Chapter 1: Needs Analysis and Time Flow Study to Assess Endoscopic Ear Surgery

# Introduction:

Middle ear surgery is traditionally performed through an external incision with visualisation of delicate anatomical structures using a microscope. More recently, minimally invasive ear surgical techniques have been developed using endoscopes to access the middle ear through the ear canal without an external incision [1], [2]. As with open microscope-guided surgery, this transcanal endoscopic ear surgery (TEES) technique, allows the surgeon to perform procedures such as ear drum reconstruction, skin growth removal and hearing bone repair [1]. The advantages of endoscopic ear surgery are as follows: removing the need for an external incision and reducing post-operative morbidity (10), improved outcomes by enhancing minimally invasive access for disease eradication (2-4), more effective disease control as shown by the reduction of the rate of reoccurring skin growth (2, 3), and better hearing due to hearing bone preservation (10, 11).

Despite the enthusiasm of some ear surgeons (otologists), endoscopic ear surgery has not as yet been accepted by all practicing otologists (5). The principle challenge with TEES is that a one-handed surgical technique is required as the endoscope is held in the other hand. Otologic instruments were developed for two-handed microscope-guided surgery so they are not optimized for the TEES environment [2]. 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 endoscopically (1, 7, 12). Nevertheless, the learning curve can be slow and frustrating. In the experience of the primary investigator (PI), technological advances in the design of the endoscope, camera and suction dissection instruments have lead to incremental stepwise jumps in this learning curve (13). Therefore, the potential for improving the TEES experience lies in instrumentation and training of surgeons.

The following is from: [3]

* The endoscope provides direct vision of the target operating field and avoids the need of extra exposure and drilling, which is required while operating with the microscope. The microscope requires a wide portal for illuminating and visualizing the operative field.
* Cholesteatoma resection is considered complete after a final survey with the angled endoscope, which confirms that no cholesteatoma is left in the hidden recesses
* Require aspiration (suction) instruments to perform dissection and aspiration at the same time to overcome the single-handed operating constraint of TEES.
* The following are benefits of the endoscope over the microscope:
  + Wider angle of view
  + Better visualization of structures that are parallel to the axis of the microscope
  + Visualization of deep recesses and hidden structures within the middle ear
  + Ability to visualize beyond the shaft of the surgical instruments
* Disadvantages:
  + Loss of depth perception and binocular vision
  + One-handed surgical technique required
  + Need bloodless field and need to maintain attention to hemostasis
  + Fogging and smearing of endoscope tip
  + Reliable physician training
  + Cost of equipment
* The needs of TEES are different from traditional microscopic surgery where you need to drill bone (mastoid) to access the surgical field. Thus many microscopic surgery instruments are meant to cut bone and
* According to the authors, incorporating suction inside the shaft of the tools is very beneficial because it helps the single-handed surgeon control bleeding, while cutting, dissecting or manipulating tissues while holding the endoscope with the other hand and to operate in a clean bloodless field and the limitation of the panetti sucker is the possibility of occluding the lumen of the tool but the tool also addresses the need for limiting the number of instrument exchanges during surgery as the surgeon can dissect and aspirate at the same time
* The indications for exclusive TEES are growing and this paper calls for a push toward developing more instruments that can work within the viewing range of the 30 and 45 deg. Endoscopes
* The authors, who have more than 15 years of TEES experience suggest that adapting and refining regular microinstruments to include longer, lender shafts with single or double curvatures, smaller microtips have been essential for TEES
* TEES requires the standard otologic microinstruments that are familiar for otologists and modified TEES instruments that have curved suction cannulae, curettes, cupped forceps and suction incorporated into the shaft of the round cutting knife – the curve is necessary to work with the 30 deg or 45 deg scopes to ease reaching into the hidden recesses of the middle ear without the need for extra drilling for visualization and instrument handling and to make it possible to remove pathologic conditions around the corner
* Need to modify more instruments to adapt for angled vision endoscopes (30 deg and 45deg) is essential
* Outlines the advanced technologies that have improved otology surgery

“Feasibility and advantages of transcanal endoscopic myringoplasty”: [4] – good paper with explanation of TEES myringoplasty

* Compares visibility using endoscope vs. microscope
* When comparing microscopic and endoscopic views of myringoplasty (ear drum reconstruction) the endoscopic approach is: minimally invasive (no skin incision), TEES myringoplasty can be performed regardless of the perforation size, narrowness, protrusion of EAC, entire tympanic membrane can be viewed in single field with clear visualization of the perforated edges – even when ear canal was curved; the anterior edge of perforation not visible under microscopy for 5/25 ears
* Endoscopic approach – tympanic cavity observable through the perforation, orifice of the tube, ossicular chain, tympanic isthmus (through large perforations), successfully performed simple underlay technique or with intracanal incision in cases of marginal perforation

