Response to Scientific Peer Review by Dr. Sharon Cushing - Please see the highlighted sections where specific recommendations were added.

Study Design (General Overview):

The time flow analysis will be recorded by the MASc student during ear surgery. The surgery will be divided into steps, described in the data collection form located in Appendix B. The type of instruments used during the different steps and the number of changes between 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.

Participants

The time flow study will include two kinds of participants: patients, who will be undergoing ear surgery, and surgeons, who will be performing the ear surgery.

Participant Recruitment

The PI's colleagues in otolaryngology are interested in this project and would also like to improve their experience with TEES. Three additional surgeons from SickKids and one from Toronto General Hospital have expressed interest in participating in this study.

Inclusion criteria

Patient participants: 40 surgical patients, who require cholesteatoma surgery or tympanoplasty (surgical repair of perforated ear drum).

Surgeon participants: 5 surgeons with more than one year of experience in endoscopic ear surgery. The PI, three additional surgeons from SickKids and one surgeon from Toronto General Hospital will be asked to participate.

Comment [AS1]: Recommendation 1: 1) In participant recruitment it was initially unclear to me that the PI would be a participant - I was having a hard time adding it up to 5 (3 HSC surgeons + 1 TGH surgeon + PI)

Exclusion criteria

Residents and fellows who are in training. It would be inappropriate to include surgeons in training in the study as their lack of experience will contribute to delays and lack of efficiency in time flow, so confounding the estimate of the contribution of instrument design to surgical time flow. Although the ability of trainees to use different instruments in TEES and the impact of their level of experience on this ability would be of interest, they are beyond the current scope and design of this study.

Study intervention

Each surgeon will be observed and recorded performing ten operations. The steps that are recorded will be performed by the experienced surgeon who has given consent for the study. The time and number of instruments changed will be recorded for the steps outlined in the Data Collection Form, included in Appendix B.

Comment [AS2]: Recommendation 2: Recommend clarifying the role of training in the study is the intention to have the studied surgeons performing the whole operation from start to finish for the designated study surgeries or could residents/fellows participate but metrics just wouldn't be counted during that timeframe where a trainee was operating

Outcome measures

The following outcomes will be measured: duration of the surgical steps described above and the number of times the surgeon changes the tool he/she is using during the step.

Statistical analysis

The factor to be studied is the type of instruments used for each surgical step. The block is the surgeon. The response is the time required for the surgical step. Therefore, an ANOVA will be used to determine if there is a statistical difference in the time to complete a surgical step depending on the instruments used.

Ethical concerns

The identity of the surgeon will not be linked to the time flow data, to ensure there is no risk of participant embarrassment regarding surgical efficiency compared with peers.

Budget

The total budget is given in the table below.

Personnel	Description	Price/Unit	Unit	Qty	Total Cost
Master's Student	Stipend	23465	year	0.5	11732.5

Since this study is observational, it just requires the time of the Master's student to conduct the study.

Participant Consent

Patients who are eligible for TEES during their surgery will be asked to fill out a consent form or assent form depending on their capacity.