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VIRTUAL REALITY SIMULATION FOR MYRINGOTOMY TRAINING WITH HAPTIC FEEDBACK

Govind Singh Rehal
Western University

VIRTUAL REALITY SIMULATION FOR MYRINGOTOMY TRAINING WITH HAPTIC FEEDBACK

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by
Govind Singh Rehal

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The University of Western Ontario
London, Ontario, Canada

THE UNIVERSITY OF WESTERN ONTARIO
School of Graduate and Postdoctoral Studies

CERTIFICATE OF EXAMINATION

Supervisor

Dr. Hanif M. Ladak

Supervisory Committee

Dr. Sumit K. Agrawal

Dr. Rajni V. Patel

Examiners

Dr. Miriam A. M. Capretz

Dr. Mahmoud El-Sakka

Dr. Jagath Samarabandu

The thesis by

Govind Singh Rehal

entitled:

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Abstract

Myringotomy is a surgical procedure in which an incision is made in the eardrum, primarily to treat middle-ear infections. It is a difficult procedure for surgical residents to master because excellent hand-eye coordination is required to work under a surgical microscope and within the narrow ear canal. We have been developing a virtual-reality based surgical simulator for training residents. The current simulator does not include tactile feedback, but such feedback is a very important part of ear surgery. Therefore, the objectives of this work were to incorporate haptic feedback capability into our simulator, estimate the haptic parameter for the eardrum and perform a face validity study to test the effectiveness of the simulator. The results from the face validity study are very encouraging. The simulator is the first of its kind, and with further refinement has excellent potential to be of benefit in the training of proficient surgical residents.

Keywords: virtual reality, haptics, simulator, myringotomy, ear surgery, training.

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Chapter 1: Introduction

1.1 Motivation

The human ear is a complex organ that is sub-divided into the external ear, middle ear and inner ear. Middle-ear diseases like middle-ear infection cause excessive fluid or pus to collect in the middle-ear cavity. If allowed to further accumulate, this fluid build up can result in inflammation of the middle ear thereby causing pain, discomfort or even hearing loss to the patient. In order to cure these persistent disorders, the fluid needs to be removed.

Myringotomy is a common and effective procedure to cure this ailment. During this surgical procedure, an incision is made in the eardrum to suction out the fluid built up in the middle-ear cavity. Often, a ventilation tube is placed to restrain the quick healing of the eardrum and to equalize pressure between the middle-ear cavity and the atmosphere.

Myringotomy is the most common paediatric surgical procedure in North America with more than 1 million operations being performed annually [1]. In Canada alone, for every 100,000 children under the age of 10, there are 1,585 incidents of myringotomy reported every year [2,3]. It is a complex procedure that consists of several discernible stages. The surgery requires high dexterity. There is enormous potential for human-error at every stage of the surgery that if committed can result in undesired circumstances in relation to poorer long-term hearing outcomes or greater morbidity. Elimination of the commonly occurring errors significantly reduces the human error probability [4]. This signifies the need for an effective training tool that can help reduce the potential for surgical errors and train residents for better hand-eye coordination. A virtual-reality myringotomy simulator is being developed to fulfil this need and train otolaryngology residents in aspects of myringotomy.

1.2 Ear anatomy

To better understand the steps in myringotomy, a brief introduction to ear anatomy is provided here. A schematic diagram of the ear is shown in Figure 1 for reference. As stated before, the human ear is divided into three main parts: external ear, middle ear and the inner ear.

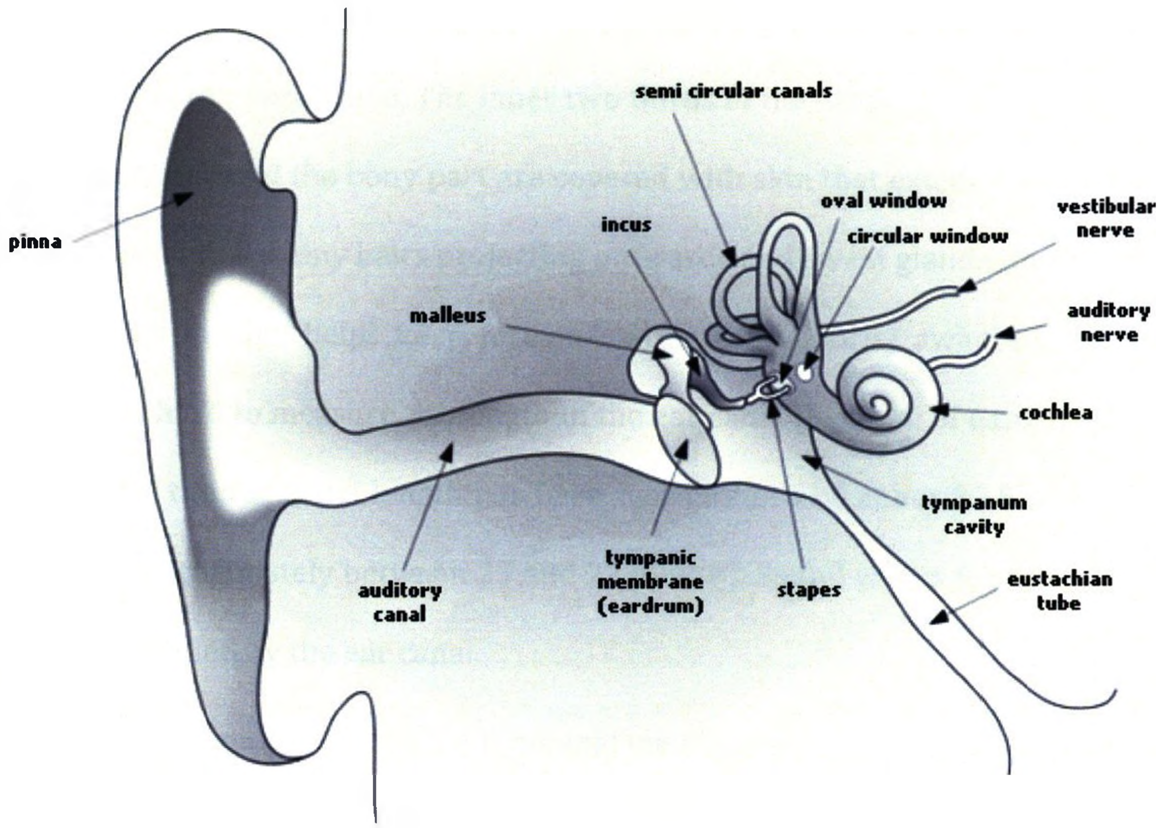

Figure 1: The human ear. A schematic cross-section of the human ear with important structures labeled (the length of the auditory canal is not to scale). This image was adapted from Dan Pickard's image that was released into the public domain [5].

The external ear consists of the pinna and the ear canal. The pinna, also called the auricle, is the visible part of the ear that is attached to the side of the head. It is a convoluted funnel-like structure with eminences and depressions on its surface. Made up of one single piece of cartilage, it gives form to the ear. Sound waves are collected by the pinna and are directed towards the middle ear through the ear canal.

The ear canal (also called the external auditory canal) follows the pinna and protracts into the head. The open end of the canal is attached to pinna and the other end is closed by the eardrum. The ear canal consists of cartilaginous and bony parts. The outer one third of the canal is made up of cartilage of the pinna and is firmly attached to the temporal bone. The inner two thirds of the canal is made of bone [6]. Both the cartilage and the bony part are covered with skin that extends to cover the eardrum. The skin has tiny hairs projecting outwards and sweat glands that produce earwax which in turn helps keep foreign matter (e.g., debris) away. In children, although it is hard to measure the length of the ear canal (because of eardrum being parallel to it), the ear canal length has been measured to be about 22.5 mm [7]. In adults, it is approximately between 25 and 27 mm [8]. Sound waves funneled by the pinna are amplified by the ear canal.

The eardrum, also called the tympanic membrane, separates the external ear from the middle ear. The eardrum converts acoustical pressure variations of sound in the ear canal to mechanical vibrations of the middle-ear bones and is the major contributor to the impedance-matching function of the middle ear in which the low acoustic impedance of air in the ear canal is matched to the high impedance of fluid in the cochlea. It is a translucent structure that is composed of a very thin layer of connective tissue. The eardrum is a conical shaped structure and its sides are curved convex outward [9]. Its thickness has been measured and reported to lie between 30 and 90um [10]. The perimeter of the eardrum is firmly attached to the bony part of the ear canal. The manubrium which is the long handle-like portion of the malleus, the most lateral bone in the middle ear, is attached to the eardrum along its radius (see Figure 2).

From a surgical perspective, the human eardrum is often divided into four main quadrants with respect to the umbo in the center; the umbo is the most inferior point of the manubrium (see Figure 2). The quadrants are the postero-superior, the antero-superior, the antero-inferior and the postero-inferior quadrants (see Figure 2). Many surgeons prefer to make an incision in the inferior half of the eardrum, and many specifically prefer the antero-inferior quadrant. This is done to avoid potential trauma to the incus, one of the three middle-ear bones that is immediately behind the superior half of the eardrum. The antero-inferior region of the eardrum is reflective in nature. A bright cone of light can be seen along this region when it is being examined with a light source as in otoscopy, which refers to visual examination of the ear canal and eardrum. This cone of light acts as a landmark for surgeons to orient and decide the region for the incision to be made.

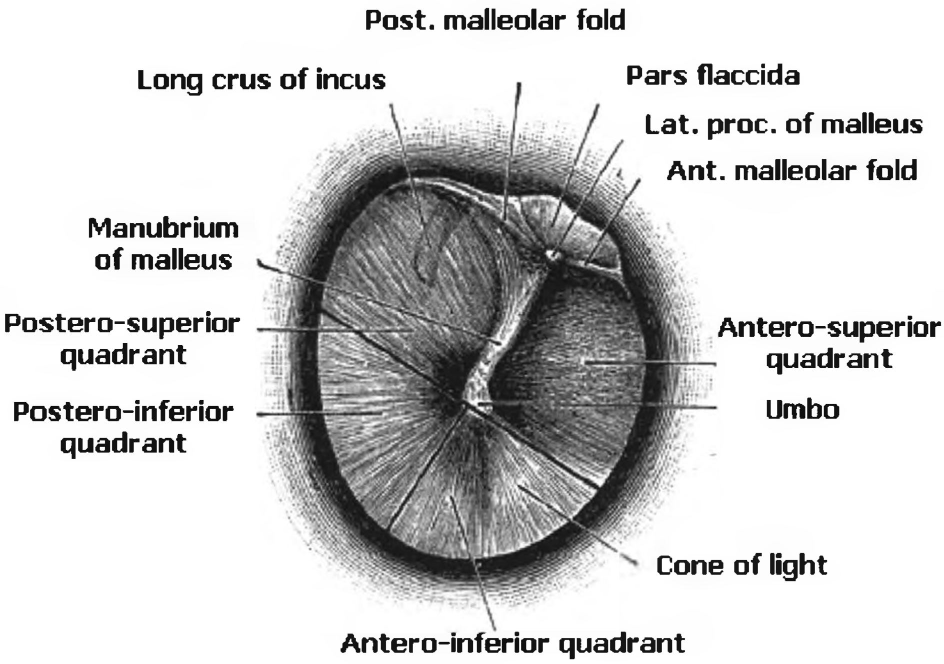

Figure 2: The human eardrum. Image was adapted from an image reproduced from the Gray's Anatomy and released into the public domain [11].

The middle ear is comprised of three ossicles that lie within an air filled cavity between the eardrum and the oval window of the spiral-shaped cochlea. This narrow cavity of the middle ear, also called the tympanic cavity, is connected to the nasal cavity by the Eustachian tube. The Eustachian tube's main purpose is to maintain equal pressure between the middle ear and the throat (the outside air pressure). The three ossicles are named the malleus, incus and stapes. These are Latin words which mean hammer, anvil and stirrup, respectively and are assigned to the ossicles because of their structural resemblance to these objects. The eardrum is attached to the malleus which is connected to the incus that in turn adjoins the stapes.

Sound waves in the ear canal cause the eardrum to vibrate. This in turn causes the ossicles to vibrate, resulting in transfer of vibrations to the fluid of the cochlea since the stapes directly connects to the oval window of the cochlea. The middle-ear bones are thought to act as a lever system at low frequencies that contribute to the impedance-matching function of the middle ear. The main contribution to the impedance-matching function is made by the areal ratio of the much larger eardrum to the much smaller oval window. This difference in size results in increased pressure being applied to the cochlear fluids behind the oval window.

The middle ear is prone to infection (otitis media), mainly because of dysfunction of the Eustachian tube. In advanced stages of infection, myringotomy needs to be performed to drain the accumulation of fluid behind the eardrum caused by the infection.

The inner ear, also called the labyrinth, is an organ responsible for the senses of hearing, balance and motion. It consists of the cochlea and the vestibular system. The spiral-shaped cochlea transmits the mechanical signals passed on from the middle ear in the form of waves through the fluid contained within it. It then translates vibrations of the fluid into nerve impulses or electrical signals which are finally transmitted to the brain via the auditory nerve. As can be seen in Figure 1, the vestibular system consists of the semicircular canals. The vestibular system along with the visual system, provide information to the brain pertaining to the ability to sense balance and motion when the head is moving.

Myringotomy primarily concerns the external ear and the tympanic membrane. The malleus and incus of the middle ear may be involved in the sense that during surgery, there is a high probability that the surgeon or a resident accidently penetrates deep enough to injure the malleus or incus with the blade.

1.3 Myringotomy

Myringotomy is a surgical procedure during which a surgical blade is guided down the ear canal, an incision is made in the eardrum, the accumulated fluid is removed from the middle ear cavity and a ventilation tube is placed. Myringotomy is the most common treatment for chronic otitis media with effusion (i.e., chronic build up of middle-ear fluid).

Myringotomy is usually the first ear operation that new Ear-Nose-Throat (ENT) surgical residents learn. It is a complex procedure that consists of several discernible steps and involves several specialized surgical tools. As shown in Figure 3 and Figure 4, the tools involved in the procedure are: suction tips, specula, myringotomy blades, crocodile forceps, ventilation tubes and curettes along with the surgical microscope (as can be seen in Figure 5).

