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| University of toronto |
| Developing Instruments to Facilitate Endoscopic Ear Surgery |
| Thesis Progress Report |
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| **10/5/2017** |

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# Introduction and Literature Review

## 1.1. Middle Ear Surgery:

Middle ear surgery is a type of ear surgery, or otological surgery, that is done to repair the ear drum (tympanoplasty), hearing bones (ossiculoplasty) and remove tumors (cholesteatoma) that grow within the middle ear and mastoid. This type of surgery is challenging as it requires precise, microscopic movements, without touching the facial nerve which is present in the surgical field.

### 1.1.2. Microscopic vs. Endoscopic Ear Surgery:

Traditionally, ear surgery is performed by cutting away tissue through a postauricular incision, as shown in Panel 1 of Figure 1, to access the middle ear space and uses a microscope to access and visualize the surgical field. This is an invasive method of surgery, resulting in a scar. A new approach to ear surgery involves inserting an endoscope through the ear canal, a natural orifice, to provide direct access and a wide angle view into the middle ear. Using an endoscope reduces the time required to gain access, drill bone for exposure and close during middle ear surgery and allows visualization of hidden recesses within the middle ear including: the sinus tympani, anterior and posterior epitympanum and hypotympanum [1][2][3][4]. As well, the endoscope allows visualization past the shaft of the instrument, such as the drill, which is a problem during microscopic surgery [5]. Panel 3 A and B in Figure 1 shows the difference in operating room setup and view of the microscope vs the endoscope. Panel 3 C and D in Figure 1 show the difference in view between the microscope and endoscope.

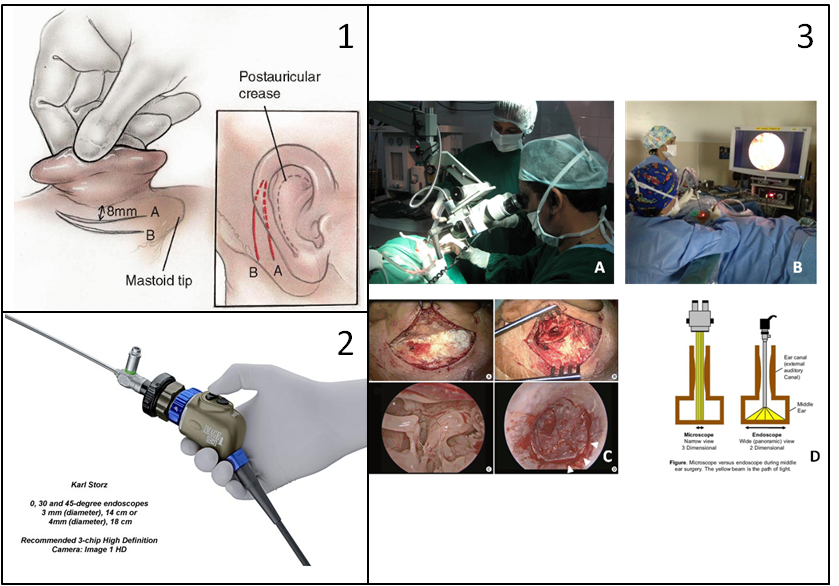
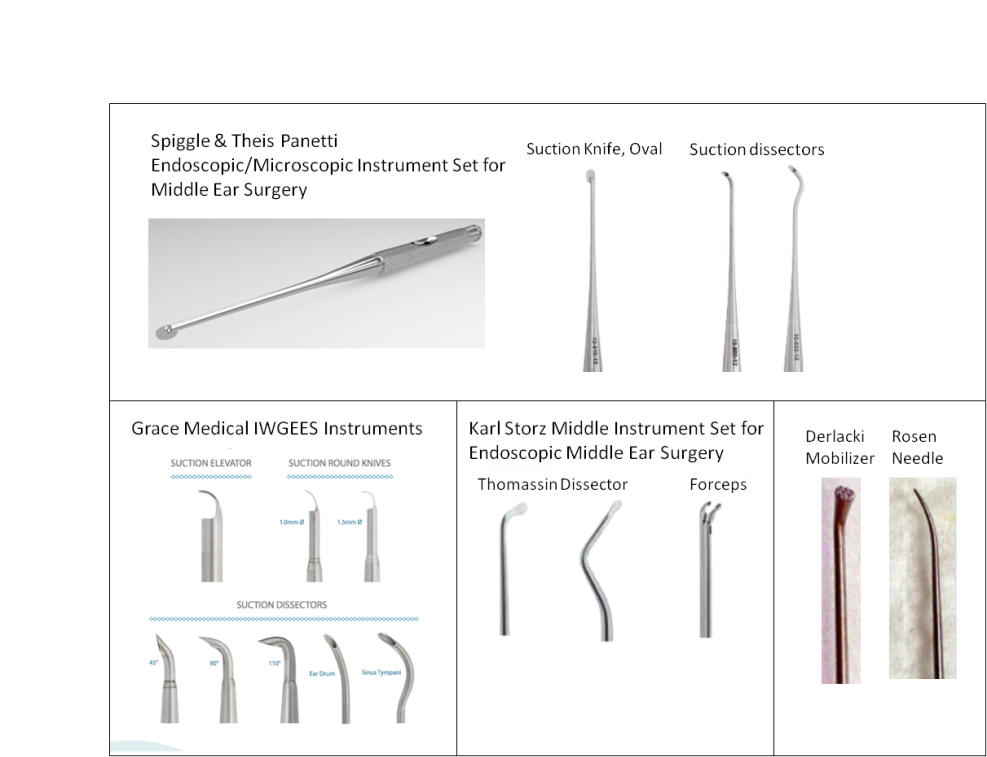


