



WPI

Expandable Blades for Precision Veterinary Myringotomy

A Major Qualifying Project

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Table of Contents

Abstract.....	1
1.0 Introduction.....	2
2.0 Background.....	4
2.1 Ear Infections in Small Animals	4
2.2 Anatomy of the Middle Ear	5
2.3 Current Medical Practices	6
2.4 Issues with the Current Practice for Animals.....	9
2.5 Surgical Instruments and Materials Selection.....	10
2.6 Current Medical Equipment.....	11
3.0 Statement of Design Problem	16
3.1 Initial Client Statement	16
3.2 Objectives, Functions, and Specifications	16
3.2.1 Versatile	17
3.2.2 Compatible.....	17
3.2.3 Inexpensive	17
3.2.4 Safety	17
3.2.5 Pairwise Comparison Chart	18
3.3 Revised Client Statement.....	19
3.4 Project Timeline.....	19
4.0 Design Process	21
4.1 Design Alternatives.....	21
4.2 Design Selection	24
4.3 Preliminary Designs.....	28
4.3.1 Interchangeable Blade Models.....	30
4.3.2 Reverse Scissor Models	33
4.4 Development of Final Prototype.....	38
4.4.1 Clevis Design.....	39
4.4.2 Sheathing.....	41
4.4.3 Spacers and Pins	42

4.4.4 Final Prototype with Compiled Components	43
4.4.5 3D Printed Prototypes	45
4.5 Manufacturing.....	46
4.5.1 Cost Analysis	46
4.5.2 Linkages and Blades	47
4.5.3 Clevis	49
4.5.4 Sheathing and Pull Wire	50
4.5.5 Assembly.....	50
5.0 Experimental Designs	52
5.1 Catheter Force Experiment	54
5.2 Blade Experiment: Bovine Tendon.....	54
5.3 Blade Experiment: Force to Puncture Membranes	56
5.4 Blade Experiment: Effect of Blade Shape on Membrane Incision	57
6.0 Results.....	58
6.1 Force Experiment Results	58
6.2 Blade Experiment Results (Bovine Tendon).....	60
6.3 Blade Experiment Results: Force to Puncture Membranes.....	61
6.4 Blade Experiment Results: Effect of Blade Shape on Incision Size	63
6.5 Verification and Validation.....	66
6.5.1 System Constraints.....	66
6.5.2 Stress Analysis	67
6.5.3 Deformation Analysis	69
6.5.4 Failure Criteria	70
6.6 Summary of Results.....	71
6.6.1 Summary of Force Tests	71
6.6.2 Summary of Membrane Test.....	71
7.0 Discussion.....	72
7.1 Compare to Current Devices.....	72
7.2 Achieving Objectives & Limitations	73
7.3 Ethical Concerns	74
7.4 Health and Safety Concerns.....	75
7.5 Compliance to Industry Standards	75

7.6 Economics and Manufacturability	76
7.7 Societal & Political Concerns	77
7.8 Environmental Concerns.....	78
8.0 Conclusions.....	78
8.1 Project Success.....	78
8.2 Summary of Final Design	79
8.3 Future Suggestions.....	79
References.....	81
Appendices.....	86
Appendix A: Tympanic Membrane Variability	86
Appendix B: Copyright Permission	87
Appendix C: Table of Patents Relating to the Tool.....	91
Appendix D: Individual Pairwise Evaluation Charts & Total	93
Appendix E: French Catheter Scale.....	95
Appendix F: Tufts Doctor Interview.....	96
Appendix G: Other Cutting Techniques	97
Appendix H: Individual Design Matrix Charts & Total	98
Appendix I: Pictures of Initial Designs.....	105
Appendix J: Force Experiment	108
Appendix K: Experiment 1 Arduino Code	111
Appendix L: Bovine Tendon Blade Experiment.....	112
Appendix M: In-Spec 2200 Instron Set-up and Calibration	117
Appendix N: PDMS Curing Protocol	121
Appendix O: MATLAB Program for Standard Curve.....	122
Appendix P: Cadaver Form	124
Appendix Q: Force to Puncture Membranes.....	126
Appendix R: Blade Shape on Tearing.....	128

List of Figures

Figure 1: Key features and characteristics of the canine ear	5
Figure 2: Catheter as used in procedure.....	7
Figure 3: Surgical otoscope used to visualize the ear canal.....	7
Figure 4: An image of the tympanic membrane, with the regions of the membrane labeled, as seen through an otoscope (Appendix B, Daigle, 2012)	8
Figure 5: 1990 Specialized Myringotomy Tube by 3M Innovation Properties Co used to promote proper healing and reduce the chance of infection	12
Figure 6: Surgical Knife with Retractable Blade and Depth of Cut Control by Ravi Nallakrishnan 1995 used to create small incisions to minimize damage to surrounding tissues	14
Figure 7: Drawings of the blade and sheathing mechanism of the simplistic design, showing the identical sizes of the blade and sheathing	26
Figure 8: Reverse Scissors (left) & Scissor (right) preliminary designs	27
Figure 9: Trigger and push-button mechanisms	28
Figure 10: Proof of Concept made with pen mechanism, outer plastic tubing, and inner wire, and a small blade	29
Figure 11: Retracted (left) & Extended (right) Interchangeable Blade Design as designed in SolidWorks	30
Figure 12: Push-button mechanism as designed in SolidWorks.....	30
Figure 13: Proof of concept of Interchangeable Blade design at 10X scale with 3D printed push button mechanism and blade, an internal spring, polyurethane outer tubing, and silicone inner tubing cut to size	31
Figure 14: Close up view of the difference in elongation of inner tubing and scalpel blade for the Interchangeable Blade proof of concept	32
Figure 15: Reverse Scissors (left) & Scissor (right) 3D models.....	33
Figure 16: Inner sheathing covering blade mechanism	34
Figure 17: Outer sheathing enclosing blade mechanism and inner sheathing	34
Figure 18: Reverse Scissor (left) & Scissor (right) fully closed with sheathing	35
Figure 19: Reverse Scissors (left) & Scissor (right) with exposed blades and sheathing retracted	35
Figure 20: Reverse Scissor (left) & Scissor (right) with fully extended blades and sheathing retracted.....	36
Figure 21: Flexible surgical scissor design used for minimally invasive surgical applications ...	36
Figure 22: Fully assembled Reverse Scissors mechanism closed (left) and open (right).....	37
Figure 23: Fully assembled prototype with reverse scissor mechanism, flexible sheathing, and push button mechanism.....	38
Figure 24: Pin-Slot Clevis design	39

