**Instrument Validation Paper Outline**

Neurotology and Otology – more appropriate for the intended audience (TEES surgeons)

Abstract:

Introduction/Background:

*Clinical Motivation:*

* “Comparison of Middle Ear Visualization With Endoscopy and Microscopy” outlines what is visible by the endoscope vs. microscope and this paper will outline how this new instrument can reach structures visualized by the endoscope
* TEES is a minimally invasive surgical technique – list benefits
* One-handed surgery
* Tools for TEES (such as...) are being developed but according to Needs Analysis study they are still not sufficient to facilitate the technique
* Need: low adoption due to learning curve thus need better instruments to facilitate the surgery
* Continuation of the Needs Analysis study

**Methods:**

*Tool Description:*

* Describe the tool – function, how it is to be used
* Suction design decisions

*Surgeon Survey:*

* Explain how we designed the surgeon feedback survey
* Explain the survey
* Why use likert scale?
* Participants: from TEES course in November, 2017, from Modena meeting in April, 2018, residents/colleagues at SickKids

*Performance Testing:*

* How does it address the needs analysis – reaching structures, dissection and removal of cholesteatoma (from need ratings), suction (from comments)
* Reach test protocol: print temporal bones from CT scans with highlighted targets, ask surgeons to reach targets with endoscope, count how many targets were reached COMPARED TO EXISTING TOOLS **– propose this as a new testing method to test the efficacy of newly developed tools**
  + Temporal bones printed with atticotomy
  + Will compare number of targets reached for new instrument vs. Thomassin, Panetti, Rosen needle which are commonly used tools as per “Instrumentation and Technologies in Endoscopic Ear Surgery”, “Pediatric endoscopic ear surgery in clinical practice: Lessons learned and early outcomes”, “Introducing Endoscopic Ear Surgery into Practice” where experienced TEES surgeons review TEES techniques
  + Which tools to compare? Why did we choose those tools to compare with?
  + Results:
* Dissection and removal of cholesteatoma:
  + Have a piece of putty (similar to cholesteatoma consistency?? – would have to validate that this is similar to cholesteatoma) inside the temporal bone model and compare between current and new tool on dissecting/removing this cholesteatoma
* Testing suction?

*Statistical Analysis:*

* Explain the statistical analysis methods
* What kind of data was collected? Non-parametric? Ordinal?

Results:

*Surgeon Survey:*

* Present the stats results from the survey

*Performance Testing:*

* Present results
* How many people participated?

**Discussion:**

*Surgeon Survey:*

* What did we learn from the surgeon survey?
* What are the strong points of the tool?
* What are the limitations of the tool?
* How would the tool be redesigned?

*Performance Testing:*

* Current tools vs new tools? What was the result and what did we learn?
* Are some better than others? How would we tell how one tool is better than the other?

*Limitations:*

* Of the surgeon survey
* Of participant selection
* Of the performance testing protocol/procedure