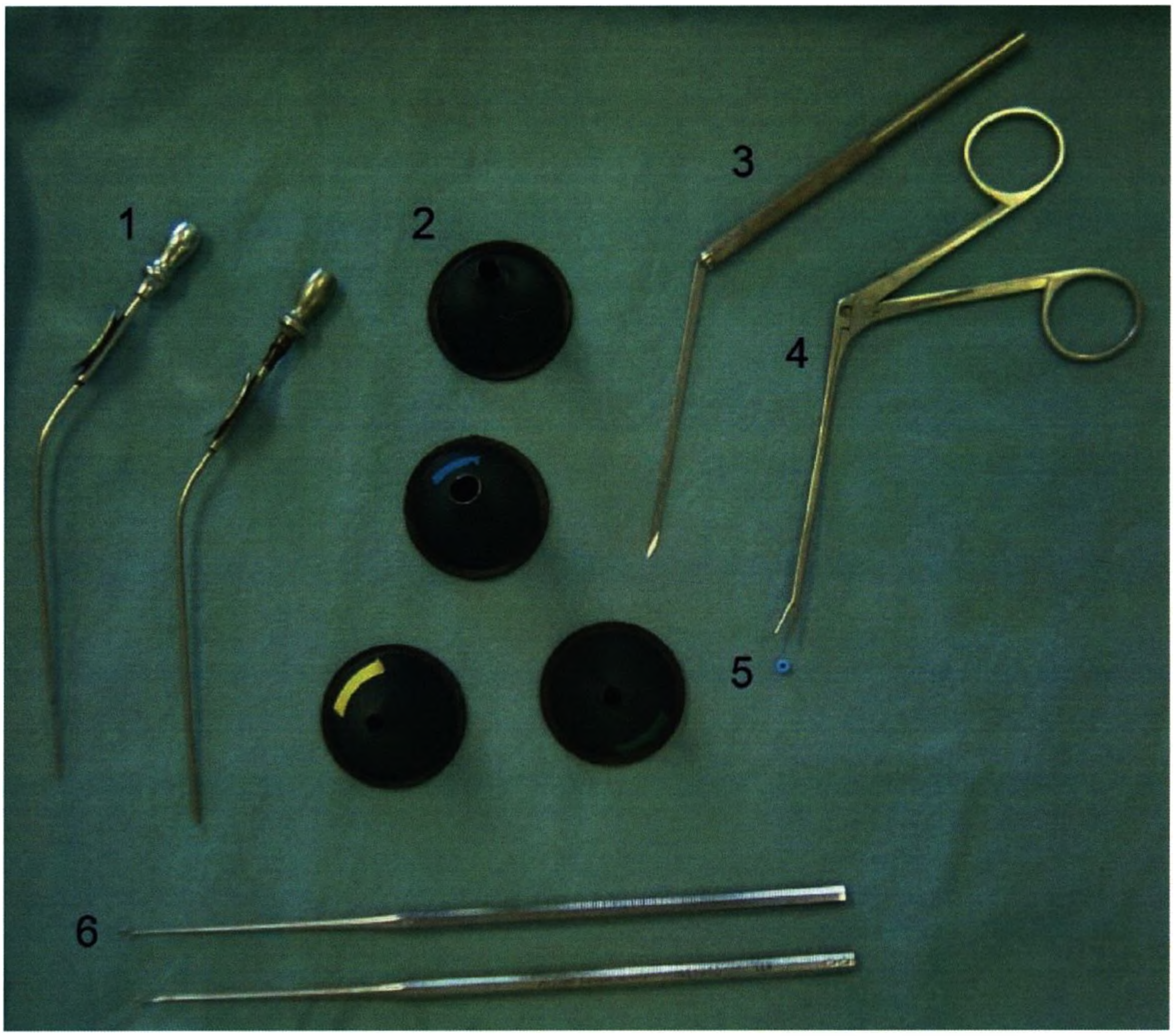

Figure 3: Tools used in myringotomy. The labelled tools are as follows: 1 suction tips, 2 specula, 3 a bent myringotomy blade in handle(straight blade is also available and shown in 4), 4 crocodile forceps, 5 ventilation tube, 6 curettes.

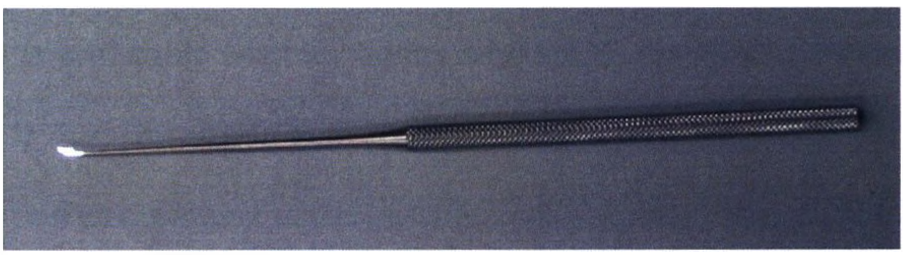

Figure 4: A straight sickle blade. The bent blade has been shown in Figure 3.

The tools involved have specialized functions and are used individually or in combination during different stages of the procedure.

Figure 5: A demonstration of myringotomy. The patient has a speculum inserted in the ear, and the surgeon looks through a surgical microscope into the patient's ear.

The process of myringotomy starts with anesthetising the patient. Local anaesthesia is preferably used for adults whereas in the case of children, general anaesthetic is used to restrain their movement during the surgery. Figure 5 depicts the posture and environment of the myringotomy surgery. The patient is positioned on the operating table and the surgeon adjusts the surgical microscope and its magnification setting to the point that the ear to be operated upon is clearly visible. A speculum (see item 2 in Figure 3) of appropriate size is selected and placed in the ear canal. It is a funnel like tool that is positioned to straighten the ear canal and provide a clear view of the eardrum. Once oriented to the right position, the surgeon uses the speculum as an aid for blade movement as described below. Once adjusted to the optimal position, it is usually held by the surgeon's non-dominant hand. The ear is then examined for any wax or other obstructions. If these exist, they are delicately removed by scraping using a curette (a tool made of stainless steel with a ring-like tip, marked as item 6 in Figure 3). Once the view of the eardrum is clear, the surgeon draws a bent or a straight myringotomy blade as seen in Figure 3 (item 3) or Figure 4 respectively and while resting its edge on the speculum, guides it down the ear canal towards the eardrum. The blade is then positioned just above the preferred point of incision on the eardrum and then gently moved down to make an incision. It is important that the incision is singular, correctly positioned and oriented, unidirectional and of appropriate size. Once an incision is made, the suction tube is then used to draw fluid out of the middle-ear cavity. Finally, the ventilation tube (item 5 in Figure 3) is placed in the incision using the crocodile forceps (item 4 in Figure 3). The ventilation tube is a small tube made of plastic. The incision made on the eardrum can quickly heal without giving enough time to the middle ear to heal. In order to avoid the quick healing of the eardrum and to drain any subsequent effusion and equalize pressure differences between the middle ear and atmosphere, a ventilation tube is placed. At the end of the procedure, cotton is usually placed in the ear to contain any residual secretions of middle-ear fluid. The ventilation tube keeps the middle ear aerated for adequate time and then falls outwards in a few months.

Myringotomy involves dexterity that can be achieved by practice and experience. The surgeon should be able to precisely control all the surgical tools in the constrained space of the ear canal. The operating surgeon also needs to have excellent hand-eye coordination to effectively work under a microscope. All of the sequence of steps in myringotomy are prone to errors [4]. A surgeon may select a speculum size that is too big or too small to appropriately fit the ear canal. A speculum that is too small will obstruct the view of the eardrum. Surgical residents also find adjusting the microscope to the right magnification challenging. The incision made on the eardrum can be inappropriate in terms of the size and direction: Too large an incision will not hold the ventilation tube and too small an incision will not allow the ventilation tube to fit into the incision. The resident or the surgeon can accidently hit the middle-ear anatomy (e.g., malleus), potentially disrupting the ability of the middle-ear bones to transmit sound from the eardrum to the cochlea. The ear canal can also be accidently cut while moving the blade down the ear canal. This may result in blood oozing out and filling the ear canal thereby blocking the view of the eardrum. All of these errors may result in delay or even abortion of the surgery. They may also result in discomfort to the patient and in some cases partial or complete hearing loss.

It was reported in a study that most frequent error while performing myringotomy was the failure to perform a unidirectional incision [4]. The same study reported that this error was followed in frequency by multiple attempts to insert the ventilation tube, multiple attempts to perform an incision, and the microscope magnification being set too high. It was also reported that if the two most frequently occurring errors are eliminated, the human error probability would be halved.

1.4 Myringotomy training

Myringotomy is performed around the world without any significant difference in the technique used from place to place. Also it involves a set sequence of discernible steps. This has resulted in formulation of standardized procedures for myringotomy training.

1.4.1 Current methods

The apprenticeship method is one of the most common methods used in operating environments to train surgical residents. It involves a "see one, do one, teach one" approach which is the most prevalent method for training on procedural skills in surgery [13]. The surgical residents improve their skills by repeated practice and experience on actual patients. The main drawbacks of this training method are: (1) potential for harm to the patient, (2) practice is only limited to patient types that present which may be small given the duration of residency programs and (3) patient types cannot easily be shared.

Physical models of the ear are available for practicing myringotomy. These generally consist of a tube to represent the ear canal and a synthetic membrane (e.g., latex) placed at one end to represent the eardrum. Some of the available physical models used for training are: the Wigan Grommet Trainer [2], the Bradford Grommet Trainer [3], and the Artificial Ear Trainer [14].

The Bradford grommet trainer consists of a membrane that is held in between two temperature probes. The markings on the membrane act as visual cue for the resident to position and plan the incision.

The Wigan grommet trainer is similar to the Bradford grommet trainer in construction. It involves materials like cellophane that makes up the membrane and oxygen tubing to hold the membrane in place. Oxygen tubing can be bent at any angle thereby letting membranes of different sizes fit on it. This helps in generating multiple scenarios with ear canals of different sizes to train upon.

The Artificial Ear is also a training tool used to improve the fine motor skills of the resident. It consists of a plastic drill cover, a vinyl glove, a small bottle and a pin. The plastic cover can be cut to any length and at any angle to generate training scenarios having different sized ear canals and angular tympanic membranes. Once modified as per the requirement, a piece of vinyl glove is wrapped on top of the plastic drill cover to represent the tympanic membrane. It is then fitted in the stem of a small bottle. The bottle may be filled with liquid like cornstarch to simulate effusion. A pin can be inserted into the bottle to add to the challenge. It acts as a marker and defines a region to place the ventilation tube.

Physical simulators are inexpensive to setup and can be prepared quickly. But unfortunately, by using these for training, it is not possible to effectively quantify the progress or improvement of the resident with repeated practice. These can be used only once and need to be reconstructed or replaced after every single use. It is hard to generate physical replicas to mimic different scenarios with different ear canal sizes and shapes and different stages of eardrum disease.

Moreover, a common complaint is that the materials do not have the same mechanical behaviour as real tissues.

1.4.2 Virtual reality simulators

A virtual reality simulator is a device that replicates a physical scenario via a computer simulation. The virtual environment is usually displayed to the user through a computer screen or through stereoscopic displays in real time. The display can be augmented by different modalities like 3-dimensional sound and tactile feedback to improve the realism in the simulation. The foremost aim here is to represent the real environment accurately and efficiently. The rapid growth of technology has made the case of virtual simulators viable.

Virtual reality simulations have been incorporated in a wide range of fields ranging from surgical training [15], military training [16], and arts and education [17]. In terms of surgical simulators, many virtual reality simulators have been developed to simulate the surgeries like laparoscopy, endoscopy and temporal bone drilling.

Laparoscopy is a minimally invasive surgery which involves operating on the internal aspects of the abdomen and pelvic regions through a small incision made in the navel. Simulators like LapSim [18] and MIST-VR [19-22] have been developed and have been shown to be reliable assessment tools for skills needed in laparoscopy. MIST-VR has also been shown to be an effective training tool for laparoscopic surgery [23].

An endoscopic simulator [24] has also been developed and evaluated for its impact on the performance of the surgeons with endoscopy. Endoscopy is a minimally invasive technique by which the inner body parts of a patient are examined or accessed. In this procedure, an endoscope (a tube with a lens system attached to the tip for transmitting the image to the viewer) is passed into the body through a small incision to reach the inner body part. Results from an evaluation study of the simulator have been positive [24]. The study found that the simulator improved the performance of residents in the operating room. Residents who trained on the simulator performed consistently better than other residents who did not in all the metrics measured during evaluation.

A virtual temporal bone drilling simulator has been developed and evaluated as well [25]. It simulates the temporal bone surgery in a three-dimensional simulation with haptic feedback. The simulator was reported to be an effective tool to teach surgical anatomy and for planning the proposed surgery. Through a study, it was reported to have some degree of face, content, and concurrent validity. It was found to be an effective tool for teaching the surgical anatomy and the technique of performing temporal bone drilling [25].

Once a simulator has been designed, it is important to validate it to ascertain the extent of its usefulness to the scenario that it is simulating. The validity of a simulator is also done to ensure that a simulator is truly simulating an operation and does what it is supposed to do [26]. Testing the validity of a simulator can take the form of a face validity, content validity, internal validity and construct validity.

Face validity, in terms of simulation, is a property of a test that measures to see if the simulation appears to do what it is intended to do. In the case of simulation, it is typically done by asking experienced people if the simulation appears reasonably adequate in terms of modelling the live operation. If they feel that it does, then the simulation is supposed to have face validity. Questionnaires administered to experienced users are a useful tool to conduct face validity. Questions can be directed towards any aspect of the simulation like realism, effectiveness, accuracy and usefulness. Face validity is usually the first step on the course of validating a simulator.

Content validity (also called logical validity) is another tool to validate a simulator. It measures to see if all that is represented in a natural scenario, is included in the simulated product. In terms of surgical simulation, it determines if all components deemed essential in the live operating environment are included in the simulation or not. If all the components are included, the product is said to have a high content validity. A prevalent method of measuring the content validity is by asking experienced people to use the simulator and rate it in terms of being able to perform its intended function adequately or not.

Internal validity investigates the cause and effect relationship between two components of a simulation. In terms of virtual-reality simulations, it is done to ascertain if by using a simulator, the user's skills at performing a specific simulated task actually improve.

To ascertain if the user's acquired skills are transferred to the operating theatre, a construct validity study is performed. A construct validity is done to determine the correlation between two variables of interest. To determine the construct validity, the performance of the subjects at a surgical task is measured before and after receiving training in the simulated environment. Both these findings are compared to find a correlation.

1.4.3 Virtual reality myringotomy simulator

Because of the manifold disadvantages of the existing training tools (physical models and apprenticeship method as discussed in section 1.4.1), a need for an effective training tool was highlighted. A virtual reality myringotomy simulator was developed by Wheeler *et al.* [27]. Figure 6 shows Wheeler's simulator. When using the simulator, a 3D graphical model of the ear canal and eardrum are presented to the user via a mock surgical microscope consisting of a visor for stereoscopic display. The visor is mounted to an adjustable stand that has the same degrees of freedom as a typical surgical microscope. The user can interact with the simulated ear using real surgical tools. As the tools are moved in real space, their positions and orientations are tracked by a motion tracker and displayed by means of virtual tools on the visor. Interactions between virtual tools and the simulated anatomy are detected by a physics software library and rendered on the visor.