Figure 25: Slot Clevis design	40
Figure 26: Half Clevis with attachment straps.....	41
Figure 27: Segment of spiral sheathing	42
Figure 28: Side view of the spacers (left) and front view of the spacers (right) in the assembly.	42
Figure 29: Flared pins used to hold the linkages and blades together in the assembly	43
Figure 30: 3D model of the final design in the fully sheathed position.....	44
Figure 31: 3D model of the final design in the puncture position	44
Figure 32: 3D model of the final design in the fully expanded position	45
Figure 33: Final 3D printed prototype in the fully sheathed position.....	45
Figure 34: Final 3D printed prototype in the fully extended puncture position	46
Figure 35: Final 3D printed prototype in the fully expanded position	46
Figure 36: Sheet of metal from which the blade and linkages were cut	47
Figure 37: Cutting the miniature stainless steel tubing to size using a rotary tool with a cut-off wheel attachment	48
Figure 38: Blades with miniature precision stainless steel tubing laser welded flush to one end	48
Figure 39: Blade and linkage assembled with peened miniature stainless steel tubing.....	49
Figure 40: Clevis, showing the top slot for pins, and side slot for linkages	49
Figure 41: Back handle of the device showing the S wire bend.....	50
Figure 42: Clevis of the device showcasing the peened pins and linkage assembly	51
Figure 43: Setup for the force experiment using an Arduino Uno and force transducer.....	54
Figure 44: Setup for Blade Experiment	55
Figure 45: Blade types used for testing.....	56
Figure 46: Set up of the In-Spec 2200 Instron for the force to puncture experiment	57
Figure 47: Set up of the Instron 5544 with intestinal submucosa for the blade shape test.....	58
Figure 48: Transducer data demonstrating the force applied with the catheter by each doctor ...	59
Figure 49: Triangular blade force over time test graph	60
Figure 50: Bovine tendon lacking uniformity and integrity	61
Figure 51: Force required to puncture tympanic membrane.....	62
Figure 52: Force required to puncture intestinal submucosa	62
Figure 53: The mean force required to puncture the membrane, using 3 different blade types, with standard deviation	63
Figure 54: Experimental intestinal submucosa fixed and punctured with scale bar for reference	64
Figure 55: Graph comparing puncture forces vs. extension of each of the 3 blade types. The puncture force of each dataset is indicated with a star	65
Figure 56: Boundary conditions and constraints of device assembly.....	67
Figure 57: Stress distribution of the pins calculated by ANSYS.....	68
Figure 58: Calculated total deformation of system in mm	69

List of Tables

Table 1: Key Objectives.....	16
Table 2: Pairwise Comparison Chart	18
Table 3: Basic Functions and Specifications	19
Table 4: Project Timeline.....	20
Table 5: Alternative Designs	22
Table 6: Knife Designs	22
Table 7: Sheathing	23
Table 8: Retracting Mechanism	23
Table 9: Design Matrix Weights.....	23
Table 10: Example Knife Matrix Calculation.....	24
Table 11: Knife Matrix Totals	24
Table 12: Mechanical properties of various materials used to mimic the tympanic membrane	53
Table 13: Maximum puncturing force for both doctors.....	59
Table 14: Percent Cut of Different Blade Types.....	64

Authorship

All parts of this report were completed equally by all team members.

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Abstract

Middle ear infections are a common disease in canines. Treatment for the disease often involves using a catheter for myringotomy, or puncture of the tympanic membrane for flushing of the middle ear. Current practices are inefficient and traumatic, sometimes requiring multiple incisions and excessive force. The goal of this project was to design a flexible and safe device to traverse the ear canal and cut the tympanic membrane in one pass. The device must be compatible with current surgical processes and be safe to use before, during, and after surgery. Through rapid prototyping, finite element analysis, and experimental testing with a scaled prototype, the team can conclude that this design successfully fulfills the objectives set forth by the clients.

1.0 Introduction

Approximately 16% of dogs with a reported ear infection experience otitis media and require medical attention (Moriello, 2013). Otitis media is a common disease in small animals due to the shape of their ear canal. A dog's ear canal is different than a human's in that it extends along the side of the face and makes a right angle (Cole, 2009). This makes dogs more susceptible to fluid buildup in the ear, which leads to an ideal environment for bacterial growth and pressure buildup behind the tympanic membrane. A small incision made in the tympanic membrane, known as a myringotomy, is often performed to relieve pressure and drain excess fluid from the ear. This is a relatively painless, non-invasive procedure that only takes 15 to 30 minutes to complete per ear.

Currently, there are no tools on the market to effectively perform a myringotomy on small animals. Veterinarians are forced to use tools designed for human ear canals, which are not flexible enough to reach the tympanic membrane of small animals, or cut their own tools from catheters. One patent in particular, a sheathed and retractable surgical tool combination, is effective at safely and efficiently puncturing a membrane, but lacks the flexibility necessary for a myringotomy procedure on dogs or cats (Aikins, 1985). An existing device that meets the flexibility requirements of the procedure, but is not intended for use in a myringotomy, is a set of biopsy forceps. While the forceps are effective at safely navigating to the tympanic membrane, their intended use does not involve an incision. Also, existing tools are unable to cut through the tympanic membrane in a single pass, causing unnecessary irritation and inflammation. There is a clear need for a specialized tool to perform myringotomies in small animals.

The goal of this project is to design a flexible, one-handed myringotomy tool to cut the tympanic membrane in one pass and not damage the ear canal. The tool will be versatile to accommodate a large variety of patient and surgeon needs, including incision size and different patient sizes. It must be compatible with current surgical processes and equipment. The tool will also be cost-effective and safe for patients, surgeons, and equipment.

2.0 Background

2.1 Ear Infections in Small Animals

Otitis media is a common disease among pets, specifically dogs. It is caused by the buildup of bacteria in the middle ear and leads to inflammation (Kowalski, 1988). It typically occurs as a direct consequence of otitis externa, or inflammation of the ear canal. Animals are more susceptible to ear infections after being exposed to water, which creates a moist environment that aids in bacterial growth.

After an individual is diagnosed with an ear infection it is important to isolate the bacteria present so that the individual can be treated. *Malassezia canis* and coagulase-positive staphylococci are the most common types of yeast and bacteria found in ear infections. These particular types indicate a single infection, whereas other types of bacteria and yeast may indicate mixed infections. Doctors typically use smears in order to diagnose an individual and determine which type of treatment is appropriate (Kowalski, 1988). It is also critical to know which drugs are effective for certain types of bacteria.

