**The Current Limitations and Future Direction of Instrument Design for Totally Endoscopic Ear Surgery: A Needs Analysis Survey.**

Short title: Needs analysis for endoscopic ear surgery instruments.

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* **Basic Science Reports:**
  + 3500 words. This count does not include the abstract, references, tables, or figure legends.
  + 6 main figures and tables. Individual figures may consist of figure parts (Figure 1A, 1B, etc), but additional figures and tables should be submitted as Supplemental Digital Content.
  + Title page – submitted as a separate word document

## **Abstract**:

* 250 words
* **Hypothesis:**Brief, clear statement of the main goals of the investigation.   
  **Background:** Concise; designed for orientation of the reader who is unfamiliar with this line of investigation.   
  **Methods:** Succinct summary of techniques and materials used.   
  **Results:** Include statistical measures where appropriate.   
  **Conclusion:** Include only those directly supported by data generated from this study. Emphasize clinical relevance wherever possible.

## **Introduction**:

Endoscopes can facilitate middle ear surgery by providing direct access and a wide angle view into the middle ear, reducing the time required for gaining access, drilling bone for exposure and wound closure. They provide clearer visualization of otherwise hidden recesses within the middle ear including: the sinus tympani, anterior and posterior epitympanum and hypotympanum1,2,3,4. Endoscopes also provide better visualization beyond the shaft of surgical instruments, than the direct line of sight in trans-canal microscope-guided surgery5.

Despite growing enthusiasm, totally (also known as trans-canal) endoscopic ear surgery (TEES) is not currently accepted as a feasible option by all otologists6,7.  The principal challenge with TEES is that a one-handed surgical technique is required because the endoscope is held in the other hand6,8. During traditional surgery, instruments in the non-dominant hand usually maintain retraction and suction to remove blood from the operative field while the dominant hand performs more delicate maneuvers8. Otologic instruments and surgical techniques have been developed for two-handed surgery guided by an operating microscope. As such, they are not necessarily optimized for the TEES environment. Although most otologists have been trained and gained experience with this two-handed surgical approach, by learning different surgical techniques and gaining experience with the endoscope, many cases can be performed totally endoscopically1,6,8,9. Nevertheless the learning curve for many surgeons is long and, even with experience, many aspects of TEES surgery remain challenging10,1,6.

Technological advances in the design of the endoscope, camera and suction dissection instruments have lead to incremental advances in our ability to perform more difficult cases using TEES techniques 10,3. In order to further advance the development of TEES technology and instruments to facilitate TEES, it is important to have a detailed understanding of the limitations of current instruments and the specific challenges that surgeons face. We hypothesize that otologists need better instrumentation to facilitate specific challenges posed by TEES. Further, we hypothesize that otologists performing greater proportions of surgeries using TEES will experience different challenges than those who use TEES less frequently. Similarly, we hypothesize that those surgeons who use instrument sets that are specialized for TEES may experience different challenges that those who do not. We conducted a mixed-methods study to explore these hypotheses.

## **Materials and Methods:**

### *Study Design:*

Ethics approval was obtained for this study from the institution’s Research Ethics Board (REB number: 1000055626).

This cross-sectional study employed a mixed-methods self-administered online questionnaire consisting of nine questions. As no existing or validated surveys tools were found, a custom questionnaire was developed. The content was based on a literature search and on interviews with the principal author and other medical professionals with expertise in the area. The questionnaire was piloted amongst local otologists with varying degrees of TEES experience. The results of the pilot questionnaire were then used to create a final version of the questionnaire. Participants were asked to identify their need for better instruments to address the following challenges: i) bleeding control ii) keeping the endoscope lens clean iii) cutting and/or removing bone iv) reaching structures visualized by the endoscope v) dissection and removal of cholesteatoma vi) moving and positioning a graft into the intended place. In addition, participants were asked to describe any other types of instruments that they would find useful while performing TEES. The responses were scored using multiple choice, yes/no, an analog scale and an open-ended free-text response. The analog scale was anchored with verbal descriptions to ensure comparability between participants. Questions were also included to collect participant demographics, in particular, on the proportion of middle ear surgeries performed with TEES and the surgeon’s use of specialized TEES instrument sets.

