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A Method Paper for the External Auditory Canal Anthropometrics Study

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Capstone Document

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By

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ABSTRACT

The anthropometrics of the external auditory canal (EAC) is clinically pertinent to producing effective custom hearing protection devices (HPD). If custom HPDs are incorrectly fit, they will not attenuate an appropriate level of sound, increasing the likelihood that the user might be exposed to hazardous intensity levels. Researchers have attempted to measure the EAC using a multitude of approaches. Research technology, called ear scanning, appears to provide the ability to measure the EAC effectively. This study was designed to identify a procedure to accomplish the following: (1) characterize the anthropometric differences between male and female external ears. (2) identify differences between digital-scan and physical-material of external ear impressions. (3) compare digital EAC scans to crude methods used for ear canal measurement. To explore each aim, an investigation of external ear anthropometry should be undertaken using virtual ear impression technology. Such studies are scant in the literature. A review of pertinent literature revealed that a gold standard for quantifying ear canal anthropometrics is unavailable. This finding persuaded a summation of the current literature associated with techniques used for quantifying ear canal anthropometry.

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VITA

CLARA J. MARCHINI

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PUBLICATIONS AND PRESENTATIONS

Belke, H., Rothbauer, N., **Marchini, C.,** and A. Joseph. (2019*). Identification of published audiology case reports in a general and highly-specified search*. Presented at the Illinois State University Research Symposium, April 5, 2019. Normal, Illinois.

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CHAPTER 1

Introduction

Background

The purpose of a hearing protection device (HPD) is to form a barrier between hazardous sounds in the environment and the more medial components of the auditory system. If an HPD has not been designed to be easily inserted, comfortably used, and adequately protective, it will likely not provide the level of sound attenuation proposed by the product manufacturer. It may be argued that insertion and comfort are dependent on the shape of the external auditory canal, which may be represented in a variety of shapes and sizes in humans. The research literature has identified left and right ear-size differences for 25% of adult subjects (Joseph, 2004). Using a randomized experimental design, Joseph (2004) used a spherical device to measure each subject's external auditory canal (EAC) and discovered that women have a need for smaller sized earplugs than men. For females, commercial off-the-shelf (COTS) earplugs must conform to the shape and size of a smaller ear canal, or the likely result will be a mis-fitted HPD, over-exposure to noise, and eventual auditory damage. Logically, we might infer that routine use of *one-size-fits-most* HPDs is likely to result in undesirable auditory outcomes in one ear for up to 25% of adults, while a substantial number of females may experience chronic discomfort with inserted HPDs because most products are more suitably designed for the male EAC.

The EAC serves as the primary location for the insertion of HPDs by wearers throughout the industrial, military, and recreational sectors. Still, several popular COTS HPDs are not ergonomically designed and appear to be inconsistent with human ear canal anthropometry. Product discomfort, which yields complaints of tightness, pressure, and stiffness can serve as an obstacle that reduces compliance with consistent HPD use for noise-exposed populations. For example, a number of earplugs have been designed in a cylindrical configuration, which does not model the conical morphometry of the auditory meatus. Empirically, because males comprise the gender majority within the industrial and military populations, most HPD manufacturers offer a product size that is well-suited for the male ear canal (size: medium-to-large). Said differently, earplugs tend to be a size that is compatible with the average male, but this is likely a size too large for the average female user (size: small). Such an HPD design bias has produced less effective and more uncomfortable earplugs for women. From that perspective, it might be advisable to design an investigation to identify external-ear gender differences and areas of improvement for female and male users of inserted HPDs. Nevertheless, features of the EAC must be considered during the inserted-HPD design phase.

The EAC can be separated into three distinct regions: (1) aperture of the external auditory meatus (EAM) to the first bend of the canal, (2) first bend to the second bend of the canal, and (3) second bend to the tympanic membrane (TM). Various investigators have described alternative methods of quantifying the EAC. In an effort to eliminate the need for invasive or unpleasant procedures, Grewe et al., (2013) aimed to develop a method for measuring the EAC using high-resolution computed tomography (HRCT). In a similar fashion, Yu et al (2015) used computed tomography (CT) scans to measure the average height and width of the EAM and the average depth of the EAC in relation to the first and second bends. Computed tomography scans combine a sequence of radiologic (X-ray) images obtained from several angles, leveraging computer technology to develop cross-sectional images (slices) of the tissues.

In the literature, studies that have investigated external ear canal anthropometry using virtual ear impression technology are scant. More than 30 years ago, a noninvasive optical procedure using an operating microscope was described that could be administered for determination of the length of the open ear canal or intermediate canal segments defined via anatomical points of reference (Zemplenyi et al., 1985). The study reported that the mean length of male and female ear canals was 25mm, and 24mm, respectively. Even a sophisticated examiner could not accurately measure the ear canal length of subjects with significant canal bend without, first, straightening the canal with an inserted speculum. Zemplenyi and associates (1985) used five male and five female subjects to examine the difficulties associated with human ear canal morphology identification when measurements are made repeatedly. In addition, CT and binocular microscopy instrumentation is not inexpensive. Today, surgical binocular microscopes cost 30 to 100,000 dollars, making them uncommon in most audiology clinics.

An HRCT method was used with 100, 18-83-year-old cochlear implant users to measure the size and geometry of the ear canal and to determine whether gender or age was a significant variable (Grewe et al., 2013). High resolution computed tomography accurately represented the size and shape of the ear canal, identifying a mean ear canal length of 23.6 mm for the right and 23.5 mm for the left. To assist with the identification of the lateral ear canal boundary, investigators collected earmold impressions (EMIs) for the first 15 subjects. During the measurement phase, the software incurred an error between measurements taken in the coronal and sagittal planes, so a correction factor was applied. Grewe et al., (2013) found no statistically significant difference between the right and left mean-corrected ear-canal length measurements, ear-canal shape, or angle of the ear canal.