“comparison of middle ear visualization with endoscopy and microscopy” [5]

“Transcanal Endoscopic Ear Surgery for Pediatric Population with a Narrow External Auditory Canal” [6]

* 31 pediatric patients, average ear canal diameter 5 +/- 1 mm (anterior-posterior diameter), 5.9 +/- 1.3mm (superior-inferior diameter)
* study shows that TEES can be done safely and effectively on pediatric patients with a narrow EAC using a 2.7mm endoscope

### Purpose:

To assess the current needs of endoscopic ear surgery in order to design an instrument to address these needs.

The assessment of endoscopic ear surgery will comprise two separate parts: (a) a time-flow analysis in the operating room of the PI and (b) a survey of endoscopic ear surgeons’ experience.

# Part 1: Time Flow Analysis:

A time flow study was used to analyze the efficiency of TEES.

## Background:

Rube et al. Recorded the time for MRI-guided angioplasty and assessed the efficiency and feasibility of the proposed workflow and framework for this type of procedure [7]. Similarly in an attempt to show the efficiency of a dedicated minimally invasive operating room (OR), Hsiao et al. recorded the time for steps during laparoscopic procedures in two types of OR’s: a dedicated minimally invasive OR and a traditional OR [8]. A time flow study was also used to measure the patient wait times before and after restructuring the practice patterns to assess the efficiency of the new practice [9]. Time flow studies have been employed to analyze the efficiency and compare between surgery procedures and hospital protocols.

This study will also assess the feasibility and efficiency of endoscopic ear surgery using the same method: recording the times of steps in the procedure. This will aim to determine the inefficiencies and address the steps where further instrument design would be beneficial. This would also provide a good benchmark against which to measure efficiency and feasibility of future tools that would be developed.

## Method:

The time flow analysis will measure the duration of predetermined steps during the surgery as well as the number of changes between instruments. This will breakdown and quantify the period of time associated with the completion of a particular task; it is used across a variety of fields, including medicine (14). This will aim to measure the efficiency of current endoscopic ear surgery and provide areas where instrumentation redesign is required. The time flow analysis will be recorded by the MASc. student during ear surgery. These will be divided into preparation, tympanomeatal flap elevation, access to tympanomastoid sub-sites for cholesteatoma removal, graft positioning, and ossiculoplasty. The type of instruments used during these different maneuvers and the number of changes between different instruments will also be noted. These observations will also lead to an appreciation of the ergonomic requirements of instruments during ear surgery and the design advantages of different instruments for specific maneuvers.

It is anticipated that variance in time-flow between cases will be high between cases based on patient specific factors such as extent of bleeding, ear canal morphology, extent of disease. Nevertheless, this methodology will provide a more accurate assessment of surgical practice and challenges than anecdotal surgeon’s recall. Steps demanding a disproportionate amount of time or multiple changes in instrument will be determined from analysis of these data. This will reveal procedural areas in which surgical efficiency may be improved by instrument modification.

Steps to conduct the study:

1. Obtain consent (clinic by the nurse) – noted in the patient’s chart
2. Dr. James will tell me what date/time of surgery I should attend to fill in the data collection table
3. Assign the date/time/type of surgery a 5 digit code (as recorded in the key code sheet)
4. Attend the surgery and fill out the form

Data was collected on a spreadsheet with the following data table:

|  |  |  |  |
| --- | --- | --- | --- |
| Surgery: |  | Study Number: XXXXX | |
| Tympanoplasty | Step | Date/notes | Time (min) |
| Cleaning Out Ear canal |  |  |
| Injecting Anaesthesia |  |  |
| Hair Trimming |  |  |
| Cleaning Edges of Perforation |  |  |
| Making Skin Incision |  |  |
| Raising Flap |  |  |
| Preparing Graft |  |  |
| Placing Graft |  |  |
| Replacing Flap |  |  |
| Packing Ear Canal |  |  |
| Surgery: |  | Study Number: XXXXX | |
| Cholesteatoma Removal | Step | Date/notes | Time (min) |
| Cleaning Out Ear canal |  |  |
| Injecting Anaesthesia |  |  |
| Hair Trimming |  |  |
| Cleaning Edges of Perforation |  |  |
| Making Skin Incision |  |  |
| Raising Flap |  |  |
| Preparing Graft |  |  |
| Placing Graft |  |  |
| Replacing Flap |  |  |
| Packing Ear Canal |  |  |

The patient chart states whether or not the patient has consented to recording their surgery duration. The date and time of the surgeries of patients who had consented are linked to the 5 digit code in a separate spreadsheet. This key sheet and the results sheet are kept in a file on a SickKids research computer.

