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Development and Validation of a Probe Tube Placement Training Simulator

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Abstract

For over 90% of individuals with hearing loss, hearing aids are the primary method of treatment. Recent studies have shown that most hearing aids are not personalized properly to patients, resulting in poor hearing outcomes. Poor training methods has been proposed as a possible reason for these findings.

A training simulator was developed consisting of a mannequin head with flexible, anatomically correct ears, and an optical tracking system for tracking the insertion of diagnostic equipment into a 3D printed ear canal. The simulator provides an outlet for trainees to practice their clinical procedures while receiving validated feedback, without the need for an instructor.

Two validation studies with students and experts were completed. Experts found the simulator to provide an improved educational experience, while students who used the simulator found increased skill development. Further steps are currently being taken to incorporate this validated simulator into training programs in the field.

Keywords

Co-Authorship Statement

This master's thesis includes two journal articles. The first article, Chapter 3, is currently published in the Journal of the American Academy of Audiology (JAAA). Chapter 4, is submitted and currently under review by JAAA.

Chapter 3: Chapter 3 was adapted from the paper published in JAAA.

Koch RW, Moodie S, Folkeard P, Scollie S, Janeteas C, Agrawal SK, Ladak HM (2018). Face and Content Validity of a Probe Tube Placement Training Simulator, *Journal of the American Academy of Audiology*, doi: https://doi.org/10.3766/jaaa.17114

While the initial motivation for the creation of the simulator came from S. Scollie, and P. Folkeard, the validation of this simulator through a face and content validation study was proposed by H. M. Ladak and S. K. Agrawal. My contribution involved planning the study, organizing and running the study, including scheduling of participants and conducting the sessions, analysis of the data, and the writing of the manuscript. S. Moodie, P. Folkeard, and S. Scollie, aided with the execution of the study, contacted participants, and advised on the development of the simulator. C. Janeteas printed parts of the simulator without cost.

Chapter 4: Chapter 4 was adapted from the submission to JAAA.

Koch RW, Saleh H, Folkeard P, Moodie S, Janeteas C, Agrawal SK, Ladak HM, Scollie S, (2018). Skills Transference of a Probe Tube Placement Training Simulator, *Journal of the American Academy of Audiology*, Submitted and Currently under revision.

My contribution to this study was the revision of the simulator under recommendations from the first validation study; the organization, planning, and execution of the study; and analysis of the results and writing of the paper. P. Folkeard contacted participants and was the expert observer during all study sessions, H. Saleh was the volunteer observer during all study sessions and contributed to statistical analysis of the results. S. Moodie, S. Scollie, S. K. Agrawal, and H. M. Ladak oversaw the study and helped plan the execution.

Acknowledgments

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List of Abbreviations

3D	Three-Dimensional
ABS	Acrylonitrile Butadiene Styrene
BTE	Behind-the-Ear
CAD	Computer-Aided Design
CHL	Conductive Hearing Loss
CIC	Completely-in-the-Canal
CT	Computed Tomography
DSP	Digital Signal Processing
FDM	Fused Deposition Modelling
GUI	Graphical User Interface
MHL	Mixed Hearing Loss
PC	Polycarbonate
RECD	Real-Ear to Coupler Difference
RIC	Receiver-in-the-Canal
SNHL	Sensorineural Hearing Loss
TM	Tympanic Membrane
WHO	World Health Organization

Chapter 1

1 Introduction

Hearing loss is a major worldwide issue recently recognized as a priority area by the World Health Organization (WHO) (1–3). While hearing loss is an extremely disruptive disease on its own, high-reaching implications from hearing loss include social isolation, decreased intellectual functioning and high risk of dementia (4–11). In Canada, approximately 25% of individuals have some degree of hearing loss, with 5% being deaf or hard of hearing – a number expected to increase with the growing population (12). Hearing aids are the primary method of treatment for nearly 90% of all hearing loss cases (13,14).

Hearing aid technology has progressed exponentially since its introduction in the 1960s, and along with it, the methods used by clinicians to tailor the device to patients. The clinician's intricate "fitting" of the hearing aid is instrumental to the outcomes of treatment. Unfortunately, the methods of training for hearing aid fitting remain the same as with their initial introduction – procedures are still being practiced on classmates or volunteers, in which trainees receive no standardized feedback and cannot provide amplification due to safety concerns. This is particularly true with probe tube placement, or the insertion of a thin-flexible probe into the patient's ear canal to receive acoustical measurements in which to base the fitting. Partially due to a lack of proper training methods, hearing aids are often not properly fitted for patients in clinic (15–17).

Through the development and validation of a probe tube placement training simulator, we hope to encourage the use of this training technology in pre-clinical scenarios. This will help to ensure every clinician is operating within the proper standard of care, and in turn, every patient is receiving quality care. This chapter provides a brief discussion of relevant background material upon which this thesis work is based.

1.1   The Auditory System

The human auditory system can be explained in three main sections, each with their own distinct purpose in the conduction of sound. As seen in Figure 1.1, the auditory system consists of the outer ear, middle ear, and inner ear.
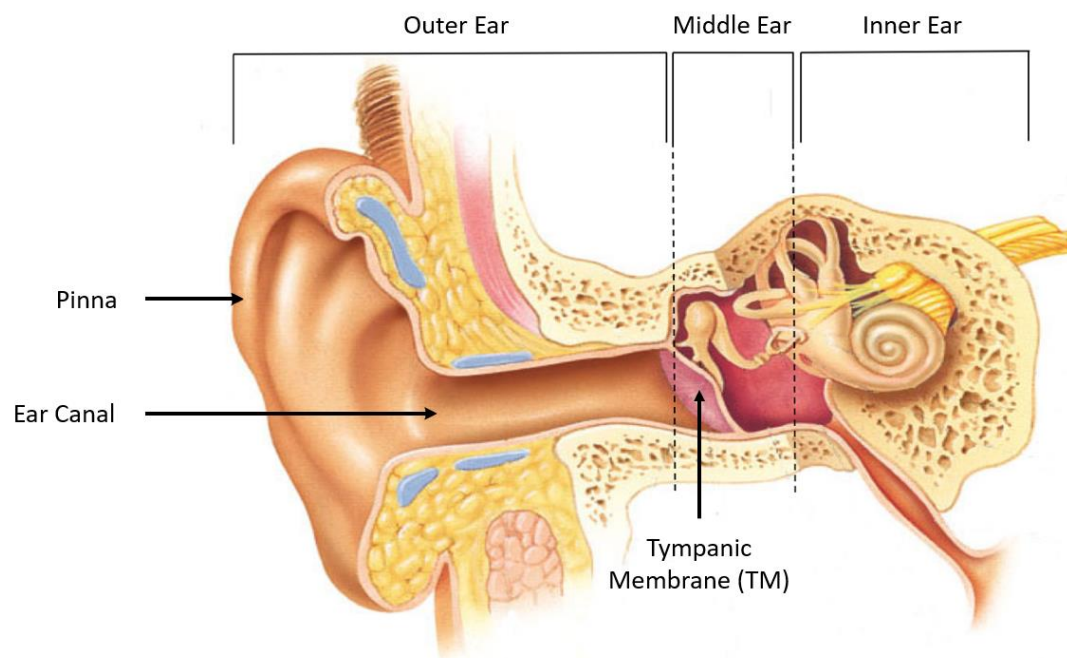
Figure 1.1: Anatomical model of the human auditory system containing the outer ear, middle ear, and inner ear (Image Courtesy of MED-EL GmbH).

1.1.1   The Outer Ear

The outer ear is the first part of the auditory system with which environmental sounds interact. The outer ear consists of the pinna, ear canal, and tympanic membrane (TM). Environmental sounds are captured by the pinna and funneled into the ear canal. The shape of the ear canal amplifies frequencies responsible for key human functions – speech and environmental sounds. Frequencies in the range of 1.5kHz to 7kHz are amplified by a factor of approximately 10 to 15dB (18). A common graphic representing this natural amplification of English sounds required in human audibility and speech is the "Speech Banana" seen in Figure 1.2 (19). Frequencies and tones associated with the

center of the graph require less sound level (loudness) to be audible, while frequencies towards the edges of the "Speech Banana" require a louder volume to become audible. This natural amplification afforded by the ear canal is important to determine a patient's hearing ability and audibility, and for the fitting of hearing devices. Different syllables and letters are responsible for different frequencies throughout this "Speech Banana", and significantly contribute to a patient's speech intelligibility, or the degree to which the acoustic signal is understood by the listener.
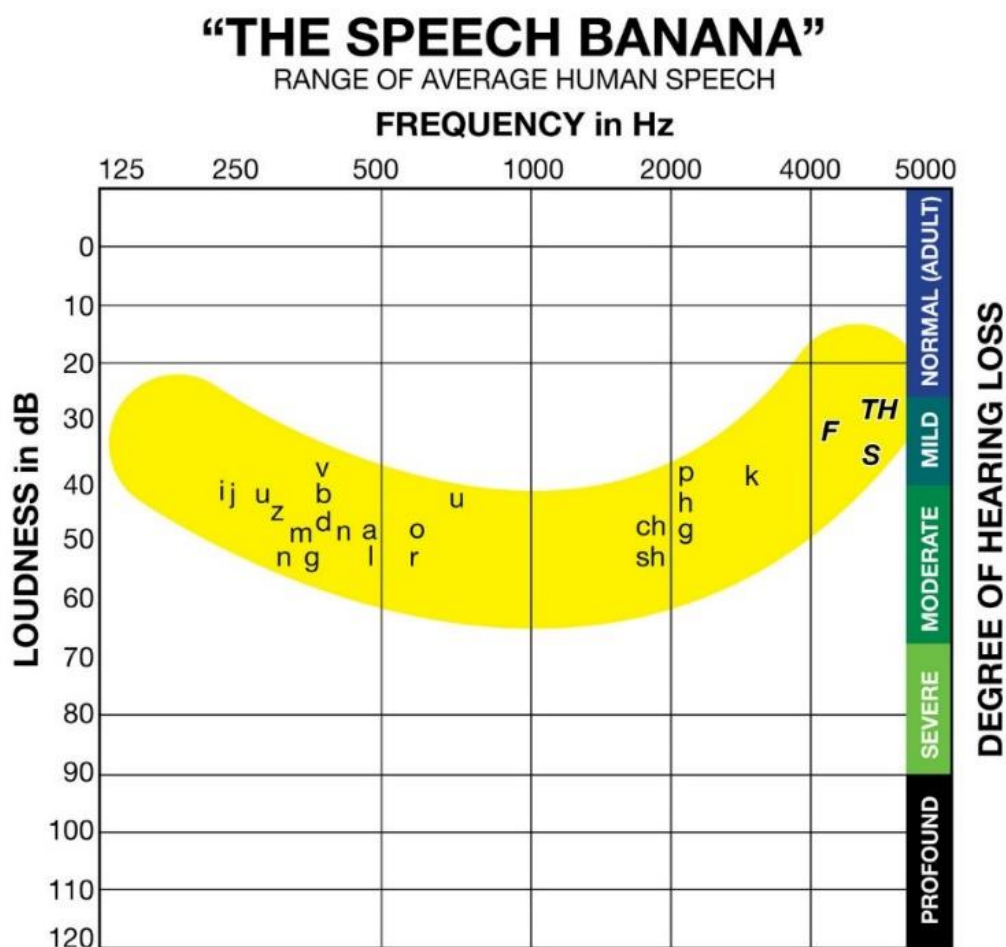
Figure 1.2: The 'Speech Banana' indicating how different frequencies and English sounds are amplified differently in the human outer ear. Typical hearing is seen within the yellow area, with louder sounds and more hearing loss downwards on the graph (Image Courtesy of ClearValue Hearing).

Once the sound has been funneled through the ear canal and the amplification through the ear canal has occurred, the sound strikes the TM causing very small amplitude vibrations corresponding to the frequency of the sound.

1.1.2   The Middle and Inner Ear

The main purpose of the middle ear is to conduct the vibration of the TM to the inner ear through an impedance matching transformer. The middle ear contains a chain of three bones that transfer the sounds into the inner ear: The malleus, incus, and stapes, seen in Figure 1.3. The malleus is the first bone in the middle ear and is attached to the TM. The malleus will vibrate with the vibrations of the TM and pass this vibration to the incus, then the stapes, which is connected to the cochlea (inner ear). The middle ear's bones are arranged in such a way to convert this energy into sound signals and provide a natural amplification across the entire frequency band via their orientation and sizes through a hypothesized lever-arm mechanism (18).
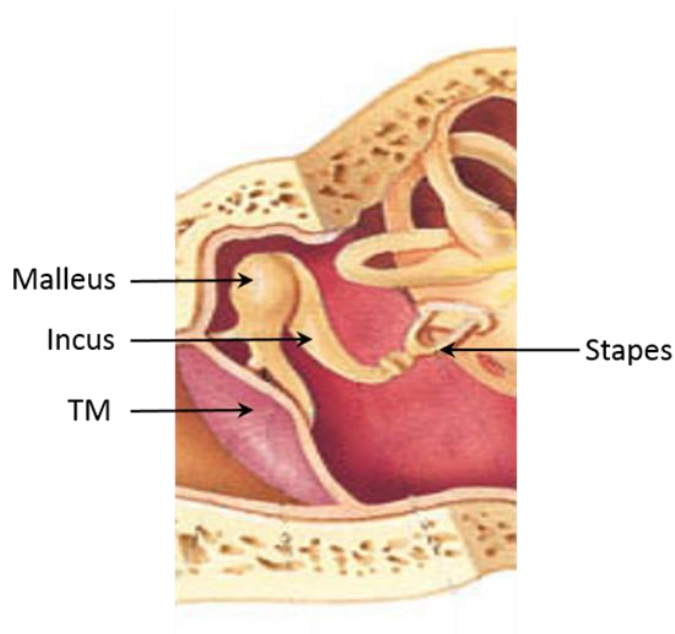
Figure 1.3: The TM and three ossicles of the human middle ear – Incus, Malleus, and Stapes – responsible for conducting sounds to the inner ear (Image Courtesy of MED-EL GmbH).

