort index of 30, which is only slightly higher (less comfort) than earplugs made from eFit scans. As mentioned, these differences were not significantly different but there appears to be a general inverse relationship between attenuation and perceived comfort for custom earplugs, similar to other types of earplugs.

While custom earplugs made from physical impressions had the highest average attenuation, not all custom earplugs are made equally. The process to produce a custom earplug depends on many factors including the skill and technique of the person making the impressions as well as the manufacturing process. The same is likely true for digital scanning fabrication methods, which depend on how well the scan was taken as well as the digital modeling and manufacturing process. Thus, while earplugs made from physical impressions showed the highest average attenuation across subjects, there were earplugs within this group that were less attenuating than earplugs made from other fabrication methods. This means, on an individual basis, some earplugs made from digital scanning methods were more protective than the traditional fabrication method for certain individuals (e.g., Subject 3). This result highlights a recognized hearing conservation best practice to fit-test hearing protection on an individual basis (OSHA/NHCA/NIOSH Alliance, 2008). Therefore, individually fit-testing custom earplugs should likely be performed regardless of the type of fabrication method. In this way, the hearing conservationist can assess the level of hearing protection provided to the individual and determine if the HPD meets the needs for that individual. If the HPD does not provide sufficient attenuation for the intended application, it may be sent back for modification or a new earplug may be needed, which may include new impressions and/or scans.

It is also worth noting that custom earplugs made from digital scans of physical earmold impressions, an accepted method currently used by earplug manufactures, were not significantly different from direct digital scanning methods. Thus, digital scanning methods can produce custom earplugs as protective as one currently accepted fabrication method. However, earplugs fabricated from scans of physical impressions were significantly less protective than earplugs made from physical impressions. This important finding may need further investigation and possibly refining of the modeling and manufacturing process of earplugs made from impression scans.

While providing sufficient protection from noise is important to reduce the risks of NIHIs, comfort is one of the most important factors for determining if an individual will wear a particular HPD (Davis, 2008; Nilsson & Lindgren, 1980). Therefore, comfort and attenuation are both important factors to consider for protecting individuals from hazardous noise. Thus, different earplugs may be better suited for different situations. For example, an earplug with a lower comfort index (i.e., more comfort) may be better suited to wear for prolonged periods (provided it attenuates adequate noise for the individual's environment). Higher attenuating earplugs, that may have less comfort, may be better suited for an individual exposed to high levels of hazardous noise for shorter time-periods. Ideally, earplugs should attenuate hazardous noise to safe levels and be comfortable to the user. This will likely reduce workers' risk for NIHIs since they would be more likely to use them.

It should also be mentioned, as anecdotal but important observations, in this evaluation no complaints were observed when scanning subjects' ears but several observations of discomfort occurred during physical impressions. No injuries occurred but several stated the process was uncomfortable and one subject even stated, "I will never have them [physical impressions] done again." Thus, the digital scanning methods were preferred by the subjects over traditional methods.

Another note, digital ear scanning methods, specifically Lantos and eFit, may permit safer capture of ear canal geometries than could otherwise be obtained from physical impressions as they permit scanning to within a few millimeters from the TM. Conversely, deep physical impressions can often be uncomfortable to unbearable for many individuals. This is because an audiologist or technician must insert an oto-block and silicone material deep within the ear canal, which presses against the thin layer of skin in the bony portion of the ear canal. This can be very uncomfortable for some individuals and a riskier procedure (compared to scanning) when attempting to estimate how deep to place an oto-block. Additionally, if the oto-block is not placed properly or in the event of a blow-by, the silicone material may have a higher chance of contacting the TM, which can lead to complications. Furthermore, it is known that physical ear impressions can cause inflammation of the ear canal and TM. Images shown from left to right in Figure 9 were taken of one subject before digital scans, after digital scans, and after physical impressions, respectively. Inflammation was not apparent after digital scanning (Figure 9, middle) but was apparent after making physical impressions (Figure 9, right). Hematomas, which are a collection of blood under the skin that may erupt through the skin causing bleeding and eventual scabbing in the ear canal, may also occur. No visible hematomas occurred in the present study but subjects experienced inflammation of the ear canal after physical ear impressions, as shown in Figure 9.