A study at the Louisiana State University School of Veterinary Medicine from 1986 to 1998 determined which types of bacteria were found in dogs and their susceptibilities to various drugs (Colombini, 2000). The study included dogs that had otoscopic, radiographic, or gross evidence of otitis media. Eighty-two dogs were involved in the study, and bacterial samples from each dog were examined for culturing. The samples were observed every 24 hours, and microorganisms present in each dog were identified. Antimicrobial susceptibility testing was then performed on the identified microorganisms via the Kirby-Bauer method (Hudzicki, 2009). Of the

82 dogs in the study, 40 were Cocker Spaniels, suggesting they are highly susceptible to otitis media. A total of 107 ears were examined in the study, and 164 different microorganisms were identified. The study found antimicrobial susceptibility profiles for each microorganism, in addition to data regarding which bacteria were most prevalent in certain breeds of dogs. The susceptibility of *Staphylococcus epidermidis* isolates was 100% for ampicillin and five other drugs, meaning that these drugs kill these bacteria entirely. This study uncovered useful information regarding the presence of specific bacteria in dogs, and which dogs are more susceptible to ear infections.

2.2 Anatomy of the Middle Ear

In general, dogs are more susceptible to ear infections than humans. This is due to the fact that their ears are shaped differently, with the ear canal extending along the face and then making a right angle, which can be seen in Figure 1 (Cole, 2009).

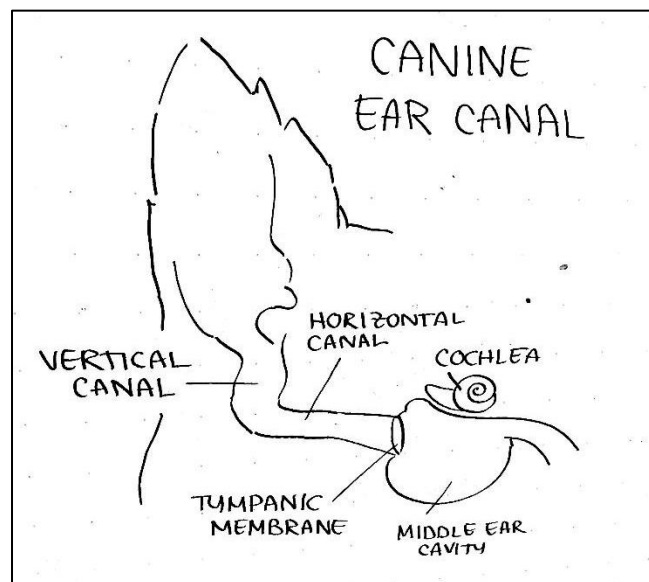


Figure 1: Key features and characteristics of the canine ear

This angle disrupts the tendency for fluid to flow out of the ear and makes it more susceptible to fluid buildup. Additionally, different breeds of dogs have ears with different pH values and humidities (Colombini, 2000). The Cocker spaniel's ears are among the highest with respect to humidity, increasing their susceptibility to otitis media.

Dogs also have varying sizes of ear canals and tympanic membranes (Eom, 2000). As can be seen in Appendix A, the diameter varies as much as four millimeters between the Pekingese breed and larger breeds. The diameters of cartilage and ear canals was also noted during a canalography procedure (Eom, 2000). In 82% of ears in this particular experiment, the tympanic membrane could not easily be visualized unless hair and debris were removed. In medical procedures, it would be necessary to cleanse the ear canal prior to performing a procedure. The diameter of the ear canal and tympanic membrane would also be taken into account to ensure that no rupturing or damage would occur.

In humans, the thickness of the tympanic membrane varies between 30 and 120 μm , depending on the location (Decraemer & Funnell, 2008). In cats, the tympanic membrane thickness varies between 5 and 20 μm (Decraemer & Dirckx, 2004). Optoelectronic holographic otoscopy shows that dog tympanic membrane thicknesses are slightly larger than humans (Chole & Kodama, 1989). This value is extremely difficult to measure due to the different layers of the membrane and the variability on a case by case basis (Aernouts, 2012).

2.3 Current Medical Practices

A myringotomy is a procedure that is performed to relieve a buildup of pressure, often caused by otitis media, from within the middle ear. To relieve the pressure caused by buildup of

purulent fluid, an incision is made in the tympanic membrane. The incision is made large enough to allow the fluid to drain or be suctioned from the middle ear using a 5Fr catheter (Myringotomy, 2016; Zewe, personal communication, 2016). The catheter can be seen in Figure 2, below.

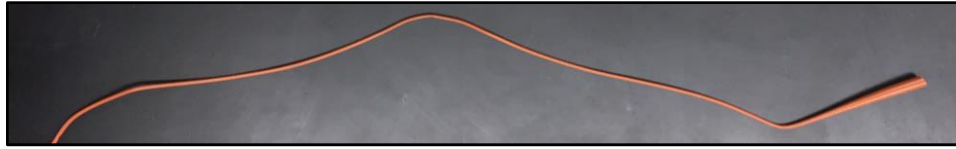


Figure 2: Catheter as used in procedure

When a myringotomy is performed on domestic animals, the animals are prepared for the procedure by cleaning the ear and administering general anesthesia. A surgeon uses an otoscope to visualize the ear canal and the tympanic membrane and determine the level of irritation within the ear. An otoscope is a specialized endoscope for examining the ear. The otoscope used by Tufts veterinary dermatologists can be seen in Figure 3, below.



Figure 3: Surgical otoscope used to visualize the ear canal

The ear canal is then cleaned of wax and hair by flushing the canal with saline solution. The otoscope is used to flatten out the ear canal for a better visual, and the location of the caudoventral quadrant of the pars tensa (where the incision in the membrane will need to be made) is determined. This can be seen in Figure 4, below (Daigle, 2012).

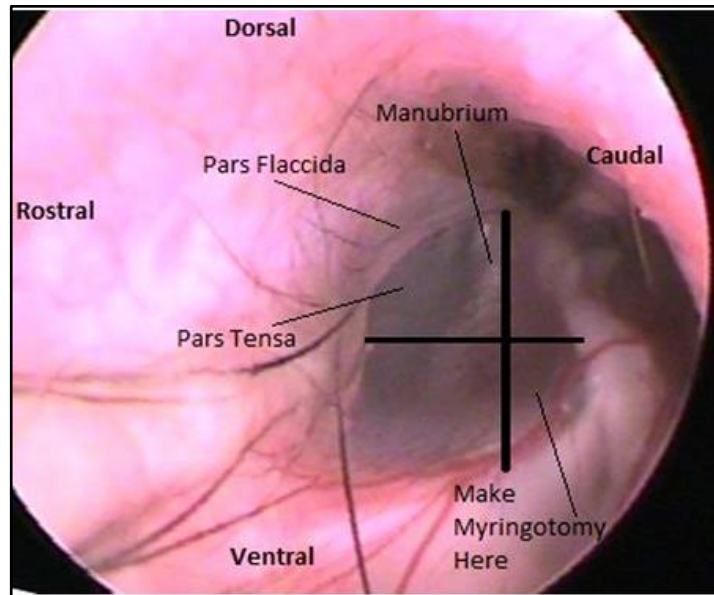


Figure 4: An image of the tympanic membrane, with the regions of the membrane labeled, as seen through an otoscope (Appendix B, Daigle, 2012)