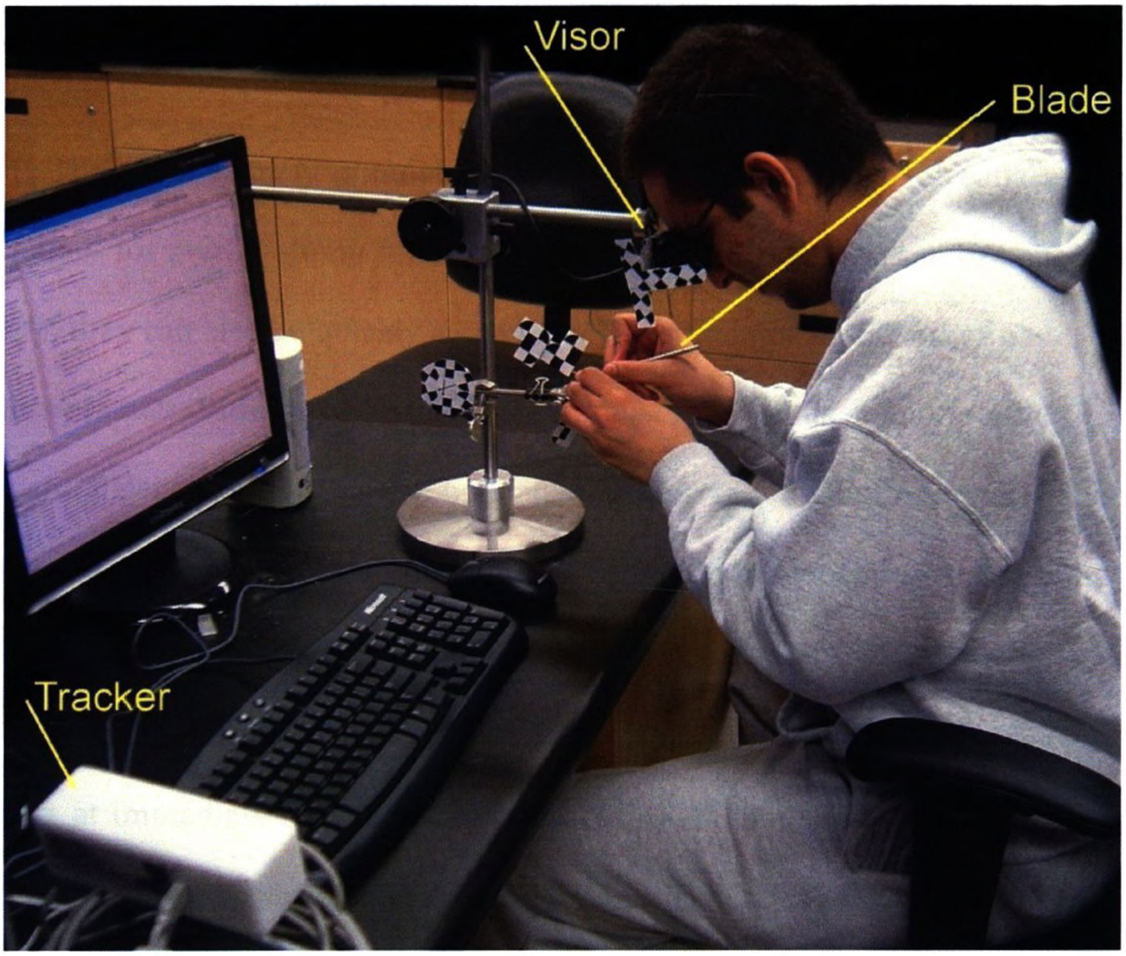

Figure 6: Simulator designed by Wheeler et al. A user is looking through the visor at the simulated scene and manoeuvring the tools.

The main objective of the simulator was to train residents and improve their fine motor skills needed to perform myringotomy. It is a multifunctional tool capable of quantifying the resident's performance on specific tasks and tracking their progress. Using the current simulator, residents can seamlessly practice tasks like navigation of the blade down the virtual ear canal, targeting an appropriate location on the virtual eardrum for the incision and drawing a line on the eardrum to indicate an incision. Haptics (force feedback) was not incorporated in this version of the simulator as it was not initially deemed relevant to these limited training tasks. Deformation of the eardrum and formation of the incision were also not included in the current version.

The myringotomy simulator has many advantages over already available techniques for myringotomy training. Although physical models can be constructed quickly, they can also be quickly exhausted. The simulator on the other hand, offers endless practice. Different scenarios comprising of ear canals of multiple shapes and sizes and diseased eardrums can be loaded at the click of a button. New models of the ear canal and the eardrum with new patient data can be added to the simulator quickly and easily as well.

Unlike in the apprenticeship method, training on the simulator does not put patients at immediate risk. In the apprenticeship method, an experienced surgeon overlooks a resident performing the surgery on a live patient and provides hands-on assistance when needed. Understandably, patients only want experienced surgeons to operate on them and do not want to hear that the individual performing the surgery is a novice and is being trained. The simulator provides a safe training environment where residents can attempt a practice run of a task which may be considered dangerous to attempt in a live scenario during the course of training under the apprenticeship method and rotating residency [28]. Surgical residents can train freely on the simulator and stay relieved from any psychological stress and the stress from organizational factors of the operating room.

The simulator also provides objective assessment of the tasks performed by the resident. Unlike the case with the existing conventional training techniques, the numerical score assigned by the simulator helps residents track their progress themselves without the need of an experienced surgeon to evaluate their skills. As myringotomy is performed by observing through a microscope, the operator requires efficient fine motor skills and hand-eye coordination to effectively perform the surgery. The virtual reality simulator helps improve the motor skills and hand-eye coordination of the operator while operating with surgical tools.

In Wheeler's simulator, a MicronTracker optical tracker (Claron Technology, Toronto, ON) [29] is used for tracking the position and orientation of the surgical tools during the simulation. It is capable of identifying the different tools and provides details about their position and orientation. It consists of two cameras separated by approximately 12 cm. These provide stereoscopic vision of the operating environment in front of them. It connects to the standard IEEE-1394 (Firewire) interface of the computer and allows the usage of real surgical tools with the simulation. All of the physical objects/tools of interest are marked with special markers that are recognized by the MicronTracker. As the marked tools move, their motion is tracked and fed to the simulation software to update the motion of corresponding virtual representations. The MicronTracker is capable of recording a maximum of 30 frames per every second. The simulation runs at double the speed of the MicronTracker and displays up to 60 frames per every second. It gathers the information from camera once in every two graphical frames that are rendered.

There are some limitations of the MicronTracker which have had significant effect on the usability of the simulator. The markers (as seen in Figure 6) always need to be in the line of sight of the camera for them to be consistently identified and tracked. If the line of sight of the markers is obstructed by hand or other objects in front of the camera, the camera will fail to record the position and orientation reading. Myringotomy involves both the hands for different tasks. Surgeons usually use the non-dominant hand for holding the speculum in the ear and the dominant hand to manoeuvre the surgical tools. There is a great likelihood that one of the hands will obstruct the camera's view of a marker attached to the surgical tool. This results in loss of position and orientation of the tool for the duration of obstruction thereby resulting in irregular movement of the tool in the simulation. Surgeons and residents who have used the simulator did raise concerns about the irregular traversal of the surgical tool in the simulation. They also found it hard to not obstruct the view of the markers from the camera and freely perform the myringotomy on the simulator. These inherent problems with the optical tracker led users to observing significant tool jitter in the simulation. Because of the jitter, the residents also found it difficult to manoeuvre the blade and perform an incision.

After the first version of the simulator was complete, a face validity study was conducted by Wheeler *et al.* to acquire feedback and suggestions from ENT surgeons and residents. No simulator developed is a perfect training tool and there is always some room for improvement. The main purpose of this study was to identify the most important fronts along which the simulator can be further improved.

Open-ended comments from surgeons participating in the study suggested that haptic feedback is more desirable than the realism provided by using the actual tools. Moreover, experienced surgeons seem to take the view that the simulator is useful in its current form or will be with the inclusion of haptics. The inclusion of haptics, therefore, serves as the main objective of this thesis.

1.5 Objectives

The objective of this work was to incorporate haptic feedback capability into the existing simulator. Haptic feedback would allow the user to touch and feel the virtual ear with the surgical tools. In order to achieve this, a haptic arm was interfaced with the simulator. Once fully integrated into the simulator, the haptic parameter for stiffness of the eardrum was estimated. To ascertain the reliability of the estimated parameter, an intra and inter-observer reliability study of the estimated parameter was conducted. The estimated parameter was incorporated in the simulator and a face validity study was conducted to evaluate the realism of the modified simulator. This study helped ascertain if the modified simulator is a realistic training tool and what areas need further improvement.

Chapter 2: Virtual reality myringotomy simulator

Because of the limitations of the currently available myringotomy training tools (physical models and apprenticeship method), ample need was felt for developing an effective training tool that can train residents in various aspects of myringotomy. A virtual reality simulator was designed to fill this gap. The first version of the simulator was designed by Wheeler *et al.* [27] and is described here along with the contribution of this work: the addition of haptic feedback.

2.1 Operation of simulator

The simulator setup with all the hardware components used can be seen in Figure 7. The simulator can be divided into three main components: the input devices, the output devices and the simulation control.

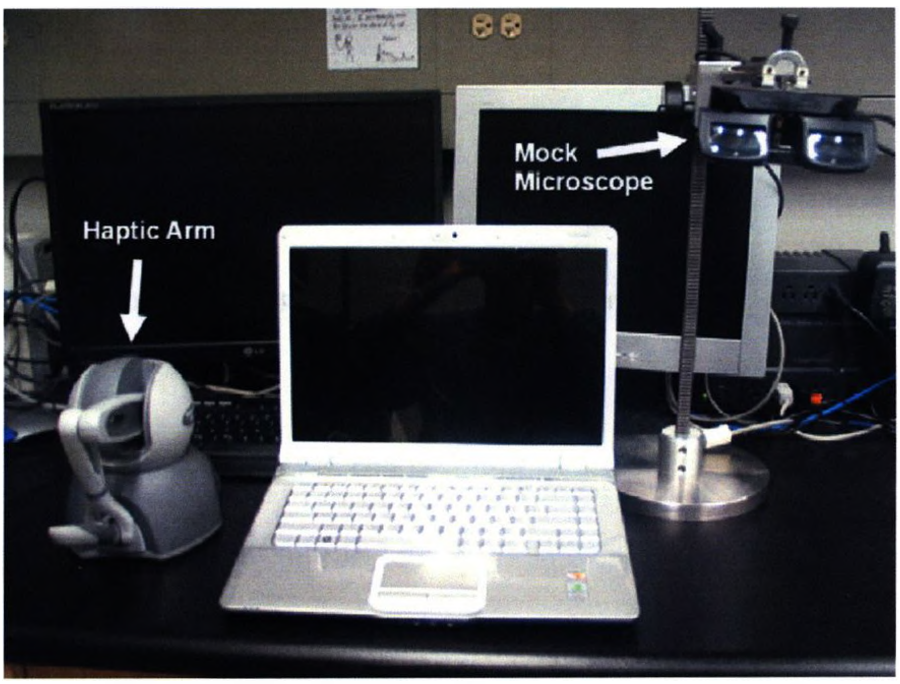

Figure 7: The virtual reality myringotomy setup.

When the simulation is running, the simulation control consistently waits for user input and processes any input as it occurs and displays the resultant output. Figure 8 shows these components and their relationships to each other. The haptic arm acts as both an input and an output device. When it is moved around, it tracks the position of the virtual blade and provides the coordinates along with the orientation to the simulation to render the blade. When it touches a virtual object, it exerts a force to the user to provide a feel of touching an object.

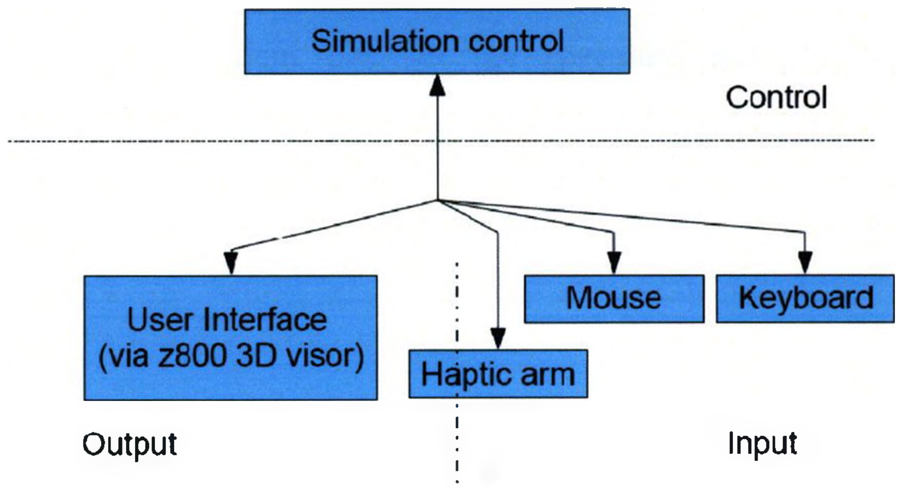

Figure 8: Simulator components.

The simulation can be started and stopped by pressing either the 'spacebar' key on the keyboard or the left mouse button.

When the simulation starts, the resident looks through the visor and initially sees a model of the ear canal and the eardrum displayed at low magnification. The antero-inferior quadrant where the incision is intended to be made is highlighted (with a translucent gray region as can be seen in Figure 9) by default to provide a visual cue to the resident. This visual cue can be toggled by pressing the 's' key on the keyboard. The magnification or the zoom factor now needs to be set. It can be increased or decreased by moving the mouse forward or backwards respectively. Keys 1 and 2 can be used to select the speculum of appropriate size (either the wide or the narrow speculum, respectively). The arrow keys on the keyboard can be used to adjust the speculum to the right position. Keys 3 and 4 are used to select the left ear or the right ear scenario respectively. Once the speculum is chosen, it can then be adjusted to the appropriate position using the arrow keys (left, right, up, down) on the keyboard to move the speculum in the required direction. Figure 9 shows a scenario where the resident has set the speculum and the magnification appropriately. The black region surrounding the eardrum is the speculum which has been typically adjusted to have a better view of the antero-inferior quadrant of the ear.