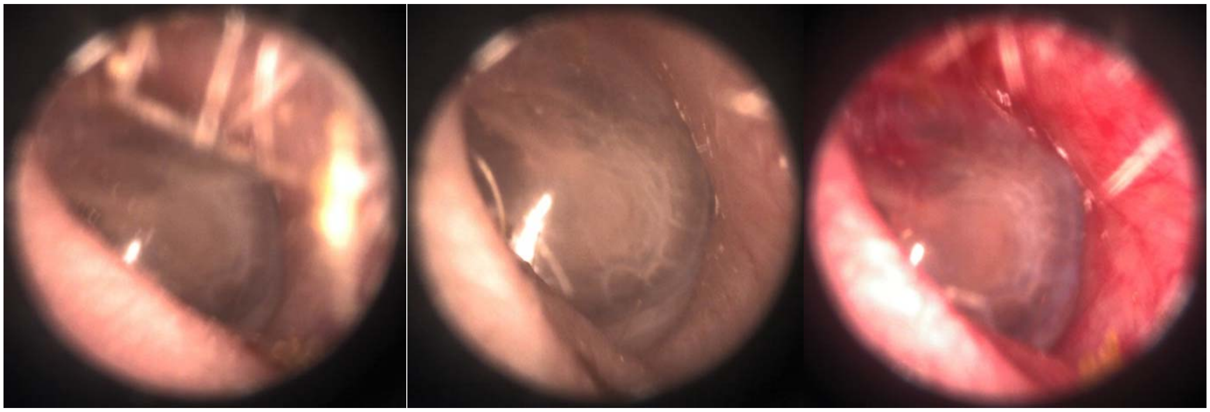

Figure 9. Ear canal images. Photos shown from left to right were taken before digital scans, after digital scans, and after physical ear impressions.

Recommendations

Digital ear scanning methods for the production of custom hearing protection are feasible. The three digital scanning systems evaluated in this study were capable of producing 3D models of the ear and custom earplugs were produced from those 3D models that would likely be useful to Service members for various situations. Digital ear scanning would likely be a better option than performing physical ear impressions for individuals that are sensitive to ear impressions and for preventing inflammation in the ear while also reducing the risk of other potential injuries. Digital ear scanning is also a quicker way of providing custom earplugs initially and likely for reproduction of custom earplugs in the future. Based on the results of this study, physical ear impressions are likely still needed for producing custom earplugs with the highest average attenuation. Future research could investigate adjustments to 3D models created by digital scanning methods to produce higher attenuating custom earplugs. It is likely that such adjustments could be made within 3D modeling software programs similar to the modeling program used in this study. These adjustments could likely be made to produce earplugs that are more protective, if desired. However, creating earplugs with higher levels of attenuation will likely be at the cost of comfort (i.e., less comfort). Additionally, while custom earplugs made from physical impressions showed the highest average attenuation in this study, processes to produce custom earplugs may vary by earplug manufacturer as well as by personnel making the ear impressions. Thus, as a best practice, custom earplugs made from traditional and digital scanning methods should be fit-tested for each individual to ensure adequate protection for the user’s needs.

Conclusions

The objective of this study was to determine the feasibility of digital ear scanning for the production of custom earplugs. Digital ear scanning technologies evaluated in this study were capable of capturing ear canal geometries and producing 3D models that could be used to create custom earpieces. Custom earplugs produced from digital scanning technologies and traditional methods were evaluated for hearing protection and perceived comfort. The results of this study suggest custom earplugs made from digital scanning methods provide significantly less hearing protection, on average, than earplugs produced from physical ear impressions. However, the results also indicate perceived comfort was significantly higher for custom earplugs made from digital scanning methods compared to traditional methods.

Digital ear scanning provides potential advantages over traditional methods such as reduced logistical hurdles (digital files rather than physical molds), reduced time to obtain a model of the ear, and reduced discomfort for subjects. Digital scanning also reduces the risk of potential injuries and inflammation currently associated with obtaining physical ear impressions. Thus, digital scanning processes are generally less invasive and produce custom earplugs considered more comfortable by users but were less protective, on average, than the physical ear impression method.

While attenuation is an important factor, the highest levels of attenuation are not necessary for every environment. For example, approximately 90% of occupational noise exposures in the United States only require about 10 dB of attenuation (Byrne et al., 2011). Workers in these types of environments would likely be better served with lower attenuating earplugs (10 dB of attenuation), which would provide sufficient protection from noise while preventing overprotection. Thus, digital scanning for the production of custom earplugs is a feasible solution for many individuals. Furthermore, if maximum sound attenuation is not needed, or if a subsequent in-situ fit test is conducted to verify the attenuation of the custom earplug, or if sound attenuation is not important, for example, for hearing-aid or communication earpieces, digital scanning methods may be preferred.