Finally, the inner ear is responsible for sending the sound signals received from the outer ear and middle ear to the brain for processing. The inner ear contains the semicircular canals, vestibule, and most importantly the cochlea – the organ of hearing. The cochlea is a spiral shaped, fluid filled labyrinth that receives vibrations from the middle ear bones. When the stapes vibrates against the cochlea, waves are induced in the cochlea's internal fluid with a frequency corresponding to that of the original sound signal. Depending on the frequency of these vibrations, different locations inside the cochlea will be stimulated (Figure 1.4). Hair cells (sensory receptors) lining the basilar membrane inside the cochlea will send a signal to the brain if activated at its specific, unique frequency. Hair cells are aligned such that cells in the apex of the cochlea are activated by low frequencies, and hair cells at the entrance (base) of the cochlea are activated by high frequencies. Once sent to the brain, the auditory cortex processes the signals to what is heard as sound.
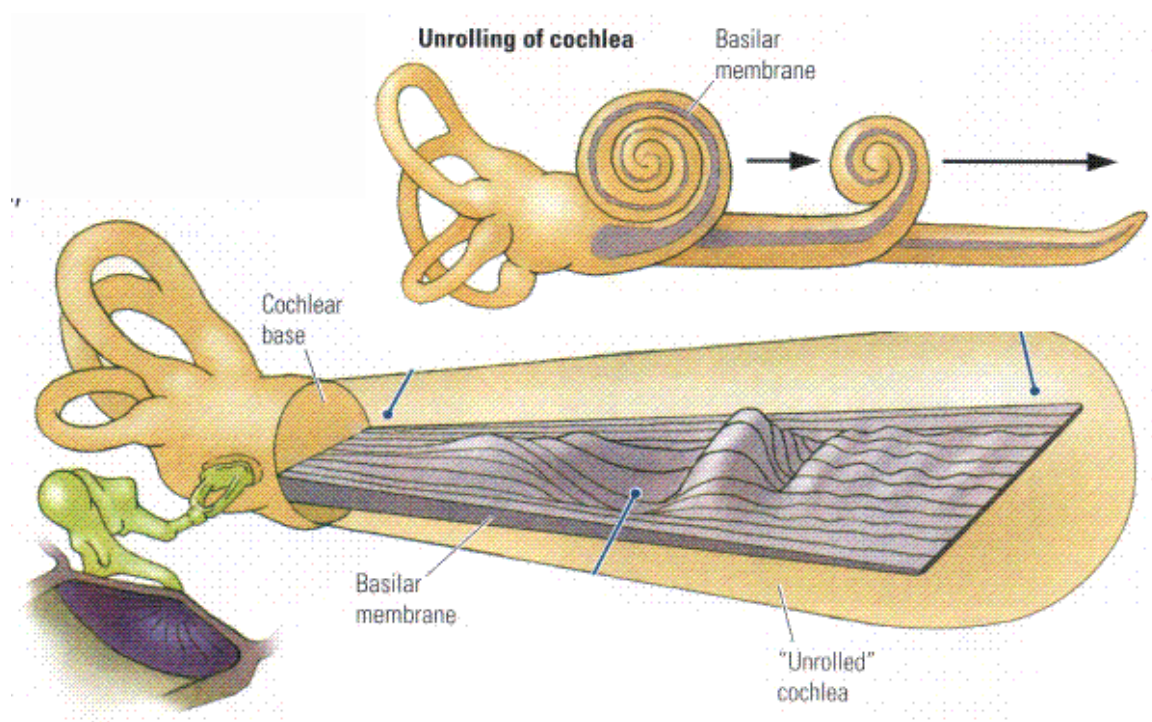
Figure 1.4: The cochlea (inner ear) and the method in which sound vibrates the basilar membrane to conduct sound to the brain (Image Courtesy of Indiana University).

1.2   Hearing Loss

As previously mentioned, each section of the ear (outer, middle, inner) is responsible for a different function in the conduction of sound. When hearing loss exists or occurs, it corresponds to a malfunction in one of these sections. Hearing loss can be classified into three main categories: Conductive hearing loss (CHL), sensorineural hearing loss (SNHL), and mixed hearing loss (MHL). CHL refers to when sound is unable to pass through the outer or middle ear. This may result from an ear infection in the ear canal or middle ear, a non-functioning TM, clogging of the ear canal (due to wax or other objects), or fluid in the middle ear space. SNHL refers to a problem in the nerve pathways from the hair cells in the inner ear to the brain. This results from degradation of the hair cells in an individual's cochlea from the natural aging process, a traumatic experience (i.e. a blow to the head, repetitive exposure to loud sounds, etc), or through illnesses and drugs. SNHL is the most common type of permanent hearing loss, and can range in its severity from a mild hearing loss to profound hearing loss. Finally, MHL occurs when there is a sudden CHL while already possessing SNHL. Different classes of hearing aids can be used to remedy most hearing loss issues, with approximately 90% of hearing loss cases able to be corrected with hearing aids (13,14).

1.3   Hearing Aids

Hearing aids are amplification devices which are used for "correcting" a patient's hearing loss. Hearing aids are made to amplify specific frequencies that a patient can no longer hear well, or in SNHL cases, whose hair cells now have a larger threshold of activation. Hearing aids can be potentially damaging to patients if fitted improperly as they can amplify sounds louder than needed. Only qualified individuals such as audiologists can prescribe and fit hearing aids to patients.

Hearing aids have developed exponentially since their mainstream introduction in the 1960's (20–22). While analog hearing aids with onboard circuits capable of real-time amplification used to be the standard, they have been replaced with digital hearing aids,

performing all necessary signal processing through their digital signal processing (DSP) chip. Henceforth, any mention of hearing aids will refer to digital hearing aids.

Figure 1.5 displays the wide range of hearing aid variations that are available. Years ago, hearing aid selection was very limited in the styles that existed. A behind-the-ear (BTE) hearing aid was one of the only aids which was prescribed to patients. These large, bulky hearing aids are easily visible and were not available in smaller sizes. Currently, there are dozens of different styles to pick from such as receiver-in-the-canal (RIC), or Completely-in-the-Canal (CIC) hearing aids, which are more discreet. The appropriate hearing aid is selected according to the severity of the hearing loss, while also considering the patient's lifestyle and preference.
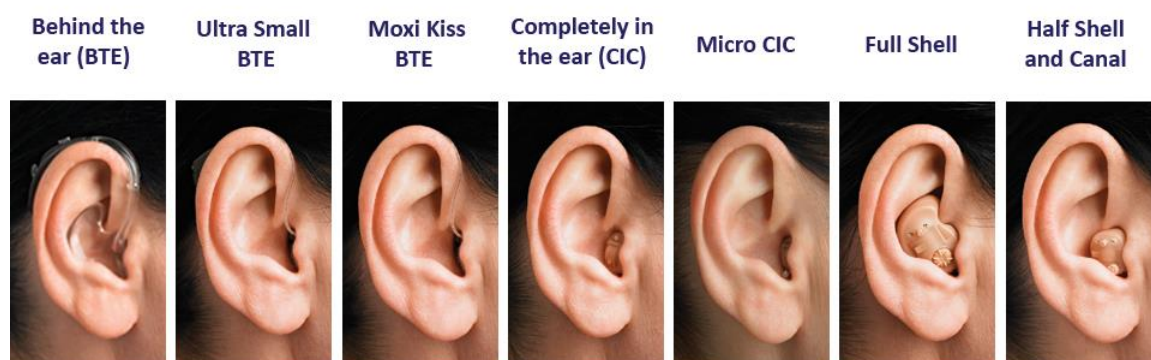
Figure 1.5: Examples of different styles of hearing aids currently available (Image Courtesy of Lachlan A.N. Smith Audiologist).

In addition to the various hearing aid styles, each aid has varying levels of technological features to improve hearing outcomes. Common features which must be programmed by the clinician include adaptive noise reduction (gain reduction for speech enhancement, transient noise reduction, and internal noise reduction), directional microphones, and environmental classification. While not crucial to the work in this thesis, it is important to note the added complexities which modern hearing aids now possess. Previous studies have shown that the complexity of these digital hearing aids and associated fitting

technology may contribute to a lack of adherence to best practices, and a resulting reduction in good patient outcomes (23–25). Each year, hearing aid manufacturers provide new technology to improve hearing outcomes for patients, but most new features add further complexities to the clinician's fitting of the hearing aid. This fitting procedure is critical for the success of the hearing aid.

1.3.1   The Prescription and Fitting of Hearing aids in Clinic

Once hearing aid candidacy is confirmed and initial discussions between the patient, their family, and the clinician have taken place, the clinician will have their first fitting with the patient. Fitting refers to the clinician's personalization of the hearing aid for the patient – ensuring the aid is properly tuned for the patient's unique hearing loss. The frequencies at which a hearing loss is present are amplified to a pre-determined amplification target to fit the aid to the patient. The clinician will fit the hearing aid according to the patient's hearing loss as seen in the hearing aid fitting software. After this initial "first-fit", the clinician must verify that the sound being delivered to the TM is meeting amplification standards outlined by governing audiology organizations (26–29). This final check of amplification is called "hearing aid verification". Hearing aid verification utilizes real-ear measurements (discussed below) to ensure the listener's individual ear canal acoustics are taken into account in the fitting process. Recent studies have shown that this verification is essential to hearing aid outcomes, and differences between the first-fit outcomes and the verified amplifications can be greater than 10dB (30,31) – a difference capable of severely affecting the speech intelligibility of the patient (32). While the use of verification is part of best practice guidelines, numerous organizations and individuals are working towards creating mandatory practice standards to ensure all patients receive proper fittings (33).

1.4   Real-ear Measures & Probe Tube Placement

To verify the hearing aid, the clinician must measure the sounds that are being delivered directly to the TM – referred to as the "real-ear". These real-ear measurements are required as studies have shown that acoustics delivered to the entrance of the ear canal are not equal to the acoustics which reach and strike the TM (34,35). The only way to

ensure that the amplification targets are being met is to measure the sounds pressure level at the TM, something that is not possible with simply a 'first fit' correction with the hearing aid software (25,34). The mechanism by which the clinician measures this real-ear measurement is by placing a thin, flexible probe tube close to the TM, as seen in Figure 1.6. This probe tube is connected to a microphone system responsible for measuring the acoustics at the TM. It has been shown that the clinician must insert this probe within 5mm of the TM for proper measurements (26,36–39).
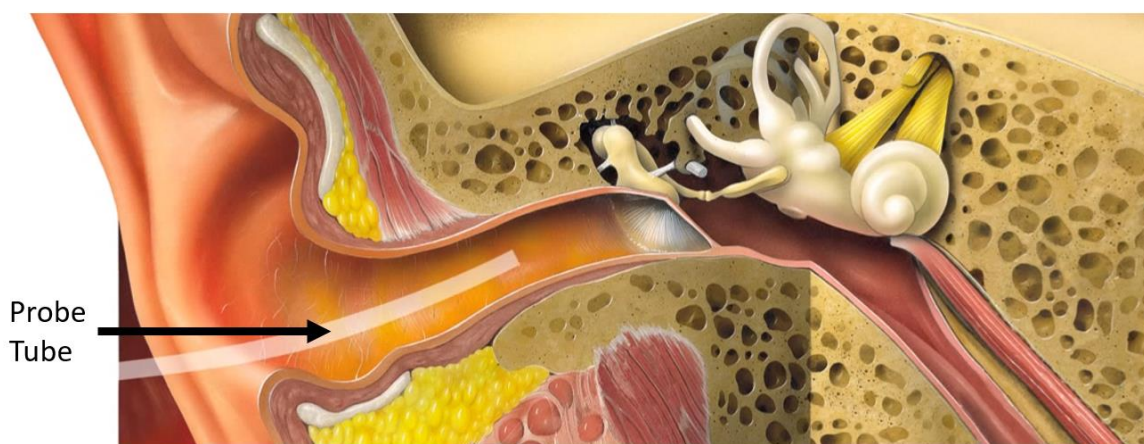
Probe Tube

Figure 1.6: Insertion of a probe tube into a human ear canal to take acoustical measurements for the fitting of hearing aids (Image Courtesy of Audioscan).

1.4.1   Issues & Difficulties with Clinical Probe Tube Placement

Placing the probe to within 5mm of the TM is a difficult target to hit – particularly for novice clinicians. Studies have shown that if the probe is farther than 5mm from the TM, standing waves from sound reflectance with the TM will negatively affect the accuracy of measurements (36,37,40,41). While the measurements increasingly improve with closer placements to the TM, the risk of contacting the TM increases as well. Contacting the TM with the probe tube causes an alarming sensation for the patient, and in pediatric cases in particular, may result in an early appointment conclusion (42). Contact with the TM can also lead to decreased confidence in the clinician – something that has been shown to impact the patient's hearing outcomes (43).

The main tool which an audiologist or hearing instrument specialist can use to gauge their probe microphone placement is an otoscope – a magnifying glass shaped to view into the ear canal. The view which the clinician would see through the otoscope is seen in Figure 1.7. For a novice clinician, it is very difficult to estimate the distance of the probe tube to the TM from this perspective.
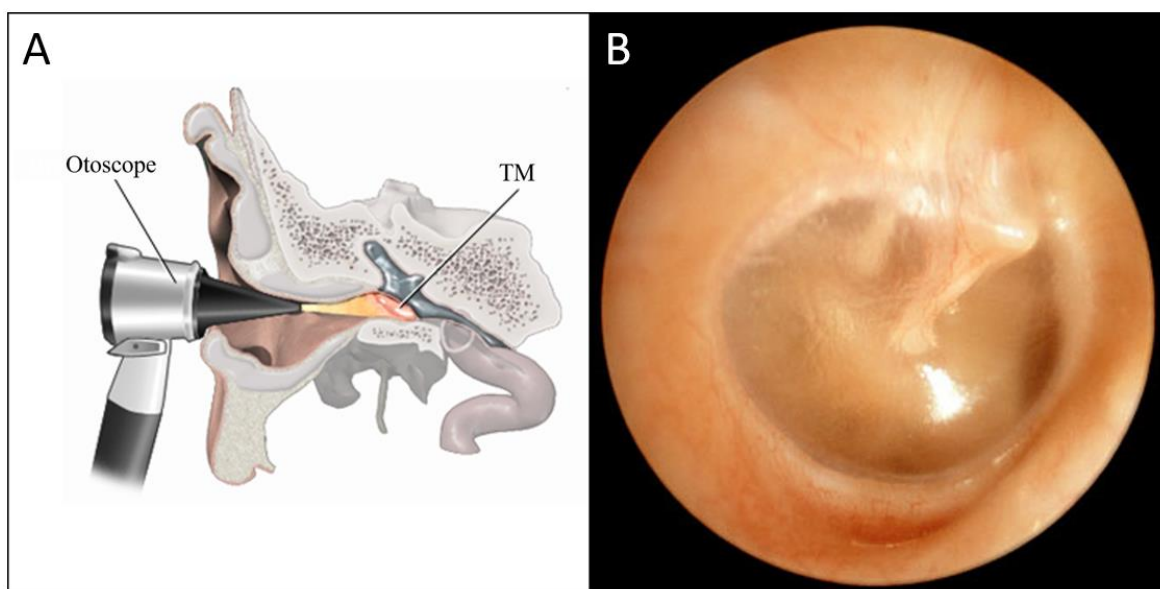
Figure 1.7: The anatomical view of an otoscope observing the TM of a patient (A), and the view seen through the otoscope directed at the TM (B) (Image Courtesy of OnHealth & Chears Audiology).

Additionally, the clinician receives no feedback regarding the placement of the probe, unless the clinician contacts the TM, causing a response by the patient. Avoiding contact with the TM is a very important part of probe placement and is discouraged during the training of clinicians. The only method to receive feedback on probe placement is through an expert who verifies its location by using the same otoscope.

Another issue with probe tube placement is the varying anatomical differences that exist across human ears. The human ear canal can vary in length, shape (s-shaped versus

straight), and amount of cerumen/hair (44–46). Each probe tube placement is slightly different, and the trainee must be comfortable encountering any situation in clinic.