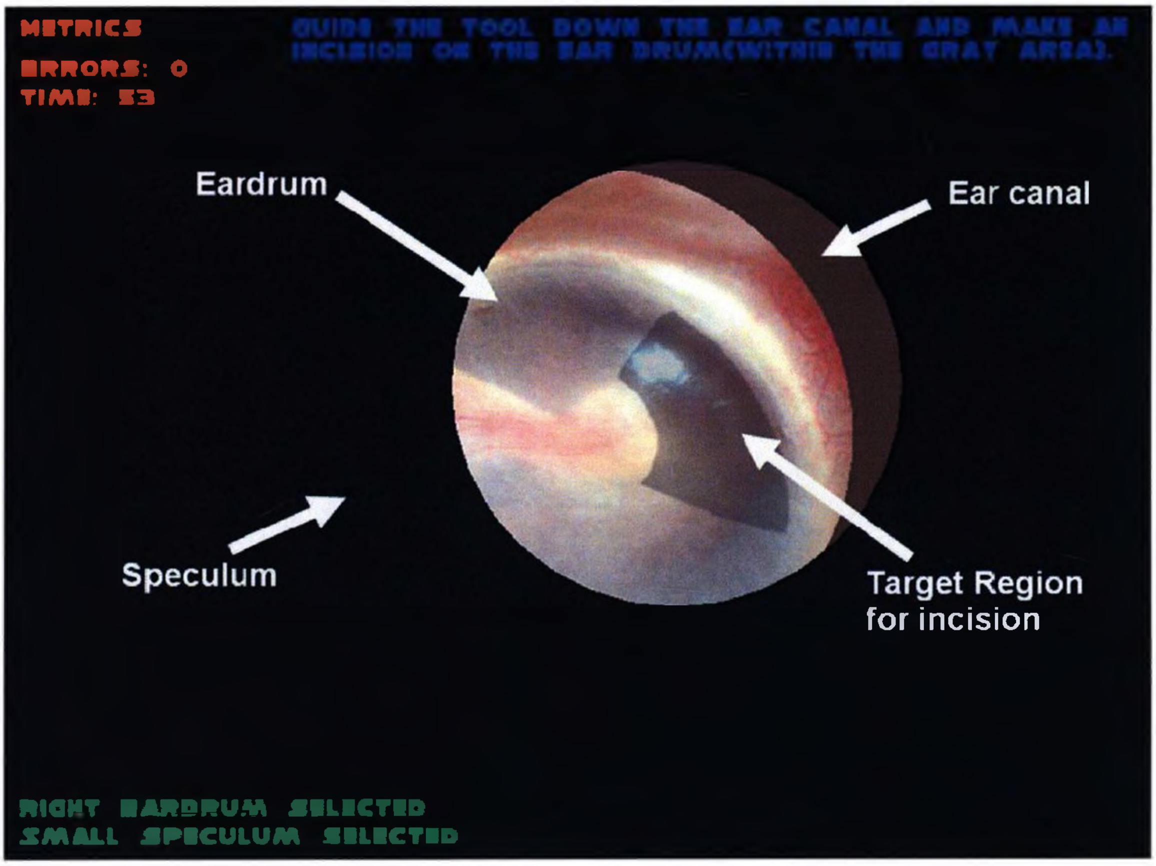

Figure 9: A view of eardrum, ear canal and speculum. The gray area is the intended target of incision. The dark brown area on the edge of eardrum is the ear canal.

Once the view of the eardrum is clear and the speculum is set in position, the residents can then move the virtual blade into the scene by moving the haptic arm. They can rest their hands on a Styrofoam block (as shown in Figure 10) which mimics the real head in that it provides a mechanism for residents to stabilize their hand movement. In reality, surgeons use the patient's head to accomplish this.

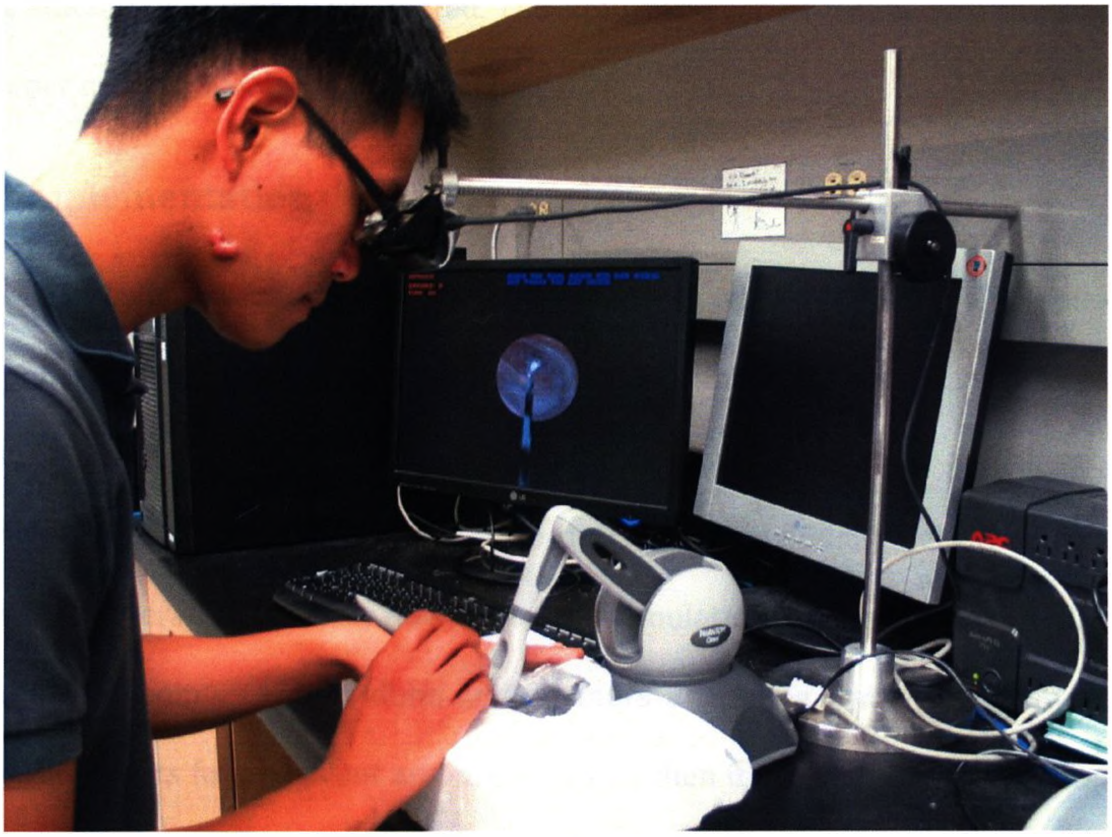

Figure 10: Simulator being operated by a user.

The blade is then guided down the ear canal by the resident to perform an incision. A visual cue of three dots marked in a straight line can be optionally displayed to help the resident in performing a straight incision. If this cue is turned off, the resident needs to decide on the position, orientation and length of the incision. On touching and then piercing through the eardrum a small translucent blue circular disk appears on the point of contact of the blade and the eardrum. This provides a visual cue to the user that the eardrum has been touched. The resident also experiences a subtle force feedback on touching the eardrum with the blade. This is done to mimic the small forces that surgeons feel while performing live myringotomy. Once the incision is performed, the blade is retrieved out of the ear canal and the operation is completed. The simulation can be stopped by pressing the spacebar or 'q' or ESC keys on the keyboard.

2.2 Implementation

The simulator consists of input devices, output devices and software components to achieve a realistic experience. The simulator uses a haptic arm, a 3D visor mounted on a stand, and a computer to closely mimic an actual surgical procedure. All the components used are described individually below. Figure 11 shows the overall simulation flow. Once the simulation is started, initialization of the required components is done and it enters a running state. In this state, the simulation waits for any event and processes it when it is triggered. The events that can occur can be either keyboard, mouse or haptic arm generated. The keyboard and mouse events will be triggered by the user when the myringotomy scenario is loaded, setting the appropriate magnification of the view and selection of the appropriate speculum size. A collision event will be called when the blade driven by the haptic arm, touches the virtual anatomy in the scene. This is termed as an incision. If the blade touches the ear canal (which is not intended), an error is reported and the error count is incremented. If the blade touches the eardrum within the intended area of collision (the gray area), the incision is drawn at the point of collision or else an error is reported and the error count is incremented. To provide a visual cue to the user, three dots can optionally be displayed on the eardrum to represent the target location and size for the incision. The user would need to touch all of them consecutively in any single direction (starting from any outer dot) to complete the incision and the operation. These dots are positioned in a straight line radially outwards towards the ear canal. As these dots are touched, the path counter gets decremented and once it is zero (which implies the incision is complete), the operation is successfully completed and a message of successful completion is displayed to the user. The user can now restart the operation or quit the simulation.

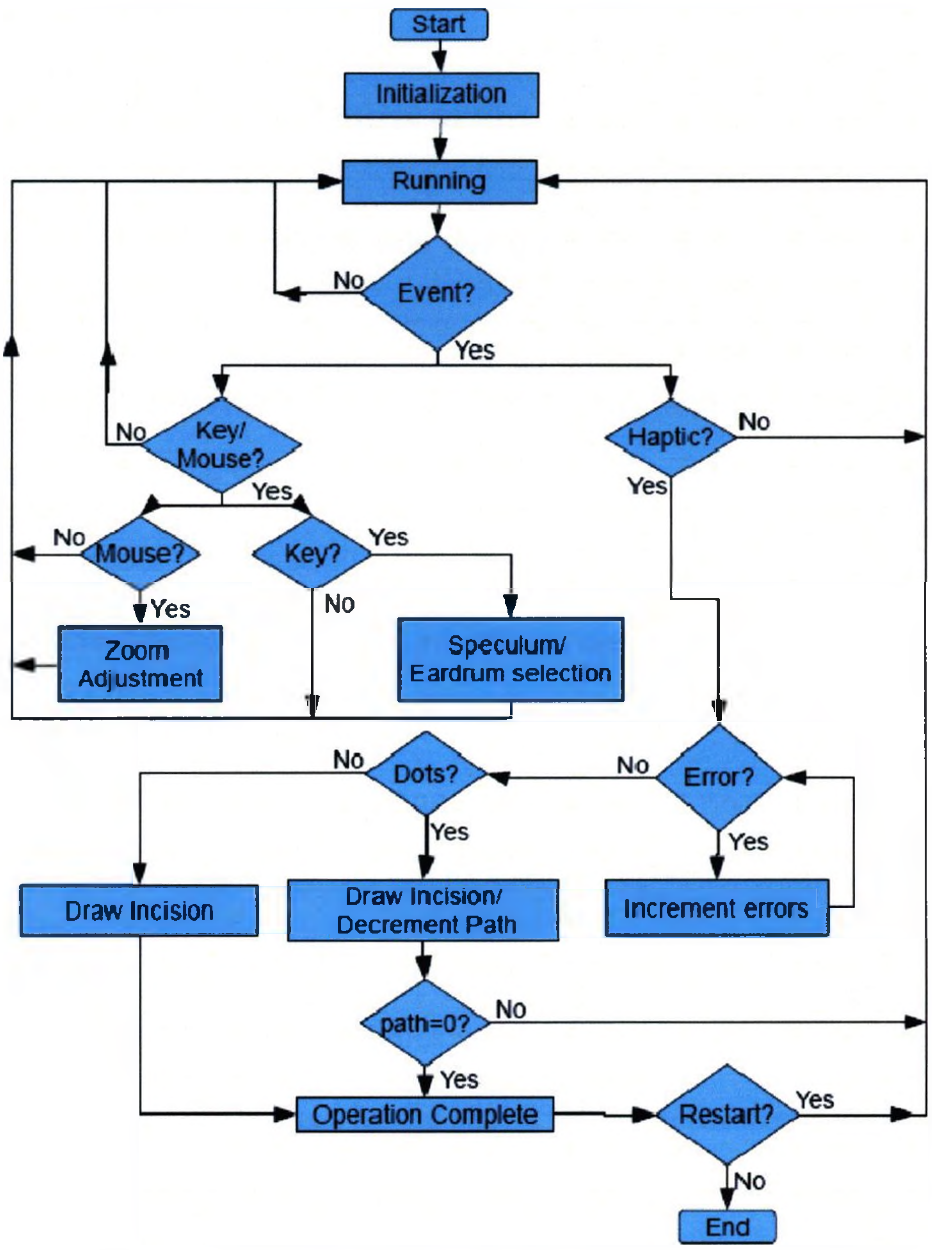

Figure 11: The flowchart depicting the simulation control.

2.2.1 Input

As described in Chapter 1, for detecting the physical surgical tools Wheeler *et al.* [27] used the MicronTracker for tracking the position and orientation of surgical tools and relating these to the simulated virtual anatomy. To overcome its shortcomings and to provide haptic feedback, it is replaced with a PHANTOM Omni Haptic Arm (SensAble Technologies, Woburn, MA, USA) [30] in the new version of the simulator.

2.2.1.1 PHANTOM Omni haptic arm

The PHANTOM Omni haptic arm was used for steering the blade in physical space. The Omni haptic arm also allows users to touch and feel the virtual objects. It provides six degrees-of-freedom positional sensing and 3 directional (x, y, z direction) force feedback capability. It has a nominal position resolution of 0.055 mm, which is suitable for this application. The device typically runs at 1000 Hz rate. Such a high frame rate signifies enhanced stability and responsiveness of the device. It is connected to the computer through a standard IEEE-1394 Firewire interface. This device also allows for the tracking of surgical tool position, orientation and interaction with virtual anatomy. As can be seen in Figure 12, a pen shaped stylus is attached to the end of the kinematic chain of the haptic arm. The user holds the stylus, retrieves it from the inkwell (dock where the stylus is put to rest) and moves it around in the space constrained by the extent to which the arm can reach. The tip of the stylus is called the device end-effector. The stylus is integrated with two momentary switches for ease of use and end user customization. The physical space can be appropriately mapped to the virtual space to touch the objects of the virtual scene with the tip of the stylus. It has a portable design and compact footprint for workspace flexibility.

Figure 12: The PHANTOM Omni haptic arm.

2.2.1.2 Keyboard and mouse

The user input from the keyboard and mouse is also required. Specific keys on the keyboard and buttons on the mouse are programmed to perform specific functions during the simulation. Table 1 provides a list of the specific functions that can be performed using the keyboard and the mouse along with their designated keys/buttons.

Table 1: Keyboard and mouse functionality.