Figure 1: Panel 1 shows the slits made to access the middle ear for invasive microscopic ear surgery [6]. Panel 2 shows an endoscope that is attached to a high definition camera, which is used to visualize the surgical field during TEES [7]. Panel 3: The top two images (A&B) show the difference between the operating room setup for microscopic ear surgery and endoscopic ear surgery [8], [9]. The bottom two images (C&D) show the difference in view between microscopic and endoscopic approaches. C is from Choi et al. who shows the difference in view between microscopic (top two squares of C) and endoscopic ear surgery (bottom two squares of C). The figure on the right shows the difference in field of view between microscope (left square of D) and endoscope (right square of D) [10], [11].

Despite the enthusiasm of some otologists, endoscopic ear surgery has a low adoption rate[12][13].  The principal challenge with totally, transcanal endoscopic ear surgery (TEES) is that a one-handed surgical technique is required as the endoscope is held in the other hand[12][9]. During traditional surgery, the non-dominant hand usually maintains suction and removes blood from the operative field while the dominant hand performs the delicate maneuvers [9]. Otologic instruments were developed for two-handed microscope-guided surgery so they are not optimized for the TEES environment. As otologists have been trained and gained experience in microscope-guided ear surgery, they have developed techniques with the according instruments and have become accustomed to a two-handed surgical approach. By learning different surgical techniques and gaining experience with the endoscope, most surgeons find that they can complete more cases totally endoscopically [14][12][1][9]. TEES reduces the invasiveness of ear surgery, however it is a relatively new technique with new tools currently being developed and sold [3].

## 1.2. TEES Instrumentation:

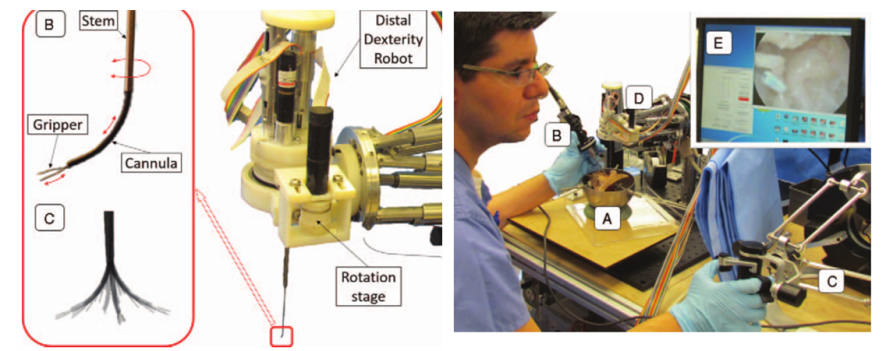
Figure 6 shows different sets of endoscopic ear surgery instruments, many of which are presented by Badr-El-Dine et al. [3]. Only one instrument is used at a time and the ear canal restricts the movement of instruments thus many have curved tips in order to reach structures. The Spiggle & Theis Panetti set incorporates suction along the shaft of its instruments in order to allow for two functionalities, suction and dissection or suction and cutting, in one tool, eliminating the need to switch between a suction instrument and dissection instrument or knife [15]. Grace Medical and Karl Storz have similar suction capabilities but the principal investigator (PI) who is an otologist and has practiced TEES for the past 12 years has preferred the curvature of the Panetti set [16], [17]. The Thomassin dissector, Derlacki Mobilizer and Rosen Needle are frequently used by the PI to position grafts and dissect tissue as their respective tip shapes are preferred to manipulate tissue effectively. The Rosen Needle tip curvature allows for dissecting tissue that is attached to the ear drum as the tip shape compliments the curvature of the ear drum, and when the needle is rotated axially, the tip follows a trajectory which is useful to manipulate tissue without having to translate the tool which would cause the instrument shaft to collide with the endoscope or ear canal wall. Technological advances in the design of the endoscope, camera and suction dissection instruments have lead to incremental stepwise jumps in the TEES learning curve [3]. However, the PI has expressed that rigid curved and straight instruments are unable to reach around corners within the middle ear space, where cholesteatoma is visible. Access to these areas requires the surgeon to remove bone from the patient. A steerable instrument with an articulating tip would be able to reach these hard-to-access areas and would make it possible for the surgeon to remove cholesteatoma within the recesses of the middle ear without taking away excess bone. In order to further develop the new technology and instruments to facilitate TEES, it is important to understand the specific challenges experienced during TEES. There are opportunities for new advancements in instrumentation and it is proposed that in order to facilitate TEES, the needs of surgeons and current limitations of tools must be determined.

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**Figure 2:** Current instruments used in TEES.

## 1.3. Existing solutions to improve access for minimally invasive middle ear surgery

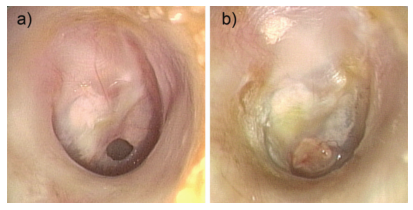
Yasin et al. presents a robotic tool that aims to allow middle ear surgeons to perform precise tasks and access hard to reach anatomical targets using a custom-designed robot that controls grippers that are attached to a shape-set nitinol tube with a fixed radius of 7.5mm at the tip [18]. The nitinol ‘cannula’ can be retracted into a stainless steel ‘stem’ and when the tool needs to reach something, the cannula extends out of the stem to curve and reach the target. This is similar to the controllable flexible instrument due to the curved tip that can be manipulated however, the robotic instrument’s tip radius of curvature cannot be adjusted to reach the desired target, i.e. cholesteatoma hidden behind tight corners like the sinus tympani. This concentric tube robot technology is also developed by the lab, however, the notched tube wrist was chosen as the articulating mechanism due to its compactness and smaller radius of curvature achievable that is required to reach around corners inside the miniature anatomy.

