Needs Analysis and Time Flow Study to Assess Endoscopic Ear Surgery

**Introduction:**

Middle ear surgery is traditionally performed through an external incision with visualisation of delicate anatomical structures using a microscope. More recently, minimally invasive ear surgical techniques have been developed using endoscopes to access the middle ear through the ear canal without an external incision [2], [3]. As with open 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 advantages of endoscopic ear surgery are as follows: removing the need for an external incision and reducing post-operative morbidity (10), improved outcomes by enhancing minimally invasive access for disease eradication (2-4), more effective disease control as shown by the reduction of the rate of reoccurring skin growth (2, 3), and better hearing due to hearing bone preservation (10, 11).

Despite the enthusiasm of some ear surgeons (otologists), endoscopic ear surgery has not as yet been accepted by all practicing otologists (5). The principle challenge with TEES is that a one-handed surgical technique is required as the endoscope is held in the other hand. Otologic instruments were developed for two-handed microscope-guided surgery so they are not optimized for the TEES environment [3]. As otologists have been trained and gained experience in microscope-guided ear surgery, they have developed techniques with the according instruments and have become accustomed to a two-handed surgical approach. By learning different surgical techniques and gaining experience with the endoscope, most surgeons find that they can complete more cases endoscopically (1, 7, 12). Nevertheless, the learning curve can be slow and frustrating. In the experience of the primary investigator (PI), technological advances in the design of the endoscope, camera and suction dissection instruments have lead to incremental stepwise jumps in this learning curve (13). Therefore, the potential for improving the TEES experience lies in instrumentation and training of surgeons.

**Purpose:**

This study aims to understand why TEES is not widely adopted by otologists and what technological advances would encourage more frequent and broader use of TEES. 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. A needs assessment survey will be conducted, using the two-round Delphi method, that examines the current limitations of TEES and how to encourage its adoption. A questionnaire will be formulated from a literature review and interviews with local otolaryngologists and sent to otolaryngologists globally. The results aim to be published to establish the requirements for training and instrument development to facilitate TEES. A time flow analysis, recording the duration of surgical steps, will also be conducted to quantify the limitations of the current instruments used in TEES, by assessing their efficiency.

**Methods:**

*Time Flow Study:*

Time flow studies aim to analyze the efficiency of procedures, and have been used for many purposes in surgery, including MRI-guided angioplasty workflow and operating room setup dedicated for minimally invasive laparoscopic surgery [4]-[5]. This study will also assess the feasibility and efficiency of endoscopic ear surgery using the same method. The time flow analysis will be recorded by the MASc. student during ear surgery. The steps will be divided into preparation, tympanomeatal flap elevation, access to tympanomastoid sub-sites for cholesteatoma removal, graft positioning, and ossiculoplasty. The type of instruments used during these different maneuvers and the number of changes between different instruments will also be noted. These observations will lead to an appreciation of the ergonomic requirements of instruments and the design advantages of different instruments for specific maneuvers. The time taken for five surgeons to perform ten surgeries each will be recorded. Each step for each surgeon will have a mean and standard error time, and statistical difference between surgeons for each step will be calculated. This will aim to determine the inefficiencies and address the steps where further instrument design would be beneficial. This would also provide a good benchmark against which to measure efficiency and feasibility of future tools that would be developed.

*Survey:*

Surveys, consisting of questionnaires, are used to gain information regarding a specific topic by consulting a wide variety of experts in the field. It has been used to assess the challenges of endoscopic neurosurgery in Britain and the current status of endoscopic ear surgery in Canada [6]-[7]. The Delphi method has been employed internationally in the field of surgery where surveys are sent out to surgeons to form a consensus about varying surgical questions such as: treatment of the retraction pockets of the tympanic membrane, developing a core set of patient-reported outcomes in pancreatic cancer, and an international consensus for sepsis and septic shock definitions [8] [9] [10].

A qualitative assessment of the challenges in endoscopic ear surgery caused by limitations in current instrumentation will be completed by performing an on line survey of surgeons that perform endoscopic ear surgery. The Delphi method will be followed to analyze the qualitative results of the survey. A preliminary survey for local otolaryngologists, with varied experience in TEES within the University of Toronto, will develop a questionnaire. Questions will ask for comments on factors that have prevented otologists from using endoscopes in otologic surgery, and for comments on the perceived strengths and weaknesses of currently available instruments for endoscopic ear surgery. The survey will then be sent, via email, to many otologists around the world, including the 60 members of the International Working Group on Endoscopic Ear Surgery (IWGEES) (http://www.iwgees.org) plus delegates that have attended courses organized by the PI and consenting members of the IWGEES. The confidential answers will be analyzed to develop another, more specific, survey that will be sent out once again to the participants. This will attempt to develop a consensus of conclusions for the survey.

The confidential survey will be provided electronically using FluidSurveys, an online survey tool (http://fluidsurveys.com). A consent form will be attached with the survey.

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

[2] M. S. Cohen, L. D. Landegger, E. D. Kozin, and D. J. Lee, “Pediatric endoscopic ear surgery in clinical practice: Lessons learned and early outcomes,” *Laryngoscope*, p. n/a–n/a, 2015.

[3] 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.

[4] M. A. Rube, F. Fernandez-gutierrez, B. F. Cox, B. Holbrook, J. G. Houston, R. D. White, H. Mcleod, M. Fatahi, and A. Melzer, “HHS Public Access,” vol. 10, no. 5, pp. 637–650, 2015.

[5] K. C. Hsiao, Z. Machaidze, and J. G. Pattaras, “Time Management in the Operating Room : An Analysis of the Dedicated Minimally Invasive Surgery Suite,” pp. 300–303, 2004.

[6] H. J. Marcus, T. P. Cundy, A. Hughes-hallett, Z. Yang, A. Darzi, D. Nandi, and D. Phil, “Europe PMC Funders Group Endoscopic and Keyhole Endoscope-assisted Neurosurgical Approaches : A Qualitative Survey on Technical Challenges and Technological Solutions,” vol. 28, no. 5, pp. 606–610, 2015.

[7] 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.

[8] A. Gerritsen, M. Jacobs, I. Henselmans, J. van Hattum, F. Efficace, G.-J. Creemers, I. H. de Hingh, M. Koopman, I. Q. Molenaar, H. W. Wilmink, O. R. Busch, M. G. Besselink, H. W. van Laarhoven, and Dutch Pancreatic Cancer Group, “Developing a core set of patient-reported outcomes in pancreatic cancer: A Delphi survey.,” *Eur. J. Cancer*, vol. 57, pp. 68–77, Apr. 2016.

[9] S. Y. Kosyakov, Y. V Minavnina, and E. V Pchelenok, “[The consensus view of the treatment of the retraction pockets of the tympanic membrane].,” *Vestn. Otorinolaringol.*, vol. 81, no. 1, pp. 78–83, 2016.

[10] M. Singer, C. S. Deutschman, C. W. Seymour, M. Shankar-Hari, D. Annane, M. Bauer, R. Bellomo, G. R. Bernard, J.-D. Chiche, C. M. Coopersmith, R. S. Hotchkiss, M. M. Levy, J. C. Marshall, G. S. Martin, S. M. Opal, G. D. Rubenfeld, T. van der Poll, J.-L. Vincent, and D. C. Angus, “The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3).,” *JAMA*, vol. 315, no. 8, pp. 801–10, Feb. 2016.

[11] “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].

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

[13] 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.

[14] A. L. James, B. C. Papsin, and B. C. Papsin, “-- Head and Neck Surgery,” no. September, 2012.