To start/stop the simulation	Spacebar or left mouse button
To select a wide speculum	1
To select a small speculum	2
To move the speculum around	Arrow keys
To select the left eardrum	3
To select the right eardrum	4
To start the myringotomy	s/S
To zoom in	Move the mouse in the forward direction
To zoom out	Move the mouse in the backward direction
To look around	Press the Right mouse button and move the mouse around
To quit the simulator	q/Q

2.2.2 Output

The virtual training environment of the simulation is seen by the resident through an eMagin Z800 3D visor (Bellevue, WA). It provides a 3-dimensional stereo display of the virtual scene and acts as a mock microscope for residents. The stereo vision helps residents to perceive the depth of different virtual anatomical structures and thereby improve their depth perception while manoeuvring with the tools. The visor headset has a compact design. The resident looks through the two 0.59 inch (diagonally) Organic LED displays which provide a high contrast display of 800 (width) by 600 (height) pixels individually. Since the visor is primarily used for gaming, it originally comes attached with a head rest which comfortably rests on the head. To integrate it into our simulator, minor modifications were done. The visor was detached from the head rest and mounted on an adjustable aluminum stand using a stiff hinge (see Figure 13). The microscope stand consists of two solid aluminum rods which are joined to each other by an adjustable joint (see Figure 7). The end of the vertical rod is attached to a solid aluminum base on which it rests. The aluminum base is heavy and makes the stand steady enough to not move during the simulation. The other rod is attached horizontally onto the vertical rod using a joint. Both the horizontal and vertical rods can be adjusted in terms of length and height to set the eye piece to the appropriate position. The eyepiece can be raised or lowered and moved forward or backwards by adjusting the length of the vertical and the horizontal rods respectively. The visor can be adjusted at any angle comfortable to the user. The stand provides an adjustable arm which mimics a real surgical microscope. The zoom or magnification scale for the viewable scene can be set using the keyboard.

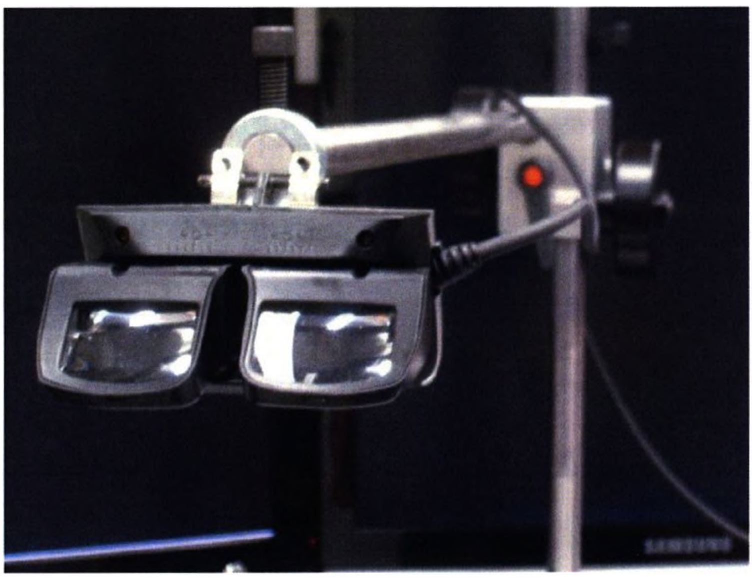

Figure 13: The z800 3D visor mounted on the aluminum stand using a stiff hinge.

2.2.3 Software system

The software has been developed solely in C++. Object-oriented design was used to make the system more modular and easily extensible. Microsoft Visual Studio 8.0 is the Integrated Development Environment tool used for designing the simulator. A Windows XP based computer (Hewlett-Packard, Palo Alto, CA) with AMD Turion™ 64 X2 Mobile Technology 803 MHz, 2GB RAM and NVIDIA GeForce GO 6150 graphics card was used for programming and designing the simulator. The Object-Oriented Graphics Rendering Engine (OGRE) [31] is used to render any graphical content that is needed to be displayed to the user in 3D. The content involves the surgical tools, the ear anatomy, instructions on how to use the simulator and the evaluated metrics. The Object Oriented Input System (OIS) [32] is used to efficiently manage the input from mouse and the keyboard. The mouse is used to set the zoom factor for the scene. The zoom function mimics the magnification that is adjusted on the surgical microscope to have a better view of the eardrum. The keyboard is used to change the anatomical models of the ear parts, to switch and adjust the surgical tools and to turn the simulation on and off (see Table 1). The Open Dynamics Engine (ODE) [33] is used to manage the physics of the objects involved in the simulation. It is used for detecting the collisions of different objects in the simulation (e.g., contact between blade and anatomy) and for acquiring information about the position of the collision and the details like edges or vertices of the objects involved. OgreHaptics [34] is a library that was used to integrate the haptic arm in OGRE. SensAble provides the software drivers which interface the Omni haptic arm with the computer. The NVIDIA graphic card drivers provided by NVIDIA provide stereoscopic display to the z800 visor.

The structure of the simulation program can be summarized in the flowchart of Figure 14. When the simulation is started, the graphics rendering context and the window are instantiated. This is followed by setting up of the haptic context. Once the graphics and haptic components are setup, the physical haptic workspace of the haptic device is mapped to the virtual geometry specified in the virtual scene. Once the spatial mapping is complete, the simulation enters a loop where it renders the graphic and haptic components and at the same time waits for any input events to occur. These events can be generated by the user using the keyboard, mouse or haptic arm. Events can originate from the haptic arm (e.g., collision of the blade with virtual anatomy, calibration of the haptic arm, etc) or from the keyboard (e.g., pressing keyboard keys to select certain virtual anatomy, moving the speculum around, starting/stopping the simulation, etc) or the mouse events (e.g., changing the view magnification, starting/stopping the simulation, etc). As soon as any event is triggered, the event handler gets called and the resultant graphic and haptic scenes are rendered.

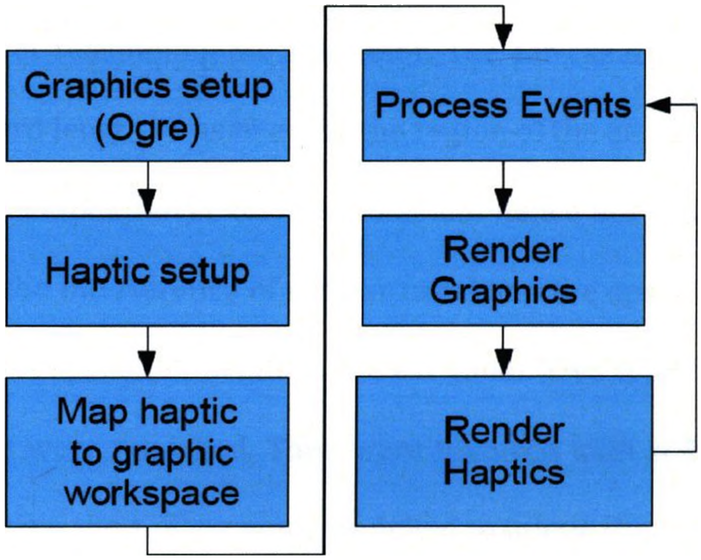

Figure 14: The simulation control structure.

2.2.4 Geometric models

The virtual scene that the resident sees while using the simulator consists of different models of the parts of the ear and of the surgical tools. All of the models used in the simulator were created using Blender 2.46 [35]. Blender is an open source modeling software application used for the creation of and replay of linear and real-time, interactive 3D content. All of the models are created as triangular meshes. Different scenarios with different eardrums, ear canals, specula, blades in terms of shapes, sizes and texture were modelled. All of these models were created with the assumption of an arbitrary but isotropic scale in Blender. The models were later calibrated to map the objects appropriately in the simulation software which uses OGRE. Specula of 2 different sizes are modelled. The specula (both narrow and wide) were modelled as black conical hollow structures to mimic the black specula (of sizes 4 mm and 6 mm tip diameter) available in the operating room. The ear canal was modelled as a cylinder of 7 mm inner diameter and 20mm length and textured with a color resembling the skin color. The ear-canal model was truncated to 1/2 of its standard length so as to avoid the region of the ear canal that is covered by the speculum positioned over the ear canal and hence not visible. This was also done to eliminate the interference of the ear canal and the speculum geometries in the region where the speculum overlaps the ear canal. Two types of surgical blades (straight and bent) were modelled. They were textured with reflective material to mimic the real surgical tools. They were modelled to mimic the myringotomy blades (provided by Medtronic of Canada, Mississauga, ON). The eardrum was modelled as a planar sheet and textured with high resolution digital images of eardrums acquired using an endoscope. Many eardrum textures were available to depict various stages of infection, and these could be applied onto the sheet with the press of a button on the keyboard.

2.2.5 Calibration of simulator

The simulator needs to be calibrated to accurately represent the different aspects of the operating environment. The virtual anatomy of the ear needs to be mapped correctly to the available physical space in the ear to effectively train residents on their manoeuvring skills within space constraints. Surgeons do feel a certain force when they touch and cut through the eardrum. The force feedback needs to be calibrated to simulate a similar force when they touch the eardrum. To improve realism, both spatial and force feedback calibration was done.

2.2.5.1 Spatial calibration

The haptic arm needs to be calibrated so that the physical work space can uniformly map with the virtual space of the simulation software. The virtual anatomic models need to be scaled appropriately to represent their real counterparts accurately. The geometric models for the eardrum, ear canal, speculum and blade were created with the assumption of a uniform but arbitrary scale in Blender. Once imported into the simulation software, the virtual models were finally scaled by a scale factor of s (determined below) so as to accurately register them with the physical workspace.

A 10 x 2 x 2 (L x W x H) unit rectangular box was modelled in Blender and rendered in OGRE without any scaling. A ruler was placed in the physical workspace in such a manner that when the haptic end-effector was placed on the 0 cm reading on the ruler, the proxy in the virtual environment mapped exactly to the top leftmost corner of the virtual box. Likewise, the whole length (10 Blender units) of the virtual rectangular box (in OGRE) was traversed and when the virtual pointer reached the extreme right end of the virtual box, the final ruler reading (R cm) was recorded.

The mapping of physical haptic space to the virtual view volume in the simulation was set to be uniform in all directions and so the scale factor was calculated by measuring the scale in x direction only. The ruler was laid out parallel to this direction.

Calculation of the scaling factor was done as follows. Ten (10) Blender units in virtual space (in OGRE) imply R cm in physical space. R was measured to be 3.4 cm, so 1 cm in physical space implies $10/R$ units in Blender. Hence, the scaling factor is $s = 10/3.4 = 2.94$ Blender units per cm.

Therefore, to make a virtual object (in OGRE) resemble its physical dimensions (in the physical space), the model in Blender was scaled by s Blender units and then rendered in OGRE. For instance, the physical speculum with 3 cm outer diameter can be modelled using a scale of $3s$ (3*2.94 = 8.82) Blender units (i.e., the speculum was scaled to 8.82 Blender units from 3 Blender units to actually represent it as of 3 cm diameter in physical space). All the models (i.e., eardrum, specula, ear canal and the blade) were then scaled by the scaling factor s calculated above.

2.2.5.2 Force feedback calibration

To improve the realism of the simulator and to simulate the real tactile feedback felt by residents while performing an incision during myringotomy, the force feedback needs to be calibrated. It is logical to believe that the calibration can be effectively done by users who extensively perform myringotomy. Two otolaryngologists and one intermediate resident were requested to use the simulator and adjust the stiffness parameter of the virtual eardrum. They adjusted the parameter of the virtual eardrum to the point that the force felt while piercing the virtual eardrum in the simulator mimicked the force that they would feel while making an incision in a real eardrum.

The Omni haptic arm exerts the contact force by using the spring-damper model shown in the Figure 15. In this method, a proxy (a hypothetical point) closely follows the haptic end-effector position as it is moved around. When a virtual haptic object is touched, the proxy stays on the outside surface unlike the haptic end-effector which may penetrate deeper. At any given time of the haptic arm penetrating a haptic object, an opposing force directly proportional to the distance between the proxy and the haptic end-effector is exerted towards the outer surface. This force-distance relationship can be expressed as:

$$\mathbf{f} = k_s \mathbf{x} + k_d \mathbf{v}.$$

In the above equation, bold lowercase letters denote vectors and italicized lowercase letters represent scalars. Here **f** is a vector representing the force exerted by the haptic arm. k_s is the stiffness coefficient for the haptic surface and k_d is the damping coefficient. **x** is a vector representing the distance traveled by the haptic end-effector with respect to the surface of the object and **v** is a vector representing the velocity of the haptic end-effector. k_s was the parameter that needed to be estimated by the surgeons and resident, and the damping coefficient was set to zero because motions during surgery are slow.

Figure 15 shows the positions of the haptic arm at three time intervals t1, t2 and t3. In this haptic model, the proxy closely follows the haptic end-effector all of the time. At time interval t1, the proxy is positioned onto the position of the haptic end-effector. At time interval t2, the haptic arm touches the surface of the haptic object and stays on the outside. Now the haptic device keeps penetrating and at time interval t3, it is at a certain distance (or depth) from the surface. Here at any given time of contact, a force cumulative of both spring force and damping force is exerted on the haptic arm in the opposing direction of its movement. The haptic arm can exert a force in the range of 0 N to 3.3 N (0.75 lbf). The level of stiffness or the force exerted by the haptic arm is normalized to lie between 0.0 to 1.0 (where 0.0 implies an object with zero stiffness and 1.0 implies maximum stiffness).

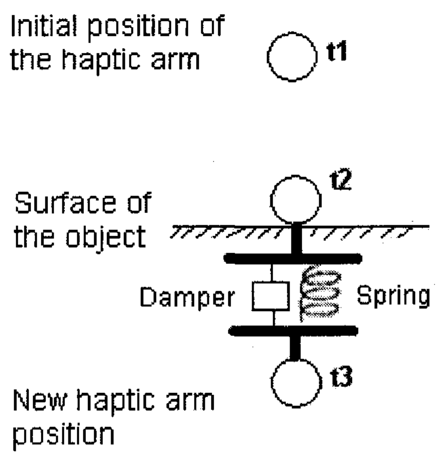

Figure 15: Proxy movement and force rendered.

For force feedback calibration, the participants used the simulator and did the estimation on five separate occasions separated by at least a day. On each of the five occasions, they adjusted the stiffness parameter of the virtual eardrum 10 times. For each of the ten times, the initial parameter value was selected randomly from the set {0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0} with elimination. Each participant then adjusted the stiffness value to the desired value. Different initial stiffness values spanning the range of available values were used in order to determine if each user converges to the same desired value representing their perception of eardrum stiffness. On completion of this estimation process, the stiffness parameter adjusted by the three participants was averaged and the final average value of 0.0173 was incorporated in the simulator for the face validity study (see Section 2.2.6). An average value was chosen so as to represent a stiffness parameter that is in close agreement to all the participants.