It is important to note that if the probe is placed improperly in the ear, the results from verification may be incorrect, and the fitting of the hearing aid and the patient's success with the hearing aid will suffer.

1.4.2   Pre-clinical Training Procedures

Students that are new to the field of audiology and patient care must be proficient in their probe tube placement before entering a clinical scenario. To gain this experience and expertise in probe tube placement, trainees practice their placements in a lab setting with their classmates, volunteers, and instructors. While this way of training has been used for years in audiology, there are several disadvantages.

First, this form of training provides no qualitative or quantitative feedback to the trainee about whether or not they are performing the placement correctly. The only way to know if the probe is placed properly is for an expert (the instructor/trainer or teaching assistant) to look into the patient's ear with an otoscope after the trainee has finished. This is extremely impractical in a lab setting, and limits how often the trainee can receive feedback.

Second, practice time for trainees is limited. Due to the nature of the procedure, the trainee must have another person to act as the patient. This results in novice clinicians only practicing the procedure with other students, or during their lab times. The need to schedule this training time with another individual is restrictive, and even if students practice in partners, there is no way to receive feedback. The only situation in which they can practice with feedback is in a lab setting where they have a 'patient' to perform the placement on, and an expert to evaluate whether it was done properly.

The last issue with current training methods is the limited anatomies which the trainee receives exposure to. The human outer-ear has large inter-individual differences, and the clinician must adjust their procedures accordingly. The length of the patient's ear canal, the shape of the ear canal, and the bends within, all vary considerably (44–46). For

example, the same probe tube placement cannot be performed for an adult male with a straight 32mm long canal and for a 5-year-old infant with an s-shaped 20mm long ear canal. While training in an audiology program, the trainee does not gain exposure to a wide collection of ear canals – typically they will gain plenty of experience with 20 – 30-year-olds due to the demographic of the program. This issue arises again when encountering extreme anatomical cases. For example, an exostosis is a bony growth within an individual's ear canal. If encountered by a novice clinician in a clinical scenario, they may not know how to perform verification including real-ear measures with probe tube placement. Even more severe, a patient with a mastoid cavity has their ear canal 'dug out' and has a large space which was previously excavated for a previous procedure. The small acceptable area of 5mm to place the probe is very difficult under these circumstances, and appropriate modifications must be taken.

In conclusion, probe tube placement is a difficult procedure to effectively train clinicians for and poor initial performance in placements may result. The main difficulties that are present in clinical probe tube placement are also found in training settings and offer no way for trainees to overcome these challenges. Through meetings with experts at Western University (Canada), it was established that this difficulty increases as training program sizes increase, and each trainee receives less time with the expert and less feedback on their placements.

1.4.3   Probe Tube Placement Usage Rates in Clinic

Compliance rates for the use of probe-mic verification is very low in clinics, with studies finding a usage rate of less than 50% (23,24,47). Numerous reasons for this lack of compliance have been cited such as the complexity of modern hearing aids, uncertain correlation with hearing aid satisfaction, cost of equipment, and poor training. With reporting bias where clinicians over-estimate how often they are performing these procedures, the usage rate is predicted to be even lower (34). Other studies have looked to quantify the harmful effects that lack of verification may have on patients.

The low usage of probe-microphone equipment, and lack of proper training methods, outline a need for a more validated and proficient method to train for clinical practice.

1.5   Literature Review of Simulation in Hearing Healthcare

A solution within educational settings to increase skill in high-risk, difficult-to-teach areas is simulation (48–54). First introduced in aviation, simulation offers a method to recreate real-world situations in educational settings in an effort to gain experience and skills before being placed into a high-risk (clinical) scenario. While real-world experience is still necessary in these situations, simulation provides an outlet to practice a procedure as often as required with exposure to varying types of anatomy. Simulation allows trainees to recreate extreme circumstances to ensure they are ready to encounter any scenario in their clinical placement.

Simulation-based medical education is becoming increasingly popular with the global simulation market expected to double from 2017 to 2022 (55). Increasing demand for minimally invasive surgeries, and increased focus placed on patient safety, presents a clear need for advanced training procedures. While the technology has evolved allowing for more advanced training solutions, the validation of these techniques is crucial in order to prove their utility in training scenarios, and to ensure that implementation will produce positive clinical results. The validation of simulation as a core solution to these problems encountered in the healthcare industry has been vital in the implementation of these devices in training programs.

There are currently various methods of simulation that are present in healthcare. Each method of simulation is tailored to the specific training need and the field in which it is present. Some key types of simulation technology include virtual reality systems with force feedback input/output, virtual patient simulation, and physical models.

While simulation has not yet been fully accepted within hearing, there are groups looking to simulate other difficult or high-risk procedures for Audiologists and Otolaryngologists. Simulation systems within hearing include OtoSim for otoscopy, Myringotomy VR for myringotomy, and a Virtual-Patient Audiology Simulator that simulates audiometric testing (56–58). While all these simulators provide utility for the clinician looking to

practice those procedures, none of them were developed to train clinicians on real-ear verification. To address the need to gain experience in probe tube placement before clinic, a physical model was chosen as the best solution.

Physical models include a physical recreation of the situation which is to be encountered in clinic. In medical simulation, this typically includes a mannequin aimed to simulate the patient in some form, with additional functionality to recreate human physiology, or to provide feedback mechanisms that increase learning opportunities. These physical simulations allow trainees to get accustomed to clinical methodologies before practicing on volunteers or operating in a clinic.

There are various ways in which these physical models can be created. While previous mannequins were made through plastic and silicone molds for realistic flexible models, three-dimensional (3D) printing has now allowed for the quick and affordable development of rapid prototypes.

1.6   3D Printing & Rapid Prototyping

3D printing is an additive manufacturing process in which various materials are injected onto a build platform to create physical models of computer generated volumes. There are several different 3D printing techniques, however in this thesis, the focus will be on two techniques: fused deposition modelling (FDM) and Polyjet.

FDM printing is the most popular and accessible 3D printing technique available in the current day. This type of printer uses a heated extruder head to melt and extrude plastic filament (PLA, ABS, PC, etc) onto a build plate. The location it is extruded to corresponds with the location specified by the 3D model in the 3D printer software. At the time of writing, FDM printing is inexpensive (roughly $1.00 for a four-inch cube), produces functional parts, and is most often used for prototyping. FDM printers can vary from $100 to $1,000,000 depending on the print volume, printable materials, and accuracy for example.

The second 3D printing technique relevant to this thesis is Polyjet printing. Polyjet refers to a technique very similar to an inkjet paper printer, but instead of dropping droplets of ink onto paper, the 3D printer extrudes miniscule droplets of liquid plastic. A UV light over the part cures the plastic into a solid. Like an inkjet printer, one can vary the colour (and material) by mixing the different material cartridges to create the ideal properties for the print job. Polyjet printers are known for smooth surfaces, precision, and varied material properties (59). The cost of polyjet printing vastly outprices FDM with entry level printers starting at $50,000 and the cost of print material for a four-inch cube starting at approximately $50 (50x that of an FDM printer), along with several maintenance requirements. This technique is used for highly precise parts with differing material properties.

Although 3D printing is advancing at an exponential rate, and the capabilities of advanced printing techniques such as Polyjet create new manufacturing possibilities, 3D printing remains incapable of producing flexible, soft parts that can mimic human tissue. If properties produced from 3D printing are not optimal for the required application, manufacturing techniques such as molding and casting can be used. This consists of using a resin (typically silicone) to create a mold and cast of the 3D printed part. The creation of these molded and casted parts in tandem with 3D printing can be extremely cost-efficient and extend the range of materials.

1.6.1   The Development of 3D Models

To obtain models to 3D print for physical mannequins, a Computer-Aided Designed (CAD) model must be developed. While common 3D object files can be found at various online repositories, specialized geometries must be created from scratch. In the healthcare field, medical scans such as computed tomography (CT) scans are used to create 3D models of patient anatomy and geometry.

While CT scans offer exact patient geometry for use in 3D models, an additional step must be completed to create models of only the relevant geometry in the image, segmentation. Segmentation refers to the outlining of relevant anatomy in an image. This is necessary in anatomical images since scans contain all of the patient's anatomy – from

air pockets and soft tissue to bone – which is not needed in the models. There are various ways in which segmentation can be performed. The anatomy can be manually segmented, where the operator outlines, or "colours in", the tissues that are required for the model. Alternatively, the segmentations can be automated through common computer algorithms. Thresholding, or defining a threshold gray level in the image and segmenting anything above or below that threshold, and region growing, the selection of a seed point and expansion outwards to a specific threshold, are two popular techniques.

After segmentation, the relevant segmented anatomy can be exported to a modeller in which a volume is created, and surfaces can be fitted to the outlines. The modelling CAD software is capable of editing and fixing this volume to prepare for 3D printing.

The creation of these 3D models and the rapid prototyping through 3D printing was an important technique that was relevant to the creation of the probe tube placement simulator. Through these methods, new prototypes can be developed in short periods of time with limited costs. The integration of these 3D printed parts with feedback mechanisms create an extremely powerful tool to offer enhanced training methods capable of better preparing trainees for clinic.

1.7   Objectives

The first objective of this thesis was to develop a probe tube placement training simulator for trainees in audiology to practice probe tube placement before entering a clinical scenario. The second objective was to validate the simulator to determine its usefulness in teaching and its ability to produce skill development for users.

Chapter 2

2 The Development of the Probe Tube Placement Simulator

The development of the probe tube placement simulator was an iterative process occurring over two years. The design has evolved substantially since its initial prototype through user feedback received from the performed validation studies (Chapter 3 and 4). Included in this chapter is the development process of the original simulator with in-depth detail of each component.

2.1 Design Requirements

While the development of the probe tube placement simulator was open-ended to allow for creative autonomy, there were several design objectives which were to be met for the simulator to be used in Western's audiology training program.

Firstly, the simulator had to provide a high-fidelity (highly realistic) training experience for trainees. The teaching and learning of audiology is a hands-on process that includes becoming both accustomed to common instruments and comfortable interacting with a patient's head and ear while performing procedures. A high-fidelity simulator (in comparison to a low fidelity/realism task trainer) (48) is favoured while satisfying the remainder of the requirements.

Secondly, users of the simulator were to receive feedback regarding how far the probe had been placed from the TM. Trainees do not receive this type of feedback in clinic – a large barrier while learning probe tube placement, as discussed in Chapter 1. The simulator must be able to measure the probe-to-TM distance with an accuracy within 1mm.

Thirdly, the simulator design was to be as cost-effective as possible, with cost of materials kept under roughly $500. Due to the limited budgets which training programs and training institutions possess, a high-priced system would not be plausible.

Finally, the system had to be lightweight, portable, and compatible across different operating systems and different hardware specifications. Training programs often require equipment to move between rooms depending on the lesson or lab that is taking place. The developed design therefore had to be adaptable to several rooms while also being able to operate on different computers within these settings.

2.2   Physical Simulator

A physical simulator was determined to be the best type of medical simulator to simulate probe tube placement due to its high-fidelity approach. Probe tube placement is one of the first hands-on procedures that clinicians perform on a patient. A physical simulator allows trainees to be introduced to the procedure and offers them a tool to practice probe tube placement while becoming comfortable with an otoscope and using real-ear measurement equipment on a patient's head.

Due to the large variation of ear anatomy that exists between individuals, an adult simulator (based on adult anatomy) and a pediatric simulator (based on infant anatomy) were built. Both simulators were developed using the same methodology, with only the head model and ears differing between the two (as seen in Figure 2.1). Henceforth, all development will refer to both the pediatric and adult models, as the adult model was developed first, and the pediatric model was a modified version of the adult model.
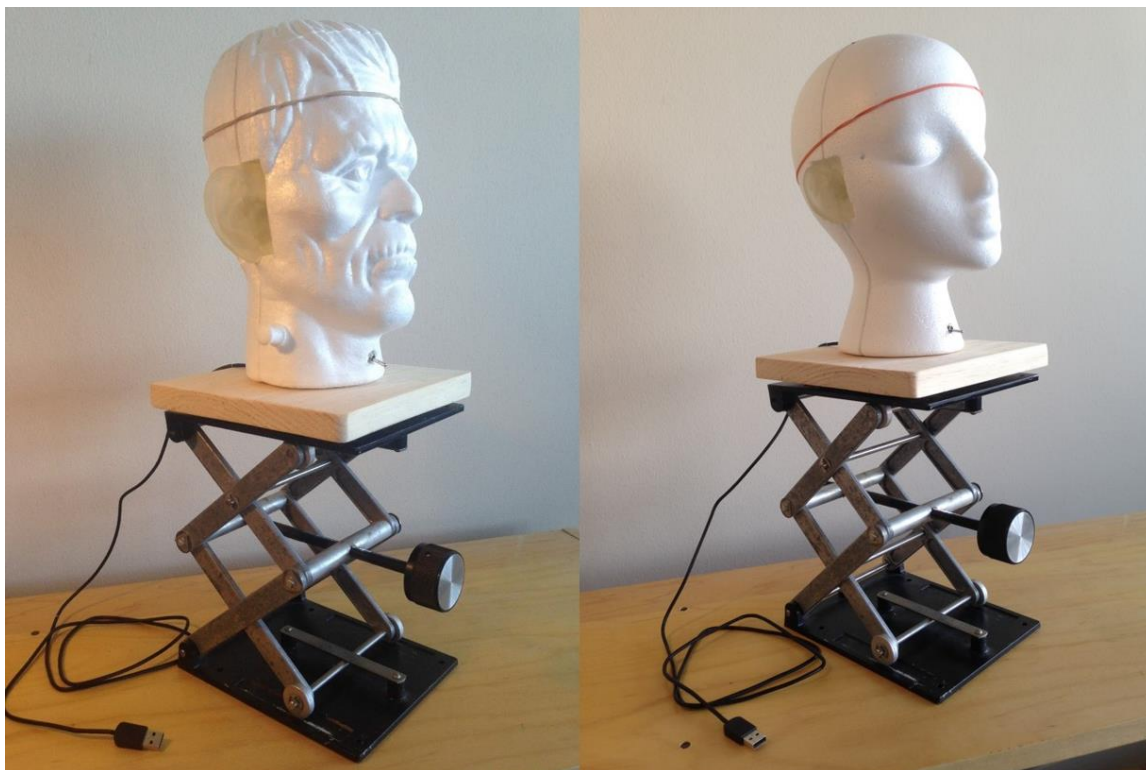
Figure 2.1: The adult (left) and pediatric (right) versions of the first probe tube placement simulator.

As seen in Figure 2.2, the physical simulator consists of three main parts: The ear model, the head model, and the optical tracking system.

