2017-2018 ONTARIO GRADUATE SCHOLARSHIP – Plan of Study

Arushri Swarup, University of Toronto, Institute for Biomaterials and Biomedical Engineering Proposed Project: Development of Surgical Instruments for Endoscopic Ear Surgery

Overview: 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. An endoscope allows visualization of the middle ear through the ear canal without an external incision [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 [2] [3]. SickKids Hospital remains one of the few centres in North America where a surgeon completes the majority of middle ear procedures endoscopically, due to the steep learning curve. The principle challenge with TEES is that a one-handed surgical technique is required while the endoscope is held in the other hand. Ear surgery instruments were developed for two-handed microscope-guided surgery so they are not optimized for TEES conditions [2] [4]. The team at SickKids has accumulated valuable insight into the strengths and weaknesses of currently available instrumentation for TEES through experience and observation of TEES. These shortcomings have hindered the use of TEES; this project will address them by engineering specialized instruments to facilitate TEES [4] [5].

Aims: *Aim 1:* To conduct a needs assessment survey, using the two-round Delphi method, that examines the current limitations of TEES and how to facilitate the technique. A questionnaire has been formulated from a literature review and interviews with local otolaryngologists. It has been sent to otolaryngologists globally and the first round of responses will be analyzed to develop the second questionnaire. A time flow analysis, recording the duration of surgical steps, is being conducted to quantify the limitations of the current instruments used in TEES, by assessing their efficiency. The team has acquired Research Ethics Board approval to conduct these studies and the results will be published to establish the requirements for training and instrument development to facilitate TEES.

Aim 2: An initial, functional prototype, developed by the supervisor and student, has been designed to access areas within the middle ear that are difficult to reach with current instruments. CT scans of patient anatomy are being used as a guide for designing optimal instrument geometry that can fit into the ear alongside the endoscope and perform the intended functions.

Aim 3: Validation testing will be conducted and published to compare existing tools to the new tool. Local, experienced ear surgeons will test the tool on cadaveric or 3D printed ear models by trying to reach areas within the middle ear that the endoscope can visualize but current instruments cannot reach. Similar to the time flow study, the time required to reach these areas will be measured to assess the efficiency and effectiveness of the tool compared to existing tools. As well, qualitative feedback, in terms of ease of use and ergonomics will be obtained from the experienced ear surgeons and statistically analyzed to evaluate the tool's performance.

Aim 4: Use the feedback to optimize the tool so that it can be used in patients in the operating room.

Significance:

The development of tools to facilitate endoscopic ear surgery aims to encourage more ear surgeons to adopt this minimally invasive surgical technique, which would reduce patient morbidity rates, recovery time and hospital stay [6]. Endoscopic ear surgery has been shown to reduce rates of residual skin growth after surgery in the middle ear as the endoscope allows greater visualization in the previously hidden recesses within the ear [7]. Additionally, the techniques developed to create new, specialized instruments could be used to create patient specific instruments by using virtual patient models and rapid fabrication methods developed in this work.

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