Results Analsyis:

Discussion:

Conclusion:

# Part 2: Needs Assessment Survey:

The needs assessment survey aims to understand surgeons’ needs when performing TEES in order to design instruments better suited for the surgery and thus encourage greater use of TEES. Limitations in current instrumentation will be assessed by following the Delphi method to survey ear surgeons. This will be done by surveying ear surgeons and asking them to rate the importance of specific instrument functionalities during TEES. This information will be used to develop design criteria against which future instrumentation and training models can be developed to facilitate practitioner use of endoscopic ear surgery.

## Literature:

Surveys and questionnaires are used to gain information regarding a specific topic by consulting a wide variety of experts in the field. Marcus et al. assessed the technical challenges of endoscopic neurosurgery and the scope for technological advances that would overcome the challenges by asking members of the Society of British Neurosurgeons to answer these questions in an online survey and analyzed using a multi-rater emergent themes analysis [10]. As well, the members of the Canadian Society of Otolaryngology filled out a survey that characterized the current status of endoscopic ear surgery in Canada and reported a generally positive attitude toward endoscopes (81%) and their potential in the future of ear surgery [11]. 53% of the survey responders indicated they would likely use endoscopes in their own future practice [11]. This also showed that the main concern of TEES was the challenge of one-handed surgery and the advantage was reduced rates of residual disease [11]. Therefore, this method has been used to gain knowledge in the field of endoscopic surgery and has been accepted as a method by members of the Canadian Society of Otolaryngology and will be used in this study to answer similar questions.

The Delphi method has been employed internationally in the field of surgery where surveys are sent out to surgeons to form a consensus about varying surgical questions such as: treatment of the retraction pockets of the tympanic membrane, developing a core set of patient-reported outcomes in pancreatic cancer, and an international consensus for sepsis and septic shock definitions [12] [13] [14].

A two-round Delphi survey was employed to conduct the survey, where the questionnaire was developed after speaking with local otolaryngologists at Toronto Hospitals, then the survey was electronically sent out to Otology groups around the world. The responses were analyzed using statistics to identify differing views. These will formulated further questions that were sent out again to the respondents. The corresponding results were analyzed to determine the final consensus.

## Method:

### Developing the Questionnaire:

The Canadian otologists’ EES survey already reported on how many surgeons in Canada use TEES (11%), what surgeries it is used for (cholesteatoma, tympanoplasty, ossicular reconstruction and what they find difficult about it (single-handed surgery, efficiency/operative time, technical difficulty, cost, managing bleeding. This questionnaire was intended to build on this one by evaluating the limitations of surgical tools.

* interviewed ear surgeons locally about what they think about TEES, we narrowed down the main difficulties the surgeons experience during surgery and how they can see it being fixed
* attended an endoscopic ear surgery course held in Toronto in October, 2016 and asked all participants to fill out a preliminary survey. They were new to TEES, and so were just developing the techniques. The more experienced surgeons who delivered lectures during the course and trained the participants had ideas about what kind of instruments they wanted. <link to file with informal feedback from course: C:\Users\arushri swarup\Documents\GitHub\Graduate-School\EES Course>
* based on the results of the preliminary questionnaire <link: C:\Users\arushri swarup\Documents\GitHub\Graduate-School\EES Course (excel doc)>, the second round of questions (submitted in the REB main application) were changed to ask the surgeons to rank their need for specific instrument functionalities

**Endoscopic Ear Surgery Preliminary Questionnaire**

Note: all answers are confidential for internal use to ultimately develop a formal questionnaire to be sent out globally.