Myringotomy procedures in small animals are typically performed with a combination of an otoscope and a puncturing device. The Karl Storz 67260 OSA Veterinary Otoscope, for example, is a reusable, versatile instrument that is compatible with multiple auxiliary surgical tools. This otoscope has a working channel with a diameter of 5 Fr. (Otoscope, 2016). A wide variety of puncturing devices are used for myringotomies. Some clinics use myringotomy knives designed for humans or spinal needles (Owen, n.d.). More commonly, veterinarians use a sterile catheter, cut at 60 degree angle to create a sharp point. This catheter is then fed through the otoscope, and poked through the tympanic membrane with one firm motion (Daigle, 2012). Once an incision has been made, fluid is aspirated from the middle ear, effectively relieving the pressure. The ear is then flushed again with sterile saline solution. Often a follow up appointment is made to ensure the tympanic membrane is healing correctly. Some methods of puncturing the membrane are more traumatic than others, so recovery time varies for each method. A jagged cut or large

hole takes longer to heal or may never close completely; a clean incision has a better chance of full recovery.

When a myringotomy is performed on humans, all pre-procedure steps are completed and a small incision is made in either the anteroinferior quadrant or the posteroinferior quadrant of the tympanic membrane (Reilly, 2016). The fluid is aspirated, and often in younger children a small eustachian tube is inserted into the incision to allow for continued draining over an extended period of time.

2.4 Issues with the Current Practice for Animals

There are some instances where the myringotomy treatment fails to properly heal or a recurrence of the original issue occurs. Often an infection or inflammation prevents the tympanum from healing, or a resistant bacterial infection causes fluid to build up within the ear. Other complications include insufficient drainage of the debris or fluid from the ear canal or failure of the owner to provide proper post procedure treatment for the animal (Cole, 2014).

A myringotomy procedure can have complications due to the shape of the animal's ear canal. One possible complication is Horner's syndrome. More often found in cats, Horner's syndrome is caused when there is damage to the sympathetic nerve fibers running through the middle ear. The side effects include possible facial nerve paralysis, vestibular disturbances, specifically in the inner ear, and possible deafness due to damage to the auditory ossicles or from damage to the inner ear (Cole, 2014).

2.5 Surgical Instruments and Materials Selection

Surgical instruments can either be reusable or disposable, and each option has significant benefits and drawbacks. A reusable instrument is vastly more expensive than a disposable when comparing initial cost, however disposable instruments must be bought regularly, whereas reusable instruments are durable and used for years (Smith, 2011). Disposable instruments are inherently less complex, as they need to be inexpensively mass produced and will be thrown away at the end of a procedure. Delicate or technical surgical work often requires more advanced, reusable instruments (Smith, 2011).

Disposable instruments are packaged sterile, while reusable instruments are repeatedly sanitized using a combination of high temperatures and pressures in an autoclave (Autoclave, n.d.; Finkiel, 2015). Though uncommon, there is a chance that the reusable instrument is not sanitized properly, leading to potential cross contamination between patients (Smith, 2011). The frequency of use of the instrument should also be considered before choosing one type of instrument over another. A reusable tool would be more beneficial when a specific procedure requiring the instrument is performed often.

Material selection for disposable and reusable instruments differs in terms of quality and cost. Materials used for disposable instruments are common and inexpensive, such as plastics and surgical steel. Surgical steel is highly resistant to corrosion and used in a wide variety of biomedical applications (Which, 2013). Plastics are commonly used for instrument handles, made using injection molding or 3D printing (Surgical, 2006; Rankin et al., 2014). Disposable tools have very rigid, simple designs; anything too complex would be unprofitable in such a low cost market.

Reusable instruments are made of higher-quality materials, though many standard-line products are made from surgical steel (Which, 2013). Metals such as Titanium and Tungsten Carbide are more lightweight and durable than surgical steel, but they are also more expensive (Which, 2013). Any plastic components of an instrument must withstand temperatures up to 200°C in order to be sterilized in an autoclave (Which, 2013). Complex instruments such as otoscopes, forceps, and snares are designed with reusability in mind to keep them cost-effective.

2.6 Current Medical Equipment

Several existing patents have been filed to address medical needs similar to a myringotomy. All of the filled inventions are intended for use in humans, but the technology can be adapted to suit the needs of some animal surgeries. Researchers use many tactics to make the necessary incision for a myringotomy procedure including chemical solutions, scalpels, or even laser dermatology, depending on the needs of the procedure.

The most common application of specialized chemistry in a human myringotomy is in the recovery from a procedure. A patent filed in 1990 by 3M Innovation Properties Co. shows a specialized myringotomy tube, intended for insertion through the myringotomy incision created by a scalpel blade, which can be seen in Figure 5 below. The tube, made of specialized bio-compounds, releases an active agent as it bio-erodes. This agent works to ensure a clean heal and prevent future infection (Muchow & Sirvio, 1991). An incision is made in the tympanic membrane for the substance to enter the ear, and the substance then releases a pharmacological agent that is able to eradicate various bacteria and mucus buildup in the ear via chemical means. The substance that is inserted into the ear is covalently bonded to the pharmacological agent, and contact with

the middle ear triggers the release of the pharmacological agent. Some examples of these pharmacological agents are antibacterials, osmotic agents, and anti-inflammatory medications. A similar device was patented in 1997, which updated the design by constructing the tube from a new form of collagen, called GELFILM (Patterson, 2002). This invention also provided lasting structural support to the ear canal and tympanic membrane.