Earmold impressions are a negative physical or digital cast of the outer ear and the EAC (Mueller, 2014). Quality EMIs are an important clinical procedure because they form the basis of production for custom earpieces. Poor EMIs can lead to products that are loose, tight, or uncomfortable, including in-the-ear hearing aids or custom-molded HPDs. Controversial earmold impression techniques place patients at risk, so identifying safe methods of obtaining negative casts of the outer ear, and specifically the EAC, would be beneficial for patients and clinicians.

Literature Review

Researchers have reported several methods that can be used to quantify the EAC. The following review of the literature is intended to characterize reports and investigations that have explored EAC anthropometry. The discussion has been divided into the following categories: non-invasive techniques, normative data, dynamic ear canal, ear canal orientation, tympanometry, EAC resonance and gain.

Non-Invasive Techniques

Yu et al (2012) aimed to develop a non-invasive in-vivo measurement of the EAC. Their approach employed tympanometry to determine EAC volume, using a 226 Hz probe tone and the EAC volume produced by the tympanometer. Their second method was a water injection procedure. For this procedure, the subject's head was stabilized with the EAC meatus in a horizontal position. A 1-mm syringe was used to inject water into the EAC. When the water began to overflow from the meatus, the EAC volume was calculated from the amount of water expelled from the syringe. The third method administered for this investigation was HRCT. A histogram mode was used to identify the boundary between the aperture of the EAM and the TM. Several images were obtained, including sagittal, axial, coronal, and axial with the outlined EAC. The EAC was measured using a voxel-style stacked tool. There was greater variability when using tympanometry to identify the EAC volume, but it was less invasive than the water injection method (Yu et al., 2012). The authors suggested that non-invasive measurement of the EAC volume might be used to identify pre-surgery volume whenever a prediction of postsurgery volume is desirable. A water injection method could not be administered on individuals with a TM perforation or recent surgical procedure.

Grewe and associates (2013) aimed to develop a method for measuring the EAC using HRCT; thereby, eliminating the need for invasive, controversial, and unpleasant protocols. In terms of imaging parameters, HRCT was comprised of an axial CT scan with a slice thickness of 0.625 mm and an overlap of 0.225 mm, resulting in an effective slice thickness of 0.625 mm minus 0.225 mm, or 0.40 mm. The investigators obtained 50 sectional views for each ear. The iPlan surgical navigation program from Brainlab was used to obtain measurements, using existing axial data for calculations. These data allowed visualization of the coronal and sagittal planes, and image manipulation allowed measurement of sectional. The length, radius, and angles of the EAC were measured bilaterally in each subject. To measure EAC length, the inner boundary was formed by an acute angle between the eardrum and the lower wall of the auditory canal. The length was determined by measuring the length of a straight line from the innermost tip of the EAM aperture to the second bend in the coronal image. To measure the radius, images from the sagittal plane were used because they revealed that the EAC was round. Radii were measured across the length of the EAC beginning at the TM extending laterally using 1 mm intervals. Using the corresponding sagittal plane, the largest diameter of the coronal and axial planes was recorded. To simplify calculations, the EAC was calculated as a round shape, not elliptical. A correction factor to reflect the EAC's elliptical shape was determined by creating a ratio between the round radii and elliptical radii. By measuring the angles within the EAC, Grewe et al. (2013) recognized the variability across participants regarding the typical *s-shaped EAC*. Volume calculations were obtained by dividing the canal measurements into cylinders that were 1 mm in depth.

Data were collected on 100 pairs of ears for an examination of the size and geometry of the EAC and age and sex differences were considered (Grewe et al., 2013). Participants were cochlear-implant recipients, equal to or less than 18 years of age with no history of EAC or middle ear surgery. Fifty-six females and 44 males participated in this study. There was no statistically significant difference in length between the right (23.6 mm) and left (23.5 mm) ears of the participants. There was no statistically significant difference of volume between the right (0.7 ml) and left (0.69 ml) ear measures, including no difference with the angle measured in the coronal plane between the right (27.61 mm) and left (27.12 mm). A statistically significant difference in EAC length between males and females was reported for both ears. For the right ear, the EAC length for males averaged 25.25 mm versus 22.30 mm for females. For the left ear, the EAC length for males averaged 25.21 mm and 22.16 mm for females. Measured EAC volumes were 0.15 ml greater for males than females in the right ear and 0.16 mm greater for males than females in the left ear. The authors reported that the techniques used in their study need to be simplified in order to be applied clinically (Grewe et al., 2013).

Yu et al. (2015) used CT to measure the average height and width of the EAM, as well as the average depth of the EAC associated with the first and second bends. High-resolution CT scans were used to obtain two-dimensional images for each participant. Thermo Scientific Amira Software, a multipurpose 2D to 5D system for analyzing biomedical research data from a variety of image modalities, such as CT, was used to display the EAC images, which included the cavum conchae, aperture of the EAM, EAC, and TM. The brush and magic-wand functions within this software were used to identify specific sections for each scan. A stack calculation tool was used to transform the two-dimensional cross-sections into three-dimensional images. Height and width measurements for the ear canal opening were measured using the Thermo Scientific

Amira Software, which rotated the three-dimensional image into its sagittal plane. Within the software application, an anthropometry tool was used to identify the longest portions of the coronal plane to measure the external EAM-aperture height. To measure the width of the ear canal opening, the widest part of the axial plane was identified. Measurements were also obtained for the coronal plane and axial plane to determine the geometric shape of the EAC.

