**The Current Limitations and Future Direction of Instruments in Totally Endoscopic Ear Surgery: A Needs Analysis Survey.**

Short title: Current Limitations and Future Direction of Instruments in Totally Endoscopic Ear Surgery.

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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 provide direct access and a wide angle view into the middle ear, reducing the time required to gain access, drill bone for exposure and close during middle ear surgery and are able to visualize hidden recesses within the middle ear including: the sinus tympani, anterior and posterior epitympanum and hypotympanum1,2,3,4. As well, the endoscope allows visualization past the shaft of the instrument, such as the drill, which is a problem during microscopic surgery5.

Despite the enthusiasm of some otologists, endoscopic ear surgery has a low acceptance rate6,7.  The principal challenge with TEES is that a one-handed surgical technique is required as the endoscope is held in the other hand6,8. During traditional surgery, the non-dominant hand usually maintains suction and removes blood from the operative field while the dominant hand performs the delicate maneuvers8. Otologic instruments were developed for two-handed microscope-guided surgery so they are not optimized for the TEES environment. 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 totally endoscopically1,6,8,9.

Technological advances in the design of the endoscope, camera and suction dissection instruments have lead to incremental stepwise jumps in this learning curve10. In order to further develop technology and instruments to facilitate TEES, it is important to understand the specific challenges experienced during TEES. It is proposed that in order to facilitate TEES, the needs of surgeons and current limitations of tools must be determined.

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 specialized TEES instrument sets may experience different challenges that those who do not. To this end, 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, Principal Investigator: Dr. Adrian Lewis James).

This cross-sectional study employed a mixed-methods self-administered online questionnaire consisting of nine questions. 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, while facilitating parametric statistical analysis. Participant demographics included the percentage of middle ear surgeries performed using TEES as well as whether the surgeon uses a specialized TEES instrument set. Participants were asked the degree to which an instrument that addresses the following challenges would be of use to the participant: 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 identify any other types of instruments that they would find useful while performing TEES. The questionnaire content was developed through a literature search on challenges experienced during TEES and the clinical experience of the principal author and his colleagues. Using this data, a preliminary questionnaire was developed and piloted amongst local otologists with varying degrees of TEES experience. The results of the pilot questionnaire were used to create the final concise questionnaire that was distributed internationally.

### Participants and Data Collection:

We identified otologists who attended the 2nd World Congress of Endoscopic Ear Surgery, members of the International Working Group of Endoscopic Ear Surgery and attendees of a TEES course in Japan. After obtaining REB approval, these otologists were invited to participate in the survey. The beginning of the online survey includes a letter of information and informed consent was assumed upon anonymous completion of the questionnaire. All information was stored anonymously.

### Data Analysis:

Visual analog scales were quantified and the means as well as the 95% confidence intervals were established. ANOVA was used to determine which challenge presented the greatest degree of need. The Kruskall-Wallis H-test was used to determine if the percentage of cases done with TEES influenced the degree of need for each challenge. The t-test was used to determine if use of a specialized TEES instrument set affected the degree of need for each challenge. Qualitative data was analyzed by grouping the responses into themes/categories which would describe additional difficulties those tools would address. Statistical analysis was performed using JPM statistical analysis software (JMP version 13.0; SAS Institute; Cary, NC).

## Results:

### Study Participants and Demographics

The questionnaire was distributed to a total of \_\_\_\_\_ surgeons and 51 surgeons completed the questionnaire with an overall response rate of <???>. 16 attendees at the 2nd World Congress on Endoscopic Ear Surgery, six attendees of the Japanese course, and 26 members of the International Working Group on Endoscopic Ear Surgery (IWGEES) responded. Of the respondents, four (7.8%) do not perform any surgeries using TEES, 16 (31.4%) perform up to 50% of surgeries using TEES, 21 (41.2%) perform 50-90% of surgeries using TEES, and 10 (19.6%) perform greater than 90% of surgeries using TEES. 40 (78.4%) of respondents use specialized TEES instrument sets.

