**Needs Analysis and Time Flow Study to Assess Endoscopic Ear Surgery**

**Background:**

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]. 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] [2] [3]. The advantages of endoscopic ear surgery are as follows: removing the need for an external incision and reducing postoperative morbidity, improving visualisation for disease eradication, including reduction of the rate of residual skin growth (cholesteatoma), and improving hearing by facilitating hearing bone preservation [4] [5] [6].

Despite the enthusiasm of some ear surgeons (otologists), endoscopic ear surgery has not as yet been accepted by all practicing otologists [7].  The principal 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. 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] [3] [8]. 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 [9]. 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 facilitate its use. It is proposed that in order to facilitate TEES, the needs of surgeons and current limitations of tools must be determined.

**Objectives and Hypothesis:**

*Hypothesis*: The investigators hypothesize that as current otologic surgical instrumentation was developed for two-handed surgery for use with an operating microscope it is not well-suited to the needs of endoscopic ear surgery. It is proposed that better understanding of the functionality of current instrumentation in TEES will identify areas where instrument design can be improved.

*Objectives:* This study aims to identify limitations in current instrument design by a) surveying otologists opinion and experience with TEES instrumentation and b) assessing instrument efficiency during endoscopic ear surgery in Toronto.

**Overview of Methodology:**

The protocol for this study forms part of a larger project aiming to develop improved instrumentation for endoscopic ear surgery. This study has two parts: (1) a needs assessment and (2) a time flow study.

*1. Needs Assessment*

The first part of this study aims to understand what factors limit the adoption of TEES by otologists and what technological advances would allow more frequent and broader use of TEES. A needs assessment survey will be conducted, using the two-round Delphi method, that examines the current limitations of surgical instruments used in TEES, in other words to assess what surgeons need to help them practice this form of surgery more readily. Information from interviews with local otologists will be used to generate a questionnaire that will be disseminated to otologists globally. These results will help guide development of new instrumentation to facilitate TEES.

*2. Time Flow Study*

As well, independent of the needs analysis, a time flow study, recording the duration of surgical steps, will be conducted to quantify the limitations of the current instruments used in TEES, by assessing their efficiency.

**Methods and Analysis:**

**Part 1: Needs Assessment Survey:**

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 [3] [10]. 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 [11] [12] [13].

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 who 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:*

For the preliminary interviews of local otologists, the PI gave a list of names of his colleagues who have had experience with TEES. The student then contacted these doctors and used the interview script outlined in the *Scripts for Participants* document.

After obtaining consent from the participants, the survey will be distributed to participants. The participants will be able to see the resulting questions in the questionnaire when the survey is emailed out to them.

The participants are otologists who will be invited to participate by email. Participants will be contacted in the following ways:

1. Publicly available information, as many ear surgeons list their email on their hospital website.

2. Contacting 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 via email 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

Refer to the *Scripts for Participants* document for a copy of the email letter request. If the medical society agrees to participate they will send the survey to their members, using the email script in the *Needs Assessment Survey* document.

The Needs Assessment Survey portion of this protocol has only surgeon participants. The survey responses will remain anonymous to the researchers and consent will be implied if the survey is filled out and received by the research team.

*Questionnaire:*

Refer to *Needs Assessment Survey* and *Needs Assessment Questionnaire* documentsfor the survey details and questionnaire.

**Part 2: Time Flow Study:**

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 [14] [15]. 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 in the *Data Collection Form* document. 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.

*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: Five surgeons with more than one year of experience in endoscopic ear surgery. The PI, three additional surgeons from SickKids and one surgeon from Toronto General Hospital will be asked to participate.

The PI, Dr. Adrian James, is also a study participant. It is necessary to include him as there are few other experienced practitioners of this technique. His inclusion as a participant will not affect the integrity of the study: his motivation for conducting this research is to improve TEES instrument design so he would not benefit from any personal biases that might interfere with the integrity of the study. There is no financial conflict of interest as this project is run as a not-for-profit endeavour.

*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. If the surgeon has recorded videos of their surgeries then they will be reviewed to gather data. The steps that are recorded will be performed by the experienced surgeon who has given consent for the study. The time and number of instruments changed will be recorded for the steps outlined in the *Data Collection Form* document.

*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.

*Ethical concerns*

The identity of the surgeon will not be linked to the time flow data, to ensure there is no risk of participant embarrassment regarding surgical efficiency compared with peers.

*Budget*

The total budget is given in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Personnel | Description | Price/Unit | Unit | Qty | Total Cost |
| Master's Student | Stipend | 23465 | year | 0.5 | 11732.5 |

Since this study is observational, it just requires the time of the Master’s student to conduct the study.

*Participant Consent*

Patients who are eligible for TEES during their surgery will be asked to fill out a consent form or assent form depending on their capacity.

Consent to participate in this study will also be sought from surgeons.

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