# Instrument Prototype Paper

* Presenting both a grasping + compliant tool and a suction + compliant tool

Journals:

* Otology and Neurotology (Alejandro Rivas’s paper on robotic assisted surgery in the middle ear)
* ASME
* JSLS, Journal of the Society of Laparoendoscopic Surgeons (Mary Frecker – testing a forceps tool using standard tasks/tests and scoring the completion of each task to evaluate a device)
* Design for Medical Devices Conference

## Abstract:

**What type of tool is it?**

A bendable/compliant tool tip with an end effector

Suction-enabled compliant tool

**What problem is it addressing?**

Inability to reach structures visualized by the endoscope

**How will we show the testing to address this problem?**

Background Research on making a 3D model to test the instruments:

* Use table 2 of “Three Dimensional Printing and its applications in otorhinolaryngology – Head and Neck Surgery” a list of articles that are relevant to 3d printing in otolaryngology which will help as a lit review for making the temporal bone test models: references from article that may be relevant: 30, 31, 32, 33, 52 (tympanic membrane grafts), 36 (3D model for endoscopic approaches), 19, 25 (case report about a personalized replica of the auricle that was 3d printed to assist in preop planning of ear reconstruction
  + 29-31 talk about implementing 3D printed models used for resident training and the residents feedback – participants were asked to qualitatively evaluate training exercises in terms of realism, anatomic accuracy, utility, efficacy – yielded positive feedback
  + Limitations: So far, 3D temporal bones don’t have well replicated middle ear bones and retain powders inside the mastoid air cells (32, 33)
  + Can print models with a pathology to aid in training
  + ElePhant uses 3D printed models with facial nerve replaced with a conductive alloy to provide user feedback on structural damage thereby letting residents make mistakes on models rather than patients (“ElePhant - An anatomical Electronic Phantom as simulation-system for otologic surgery”
* Temporal bone surgical virtual reality simulator: for microscopic surgery https://cardinalsimsoftware.stanford.edu/graphics/

Study design research paper:

“Anatomy-specific virtual reality simulation in temporal bone dissection: perceived utility and impact on surgeon confidence”

This paper talks about a virtual reality surgical simulation tool developed by Stanford to train residents for temporal bone microscopic surgery. It outlines the subtasks that the surgery was divided into and the study was administered by:

- recruiting residents

- filled out a questionnaire regarding their previous experience and their confidence level of the 12 surgical subtasks

- performed the VR simulation

- filled out the same questionnaire

- performed a cadaveric dissection with the VR program available for use

- filled out a questionnaire to rate the utility of the VR simulation platform using a 5 point likert scale and the cadaver specimens were graded

for the results - stats included t test, ANOVA, Pearson correlation, Benjamini-Hochberg correction applied to control the false discovery rate when conducting multiple comparisons. Correlations were found between confidence ratings and the cadaveric dissection score - used Pearson correlation test.

“Multi-material 3D Models for Temporal Bone Surgical Simulation” – good template

* Simulated temporal bone model using 3D printing from CT scans, 5 point likert scale used to grade modelfor anatomical accuracy and suitability as a temporal bone surgery simulator for dissection and temporal bone drilling
* “model development” section in methods is a good template to use for my own model development write up
* Subjects used the model and rated: bony anatomy, soft tissue anatomy, likeness of drilling compared to cadaveric cortical bone, likeness of drilling compared to trabecular bone, ease of use, safety, irritation due to bone dust, overall value of 3d printed temporal bone as a surgical simulation preop
* 13 attendings and residents, noted experience
* Generated mean and box plot

1. Show the range of reach
2. Show CT scan photos of where it can reach – preface that the CT scans are of patients where the surgeon had to drill bone to reach the disease
3. Show that the tip can reach the area of interest and also perform the ‘tip function’ there
   1. In a model or cadaver
   2. Show that the tip can reach a tumor (made of silastic putty?) and then suck or grasp
   3. Show that the tool tip is stiff enough so it won’t break when in bone – force to break tip? Or displacement of tip before breaking – use the stereo camera system and bend the tip and every 0.5 mm of tip displacement take a photo which would characterize what displacement (and what corresponding force) would break the tip
   4. Force vs. tip displacement