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Manufacturer's list

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A&D Engineering, Inc.	1756 Automation Parkway, San Jose, CA 95131	1-408-263-5333	https://andonline.com
Brüel & Kjær	Skodsborgvej 307 DK-2850 Nærum Denmark	+45 7741 2000	www.bksv.com
Cyfex AG	Binzmühlestrasse 15 8050 Zurich Switzerland	+41 44 9745100	www.cyfex.com
Dreve America Corporation	7625 Golden Triangle Drive Suite K. Eden Prairie, MN 55344	1-952-358-3526	http://dreve-america.com
Electro-Voice	130 Perinton Pkwy Fairport, NY 14450 US	1-800-289-0096	www.electrovoice.com
EnvisionTEC, Inc.	15162 S. Commerce Drive Dearborn, MI 48120	1-313-436-4300	https://envisiontec.com
Lantos Technologies, Inc.	50 Concord Street, Suite e-300 Wilmington, MA 01887	1-781-443-7633	www.lantostechnologies.com
Microsoft Corporation	One Microsoft Way Redmond, WA 98052	1-877-696-7786	www.microsoft.com
National Instruments	11500 N Mopac Expwy Austin, TX 78759-3504	1-877-388-952	www.ni.com
QSC, LLC	1675 MacArthur Blvd. Costa Mesa, CA 92626	1-714-754-6175	www.qsc.com
TIBCO Software Inc.	3307 Hillview Avenue Palo Alto, CA 94304	1-650-846-1000	www.tibco.com

Name	Address	Phone Number	Website
United Sciences	2277 Peachtree Rd d, Atlanta, GA 30309	1-404-975-1847	http://www.unitedsciences.com/
VIacoustics	2512 Star Grass Circle Austin, TX 78745	1-512-531-6442	https://viacoustics.com
Welch Allyn Inc.	4341 State Street Road. Skaneateles Falls, NY 13153	1-888-535-6663	www.welchallyn.com
Westone Laboratories, Inc.	2235 Executive Circle Colorado Springs, Colorado 80906	1-719-540-9333	www.westone.com

Appendix A

Table A-1. Means and standard deviations of the real-ear attenuation at threshold of custom earplugs made from physical impressions ($n = 20$)

	Third-octave band center frequency (kHz)						
Subject	0.125	0.250	0.500	1.000	2.000	4.000	8.000
1	30.90	30.25	30.20	29.25	30.00	39.05	40.95
2	26.85	31.90	34.05	35.40	33.20	43.55	44.75
3	10.45	15.90	18.30	28.45	29.75	38.05	36.70
4	24.25	24.40	25.40	22.80	32.55	42.40	50.95
5	33.00	32.95	30.55	35.20	33.40	45.05	48.60
6	22.60	26.80	31.65	32.35	30.80	38.75	43.35
7	41.75	37.00	43.80	37.50	34.10	35.15	42.35
8	8.10	9.35	8.15	13.80	24.80	21.75	39.90
9	39.70	33.95	38.75	34.70	36.20	39.85	51.05
10	30.90	31.50	33.90	36.35	32.35	40.75	45.25
11	7.40	8.85	14.40	13.45	18.55	33.05	31.75
12	33.70	36.15	40.35	38.85	38.30	44.20	28.90
13	26.05	24.90	25.60	22.60	28.15	34.75	35.90
14	42.05	43.35	52.00	42.00	34.45	41.00	40.15
15	46.40	46.15	55.10	47.40	40.75	44.25	49.20
16	23.05	26.25	27.70	27.25	28.90	41.25	44.90
17	30.60	31.25	35.05	29.55	36.40	38.75	41.25
18	11.50	9.60	10.75	14.45	20.20	28.85	29.10
19	29.30	32.10	31.00	28.55	30.10	38.75	51.50
20	25.90	24.05	25.35	23.95	28.45	36.35	39.75
Mean	27.22	27.83	30.60	29.69	31.07	38.28	41.81
s	11.26	10.45	12.22	9.28	5.49	5.63	6.88

Table A-2. Means and standard deviations of the real-ear attenuation at threshold of custom earplugs made from scanned impressions (*n* = 20)