1. How many years of experience do you have with Endoscopic Ear Surgery (EES)?
   1. <1
   2. 1-3
   3. 4-7
   4. >8
2. Approximately what percentage of totally EES do you currently do (ie. Percentage of cases without a microscope)?
   1. 0%
   2. Up to 25%
   3. Up to 50%
   4. Up to 75%
   5. Up to 100 %
3. What surgeries do you use EES for?
4. Cholesteatoma removal
5. Tympanoplasty
6. Ossicular repair
7. Other
8. None of the above
9. Do you currently use any of these dedicated EES instruments?
   1. Spiggle and Theis Panetti Instrument Set
   2. Storz Endoscopic Middle Ear Surgery Instrument Set
   3. Grace Medical IWGEES Set
10. What are the factors that hinder your use of EES? (Please circle all that apply)
    1. One handed surgery
    2. Bleeding control
    3. Effect of endoscope on depth perception of the surgical field
    4. Other, please specify below:
11. What are things that you find difficult during EES? (Please circle all that apply)
12. Gripping and/or moving an ear drum graft
13. Cutting the ear drum graft into the appropriate shape
14. Gripping and/or moving cholesteatoma
15. Keeping tissues in place or in tension while cutting or dissecting
16. Keeping the operative field clean
17. Accessing areas within hidden recesses in the ear (e.g. antrum)
18. Accessing areas that are visible via endoscope (but cannot be reached by conventional instruments)
19. Keeping the endoscope lens clean
20. What functionality of instruments do you think will improve your experience with EES? (Please circle all that apply)
    1. Suction integrated with another functionality (e.g. suction + curette or suction + forceps)
    2. Suction actuated by a pedal (rather than with finger plug hole)
    3. Increasing accessibility of instrument tips to reach all areas within the viewing angle of the endoscope
    4. None
21. If there is a tool that can reach within the recesses in the middle ear, what would you like the tip function to be?
22. Gripping something (e.g. forceps)
23. Suctioning
24. Cutting
25. Dissecting
26. A combination of the above (please specify)
27. Other
28. It is unnecessary to reach within these recesses in EES
29. Rank the functions of a tool in order of importance:
30. Facilitate graft movement and positioning
31. Suction
32. Cutting
33. Gripping (e.g. cholesteatoma, bone or ear drum graft)
34. Reaching hidden areas within the ear
35. Is there a specific instrument that you have used before or seen that you would like to be adapted for use in EES?

* Based on the responses, we decided the questionnaire would ask about most of these difficulties by asking them to rate their degree of difficulty with the following tasks
* *Rating technique*
  + Likert vs. analog visual scale these papers said that the analog visual scale was better BECAUSE [15] [16] – 10 describes what VAS and an LS are
  + <http://www.statistik.tuwien.ac.at/forschung/SM/SM-2009-4complete.pdf>
    - States that the advantages of using the continuous rating scale over the likert are:
      * Hard to discriminate between the categories
      * Cts scale – the respondent is only given anchor points and so it is up to the respondent to pick any value in between......(continue)
* The wording of the scale was taken from:
  + <http://psr.iq.harvard.edu/files/psr/files/PSRQuestionnaireTipSheet_0.pdf>,
  + <http://www.uwex.edu/ces/4h/evaluation/documents/Wordingforratingscales.pdf>

visual analog scale (used in questionnaire) vs. likert scale: [15]

* Compare LS (5 point) to VAS in evaluating perceptions of an emergency department bedside clinical teaching programme
* Evaluation questionnaires used LTS and 100mm horizontal VAS for each question, and this paper, through analyzing the correlations between the two methods for each correlation, concluded that the VAS is a reliable and valid alternative to the LS for educational evaluation, and may provide advantages in educational measurement
* The study had the participants perform a self evaluation using both the VAS (anchors labeled “definitely” and “definitely not”) and LS
* Questionnaires administered three times throughout the course of the study
* Tested for test-retest stability using the intraclass correlation coefficient and internal consistency using cronbach’s alpha. All but one question in the questionnaire had statistically significant correlation
* Conclusion: the VAS are instruments that can capture subjective phenomena quantitatively, similar to the likert scale but the LS uses ordinal scale restricting the respondent to predetermined categories
* The VAS can discriminate finer differences because of the greater range of possible scores, also this makes it more likely that the data is normally distributed
  + Can use parametric statistical analysis with a smaller sample size

The survey will then be sent, via email, to many otologists around the world, including the 60 members of the International Working Group on Endoscopic Ear Surgery (IWGEES) (http://www.iwgees.org) plus delegates that have attended courses organized by the PI and consenting members of the IWGEES. The answers will be analyzed to develop a third survey that will be sent out once again to the participants. This will attempt to develop a consensus of conclusions for the survey.

The confidential survey will be provided electronically using RedCap SickKids software.

Factors such as these will be combined with emphasis given to those reported most frequently by survey respondents to generate a list of requirements for improvements in endoscopic surgical instrumentation. The list of requirements from the survey will be combined with the summary of the time-flow data to determine areas of greatest need for instrument improvement.