It is important to assess the intra-observer reliability as well as the inter-observer reliability of the final adjusted parameter. Intraclass correlations (ICC) were used to determine the inter- and intra-surgeon consistency of the adjusted parameter, i.e., ICC is used to determine the variation between the participants and within the participants. The greater the variation between the participants is relative to within the participants, the greater is the agreement between the measures obtained by the surgeons and therefore the closer the value of ICC is to one.

2.2.6 Face validity study

Seven intermediate/senior level residents and four practicing otolaryngologists (n = 11) were asked to perform multiple myringotomies on the simulator after a five minute introduction to familiarize them with the simulator. After the myringotomies were completed, each participant independently completed a two-part questionnaire evaluating their experience. The doctors who calibrated the simulator for force feedback did not participate in the face validity study.

2.2.6.1 Contents of the questionnaire

The questionnaire was developed from a proprietary measurement instrument with prior consideration of psychometric properties. Areas that were addressed included issues related to hand-eye coordination, skill development, anatomical representation, realism associated with both visual and movement components of the simulator, judgments of the mock microscope, in addition to the perceived value of the simulator as an educational instrument. Other areas of concern were related to color, the overall geometry of ear structures, tactile feedback, instrument movement and focusing ability.

Section A of the questionnaire (Figure 16 to Figure 19) contained 18 questions that were assessed using a Likert style 7-point, equal appearing interval scale as follows: 1 = "strongly agree", 2 = "mostly agree", 3 = "agree", 4 = "neither agree/disagree, 5 = "disagree", 6 = "mostly disagree", and 7 = "strongly disagree". Section B (Figure 19 and Figure 20) was comprised of 10 "yes/no" questions that were designed to assess conceptualization of an ideal simulator. Additionally, in Section C (see Figure 21) participants were requested to respond to a single question that addressed their perception of the level of difficulty represented by the surgical simulator in comparison to a real myringotomy procedure. Finally, all participants were also permitted to provide additional written feedback and comments following completion of the other questions.

Surgical Simulation Scale

We are seeking information on a virtual-reality based simulator for myringotomy training and use of similar training approaches in medical education, and we are asking for your input. In *Section A* you will find 16 questions. Please provide your rating to each of the questions using the 7-point scale located below the question. The scale ranges from a value of "1" (Strongly Agree) to a rating of "7" (Strongly Disagree); we have also indicated descriptive terms for all other points on the scale. Please note that a response of "4" indicates that you do not agree or disagree with the statement. Your response to each of these questions should be indicated by either placing and **X** through the number that best represents your opinion about a given question, or by **circling** that number; please choose only whole numbers (do not provide a response that falls between two numbers). Please make sure that you answer all 14 questions. In *Section B* you will be asked to respond to seven Yes/No questions; please answer all of these questions by circling your selection.

Section A

1. Surgical residents and medical students should be provided with structured classroom opportunities to finely develop their hand-eye coordination prior to operating on patients.

1	2	3	4	5	6	7
Strongly Agree	*Mostly Agree*	*Agree*	*Neither Agree/Disagree*	*Disagree*	*Mostly Disagree*	*Strongly Disagree*

2. Surgical residents and medical students should be provided with independent, self-directed opportunities to develop hand-eye coordination as part of their medical education.

1	2	3	4	5	6	7
Strongly Agree	*Mostly Agree*	*Agree*	*Neither Agree/Disagree*	*Disagree*	*Mostly Disagree*	*Strongly Disagree*

3. The system that I have been exposed to is a good introduction to training basic hand-eye coordination skills that I will need as a surgeon.

1	2	3	4	5	6	7
Strongly Agree	*Mostly Agree*	*Agree*	*Neither Agree/Disagree*	*Disagree*	*Mostly Disagree*	*Strongly Disagree*

Figure 16: Questionnaire – Page 1.

4. The system that I have been exposed to permits development of skills for accurate placement of a surgical incision.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

5. The system that I have been exposed to is useful for improving skills such as using a surgical instrument under a microscope.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

6. Correct anatomical placement of the surgical incision is an important requirement for performing a myringotomy.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

7. The visual representation of the ear drum (tympanic membrane) provides sufficient realism for training of basic surgical skills associated with myringotomy.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

8. The visual representation of the ear canal provides sufficient realism for training of basic surgical skills associated with myringotomy.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

9. The visual representation of the virtual surgical instrument provides sufficient realism for training of basic surgical skills associated with myringotomy.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

Figure 17: Questionnaire – Page 2.

10. The visual apparatus ("mock microscope") closely models the features of an actual surgical microscope.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

11. The visual apparatus ("mock microscopy") is an adequate method for training basic surgical skills.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

12. The "motion tracker/force feedback arm" provides an acceptable representation of movements associated with a surgical tool.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

13. The physical instrument and the visor provide sufficient realism for training basic surgical skills.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

14. I would continue to use the system for training if it was readily available.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

15. I would recommend use of the system for training medical students and/or surgical residents if it was readily available.

1	2	3	4	5	6	7
Strongly Agree	***Mostly Agree***	***Agree***	***Neither Agree/Disagree***	***Disagree***	***Mostly Disagree***	***Strongly Disagree***

Figure 18: Questionnaire – Page 3.

16. The use of visual simulation is a valuable part of surgical training.

1	2	3	4	5	6	7
Strongly Agree	*Mostly Agree*	*Agree*	*Neither Agree/Disagree*	*Disagree*	*Mostly Disagree*	*Strongly Disagree*

17. The sense of pressure and force using the simulator is realistic.

1	2	3	4	5	6	7
Strongly Agree	*Mostly Agree*	*Agree*	*Neither Agree/Disagree*	*Disagree*	*Mostly Disagree*	*Strongly Disagree*

18. Overall, the simulator is realistic.

1	2	3	4	5	6	7
Strongly Agree	*Mostly Agree*	*Agree*	*Neither Agree/Disagree*	*Disagree*	*Mostly Disagree*	*Strongly Disagree*

Section B

1. Is "force feedback" (feeling contact force) when in the virtual ear canal important?

   Yes **No**

2. Is realistic ear canal geometry important for skill development?

   Yes **No**

3. Is realistic eardrum geometry important for skill development?

   Yes **No**

4. Is realistic simulation of bleeding important for skill development?

   Yes **No**

5. Is the use of realistic colours and textures important for skill development?

   Yes **No**

Figure 19: Questionnaire – Page 4.

6. Is realistic simulation of microscope movement important for skill development?

   Yes **No**

7. Is realistic simulation of the focus of the visual apparatus ("mock microscopy") important for skill development?

   Yes **No**

8. Is it important to simulate procedures for both the left and right ear in order to optimize skill development?

   Yes **No**

9. Is the opportunity to rest your hand on a model of the head while simulating myringotomy important to skill development?

   Yes **No**

10. Is having a sense of one's accuracy while simulating myringotomy important to skill development?

    Yes **No**

Please continue to next page

Figure 20: Questionnaire – Page 5.

Section C

Please circle your response to the question below.

Which of the following statement best describes the simulator's level of difficulty in comparison to a real myringotomy procedure?

Comparative Level of Difficulty

Much Less	**Somewhat Less**	**Equal**	**Slightly More**	**Much More**

As part of our efforts to continue to improve simulation of surgical procedures, we ask that you provide comments specific to both positive and negative aspects of the simulated myringotomy you just experienced. ***Please provide any additional comments you might have in the space below.***

Thank you for your time and input!

Original instrument developed by B. Wheeler, H. Ladak, & P.C. Doyle

Present instrument modification undertaken by L. Sowerby, G. Rehal, H. Ladak, M. Husein, S. Agrawal, & P.C. Doyle

Note: Do not quote without written permission of the authors.

Figure 21: Questionnaire – Page 6.

Chapter 3: Results and discussion

3.1 Implementation

Figure 22 shows the new simulator in use. The user can be seen holding the stylus (pen shaped attachment to the haptic arm) and moving it around to manoeuvre the blade in the scene. The user can press the upper and lower buttons on the stylus to reset the magnification in the scene and reset the simulation respectively. The primary display here is the display seen through the visor. The display was cloned on one of the monitors for the sake of observing the performance of the user.

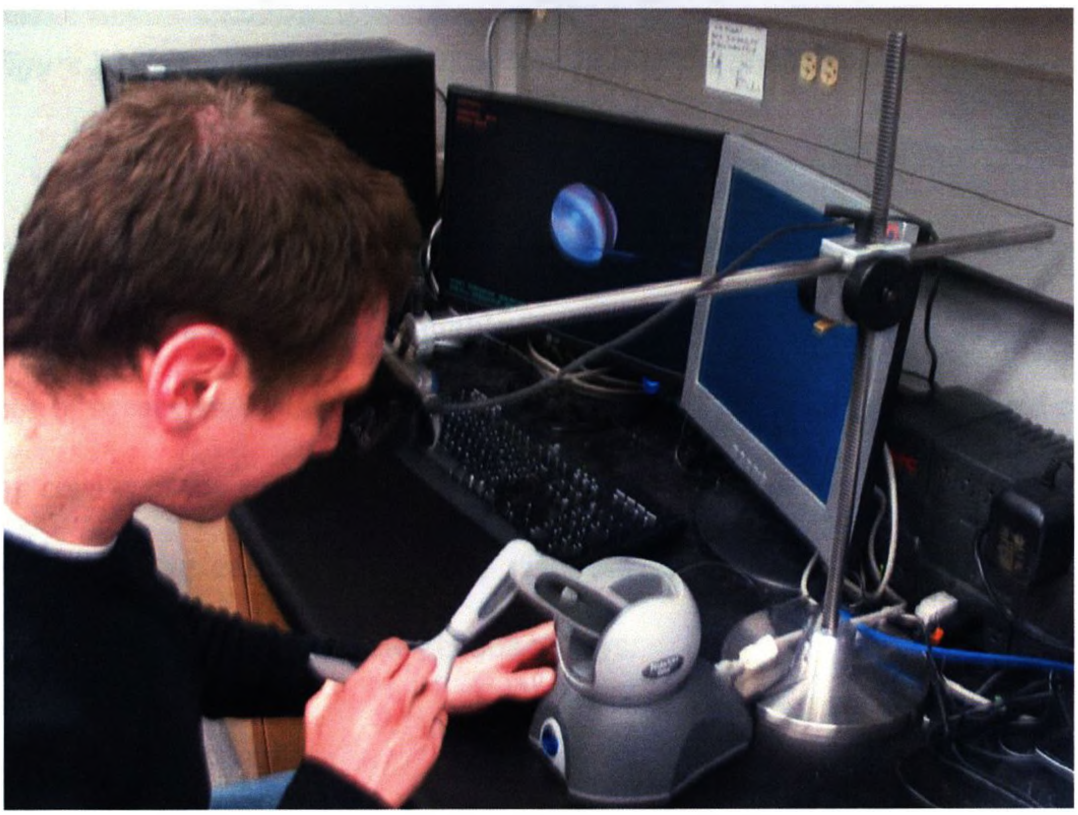

Figure 22: Simulator in use.

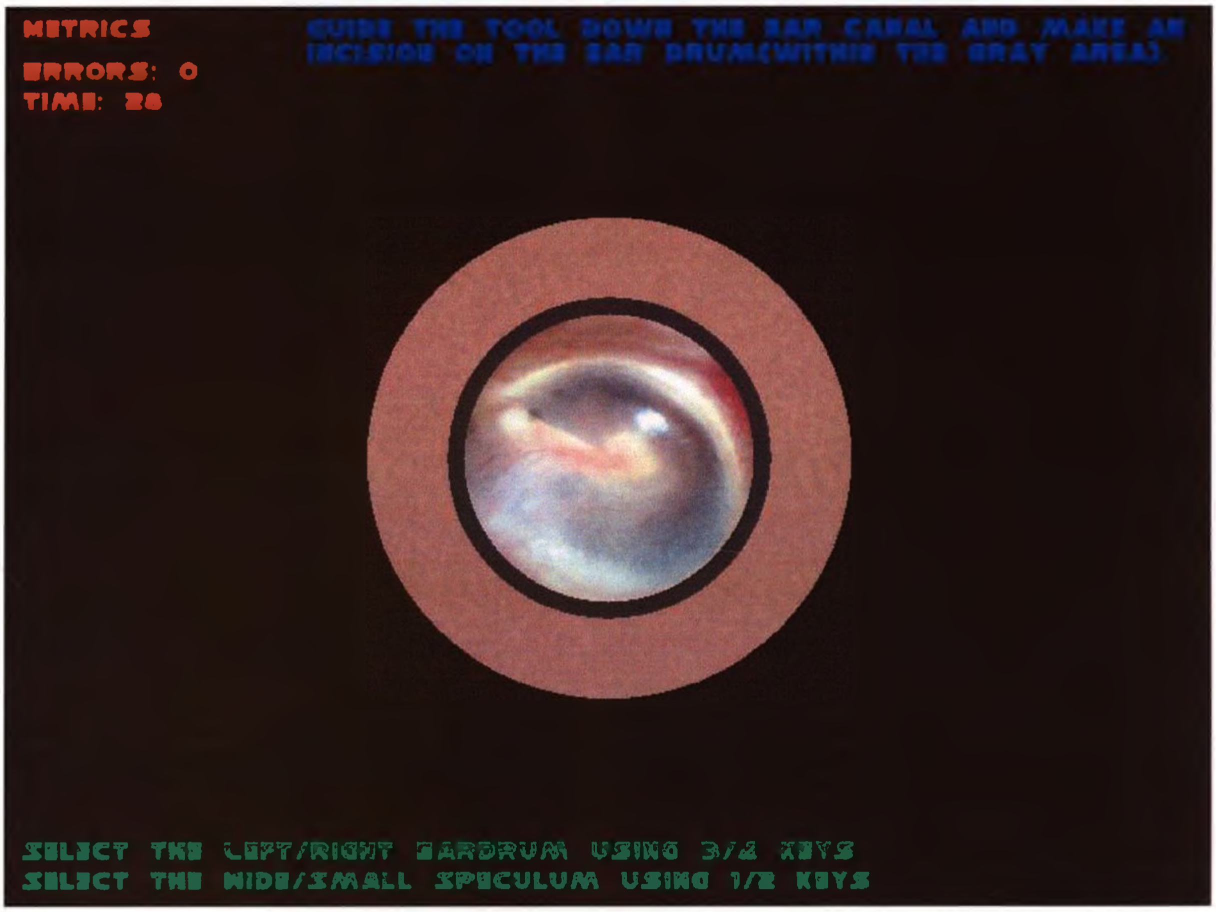

Figure 23: Initial view of simulation. The view of the anatomy that needs to be appropriately adjusted by the user.