2.2.1   Ear Model

To create a high-fidelity model for probe tube placement, CT data of cadaveric temporal bones were obtained. All cadaveric specimens were obtained with permission from the body bequeathal program at Western University (London, Ontario, Canada) in accordance with the Anatomy Act of Ontario and Western's Committee for Cadaveric Use in Research. The pinna, ear canal, and TM provided by these CT scans allowed for simulation of exact patient anatomy. CT scan data was utilized for both the adult and pediatric models, displaying drastically different anatomy. As defined by the scans, the canal length of the adult model was 32 mm whereas the pediatric ear canal length was 15

mm. To print these 3D ears, the CT scan data had to first be segmented and created into a 3D model.
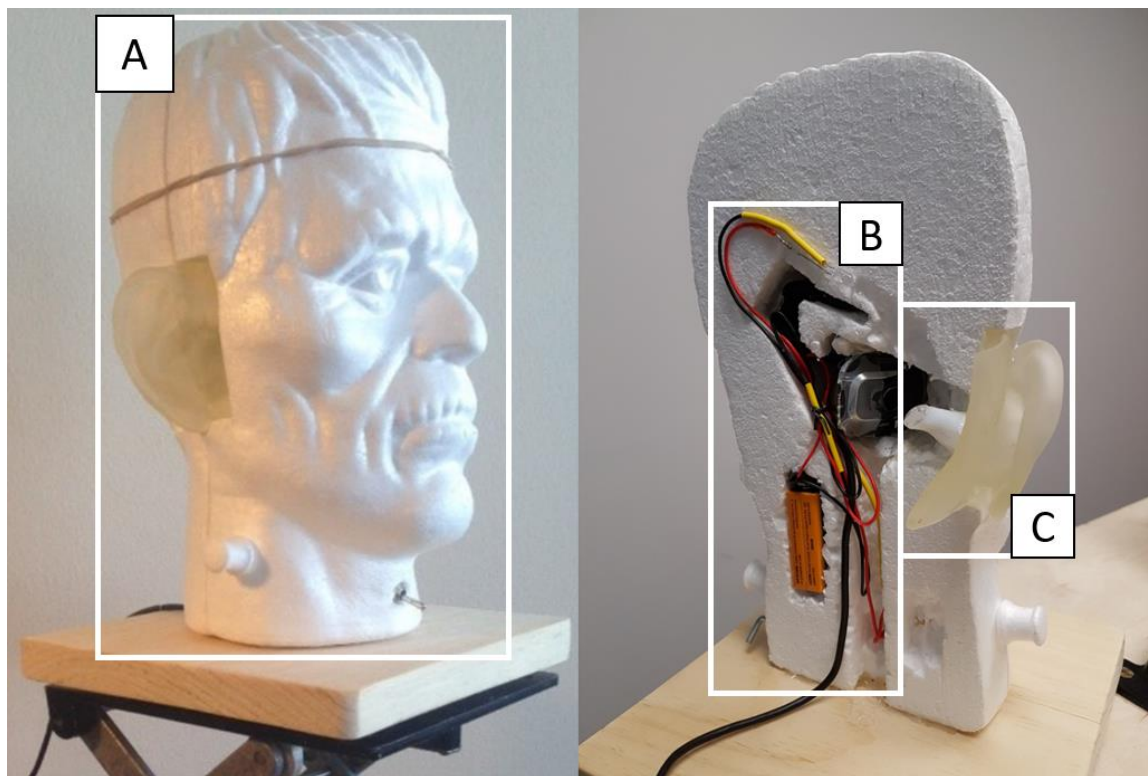
Figure 2.2: The internals of the adult simulator displaying the three parts of the simulator: The head model (A), optical tracking module (B), and ear model (C).

A step-by-step process of the ear model creation is seen in Figure 2.3. First, the CT scan data was imported into 3D Slicer (60) for segmentation and manipulation of the original images (Figure 2.3A). For the purposes of the probe tube placement simulator, the pinna, ear canal, and TM were the only necessary structures. All parts of these structures were to be segmented and succinctly integrated into one surface for printing. To segment these structures, a thresholding technique was used. Through trial and error, it was found that the proper limits of the threshold were greater than -500 Hounsfield Units and less than 200 Hounsfield Units – corresponding approximately to the radiodensity of human tissue

found in the human ear system. Even though this resulted in a suitable outline of the anatomy, there were minor deviations/outliers that had to be manually corrected – structures within the threshold that were not required in our model – as seen in Figure 2.3B. In addition, the TM is an extremely small structure which is difficult for a segmentation algorithm to capture in entirety. To correct for both these errors, the remainder of the structures had to be manually segmented. The raw CT data were examined slice-by-slice to correct for any of the relevant anatomy that was not captured. Once completed, the segmented object was exported to a 3D modelling software to prepare the design for printing.

The modelling software Geomagic Studio (3D Systems, Morrisville, North Carolina, USA) was used to smooth the automatic and manual segmentation results from 3D Slicer (60). As Geomagic Studio uses meshes to manipulate objects, functions such as relaxation and refining of the mesh were used along with restructuring geometry sculpting and shelling the existing meshes. Extensive work with these functions was performed to optimize the 3D printing process, minimizing material and time for printing (Figure 2.3C). Once completed, the ear model was exported as an .STL file to send to a manufacturer for printing.
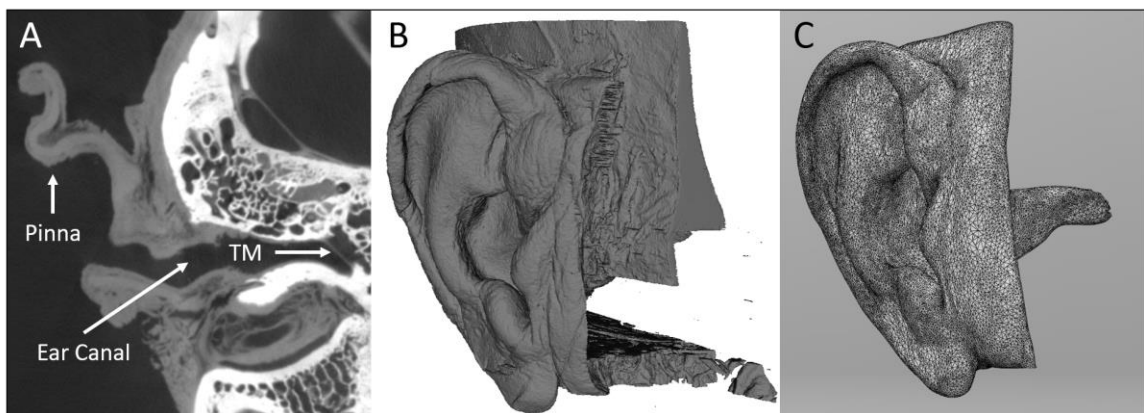
Figure 2.3: Creation of the 3D printed ear model. Pane A shows the raw CT scan which was segmented in 3D Slicer and exported as a surface (Pane B). Pane C shows the final mesh-fitted object ready to be 3D printed.

Cimetrix Solutions (Oshawa, Ontario, Canada) was the source of printing for this initial print job due to their advanced 3D printers and capability for variation of material properties throughout the same part. The human auditory system possesses structures with varying material properties such as cartilage for the outer one-third of the ear canal and bone for the inner two-thirds of the ear canal, which were important to capture in this ear model. The pinna and entrance of the ear canal was printed with a Stratasys Objet 500 Connex3 3D printer with TangoPlus FLX 930 material (Stratasys Ltd., Eden Prairie, MN, USA) at a shore value (hardness) of 27A. For the tracking system and simulator to operate effectively, the inner ear canal portion of the ear was printed in a transparent VeroClear RGD810 material and coated in a latex paint to further increase transparency. As previously mentioned, the capabilities of this Polyjet printer allowed for varied mechanical properties of the printed part throughout the same print job.

2.2.2 The Head Model

Various approaches were explored for providing a head model, but the low-cost solution of styrofoam was chosen. Styrofoam was found to be extremely inexpensive and allowed for easy manipulation. For the tracking system and ear to be mounted in the head at consistent and stable locations, the styrofoam was carved out in the desired location, and hot glue was used to secure them in place. While this approach is not ideal for repeatable production or large volumes, it was excellent for an initial proof of concept to show the feedback mechanisms that were present and to receive feedback on the operation of the simulator. When moving forward into more advanced prototypes or production units, alternative materials for the head models would be used such as 3D printing or injection molding.

2.2.3 The Tracking System

A variety of sensing modalities capable of detecting the probe tube as it was inserted into the model ear were considered; however, optical tracking was used in the final design.

Although a capacitive or inductive sensor system offers more accuracy than an optical sensor, a key factor discouraged the use of this category of sensing technology – cost. The probe tubes used by clinicians have a very small diameter (around 2mm) and are made of plastic. This is a very difficult object to detect using a capacitive or inductive sensor. Through various quotes on capacitive and inductive sensors capable of detecting such an object, it was determined that this sensor would cost greater than $2000. This hardware cost did not meet our requirements supplied by the end users, so optical tracking was explored instead.

Optical tracking allows for extremely flexible tracking through software and object tracking algorithms utilizing image processing techniques. By isolating the object in question from the background, the software can track quantitative feedback metrics about the object such as location relative to other objects in the scene, or the rate in which things occur. For the optical system, a Microsoft LifeCam HD-3000 camera was used, costing $40.

The tracking system mounted in the head model can be seen in Figure 2.2B. An LED light seen above the camera was required to provide optimal lighting. This light was necessary as the styrofoam head will be closed once in use and different lighting scenarios in which the simulator is used can drastically alter the lighting conditions inside the head. This supplied light provides a consistent scene for which the software can be optimized for. The LED is powered by a 9V battery with a switch located on the outside of the head. The circuit used to power the LED consists of a 9V battery, switch, resistor, and LED pack all connected in series. A 1kΩ resistor was used to allow for optimal brightness from the LED.

2.3   The Software

A software module was developed using Matlab (MathWorks, Natick, Massachusetts, USA) to allow for tracking of the probe tube inside the 3D printed ear canal. The key parts of the software were the two modes of operation, underlying object tracking

algorithm, and the additional graphical user interface (GUI) functionalities. The user interface was split into two different modes corresponding to the user's intention for using the simulator: practice mode or test mode.

2.3.1   Practice Mode

The *practice mode* was designed for users new to probe tube placement to receive real-time feedback regarding their placement while in a training setting. An image of the user interface in practice mode can be seen in Figure 2.4. The real-time updating image displays the location of the probe, while the feedback box labelled "Distance:" displays the exact distance the probe is from the TM. While not realistic in a clinical scenario, users of the practice mode can see typical events that may happen with the probe tube in the canal when inserting (placed along the floor vs. ceiling), or changes that may occur with the location of the probe once securing the external lanyard to the patient.
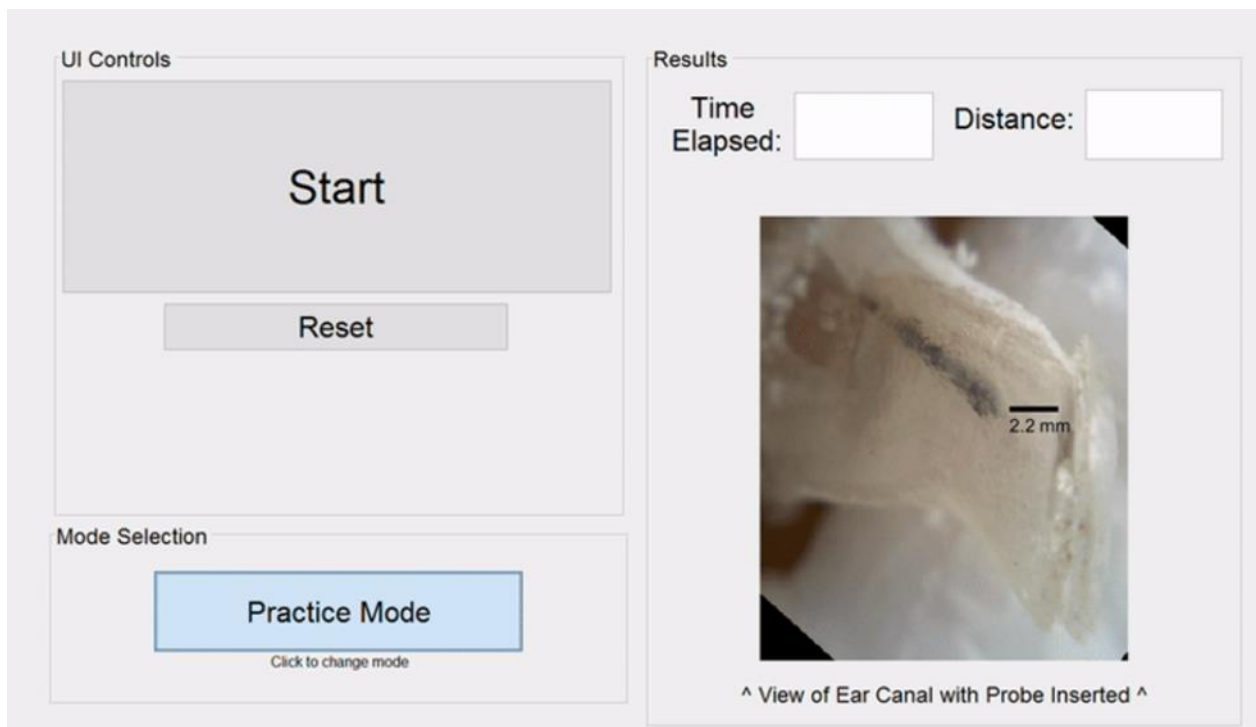
Figure 2.4: The user interface (shown in practice mode) of the first probe tube placement simulator developed using Matlab.

2.3.2   Test Mode

Test mode was developed to create an evaluation case in which students do not receive any visual feedback on their probe tube placement until they have completed the placement. Test mode uses the same interface as practice mode (Figure 2.4) but withholds the on-screen results panel until the placement is finished. To indicate the simulator is in test mode, the toggle button at the bottom left of the user interface will change labels from "Practice Mode" to "Test Mode". The aim was to simulate a clinical scenario in which the clinician must perform the entire procedure before receiving any feedback. This mode may also be used in evaluation settings. The interface feature which differentiates test mode from practice mode is the usage of start and stop buttons. When the start button in the GUI is selected, a timer begins. When finish is selected, the timer ends, and the results of the probe tube placement are displayed – the time to completion, final probe-to-TM distance, and an image of the probe inside the ear canal. If at any time during the running timer (after clicking start, and before clicking finish) the probe contacts the TM, an audible note is played through the computer's speakers. This sound indicates contact was made with the TM and simulates a patient's sudden reaction that would typically occur in a clinical setting.

2.3.3   Object Tracking Algorithm

Regardless of the mode of operation, the same object tracking algorithm was used. To track the probe being inserted into the transparent ear canal, the camera feed analyzes each frame independently from the last. The isolation of the probe from the background is a multi-step process seen in Figure 2.5. The algorithm begins with determining the ear canal background without the probe. When the program first launches, an initial picture of the ear canal is captured (Figure 2.5A). This first image is a benchmark for what the ear canal looks like without the probe tube inserted. Every frame after this first frame (Figure 2.5B) is compared to the initial image. An image subtraction occurs in which each element in the initial image is subtracted from the new image (Figure 2.5C). If there is no probe currently inside the ear canal, the subtraction will result in a matrix of zeros, indicating no probe in the ear canal. If the probe is currently in the ear canal, the matrix will be non-zero in the locations corresponding to the probe. While the probe is evident

after this initial subtraction, additional image processing must occur to outline the probe's shape and provide the outline which can be used for calculating distance.