**Figure 3:** Yasin et al. developed a steerable robot-assisted micromanipulation device for the middle ear. The left panel shows the robot with the tool extending downward out of it, and the right panel shows the surgeon teleoperating by gripping the ‘distal dexterity robot’. The gripper consists of forceps, attached to the cannula which is a nitinol tube which is shape set to a permanent radius of curvature of 7.5mm. The cannula can retract into the stem where the instrument assumes a straight position. As the cannula extends out of the stem, the tip assumes a curved shape [18].

Furthermore, Fichera et al. presents a miniature robotic endoscope that is able to pass through the Eustachian tube and visualize the middle ear using a bendable tip that uses a robotic wrist mechanism [19]. This group used patient CT scans rendered into 3D computer models to plan the path for the instrument to take to reach the middle ear through the Eustachian tube and optimized the geometry of the wrist to compliment this path. The endoscope tip was able to visualize the sinus tympani when inserted in a phantom model, which is a hard-to-access region within the middle ear. This tool is designed to be a minimally invasive diagnostic tool for middle ear diseases by eliminating the need to cut and lift the ear drum to visualize internal ear structures and provides inspiration for the design of a similar tool for TEES. Although it is a steerable instrument and able to access hard to reach areas, its purpose is visualization and performing a surgical procedure would require the insertion of another instrument with a tip that is stiff enough to perform dissection and manipulation of structures. As well, the instrument geometry is designed to enter through the Eustachian tube, not the ear canal.

Figure 4: Steerable endoscope to visualize the middle ear. 8 notches in a Nitinol Tube of inner diameter 1.60mm and outer diameter 1.80mm allow the tip to bend by pulling on a cable attached to the most distal cutout. An HD chip-tip camera and fibre-optic light sources are located at the leftmost end of the tube.

## 1.4. Cholesteatoma removal and Tympanoplasty

****Two particularly challenging procedures for TEES are cholesteatoma removal and tympanoplasty. Cholesteatoma is an abnormal skin grown that occurs behind the ear drum (tympanic membrane) inside the middle ear and its growth can damage the ossicles and/or facial nerve and cause temporary or permanent hearing loss. TEES to remove cholesteatoma is challenging because the tumors are usually located in areas that are visible through the endoscope but inaccessible via current straight and rigid tools, thus requiring the surgeon to drill bone to access those areas with straight tools. Tympanoplasty is the reconstruction of a perforated ear drum, by placing a synthetic (animal-derived) or cartilage graft on it. It is challenging to maneuver and position the graft using TEES. As these are challenging procedures, they will be the focus of this research for evaluating new developments to improve TEES.

**Figure 5:** These images, taken from James et al., are endoscopic photographs. (A) shows a perforated ear drum and (b) shows the postoperative result, 2 months after tympanoplasty surgery that used a cartilage graft [20].

# 2. Objectives/Hypotheses

This project aims to design and evaluate a new instrument that would address the challenges faced by endoscopic ear surgeons. To do this, the project is composed of two phases: phase one is the needs analysis study which surveyed experienced otologists about instruments they would like to be developed and phase two is developing and testing a prototype instrument to address the needs of surgeons.

## Phase 1: Understanding the Needs of Endoscopic Ear Surgeons

We hypothesize that otologists need better instrumentation to facilitate specific challenges posed by TEES. Further, we hypothesize that otologists’ TEES experience and use of instrument sets designed specifically for TEES will affect their need for different challenges. We conducted a mixed-methods study to explore these hypotheses.

## Phase 2: Prototype Development

Based on input from the needs analysis study, we hypothesize that an instrument with a steerable tip can reach areas visualized by the endoscope that current tools cannot. Furthermore, we hypothesize that an instrument with a steerable tip with added suction or added laser fibre will be beneficial for surgeons performing TEES.

# 3. Methods

## Phase 1: Needs Analysis Study

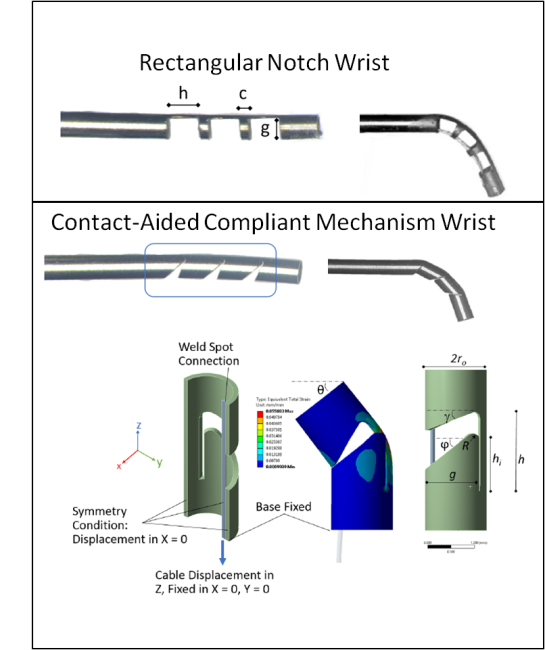
Please refer to the attached paper, to be submitted to the Otology and Neurotology journal within the next month, entitled “The Current Limitations and Future Direction of Instrument Design for Totally Endoscopic Ear Surgery: A Needs Analysis Survey.”