## Introduction:

* Background describing why you need this type of tool
* Existing tools – literature and patent search

## Methods:

* Tool requirements
  + Functional
  + Surgeon
  + Safety
* Manufacturing overview
  + Reason for certain design decisions
  + How was handle shape/design determined? – rapid prototyping, 3D printed/machined – given to surgeons to test the feel, feedback used to make it better, iterative designs, etc.
  + Cutting geometry: Used CT scans to determine the arc length and radius of curvature desired which led to narrowing down the cutting geometry

#### To figure out the geometry of the bendable tool:

* + - * Use “Through the Eustachian Tube and Beyond: A New Miniature Robotic Endoscope to See into the Middle Ear”
        + Render 3D models from CT scans (air space 3D model)
        + Identify targets to reach with the tool
        + Manually sketch the curves required to access the areas
        + Kinematics to figure out curve geometry and then cutting geometry
        + Make tool with forceps/suction/round knife?
  + Safety considerations of the cutting geometry – not too deep or it will break, not to shallow or will not bend enough
  + Materials used and why
* Cadaver testing methods
* 3D printed model – define the characteristics of the model, why it was built the way it was and how it was used to test the tool

### Validation Testing of Tool

Produce a 3D model to test the reachability of the tool and measure the following metrics:

* ability to reach intended structures with old instrument(s) vs. new instruments? PASS/FAIL
* Amount of bone removed (size of the defect) in order to reach the intended structures and compare between bendable and current instruments (curved Panetti dissectors, Rosen Needle, Thomassin)

3D model:

* How was it made?
  + Number of CT scans used
  + Why those CT scans? – their anatomy are at the limits of TEES, Dr. James did an atticoantrostomy to access the cholesteatoma
  + 3D printed
  + Soft tissue? How are we simulating that?
* what tests are we doing on the model with the tool?
  + Time to reach structures (targets specified on the 3D models)
  + Ability to reach structures
  + Feedback from surgeons (questionnaire)

## Results:

* Show the final specs of the tool – arc length, radius, cutting geometry with CT scans – want to follow up with the methods and presents the results from the CT scan investigation method used to figure out the ideal cutting geometry
* Final design specs shown
* CAD, close up pictures used to explain the final design and how the mechanism works
* Testing – bench top, cadaver, 3D printed model
* Survey results – feedback from surgeons regarding the tool presented here – survey results analysis

## Discussion:

* Limitations
* Feedback for the next iteration of the prototype
* Describe how it will be improved

Testing Notes:

* “Development of Tasks and Evaluation of a Prototype Forceps for NOTES”
  + this paper outlines a testing protocol to compare a standard instrument and prototype (forceps and cutting instrument) – it compares them using 6 tasks developed from a standard and literature
    - outlines these tasks by describing pictures
  + included comments made by surgeons while using the tool and the frequency of the comments e.g. “this tool is helpful” was said x number of times
* “A novel laryngoscope instrument stabilizer for operative microlaryngoscopy”
  + tested a stabilizer with surgeons and asked them to fill out a survey afterwards
  + results of the survey are just listed (no graph)
    - Physicians also rated instrument stability, mobility, visualization, and ease of use on a survey form. RESULTS:
      * Instrument stability was highly rated (mean score 8.8). Target visualization was felt to be somewhat impaired (mean score 6.2), and instrument mobility was also rated low (mean score 5.0). Overall utility of the instrument was rated a mean 8.7 by the 17 evaluators. All but 1 eval- uator indicated that they thought that the instrument would be useful for them in laryngeal microsurgery
* “Robot-assisted laparoscopic ultrasonography for hepatic surgery”
  + Questionnaire. All 10 subjects completed the questionnaire after the US task experiments. All subjects had extensive laparoscopic experience (>30 cases) and 40% of subjects had moderate experience (>15 cases) with laparoscopic US. The RLUS was noted by the majority of subjects to be associated with better positioning (8/10), more comfortable (6/10), greater confidence in lesion finding (8/10), less fatigue inducing (9/10), and an overall more useful tool (9/10). – this was just reported (no graph or table)
  + Tasks were performed by handheld tool and robotic tool and the surgeon gave a score for factors during each task and the scores were compared between robot and handheld tool, then t-test between the two scores to see if there is a significant difference – presented in table format