After the two images are subtracted, a cropping feature erases any values in the matrix that are outside of the ear canal to focus processing on the region of interest. As the camera and ear canal are always in the same location in the head relative to each other, this cropping box will always be at the same location within the images. This cropped image was also rotated to a consistent angle to ensure the TM was taken as a column of pixels in the image. This crop and rotation was dependent on the placement of the tracking system in the head, so customization of these features was completed after the design was completed.

After cropping, the segmentation of the probe occurs. To make the probe stand out from the background more clearly, the last 8 cm of the probe were painted black. This provided more consistent probe-tracking due to the enhanced contrast between the probe and the background. To segment this black part of the probe, thresholding was used with a gray value of 35 in the 8-bit webcam images to create a binary image (Figure 2.5D). This value of 35 meant that there was a gray value difference between the original image (no probe in canal) and the current image of greater than or equal to 35. This remained a stable benchmark as the positioning of the ear and camera remained constant, and the mounted LED circuit supplied consistent lighting. Once the threshold converted the image into a binary image, morphological operations were used to filter and smooth the result. To produce reliable segmentations of only the probe, a dilation and erosion (closing) was performed with a disk element of radius three to minimize the number of outliers in the segmentation mistakenly taken for the probe (Figure 2.5E).
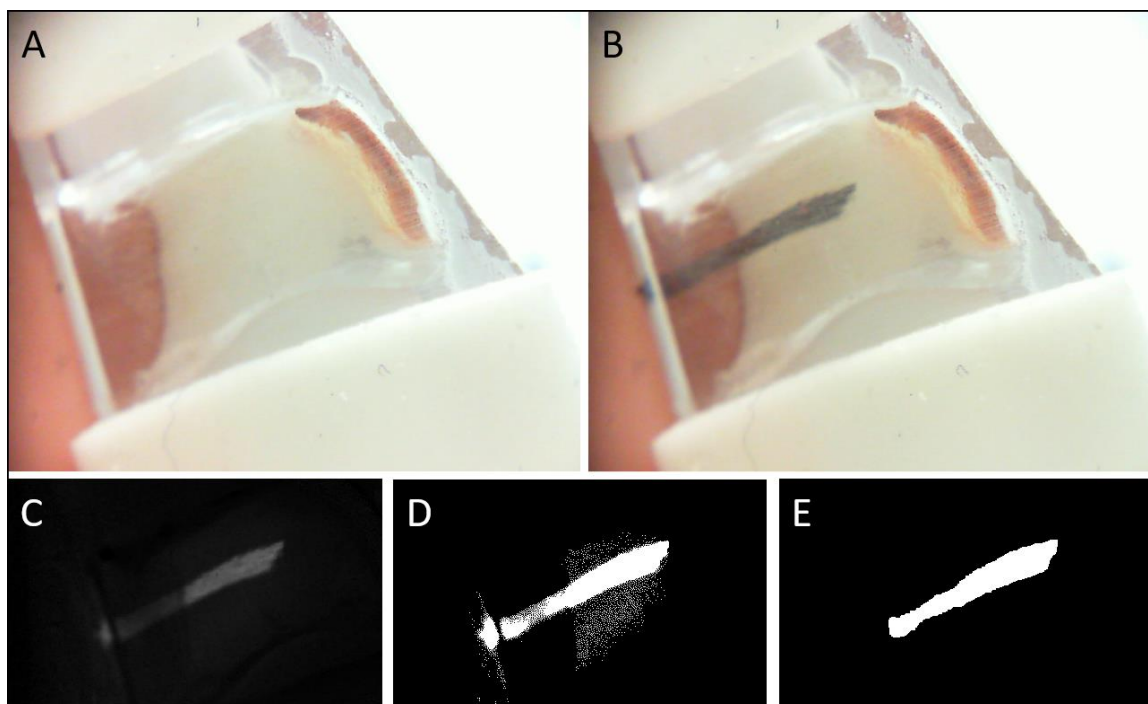
Figure 2.5: Images displaying the segmentation sequence that was needed to locate the probe. Pane A is the initial image captured by the camera for comparison. Pane B is a random frame after the first image when the probe is inserted. The result of Pane B subtracted from Pane A is seen in Pane C. A threshold is used to convert Pane C to a binary selection (Pane D), where it is smoothed using filters and morphological operations to produce the final segmentation of the probe (Pane E).

Once the probe was segmented from the background and smoothed into what was determined to be an acceptable outline of the probe in all locations of the ear canal, a function capable of assigning labels to each of the connected values of segmented objects was applied. As the segmentation and filtering was customized for optimal results in this specific environment, there was always one large segmented object which was found – the probe. If there were no objects in this image, a signal was sent to the GUI indicating there was no probe found in the ear canal.

Once the probe was segmented and located inside the ear canal, its location was calibrated with the camera's location for measurement. The camera was mounted in such

a location that the TM was perpendicular to the camera lens making a column of pixels in the image equivalent to the TM location. This precise location of the TM, along with the camera and ear canal maintaining the same locations at all times, allowed for a pixel distance to be measured from this row of pixels to the tip of the probe tube.

The distance from the TM to the tip of the probe (closest part of the segmented object to the TM location) was calculated in pixels. For example, if the TM was always located at column 300 of the image, and a bounding box around the segmented probe stretched to column 275 of the image, the probe was located 25 pixels from the TM.

Finally, the probe-to-TM distance in pixels had to be converted to millimeters. This was done by using a conversion factor between millimeters and pixel distance calculated by using landmarks on the ear canal visible in the images. The most evident landmarks used were the entrance of the canal and the tip of the TM. The distance between these two landmarks was found in the image in pixels. The ear was then removed, and the millimeter distance of these two exact landmarks was found using a micrometer. This produced a conversion factor that can be used to convert between millimeters and pixels in this location. This was repeated for several different landmarks on the ear canal to find the conversion factors. These conversion factors were then averaged to find the true conversion of 4mm/85 pixels. Using this conversion factor, the pixel distance from the tip of the probe tube to the TM was found in each frame of the camera and outputted to the user depending on the mode selected.

2.3.4   Other User Interface Functionalities

This object tracking system was integrated into a GUI developed through Matlab, seen in Figure 2.4. This interface provided the user with a single screen capable of receiving multiple forms of feedback during the probe tube placement. First, the probe-to-TM distance was clearly displayed for the user to know where in the canal the probe was currently located. Additional feedback included the time spent performing the probe tube placement and an audible response from the software if contact was made with the TM.

2.4   Conclusion

While this initial design was a valuable proof of concept, there were several parts of the simulator which could have been improved. Through consultation with the contributing audiologists and end users of the product, it was decided that this was an excellent point to seek feedback from expert clinicians on the design and to gain insight into which aspects of the simulator to focus on for upcoming developments. Through these validation studies (Chapter 3 and 4), the goal was to determine whether the probe tube simulator would prove as a useful tool for trainers and trainees, and where to focus further development. Future chapters will focus on the studies performed, and the simulator improvements produced from each round of feedback.

Chapter 3

3   Face and Content Validity of a Probe Tube Placement Simulator

3.1   Introduction

Validation of the developed probe tube placement simulator was required prior to using it in a clinical or educational setting. Face and content validity is typically an initial step in medical simulator validation (61). Face validity refers to an assessment of the realism of the simulation compared to the real situation (57,62), while content validity refers to evaluating whether the simulator could be useful in training (57,61). These two forms of validation provide valuable feedback on the simulator and highlight specific areas that may need to be improved prior to more rigorous validation.

The objective of this study was to evaluate the face and content validity of the probe tube placement simulator, as well as the barriers/facilitators to implementation of the simulator in educational settings.

3.2   Materials and Methods

3.2.1   Simulator

The simulator used in this study was previously described in Chapter 2. Both the adult and the pediatric simulator were used, offering two different anatomies on which participants could practice.

3.2.2   Participants

This study was approved by the Western University Health Research Ethics Board (REB 109083 – See Appendix A). Participants were recruited through the National Centre for Audiology at Western University (Canada) and comprised of twelve (12) clinicians and researchers, with probe tube placement experience ranging from three (3) to thirty-seven (37) years. Ten of these participants were employed as course instructors or clinical

supervisors in an audiology training program and were at some point responsible for the course training of novice audiologists, while the remainder had experience teaching novice clinicians in roles as teaching assistants and/or external clinical practicum supervisors. In addition, all participants had clinical experience performing real-ear measures for the purposes of hearing aid fitting.

3.2.3 Protocol

The structure of this study consisted of three sections: (1) operation and evaluation of the adult simulator; (2) operation and evaluation of the pediatric simulator; and, (3) content validity, applicability in an educational setting, and barriers and facilitators to use. For all evaluations, a "think aloud" approach was used (63–65) in which participants were audio and videotaped to capture their physical use and thought processes while using the simulators. Participants also completed a questionnaire aimed at providing quantitative evaluations of both simulators (see below). Sections (1) and (2) were identical, with the exception of the use of the different models: adult and pediatric.

During sections (1) and (2), the participant was given setup and operating instructions for the specific simulator they were using. The participant would follow the instructions, which guided them through each feature and aspect of the simulator, including assessing the realism of the 3D printed ear, otoscopic usage with the simulator, probe insertion in both practice and test modes, interpretation of results after/during insertion in both practice and test modes, and foam tip insertion[1]. Once the participant was comfortable with the simulator and had completed the setup and operating instructions, they were presented with the questionnaire to complete based on their experience with the simulator they had used. They were first asked to complete the face validity section of the questionnaire to assess the realism of specific aspects of the simulator. Once the face validity questions were completed, the participant was required to perform five consecutive probe tube placements in which the final probe-to-TM distance was

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[1] Foam tip insertion refers to a clinician inserting a foam "earplug" to occlude the ear canal after inserting the probe. This is a common requirement when taking certain acoustical measurements with the probe.

recorded. Any contacts with the TM were recorded. Finally, once the above was performed on both simulators, the remainder of the questionnaire was completed to evaluate the content validity, applicability to an educational setting of both simulators, and to find specific facilitators and barriers to their implementation in a clinical education setting.

3.2.4   Questionnaire

A questionnaire was developed in this study that aimed to assess the following relative to the two simulator models: face validity, content validity, applicability in an educational setting, and barriers and facilitators to implementation in clinical education settings. Questions for face validity are summarized as items in Table 3.1, while questions for content validity, applicability, and facilitators/barriers are summarized in Table 3.2. Questionnaire data were collected during a one visit session via SurveyMonkey™.

NO.	SECTIONS 1 & 2: FACE VALIDITY
1	Appearance of the ear
2	Shape of the ear
3	Texture of the ear
4	Stiffness of the ear
5	Otoscopic view of the ear
6	Length of simulator ear canal
7	Presence of relevant anatomical features
8	Proportionality of the ear to the head
9	Sturdiness of the head
10	Adjustability of the head
11	Ability to set up probe mic equipment on simulator
12	Ability to properly position the probe mic lanyard
13	Foam tip insertion experience
14	Time required to perform insertion
15	Total probe placement experience

Table 3.1: Summary of face validity questions used to assess the realism of the adult and pediatric probe tube placement simulators.

The questionnaire used a scale from 0% - 100% in intervals of 10%, with 0% indicating a strong disagreement, 50% indicating neither an agreement nor disagreement, and 100% showing a strong agreement. Participants were also given an opportunity to provide written feedback for each item. The questionnaire was developed in conjunction with several audiologists from the National Centre for Audiology to ensure all aspects of the simulator and the procedure were properly assessed.

NO.	SECTION 3A: CONTENT VALIDITY
1	Educate student on anatomical landmarks
2	Educate student on otoscopic usage
3	Provides high quality opportunity to practice probe placement
4	Provides high quality probe placement evaluation method
5	Assists students in identifying their skill level
6	Assists instructor in identifying a student's skill level
7	Simulator is not too time-consuming in an educational setting
8	Simulator is not too difficult to use in an educational setting
9	Simulator can be used to train students on all aspects of probe placement
	SECTION 3B: APPLICABILITY TO AN EDUCATIONAL SETTING
10	This simulator provides a more valid approach for teaching probe placement
11	The simulator should be implemented within clinical education programs
12	The simulator should be implemented in professional development programs
13	There will be widespread acceptance of this simulator in clinical education programs
	SECTION 3C: FACILITATORS AND BARRIERS
14	List the top three facilitators to implementing this simulator in an educational setting
15	List the top three barriers to implementing this simulator in an educational setting

Table 3.2: Summary of questions on content validity (3A), recommendations on the applicability to an educational setting (3B), and facilitators and barriers to implementation (3C).

3.2.5   Statistical Analysis

The average and standard deviation of each questionnaire section was found, as well as the average probe-to-TM distance and standard deviation resulting from the repeated placements for each simulator. The content of the open-ended responses was examined to see how it could be used to refine and revise the models, and to develop a better understanding of the barriers/facilitators to using the simulators in educational settings. The facilitators and barriers provided by the participants were ranked in terms of the most mentioned topics, and the top seven facilitators and barriers are presented.

3.3   Results

3.3.1   Face Validity (Sections 1 & 2)

Average participant rating for the realism of the adult model was 65% (SD = 18.2) while the average rating of the child model was 64% (SD = 16.4). Ratings per question are shown in Figure 3.1. Four questions out of twelve were given a negative rating (below 50%) for both simulators. These questions pertained to the evaluation of the texture of the ear, stiffness of the ear, otoscopic view of ear 'landmarks' and/or the TM, and the foam tip insertion experience.
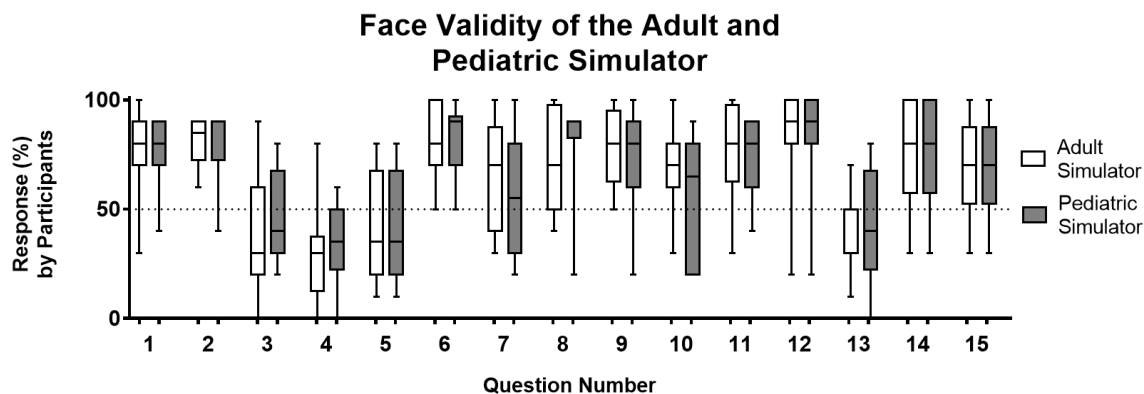
Figure 3.1: Box plot of face validity results for the adult and pediatric simulator, corresponding to the questionnaire represented by Table 3.1. White represents results from the adult simulator whereas gray represents results from the pediatric simulator.