## Phase 2: Developing an Instrument for TEES

## 3.1. Instrument Design

From the needs analysis, it was determined that the challenge that exhibits the greatest need for better instruments is reaching structures visualized by the endoscope. From the study, the use of a TEES instrument set did not significantly affect the need for an instrument that can reach structures visualized by an endoscope, thus it can be inferred that current TEES instruments are not enabling enough reach. An instrument with a tip that can assume varying levels of curvature through the surgeon’s control while in the operating field was designed, prototyped and is undergoing validation testing to address this need. The instrument’s design can be broken down into two components: the tip and the handle.

## 3.1.1. Steerable Instrument Tip Design: Wrist

****The CIGITI lab develops notched tube compliant wrists which define the underlying mechanism of the controllable flexible instrument, see Figure 10. It is a one degree of freedom compliant joint with notches cut into a nitinol tube. Nitinol is a superelastic material that is used for this application as the material properties allow it to bend into a curve and return elastically to its original shape, i.e. with no plastic deformation of the tube [insert citation]. Notches in the tube allow the wrist to have greater flexibility and the notch geometry can be customized to achieve the desired arc length and radius of curvature. The controllable flexible instruments presented here have a rectangular notch geometry and a compliant contact aided mechanism (CCM) geometry. The paper presenting these wrists “Design of a Contact-Aided Compliant Notched-Tube Joint for Surgical Manipulation in Confined Workspaces” was co-authored by myself and is to be published in the ASME Journal of Mechanisms and Robotics.

The rectangular notches are easy to machine in the CIGITI lab by myself using a micromilling machine. The CCM is laser cut and increases the strength of the wrist, while achieving the same bending angle compared to the rectangular wrist [insert citation]. The CCM wrist is beneficial for TEES as it enables a stronger, stiffer tip that would not break as easily be able to handle/dissect tissue without being flimsy.

**Figure 6:** Eastwood et al. describes the two wrists that are presented in this report. The top panel shows the simple, rectangular notched wrist geometry. This is the geometry used for manufacturing prototype 1. The bottom panel shows the contact-aided compliant notched tube, which was laser cut into a nitinol tube to manufacture prototype 2. A cable is attached at the ‘weld spot connection’ and pulling on the cable (downward as shown in the image) causes the joint to bend.

## 3.1.2. Steerable Instrument Handle Design:

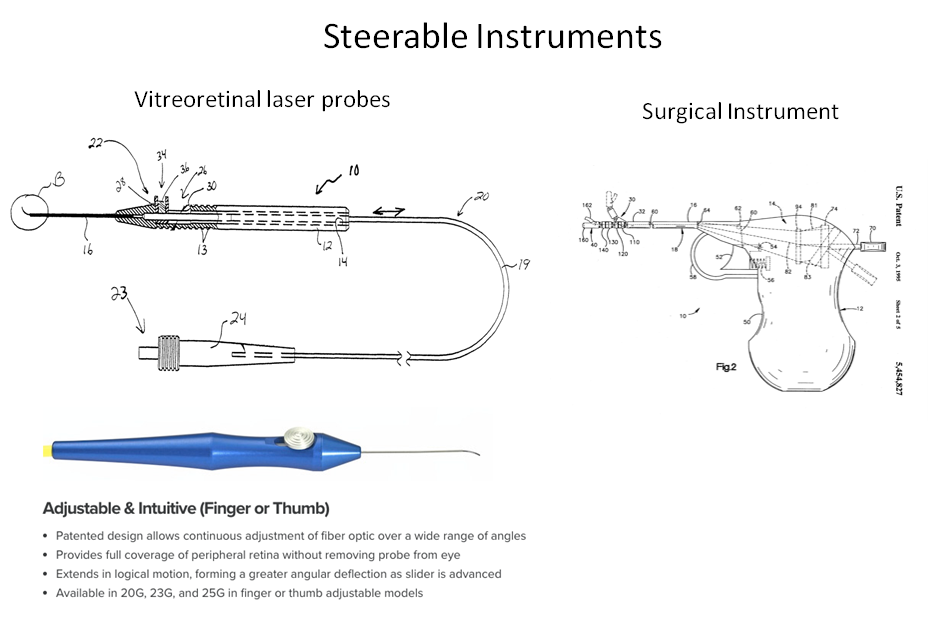
By watching the PI perform TEES cases and interviewing the PI and his colleagues at the 2016 Endoscopic Ear Surgery Course in Toronto, it was determined that a tool that can be held like current instruments would be best suited for the new TEES instrument as the surgeon would not have to learn anything new and would be able to easily adopt the new tool. The goal of the new TEES instrument would be to help the surgeon perform TEES, not frustrate them into learning how to maneuver and manipulate a new instrument. There are many steerable instruments on the market, two of which are shown in Figure 7. These are instruments where the handle design would be suitable for the new TEES instrument and both types were prototyped, but the PI preferred the feel, form and function of the handle similar to the vitreoretinal laser probes, see Figure 7.