Invitations to complete the survey were provided to members of the International Working Group on Endoscopic Ear Surgery and delegates attending international courses and conferences for endoscopic ear surgery (2nd World Congress of Endoscopic Ear Surgery, Bologna, Italy; 6th Hands on Seminar in Endoscopic Ear Surgery, Yamagata, Japan). Identifying information was not collected from participants in order to guarantee their anonymity and confidentiality.

*Data Analysis:*

Visual analog scale scores quantified the “need for better instruments” for each challenge. The data does not fit a normal distribution, as per the Shapiro-Wilk W normality test. Thus the data is nonparametric and the medians are presented. The Kruskall-Wallis H-test for nonparametric data was used to test the statistical significance of TEES experience and use of specialized TEES instruments on the need for better instruments score for each challenge. P-values <0.05 were considered to indicate statistical significance, and were calculated using the chi-squared test. Statistical analysis was performed using JMP statistical analysis software (JMP version 13.0; SAS Institute; Cary, NC). Qualitative data was analyzed by grouping the responses into themes/categories which would describe additional difficulties those tools would address. The comments were grouped based on whether they referred to an instrument change or endoscope technology change. The instrument-related comments were further filtered based on which surgical challenge that instrument would need to address.

**Results:**

### *Study Participants and Demographics:*

Fifty-one surgeons completed the questionnaire. By the timing of their responses it is assumed that 26 were recruited from survey of the IWGEES membership, 16 from attendees at the 2nd World Congress on Endoscopic Ear Surgery, and six from attendees at the Hands on Seminar in Japan. Summarized respondent demographics are included in Table 1.

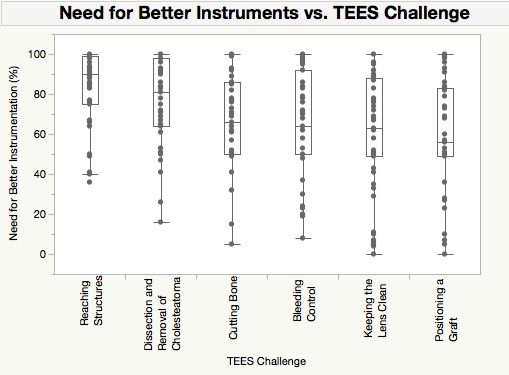
**Table 1** Demographics of Respondents based on TEES Experience and Use of a TEES Instrument Set

|  |  |
| --- | --- |
| Percent of Surgeries Performed Totally Endoscopically | Number of Respondents |
| 0% | 4 (8%) |
| Up to 50% | 16 (31%) |
| 50%-90% | 21 (41%) |
| More than 90% | 10 (20%) |
| Use of TEES Instrument Set |  |
| Yes | 40 (78%) |
| No | 11 (22%) |

### *~~Data Analysis:~~*

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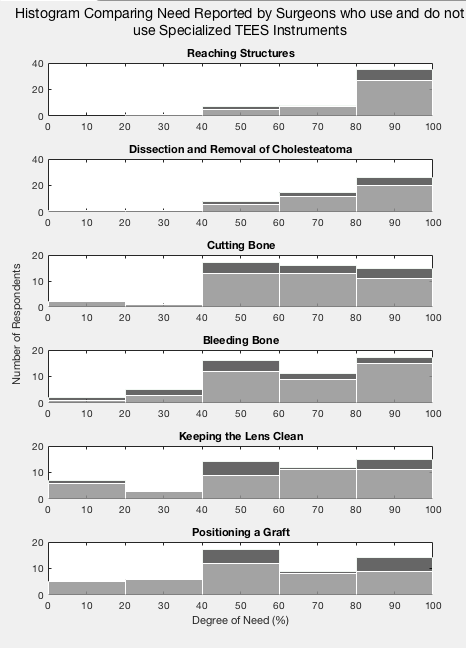
All of the parameters assessed in this survey regarding the utility of instrument design for use in endoscopic ear surgery revealed a need for improvement exceeding 50% on visual analogue scales (0 = “Not Useful”, 50% = “Moderately Useful” 100% = “Extremely Useful”). A requirement for instruments to provide better reach to structures visualized by the endoscope revealed the highest degree of need (median 90%). Instrumentation for positioning grafts in the ear were found to have the lowest degree of need for improvement (median 56%).