Twenty male and 20 female workers received HRCT scans for a study conducted by Yu et al. (2015). The investigators reported that the average male ear canal opening (height 0.96 cm and width 0.675 cm) was greater than the female group (height 0.915 cm and width 0.63 cm). Their data indicated the length of the EAC for males at the first bend upper position (0.99 cm), lower position (0.61 cm), anterior position (0.78 cm) and posterior position (0.78 cm) were greater in length than the female first-bend upper (0.965 cm), lower (0.59 cm), anterior (0.75 cm) and posterior (0.75 cm) positions in both ears. The length of the EAC for males at the second bend upper (1.64 cm) and lower positions (1.2 cm) for the left ear was similar to the right ear and longer than the second bend upper (1.49 cm) and lower position (1.16 cm) measurements for the left ear of females. The length for the right ear second bend lower position (1.24 cm), and the left ear anterior (1.38 cm) and posterior (1.39 cm) position measures for males and females were similar. For the right ear, the second bend anterior (1.43 cm) and posterior (1.43 cm) position measures were longer for females when compared to the male second bend anterior (1.39 cm) and posterior (1.4 cm) measurements. Regarding total EAC length for males, the anterior (2.7 cm) and posterior (2.69 cm) positions and upper (2.715 cm) and lower (2.485 cm) position measures were longer than the female anterior (2.5 cm) and posterior (2.55 cm) and upper (2.535 cm) and lower (2.27 cm) measurements.

For the aperture of the EAC, Yu et al (2015) concluded that the difference in height and width between males and females was 40%. The investigators concluded that, due to the greater length of the EAC opening, compared to its width, insert HPDs should be modeled using an elliptical configuration. Circular-shaped insert HPDs may not be appropriate for a significant segment of the male population. The National Standards for size indicators for insert HPDs in China are describe as follows: small (0.5-0.7 cm), medium (0.8-0.11 cm), and large (1.2-1.4 cm). Using these standards and their findings, 9% of participants were classified in the small category, 88% were in the medium category, and 9% were in the large category. For width, 5% of participants were below than the smallest category, 74% were classified in the small category, 21% were in the medium category, and no individuals were classified in the large category. In the United States, the American National Standards Institute (ANSI) S12.6-2016 (R2020) describes the use of spheres for ear-canal sizing, even though the spheres are not correlated with earplug sizes. The ANSI standard reports a range of sphere sizes that include extra-small (7.26 mm), small (8.48 mm), medium (9.27 mm), large (10.46 mm), and extra-large (11.53mm). The diameter of the spherical measurement probes on the EarGage™ device was measured by Joseph (2004) using stainless steel precision calipers by Cajon Company. The EarGage™ probe sizes were extra-small (7 mm), small (8 mm), medium (9 mm), large (10 mm), and extra-large (11 mm), which is comparable but slightly smaller than the ANSI S13.6 sphere measurements.

More precise ear canal measurements have emerged due to increasingly advanced technology. Egolf et al. (1993) investigated the use of CT scans for remote determination of ear-canal geometry. The expanded number of bandwidths in hearing-assistive devices have necessitated an increased understanding of EAC geometry. Images of EAC cross-sections were collected in each of several parallel planes from the concha to TM. The authors contrasted cadaver CT scan measurements to a silicone earmold of the scanned ear, comparing radiographic images to physical measurements from the ear impression. Using the Picker model 600SE CAT scanner, the head was imaged in 1.0 mm intervals inferior to superior, which produced parallel transverse sections. Two plastic markers were placed at the EAM to aid in orientation. In the transverse section, the entire EAC was evident, which included the concha, meatus, isthmus, and TM. The middle ear cavity and cochlea were captured as well. Transverse images were sliced in the sagittal direction from the TM to the concha in 1.0 mm sections. The silicone mold was obtained with a fast-curing liquid silicone and then cut in 1.0 mm sections by a microtome, which allowed each section of the mold to have a corresponding CT-scan section. Using a total of 26 comparison cross-sections, area and volume measurements were obtained.

The difference between the earmold and scanned images ranged from 0.18% to 25.10% (mean, 9.65%). The investigators reported that an error may have occurred, resulting in distortion during result of the silicone mold. They suggested that the earmold may not have been an exact representation of the EAC and questioned the exactness of the compared slices. Procedural disadvantages included the high cost of equipment, the health risks associated with exposure to radiation, and the difficulty pairing image and silicon mold slices.

Normative Data

In general, researchers have attempted to identify normative ear-canal data for various populations. For example, Wiley et al., (1996) proposed that screening criterion might need to be based on age if age-related differences could be identified. However, with respect to age and gender, no differences in ear-canal volume were found (Wiley et al., 1996). They discovered that older females had smaller ear canal volumes when compared to their male counterparts. Their data suggested a need for more specific norms regarding age and gender for older adults, or, if the same normative criterion is used for all age groups, this will result in a high number of false positive referrals for older adults receiving clinical-immittance measures.

Others have attempted to describe the normative differences dictated by ethnicity, gender, age, and instrumentation, but specifically, the difference in wideband acoustic immittance between Caucasian and Chinese young adults (Shahnaz et al., 2013). Six parameters were evaluated in 159 subjects, including tympanometric peak pressure and width, ear-canal volume, resonant frequency, and static admittance. Gender differences were statistically significant. Chinese subjects revealed a significantly smaller ear canal volume than Caucasians, which the authors attributed to the smaller body size of Chinese subjects.

The external ear has been adopted as a component of face recognition technology for medical and legal determinations. Using anthropometric ear measurements, Ahmed et al. (2015) examined normative data for the Sudanese population. These authors reported that normative data have been essential in supporting the diagnosis of abnormalities, design of hearing aids, and reconstruction of facial anomalies. For 200 subjects, the investigators used a digital caliper device to measure the length and width of the physiognomic ear, lobule, and concha portions of the outer ear. Lobular length was specified as the straight-line distance between the deepest point in the inter-tragal notch. Lobular width was specified as the distance between the anterior portion of the lobe and the posterior portion of the lobe. Concha length was defined as the straight-line distance between the superior concha and the inferior inter-tragal notch. Outcome data identified a statistically significant difference between males and females for all except the lobular length. Providing evidence of sexual dimorphism and significantly larger physiognomic ear width in females, Ahmed et al. (2015) concluded that auricle landmarks and ear measurements are not a reliable source of sex estimation.