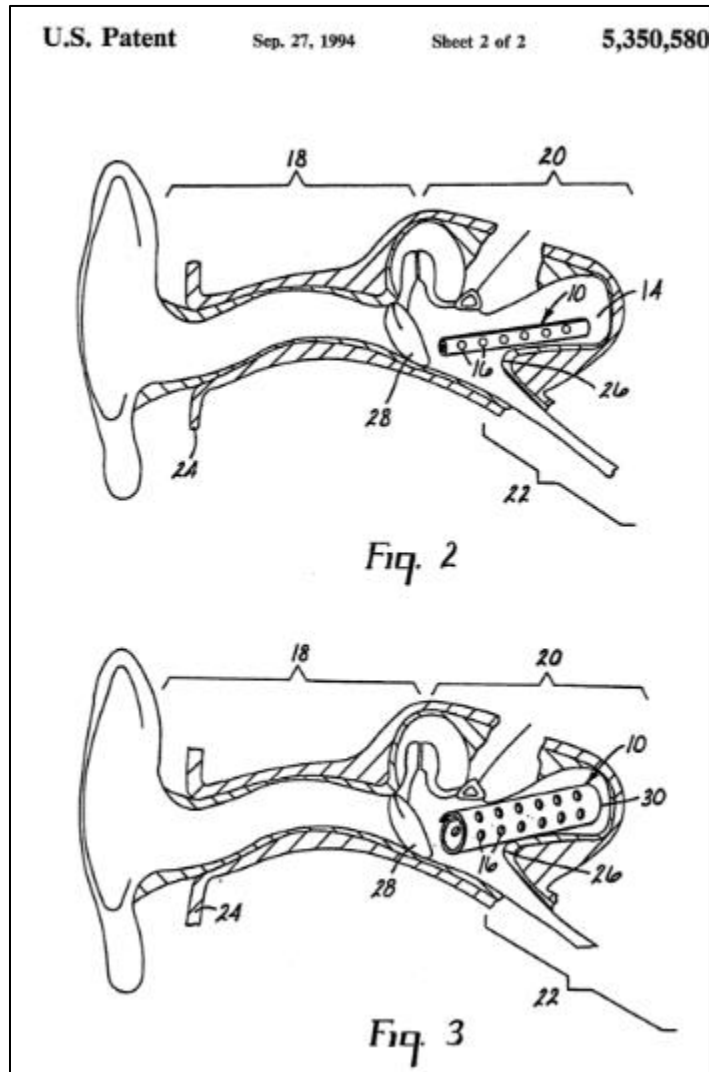


Figure 5: 1990 Specialized Myringotomy Tube by 3M Innovation Properties Co used to promote proper healing and reduce the chance of infection

Surgical scalpels are a common and popular option for creating incisions. One common hurdle, however, is the blade's easy ability to accidentally damage surrounding tissue. Several patents have been filed for inventions that prevent such damage. In 1995, inventor Ravi Nallakrishnan filed a patent for a surgical knife with a retractable blade and depth of cut control (Nallakrishnan, 1997). The apparatus for the retractable blade is thin, agile, and effective for precision surgeons to perform small incisions with minimal damage to surrounding tissues as seen in Figure 6 below. This device, however, is not intended for use in myringotomy, as it is not thin enough and is housed in a rigid shell that fails to navigate the ear canal effectively. Many other devices are similar to Nallarishnan's retractor blade, but all face the same challenge of being too rigid (Aikins, 1985 & Edens, 2003). Specialized blades have been developed for procedures such as ligament cuts and spinal surgeries, but are also too rigid for a myringotomy procedure in a small animal (Ferree, 1985).

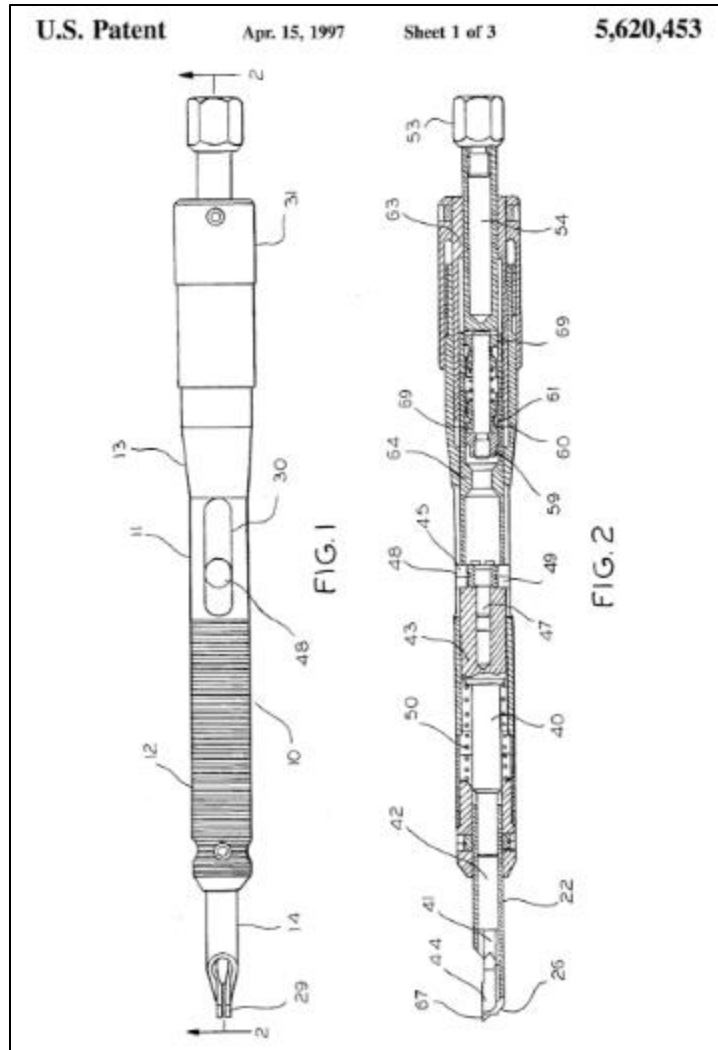


Figure 6: Surgical Knife with Retractable Blade and Depth of Cut Control by Ravi Nallakrishnan 1995 used to create small incisions to minimize damage to surrounding tissues

Tools used in blood vessel mechanics provide an excellent example of instruments that provide atraumatic navigation of the ear canal in animals. In 2002, Maquet Cardiovascular LLC filed a patent for a device that could seal a vessel during coronary bypass surgery (Taylor, Aldrich & Baughman, 2002). Although creating an incision is not the purpose of this device, the flexibility and maneuverability of such a device is extremely advantageous for procedures that require stability, as the device is equipped with a stabilizing technology that guides it through narrow vessels, or even through a beating heart.

The final major approach for similar procedures is the use of laser dermatology. Lasers provide very precise cuts and cauterize the wound immediately, preventing bleeding (Brauer, 1999 & Uram, 1999). Several medical device companies have utilized this technology, such as Clinicon Corporation. In 1997, the company filed a patent for a flexible delivery system for a surgical laser. The device works by reflecting a laser through a thin tube, concentrating a CO₂ laser on a surgical site. The laser is intended for biological tissue (Brauer, 1999). Similarly, Beaver-Visitec International, Incorporated has developed a laser specifically for myringotomy in humans (Uram, 1999). The company filed a patent in 1996 for a surgical contact laser that would attach to the end of an endoscope for the procedure in humans. The device is not flexible, as it is intended for humans, and is also expensive, often in the range of several thousand dollars per device when factoring in the material costs and the CO₂ laser (Uram, 1999). A comprehensive list of patents can be found in Appendix C.