	Third-octave band center frequency (kHz)						
Subject	0.125	0.250	0.500	1.000	2.000	4.000	8.000
1	25.05	15.80	15.70	21.15	28.90	35.75	40.00
2	17.95	17.15	18.20	19.80	29.75	42.10	35.15
3	25.85	24.95	24.50	22.80	27.50	34.35	34.85
4	13.85	17.35	17.95	19.80	28.20	35.30	30.45
5	3.20	7.00	11.95	17.25	24.05	27.55	33.75
6	13.45	14.40	14.75	15.40	28.20	35.80	38.40
7	26.45	27.35	28.05	22.50	29.25	39.00	40.35
8	17.60	16.80	12.45	16.25	22.05	35.20	23.85
9	13.45	11.50	14.60	15.00	25.30	31.70	23.95
10	25.60	23.65	24.55	25.05	29.65	36.20	36.65
11	9.15	7.75	8.25	7.05	22.10	28.20	20.90
12	14.45	11.90	4.50	10.35	25.15	31.30	22.50
13	18.85	23.40	12.00	17.55	23.20	37.40	24.35
14	8.00	6.15	9.45	13.60	18.55	26.00	17.95
15	5.45	3.85	9.70	7.05	17.55	25.95	23.10
16	4.40	7.85	3.85	9.05	21.50	28.20	17.25
17	15.60	17.75	11.95	17.20	24.20	18.80	18.10
18	10.45	10.85	10.35	8.70	13.10	14.65	22.85
19	9.70	8.85	13.85	16.80	25.20	30.20	17.15
20	10.00	12.30	12.40	16.65	22.75	31.65	32.35
Mean	14.43	14.33	13.95	15.95	24.31	31.27	27.70
s	7.23	6.74	6.29	5.30	4.43	6.66	8.09

Table A-3. Means and standard deviations of the real-ear attenuation at threshold of custom earplugs made from 3Shape Phoenix™ scans (*n* = 20)

	Third-octave band center frequency (kHz)						
Subject	0.125	0.250	0.500	1.000	2.000	4.000	8.000
1	12.85	15.00	14.20	14.30	21.95	25.00	23.80
2	24.65	20.35	12.15	19.15	27.35	36.55	30.00
3	13.50	14.30	16.50	18.70	29.70	35.05	21.75
4	18.40	17.35	12.05	14.25	24.25	25.10	26.10
5	6.60	10.75	16.70	19.05	23.70	29.15	30.65
6	2.65	1.75	3.55	13.80	23.05	20.55	11.65
7	8.90	10.05	11.95	15.25	22.30	31.70	17.40
8	23.30	17.15	14.55	19.00	27.05	36.90	32.35
9	12.40	12.60	9.70	10.80	20.00	28.45	23.70
10	17.95	16.15	17.45	16.05	27.80	40.10	37.35
11	11.75	13.45	5.60	6.85	13.05	20.85	20.20
12	9.00	8.55	4.75	13.80	23.00	29.45	23.45
13	24.95	25.40	16.95	19.75	28.70	34.60	32.35
14	16.60	15.80	14.60	16.20	23.05	32.00	20.15
15	1.05	5.55	6.55	4.65	14.50	28.10	22.65
16	4.20	5.00	5.60	4.40	16.20	20.40	14.55
17	3.35	5.15	5.10	4.50	15.35	16.60	10.70
18	-0.65	5.80	7.00	10.10	12.25	26.50	10.25
19	2.95	3.15	6.45	14.25	20.15	26.60	16.20
20	20.10	23.05	25.85	25.35	29.60	42.95	43.00
Mean	11.73	12.32	11.36	14.01	22.15	29.33	23.41
s	8.12	6.69	5.82	5.70	5.51	6.99	8.90

Table A-4. Means and standard deviations of the real-ear attenuation at threshold of custom earplugs made from United Sciences eFit™ scans (*n* = 20)

	Third-octave band center frequency (kHz)						
Subject	0.125	0.250	0.500	1.000	2.000	4.0000	8.000
1	22.90	23.60	15.75	19.80	25.25	31.40	31.65
2	23.20	18.00	12.35	17.90	27.80	37.70	28.55
3	24.15	24.40	20.80	17.95	28.70	36.60	37.70
4	4.95	7.40	10.65	11.70	20.35	23.85	18.70
5	1.15	0.75	1.25	14.95	22.00	17.25	15.15
6	3.10	3.05	3.00	5.00	14.30	22.10	21.90
7	26.80	24.90	20.60	21.40	29.70	40.30	40.40
8	19.85	15.80	12.50	16.60	21.10	32.10	29.95
9	23.55	21.90	27.00	22.55	29.50	41.85	43.80
10	9.60	12.70	4.75	8.10	14.75	15.20	14.00
11	9.50	10.65	7.10	10.00	25.90	28.95	28.25
12	29.95	25.95	20.25	21.25	28.50	34.25	29.15
13	11.80	12.45	15.45	14.60	23.95	29.20	22.85
14	4.50	5.20	12.90	9.10	16.20	32.50	20.50
15	23.65	21.20	20.65	18.40	27.90	33.80	28.85
16	16.55	17.00	15.05	15.00	22.55	19.95	18.85
17	23.20	20.45	22.45	18.55	21.75	28.50	32.65
18	5.80	11.65	23.00	20.60	27.90	28.90	35.80
19	1.90	3.20	-0.30	8.15	16.15	23.25	23.80
20	2.10	3.05	6.15	10.60	24.80	30.10	18.20
Mean	14.41	14.17	13.57	15.11	23.45	29.39	27.04
s	9.86	8.33	7.94	5.23	5.05	7.33	8.42