Once the scenario is loaded, the user sees the eardrum and the ear canal at low magnification, which is not suitable for myringotomy (see Figure 23). The total number of errors and total time taken for completing the task are displayed on the left top corner of the screen. The user uses the mouse to set the magnification of the scene so that the eardrum is clearly visible. A speculum of appropriate size is selected and positioned using the keyboard keys.

Figure 24: A scenario with left ear and wide speculum selected. The gray area marks the region where the incision is intended.

Figure 23, Figure 24 and Figure 25 show different scenarios where both ears (left and right) and specula (wide and narrow) are selected. In these figures, the black region surrounding the eardrum is the speculum. In Figure 25, the microscope has been adjusted to the appropriate magnification.

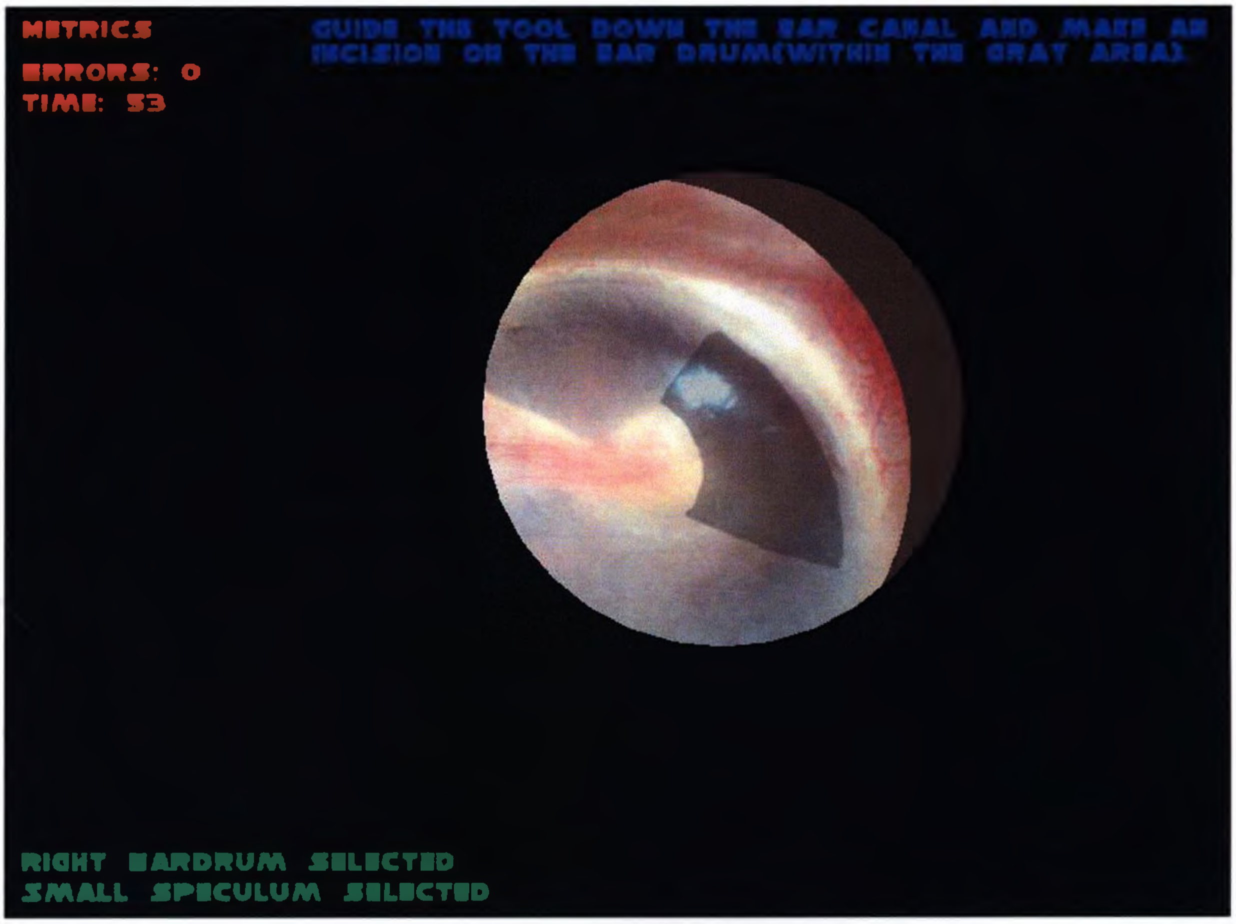

Figure 25: A scenario with magnified view. The right eardrum and small speculum have been selected. The black region is the speculum and the eardrum is visible through it.

Once ready, the user presses the ‘s’ key on the keyboard and the gray area (visual cue for desired region for incision) disappears. As can be seen in Figure 26, a blade is being guided down the ear canal by the user to perform an incision. Total time taken (in seconds) and total number of errors are displayed in the top left corner of the simulation. The simulator increments the error count every time the user accidently nicks the ear canal with the blade or makes an incision outside the gray region.

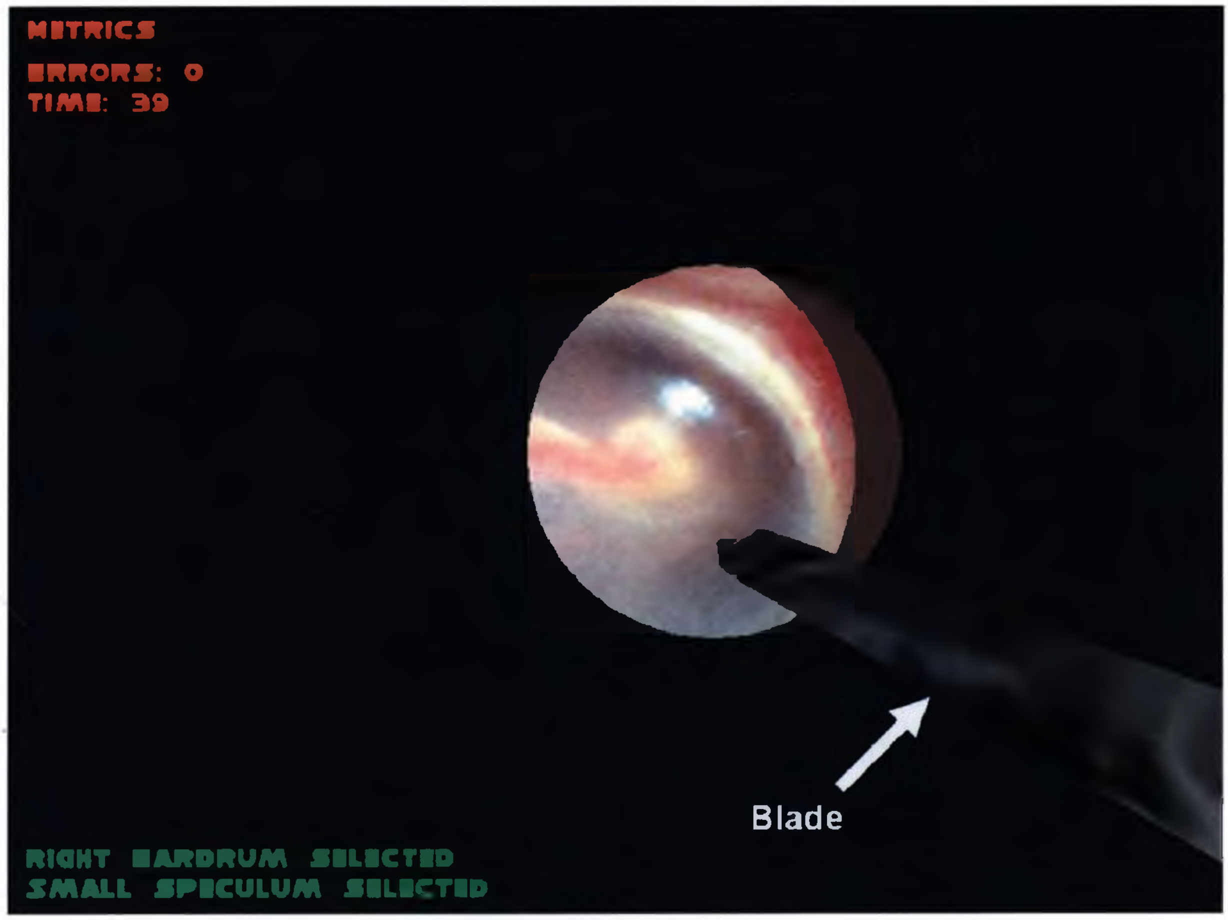

Figure 26: A scenario where blade is being moved around. A blade is been moved into the ear canal and an incision is about to be made on the eardrum.

On touching the eardrum, the user feels a tiny contact force as the blade penetrates into the eardrum. The user moves the blade preferably in the radial direction and completes the incision (as seen in Figure 27). As the blade moves through the eardrum, the simulation draws a red line along the path that the blade traverses. This line represents the incision. A small translucent disc in blue colour also appears on the eardrum at the point of contact of the blade and the eardrum and follows the contact point where ever the blade touches the eardrum surface. This acts as a visual cue for better depth perception by the user and signifies that the blade is touching the eardrum.

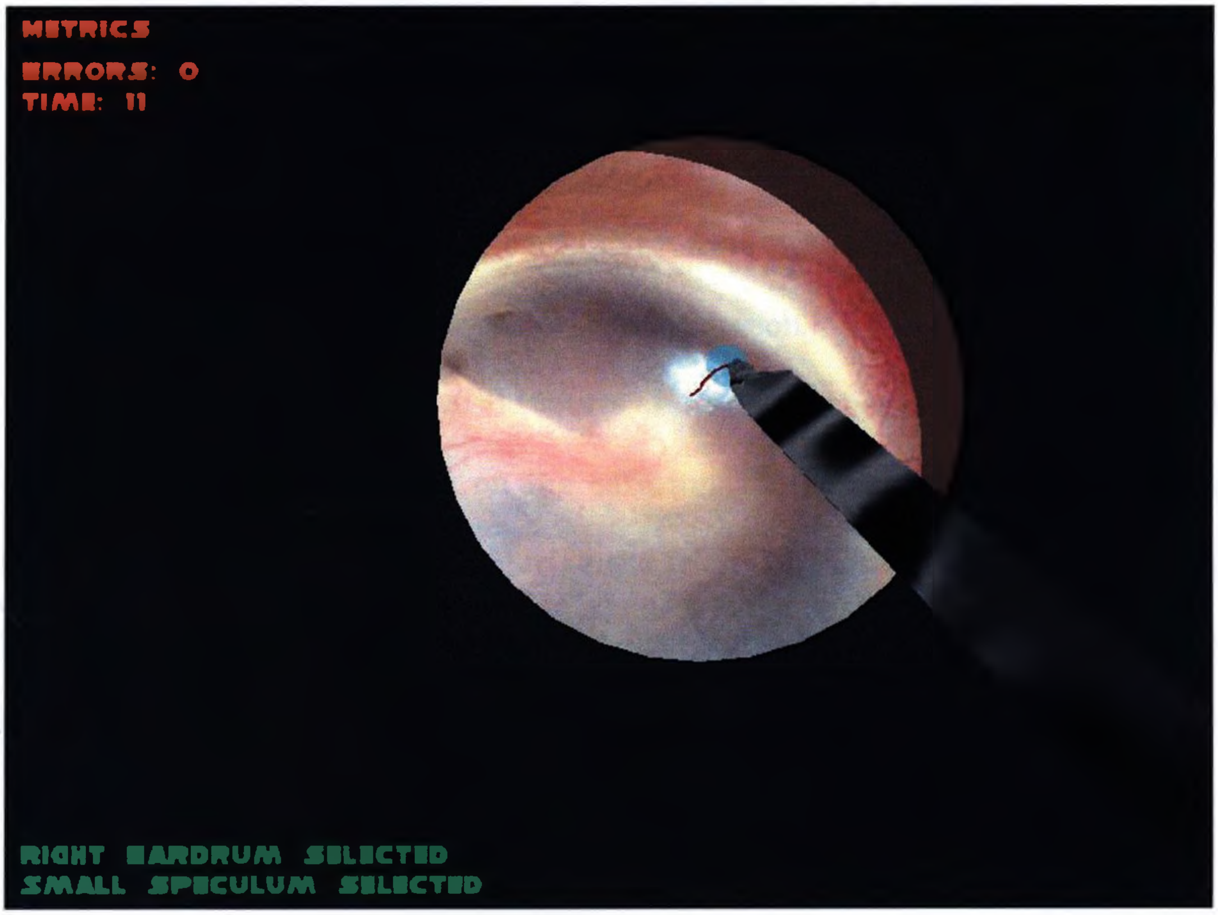

Figure 27: A virtual myringotomy is being performed. The user has selected a small speculum and is operating with a surgical blade in the right ear. An incision being made can be seen as a red line.

3.2 Stiffness parameter estimation

The Intraclass correlation for the five trials for the three surgeons were 0.115, 0.022 and 0.449. Only one of the surgeons had a significantly reliable measure (0.449, i.e., >0.4). However, an ICC of 0.449 is not considered greatly reliable as only 45% of the variation in the data is attributable to agreement of measurement. Ideally, one should accept an ICC of >0.80 as meaningful agreement. The ICC of the surgeons for their five trials averaged together was 0.046. Mean differences between the trials and surgeons were determined. There were no significant differences between trials for two surgeons. The mean difference for one surgeon was found to be significant with $F(3,24)=16.23$ and $p<0.001$ where F refers to the F-test statistic. The mean difference between the surgeons was found to be significant $F(2,18)=132.78$ with $p<0.001$. The mean differences between the surgeons suggest that the reference point from which surgeons evaluate the resistance of the tissue differs from surgeon to surgeon.

Considering the minimalistic nature of the force experienced by the surgeons while performing the incision on the eardrum, the surgeons were found to be perceiving the forces differently during the trials. The potential factors that may have affected the adjustments made by the surgeons during the trials could be one or more of the following. First, the trials were scheduled during different times of the day as per the availability of the surgeon. Factors such as fatigue from the day's work may have played a role in the variation of the adjustments made. Second, the number of myringotomies done around the time of the trial may have an influence. Presumably, if more myringotomies are done around the time of a trial, especially just before a trial, the surgeon will better remember the stiffness of an actual eardrum and will be better able to adjust the stiffness parameter in the simulator. Third, the force feedback experienced by surgeons varies for different types of diseased eardrums. Fourth, the forces can be perceived differently by different surgeons depending on the way the haptic stylus is held. Fifth, the thickness and weight of the stylus pen of the haptic arm (used to mimic the blade) may have resulted in the changed haptic perceptivity and inconsistency of the haptic arm in simulating the small forces experienced by the surgeons. Finally, although the haptic arm used in this work is sufficient for this application, a haptic device with better force resolution would be more suitable for rendering the small forces encountered in myringotomy.

