Title:

Introduction:

Imagine a world where all surgeries are performed minimally invasively, a technique that reduces trauma to the body, scarring, recovery time and length of hospital stay [1]. Middle ear surgery is traditionally performed through an external incision with visualisation of delicate anatomical structures using a microscope. More recently, surgical techniques have been developed using endoscopes to access the middle ear through the ear canal without an external incision [2, 3]. It has been found that endoscopic surgery can improve outcomes by enhancing minimally invasive access for disease eradication and reducing post-operative morbidity (2-4). More effective disease control has been shown with reduction in rates of residual mesotympanic cholesteatoma (2, 3) and better hearing from ossicular preservation (10, 11). 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]. As clear access to the ear drum and tympanic membrane and recesses of the tympanic cavity can be achieved without an external incision, the patient benefits from a reduction in post-operative morbidity (10). Despite the enthusiasm of some 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 all well suited to TEES conditions [3]. Throughout middle ear surgery, the non-dominant hand is often used to suction blood from the field and retract soft tissue during dissection. As otologists have been trained and gained experience in such techniques with such instruments, they 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 a larger and larger proportion of tympanoplasty and cholesteatoma surgeries endoscopically (1, 7, 12). Nevertheless, the learning curve can be slow and frustrating. In the experience of the primary investigator (PI), technological advances have lead to incremental stepwise jumps in this learning curve. Examples of beneficial technologies include high definition cameras and monitors, 3mm diameter endoscopes and suction dissection instruments (13).

These shortcomings have hindered the use of TEES and will be addressed by this project which will utilize mechanical engineering principles to develop specialized instruments for TEES [4, 3]. While previous instruments were developed by surgeons over decades through trial and error, modern engineering techniques provide the opportunity to rapidly design and produce ergonomic functional instruments optimised to facilitate this new branch of surgery.

We propose that new instrumentation can be developed specifically for one-handed endoscopic surgery to overcome the limitations of current instruments. By overcoming this barrier to progress in the field of endoscopic surgery, the advantages of minimally invasive surgery will be accessible to more otologists to the benefit of patients with chronic ear disease.

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 colleagues in the field and personal experience, it is recognized that limitations of these instruments include suction cannulae that are too narrow leading to frequent occlusion and flexible instability, and small-tipped dissectors and picks that rarely reach requisite recesses within the ear. The round knife has an unusually flat angle from the shaft of the instrument that is widely considered suboptimal. An innovative set developed by Panetti (13) incorporates suction into dissection instruments with an ingenious rotating connector (Spiggle & Theis Medizintechnik GmbH; Burghof, Germany). Although providing valuable benefit in clearing blood from the field during dissection, criticisms of these instruments have included: the thumb control for suction which rotates out of reach when the instrument is manipulated; dissection tips which are too pointed; lumen of the suction not reaching the cutting edge of the round knife; longer curved dissectors lacking the delicacy required for small recesses.

Research: question, hypothesis, objectives

Evaluate the reasons for surgeons not adopting TEES and conduct a time flow analysis to develop design requirements and criteria to develop better TEES tools to encourage TEES use. Questionaire for surgeons in the field of endoscopic ear surgery. Time flow analysis using existing and modified instruments.

This application seeks to shift current clinical practice in surgery for chronic middle ear disease by creating novel instrumentation that will facilitate the practice of endoscopic ear surgery. Practitioners of endoscopic ear surgery will be surveyed to reveal the barriers they faced when adopting the technique, and that they continue to experience in endoscopic ear surgery. A comprehensive assessment of existing instruments, including intra- operative time-flow analysis, will be used to identify potential design limitations of currently available instruments that. Innovative solutions to these barriers will be developed including on-line focus-group based discussions, concentrating on enhancing multi-functionality of instruments to be operated easily with one hand.

Literature review

Specific aims + methods

The overall goal of this project is to develop and test new surgical instruments that are well-suited to the specific needs of surgeons practising endoscopic middle ear surgery. To achieve this goal the specific aims are to: 1. conduct a needs assessment to understand the functional limitations of currently available otologic surgical instruments as used in endoscopic ear surgery

The project comprises three distinct parts toward the development of novel surgical instrumentation for endoscopic ear surgery: (1) to complete a needs assessment, (2) to design and prepare instrument prototypes, and (3) to evaluate the prototype instruments. The basis of this grant application is to support a graduate student from the MASc program at the Institute of Biomaterial and Biomedical Engineering (IBBME) University of Toronto for these purposes.

1) Needs assessment

The needs assessment 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.

a) Time-flow analysis Time-flow analysis is an approach used to 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). The MASc student from the IBBME will observe endoscopic ear surgeries and note the time taken to accomplish pre-determined steps in the surgery. Broadly, 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 observation will also lead to an appreciation of the ergonomic requirements of instruments during otologic survey 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.

b) Survey 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.

Open-ended questions based on the personal experience and time-flow analysis of the PI will be generated and piloted on a subset of six other otologists known to have varied experience in endoscopic ear surgery within the University of Toronto. 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. Responses to these questions will be used to design the survey which will also include open-ended questions to capture the breadth of different experiences within the field. The survey will be provided electronically using FluidSurveys, an online survey tool (http://fluidsurveys.com).

Participants for the wider survey will be recruited by email and personal communication from the PI, and will include 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. Involvement in the survey will be anonymized to encourage accurate disclosure of surgeons’ challenges. Responses to the survey will be collated to find common themes.

A high response rate to the survey is anticipated, as the IWGEES members are well known to the PI and enthusiastic supporters of positive innovations in the field.

An open-coding thematic content analysis procedure will be applied to the data (15, 16) whereby the three investigators will independently review each response, coding line by line while noting key themes and patterns in the needs or functional requirements that the instrument should satisfy. The investigators will compare and contrast the themes and their relationships amongst each other. Any discrepancies will be resolved through discussion amongst all investigators. Using an iterative process, codes will then be organized according to those with similar meanings (15, 16).

From the PI’s personal experience and prior communication with IWGEES members and participants of Endoscopic Ear Surgery Conferences worldwide, it is anticipated that the following challenges and needs will be revealed: • Difficulty clearing blood from the field • Difficulty retracting soft tissue flaps during dissection

• Access to deeper recesses of the middle ear cleft that are revealed by endoscopy, but beyond the reach of conventional instruments • Difficulty with bone removal beyond atticotomy curettage • Difficulty with graft positioning.

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 combing functions of current instruments into single tools that can be simply operated with one hand.

The strength of this methodology is that opinion will be sought widely in order to develop instruments that meet the needs of a large number of surgeons. A potential weakness 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.

Expected outcomes

Significance

Understanding the needs for surgeons to adopt endoscopic ear surgery and modifying instruments to address those needs would aim to increase the adoption of the surgical technique.

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, 7, 8]. 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.

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