Variation of the human ear from a context of age, gender, and ethnic group, with a focus on structural ear prominence, has been examined (Alexander et al., 2011), an issue germane to facial-plastic surgeons who perform otoplasty. Using 420 subjects, Alexander et al. (2011) recorded age and ethnic origin and classified whether ears were normal or prominent. Ethnic groups under analysis were Caucasian, Afro-Caribbean, Indian subcontinent, and Asian or mixed. Eight measurements were obtained, including (1) ear length, which was defined as the most dependent part of the lobule and the most distant portion of the auricle; (2) ear axis, which was defined as the angle between the ear length and the vertical; (3) antihelix "*take-off*" angle; (4) lobule length and width; (5) auricle width; (6) concho-mastoid angle; (7) concha-bowl depth; and (8) helical- mastoid distance. Ear prominence was physically measured at the helical root and tragus, while subjectively measured by the perception of the principal investigator and subject. Three instruments were used to collect experimental measures: (1) a Venier caliper, (2) a goniometer, and (3) a syringe-like device. The majority of measurements for the left and right ears were symmetrical, but the symmetry was greater for the height and width measurements and less for the concha depth and the concho-mastoid angle. Differences between ethnic groups were discovered (Alexander et al., 2011). For example, Indian subcontinent subjects presented with largest ears, followed by Caucasian and Afro-Caribbean groups, but this was only observed for males, not females.

Dynamic Ear Canal

The outer ear, EAC, and adjacent components of the peripheral auditory system should no longer be erroneously classified as passive or static. Many characteristics of the active EAC have been reported in the literature (Oliveria et al., 1992). The EAC was once considered a passive conduit to an active, mechanical middle ear system, but Oliveria et al. (1997) proposed three phases by which a dynamic ear canal could be recognized. These included brief periods of time (as the jaw moves), weeks and months (as cerumen is produced), and over the course of years (as aging occurs). Changes in the EAC that happen in brief periods, in seconds to minutes, can be illustrated through magnetic resonance imaging (MRI) or in a silicone impression.

The advantage of applying MRI is its unique ability to illustrate how the temporomandibular joint (TMJ) interacts with the EAC (Oliveria, 1997). Use of MRI confirmed that the head of the mandible pulls on the anterior soft tissue as the jaw opens, thus changing the shape of the EAC and adjacent structures. The advantage of using a silicone impression of the EAC is its ability to demonstrate the effect of several mandible positions (Oliveria et al., 1997). Increased understanding of this phenomenon might enhance user satisfaction with HPDs. Additionally, the effects of aging can be observed in the ear canal. It has become evident that the consequences of EAC aging are decreased skin elasticity, decreased adipose tissue that supports the EAC, and drier skin. Alvord et al. (1997) reported that the skin tissue that comprises the EAC has several vital characteristics. Changes in the physical characteristics of the EAC can negatively affect the fit and comfort of HPDs. The dynamic nature of the EAC is a culmination of human factors that contributes to variability between patients.

Pirzanski and Berge (2005) examined the interaction between mandibular movement and softness of the EAC. These investigators hypothesized that (1) as long as the impression is fully representative, the type of ear impression material and procedure are irrelevant, (2) the EAC of a child is less affected by movement of the mandible due to its softness, (3) the ear canals of men and women are dynamically similar, (4) an individual will have similar size and softness in both ears, thus will be affected by mandibular movement equivalently and (5) widening and softness of the EAC may be established during an examination. The authors assessed ear canal dynamics by obtaining EMIs using various techniques and materials, then measured and compared the EMIs. External auditory canal diameter was measured at three positions: the aperture, mid-section, and second bend. Pirzanski and Berge (2005) reported that the impression technique and material could change the size of the canal portion of the impression, and most individuals were not significantly affected by mandibular movement because their canals were firm. Moreover, female and male EACs have similar dynamics. The use of viscous silicon impression material, including an open mouth approach, provided the most accurate EMIs (Pirzanski and Berge, 2005) and EAC physiology should be considered when measurement differences cannot be directly explained.

Ear Canal Orientation

On a horizontal plane, the TM is at a 45^{o} angle to the EAC. The effects of EAC orientation, sound pressure distribution, and TM movement were explored by Cheng et al. (2015). An artificial EAC was constructed from a human cadaver temporal bone sample and sound pressure was measured with a stroboscopic holographic to quantify the movement of the TM. To investigate the effect of TM orientation on the EAC, they rotated the artificial EAC relative to the TM and introduced broadband sounds close to the TM. Cheng et al. (2015) concluded that TM motion patterns do correlate with the sound pressure variations, and the motion of the TM is primarily due to its mechanical properties, shape, and boundary conditions.

Tympanometry

Cerumen impaction is a leading cause of referrals for otologic care. Tympanometry has been one of the integral assessments for differential diagnosis of outer and middle ear pathology. The accuracy of tympanometric evaluation of EAC volume was examined by Al-Hussaini and colleagues (2011). Because cerumen is naturally occurring in the EAC, cerumen occluded and unoccluded ears were assessed. Al-Hussaini et al. (2011) aimed to use the tympanometer as a tool to assess whether cerumolytics are an effective treatment for cerumen impaction. Their data indicated that there was not a significant correlation between the degree of impaction and the accuracy of the tympanometer. Most importantly, the tympanometer was inaccurate when EAC volume exceeded 1.4 cm^3. The effect of temperature and accuracy of tympanometric evaluation of EAC volume was then investigated (Al-Hussaini et al., 2014). When the EAC volume was above 1.4 cm^3 and there was no temperature effect. By comparison, at 32 degrees, the tympanometer was inaccurate above EAC volume of 1.0 cm^3. The authors reported that tympanometers function well at ambient temperature and their accuracy is generally unaffected by temperature.