**FIG. 1.** Mean degree of need reported for each TEES challenge. The error bars indicate standard error, n = 51.

### Challenges during TEES that exhibit the greatest degree of need by surgeons:

The average degree of need exceeded 50% for all challenges. Reaching structures visualized by the endoscope resulted in the highest degree of need (mean 83%, 95%CI 76-89%) although the degree of need was not statistically different from the degree of need for dissecting and removal of cholesteatoma. Conversely, positioning the graft resulted in the lowest degree of need (mean 58%, 95%CI 52-65%), although this was not statistically different from the degree of need for keeping the endoscope clean.

### Effect of percentage of surgeries performed totally endoscopically on TEES challenges:

There was a statistically significant difference in the degree of need for reaching structures and for positioning a graft, depending on the percentage of surgeries performed endoscopically. For reaching structures, X2(2) = 8.9481, p = 0.0300 with mean scores of 76, 72, 88, and 92, respectively, for surgeons who perform none, 0 – 50%, 50 – 90%, and greater than 90% of surgeries using TEES. For positioning a graft, X2(2) = 12.8438, p = 0.0050 with mean scores of 50, 44, 60, and 81, respectively, for surgeons who perform none, 0 – 50%, 50 – 90%, and greater than 90% of surgeries using TEES. The remaining challenges were not significantly dependent on the proportion of cases performed using TEES.

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

Respondents who used a specialized TEES instrument set had a significantly lower mean degree of need for positioning a graft than those who did not use a specialized set, with means of 55 and 71, respectively (p=0.002).

### Qualitative Results:

Note: the following are the comments regarding instrumentation to facilitate TEES, how do you think we should present the data?

* Table format – there are 6 tables/figures allowed so we have not reached that limit yet. I think the table format is easier to read and understand
* Paragraph format
* Figure format – Papers have broken down the responses into themes and listed how many comments belonged in each theme in a figure, with accompanying text

**Table 1.** Comments from respondents regarding future instruments to be developed to facilitate TEES. The comments in red describe both reaching areas and suction-enabled tools.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Endoscope** | **Instrument** | | | | |
|  | **Suction** | **Cutting Bone** | **Reaching areas** |  | **Cutting** |
| flexible | 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 (retractible) | angled shaft to keep hands from bumping into each other | 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 | Remove vascular lesions without causing bleeding |  |
| Continuously cleaning lens | disposable curved and angled suckers | Piezoelectric drill is quite useful | Instruments with working angles that can be adjusted | Specialized for coagulations |  |
| 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 | Mechanical scalpel and/or curette |  |
| Flexible joint by storz to fix endoscope to allow bimanual work is useful but too thick | Curved suction |  | Modify the whirly bird instrument (from Bausch and Lomb) 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 cholesteatomatous matrix at different sites |  |  |  |  |
|  | Dissection + suction simultaneously |  |  |  |  |
|  | 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 |  |  |  |  |
|  | Suction smoke during laser surgery (separate or or mounted on the laser tip) |  |  |  |  |
|  | Suction specifically designed for sinus tympani |  |  |  |  |

When asked “Are there any other instruments that you would like to see modified or developed for endoscopic ear surgery? Please give examples”, 21 comments were received and many of the comments suggested identified a need for the development of instruments that could address multiple challenges faced in TEES. The comments included 8 (38%) addressing the need to reach structures, 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 the graft.

Ten (48%) comments suggested improvements to instruments to address challenges arising from a need to reach structures and remove cholesteatoma. Four (19%) of these comments identified a need for different curved suctions and another 2 (9%) comments identified a need for additional curved instruments to reach into middle ear recesses and the mastoid. A need for suctions and instruments specifically designed to access the sinus tympani were identified in 4 (19%) comments. Two (9%) comments identified a need for flexible instruments to reach the mastoid and middle ear recesses in TEES. Four (19%) respondents identified a need for improving bone removal techniques in endoscopic surgery with 2 comments focusing on improving visualization with drilling alongside endoscopes and 2 comments focusing on further development of piezoelectric surgical instruments. Three (14%) comments suggested developing new instruments to manage bleeding, with two (9%) focusing on coagulating instruments such as bipolar. One (5%) comment suggested development of an instrument combining suction with bipolar to facilitate hemostasis. One (5%) comment identified a need for modification of endoscope such that there would be a continuously cleaning lens. No comments suggested development of new instruments to help position grafts in TEES.

