Needs Analysis and Time Flow Study to Assess Endoscopic Ear Surgery

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BME1450 Thesis Proposal

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**Abstract:**

BACKGROUND: Endoscopic ear surgery is a minimally invasive technique to operate inside the middle ear through the ear canal. Though the benefits of reduced length of hospital stay and patient morbidity are valued, ear surgeons hesitate to adopt the technique because it requires one-handed surgery and existing tools, designed for two-handed traditional invasive microscopic ear surgery, are not optimized for single-handed endoscopic ear surgery.

OBJECTIVE: This study proposes to understand the specific needs, instrument limitations and technologic advancements required to increase adoption of endoscopic ear surgery.

STUDY DESIGN: Part one of this study is to conduct a needs assessment survey, following a two-round Delphi method, where a questionnaire will be sent out to ear surgeons globally. This will aim to identify the current needs and technological limitations that surgeons experience in endoscopic ear surgery. Part two will be a time flow study to record duration of surgical steps to assess the current limitations of tools and techniques during endoscopic ear surgery. This data will be collated to develop requirements and criteria against which future instrumentation for endoscopic ear surgery can be developed to increase the adoption of endoscopic ear surgery.

EXPECTED OUTCOMES: As a result of discussions with the primary investigator (an ear surgeon at SickKids hospital) and his colleagues, it is anticipated that the needs assessment survey will show that ear surgeons experience the following difficulties during endoscopic ear surgery: keeping the operative field clean, keeping the endoscope lens clean, cutting bone, single-handed surgery, reaching structures within the middle ear, and gripping structures. The two-round Delphi method will conclude this in a rigorous format, as it is an accepted survey technique in many other areas of surgery. The time flow analysis will identify the inefficiencies during different surgical steps where intervention is required, which may require redesign of existing instruments.

SIGNIFICANCE: These needs and limitations will yield criteria against which instrumentation should be developed. This will be addressing a knowledge gap in the field of endoscopic ear surgery and will motivate industry and academic researchers to develop better instruments and training modules to increase the adoption of endoscopic ear surgery.

**Introduction:**

Middle ear surgery is traditionally performed through an external incision with visualization 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 trans-canal endoscopic ear surgery (TEES) technique, allows the surgeon to perform procedures such as ear drum reconstruction, skin growth removal and hearing bone repair (2) (3). The advantages of endoscopic ear surgery are as follows: removing the need for an external incision and reducing postoperative morbidity (4), improving visualization for disease eradication (5) (6), including reduction of the rate of residual skin growth (5), and improving hearing by facilitating hearing bone preservation (4) (7).

Despite the enthusiasm of some ear surgeons (otologists), endoscopic ear surgery has not as yet been accepted by all practicing otologists (8). The principal challenge with TEES is that a one-handed surgical technique is required as the endoscope is held in the other hand. Ear surgery instruments were developed for two-handed microscope-guided surgery so they are not optimized for the TEES environment (2) (9). 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 (2) (3) (9). 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 (10). There is a knowledge gap in the literature where it is not reported exactly why surgeons have not adopted the technique, and what technological and/or training advances would encourage greater adoption. It is proposed that in order to improve the adoption of TEES, the needs of surgeons and current limitations of tools must be determined.

**Research Question:** Why is transcanal endoscopic ear surgery (TEES) not widely adopted by otologists and what technological advances would encourage more frequent and broader use of TEES? **Hypothesis:** TEES is recognized for its potential and the investigators hypothesize that by conducting a needs analysis survey and a surgical time flow analysis, current limitations of TEES will be developed to develop criteria to improve the adoption of TEES. **Research Objectives:** In order to increase the use of TEES we need to understand: a) the reason for surgeons not adopting TEES by conducting a questionnaire for surgeons and b) limitations of existing tools by conducting time flow analysis.

**Specific Aims and Methods:**

**Part 1: Needs Assessment Survey:**

The aim of the needs assessment survey is to understand the reason why ear surgeons are not using endoscopic ear surgery and what would increase its use. Surveys are widely used to gain information regarding a specific topic by consulting a wide variety of experts in the field. They have been used to assess the challenges of endoscopic neurosurgery in Britain and the current status of endoscopic ear surgery in Canada (9) (13). 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 issues 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 (14) (15) (16).