3.3.2   Distance-to-TM Results (Sections 1 & 2)

The average distance-to-TM for all participants combined was 3.7 mm (SD = 1.82) for the adult model with TM contact 12% of the time across all trials. With the child model, participants achieved an average distance-to-TM of 2.8 mm (SD = 0.94) with TM contact 5% of the time.

3.3.3   Content Validity and Applicability to Educational Settings (Section 3)

The content validity (section 3A, i.e., questions 1 – 9 of Table 3.2) was intended for evaluating the teaching value of this simulator and had an average score of 78.7% (SD = 17.0) with only one question producing a negative response. The applicability to an educational setting (section 3B, i.e., questions 10 – 13 of Table 3.2) had an average score of 80.0% (SD = 5.33) with no negative responses being reported. All the above data are seen in Figure 3.2, and all recorded facilitators and barriers can be seen in Table 3.3.
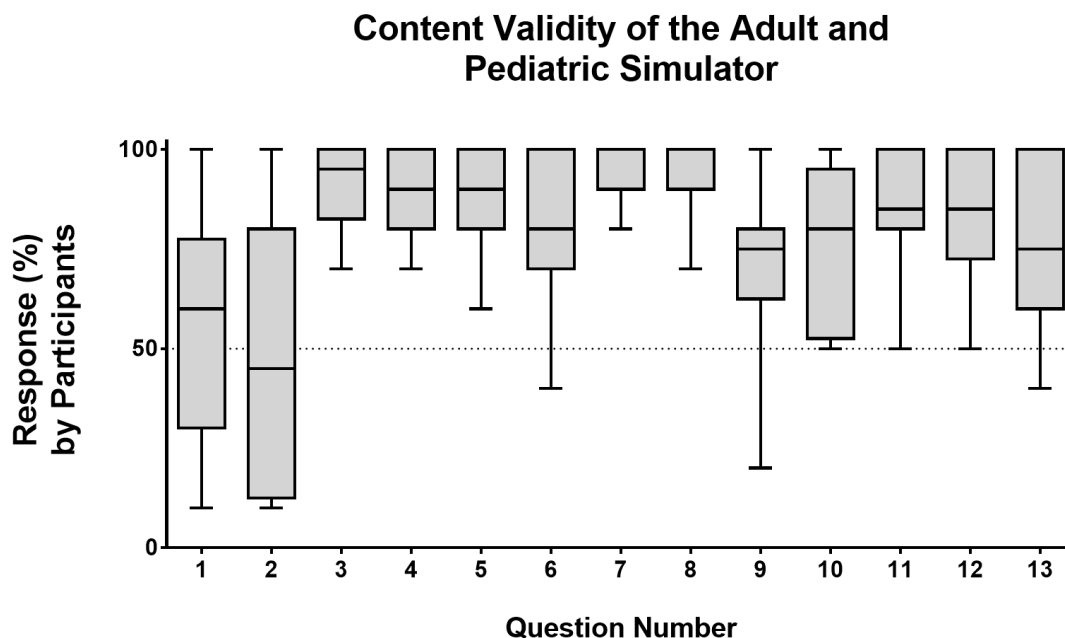
Figure 3.2: Box plot of content validity results for both simulators, corresponding to the questions asked in Table 3.2.

3.4   Discussion

Simulator systems are typically evaluated for face and content validity at an early product development stage, in order to glean systematic feedback prior to developing final versions for use in educational programs (61,66). This study completed a first level face and content validity evaluation of a prototype simulated patient designed to assist in teaching probe tube placement prior to real-ear measurement, by allowing experienced clinical instructors of audiology coursework to use the simulator and provide structured feedback. For the first level of evaluation of this simulator, results from this study were generally positive, with the majority of the questions receiving above a 50% rating. By using experts in probe tube placement, we obtained feedback from audiologists who have had extensive experience performing clinical probe tube placements, and in most cases, have taught students and other professionals how to properly place a probe tube within both adult and child-sized ears. These participants are aware of the barriers that exist in learning probe tube placement techniques and are representative of professionals who

may make use of a product such as this simulator in professional situations such as course or lab instruction, or in clinical practica.

The face validity average of 65% (SD = 18.2) for the adult simulator and 64% for the pediatric simulator (SD = 16.4) were reasonable considering the questions that lowered this score. The lowest scores reported for both models were attributed to the texture and stiffness of the 3D printed ear, foam tip insertion experience, and the otoscopic view of the ear canal and TM. The lack of realism in the texture and stiffness of the ear causing an unsatisfactory foam tip insertion may be due to the method of creating the ear. By using a multi-material printer to print the ear, the shore value (hardness) was customized according to material properties of human auricular cartilage found in the literature. With Young's modulus (i.e., intrinsic stiffness) values ranging from 0.8 – 8 MPa (67–69), a lower value of 1 MPa was chosen for this model and converted to an approximate shore value of 27A, using Gent's relationships (70). This value of 27A is currently the softest material available to be 3D printed, meaning any future improvements of the stiffness and texture of the ear will require a different method, such as silicon molds, to create the ear. Additional material properties will also need to be considered, as flexibility was a large issue, with clinicians unsuccessfully attempting to open the canal by pulling the posterior part of the pinna up and back. Using materials such as silicon will likely increase the flexibility of the ear, and result in more positive ratings by clinicians. The unrealistic otoscopic view may be due to how the simulator was optimized to improve the accuracy of the probe-to-TM distance measurement. For the camera to best locate the probe inside the canal, the ear canal was made as transparent as possible, and an internal light was situated behind the camera. As both of these design decisions seemed to degrade the otoscopic image of the ear canal and TM, further optimization will be needed to improve the otoscopic image while not negatively impacting the camera's view of the canal. In addition, the TM will be further discriminated from the ear canal to ensure the user can visualize the ear canal using the TM as a consistent landmark.

Quantitative results showed that the average probe tube-to-TM distance was within the 5mm guideline with only one participant having an average of their five placements greater than the recommended 5 mm. It was observed that participants primarily in

research and participants who had the least clinical experience achieved a closer placement of the probe tip to the TM while those who primarily work in a clinic achieved farther distances from the TM (perhaps to avoid any accidental contact with the TM). As all participants were relative experts who routinely perform probe tube placements, it is reasonable to expect that all results are within proper distances from the TM. On a person-to-person basis, most participants were consistent with their own five placements, showing that their technique for placement is repeatable and well-practiced, as may not be the case with students.

Individual question scores for content validity and applicability to an educational setting (sections 3A & 3B, respectively) were both generally high, while receiving low scores for the same topics that received low scores for face validity (texture, stiffness, and otoscopic view of the ear). In addition, two neutral responses were given regarding (1) no presence of anatomical landmarks and (2) otoscope usage. These two aspects of probe placement are difficult with the simulator in its current form as the landmarks are not easily distinguishable and the lack of flexibility in the pinna and ear canal makes clinical otoscopy difficult. The improvements mentioned above (producing silicone ears with improved shore values and more distinct landmarks) will help address these issues.

The facilitators and barriers (as seen in Table 3.3) provided by the participants outline the strengths and weaknesses of the current iteration of the simulator. The top three major barriers to successfully implementing this simulator in an educational setting include the current texture and stiffness of the ear, lack of landmarks, and the potential cost for educational institutions to implement this into their program. To address the third barrier, the materials used in this simulator are relatively inexpensive, with the 3D printed ear being the most expensive part. As future iterations of the ear may include silicon molds instead of utilizing 3D printing, this cost will decrease further, making this an extremely affordable simulator, capable of being purchased by most institutions. Other barriers listed include the lack of realism, inability to record accurate acoustical measurements of the ear, suboptimal user interface, and only having two anatomies to practice (the pediatric and adult). These issues will be addressed with future iterations of the design.

The facilitators listed (Table 3.3) demonstrate the uses of this simulator and the benefits it may have in an educational setting. While improvements are needed, the simulator allows students to practice probe tube placement in a controlled, low stress environment, while receiving visual, auditory and quantitative feedback to help them progress their skill level before advancing to clinic. In addition, a well built, relatively inexpensive head simulator with a variety of realistic ears developed from CT scans may also be used for other applications. Opportunities to use the simulator to assess a clinician's skill, to know the exact distance from the TM for research purposes, and to test real-ear measurement systems using this probe-to-TM distance are a few examples. Within an educational setting, and with specific additional features, a simulator such as this could be used for practicing the fitting of an adult ear with a receiver-in-the-ear (RICs) or slimtubes of the correct size, cutting earmold tubing to size for correct positioning of a behind-the-ear aid (BTE), setting up for complex real-ear measurement setups such as contralateral routing of signal (CROS and BICROS) or open fittings and using monitoring headphones. Once improved, this model could be used to improve skills such as otoscope usage and basic understanding of the anatomy and variation that may exist between individuals.

Rank	Facilitators	Barriers	Solution
1	Ability to learn and practice in a controlled, low stress, safe environment	Stiffness & Texture →	Future ears made of silicon will increase flexibility and increase skin texture realism
2	Visual and auditory feedback received after insertion of probe	Lack of anatomical landmarks & difficulty visualizing canal →	Allow usage of otoscope light and optimize otoscopic image by discriminating the common landmarks
3	Ability to obtain accurate results of probe-to-TM distance measurement	Potential High Cost →	Materials used have low cost and simulator will be an inexpensive teaching tool
4	Simulator features and ease of use	Some aspects not realistic (movement, shoulders) →	Future iterations will look at adding partial shoulders to the model and possible actuation of the base of the simulator
5	Realistic aspects of simulator	Not acoustically accurate →	Future iterations will test real-ear measures at each stage of development to confirm proper acoustical measurements
6	Provides ear anatomies which would not have previously been possible to practice on	Suboptimal User Interface →	Major usability issues have been found and a new user interface will look to fix these issues
7	Alternate uses	Lack of multiple anatomies →	More simulator options will be later available with more potential patient anatomies (2+ adult anatomies & 2+ child anatomies)

Table 3.3: Facilitators and barriers in implementing the simulator in an educational setting. Rank 1 showing the number one facilitator and the number one barrier in implementing this simulator into an educational setting, as suggested by participants.

3.5   Conclusion

The probe tube placement simulator is a novel tool for instructors and students to gain experience in probe tube placement before entering clinical practice. The results of the face and content validity study are encouraging for this simulator and show a clear set of characteristics of the simulator which must be improved before any widespread use. With the participants' final opinion that this would be recommended for use in clinical education programs, these pressing issues will be explored, and future iterations will be tested with experts and students to ensure its success in an educational setting.

Chapter 4

4   Skills Transference of a Probe Tube Placement Training Simulator

4.1   Introduction

After positive results from a face and content validity study and experts in the field recommending its continued development and usage in training programs, key areas needing improvements were examined. Once suitable design improvements were made, one more step in validation was needed to determine the simulator's effect in training programs. A final form of validation that is performed on medical training simulators is a skills transference study (53,57,71,72). A skills transference validation study looks to determine if skills learned on this simulator effectively translate to clinical scenarios.

The objective of this study is to evaluate the skills transference of the probe tube placement simulator, and to determine if the use of this simulator in pre-clinical scenarios will increase the competence and confidence in individuals in clinic.

4.2   Materials and Methods

4.2.1   Simulator

While the simulator has been previously described in Chapter 2 and 3, several improvements have been made regarding suggestions from the participants in the first validation study. The following improvements were only implemented on an adult model for the purposes of the present study. These updates incorporated a realistic 3D printed head model, swappable silicone ears to represent variability in ear-canal anatomy, and an improved mounted optical tracking system for tracking the location of the probe microphone inside the ear (Figure 4.1). While the previous simulator used a directly 3D printed ear printed with a Stratasys Objet 500 Connex3 3D printer (Stratasys Ltd., Eden Prairie, MN, USA), the improved silicone outer-ear was created by printing the ear with a Lulzbot Taz 6 printer (Aleph Objects, Loveland, Colorado, USA), and using silicone to

mold and cast the Pinna and entrance to the canal. In comparison to the previous simulator, a casting and molding technique was used in this prototype as current 3D printing does not allow for the printing of highly flexible materials with complex structures. A silicone shore value (hardness) of 2A was selected by experts after experimenting with various material hardness properties. When this silicone pinna is inserted into the head, the entrance of the canal aligns with a 3D printed transparent ear canal fastened to the head. The ear canal is printed with a Stratasys Objet 500 Connex 3 using transparent material (VeroClear-RGD810), to allow for measurement of probe tube depth to the tenth of a millimeter from the tracking system.

Figure 4.1: The updated simulator showcasing the new flexible silicone ear and the fully 3D printed head model.

The previous Styrofoam head was replaced by a fully 3D printed head and shoulders. The new head was printed out of Polycarbonate (PC) – Acrylonitrile Butadiene Styrene (ABS) on a Stratasys Fortus 40mc 3D printer at a slice height of 0.254 mm. The existing camera system remained mounted inside the head model, utilizing a Microsoft LifeCam HD-3000 connected to a typical laptop running Windows. The user interface responsible for providing users with feedback metrics such as probe-to-TM distance and time-to-insert was redesigned using OpenCV (73) for image processing and object tracking, and Qt 5.11 (The Qt Company, Espoo, Finland) for user interface design. The simulator focused on two aspects of probe tube placement, and so two modes were developed in the program: 1) Practice Mode, and, 2) Test Mode. In Practice Mode, users view a coronal image of the ear canal seen from an anterior position at any point during their practice with an exact probe-to-TM distance to know probe positioning inside the ear canal. While in Test Mode, this image and feedback is only available after they have finished placing the probe. If at any point during an insertion in Practice or Test Mode the user contacts the TM, a 'grunt' stimulus will be played to alert the user of contact with the TM.

4.2.2 Participants

The study was approved by the Western University Health Research Ethics Board (HREB 110394 – See Appendix B). Participants were recruited through a first-year graduate-level audiology course that introduces procedures for the fitting of hearing aids. Twenty-five novice clinicians in this first-year class chose to participate. These students were comprised of individuals in their second semester of their audiology program, with less than 10 hours of clinical experience. Upon beginning the study, participants reported having zero to three hours of experience in probe tube placement.

4.2.3 Protocol

The study performed was a randomized controlled trial in which participants were placed into one of two groups: the control group or the simulator (treatment) group. The study consisted of three parts: (1) Pre-test evaluation, (2) Training period, and (3) Post-test evaluation.