Eight (38%) comments from respondents focused on modifications to endoscopes and the use of endoscopes in TEES. Four comments identified a need for endoscope holders to facilitate two handed operating with a stationary endoscope. Two (9%) comments focused on improving visualization using endoscopes that are flexible or endoscopes with a continuously cleaning lens. One (5%) comment identified a need for more instruments with curved shafts to facilitate working alongside the endoscope.

From the comments regarding instrumentation to facilitate TEES, 10 out of 21 responses described an instrument that combines suction with another function, such as dissection, cautery and reach via shaft shape. 10 comments described an instrument that could reach areas better and four comments mentioned a tool that combined reach and suction. Four described an instrument to hold the endoscope and four comments described an instrument that could drill bone while combining irrigation and suction or with better visualization.

## Discussion:

We have conducted a cross-sectional mixed-methods survey to identify, quantify, and describe the challenges otologists face with TEES. A survey on TEES for Canadian otologists has reported that 11% of otologists in Canada use TEES for cholesteatoma, tympanoplasty, and ossicular reconstruction surgeries and they find the following factors difficult about TEES: single-handed surgery, efficiency/operative time, technical difficulty, cost, managing bleeding6. This questionnaire was intended to build upon this research by measuring the degree to which surgeons experience specific challenges during surgery and whether they could be addressed by a specialized surgical tool. Whileprevious studies have sought to identify challenges experienced during specific TEES surgeries, fewer studies have attempted to identify these challenges as well as instruments that could address these challenges. This survey included respondents internationally to get a world-wide response on what challenges during TEES require instrumentation.

Reaching Structures & Dissection & Removal of Cholesteatoma

While endoscopes facilitate excellent visualization, reaching structure as well as dissection and removal of cholesteatoma remain significant challenges in TEES surgery. Difficult to reach anatomical recesses include the sinus tympani, facial recess, and anterior epitympanic recess3. As a result of inadequate access, patients may be at increased risk of residual disease if these areas are involved with cholesteatoma11,12. Further, surgeons may have to modify their approach to reach these areas, potentially necessitating a post-auricular approach or additional bone removal with a TEES approach thus resulting in more aggressive surgery. While specialized instruments with curved tips have been developed to address this, the curves in the shafts are fixed and there are areas where these instruments still cannot reach3.

These challenges were found to have the greatest need by respondents on visual analog scale. Further, when asked about need for development or modification of new instruments, more than 30% of the comments focused on the need for instruments that address these challenges. This indicates that otologists struggle with these aspects of endoscopic ear surgery. The degree of need for reaching structures was lower for surgeons who perform a lower proportion of cases using TEES. This may be because surgeons who perform lower proportions of cases using TEES may be more likely to use a microscope when they need to access deep recesses in the middle ear and mastoid. As a result, this may result in a lower degree of need for reaching structures for their TEES cases where as for surgeons who perform more difficult using TEES, this may remain a challenge with a significant degree of need. Interestingly, the degree of need for these challenges did not differ amongst respondents depending on use of specialized TEES instrument sets. This suggests reaching structures as well as dissection and removal of cholesteatoma remain significant challenges despite current specialized TEES instrument sets. 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

Cutting and removing bone allows visualization of and access to areas within the middle ear that cannot be seen by the endoscope or reached by existing instruments. While straight and angled endoscopes facilitate a broader field of view than line-of-sight microscopic surgery, bone removal may still be necessary for visualization and access of recesses within the middle ear and mastoid. Currently, bone removal can be accomplished with bone curettes, osteotomes, drills, and piezoelectric bone instruments. Nevertheless, this was still found identified as the challenge with the third greatest degree of need in our survey. 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 bone may be difficult; osteotomes may be imprecise working along endoscopes in the confines of the middle ear; drills may be difficult to use alongside endoscopes and bone dust from drilling may impair visualization with the endoscopes; Pizeoelectic surgical instruments, while effective, are very expensive. The degree of need was not significantly dependent on use of a specialized TEES instrument set or the proportion of middle ear cases accomplished with TEES.