The surgeons also suggested that a visual cue should be provided in combination with the force feedback to augment the feel and realism. This suggestion was incorporated into the simulator by displaying a blue coloured translucent disc at the point where the blade intersected the eardrum. This combination of visual cue along with the tactile feedback was considered better than the tactile feedback alone.

3.3 Face validity study

Responses from all 11 participants were collated for each question of the questionnaire. Scores of less than 4 signify favourable results with lower scores indicating a more effective simulator. Specific to the 18 scaled questions (Section A), the mean, median, mode, standard deviation and minimal and maximal scores for each question are provided in Table 2.

As can be seen, for the majority of questions, participants were highly consistent in their scaled responses. Based on Table 2 and Figure 28, most of the questions revealed remarkable consistency in responses across the 11 participants. When all 18 questions are considered, favourable responses (i.e., scaled scores of 1, 2 or 3) predominated for all questions except for Question 17. In this question, 6 of the 11 responses were provided at 4 (neither agree/disagree) and the remaining 5 were toward the more negative side of the scale (i.e. scaled scores > 5). When all 18 questions are considered (a total of 198 total responses), 21 responses (10.6%)

were judged by participants in a neutral manner (i.e. a "4"). Of the remaining 177 scores, 146 (82.4%) represented favourable responses.

Table 2: Statistical analysis of feedback questions.

Question Part A	*Mean*	*Median*	*Mode*	*Standard Deviation*	*Minimum Scaled Score*	*Maximum Scaled Score*
1	2.36	2	2	1.02	1	4
2	2.27	2	2	0.90	1	4
3	3.36	3	3	1.43	1	6
4	3.09	3	3	1.30	1	6
5	3.27	3	3	1.19	1	5
6	1.18	1	1	0.40	1	2
7	2.27	2	2	0.90	1	4
8	3.27	3	3	2.05	1	7
9	3.27	3	4	1.34	1	6
10	3.72	3	3	1.95	1	7
11	3.63	3	3	1.91	1	7
12	3.27	3	3	1.34	1	6
13	3.18	3	3	1.47	1	5
14	3.45	3	3	1.43	1	6
15	3.09	3	3	1.30	1	6
16	2.45	3	3	0.68	1	3
17	4.0	4	3	1.61	2	7
18	3.81	3	3	1.25	3	6

Finally, an assessment of responses across all questions indicated a Cronbach's alpha of 0.919 demonstrating exceptional consistency across the 11 participants. This finding concurs with the information obtained through the measures of central tendency (Table 2).

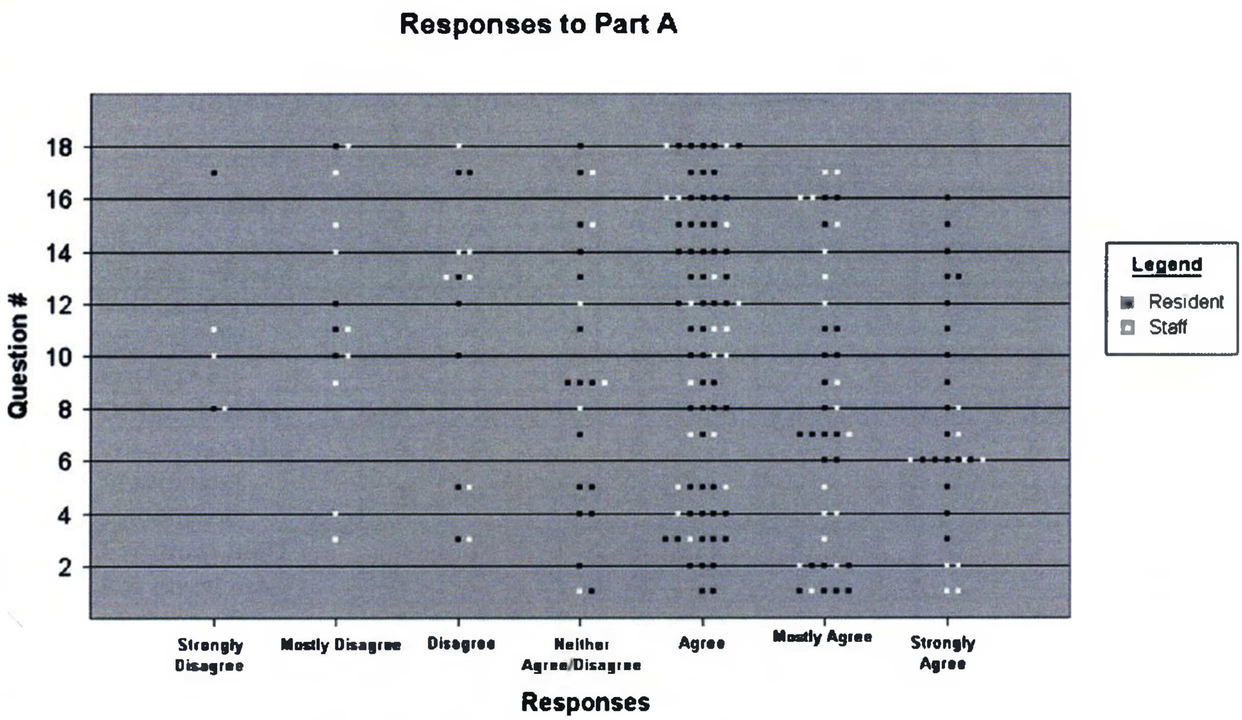

Figure 28: Response chart for Section A.

When the 10 Yes/No questions (Section B) were assessed, 6 of them exhibited a uniform "Yes" response from all participants (Questions 1, 2, 3, 6, 9, and 10 - see Table 3). For the remaining 4 questions in that section, three of them revealed a "yes" response for 9 of 11 participants, and one revealed a "yes" response for 10 of 11 participants. Although a participant's decision on this section of the questionnaire was indeed a binary, forced-choice response, a full 94% of responses indicated an affirmative impression relative to the questions posed. The simulator was felt overall to be "much less" difficult than a surgical myringotomy by 6 participants. Of the remaining 5 participants, one participant each found it "somewhat less", "equal" and "much more" difficult in nature, with 2 participants finding it "somewhat more" difficult. Three of the four practicing otolaryngologists found it "much less" difficult than an actual myringotomy procedure.

Table 3: Summary of the responses from the participants of face validity study.

Ques	Details	Participants										
		1	2	3	4	5	6	7	8	9	10	11
A1	Structured prior	3	2	2	4	3	2	2	2	1	4	1
A2	Independent opportunities	3	3	2	3	4	2	2	2	1	2	1
A3	Basic H-E	3	3	1	5	3	3	3	3	2	5	6
A4	Devlp. of skills	4	3	1	4	3	2	3	3	2	3	6
A5	Improving skills	4	3	1	5	3	3	3	4	2	3	5
A6	Anatomical placement	2	1	1	2	1	1	1	1	1	1	1
A7	Ear drum real?	4	3	1	2	2	2	2	2	1	3	3
A8	Ear canal real?	3	3	1	2	7	2	3	3	1	7	4
A9	Virtual knife?	4	3	4	4	3	4	2	1	2	3	6
A10	Models micro	6	5	1	3	2	3	3	2	3	7	6
A11	Visual apparatus	6	3	1	4	2	3	3	2	3	7	6
A12	Mvmt rep?	5	3	1	3	6	3	3	3	2	3	4
A13	Realism?	4	3	1	5	1	3	3	3	2	5	5
A14	Would use?	3	4	1	3	3	5	3	3	2	5	6
A15	Recommend use?	3	3	1	4	3	3	2	3	2	4	6
A16	Visual simulation	3	3	3	3	2	3	2	1	2	3	2
A17	Pressure and force	5	4	3	5	7	4	3	3	2	2	6
A18	Realistic	4	3	3	3	6	3	3	3	3	5	6
B1	Force feedback	1	1	1	1	1	1	1	1	1	1	1
B2	Earcanal geom	1	1	1	1	1	1	1	1	1	1	1
B3	Eardrum geom	1	1	1	1	1	1	1	1	1	1	1
B4	Simulation bleeding	1	1	1	1	0	0	1	1	1	1	1
B5	Realistic colors	1	1	1	1	0	1	1	1	1	0	1
B6	Micro mvmt	1	1	1	1	1	1	1	1	1	1	1
B7	Focus of visual apparatus	1	0	1	1	1	1	1	1	1	0	1
B8	L and R ear	1	1	1	0	1	1	1	1	1	1	1
B9	model head	1	1	1	1	1	1	1	1	1	1	1
B10	Accuracy of cut	1	1	1	1	1	1	1	1	1	1	1
C	Level of diff	1	2	1	5	1	4	3	1	1	1	4

Face validation is the first step in determining a training system's ability to accurately depict the procedure being simulated. The results in this study demonstrate good-to-excellent face validity in most areas. In particular, positive responses were present for the anatomic detail of the eardrum, and for the feeling that the simulator would help with the development of hand-eye coordination, making an accurate incision and improving microscope skills. The worst scores were related to the simulated ear canal and the respondent's perception that force and pressure were not sufficiently realistic. Even more encouraging were the results from part B. The participants agreed overwhelmingly that ear canal and tympanic membrane geometry, force and pressure sensation, simulation of bleeding and feedback regarding errors would make the simulator more realistic and useful.

Potential flaws with the face validation of the simulator include institutional bias as all participants were residents or surgical staff at the institution where the simulator was developed. In contrast, however, this bias may also lead to highly critical feedback in that developers and staff physicians have strong working ties and may more openly express such concerns. This open feedback was especially apparent in the request for additional comments at the end of the questionnaire. In this section, participants noted that microscope manipulation and head positioning are skills not currently simulated, and that using the speculum as a fulcrum is an important feature to include in future refinements of the simulator. The fact that programming the eardrum and the incision with deformations would add to the realism of the simulator was also indicated in the feedback received from the surgeons. It was also suggested that the eardrum be modelled as completely compliant and the middle-ear and the ear canal as rigid bodies.

Chapter 4: Conclusion and future work

A virtual reality simulator was designed that simulated magnification adjustment, speculum positioning, tool navigation and incision making on the eardrum. Tool jitter which existed in a previous version of the simulator using optical tracking was eliminated with the implementation of the haptic arm. Moreover, force feedback from the eardrum during the simulated incision was implemented.

Based on the results from the face validity study, the current 3D myringotomy simulator demonstrates good-to-excellent face validity. There was positive response by the surgeons towards the simulator. They would recommend its use in a training environment. These suggestions are borne out through the results obtained via our proprietary questionnaire that addressed multiple areas specific to the simulation task. The face validity testing was also successful in highlighting aspects of myringotomy for inclusion and for carving the future path for improvements in the myringotomy simulator. Based on the feedback from the surgeons, there are significant improvements needed in the future.

Based on these suggestions, the eardrum may be better modelled as completely compliant. The middle-ear structures (ossicles) and the ear canal should be modelled as completely rigid. In the current simulator, the ear canal was represented by a uniform cylinder, textured with brown color (representing skin). It was evident from the feedback that the ear canal model lacked realism. In the future, the cylinder will be replaced with a mesh model that is based on computed tomography images of real ear canals. These meshes will be textured using endoscopic images of real ear canals in order to achieve photorealistic rendering.

Adding deformations to the eardrum would be the next step in further development of the simulator. The surgeons who used the simulator during the face validity study suggested that adding the deformation effect to the virtual eardrum could give a feeling as naturally perceived during live myringotomy. Thus it may be more appreciated by the surgeons when they touch the eardrum with the blade. It would also improve the interactive manipulation of the virtual eardrum. Methods of implementing the deformations like finite-element analysis or mass-spring modelling will be investigated and implemented. Once the deformable eardrum is implemented, the formation of the incision will need to be modelled. Visual cues like deformation can improve the user's perception of depth of penetration of the middle-ear cavity.

The mock microscope also needs to be redesigned. The original design intent was simply to provide a realistic viewing mechanism. However, study participants indicated that positioning and orienting the microscope is a difficult skill to learn. In the current simulator, the visor was attached to an aluminum stand. Although the stand was adjustable to the appropriate position, the adjustments to the stand were done in a way that did not effectively simulate the process of adjustments in an actual microscope. In real life, a surgeon would hold the microscope eye piece and move it around appropriately to the appropriate position near the head. Whereas with the mock microscope, the adjustments were done by rotating the wheels attached to the gears that are located on the joints of the aluminum rods. This helped to adjust the height and distance of the eyepiece from the head. To improve the representation of the microscope in the simulation context, a real microscope which consists of a mechanical arm attached with an eye piece on one end will be retrofitted with a visor so that the visor can be moved freely in all directions. Likewise, the visor would need to be adjusted in a similar way as is done by surgeons during live surgery.

For the face validity of the current simulator, a Styrofoam block was made and used to simulate the patient's head. To perform myringotomy, the surgeons rest their non-dominant hand on the head (close to the ear) of the patient to hold the speculum that has been positioned in the ear canal. The head provides support to the hand and makes the grasp of the speculum steady. While performing the virtual myringotomy, this block acted as the head and was positioned in front of the haptic arm. The virtual eardrum and the ear canal were positioned within the block. Although the block mimicked the human head in terms of providing resting support to the surgeon, it did not provide enough realism. In the future, a physical model of the head would be acquired to better simulate the head of a patient.

In the future, we would use a higher fidelity arm capable of rendering small forces. Initially only SensAble devices were available in our laboratory. They are mechanical devices using motors and encoders and have considerable inertia and static friction. Recently magnetic levitation haptic interface devices have been developed and are commercially available. The Maglev 200 System (Butterfly Haptics, Pittsburgh, PA) [36] is a haptic device interface which will be used in future. It is free from any mechanical linkages and consists of a single moving part (flotor) levitated by magnetic fields [37]. It has zero static friction and zero mechanical backlash. This is very important to achieving high fidelity interaction with virtual anatomy.

Once these areas have been addressed, the simulator will be tested for internal and construct validity. This is where the extent of the simulator's ability to actually improve the skills of surgeons at myringotomy will be determined and analysed. It is important to test the simulator for construct validity as it is a benchmark that has to be achieved by a tool to be able to gain acceptance in residency training programs. Participants during the face validity study indicated their willingness to use the tool for training on hand-eye coordination. Ultimately, this simulator has excellent potential to show actual virtual-reality to operating room skills transference and become a useful tool in the training of future otolaryngology residents.

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