The process of aging can change the nature of the EAC (Yu et al., 2011; Mazlan et al., 2015), including stiffening of the TM and ossicular chain. Wideband acoustic admittance can assess the middle ear mechanism across a range of frequencies (0.25-8.0 kHz). Mazlan et al. (2015) performed conventional tympanometry using a 226 Hz probe tone, followed by wideband acoustic admittance, discovering that young adults have significantly lower energy reflectance than middle-aged subjects. No differences were found between middle-aged and older adults, however, there appears to be a need for norms for interpretation of wideband acoustic admittance data. Shanks et al. (1993) investigated three methods of compensating multiple frequency acoustic admittance measurements for EAC volume and reported that volume estimations are distinctly different at extreme ends of the pressure scale.

Ear Canal Resonance and Gain

An altered EAC can change sound quality, for example, for listeners who receive surgical modifications. Van Spronsen et al. (2015) investigated the effects of surgical modifications on the perception of sound, specifically in the osseous portion of the EAC. They reported a decrease in resonance frequency when the osseous portion of the EAC was surgically altered. Patients should be counseled on the effect of EAC modification on the sound propagation and perception. The authors indicated that patients with EAC modifications might experience poor and unnatural sound quality. Another study found an association between the test frequency of the maximum temporary threshold shift (TTS) and the physical characteristics of the EAC (Gerhardt et al., 1987).

According to Ryan et al. (2016), TTS is a threshold change after exposure to high-intensity noise that spontaneously recovers to baseline levels within hours, days, or weeks following exposure. The amount of shift depends on a few factors: (1) the intensity-level of the exposure, (2) the duration of exposure, and (3) the physiological characteristics of the person's auditory system. It is well known that the pure-tone audiometric threshold responses affected by hazardous noise exposure are within the range of 3,000 to 6,000 Hz. (Gerhardt et al., 1987).

There are several theories that postulate why noise causes most damage at 3,000 to 6,000 Hz. One theory is that the resonant frequency of the outer and middle ear influences the frequency of sound transmitted to the inner ear, specifically, the cochlea, where noise causes most harm to the auditory system. Gerhardt et al. (1987) calculated EAC length based on its volume and diameter. The EAC diameter was determined by using an EarGage™ device. Then, a silicon impression was taken of the canal and the diameter was of the impression was measured with a caliper. Analysis of the data showed that 30 (54%) of the subjects experienced the most TTS at 4,000 Hz, 17 (30%) had their greatest TTS at 3,000 Hz and 9 (16%) at 6,000 Hz. Subjects with TTS at 3,000 Hz revealed the largest mean EAC volume and the subjects who had the greatest TTS at 6,000 Hz revealed the smallest mean ear canal volume (Gerhardt et al. 1987).

The outcomes from this study should encourage clinicians to consider counseling patients about the impact of EAC size and risk for threshold shift.

Tlumak et al. (2013) investigated the relationship between changes in the EAC during a resonant frequency shift feedback. Frequency-shifted auditory feedback is the phenomenon in which an individual sustains phonation and alters their voice to compensate for the fundamental frequency. Eight subjects were prescribed a head-mounted directional hypercardioid microphone with a fundamental frequency preset processor program that was used to split the acoustic signal. Probe-tube microphones were used to measure signals in situ. The investigators reported that feedback time delays lead to both feedback and spoken signal this was produced out of phase, a phenomenon that results in approximately 6 dB of gain.

The EAC is responsible for providing gain in a specified frequency range for signals directed to the concha and navigating through the EAM to the middle ear. The EAC can be altered as a result of age and surgery, which causes its resonant frequency to change. Real-ear probe-microphone measurements permitted Yu et al. (2011) to identify the differences in gain for subjects with normal hearing. Real ear measurements were obtained at several positions along the EAC: first bend, second bend, and TM, which were identified by otoscopic examination. The authors identified that gain for 4,000 Hz was affected more by the shape of the EAC, while gain below 2,000 Hz was mostly influenced by EAC length (Yu et al., 2011). There was minimal gain near the TM at 500 and 1,000 Hz, although a 14 dB increase was evident at 3,000 Hz. At the first bend in the EAC, there was minimal gain at 500 and 1,000 Hz and a maximum gain at 3000 Hz (8 dB), while at the send bend of the EAC, maximum gain was observed at 2,000 Hz (9 dB). Altogether, this study revealed that EAC length and shape affected gain.

Summary

A review of the literature revealed that several studies that identified non-invasive techniques that might replace the conventional earmold-impression procedure administered in clinical settings. The techniques discussed in these reports included water injections for EAC volume, HRTC imaging, and various types of CT scan protocols. Although these alternative techniques delivered accurate data, they were not practical or affordable for day-to-day clinical business. The literature indicated that there is need for more specific normative data for age, gender, and ethnicity regarding immittance measurements, anthropometric ear measures and ear prominence. The dynamic nature of the EAC was acknowledged in several reports because the mandible can readily alter EAC shape. Further, however, EMIs may not be significantly affected by mandibular movement but EAC physiology should be considered when differences of dimensional measurements cannot be explained directly.

The influence of variables such as EAC orientation, sound pressure distribution, and TM movement have been examined, and a correlation between TM movement and sound pressure variations was discovered. Tympanometry, a common clinical procedure, may be used to evaluate the EAC, but its findings may be unreliable for individuals with excessive EAC volumes. Wideband acoustic admittance testing may have clinical utility, but norms for young adults, middle-aged, and older adults may need to be explored. The literature revealed that the EAC can alter sound quality for individuals with surgical modifications of the EAC because of subsequent change of the natural resonance frequency. In addition, size of the EAC can moderate the TTS frequency following exposure to hazardous noise. Finally, the gain frequency characteristics of the EAC may be determined by the shape and length of EAC and has been associated with specified points along the entire EAC.

