Needs Analysis and Time Flow Study to Assess Endoscopic Ear Surgery

**Page numbers, version date**

**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] [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 [2] [3]. 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 improving visualisation for disease eradication (2-4), including reduction of the rate of residual 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 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 [2] [4]. 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). 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.

**Objectives and Hypothesis:**

*Objectives:*

In order to increase the use of TEES, the following will be investigated: a) the reason for surgeons not adopting TEES and b) limitations of existing tools. This will aim to understand why TEES is not widely adopted by otologists and how its adoption can be improved.

*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.

**Overview of Methodology:**

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

*1. Needs Assessment*

The first part of this study aims to understand why TEES is not widely adopted 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 TEES and how to facilitate its adoption. A questionnaire will be formulated from a literature review and interviews with local otolaryngologists and sent to otolaryngologists globally. The results aim to be published to establish the requirements for instrument development to facilitate TEES.

*2. Time Flow Study*

As well, independent of the needs analysis, a time flow analysis, 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, consisting of questionnaires, are used to gain information regarding a specific topic by consulting a wide variety of experts in the field. It has been used to assess the challenges of endoscopic neurosurgery in Britain and the current status of endoscopic ear surgery in Canada [4] [5]. 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 [6] [7] [8].

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. A preliminary survey for local otolaryngologists, with varied experience in TEES within the University of Toronto, will develop a questionnaire. Questions will ask for comments on factors that have prevented otologists from using endoscopes in otologic surgery, and for comments on the perceived strengths and weaknesses of currently available instruments for endoscopic ear surgery. 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. The confidential answers will be analyzed to develop another, more specific, survey that will be sent out once again to the participants. This will attempt to develop a consensus of conclusions for the survey.

*Participant Recruitment:*

The participants are ear surgeons. The survey will be emailed to surgeons. 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. The PI is a member of many otological societies from which he frequently receives surveys relating to aspects of current practice. The PI will seek permission from these societies to survey their members.

These email addresses will be kept in a master spreadsheet, separate from the results of the survey.

*Questionnaire:*

Refer to Appendix A for the survey details.

**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 [9] [10]. 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 are willing to participate in this study.

*Inclusion criteria*

Patient participants: 40 ear surgical patients, aged 0-18 years, who require cholesteatoma surgery or tympanoplasty surgery.

Surgeon participants: 4 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 they might become nervous and are not as experienced, causing slower times.

*Study intervention*

Each surgeon will be recorded for 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.

*Ethical concerns*

It is up to the surgeon’s discretion as to what tools should be used to ensure the safety of their patient. Therefore, if the new instrument is used for the surgery it is only if the surgeon assesses that it would be safe and effective to perform the surgery.

The data will not link the identity of the surgeon or the patient to the results, so there will be no risk of participant embarrassment.

*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*

There are two different types of surgery where the time flow study will be conducted: tympanoplasty and cholesteatoma removal. Each type of surgery will have its own set of consent forms for the patient participants. Cholesteatoma patients are already asked to fill out a consent form for another observational study: *Prospective study of predictive factors in paediatric cholesteatoma.* These consent forms will be used for the cholesteatoma patients, and amended to add a line requesting consent to time the surgery. There will be new consent forms for tympanoplasty requesting consent to time surgery.

For the cholesteatoma patients, who have a CT scan and have provided consent to use their CT for anatomical analysis and modeling purposes in the Prospective study of predictive factors in paediatric cholesteatoma, the study number will be recorded on the corresponding CT scan as well. The CT scan will be wiped of all patient identifiable information and only the randomly generated 5-digit code will be used to link the CT scan to the recorded surgical times.

Consent to participate in this study will be sought from the surgeons and the patient, who has capacity, and/or guardian, if the patient does not have capacity, involved in the surgery.

Needs Assessment Survey:

This portion 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.

Time Flow Study:

Consent will be based on capacity. If the participant doesn’t have the capacity to provide consent, assent will be obtained and the parent/guardian will sign for consent.

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