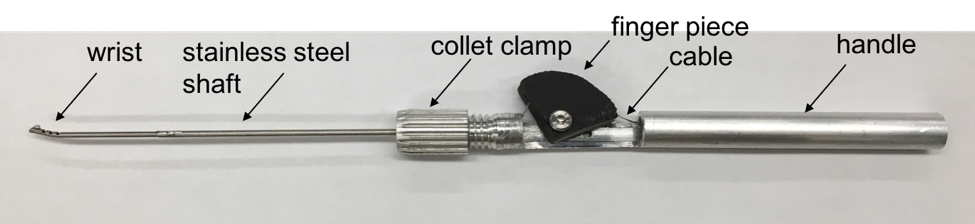
Figure 7: These are two examples of current instruments that are steerable. The vitreoretinal laser probes are used to deliver laser energy to the retina for therapy. The slider at the handle allows the surgeon to push out the preshaped 90o nitinol tip. The surgical instrument is a manually engageable handle + steerable tip with pin joints [21], [22].

## 3.1.3. Instrument Development:

The instruments developed will aim to satisfy three objectives: reaching structures visualized by the endoscope, suction blood and fluid, orient a laser fibre and dissect tissue. The first objective is the primary objective as it is the surgical challenge that exhibits the greatest need for better instruments by TEES surgeons. Suctioning blood and fluid while performing another function (i.e. reaching, and dissecting) mimics the Panetti instrument set, which is preferred by the PI. The PI commonly uses a laser to ablate tissues where cholesteatoma was residing in order to ensure it does not recur by burning any residual cholesteatoma cells [23]. The PI usually bends the laser fibre so that it can be aimed at the intended target; orienting the tip using a steerable instrument would make it easier to laser the target as the fibre would not have to be extracted from the ear canal, bent and then put back in rather, the laser can be oriented at the surgical site. Dissecting tissue is a surgical functionality that is important

## 3.1.3.1. Objective 1: Reaching Structures Visualized by the Endoscope – Instrument Wrist and Handle Design

The wrist mechanism aims to satisfy the objective of reaching structures visualized by the endoscope. The wrist was manufactured using a nitinol tube, outer diameter (OD) = 1.24mm, inner diameter (ID) = 1.03mm. This tube was chosen as its ID is greater than the ID of a 19 gauge sucker, which is the smallest diameter sucker used for TEES by the PI. The nitinol notched tube was laser cut in the CCM pattern by Pulse Systems, USA. Refer to Figure 8 for a picture of the instrument. The nitinol wrist was soldered to a stainless steel shaft that is clamped in a collet, using a collet clamp, at the distal end of the handle. The handle was machined so the collet clamp can be threaded onto the distal end and there is room for the finger piece to rotate. The cable, soldered to the tip of the wrist, runs along the tube and is clamped in the finger piece.

******Figure 8:** Controllable flexible instrument: reaching prototype. The wrist consists of notches milled into a nitinol tube, connected to a stainless steel shaft that is clamped onto the handle that consists of a finger piece that controls the cable displacement of the cable attached to the nitinol wrist. Moving the finger piece back causes cable displacement and thus wrist actuation.

To finalize the design of the wrist such that it will reach the areas of interest within the middle ear during TEES, a simple experiment was conducted to find the appropriate range for radius of curvature and arc length of the wrist required to reach difficult-to-reach areas within the middle ear. Fichera et al. described the process used to create a steerable endoscope, < 2mm in diameter like the instrument prototype, with a notched nitinol tube wrist and an HD camera mounted on the tip [19]. In order to determine the appropriate curvature of the wrist, they generated 3D models of patient middle ear space by CT scan image segmentation. On these models, target points for the endoscope were identified and the optimal paths to reach the target points was computed using a computer software developed by the research group. These paths maximized visual coverage of the sinus tympani (area where cholesteatoma generally recurs), and the associated bending angle and arc length was calculated as shown in reference [2] of the paper. They used a nitinol tube which is larger than the proposed tool (OD = 1.8mm, ID = 1.6mm) which validates that this tube size will fit inside the middle ear space.