A qualitative assessment of the challenges in endoscopic ear surgery caused by limitations in current instrumentation will be completed by performing an online survey of surgeons that perform endoscopic ear surgery. The Delphi method will be followed to analyze the qualitative results of the survey.

Preliminary interviews of local otolaryngologists, with varied experience in TEES within the University of Toronto, will be conducted by an IBBME MASc student (Arushri Swarup). Questions will ask for comments on factors that have prevented otologists from using endoscopes in ear surgery, and for comments on the perceived strengths and weaknesses of currently available instruments for endoscopic ear surgery. Their opinions will be de-identified and collated to develop a list of requirements for improvements in instrument design. In order to determine the relative priority of these requirements, a pilot questionnaire will be developed to ask a wider group of otologists to rate the importance of each requirement and will include further open-ended questions for additional comments. Invitations to participate will be sought from the 60 members of the International Working Group on Endoscopic Ear Surgery (IWGEES) (http://www.iwgees.org) plus delegates known to the PI from attendance at ear surgery courses. Results from this pilot questionnaire will be used to generate a formal questionnaire for a global survey of otologists’ opinions. This will attempt to develop a consensus on priorities for improvements in TEES instrumentation.

*Participant Recruitment:* The participants are otologists who will be invited to participate by email. The email addresses will be obtained in two ways: 1) publicly available information, as many ear surgeons list their email on their hospital website. 2) the mailing list of otological societies. Online surveys of surgical practice are frequently distributed by such societies. The following societies of which the PI is a member will be contacted asking for permission to survey their members:

* Canadian Society of Otolaryngology - Head and Neck Surgery
* American Society of Otology
* Politzer Society
* European Academy of Otology and Neurotology
* British Academy of Otolaryngology - Head and Neck Surgery
* International Working Group on Endoscopic Ear Surgery

**Part 2: Time Flow Analysis:**

Time flow studies aim to analyze the efficiency of procedures, and have been used for many purposes in surgery, including MRI-guided angioplasty workflow and operating room setup dedicated for minimally invasive laparoscopic surgery (11) (12). This study will assess the feasibility and efficiency of endoscopic ear surgery using the same method.

*Study Design (General Overview):*

The time flow analysis will be recorded by the MASc student during ear surgery. The surgery will be divided into steps, described below. The type of instruments used during the different steps and the number of changes between instruments will also be noted. These observations will lead to an appreciation of the ergonomic requirements of instruments and the design advantages of different instruments for specific maneuvers. The time taken for five surgeons to perform ten surgeries each will be recorded. Each step for each surgeon will have a mean and standard error time, and statistical difference between surgeons for each step will be calculated. 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. The last half of surgeries will be done using the new tools developed for improving TEES. The results will be compared statistically.

*Participants*: The time flow study will include two kinds of participants: patients, who will be undergoing ear surgery, and surgeons, who will be performing the ear surgery.

*Participant Recruitment*: The PI’s colleagues in otolaryngology are interested in this project and would also like to improve their experience with TEES. Three additional surgeons from SickKids and one from Toronto General Hospital have expressed interest in participating in this study.

*Inclusion criteria*: Patient participants: 40 surgical patients, who require cholesteatoma surgery or tympanoplasty (surgical repair of perforated ear drum). Surgeon participants: 5 surgeons with more than one year of experience in endoscopic ear surgery.

*Exclusion criteria:* Residents and fellows who are in training. It would be inappropriate to include surgeons in training in the study as their lack of experience will contribute to delays and lack of efficiency in time flow, so confounding the estimate of the contribution of instrument design to surgical time flow. Although the ability of trainees to use different instruments in TEES and the impact of their level of experience on this ability would be of interest, they are beyond the current scope and design of this study.

*Study intervention*: Each surgeon will be observed and recorded performing ten operations. The time and number of instruments changed will be recorded for the steps outlined in the Data Collection Form, included in Appendix B.

*Outcome measures*: The following outcomes will be measured: duration of the surgical steps described above and the number of times the surgeon changes the tool he/she is using during the step.

*Statistical analysis*: The factor to be studied is the type of instruments used for each surgical step. The block is the surgeon. The response is the time required for the surgical step. Therefore, an ANOVA will be used to determine if there is a statistical difference in the time to complete a surgical step depending on the instruments used.