The myringotomy patents that are currently on the biomedical market are specialized primarily for human procedures. Characteristics of each design are valuable when developing a tool for animal surgery, but a device that meets each specific need of a myringotomy tool has yet to be patented and filed.

3.0 Statement of Design Problem

3.1 Initial Client Statement

The clients would like a tool that makes performing myringotomy procedures easier and more precise. The clients perform this procedure on dogs and cats with middle ear disease, also called otitis media. The myringotomy device should allow the clients to flush and clean the middle ear, which can entrap mucus or infection and create clinical problems in pets. Ideal features of the tool would include: compatibility with the current video otoscope, ability to feed through the port without damaging the scope or ear canal, reusability and sterilizability (gas or autoclave), and the ability to be ensheathed or retracted. The tool must be sharp and capable of incising the tympanic membrane on the first pass, flexible enough for manipulation through the scope, and stable enough for precise placement. The tool must be able to be operated using only one hand, and its depth of cut must be appropriate for various breeds of cats and dogs.

3.2. Objectives, Functions, and Specifications

To create a revised client statement, the team determined the set of requirements that the myringotomy tool must meet based on background research and client input. These objectives are shown in Table 1 below.

Table 1: Key Objectives

Key Objectives
Versatile
Compatible
Inexpensive
Safe

3.2.1 Versatile

For the scope of this project, versatility means that the device can be used to puncture the tympanic membrane at multiple thicknesses for a variety of different sized cats and dogs. Although canal diameter does not vary significantly between animals, the thickness of the tympanic membrane is dependent on the condition of the animal's ear. The device must also be workable in the hands of any trained surgeon, whether he/she is right handed or left handed.

3.2.2 Compatible

Compatibility of the device pertains mainly to the surgical methodology of its use. The device must be able to be used one-handed, therefore functioning in tandem with common veterinary surgical equipment such as a handheld endoscope or otoscope. Additionally, the device must adhere to the sterilization standards of all surgical equipment. The device must be comprised of an inexpensive material intended for single use, or it must be made of a sterilizable material that can be reused.

3.2.3 Inexpensive

The objective of the device is to limit the cost of the product to the surgeon and the animal owner. The device can either be disposable or reusable. If disposable, the device must be inexpensive to manufacture in large quantities. If reusable, the device needs to be sterilizable and durable enough for use in multiple surgeries in order to maximize cost-effectiveness.

3.2.4 Safety

Subject Safety

The tool must be safe for the subject and cannot scratch the inside of the ear canal, as this is dangerous for the patient and can cause inflammation and scarring.

User Safety

The tool must be safe both for the user and for other equipment used in the process. The user should be educated on proper use of the tool in order to avoid injury. The design of the device assumes that the user is a licensed veterinarian and therefore competent in the use of surgical tools.

3.2.5 Pairwise Comparison Chart

The objectives in Table 1 are listed in order of greatest priority based on the results of the Pairwise Comparison Chart. In a Pairwise Comparison Chart, each objective is evaluated individually against each of the other objectives. An example Pairwise Comparison Chart completed by the team is shown in Table 2. A complete series of charts can be found in Appendix D.

Table 2: Pairwise Comparison Chart

Objectives	Versatile	Compatible	Inexpensive	Safe	Total Score:
Versatile	X	1	1	1	3
Compatible	0	X	1	1	2
Inexpensive	0	0	X	0	0
Safe	0	0	1	X	1

In order to be successful, the tool must satisfy all of the functions listed in Table 3 below. It must be able to cut in one pass and retract. The tool needs to be flexible enough to maneuver through the ear canals of various patients and be sheathed to limit damage inside the ear canal. The tool must also allow for one-handed use to enable simultaneous use of an otoscope.

Table 3: Basic Functions and Specifications

Functions	Specifications
Cut in One Pass and Retract	Otoscope limited to a 5 Fr. catheter
Flexible	Cut size of 5 Fr. or larger
Used One-handed	Tympanic membrane diameter 4-8mm
Protected	Depth of cut limited to 2mm

The design of the tool is constrained to the following criteria, listed in Table 3. The tool must be compatible with the current otoscope used by the Tufts' veterinarians, which only allows for a maximum 5 French (Fr) catheter (dimensions of catheter sizes in millimeters can be found in Appendix E). The incision size, however, must be greater than or equal to 5Fr to allow for a proper cleaning of the ear, as specified by Dr. Zewe in Appendix F. These constraints are due to the diameter of the ear canal and the dimensions of the tympanic membrane.

3.3 Revised Client Statement

The goal of this project is to design a flexible, one-handed myringotomy tool to cut the tympanic membrane in one pass and not damage the ear canal. The tool will be versatile to accommodate a large variety of patient and surgeon needs, including incision size and different patient sizes. It must be compatible with current surgical processes and equipment. The tool will also be cost-effective and safe for patients, surgeons, and current equipment.

3.4 Project Timeline

In order to measure project progress on a task-oriented basis, a weekly action plan was determined at the start of each working week in conjunction with the project timeline, which can

be seen in Table 4. Goals were set each week to ensure deadlines could be met. This flexibility in task distribution allowed for adjustment of project work as new information became available.

Table 4: Project Timeline

Task/Deliverable	A Term					B Term					C Term					D Term														
	9/9	9/15	9/23	9/30	10/7	10/14	10/28	11/4	11/11	11/18	11/25	12/2	12/9	12/16	1/13	1/20	1/27	2/4	2/11	2/18	2/25	3/3	3/17	3/24	3/31	4/7	4/14	4/21	4/28	5/5
Background Chapter	█	█	█																											
Introduction Chapter			█	█	█																									
Proof of Concept				█	█	█																								
Interview Veterinarians																														
Reach Out to Other Companies																														
Preliminary Designs																														
Prototyping																														
Methodology Chapter																														
Testing/Alternative Design																														
Data Analysis/Results Chapter																														
Conclusion Chapter																														
Executive Summary																														
Presentations																														
Report Revisions																														

4.0 Design Process

4.1 Design Alternatives

Once the design objectives and functions were ranked, the team brainstormed ideas to meet these criteria. The team decided to split the design into three separate parts: the retracting mechanism, the sheathing mechanism, and a puncturing mechanism. The first step was to explore a wide range of methods for cutting a membrane. Simple designs, such as cutting with a blade, were compared with more eccentric ideas. Some tools involve lasers or electrical current (Shaw, 1973), to cut and cauterize membranes. An example of this technology can be found in patents filed by Bovie Medical Corporation for cold-plasma cutting surgical blades. These devices operate through an induced current at the tip of the blades, allowing for smooth, clean cuts that do not bleed (Rencher, Konesky, Simeonov, 2010). Other tools, like flexible, motorized drills, can quickly puncture holes of various sizes (Hall, 1964). Additionally, there is a variety of medical grade chemicals for precisely dissolving bacteria and mucus inside the ear, such as antibacterials and osmotic agents (Muchow, 1991). The tympanic membrane could also be dissolved by various detergents (Hayworth, n.d.). The detergents are able to degrade membranes by breaking protein-protein interactions. Strong acids such as hydrofluoric acid would have similar effects.

