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 [2], [3]. 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]. 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 [3]. 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). It is proposed that further potential for extending indications and improving outcomes in endoscopic ear surgery lies in the development of dedicated instrumentation designed for the purpose.

**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 develop criteria against which new instrumentation will be designed and tested using 3D printed and computer models of the ear.

*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 and new instruments will be fabricated and tested, using mechanical engineering design principles, to address these needs to improve the adoption of TEES.

**Overview of Methodology:**

The following outlines the four parts of the project.

*Part 1: Needs Assessment*

This protocol forms part of a project aiming to develop improved instrumentation for endoscopic ear surgery. 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. We hypothesize that a needs analysis study, including a survey and time flow analysis, will provide an answer to this question and help develop criteria against which new endoscopic ear surgery tools can be developed. 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. 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.

*Part 2: Design and Fabrication of New Instruments*

The second part of the study aims to develop and fabricate new instruments for TEES using the results of the needs assessment, the primary investigator’s experience of TEES, and models of the ear developed from patient’s CT scans. The instruments will be designed to optimize functionality, ease of use and maneuverability of the tool within the ear canal alongside an endoscope. 3D computer models will be constructed from the CT scans and used as a guide for the geometry and size specifications for the new instruments. The CT scans will provide real anatomy against which to design the instruments to ensure that they are able to access the hidden recesses within the ear, through the ear canal and alongside the endoscope. New instruments will be computer modeled, 3D printed, tested inside 3D printed ear models, redesigned and a secondary metal prototype will be fabricated using a mill machine at an engineering lab at SickKids.

*Part 3: Validation Testing*

Validation testing of the secondary prototypes will be conducted and published to compare existing tools as well as the new instrument designed. A mock operating room setting will be used where surgeons will test the tool on cadaveric or 3D printed ear models by performing an ear drum replacement procedure and trying to reach hidden recesses behind the ear drum. The number of tries to pick up and place the graft and time to complete the procedure will be measured to assess the efficiency, functionality and ease of use of the tool. As well, qualitative feedback, in terms of ease of use and ergonomics, will be obtained.

*Part 4: Final Prototype Evaluation*

The feedback from the validation testing will be used to develop a final prototype of the tool out of sterilizable nitinol and stainless steel. The design will be optimized to be used by the PI in a patient to perform middle ear surgery. The surgical steps that employ the new tool(s) will be timed, similar to the time flow analysis and compared to previous times with current tools to evaluate the new tools. As well, the surgeons who employ this tool in their surgery will be asked to fill out the needs assessment survey again. This will validate the hypothesis that a tool designed to address the criteria determined in the needs assessment would make TEES more safe, efficient and/or effective.

**Methods and Analysis:**

**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 [4]-[5]. 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.

*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 following steps:

1. Cleaning the ear canal
2. Injecting the local anaesthetic
3. Trimming the ear hairs
4. Cleaning the edges of the ear drum perforation (if applicable)
5. Making the skin incision
6. Raising the skin flap
7. Preparing the ear drum graft
8. Positioning the ear drum graft in place
9. Replacing the skin flap
10. Packing the ear canal

*Data Collection Table:*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Surgery: |  |  |  |  |  |  |  |  |
| Tympanoplasty | Step | CT scan code\* | Date/notes | Time (min) | Date/notes | Time (min) | 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: |  |  |  |  |  |  |  |  |
| Cholesteatoma Removal | Step | CT scan code\* | Date/notes | Time (min) | Date/notes | Time (min) | 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 CT-scan code will be a randomly generated 5-digit code that will be assigned to the CT scan from the patient. The CT-scan will be wiped so that there is no personal patient information on it and it will be labeled with the 5-digit code. This code will be associated with the times for each surgical step as well, as seen on the table.

*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 using the new instrument, compared to the surgery using a current instrument. As well, it will be noted whether or not the tool was used to successfully complete the step, or if the surgeon used another tool instead.

