Developing Novel Instrumentation to Facilitate Transcanal Endoscopic Ear Surgery

Harry Barberian Scholarship Application, March 3, 2017

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Location of Laboratory or Institution: Hospital for Sick Children Toronto

Transcanal endoscopic ear surgery (TEES) is a new and growing surgical technique that allows otologists to perform middle ear surgeries by feeding an endoscope and instrument through the ear canal without a skin incision [1] [2]. As compared to traditional, invasive microscopic surgery, minimally invasive TEES allows for more effective visualization, cholesteatoma removal and ossicle preservation [2] [3]. As well, TEES has been shown to reduce the length of hospital stay, overall procedure cost and scarring [2] [4]. However, the adoption rate of TEES is low and one explanation why is that existing instruments designed for two-handed microscopic surgery are not optimized for one-handed TEES, making it challenging [5]. This project proposes the design of **novel instruments** to facilitate TEES and allow more surgeries to be completed minimally invasively to **benefit the patient and hospital.** To do this, the limitations of current TEES tools will be identified to develop appropriate design criteria for new instrumentation.

The PI of the project is an experienced TEES surgeon at the Hospital for Sick Children in Toronto (SickKids) and is collaborating with a University of Toronto Engineering Master’s student at the CIGITI lab in SickKids. This collaboration provides the **resources and expertise** required to meet the project aims. *Aim 1 (months 1-9):*A needs assessment survey, sent to 100 otologists internationally, will follow a two-round Delphi method to identify instrument functionalities that would facilitate TEES and address surgeons’ needs. *Aim 2 (months 1-9):* A time-flow study will record the duration of surgical steps for common TEES procedures. It will be conducted by observing a total of 50 surgeries performed by five surgeons at SickKids. The results of these two studies, statistically analyzed using ANOVA for parametric and non-parametric data, will determine the current inefficiencies of TEES and the desired functions of new tools. A Research Ethics Board (REB) application has been submitted to SickKids. *Aim 3 (months 3-5):* A virtual model of TEES will be developed to aid the design of new tools. The model will integrate middle ear anatomy, rendered into 3D using CT scans, an endoscope and an instrument. This will develop a platform to design tool prototypes that can fit inside specific patient anatomy. Tool prototypes will be tested by surgeons in 3D printed anatomical models and cadavers. SickKids, CIGITI and Mount Sinai’s surgical skills centre will provide the surgeons, 3D printing facilities and cadavers, respectively, to obtain feedback for prototypes. Feedback will be used to optimize the prototype so it can be further developed to be used by surgeons in patients during TEES.

SickKids remains one of the few centres in North America where a surgeon completes the majority of middle ear procedures using TEES. As well, CIGITI has developed virtual surgical simulation models and medical-grade tools for endoscopic neurosurgery under close collaboration with surgeons. Thus this project will present a unique platform to develop patient-specific tools, advancing the capabilities of instrumentation to facilitate minimally invasive surgery to ultimately **send patients home sooner and safer.**

**References:**

[1] A. L. James, “Endoscopic Middle Ear Surgery in Children.,” *Otolaryngol. Clin. North Am.*, vol. 46, no. 2, pp. 233–44, Apr. 2013.

[2] R. Obholzer, J. Ahmed, F. Warburton, and M. J. Wareing, “Hearing and ossicular chain preservation in cholesteatoma surgery.,” *J. Laryngol. Otol.*, vol. 125, no. 2, pp. 147–152, 2011.

[3] M. Badr-el-dine, “I n s t r u m e n t a t i o n a n d Tec h n o l o g i e s in E ndos c o p i c Ear Su r ge ry,” *Otolaryngol. Clin. NA*, vol. 46, no. 2, pp. 211–225, 2013.

[4] N. Nassif, M. Berlucchi, and L. O. R. de Zinis, “Tympanic membrane perforation in children: Endoscopic type I tympanoplasty, a newly technique, is it worthwhile?,” *Int. J. Pediatr. Otorhinolaryngol.*, vol. 79, no. 11, pp. 1860–1864, 2015.

[5] 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.

**Detailed Budget**

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| --- | --- | --- | --- | --- | --- |
| Item | Description | Price/Unit | Unit | Qty | Cost (CAD) |
| Ear Surgery Instruments: These will be 3D CAD modeled for the virtual model to understand where in the ear anatomy current instruments are able to reach. New tools will be designed by modifying current instruments or using these instruments as a base to design from. | | | | | |
| Rosen Needle (small) |  | 75.5 | piece | 3 | 226.5 |
| Rosen Needle (large) |  | 152.6 | piece | 3 | 457.8 |
| Panetti - 10-800-12 | Suction dissector for ear drum single curved, left side, 3 mm | 658 | piece | 1 | 658 |
| Panetti - 10-802-12 | Suction dissector for sinus tympani, double curved, backwards, left side, 6 mm | 658 | piece | 1 | 658 |
| Panetti - 10-850-00 | connector | 472 | piece | 1 | 472 |
| 19 Gauge Suction Cannula |  | 30 | piece | 2 | 90 |
| T-Tube Inserter |  | 75 | piece | 1 | 110 |
| KNIFE MCO5D MICROFRANCE SUCTION RND 2MM |  | 274.5 | piece | 1 | 274.5 |
| KNIFE MCO5E MICROFRANCE SUCTION RND 3MM |  | 274.5 | piece | 1 | 274.5 |
| PICK MCO989 180MM CVD MONOPOLAR LEGENT |  | 251.1 | piece | 1 | 251.1 |
| CABLE CP391 1.8M MONOPOLAR |  | 51.3 | piece | 1 | 51.3 |
| Sub-Total + tax | | | | | 3523.7 |
| Prototyping Materials: These materials will be used to fabricate various prototypes of instruments and 3D print physical ear anatomy models. | | | | | |
| Nitinol Tubing - NDC | - Inner diameter > 0.039"  - Material used for the distal end of the tool. | 80 | ft (min. 4 ft) | 4 | 320 |
| 3D Printing Budget | - Cost of printing material used at CIGITI lab to print prototypes and ear anatomy | 40 | piece | 20 | 800 |
| Prototyping Expenses\* | - Tools used to assemble and machine prototypes include: milling machine bits (end mills), drill bits, solder, screws, nuts, bolts, etc.  - Aluminum and stainless steel for body of new instrument, machining the metal, laser cutting of nitinol tubes to achieve desired shape  \*Note: this is an estimate as there will likely be many rounds of prototyping. Higher fidelity prototypes that would require more sophisticated machining and fabricating techniques would be outsourced. | - | - | - | 2500 |
| Sub-Total + tax | | | | | 3620.00 |
| Grand Total | | | | | 7143.70 |