**FIG. 1.** Box and Whisker plot comparing the reported need for better instruments for each TEES challenge.

### *Effect of using a specialized TEES instrument set on TEES challenges experienced:*

There were no significant differences in the need for better instruments for any challenge between surgeons who use a specialized TEES set and those who did not.

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**FIG. 2.** Histograms comparing the reported need to address each of the six challenges, comparing surgeons who do not use a specialized TEES instrument set (dark fill) with surgeons who use a specialized TEES instrument set (light fill, 78% of respondents).

### *Effect of surgeons’ endoscopic experience:*

There was a greater perceived need for better instruments to reach structures and to position a graft by respondents who perform a greater proportion of cases endoscopically. For surgeons who perform none, 0 – 50%, 50 – 90%, and greater than 90% of surgeries using TEES, the median reported need for instruments with better reach were: 91%, 90%, 91%, and 91%, respectively (X2(2) = 8.9, p = 0.03). For positioning a graft, the median reported need for better instruments were: 51%, 56%, 56%, and 57%, respectively (X2(2) = 12.8, p = 0.005). Other parameters were not significantly dependent on the proportion of cases performed using TEES.

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**FIG. 3.** Histograms of reported need for better instruments for reaching structures visualized by the endoscope and positioning a graft. These were the difficulties that were significantly affected by TEES experience.

### *Qualitative Results:*

**Table 2** Tabulatedcomments from respondents to the question: “Are there any other instruments that you would like to see modified or developed for endoscopic ear surgery? Please give examples.” Bold type highlights suggestions consistent with the two key parameters identified by the survey: reaching areas better and suction-enabled tools.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Endoscope** | **Instrument** | | | |
|  | **Suction** | **Cutting Bone** | **Reaching areas** | **Cutting** |
| Flexible endoscope | Suction elevators to control amount of suction | single handed drilling - irrigation and suction at the same time | Reach disease in the mastoid through the canal (retractable) | Curved round knife for better incision of the skin in first step of any middle ear surgery |
| Endoscope holder to facilitate 2-handed surgery | Bipolar with suction | Bone cutting – piezoelectric | Bent and longer instruments to reach supratubal recess or deep sinus tympani |  |
| Continuously cleaning lens | Disposable curved and angled suckers | Piezoelectric drill is quite useful | Instruments with working angles that can be adjusted |  |
| Feasible endoscope holder | Suction + blunt dissector | Drill that can remove bone without obscuring vision | Tool that can reach structures and disease that are visible by the endoscope |  |
| Flexible joint endoscope holder to allow bimanual work is useful but too thick | Curved suction |  | Modify the whirly bird instrument as they are too short to dissect cholesteatoma in deep sinus tympani. |  |
| Endoscope holder to help the two-handed technique | **Suction with different angles to suction cholesteatoma matrix at different sites** |  | Angled shaft to keep hands from bumping into each other |  |
|  | Dissection + suction simultaneously |  | Remove vascular lesions without causing bleeding |  |
|  | **Improved curved suctions able to reach and aspirate cholesteatoma matrix from attic and sinus tympani (difficult to reach areas) current Storz curved suctions are too flimsy, thin and long** |  | Specialized for coagulations |  |
|  | Suction smoke during laser surgery (separate or mounted on the laser tip) |  | Mechanical scalpel and/or curette |  |
|  | **Suction specifically designed for sinus tympani** |  |  |  |

Answers to the question: “Are there any other instruments that you would like to see modified or developed for endoscopic ear surgery? Please give examples” are reported in Table 1. The comments included 8 (38%) addressing the need for new instruments to reach structures that can be seen by endoscopes but not reached by current instrumentation, 10 (48%) addressing the need for improved dissection and removal of cholesteatoma, 4 (19%) addressing the need for improved bone removal, 6 (29%) addressing the need for improved bleeding control, and 1 (5%) addressing the need for keeping the lens clean). No comments specifically addressed the need for development of instruments to address the challenge of positioning soft tissue grafts.

