Background:

Minimally invasive surgery is being adopted in many types of surgery and the endoscope has allowed this to be possible through the ear canal for middle ear surgery [1] [2]. As with traditional, invasive 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, through the ear canal [1]. Thus, operating through a natural opening of the body eliminates the need for an external incision, which is not the case for many types of minimally invasive surgery [1]. The principle challenge with TEES is that a one-handed surgical technique is required as the endoscope is held in the other hand. Otology instruments were developed for two-handed microscope-guided surgery so they are not all well suited to TEES conditions [1].

A survey reported that out of 80 Canadian ear surgeons (otologists), less than 10% have performed more than 50 surgeries using TEES, 70% use endoscopes to aid surgery or in the clinic and 50% are likely to use TEES in the future [3]. Thus, TEES is recognized for its potential and the investigators believe that through better training and instrumentation, its adoption will be improved. The project investigator is an ear surgeon The Hospital for Sick Children is one of the very few centres in North America where a surgeon completes the majority of middle ear procedures endoscopically (can’t find a reference for this).

This project aligns with CIHR’s mandate as TEES is a surgical technique being used internationally and the objective of the project is to encourage greater use of the technique and TEES allows more effective skin growth removal surgery while preserving the delicate structures within the middle ear (<http://www.sinuscentro.com.br/iwgees/group.htm)> [2].

The principle challenge with TEES is that a one- handed surgical technique is required while the endoscope is held in the other hand, this makes the surgery more difficult, and requires enhanced training [3]. Otologic instruments were developed for two-handed microscope-guided surgery so they are not all well suited to TEES conditions [2]. 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 [2] [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.

Objectives and Hypothesis:

To understand why otologists have not adopted TEES and what current instrument limitations are to develop surgical instruments that facilitate one-handed surgery for TEES. To achieve this, tools will be designed to improve grip and manoeuvrability of synthetic grafts and enable accessibility in hard to reach places within the middle ear. Increasing functionality of surgical instruments by manipulating angular geometry, adding pushing mechanisms and adding suction capabilities, will increase control during TEES, replicating manoeuvres for which two hands are traditionally required.

We hypothesize that a needs analysis study will provide an answer to this question and help develop criteria against which new endoscopic ear surgery tools can be developed.

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.

Experimental Approach:

Methods/Procedures:

*Aim 1:*A needs assessment survey, using the Delphi method, will be conducted to determine the requirements to address in order to encourage more surgeons to train in and employ TEES. A list of questions will be formulated based on local otolaryngologists’ feedback, and a survey will be sent to otolaryngologists globally. The results will then be published to establish the requirements to enable training and development of endoscopic ear surgery. A time flow analysis recording the duration of surgical steps will also be conducted to quantify the limitations of current instruments used in endoscopic ear surgery, by assessing their efficiency. This data will be analyzed statistically and published in a peer-reviewed otolaryngology journal, to address this knowledge gap. This analysis will ensure that the tools are designed for the surgeon to use effectively, safely and efficiently.

*Aim 2:*An initial, functional prototype, developed by the supervisor and student, was designed to facilitate manipulation of a synthetic graft during ear drum reconstruction surgery. New instruments in response to the needs assessment will also be developed, for example to ease control of bleeding and to access hard to reach places in the middle ear, with one hand operating. The instruments will be designed to optimize functionality, ease of use and maneuverability of the tool within the ear canal alongside an endoscope.

*Aim 3:* Validation testing 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.

*Aim 4:*Collaborate the obtained feedback to optimize the tool so it can be used in patients in the operating room.

These aims will be accomplished by integrating the pillars of CIHR: biomedical engineering, by developing tools, clinical research, by testing the tools in CT-scan generated 3D printed ear models and this will all aim to increase the adoption of TEES which will positively affect the healthcare system, due to the minimally invasive surgery benefits to the hospital and patient because of shorter hospital stay and less patient morbidity [4].