CHAPTER 2

Methods

The methods described below are a suggested approach for an external ear canal anthropometric study. To determine if there are distinct differences between male and female EAC morphology, a study design that includes digital ear scans, conventional EMIs, and caliper measures would be indicated. The targeted investigation would aim to identify the differences between female and male EACs, right and left EACs, and physical and digital (scanned) EMIs, using physical EMIs and digital ear scans collected from study subjects, and custom earpieces ordered from a manufacturer.

Subjects

Adult subjects from a Hearing Conservation Program should be consented and instructed before ear scans and physical EMIs are permitted. Scans and EMIs should be collected for both ears. A variety of digital scans may be obtained on participants, including scans of EACs, physical EMIs, and custom-molded HPDs. Given the ease of scanning procedures, this study may be implemented in the laboratory, in the field, or by use of a mobile-testing trailer.

Instrumentation/Equipment

A precision instrument, such as the iGaging Absolute Origin 0-6" Digital Electronic Caliper, could be used to obtain the physical measurements of the EMIs and custom-molded HPDs. A portable otologic digital scanning device, such as the AURA 3D handheld ear scanner with Lantos™ View version 2.1.0.534 (Lantos Incorporated, Boston, Massachusetts), could be used to obtain digital images of the EAC. A computer-aided design software that is capable of manipulating 3D images, such as the Autodesk NetFabb Standard 2018.3, could be used to measure, modify, and save digital images. Physical EMIs and digital ear scans could be forwarded to a custom earplug manufacturer to create HPDs for study subjects.

Environment

For those investigators who do not have access to an ear-scanning instrument, the data could be collected elsewhere, by another laboratory that owns, or has access to, the equipment. That laboratory could serve as the central data-collection point and collect the physical EMIs and digital ear scans. Each of the EMIs, physical HPDs and digital images could be analyzed at a remote location, such as our laboratory at Illinois State University. All products could be returned to the central laboratory after completion of measurements.

Procedures

Physical Measurements

The physical measurements could be conducted after the products are made by a manufacturer. Using sewing pins, markers could be placed at the meatus, as well as the first and second bends, to facilitate consistent positions along the EAC for administration of physical measurements. Caliper measures could be obtained at each position that has been marked, and measurement data recorded on a spreadsheet. Given the pliability of earmold impression material, the examiner should position the calipers so that gentle contact is made with the material during measurements. If the caliper is clamped to the mold, the measurement obtained might be inaccurate. Finally, each measurement should be conducted twice to ensure that recorded values have been verified. To document the data, consider using a form such as the one displayed in **Appendix A**.

Digital Images

In order to obtain the desired values for the digital images, the data collection protocol could be captured in several steps. To prepare for the scanned images for analysis raw image data should be recorded before any modifications are made to digital images. Dimensional measurements could be made by measuring the lateral side of each of the three slices, the most medial parts of the modified EAC.

To conduct dimensional measurements, double click on the file and *add parts*. Then, select prepare drop-down menu and choose the *select run repair script* option. Select the *extended repair* option and *execute*. The image should turn blue when prepared for editing. Once prepared, select the *analyze* drop-down menu, choose *run platform overview* and then record necessary initial measurements, including area, volume, and length. Raw measurements should be conducted before removing any unwanted sections of the sample. After the raw measurements have been recorded, the image would then be ready for modification.

For modifications, first select the *modify* drop-down menu and choose *free cut*. Within the *plane cut* tab, create a cutting plane vertical to the surface. Click somewhere on the image to generate a cutting plane. Reduce the size of the plane by right-clicking and grabbing the anchors. A left click on the mouse would allow movement of the resize plane. Situate the plane at the base of the image. Make every effort to retain as much of the impression as possible. Grab the anchor in the middle to move the entire plane or engage the anchors on the sides to adjust the angle of the plane. Select *cut* in the panel on the left side and *trimming procedure* for data preparation of the modified image. The sections should be left together once the cuts are made to record the image area, volume, and length. Select the *modify* drop-down, then select *free cut*, *plane cut*, and the original cutting tool will appear for completing measurements. Be sure to select positions for slicing (cutting) the samples that are consistent with the physical-measurement (sewing pin) approach.

The cutting planes should be moved into position for measurement of the concha to EAM (aperture) segment. Select *cut* in the panel on the left side and record area, volume, and length measurements for concha to EAM. Repeat the above cutting procedure for the remaining measurements of EAM to 1st bend, 1st bend to 2nd bend and finally the 2nd bend to the tip of the sample. For each subject, left and right digital scanned impression samples should be analyzed, followed by scanned physical samples, both left then right. A form that could be used to document the measurement data for each subject has been provided (see **Appendix B**).

Database search

To conduct a comprehensive literature review, a database search was administered to obtain resources using search terms such as *external auditory canal*, *external auditory meatus*, and other similar terms. At the time this report was submitted, 44 relevant papers were identified by the search. The search identified relevant publications from the decades 1970 to 2010, and it was evident that the majority of the publications (22), emerged from 2010-2020. Table 1 contains the search terms and the databases that were used for the comprehensive literature review.

CHAPTER 3

Recommendations

An experiment should be conducted to identify the differences between conventional, controversial, and invasive EMIs and digital ear scanning, using measurements of the EAC. In order to compare digital ear scans and physical EMIs, it might be done more accurately by measuring the volume and dimensions of the aperture, first bend and second bend in an adequate sampling of ears and participants. Volume measurements for the external auditory meatus to 1^{st} bend, and 1^{st} bend to second bend, including height and width measurements, could be the most accessible data. To determine the difference between male and female and left and right ears, a similar procedure can be followed with an emphasis on the dimensional measurements. Clinical validation is necessary, and it will be imperative to identify the difference across the population in the EAC configuration and size.