While all of these methods would produce a hole in the membrane, the healing capabilities of the membrane must be taken into account. Traumatic tools can damage the membrane and prevent healing or damage the nerves in the surrounding tissue. A variety of alternative designs are listed in Table 5, showcasing their disadvantages.

Table 5: Alternative Designs

Design	Inhibits Healing	Too Large a Hole	Too Much Force	Uncontrollable	Too Expensive
Laser	X				X
Bovie	X				
Drill	X	X	X		
Hydrofluoric Acid	X	X		X	
Detergents	X	X		X	

Project budgetary constraints, manufacturability, and client preferences were also taken into account, and therefore, the puncturing and cutting mechanism was restricted to blade designs. These blade designs, as well as sheathing and retracting mechanisms can be seen in Tables 6-8. A comprehensive list of puncturing techniques can be found in Appendix G.

Table 6: Knife Designs

Idea	Defining characteristics	Pros	Cons
Knife	<i>Fixed metal knife</i>	Stable	Cannot be replaced
Interchangeable Blade	<i>Replaceable blades</i>	Replaceable, Cheap	Small, could fall out into ear
Philips head knife	<i>Fixed, cross blade design</i>	Creates larger hole	Fragile, Difficult to manufacture
Plastic knife	<i>Blade made of plastic</i>	Cheap material, disposable or reusable	Sharpness, manufacturing, durability
Reverse Scissors	<i>Outward facing blades</i>	Incision > 5Fr.	Difficult to sheath

Table 7: Sheathing

Idea	Defining characteristics	Pros	Cons
Catheter	<i>5 Fr. catheter</i>	Commonly used	Single blade cannot be large enough for 5 Fr. incision
Frog Tongue	<i>When forceps retract up, the knife is exposed</i>	Sheathed, more precision, operator control	Single blade cannot be large enough for 5 Fr. incision

Table 8: Retracting Mechanism

Idea	Defining Characteristics	Pros	Cons
None	<i>No retracting mechanism</i>	Operator controlled incision	Variable
Push Button	<i>Curved tubing, uses a click mechanism to extend knife</i>	Simple, can navigate through the ear canal	Enough force to pass through membrane
Trigger	<i>Similar to Karl Storz forceps design</i>	Simple, more user control	Enough force to pass through membrane, complex design

A design matrix was then created to select the design for each aspect. Objectives were weighted based on the pairwise analysis and feedback from the Tufts veterinarians. These weighted values were used in a preliminary design matrix to determine which designs would be most effective at meeting each objective. As seen in Table 9 below, versatility was awarded the highest weight when tabulating the values in the design matrix, while cost had the lowest weight. Feasibility of manufacturing was also included in the matrix to make sure a design was chosen that would be realistic for the project team to produce.

Table 9: Design Matrix Weights

Design Idea	Safety	Cost	Compatibility	Versatility	Feasibility
Weight (1-10)	5	3	7	9	8

The team and the clients rated how well the designs would accomplish each objective on a scale from 1-10 (1 being not at all, 10 being completely). Each objective was given a weight based on their ranking on the Pairwise Comparison Chart. The rating and the weight were then multiplied, giving a final value for each design in each category. An example of this calculation can be seen in Table 10 below.

Table 10: Example Knife Matrix Calculation

Knife	1-Fixed	7	4	3	3	7	
	Final Value	35	12	21	27	56	151
	2-Exacto blade	5	8	6	7	8	
	Final Value	25	24	42	63	64	218
	3-Phillips Head	4	4	4	4	4	
	Final Value	20	12	28	36	32	128
	4-Plastic	7	9	6	4	8	
	Final Value	35	27	42	36	64	204
	5-Reverse Scissors	6	4	8	8	4	
	Final Value	30	12	56	72	32	202

Team members and clients completed this exercise, and the totals for the knife design matrix can be seen in Table 11 below. All the design matrices can be found in Appendix H.

Table 11: Knife Matrix Totals

Knife	1-Fixed							
	Final Value	289	261	151	221	189	125	126
	2-Exacto blade							
	Final Value	287	239	218	239	194	142	130
	3-Phillips Head							
	Final Value	210	186	128	180	185	163	168
	4-Plastic							
	Final Value	242	259	204	232	189	145	156
	4-Reverse Scissors							
	Final Value	258	216	202	174	210	193	155

4.2 Design Selection

As shown in Table 11, the Interchangeable Blade design obtained the highest score in the knife design matrix, because it was considered the most versatile and compatible design. The Plastic Knife had the second highest score because of its high ratings for cost and safety. The third design, the Reverse Scissors, was a less feasible design; however, it fulfilled more of the desired

criteria. After conversing with the clients, it was determined that meeting the criteria of making an incision larger than 5 Fr. (1.66mm) was preferred.

Three options were considered for the knife design. The Scissors design and the Reverse Scissors design focus on reusability and maximizing performance based on the design requirements. However, these particular designs are more costly and difficult to manufacture. The Interchangeable Blade design, on the other hand, focuses on manufacturability and disposability, but would not achieve an incision size of greater than 5 Fr.

In order to ensure that the blade has the capabilities of making the proper incision size, the team decided to look into different types of blades. There are several different standard types of scalpel blades, and through research the team decided that scalpel blades numbers 22 and 23 are shaped in a way that would be able to accomplish the necessary cut. Each one of these blades is rounded at the end, making it easier to cut the maximum sized hole without having to puncture as deeply. Blades that are more triangular and are not rounded at the end, such as scalpel blades 11 and 12, are not able to make the proper sized hole unless they are punctured much deeper into the material of interest (Types of Scalpel Blades, n.d.). Rounded blades also reduce the risk of chipping or breaking, which is a concern for blades that taper to an extreme point.

In the Interchangeable Blade design shown in Figure 7, the blade is the same size as the sheathing. The blade extends, and may simply puncture the tympanic membrane and make a hole that is 5 Fr. This may or may not be large enough for the insertion of a 5 Fr. catheter, which will be determined through further testing. Due to the simplicity of the design, this will be prototyped and tested experimentally.