Surgeons previously contacted for the survey will be sent copies of the findings and invited to offer suggestions for improvements in instrument design. It is anticipated that the response rate to this request may be low as surgeons may be protective of their own ideas, but may still help to generate some innovative solutions. Any solutions offered will be combined with concepts already developed by the research team to generate innovative designs for novel instrumentation. The strengths and weaknesses of current otologic instruments will be included in this review and attention paid to combining functions of current instruments into single tools that can be simply operated with one hand.

This methodology will collect insight from a variety of surgeons, however, a potential limitation would be a lack of adequate or representative responsiveness from survey participants. However, the creation of practical and innovative solutions to the challenges of endoscopic surgery is not dependent upon a high survey response rate. Having taught at multiple surgical courses, participated in seminars, attended endoscopic conferences around the world, and by associating with other leaders in the field, the PI has considerable insight into the current status of activity and opinions within the field of endoscopic ear surgery.

Statistical Analysis of survey results:

Goal of needs analysis: determine instrument functionalities that would address difficulties experienced during TEES.

Questions:

1. What is the most desired functionality/ies?
2. Does experience affect the most popular desired functionality? If so, which functionality would we choose to tackle? Do we want to address experienced surgeons’ problems or non-experienced surgeons’ problems? The latter would aim to make instruments so that it’s easier for people trying out TEES for the first time. Expect the most popular response to be suction.

For second round of questions: could ask: what tools would you like? E.g. suction accompanied by: dissector, knife, etc.

Data: non-parametric – cannot be defined by mean because it is arbitrary numbering/ranking

Use Kruskall-Wallis test (which is a nonparametric way of doing ANOVA – not as much power as ANOVA but data does not satisfy normality assumptions of ANOVA therefore do this test instead)

Factor = groups varying by experience e.g. group 1 = <5 years, group 2 = >5 years, group 3 = >15 years

Result = nonparametric, ordinal categorical data

Organize data as follows:

Experience question\_1 question\_2 question\_3

1 50 69 30

3 60 78 90

2… etc.

1

1

1

3

do the kruskall wallis test to see if there is a difference between the groups with experience on the tool functionality ie. Does the factor of being in a different experience group have an effect on the preference of certain tools desired for TEES?

if there is a difference between groups, can do a whitney mann test if there is a statistical difference between groups

use a frequency table to see what the consensus is

stacked bar chart to present all the data

*Existing Tools:*

Currently, only a limited selection of instruments is available for endoscopic ear surgery. One set of instruments, known as the IWGEES set (Karl Storz GmbH & Co. KG; Tuttlingen, Germany) was developed from the work of Thomassin (9). From discussions with the PI and his colleagues, the following are limitations of these instruments: narrow, occlusion-susceptible suction tubes, inability to reach requisite recesses within the ear, and suboptimal tip design to perform the necessary functions. An innovative set developed by Panetti (13) incorporates suction into dissection instruments with an ingenious rotating connector (Spiggle & Theis Medizintechnik GmbH; Burghof, Germany). The ability to clear blood from the operating field is an advantage to the tools, however, the following limitations exist: inaccessibility of the thumb to suction control while manipulating the instrument, inappropriate tip design, suction not reaching the tip of the instrument, longer curved dissectors lacking the delicacy required for small recesses.

This project will aim to assess these limitations, including input from a variety of surgeons, and develop design criteria to improve the instrumentation.

**Abstract**: background, methods, results, conclusions, keywords: questionnaire, survey, endoscopic ear surgery

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A good background information article is: [17]

* Endoscope allows assessment of ear drum in clinic and minimally invasive access to the middle ear for surgical procedures, and is a great teaching tool as you can record endoscopic images and there is a large screen so people can see
* Endoscope allows effective cholesteatoma while preserving the hearing bones (ossicles) and tympanic membrane and reduces residual cholesteatoma
* An external incision is avoided which provides relief for parents, same day discharge and lower morbidity (find an article stating lower morbidity)
* Allows panoramic view of middle ear cleft
* Requires training and resources
* Adult size and size of middle ear and tympanic membrane are approximately similar, so tools of the same size can be used for both types of surgery
* Most common procedures done endoscopically: tympanic membrane perforation reconstruction and cholesteatoma, but in children cholesteatoma reaches deep into the mastoid which is beyond the limits of totally endoscopic permeatal approach

Use this article when talking about tympanoplasty and considerations for time flow study [18]