Table A-5. Means and standard deviations of the real-ear attenuation at threshold of custom earplugs made from Lantos AURA™ scans (*n* = 20)

	Third-octave band center frequency (kHz)						
Subject	0.125	0.250	0.500	1.000	2.000	4.000	8.000
1	15.05	7.40	7.00	17.40	25.15	27.05	22.45
2	14.60	17.70	16.20	24.75	30.50	31.20	22.85
3	25.50	28.75	21.30	22.95	30.65	36.90	37.30
4	13.10	13.80	19.25	17.65	26.65	29.20	22.85
5	2.90	3.70	7.35	17.55	25.00	23.40	29.95
6	20.30	17.25	17.55	23.10	32.30	36.15	37.35
7	21.90	21.50	24.30	25.30	31.20	33.80	32.20
8	8.45	8.15	8.50	11.10	19.45	29.25	28.15
9	17.50	13.30	16.90	16.35	27.75	28.85	27.00
10	16.15	16.10	15.35	16.70	27.35	32.95	35.70
11	26.35	22.40	18.50	23.90	33.55	27.65	42.40
12	15.85	12.80	11.80	15.55	27.10	24.80	39.70
13	23.95	24.70	18.10	22.95	29.40	33.30	41.45
14	15.45	14.15	13.70	18.95	23.70	28.90	27.75
15	2.80	2.70	5.75	2.40	14.45	23.30	17.20
16	17.65	17.35	11.55	20.15	30.25	29.50	19.15
17	16.25	25.75	25.20	20.30	20.10	16.55	34.10
18	27.20	20.85	27.20	22.10	31.50	34.80	23.35
19	7.30	10.75	10.60	14.15	26.05	27.70	25.90
20	20.40	17.05	10.95	18.10	23.80	27.75	25.95
Mean	16.43	15.81	15.35	18.57	26.80	29.15	29.64
s	7.07	7.08	6.23	5.36	4.82	4.89	7.52

Table A-6. Means and standard deviations of the real-ear attenuation at threshold of custom earplugs made from 3D printing (*n* = 20)

	Third-octave band center frequency (kHz)						
Subject	0.125	0.250	0.500	1.000	2.000	4.000	8.000
1	16.80	15.65	8.45	19.50	25.85	39.40	26.75
2	7.05	5.15	8.10	2.50	13.60	27.15	19.00
3	6.75	5.25	2.20	0.85	20.25	21.25	24.60
4	26.65	24.65	17.95	21.85	32.60	44.90	39.05
5	24.75	22.50	20.10	21.25	27.20	41.90	31.85
6	19.85	18.00	16.60	17.45	29.95	31.65	26.30
7	23.45	25.60	21.25	23.75	30.90	35.25	34.45
8	8.10	10.80	16.05	16.45	26.00	28.20	15.80
9	2.35	4.10	8.00	16.70	24.60	29.65	20.25
10	11.20	14.10	22.35	31.20	33.75	36.75	39.00
11	34.50	36.45	45.90	32.50	34.15	46.50	48.65
12	26.95	25.00	25.35	26.00	29.70	42.15	40.40
13	0.35	1.60	-2.55	1.50	7.60	30.95	19.90
14	28.75	26.95	28.80	24.65	32.20	39.00	40.00
15	20.90	18.85	16.85	18.45	24.85	42.55	30.25
16	13.80	13.20	14.95	15.60	28.75	24.55	17.85
17	1.45	-0.15	0.55	2.50	11.90	17.25	9.05
18	3.60	3.75	2.40	7.95	8.75	6.60	27.45
19	2.40	1.80	0.30	5.55	-0.25	4.70	7.70
20	-0.10	4.80	2.20	0.40	11.90	23.05	9.50
Mean	13.98	13.90	13.79	15.33	22.71	30.67	26.39
s	11.06	10.54	11.96	10.35	10.18	11.91	11.62

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