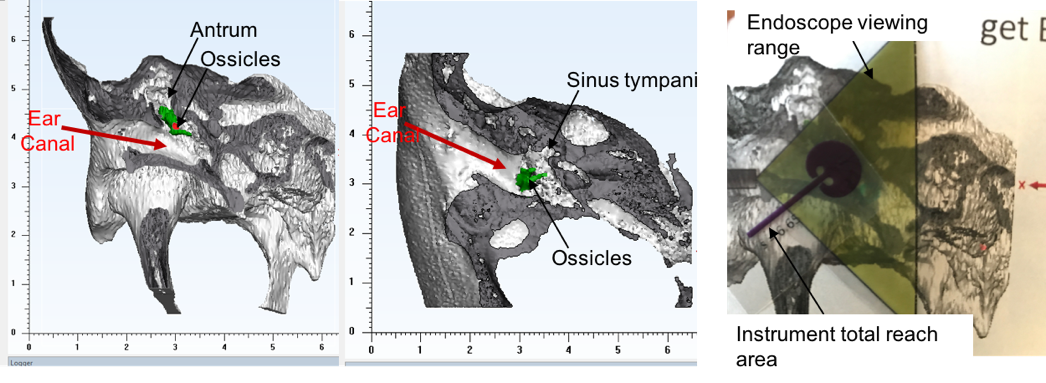
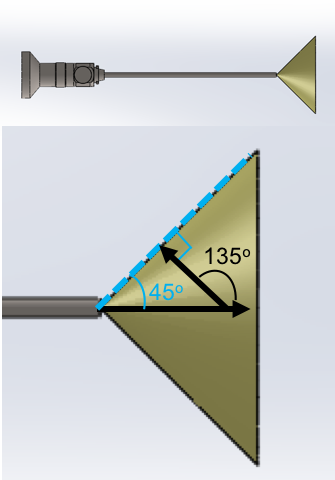
To determine the approximate, appropriate range of motion for the proposed tool to reach in difficult to reach areas within the middle ear during TEES, a simplified, modified approach, inspired by the Fichera et al. study was used. The range of arc length and radius of curvature needed to be identified. The PI provided 9 CT scans from patients with difficult TEES anatomy where bone had to be removed to access the cholesteatoma to remove it. The CT scans were segmented using Materialise Mimics and 3-Matic image segmentation software. 3D models of the patients’ temporal bone were rendered and within these, specific anatomy: the sinus tympani and antrum were identified, see Figure 9. ****The next step was to determine the range of arc lengths for the new tools, see Table 1. The radius of curvature is bound by the outer radius of the tube: minimum radius of curvature = 2 X tube OD. Based on this, a sketch of the range of articulation for the tool from minimum radius of curvature to straight was rendered for different arc lengths. Dahm et al. reported the anatomical measurements on 60 cadaver specimens, and reported that the average distance between the promontory and tympanic spine is 7.48mm for all specimens and this distance doesn’t change with age [24]. This describes the maximum arc length that is limited by the anatomy of the middle ear as this is the distance between the endoscope at the medial end of the ear canal where the middle ear begins and the promontory which is a boney projection, see Figure 11. This distance will be used to define the max arc length of the tool as it is approximately the length of the middle ear and a longer instrument would not fit within the middle ear. Using Matlab, 10 arc lengths were randomly generated to span the range 2.92-7.5mm and these were used to generate a 2D sketch of the workspace/reaching area of a wrist with that arc length sweeping from radius of curvature 1.24 mm to straight. The desired bending angle is 135o, which allows the instrument tip to access a region that is on the boundary of the 0o endoscope, see Figure 10. These were superimposed on the cross sections of the 3D models to select the parameters for the next prototypes. The 2D tool range of articulation sketch, 2D endoscope viewing angle and anatomy were printed and overlaid to determine the appropriate arc lengths to reach the targets, see Figure 9. A smaller arc length yields a stiffer tip, which is desirable for dissection and better control of the instrument. Since the anatomy was variable, the minimum and maximum arc length were both desirable as the minimum would allow for dissection with a stiffer tip and the maximum would allow for maximum reach.

Figure 9: 3D virtual model of temporal bone anatomy used to identify structures for the new tool to reach. The ossicles (three hearing bones) are coloured in green. The ear canal is the channel indicated by the red arrow. The sinus tympani and antrum are shown and are the hard-to-reach areas where cholesteatoma is often found. The image on the right shows the 2D range experiment. The ‘instrument total reach area’ is a 2D area that describes the range of motion of the tip when it is articulated from totally bent to straight. The endoscope viewing range is shown in yellow, which highlights the area visualized by the 0o endoscope.

Figure 10: 0o Endoscope viewing range. It shows that in order to reach the boundary of the viewing range, a tool tip would need to be oriented 135o from straight.

Table 1: *Radius of Curvature and Arc Length Range Calculations*

|  |  |  |
| --- | --- | --- |
|  | **Radius of Curvature (Rc)** | **Arc Length (s)** |
| Min | Rcmin = 2\*Ro = **1.24mm**  Smin = minimum arc length  Ro = outer radius of NiTi tube | S = rθ  S = 1.24\*3pi/4 = **2.92mm**  To achieve bending angle = 135deg. To reach the boundary of the 0deg endoscope field of view |
| Max | S=Rc\*θ  Rc = s/θ = 7.5/(3\*pi/4) = **3.18mm** | **7.5mm**: distance between promontory (bony boundary of middle ear) and tympanic spine\* |

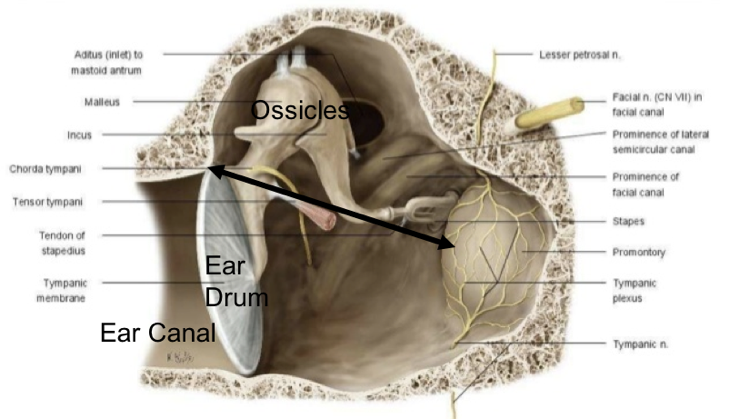


Figure 11: Image showing middle ear anatomy. The black arrow shows the approximate distance between the tympanic spine and the promontory [25].

