**The Development of New Instrumentation to Facilitate Endoscopic Ear Surgery**

**Background:** The endoscope has allowed minimally invasive surgery to be possible through the ear canal, a natural opening of the body, for middle ear surgery, without the need for an external incision [1] [2] [13]. As with traditional, invasive microscope-guided ear surgery, transcanal endoscopic ear surgery (TEES) allows the surgeon to perform common procedures such as ear drum reconstruction, skin growth removal and hearing bone repair, through the ear canal [1]. TEES is a one-handed surgical technique and this has discouraged many ear surgeons (otologists) from adopting it as current instrumentation, designed for two-handed use, does not facilitate operating single-handedly alongside an endoscope [3]. However, the endoscope allows for: better visualization of the middle ear, more effective surgical skin growth removal, preserving the hearing bones, and relief for patients and families as a skin incision is not required [13]. A survey reported that out of 80 Canadian otologists, the adoption rate of TEES is less than 10% but 50% are likely to use it in the future [3]. Although, the literature has not yet reported specific reasons as to why TEES adoption is low; there is little knowledge as to how to improve its use.

**Objectives and Hypothesis:** 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 models of the ear. 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 improve the adoption of TEES. 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, facilitating safer, more effective middle ear surgery in Canada [2].

**Experimental Approach and Methods/Procedures:** *Aim 1:*A needs assessment survey, sent to otologists internationally, will follow a two-round Delphi method to determine the requirements to increase surgeon adoption of TEES. Questions have been developed based on local otolaryngologists’ feedback on TEES. A time flow analysis, recording the duration of surgical steps, will quantify the efficiency of current instruments to determine the limitations of TEES. Statistically analyzed data will be submitted to peer-reviewed otolaryngology journals, to address this knowledge gap and provide criteria for the development of safe, effective, efficient and valuable tools to facilitate TEES. *Aim 2:*An initial, functional prototype was prototyped and tested by the supervisor and student to facilitate ear drum reconstruction surgery. New instruments in response to the needs assessment will also be developed to ease control of bleeding and to access hard to reach places in the middle ear. 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 with new prototypes. A mock operating room setting will be used where surgeons will test the tool on cadaveric or 3D printed ear models by performing ear drum reconstruction and dissecting hidden recesses behind the ear drum. Qualitative feedback and time required to successfully complete procedures will be recorded and analyzed, similar to the time flow analysis, to assess the value, efficiency, functionality and ease of use of the tools. *Aim 4:*Use the obtained feedback to optimize the tool so it can be used in patients in the operating room. These aims will be integrating the pillars of CIHR: biomedical engineering, by developing tools; clinical research, by testing the tools in 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 instrumentation will be developed based on existing tools for endoscopic neurosurgery, thus the tools will be applicable to neurosurgery and other minimally invasive surgery in bony cavities such as sinus, nasal, spinal and arthroscopic surgery as well as neurosurgery[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.This positively impacts the healthcare system by reducing patient morbidity rates and hospital stay. 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].

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