**Director’s Innovation Award 2016**

**Research Proposal**

The aim of this project is to develop and evaluate innovative surgical instruments for the new and growing field of endoscopic ear surgery, a minimally invasive technique. By employing an endoscope during middle ear surgery, the middle ear can be accessed through the ear canal without an external incision [2, 3]. 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 [2]. The Hospital for Sick Children remains one of the very few centres in North America where a surgeon completes the majority of middle ear procedures endoscopically. The learning curve to reach this status has been slow, taking many years, but the wealth of experience accumulated has given valuable insight into the strengths and weaknesses of currently available instrumentation for endoscopic ear surgery.

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. Otologic instruments were developed for two-handed microscope-guided surgery so they are not all well suited to TEES conditions [3]. 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 [3, 4]. 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.

**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.

**Aim 2:** A prototype, developed by the supervisor and student, was designed to facilitate manipulation of a synthetic graft during ear drum graft replacement 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 resident and staff surgeons will test the tool on cadaveric or 3D printed ear models by performing an ear drum replacement procedure. 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.

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 [5-7]. 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.

**Research Training Environment Statement**

The Department of ORL-HNS at the Hospital for Sick Children will be funding the Master’s student’s stipend. The supervisor and student have received a Perioperative Services Innovation Project grant from the Hospital for Sick Children and the Harry Barberian Scholarship Award from U of T to fund materials and tools. The following labs have provided equipment and expertise to support successful completion of the proposed project: Centre for Image Guided Innovation and Therapeutic Intervention (CIGITI) at SickKids, the Surgical Skills Centre (SSC) at Mount Sinai Hospital and the Institute of Biomaterial and Biomedical Engineering (IBBME). The labs have been successfully used by the investigators to develop a functional initial prototype. CIGITI will provide bench space, technical support and machines to manufacture instrument prototypes. IBBME and CIGITI will provide office space and computer software to design instruments. The SSC will facilitate prototype testing using cadaveric temporal bone models by trained personnel. The SickKids operating room will be used for needs assessment and evaluation of instruments during surgery.

This project encapsulates an overarching goal of collaborating between two IBBME research themes of Engineering in a Clinical Setting and Biomaterials and Regenerative Medicine as this new tool will be used to facilitate ear drum reconstruction surgery which places a synthetic graft implant biomaterial to treat a patient’s damaged or perforated ear drum in the clinical setting of the operating room.

The primary investigator, Otorhinolaryngologist Dr. James, is recognized internationally for his experience in endoscopic ear surgery. He will provide guidance on surgical ergonomics, functional requirements of instruments and feasibility of design proposals. He has previously developed instrumentation for minimally invasive cochlear implant surgery. Co-supervisor Dr. Andrysek has supervised multiple graduate students through the MASc and MHSc programs at IBBME and his experience with medical device design will provide technical engineering support for the project.

Dr. James and Dr. Andrysek have not previously collaborated as investigators on a project, and therefore this proposal represents a new and meaningful collaboration. As part of a design team, Arushri undertook an undergraduate engineering design project with Dr. James as the supervisor to design an instrument to facilitate graft manipulation for TEES. The prototype was successfully validated inside a cadaver ear at the SSC. Thus, Dr. James, Dr. Andrysek and Arushri will be collaborating with IBBME to further develop this prototype and design new instruments for TEES.

We believe that the combination of surgical and engineering experience with state of the art facilities for design, manufacturing and testing of novel instruments provides an excellent training opportunity, and the likelihood of successful outcomes from the project, including generation and dissemination of novel research (as conference and peer-reviewed journal papers), as well as development and potential commercialization of novel new medical instruments.

**References:**

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