## **Discussion:**

We have conducted a cross-sectional mixed-methods survey to identify, quantify, and describe the challenges otologists face with TEES. A recent survey of Canadian otologists,found the following factors difficult with TEES: single-handed surgery, efficiency/operative time, technical difficulty, cost, managing bleeding6. This questionnaire was intended to build upon those findings by measuring the degree to which surgeons experience specific challenges during surgery to guide the development of otoendoscopic instrumentation that could facilitate such surgery. By distributing this survey to otologists with an interest in otoendoscopic surgery internationally, a broad range of opinion and experience has been captured. The survey reveals a strong perception of need for improved instrumentation particularly to facilitate dissection in areas that are beyond the reach of conventional instruments but can be seen clearly with endoscopy.

*Reaching structures & cholesteatoma removal*

By providing a wide-angled view and placing illumination with the point of sight beyond the confines of the ear canal, with the additional option of a 30°, 45° or 70° off-axis view, the endoscope provides clear visualisation of structures that are obscured from view with the direct line of sight of an operating microscope. Current otologic instruments have been developed for use within the narrow field of view of the operating microscope and cannot reach to the limits of what is now visible with endoscopes. Examples of areas that are difficult to reach through the ear canal include the sinus tympani, anterior epitympanic recess and antrum3,4.  While specialized instruments with curved tips have been developed for this purpose3, our survey reveals the highest need for endoscopic instrumentation is a more extended reach. Of note, this need was higher among surgeons that perform a greater proportion of cases with TEES. This may be because surgeons who perform fewer TEES may be more inclined to use a more invasive open approach with more extensive bone removal to gain access to the difficult areas. Perhaps surprisingly, the degree of need for these challenges did not differ amongst respondents depending on their use of specialized TEES instrument sets. This suggests reaching structures as well as dissection and removal of cholesteatoma remain significant challenges despite the availability of current TEES instrumentation. Certainly, these results suggest that future instrument development should focus on instruments that improve our ability to reach structures and facilitate dissection and removal of cholesteatoma.

### *Cutting and removing bone*

While straight and angled endoscopes facilitate a broader field of view than line-of-sight microscopic surgery, bone removal is still necessary for visualization and access. For cholesteatoma surgery, the scutum and adjacent canal wall must often be removed and, for any TEES access, canalplasty can be required if the bony meatus is unusually narrow or curved. Currently, bone removal can be accomplished with bone curettes, osteotomes, drills, and ultrasonic instruments. Nevertheless, our survey shows this remains a challenging task in endoscopic ear surgery. The degree of need for easier bone removal was not significantly dependent on the surgeon’s availability of a specialized TEES instrument set or the proportion of middle ear cases accomplished with TEES. This may relate to some of the limitations with each of the current bone removal techniques: bone curettes offer precise bone removal, however, bone removal is slow and removal of large amounts of dense bone is difficult; osteotomes may be imprecise working along endoscopes in the confines of the ear canal; use of drills is impeded by accumulation of bone dust as simultaneous suction is not available with one-handed surgery; ultrasonic bone removal tools, while effective, also obscure the field somewhat with irrigation of bone debris and are currently very expensive.

### *Bleeding control*

Management of intraoperative bleeding was also reported as a significant challenge when performing TEES. Intraoperative bleeding may impair surgical field clarity and obscure target tissues and this may lead to increased rates of residual cholesteatoma11. To manage this, techniques such as hypotensive anesthesia, patient positioning, local vasoconstrictors, and atraumatic surgical techniques have been employed8,11,12. In addition, specialized instrument sets have been developed specifically to improve bleeding management in TEES, incorporating a functional tip with a rotatable suction shaft to allow for cutting, dissection or tissue elevation while suctioning3. Previous studies have identified management of intraoperative bleeding as a significant challenge faced in TEES 3,4,5,6,12. Our study confirms that this is a challenge with a significant degree of need on visual analog scales. Interestingly, despite that fact specialized TEES instrument sets are specifically designed to address this challenge, the degree of need for surgeons who used specialized TEES instrument sets was not significantly different from surgeons who did not. The majority of qualitative comments also reported that an instrument combining suction with an additional functionality, such as dissecting, cauterizing or reaching deeper into the ear, would be beneficial for TEES.