**Expected Outcomes:**

As a result of the PI’s personal experience and communication with his colleagues and ear surgeons who attended an Endoscopic Ear Surgery skills course in October, 2016, it is anticipated that the following difficulties will be revealed in the needs analysis survey: clearing blood from the operating field, keeping the endoscope lens clean, dissecting, gripping structures, accessing structures that are visible with the endoscope’s wide viewing angle, bone removal beyond certain anatomy, and difficulty with ear drum graft positioning. As well it is anticipated that understanding the needs for TEES and identifying the inefficiencies during surgery would provide a basis of what type of instrumentation should be optimized to improve its adoption.

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.

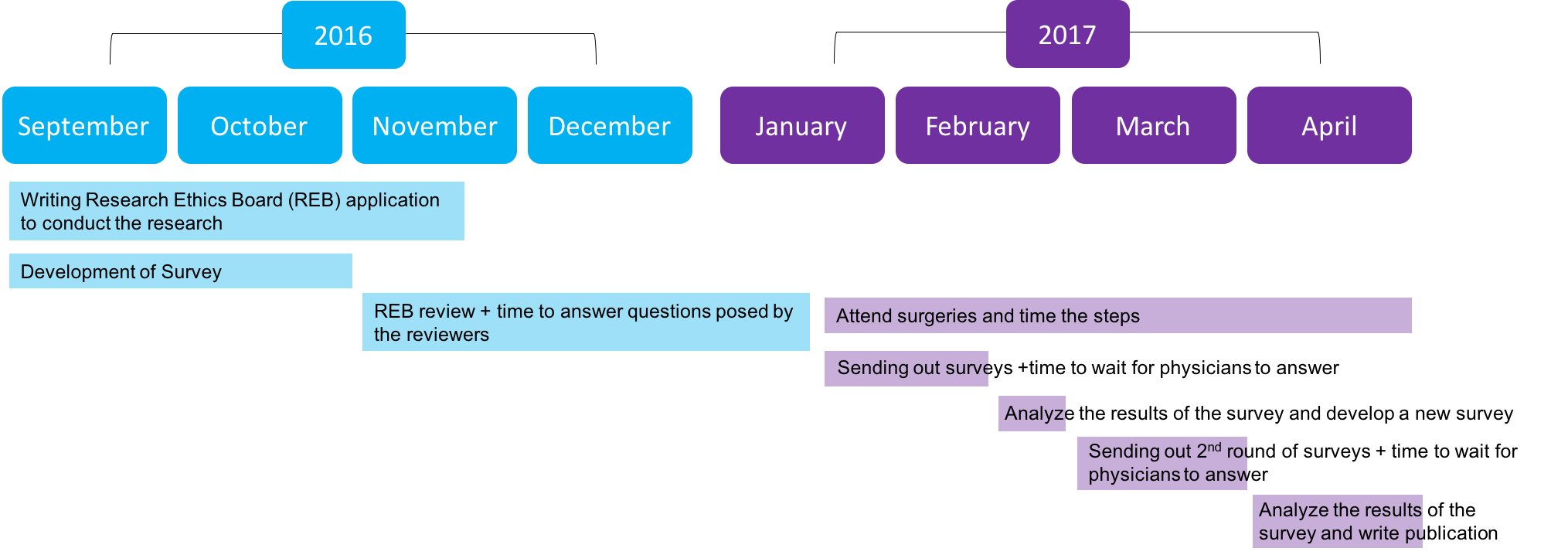
This methodology will collect insight from a variety of surgeons, however, a potential limitation would be a lack of adequate or representative responsiveness from survey participants. However, the creation of practical and innovative solutions to the challenges of endoscopic surgery is not dependent 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.

See Appendix A for timeline.

**Significance and Conclusions:**

It is anticipated that new TEES instruments will increase the range of ear procedures that can be completed minimally invasively and increase the speed and effectiveness of surgery. The design techniques and instruments created will also be applicable to other minimally invasive surgery in bony cavities such as sinus, nasal, spinal and arthroscopic surgery [1], [11], [12]. It could be envisaged that ultimately, virtual patient models could be used with rapid prototyping and fabrication to create patient specific specialist instruments so extending the limits of minimally invasive surgery even further.

Appendix A: Timeline



Boxes show approximate length of time required to complete the tasks.

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