*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*

The consent forms will ask for consent for the following:

* Duration of different steps during surgery.
* Details about ear anatomy, from pictures taken of the ear drum in clinic, from what is found during surgery and from any scans the patient may need as part of his/her treatment (eg CT scan or MRI scan).

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. The cholesteatoma removal surgery already has consent forms requesting the use of CT scans from the patient. They will be amended to request permission to record times of surgical steps.

Please see the attached consent and assent forms. The following forms will be included. Consent is received if the participant signs for consent. Consent can be withdrawn at any point, and that will not reflect negatively on the participant. This study is for research purposes only. Declining to participate will not affect the participant in any way, be it professionally or the standard of his/her care.

Consent to participate in this study will be sought from the surgeons and the patient and/or guardian involved in the surgery. The following is a list of forms:

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:

* Surgeon Participant Consent Form
* Patient Participant Consent Forms:
  + Patient Consent Form (to be filled out by patients who are at least 12 years old)
  + Patient Assent Form (to be filled out by patients who are less than 12 years old)
  + Parent/Guardian Consent Form (to be filled out by patient’s parent or guardian if the patient is unable to make a decision)

**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 [6]-[7]. 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 [8] [9] [10].

A qualitative assessment of the challenges in endoscopic ear surgery caused by limitations in current instrumentation will be completed by performing an on line 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:*

The email will contain the following email script:

Dear Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

I am Dr. Adrian James, an otolaryngologist at the Hospital for Sick Children in Toronto. I practice endoscopic ear surgery and I am conducting a study to understand how to increase the adoption of totally endoscopic ear surgery. We would like to invite you to participate in this voluntary, anonymous online survey, where your identity will not be revealed to us. Your participation or non-participation in this survey will be unknown and will not affect your professional status and/or integrity in any way. The survey is to aid in the research of understanding the current experience of endoscopic ear surgery and why it is not widely adopted. This study will be conducted using the two-round Delphi method. The responses of this survey will be collated to develop a second round of more specific questions, which will be sent out in another survey.

Please click on the link below if you are willing to participate in the survey:

[INSERT LINK TO SURVEY]

Landing Page of Survey:

“This research study aims to understand why totally endoscopic ear surgery has had a low rate of adoption and practice thus far and how to increase its use among otologists. This voluntary survey’s objective is to collect data to answer these research questions by surveying practicing otologists, and to publish the results in a research journal to fill this knowledge gap. The survey will be conducted via a two-round Delphi method. The responses of this survey will be collated to develop a second round of more specific questions, which will be sent out in another survey. The results will then be analyzed and presented in a paper in an otology research journal.

It is important to note that this survey is completely voluntary and will remain confidential and anonymous to the researchers. There will be no way to identify the participant to their answers to the survey. As well, participation or non-participation in this survey will not affect your professional integrity in any way. This survey is purely for research purposes.

By answering the questions in the survey and submitting it, it will be implied that you consent to filling out your survey and the researchers using the anonymous data to analyze and present it.

We thank you for your time. Please click below to begin.”

*Questionnaire:* Please refer to attached Questionnaire, print out the survey

In the case that we do not receive any responses within two weeks, we will send out one follow-up email to the invited participants. The email will read:

“Dear Dr.\_\_\_\_\_\_\_\_\_\_,

This is a friendly follow up email to the request to participate in the voluntary survey, linked below, to gather information about why totally endoscopic ear surgery is not widely adopted and practiced. This will aid in a research study aiming to understand the answers to these questions.

It is important to note that this survey is completely voluntary and will remain confidential and anonymous to the researchers. There will be no way to identify the participant to their answers to the survey. As well, participation or non-participation in this survey will not affect your professional integrity in any way. This survey is purely for research purposes.

By answering the questions in the survey and submitting it, it will be implied that you consent to filling out your survey and the researchers using the anonymous data to analyze and present it.

We thank you for your time. Please click below to begin.”

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