-suggested future design focus?

### Bleeding control

-discuss the nature of the challenge

-identified this as a challenge

-compare this to existing literature on the topic (i.e. did we identify this as being a greater concern? Subgroup analyses?)

-discuss existing methods managing bleeding

-discuss potential future ways of managing

Management of intraoperative bleeding represents 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 employed8,11,13. In addition, specialized instrument sets have been developed specifically to improve bleeding management in TEES3. These instruments incorporate a functional tip with a suction shaft to allow for cutting, dissecting or elevating tissues while suctioning3. Previous studies have identified management of intraoperative bleeding as a significant challenge faced by otologists when performing TEES (by 24% of Canadian Otologist respondents in Lea et al.’s survey) 3,4,5,6,13. Our study confirms this finding. 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 those who used specialized TEES instrument sets was not significantly different from those who did not.

Moreover, from this questionnaire, bleeding control exhibited a mean need of 67% and nine of the seventeen comments from respondents described that an instrument combining suction with another functionality, such as dissecting, cauterizing or reaching, would be beneficial for TEES.

### Keeping the endoscope lens clean

Fogging and smearing of the endoscope tip is a challenge of TEES and surgeons must pause surgery, remove the fogged lens, and wipe it clean on a defog pad periodically3,13. This can be time consuming during surgery. Moreover, compromised visualization may potentially increase the risk injury to middle ear structures or the tympanomeatal flap as the instruments and endoscopes are repeatedly introduced and removed from the ear to facilitate cleaning the endoscope lens. 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%. Currently, this is managed by … ?

### Moving and positioning a graft into the intended place

In tympanoplasty surgery, the approach, graft material and graft placement technique vary depending on the training, case load, resources and experience available to the surgeon14. During TEES tympanoplasty the graft must be inserted into the ear canal and positioned single handedly in the desired orientation14. Performing this technique single handedly is, in the authors’ experience, quite challenging. Nevertheless, this was identified as the challenge with the lowest mean degree of need.

and so perhaps a tool that facilitates graft manipulation would be helpful for TEES surgeons. Lea and Mijovic show that cartilage or graft placement is easier when using two hands in a surgery video8

### Implications of the Findings

The findings from this needs analysis study can be used for future development of tools to facilitate TEES or to develop training/teaching models. The team hopes that otologists will continue to study the needs of TEES to continually improve upon the technology available to facilitate its use (?????).

### Limitations

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 perform 0% of surgeries totally endoscopically (8% of respondents). Furthermore, the questionnaire did not ask the types of surgeries that the respondents normally perform using TEES. Therefore, the results may be influenced by this bias of respondents. This would affect the results as surgeons who perform primarily cholesteatoma surgeries might face different challenges, such as dissection and removal of cholesteatoma, during surgery than surgeons who perform primarily tympanoplasties, where a major challenge could be positioning the graft. Low response rate. The questionnaire, with 11 questions, was designed to be very short and easy to complete but it still received a low response rate. This probably affected the statistical analysis of the results, where ideally 100 or more responses would be sufficient (?????). The surgeons who responded are probably biased towards using TEES and therefore, the responses did not include opinions from surgeons who are not interested in TEES. However, since this study aims to identify the needs of TEES surgeons, this limitation is not so significant as we want to know the opinions of surgeons who practice TEES and are therefore interested in TEES. It would be interesting to see how/if the challenges between microscopic otologists and TEES otologists vary. The questions asked before the comments section may have prompted specific responses as many of the responses were related to the TEES challenges presented.

## Conclusion:

The average degree of need for each TEES difficulty was greater than 50%. Reaching structures visualized by the endoscope scored the greatest degree of need. People who performed greater than 90% of surgeries totally endoscopically reported a significantly greater need for reaching structures and positioning a graft. Respondents who use a specialized TEES instrument set had a significantly lower need for positioning a graft. Out of the 21 comments received about improving TEES instrumentation, 10 mentioned a tool for suction and 8 mentioned a tool for reaching structures.

compare key findings with other literature

limitations of study

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