Study Limitations

Few limitations may be expected for the study. First, the *Netfabb* software measurements will be rounded up to the second decimal point. This may introduce a rounding error that might impact the data analysis. Second, the *Netfabb* software may not be intended for anatomical applications because some of the tools in the program appear to be unable to execute concave measurements. Some of the digital images may have incurred cavities or additional material within the image from the scanner, so measurement error may be a heightened concern during analysis.

Future Research

In summation, data collection could be administered with the test procedures discussed above. Suggested research questions might include (1) before a product is manufactured, are data from a digital ear scan representative of the physical earmold impression? (2) is a scan of the ear canal equivalent to the scan of the manufactured product? (3) is a scan of the physical EMI a good approximation of a scan of the manufactured product? (4) is manufactured product created from a 3D scan of the physical EMI the same as the product created from a physical earmold? and (5) are the examiner measurements that were obtained using a caliper, approximate the digital measurements from an ear scan?

Additional research may include a comparison between the various manufactures of digital ear scanners to identify if there are any differences between the products manufactured. Finally, ethnic variations should also be investigated to provide equitable access to highly specified, person-centered, individualized, quality hearing-health care and products.

TABLES AND FIGURES

Table 1. Databases and search terms

Milner[1]	**WorldCat**[2]	**Google Scholar**[3]	**PubMed**[4]
• ear canal volume • external ear canal volume	• ear canal volume	• ear canal volume	• EAC AND normative • EAC • external ear canal • external ear size • real ear measurement • real ear measurement AND acoustic properties • acoustic properties ear canal

Databases: (1) Milner Library online search portal; (2) WorldCat.org library catalogue; (3) Google Scholar online broad search engine; (4) PubMed biomedical MEDLINE literature search via National Library of Medicine.

Figure 1. Recommended trimming procedure for the Westone® EMI using NETFABB; illustration produced by Antony Joseph AuD PhD

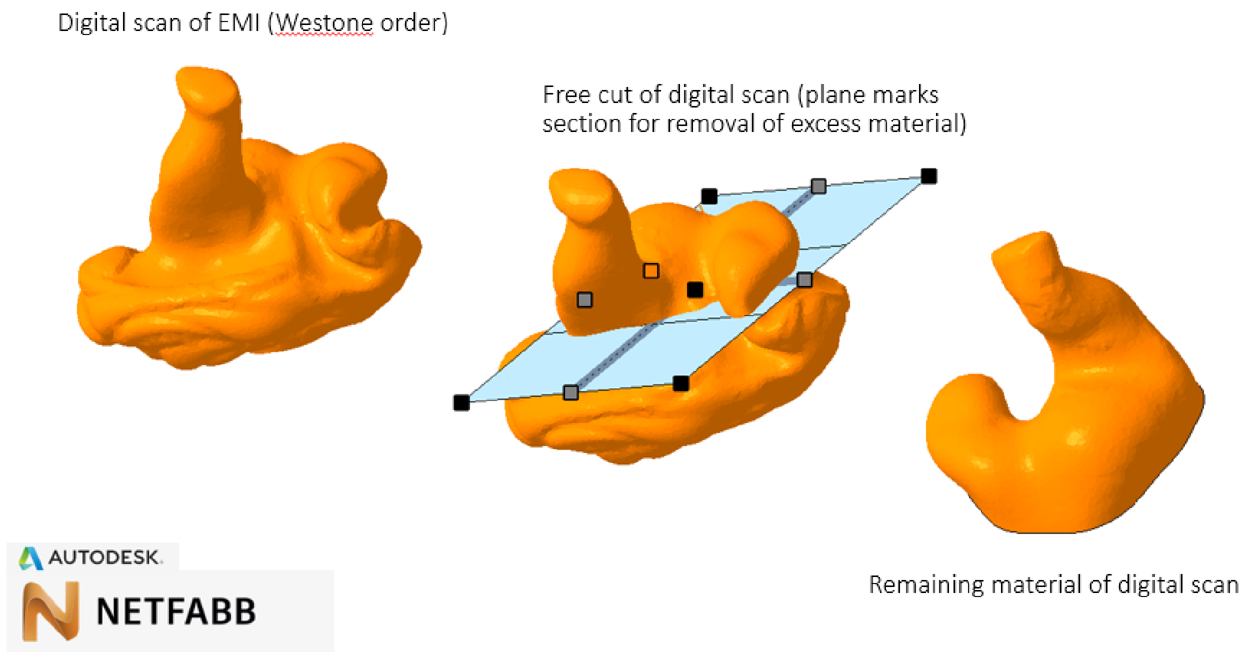
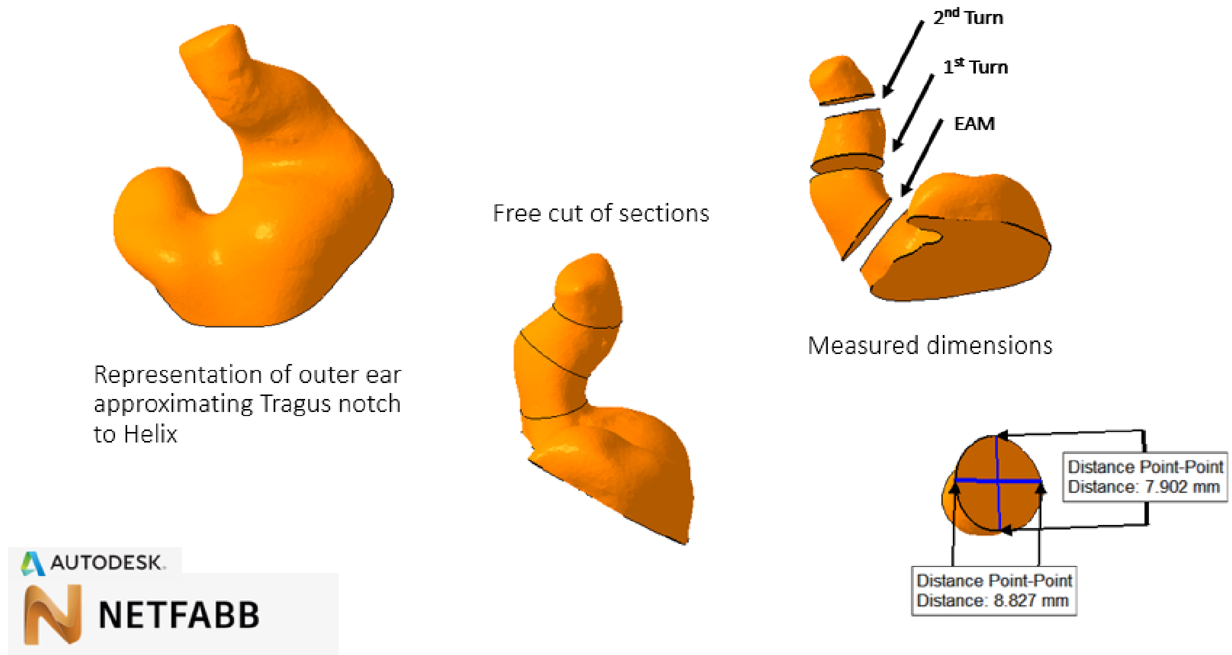