## 3.1.3.2. Objective 2: Suction Instrument

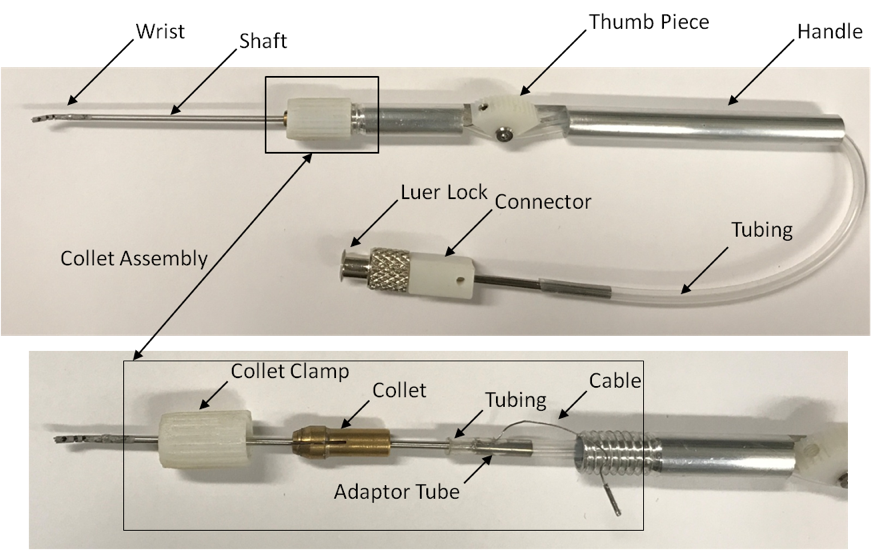
This instrument incorporates the wrist, and is therefore steerable, with the added functionality of suction. Plastic tubing is attached to the shaft and runs along the handle of the instrument and terminates at a connector which is connected to a luer lock. The luer lock allows the suction instrument to be connected to the suction port in the operating room. The zoomed in section of Figure 12 shows that the cable exits the tubing and is accessible to be secured in the thumb piece. The suction instrument is able to suction liquid. Further testing will compare the suction power with the 19 gauge sucker and Panetti instruments.

Figure 12: Outlines the components in the suction tool prototype.

## 3.1.3.3. Objective 3: Laser Instrument

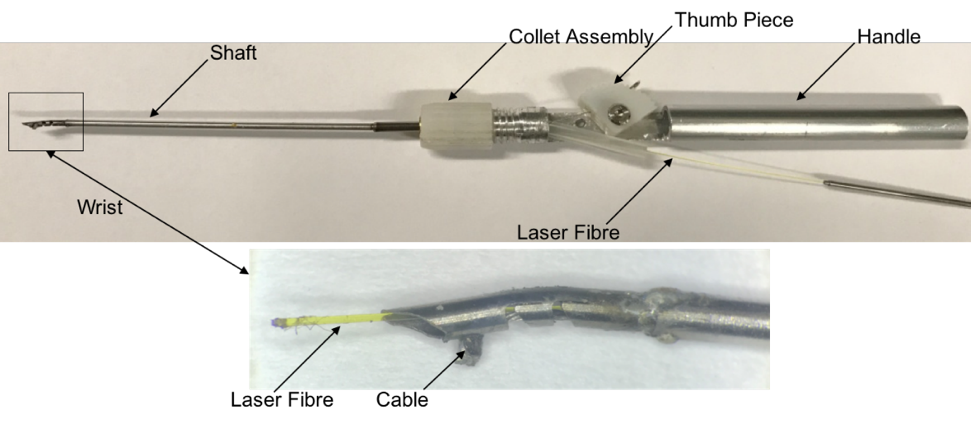
 This instrument is manufactured similar to the suction tool prototype but instead of the tubing running along the handle, it provides a channel for the laser fibre to be fed through to the tip.

Figure 13: Outlines the components in the laser fibre tool prototype.

## 3.1.3.4. Objective 4: Dissection-Enabled Instrument Tip

Refer to Figure 14. The tip of the instrument was milled such that the tip shape would be able to dissect tissue. As the shape of the tip is a cylinder, similar to the Thomassin Dissector shaft which is commonly used by the PI for dissection, the tip was milled to a shape similar to the Thomassin Dissector. Testing the instrument tip using a dissection test will be used to further inform this design.

Figure 14: Shows a zoomed in view of the dissector tip, inspired by the Thomassin Dissector Tip.

## 3.1.4. Testing Objective 1 – Reaching Structures Visualized by the Endoscope:

The reach of the instrument was tested using 0o endoscope and 3D printed temporal bone models that were constructed from patient CT scans. Similar to the 2D anatomy target experiment, the CT scans were segmented using Materialise Mimics and 3-Matic image segmentation software. 3D models of the patients’ temporal bone were rendered and were 3D printed on a powder printer. Refer to Figure 15 for testing images. A 2.7mm diameter, 0o endoscope with an HD camera was inserted with the tool into the ear canal of the model, alongside the instrument, to simulate TEES and to evaluate if the tip was able to reach hard-to-reach structures and dissect structures. It was able to reach the sinus tympani and trace the antrum boundary. As well, the tip was stiff enough to dissect the boundary of the antrum, simulating dissecting cholesteatoma.

**Figure 15:** **Left image: tool reaching the sinus tympani.** This is a model of the left temporal bone. The promontory is a landmark bone inside the middle ear, behind the ossicles. The sinus tympani is shown and is very difficult to reach into with standard, rigid tools to dissect and remove cholesteatoma. Often, the cholesteatoma is visualized in the sinus tympani with the endoscope but the tools cannot reach inside to extract it. This image shows, with an endoscope view, that the controllable, flexible instrument can reach into the sinus tympani. **Right image: tool reaching the antrum boundary.** This is a model of the left temporal bone. The model has been cropped so that the antrum is visible in this bird’s eye view. Cholesteatoma had eroded the ear canal in this patient like an atticoantrostomy, a hole in the ear canal where the instrument is coming through. Thus, the instrument is introduced through that opening and the tip can reach and dissect the boundary of the antrum.