4.2.4 Pre-test

At the pre-test evaluation (Part 1), the participants had no knowledge of which group they were assigned to. During this pre-test, both a volunteer and an expert evaluator (audiologist) were present in the room. To begin the pre-test session, the participant completed the first half of the self-efficacy questionnaire (Table 4.1A) regarding their confidence in performing a probe tube placement and foam tip insertion. Following the survey, the participant prepared the equipment for a Real-Ear-to-Coupler Difference (RECD)[2] measurement procedure (Audioscan Verifit VF1) and inserted a probe tube into the volunteer's ear. After they were satisfied with their probe tube placement (using otoscopy to verify placement), the participant inserted a foam-tip connected to an RECD transducer and measured the volunteer's RECD values. RECD measurements were exported to a data file for further analysis. Following this measurement, the participant completed the self-efficacy survey (Table 4.1B), the expert filled out their survey assessing the participant's performance (Table 4.1C), and the participant was informed on their randomly assigned group.

4.2.5 Training Period

The training period (Part 2) consisted of two-weeks in which the participants were instructed to practice as much or as little as they would for a practical exam. The training period was restricted to two weeks as not to interfere with coursework, and to allow the control group enough time to practice with the simulator if they desired before their program's practical exam. Each participant was given a practice diary to log the amount of time they practiced using each method of training, depending on their randomized group allocation.

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[2] RECD is a real-ear measurement that refers to the difference in decibels between the sound pressure level at the TM measured with a probe tube on a patient and a calibrated transducer that simulates an average adult's ear canal. This measurement is used to accurately predict the hearing aid output to determine if the aid is correctly fitted for the patient.

4.2.6 Post-test

The post-test sessions were identical to the pre-test sessions, with the same volunteer and expert evaluator present. The student performed an RECD measurement by placing the probe tube and foam tip, followed by completing the same questionnaire as the pre-test. Upon completion of the test sessions and training period, the expert evaluator performed an RECD measurement on the volunteer for a gold standard comparison.

4.2.7 Student Questionnaire (Table 4.1A, 4.1B)

The Student Questionnaire aimed to examine each participant's level of self-efficacy in four areas: (1) placement of the probe tube within 5mm of the TM; (2) placement of the probe tube without contact with the TM; (3) placement of a foam tip after probe tube placement such that the probe tube did not move (closer to, or further from, the TM); and (4) self-efficacy in placing a probe tube in a clinical setting. The survey questions consisted of Likert-scale responses that ranged in 10% increments from 0% to 100% (0% = "cannot do at all"; 50% = "sometimes can do"; 100% = "always can do").

4.2.8 Expert Evaluator Questionnaire (Table 4.1C)

The Expert Evaluator Questionnaire aimed to measure how the evaluator perceived the participant's ability to conduct most aspects of the RECD measurements, and key factors that lead to a successful/unsuccessful execution in clinic. The items were similar to the aspects of probe tube placement and RECD measurement the participants would be evaluated on during their course practical examination. The survey questions consisted of Likert-scale responses that ranged in 10% increments from 0% to 100% (0% = "strong disagreement"; 50% = "neither agree nor disagree"; 100% = "strong agreement").

SECTION	NO.	PARTICIPANT SELF EVALUATION *BEFORE* PLACEMENT
A	1	You can place the probe within 5mm from the TM
	2	You can place the probe without contacting the TM
	3	You can insert the foam tip without affecting the probe's location
		PARTICIPANT SELF-EVALUATION *AFTER* PLACEMENT
B	4	How certain are you the probe was within 5mm of the TM
	5	How certain would you be to insert the probe within 5mm of the TM on a patient in clinic tomorrow
		EXPERT EVALUATION *AFTER* PLACEMENT
C	6	The probe was easily inserted into the ear canal
	7	The probe remained in the same location once inserted
	8	The participant inserted the foam tip with ease after the probe
	9	The participant appeared confident while performing the measurements
	10	The volunteer appeared confident in the student's technique/skill

Table 4.1: The questionnaire used to evaluate the participant's skill and confidence in real-ear measurement during the pre- and post-test scenarios.

4.2.9   Statistical Analysis

Data analysis conducted on the questionnaire data used a Wilcoxon t-test to determine significance within groups to compare pre- vs post-test results, and a Mann-Whitney U t-test to test significance for group differences (simulator vs. control group), in which a significance of $p<0.01$ was chosen. A two-way mixed ANOVA was used to examine time effects between pre- and post-tests, group effects between the simulator and control groups, and interactions to determine whether they were present for all of the measures. A value of $p<0.05$ was chosen for the ANOVA.

For the RECD measurements, the average level of the frequency-specific RECD values were reduced to three bands for analysis to represent the frequency ranges that are

affected by venting in the low frequencies, probe placement in the high frequencies, and the mid-frequency range in between. These were: low-frequency (200 – 945 Hz), mid-frequency (1000 – 2800 Hz), and high-frequency (3000 – 8000 Hz) (74). A non-linear mixed model statistical method was used for analysis using RECD value, treatment, session, and frequency, in which significance was considered $p < 0.05$. Means within each frequency band were calculated and descriptively compared to a gold standard measurement (expert evaluator's measurement of the RECD) for both pre- and post-test measurements of each group.

4.3   Results

4.3.1   Overview

Results from the questionnaire and RECD measurements are presented in the following sections: Pre-test simulator vs pre-test control, comparison of training times for each group, post-test simulator vs post-test control, and pre-test vs post-test for the simulator and control group.

4.3.2   Pre-test Comparison Results

All questionnaire pre-test results from both groups were not significantly different, and all RECD measurements between the two groups were not significantly different.

4.3.3   Training Times

The control group practiced using traditional methods for 115 minutes (SD = 71 minutes), while the simulator group practiced with traditional methods for 98 minutes (SD = 53 minutes) on average, but no significant difference was found between these two groups. The simulator group supplemented their traditional methods of training with 71 minutes (SD = 31) of simulator usage on average. The total training time for the simulator group was 169 minutes (SD = 58) showing a significant difference between the control group's total training time of 115 minutes (SD = 71, p = 0.036).

4.3.4   Post-test Comparison Results

All questionnaire post-test results between the two groups were not significantly different. RECD measurements between groups in the post-test session were not significantly different in any bands.

4.3.5   Pre- vs Post-test Results: Questionnaire

Three questions (Questions 1, 3, 5) out of ten revealed significantly improved results for the simulator and control group, while three other questions (Questions 2, 8, 9) showed significantly improved results for only the simulator group (p = 0.0078, 0.0078, and 0.0078), as seen in Figure 4.2. The remaining four questions (Questions 4, 6, 7, 9) showed non-significant improvements for both groups. These questions suggest use of the simulator produced improved results for confidence in placing the probe without contacting the TM, improved usage of the foam tip, and increased perceived confidence.

The two-way mixed ANOVA revealed no significant group effect, a consistent time effect for each question, and interactions for Question 3 and 9 (p = 0.0494, and 0.0402, respectively). The interactions can be seen in Figure 4.2, with the simulator group showing notable improvement in placing the foam tip without affecting the probe, and perceived confidence.

4.3.6   Pre- vs. Post-test Results: RECD Measurements

In the RECD results, it was found that the high, mid, and low frequency bands of the simulator group all showed a significant effect of the simulator use on the RECD values (p <0.001, x2 = 36.9; p = 0.0045, x2 = 8.06; p <0.001, x2 = 29.6; respectively). All post-session frequency band results were closer to the expert's RECD measurements on the test participant, suggesting improvement (Figure 4.3). In the control group, only the high frequency band showed a significant effect from the training period on the RECD values (p = 0.0029, x2 = 8.90). These values were also found to be closer to the expert measurement than the pre-session values. Results suggest that the simulator group had

more improvements in their RECD measurements in the mid and low frequencies than the control group.
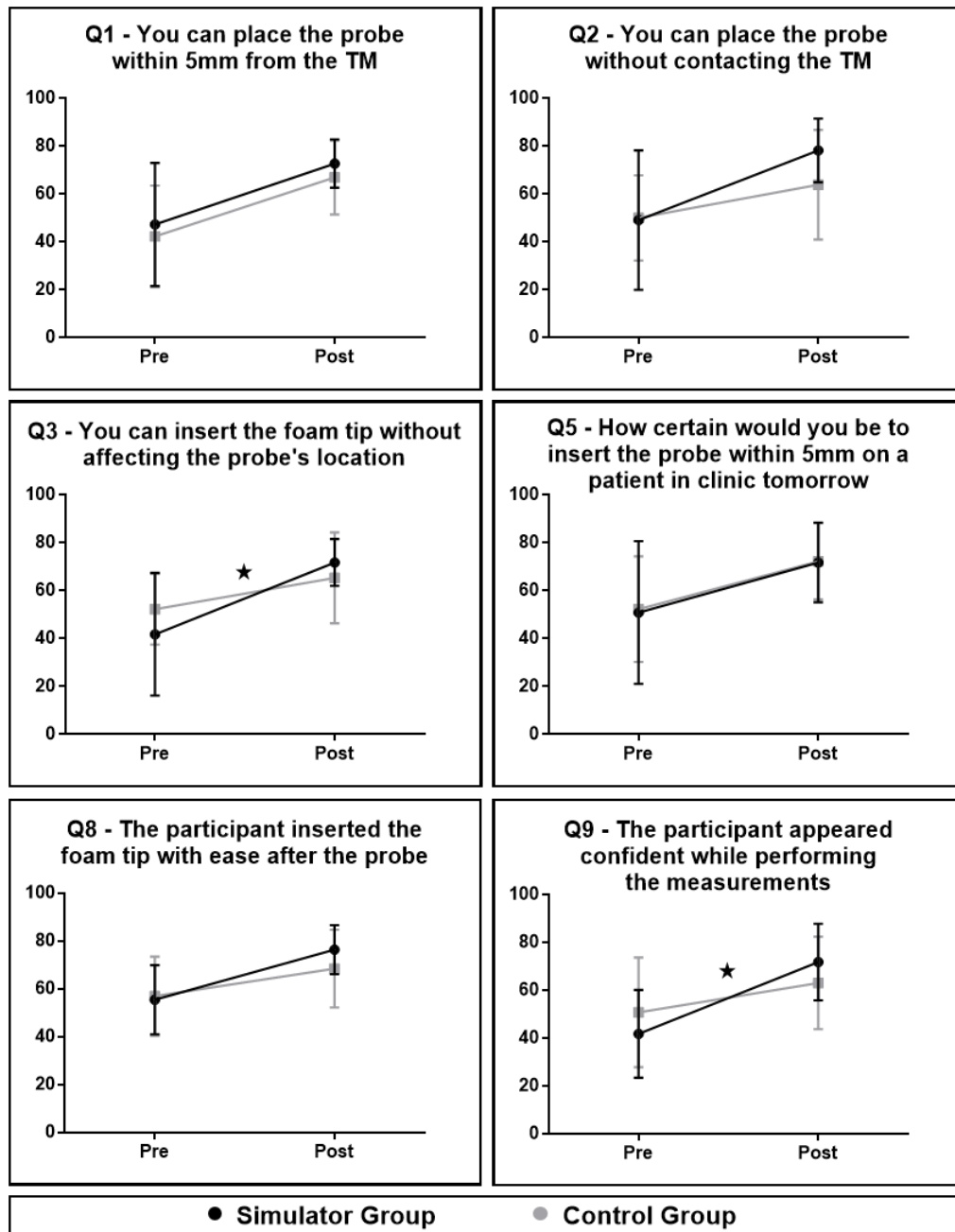
Figure 4.2: ANOVA Results from the questionnaire results comparing the pre-test results to the post-test results for both the simulator and control group. The x-axis denotes the rating from 0-100% in agreeance with the statement, and a star represents an ANOVA interaction.
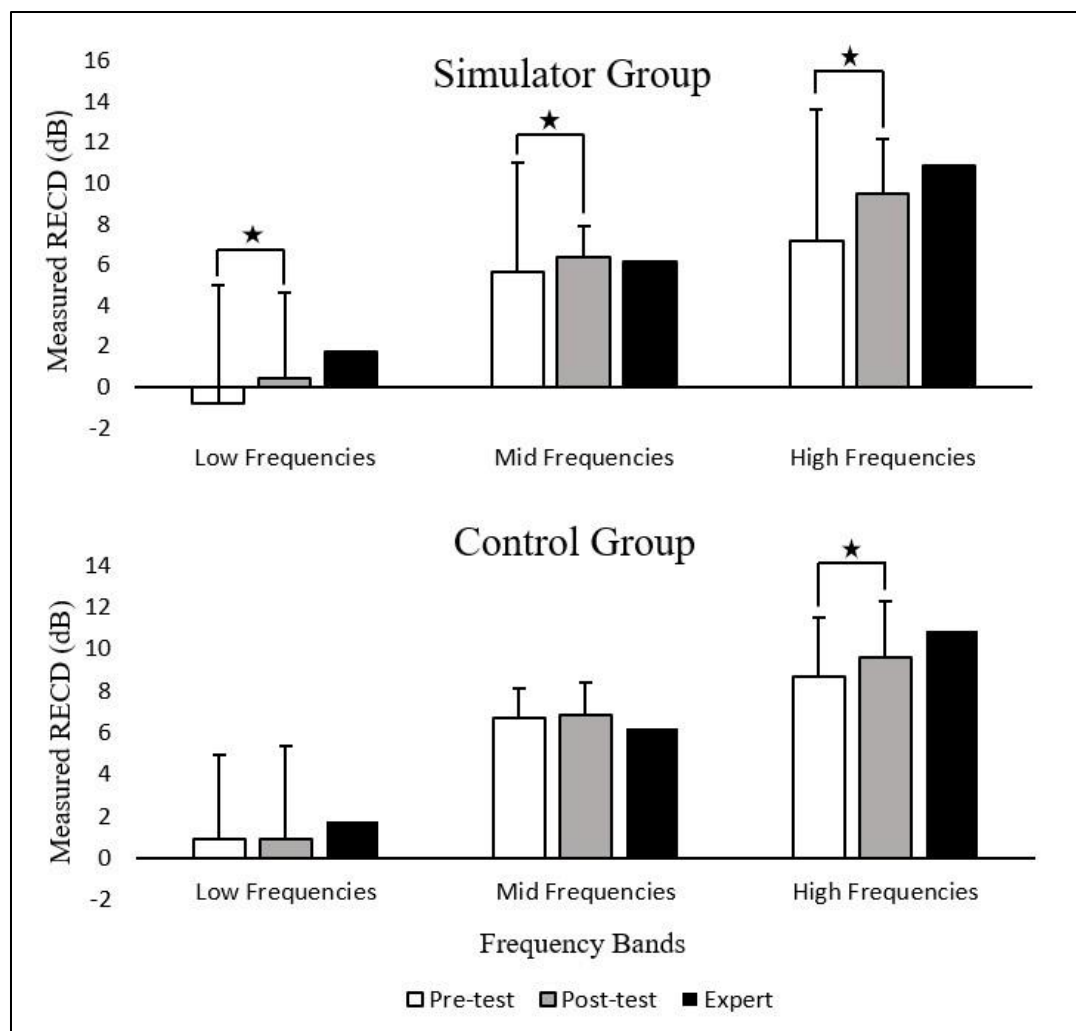
Figure 4.3: Bar graph displaying the means of the RECD measurements made by the simulator group (top) and control group (bottom) in the pre- and post-tests. Session measurements with a significant difference between the two sessions are marked with a star. Standard deviations are also displayed.