Figure 2. Images of recommended cuts and dimensional measurements using NETFABB; illustration produced by Antony Joseph AuD PhD



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Appendix A

Physical Data Form

External Auditory Canal Anthropometric Study (EACAS)
Measurement Protocol (physical measures with i-Gauging calipers)

Demographic Data (Digital File Nomenclature):
Subject # (4-digits): ____________________
Female/Male (00/01): ____________________
Ear Designation (L)eft/(R)ight: ___________**

- Ensure subject file number is entered on Data Sheet
- Indicate gender
- Verify that you mark the correct ear and are working with the correct ear (side)

Legend: (H)eight, (W)idth, (C)ircumference, (L)ength, (V)olume, (O)ther; all measurements reported in millimeters (mm)

- Mark the correct data table with examiner name
- Mark the correct table with recorder name

To use the i-Gauging Device:

- Turn calipers on
- Ensure gauge is closed (edges are touching)
- This may be done manually or with wheel
- Zero device using button
- Use wheel to expand device
- Make first measurement
- Use inside segment when possible
- Use thin surface segment when practical
- Use wheel to make fine adjustments to gauge
- Enter measurement (millimeters, mm) into table

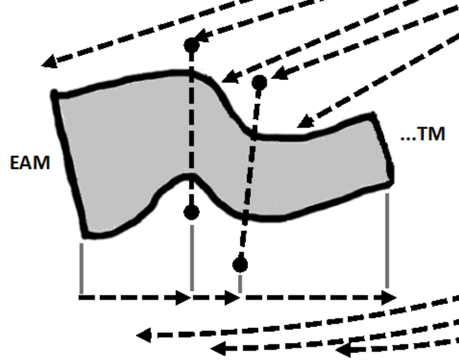
Physical EMI (impression of ear)
Measurement: i-Gauging calipers
Examiner: _______________ Recorder: _______________

measurement	H	W	C	L	V	O
Aperture (EAM)						
1st turn/bend						
Isthmus						
2nd turn/bend						
Osseo tympanic						
EAM to 1st turn						
1st to 2nd turn						
2nd turn to tip						
EMI area						
EMI volume						

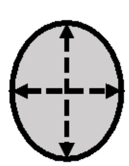
Notes/observations:

___ **Data entered into electronic database**

View of EAC is from top (transverse): AS



Use the sewing pin to mark the endpoints of your measurement, then use the calipers to make the measurement, record this value



The first five measures will be made from the estimated midpoints of the impression (height and width measures), use the sewing pin guide

Because the guide is from the top of the head (transverse view), make you marks in this fashion – the turns of the EAC (bends) are most easily identified by looking down from the top as most canals (looking from outside-in) have a sigmoid, snake-like form – the canal leads anteriorly, then posteriorly, then anteriorly to the TM

Appendix B

Digital Data Form

LL## (Left Lantos Scan of Actual Ear) **DIGITAL**
Pre-product

NETFABB	**INITIAL MEASUREMENTS (RAW/MOD)**			☐ **Artifact evident within original image (STL file)**
Use Platform Overview	**Area** ^{cm3}	**Volume** ^{cm3}	**Length***	
Raw image				
Modified (MOD) image				*measurements reported in millimeters (mm)*

	DISTANCE MEASUREMENTS (MOD)				**DIMENSIONS (MOD)**	
Use Platform Overview	**Area** ^{cm3}	**Volume** ^{cm3}	**Length***		**Height**	**Width**
Concha to EAM				Aperture (EAM)		
EAM to 1st turn				1st turn/bend		
1st to 2nd turn				Isthmus		
2nd turn to tip				2nd turn/bend		
				Osseo tympanic (if poss.)		

☐ **Data entered into electronic database**

RL## (Left Lantos Scan of Actual Ear) **DIGITAL**
Pre-product

NETFABB	**INITIAL MEASUREMENTS (RAW/MOD)**			☐ **Artifact evident within original image (STL file)**
Use Platform Overview	**Area** ^{cm3}	**Volume** ^{cm3}	**Length***	
Raw image				
Modified (MOD) image				*measurements reported in millimeters (mm)*

	DISTANCE MEASUREMENTS (MOD)				**DIMENSIONS (MOD)**	
Use Platform Overview	**Area** ^{cm3}	**Volume** ^{cm3}	**Length***		**Height**	**Width**
Concha to EAM				Aperture (EAM)		
EAM to 1st turn				1st turn/bend		
1st to 2nd turn				Isthmus		
2nd turn to tip				2nd turn/bend		
				Osseo tympanic (if poss.)		

☐ **Data entered into electronic database**