Multiple iterations of the prototype were manufactured and tested. The controllable flexible instrument, see Figure 8, was presented at the 2nd World Congress for Endoscopic Ear Surgery in Bologna, Italy in April, 2017. It showed otologists the proof of concept that a controllable, flexible manually-operated instrument can reach structures visualized by the endoscope that are difficult to reach with conventional instruments.

Figure 12 and Figure 13 show the instruments that have incorporated suction, laser fibre and dissection at the tip and aim to be presented at the Sentac 2017 Annual Meeting on pediatric otolaryngology and will be submitted the IEEE Engineering in Medicine and Biology Conference, 2018.

# 4.0. Future Work

## 4.1. Validation Testing of the Instrument

The requirements in Table 2 will be tested to validate the tool for use during TEES. The functional requirements will be tested inside the 3D printed models generated by the nine patient CT scans.

**Table 2:** *Design Requirements Table*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Requirements:** | **Description:** | **Metric:** | **Prototype 1** | **Prototype 2** |
| **Functional Requirements:** | | | | |
| Reach areas visualized by the endoscope | The tool tip can touch/access the areas within the middle ear that are visualized by the endoscope. | Number of target areas touched/accessed |  |  |
| Reach hard-to-reach areas such as the sinus tympani, boundaries of the antrum | The tool tip can touch/access the sinus tympani and boundaries of the antrum. These are areas identified as hard-to-reach by the PI | Sinus Tympani: PASS/FAIL  Antrum boundary: PASS/FAIL |  |  |
| Tip stiffness | The tool tip can withstand forces applied at the tip by bony structures and soft tissue | Force required to break tip (N) |  |  |
| Tip can dissect tissue | The tool tip is able to handle, manipulate and/or maneuvre soft tissue in order to perform surgical tasks. | The tip can dissect mock cholesteatoma, fabricated out of silicone. PASS/FAIL |  |  |
| Suction | The suction power is comparable to the 19-gauge sucker and/or Panetti instruments. | Flow rate |  |  |
| **User Requirements:** | | | | |
| Easy to control (grip and ergonomics of handle) | The surgeon can control the tool easily. | Surgeon feedback (Likert scale rating) |  |  |
| Easy to use (grip and ergonomics of handle) | The surgeon can easily use the tool to perform its functionality (tip bending, suction, laser fibre orientation, etc.) | Surgeon feedback (Likert scale rating) |  |  |
| Feels like an existing tool | The tool feels like the current tools used by the surgeon such that they do not have to learn how to use a completely new tool design. | Surgeon feedback (Likert scale rating) |  |  |
| **Constraints:** | | | | |
| Fit alongside the endoscope | The tool shaft can move within the ear canal without being constricted by the endoscope. | Surgeon feedback (Likert scale rating) |  |  |
| Fit inside the ear canal | The tool shaft can fit inside the ear canal and can move easily, with enough clearance. | Surgeon feedback (Likert scale rating) |  |  |
| Sterilizability | The tool can be sterilized as per hospital standards so it can be used in patient. | PASS/FAIL |  |  |

The tool will be manufactured for sterilizability and using medical grade materials for all parts. At this stage of the project, however, a proof of principle prototype has been constructed and does not comply by the necessary ISO 13485 standards for medical devices. Furthermore, the handle and thumb piece will be further developed in the future for ergonomic design and this design will be informed by user feedback.

## 4.1.1. User Feedback:

The goal of this testing is to gain user feedback to inform design changes to generate the next version of the instrument.

### Test 1: Target Reachability

Goal: quantify reachability. Temporal bone models will be 3D printed where the targets, determined by the PI, to be reached by the instrument tool tip will be coloured. Using an endoscope, the current tools (Panetti and Karl Storz sets) and the controllable wristed tools will be tested inside the models. The number of targets reached by each tool will be tallied to determine which tool(s) have better reach. This will also inspire the next iteration of tool tip design.

### Test 2: User Feedback

Goal: assess user feedback during surgery, and the methods of acquiring user feedback by Armstrong et al, Schneider et al. and Addis et al. will be used to validate the instrument prototype. Armstrong et al. tested a novel laryngoscope instrument stabilizer by asking surgeons to use it and fill out a survey about the instrument functionality, stability, safety and utility of the instrument and presented the mean Likert scores of each question [26]. Similarly, Schneider et al. tested a robotic-assisted laparoscopic ultrasonography for hepatic surgery by asking 10 subjects to complete a questionnaire after performing specific task experiments, using the robotic tool and a handheld tool, the experience of participants was noted, and they were asked to comment on instrument functionality, comfort, ease of use and usefulness of the tool [27]. The scores were analyzed using a t-test to test for a statistical difference. Addis et al. outlined a testing protocol to compare a standard instrument and a prototype forceps and cutting instrument [28]. Six tasks were developed using a standard and literature and participants testing the tool were asked to comment on the tool’s performance; the frequency of specific comments, e.g. “this tool is helpful” were assessed.

Furthermore, another PhD. candidate from CIGITI is testing a similar instrument for neurosurgery using a user feedback survey; their REB will be amended to conduct this validation study which has the same scope, objectives and outcomes, but for another surgical environment. The validation of the instrument prototypes will undergo a similar validation testing protocol. The user feedback survey (see Appendix A) will be used to obtain surgeon feedback on the following aspects of the tool: instrument form, operation, functionality (including using the instrument tip to bend and dissect mock cholesteatoma), performance, safety, functionality and comfort. The Likert Scale scores will be analyzed using non-parametric Kruskal Wallis statistics method and qualitative comments will be summarized in a journal paper.

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Timeline

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