4.4 Discussion

In medical simulator research, a typical validation sequence consists of an initial study aiming to receive early-stage feedback (face and content validity), backed with quantitative studies to prove its utility within educational settings (construct validity, discriminant validity, skills transference validity). Our previous study (75) confirmed the

simulator's training ability and provided feedback to guide the product development discussed above. The current study accomplished a second-level evaluation of the developed audiology training simulator designed to assist students with learning probe tube placement and real ear measurement by facilitating practice with feedback, without the need for an instructor or fellow student. While the first-level face and content validity study previously performed on an early prototype of the simulator recruited experts to evaluate the simulator, the present study required novice students in order to observe skill progression throughout the duration of the study. Completion of the study within the student's course-load introduced challenges. First, the timeframe of the study was very limited. Students in the audiology program at Western University have a practical exam in probe tube placement one month following their first probe tube placement lab session. Due to this schedule, the training period of this study was limited to two weeks to guarantee the control group equal opportunity to use the simulator after the completion of this study but before their practical exam as required by HREB. Second, the pre- and post-test sessions were limited to one probe tube placement to work within the time frame of the study, and to accurately replicate a clinical scenario in which students would have time for one placement. Despite these limitations, the study found several meaningful results.

No significant pre-test differences were found in either the questionnaire or the RECD results, suggesting that both the simulator and control group were at equivalent skill levels at the beginning of this study. Additionally, no significant post-test differences were found. There were no significant improvements when only comparing post-test results.

When observing pre- vs post-test sessions within groups, there were several notable results between the questionnaire and the real-ear measures. First, Question 2 (self-evaluation for "You can place the probe without contacting the TM") produced a significant improvement for the simulator group but not for the control group. This result along with the positive trend in the ANOVA for the same question (Figure 2) suggests the simulator's feedback mechanisms of contacting the TM and providing users insight into where the TM is located in the simulated ear canal may have an impact on the

clinical performance of their probe tube placement. Recall that the control group practiced on one another and were likely motivated to avoid contact with the TM during practice. With the simulator, it is feasible to practice intentionally placing the probe tube too far in order to learn how to avoid this without fear of an aversive experience for one's classmate. This study only measured the time span of student practice with the simulator, so we have not directly assessed whether this factor is important for students' perceived confidence in not striking the TM. High frequency similarities in the RECD measures may also suggest that the probe depth is comparable between the two groups, but with the simulator group being less likely to contact the TM, which is an important aspect of clinical probe tube placement.

Second, several results suggest that participants who used the simulator had better usage of the foam tip to occlude the ear canal. Question 3 (self-evaluation of "You can insert the foam tip without affecting the probe's location") produced an interaction in the ANOVA, while the expert's evaluation of the participant easily inserting the foam tip (Question 8) produced significantly improved results for the simulator group, but not for the control group. The simulator's ability to provide real-time feedback on the probe's position while inserting the foam tip may allow for users to be more aware of these changes in a clinical scenario. The RECD measurements also reiterate that the foam tip may have better occluded the ear canal within the simulator group than the control group, as significant changes were found in the low frequency band of only the simulator group. Again, this reflects a better overall level of competency with the details of the measurement procedure.

Third, the ANOVA presented interactions between the two groups in the participants' confidence to place the foam tip without affecting the probe (Question 3), and the participants' perceived confidence (Question 9). Confidence is extremely important in clinic, with studies showing that clinician confidence, and the patient's perception and trust of the clinician influence hearing outcomes (31,43). A new clinician entering clinic with improved confidence may not only deliver better care to the patient, but also improve the patient's trust. This may also relate to the issues around additional practice noted above.

Finally, the RECD results reinforced the questionnaire results. The significant improvements found within the RECD measurements in the simulator group suggest more improved measurements were taken in the post-test scenario for the simulator group. The improved occlusion of the ear canal with the foam tip may be related to the probe tip insertion depth suggested by the RECD. The control group's higher propensity to touch the TM with the probe, along with the similar high frequency RECD values suggest a deeper insertion depth than the simulator group.

These positive results are also present with a non-significant difference between traditional training times. Recall that the simulator group only supplemented their training with the simulator, so this overall improvement in competency may reflect additional practice time. While this may or may not be attributable to the simulator itself (i.e., perhaps more traditional practice could have achieved the same result), we note that additional practice via the simulator does not require a lab partner, and therefore may support flexibility and independence in performing additional practice sessions while learning key procedures.

As the simulator is still a working prototype, final feedback was received from the participants in the form of written recommendations. Participants noted the most beneficial parts of the simulator for probe tube placement were: (1) the ability to practice on their own; (2) the ability to know how deep they were placing the probe tube; and (3) the ability to know exactly how to judge when the probe tube was placed within 5 mm of the TM.

Next steps for this project include continued improvement to the simulator. As development on the simulator evolves, more ear anatomies will be available (e.g., large ear canal, small ear canal, pediatric ears, exostosis, mastoid cavity), and specific training use cases for the simulator will be created. With these results showing encouraging effects of simulator use in clinical programs, there are several other procedures which still cannot be simulated in an educational setting. Initial tests have been performed with earmold impressions and the insertion of RICs and earmolds into the canal with the algorithm providing feedback to the location of the mold, the RIC tip or the otoblock in

the canal. Additional work will be put towards incorporating this into the design and ensuring the clinical training needs are met.

4.5 Conclusion

In conclusion, this study has found benefits to trainees' usage of the probe tube placement simulator. Results suggest that students who supplemented their traditional training with the simulator were less likely to contact the TM in a clinical scenario, more likely to perform a better ear canal occlusion resulting in improved RECD measurements in the low frequencies, more likely to achieve appropriate probe tube placement with improved RECD measurement in the high frequencies, and more likely to appear confident. With two validation studies completed, future work will aim to address final concerns, and the initial supplying of this simulator system to training programs to improve trainee performance while decreasing the workload on instructors.

Chapter 5

5 Conclusions and Future Work

5.1 Conclusions

The purpose of this project was to develop a training simulator for audiologists to use in training programs to improve their performance in clinic. Through the developments that occurred, and the two validation studies which looked to evaluate the effectiveness of this simulator, clinicians and trainers can confidently use this simulator knowing it will have positive results on novice clinicians and lessen the required time of the trainer.

In Chapter 2, we outlined a development process that was done step-by-step to ensure it complied with the audiologist's requests and needs in their training program. This initial simulator was an excellent point at which to receive expert feedback and find areas of improvement to focus on next. The simulator described in this section offered as an excellent minimum viable product which allowed for extensive future development.

In Chapter 3, a face and content validity study was presented showing expert feedback on the simulator regarding its realism, teachability, and applicability in educational settings. Overall, results were positive with all participants recommending implementation in training programs while encouraging further development.

In Chapter 4, the key improvements made to the simulator were described, and the final skills transference validity study was completed. From the results of the study we provided evidence for the simulator's utility in educational settings, with better clinical results being found by participants who used the simulator. While minor improvements can still be made, it was determined this simulator was at a level of development which could allow implementation into Western's Audiology training program at the National Centre for Audiology.

5.2   Future Work

With two validation studies completed, results have suggested the simulator has an important and useful implementation inside training settings with the skills transference study showing a benefit to using the simulator within educational settings. While the skills transference study shows that the simulator is ready for implementation in training programs, and possibly into curriculums in the near future, there are some final improvements which were outlined from the skills transference study. These included a more reproducible 3D printed head, two silicone ears instead of one, a better fastening mechanism between the transparent ear canal and the silicone outer ear, and minor software improvements and optimizations.

Probe tube placement is only one of the procedures which audiologists are required to learn to operate in a clinic and effectively fit hearing aids. There are several other procedures such as earmold creation and insertion that are more invasive and present a greater risk to patients. With this fully developed physical simulator acting as a platform for hands-on education, further work can be put into expanding its usages suggested at the end of Chapters 3 and 4 to further increase its usage within training programs.

Within the last six months, this project has resulted in a spin-off company named AHead Simulations founded in March 2018. AHead Simulations, after receiving $110,000 in funding, will look to take the simulator to market, and build upon its success. Audiology is a crucial medical field as hearing loss cases continue to increase. Growth in the industry will be large, and work has to be done to help correct issues within the field as mentioned in this thesis. The low number of clinics performing best practices and the hundreds of thousands of ill-fitted hearing aids are a huge problem which needs to be addressed before the industry growth is too much. Future developments on this specific probe tube placement simulator will slow, but more improvements on expanding past probe tube placement and creating an educational platform for audiology will be stressed. With this probe tube placement simulator acting as the initial foundation for audiology training, developments will expand the utility of the simulator, and this head and ear system will be the core of future developments. With enough capital and work into this

simulation, we hope to improve the quality of clinical care to ensure all patients are being provided with the best hearing aid outcomes possible.

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Appendices

Appendix A: Face and Content Validity Ethics Approval Notice

Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Prof. Hanif Ladak
Department & Institution: Schulich School of Medicine and Dentistry, Western University

Review Type: Delegated
HSREB File Number: 109083
Study Title: Probe Tube Insertion Simulator Evaluation
Sponsor: Natural Sciences and Engineering Research Council

HSREB Initial Approval Date: June 02, 2017
HSREB Expiry Date: June 02, 2018

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Western University Protocol		2017/06/02
Letter of Information & Consent		2017/06/02
Advertisement	Email script for recruitment	2017/05/16
Data Collection Form/Case Report Form	Revised Questionnaire	2017/05/29
Instruments	Instructions on Set-up Document	2017/02/15
Instruments	Instructions of OPERATION of Simulator	2017/02/15
Instruments	Survey Questionnaire	2017/02/16

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Western University, Research, Support Services Bldg., Rm. 5150
London, ON, Canada N6G 1G9 t. 519.661.3036 f. 519.850.2466 www.uwo.ca/research/ethics

Appendix B: Skills Transference Validity Ethics Approval Notice

Western
Research

Date: 18 January 2018

To: Prof. Hanif Ladak

Project ID: 110394

Study Title: Evaluating the Skills Transference of a Probe Tube Insertion Simulator

Application Type: HSREB Initial Application

Review Type: Delegated

Full Board Reporting Date: 06FEB2018

Date Approval Issued: 18/Jan/2018 16:07

REB Approval Expiry Date: 18/Jan/2019

_____

Dear Prof. Hanif Ladak

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. All other required institutional approvals must also be obtained prior to the conduct of the study.

Documents Approved:

Document Name	Document Type	Document Date	Document Version
Letter of Information_Students_2018_01_15_CLEAN	Written Consent	15/Jan/2018	2
Letter of Information_Volunteer_2018_01_15_CLEAN	Written Consent	15/Jan/2018	3
PracticeDiary_01_15_2018	Instrument	15/Jan/2018	2
Recruitment_script_01_15_2018_CLEAN	Recruitment Script	15/Jan/2018	2
SkillsTransferenceQuestionnaire2018_01_15	Paper Survey	15/Jan/2018	2

Documents Acknowledged:

Document Name	Document Type	Document Date	Document Version
StudyProtocol_PTS_2017_11_02	Protocol	02/Nov/2017	1

No deviations from, or changes to, the protocol or WREM application should be initiated without prior written approval of an appropriate amendment from Western HSREB , except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial.

REB members involved in the research project do not participate in the review, discussion or decision.

The Western University HSREB operates in compliance with, and is constituted in accordance with, the requirements of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Curriculum Vitae

Name: **Robert Koch, B.E.Sc.**

Education:

2016 – Present	**MESc (Biomedical Engineering)** *Western University, London, Ontario, Canada* Thesis: Development and Validation of a Probe Tube Placement Training Simulator
2007 – 2011	**B.E.Sc (Electrical Engineering)** *Western University, London, Ontario, Canada* Specialization: Biomedical Systems and Signals

Honours and Awards:

2018 – 2019	Ontario Centres of Excellence TalentEdge
2018 – 2019	Ontario Centres of Excellence TalentEdge
2017 – 2018	TechAlliance BURST Grant
2017 – 2018	NSERC Canadian Graduate Scholarship – Masters (CGSM)
2016 – 2017	Ontario Graduate Scholarship (OGS)
2016	ECE Capstone Project Presentation Winner
2015 & 2016	NSERC Undergraduate Student Research Award (USRA)
2012 – 2016	Western University's Dean's Honour List

Related Work Experience:

2018	President & Founder AHead Simulations Inc. London, Ontario, Canada
2018	Graduate Teaching Assistant (Introduction to Electrical Engineering – ECE2238)
2016 & 2017	Graduate Teaching Assistant (Introduction to Digital Image Processing – ECE 4445)
2016	Graduate Research Assistant Auditory Biophysics Lab, Western University, London, Ontario, Canada

2015   Electrical Engineering Co-op Student
        General Dynamics Land Systems
        London, Ontario, Canada

Publications:

1. **Koch, RW**, Saleh, H, Folkeard, P, Moodie, S, Janeteas, C, Agrawal SK, Ladak, HM, Scollie, S, (2018). "Skills Transference of a Probe Tube Placement Training Simulator" *Journal of the American Academy of Audiology*, Submitted August 3, 2018.

2. **Koch R,** Moodie S, Folkeard P, Scollie S, Janeteas C, Agrawal S, Ladak H. "Face and Content Validity of a Probe Tube Placement Training Simulator." *Journal of the American Academy of Audiology,* Accepted December 17, 2017.

3. **Koch R,** Elfarnawany M, Zhu N, Ladak H, Agrawal S. "Evaluation of Cochlear Duct Length Computations Using Synchrotron Radiation Phase-Contrast Imaging." *Otol Neurotol.* 38(6), e92-e99

4. **Koch R**, Ladak H, Elfarnawany M, Agrawal S. "Measuring Cochlear Duct Length – A Historical Analysis of Methods and Results." *Otolaryngol Head Neck Surg*. 46(1), p.19

Conferences and Presentations:

1. **Koch RW**, Saleh H, Folkeard P, Moodie S, Agrawal SK, Ladak HM, Scollie S, (2018). "Skills Transference of a Probe Tube Placement Training Simulator", Poster presented at: *International Hearing Aid Research Conference (IHCON)*, August 15-19, 2018, Lake Tahoe, CA, USA

2. **Koch, RW**, Moodie S, Folkeard P, Scollie S, Agrawal SK, Ladak HM, (2018). "Evaluation of a Novel Probe-Tube Placement Training Simulator", Poster presented at: *American Academy of Audiology Annual Meeting (AAA 2018),* April 18-21, 2018, Nashville TN, USA

3. **Koch RW,** Elfarnawany M, Zhu N, Agrawal SK, Ladak HM, "Evaluation of Cochlear Duct Length Using Synchrotron Radiation Phase-Contrast Imaging", Poster Presented at: *London Health Research Day (LHRD 2017),* March 28, 2017, London, ON, CA

4. **Koch RW,** Elfarnawany M, Zhu N, Agrawal SK, Ladak HM, "Evaluation of Cochlear Duct Length Using Synchrotron Radiation Phase-Contrast Imaging", Poster Presented at: *Association for Research in Otolaryngology Annual Meeting (ARO 2017),* February 11-15, 2017, Baltimore, MD, USA