### *Endoscope technology*

Keeping the endoscope lens clean was identified as the challenge with the second lowest degree of need in our survey, however, the mean degree of need still exceeded 60%. Fogging and smearing of the endoscope tip is a challenge during TEES making surgeons pause surgery, remove the endoscope from the ear and wipe it clean on a defog pad periodically3,12. This can be time consuming. On the other hand, frequent removal of the endoscope from the field may be beneficial in preventing heating from the light source and, thus, reducing the risk of thermal injury within the ear13.

A minority of respondents to the survey indicated that an endoscope holder might be advantageous to allow two-handed surgery. While some surgeons promote this approach14,15 the majority of TEES surgeons have persisted with development of one-handed techniques. One major disadvantage of a static endoscope is small adjustments cannot readily be made to optimize the angle of view or to allow safe introduction and manipulation of instruments in the ear. Potential safety hazards include the risk of thermal injury13 or traumatic injury should inadvertent movement of the patient occur. Any further use and development of endoscope holders for TEES should take these limitations and potential risks into account.

### *Moving a graft into the intended place*

During TEES tympanoplasty the graft must be inserted into the ear canal and positioned single handedly in the desired orientation16. Performing this technique single handedly is, in the authors’ experience, quite challenging. While the authors had anticipated that a novel tool to facilitate one-handed graft manipulation would be helpful, the survey found this challenge had the lowest mean degree of need. A wide variety of techniques is used in tympanoplasty with choice of approach, graft material and graft placement technique influenced by the surgeon’s training, case load, resources and experience16. We are aware that graft placement techniques that work well with two hands and a microscope may not be ideally suited for one hand and an endoscope10. One potential explanation for greater ease of graft placement by some surgeons is that different techniques are used that are better suited to TEES and that these may overcome limitations of instrument design.

### *Limitations*

\*\*limitation in participants with low percentage of TEES cases\*\*\*

The questionnaire was sent to otologists who are interested in endoscopic ear surgery as the questionnaire asked participants to rate their experience on TEES. There is a low representation of surgeons who do not perform TEES (8% of respondents). This is expected in the environment that the survey was distributed in. These environments were selected because the surgeons in these environments were expected to have the most insight on TEES. We have therefore not necessarily fully captured the opinions of surgeons who have chosen not to practice TEES because of limitations in instrument design. Since this study aims to identify needs in TEES, it was important to capture the opinions of those with experience using the technique.

The questionnaire was developed by conducting a literature search and interviews of otologists in an attempt to identify all relevant instrument needs for TEES. Responses to the open ended question seeking qualitative information for needs analysis raised similar issues to the challenges listed in the questionnaire. It could be argued that the content of these responses was influenced by content of the prior questions. However a few other needs were raised (such as suggestions for endoscope holder) so it is likely that the mixed methods design has addressed the important instrument needs in TEES

It is not possible to calculate the response rate for this survey as the denominator is not known. It is estimated that a few-hundred conference delegates were invited to take part but only a small proportion did so. At least one third of the IWGEES membership responded, though the exact proportion is not known as many responded to a prior invitation to participate at a conference. The questionnaire was designed to be very short and easy to complete in order to maximize the chance of cooperation from busy practitioners. Although the survey was distributed to an international audience it was only available in English so limiting our ability to canvas opinion from non-English speakers.

## **Conclusion:**

The average need for better instruments for each TEES challenge was greater than 50%. Reaching structures visualized by the endoscope scored the greatest degree of need. People who performed a greater percentage ofs surgeries totally endoscopically reported a significantly greater need for reaching structures and positioning a graft. There was no significant effect of using a specialized TEES instrument set on the need for better instruments for any of the challentes. Out of the 21 comments received about improving TEES instrumentation, 10 mentioned a tool for suction and 8 mentioned a tool for reaching structures.

# **Acknowledgement:**

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