**Significance:**

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 [4] – [6]. It could be envisaged that ultimately, virtual patient models could be used with rapid prototyping and fabrication methods, developed by this project, to create patient specific specialist instruments to extend minimally invasive surgery.

These tools will be derived from endoscopic neurosurgery tools that can be used manually and via robot therefore, the potential to further develop these tools – can be designed for use with robotic surgery which is (give a number on how big robotic surgery is and a description of its niche)

Therefore, these tools can be used for neuro, sinus, ear, and more to come

**Expected Outcomes:**

As per informal discussions with otologists at SickKids, the needs analysis survey will show that surgeons find one handed surgery and bleeding control the major challenges in endoscopic ear surgery. They have conveyed that future tools whose primary functions are coupled with suction would be beneficial to aid surgeons while performing this new type of surgery. As well, it is expected that the new tool will encourage more use of endoscopic ear surgery by easing the procedure and increasing efficiency.

**Impacts on Endoscopic Ear Surgery and Patients:**

The development of tools to facilitate endoscopic ear surgery aims to encourage more ear surgeons to adopt this minimally invasive surgical technique and therefore reduce patient morbidity rates and send patients home sooner so they can go back to their normal lives. Endoscopic ear surgery has been shown to reduce rates of residual skin growth after skin growth removal surgery in the middle ear as the endoscope allows greater visualization in the previously hidden recesses within the middle ear [7].

3.

References\*

List the references in your research proposal here. **Maximum 4,500 characters (with spaces), which is equivalent to about 1 page single spaced in Microsoft Word, 10 point Arial font.**

[1] A. James, "Endoscopic Middle Ear Surgery in Children", Otolaryngologic Clinics of North America, vol. 46, no. 2, pp. 233-244, 2013.

[2] C. Carlos, W. Parkes and A. James, "Application of 3-dimensional Modeling to Plan Totally Endoscopic Per-Meatal Drainage of Petrous Apex Cholesterol Granuloma", Otolaryngology -- Head and Neck Surgery, vol. 153, no. 6, pp. 1074-1075, 2015.

[3] M. Tarabichi, “Endoscopic Middle Ear Surgery,” Ann. Otol. Rhinol. Laryngol., vol. 108, no. 1, pp. 39–46, 1999.

[4] “Benefits of Minimally Invasive Surgery | AIMIS.” [Online]. Available: http://www.aimis.org/benefits-of-minimally-invasive-surgery/. [Accessed: 14-Nov-2015].

[5] “AANS - Minimally Invasive Spine Surgery MIS.” [Online]. Available: http://www.aans.org/patient information/conditions and treatments/minimally invasive spine surgery mis.aspx. [Accessed: 17-Nov-2015].

[6] “Endoscopic Nasal & Sinus Surgery.” [Online]. Available: http://care.american- rhinologic.org/ess. [Accessed: 17-Nov-2015].

[1] H. Kanona, J. S. Virk, and A. Owa, “Endoscopic ear surgery: A case series and first United Kingdom experience.,” *World J. Clin. cases*, vol. 3, no. 3, pp. 310–7, 2015.

[2] A. L. James, “E n d o s c o p i c Mi d d l e E a r S u r g e r y in C h i l d ren,” *Otolaryngol. Clin. NA*, no. November, 2012.

[3] M. Yong, T. Mijovic, and J. Lea, “Endoscopic ear surgery in Canada : a cross-sectional study,” *J. Otolaryngol. - Head Neck Surg.*, pp. 1–8, 2016.

[4] “Benefits of Minimally Invasive Surgery | AIMIS.” [Online]. Available: http://www.aimis.org/benefits-of-minimally-invasive-surgery/. [Accessed: 14-Nov-2015].

[5] Ã. A. L. James, Ã. S. Cushing, and Ã. B. C. Papsin, “Residual Cholesteatoma After Endoscope-guided Surgery in Children,” pp. 196–201, 2015.