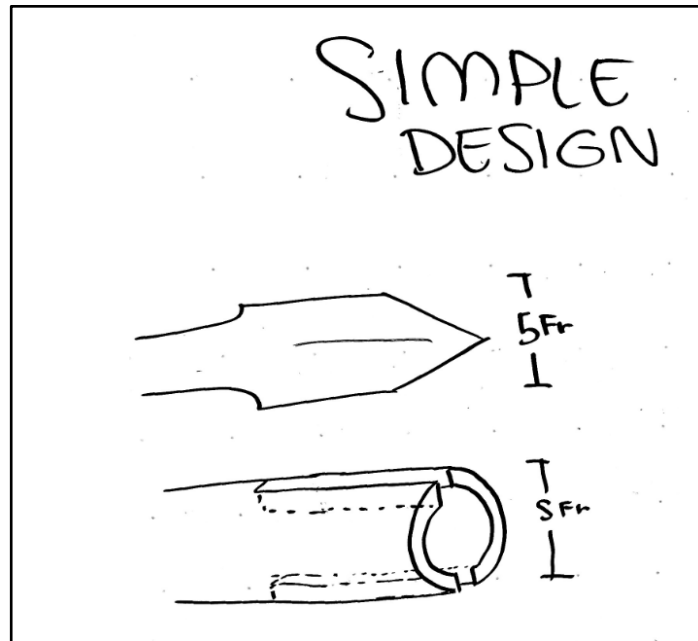


Figure 7: Drawings of the blade and sheathing mechanism of the simplistic design, showing the identical sizes of the blade and sheathing

The Reverse Scissors idea has the blades facing outwards as shown in Figure 8. The Scissors design is a similar configuration but has the blades facing outwards, like scissors, which is also shown in Figure 8. The main difference between these two designs is their movement. The Reverse Scissor design would involve retracting the catheter, puncturing the membrane, and then extending the blades outward separating more of the tympanic membrane. The Scissor design would involve retracting the catheter, extending the blades outwards to create one large V shaped blade, and then puncturing through the membrane. Both designs are capable of creating an incision greater than 1.66mm, so these designs were modeled in SolidWorks. Due to their complexity, assistance from a company that specializes in creating a design on this small scale was consulted to determine if creation of the tool was feasible.

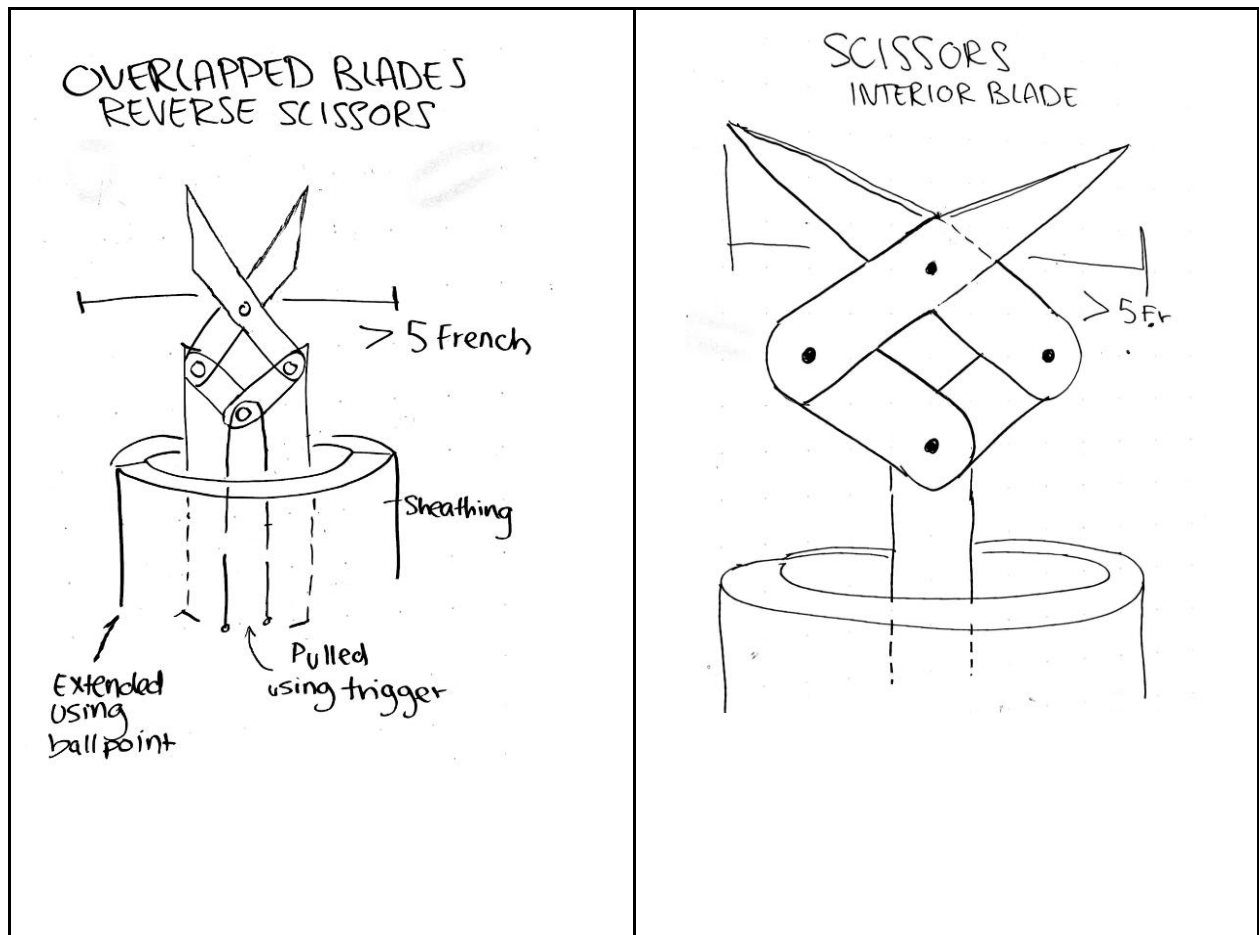


Figure 8: Reverse Scissors (left) & Scissor (right) preliminary designs

The highest ranking design idea in terms of sheathing was using a 5Fr catheter. The design is simple and is also the largest diameter of catheter possible when used in combination with the otoscope. Another sheathing design was the Frog Tongue mechanism that can be seen in Appendix I. It is a complex design that rated high in safety but poorly in feasibility and cost.

The highest rated designs for the retracting mechanisms were the push button mechanism and the trigger mechanism. The push button mechanism will be utilized for the simplistic Interchangeable Blade design, which will only involve the outward extension of the knife, puncturing into the tympanic membrane.

The push button and the trigger mechanisms were combined to create a dual mechanism necessary to accommodate the Reverse Scissor and Scissor designs, which both require two modes of movement. First, the knife must be unsheathed; second, the blades must be extended outwards to create the incision. An example configuration is shown below in Figure 9.

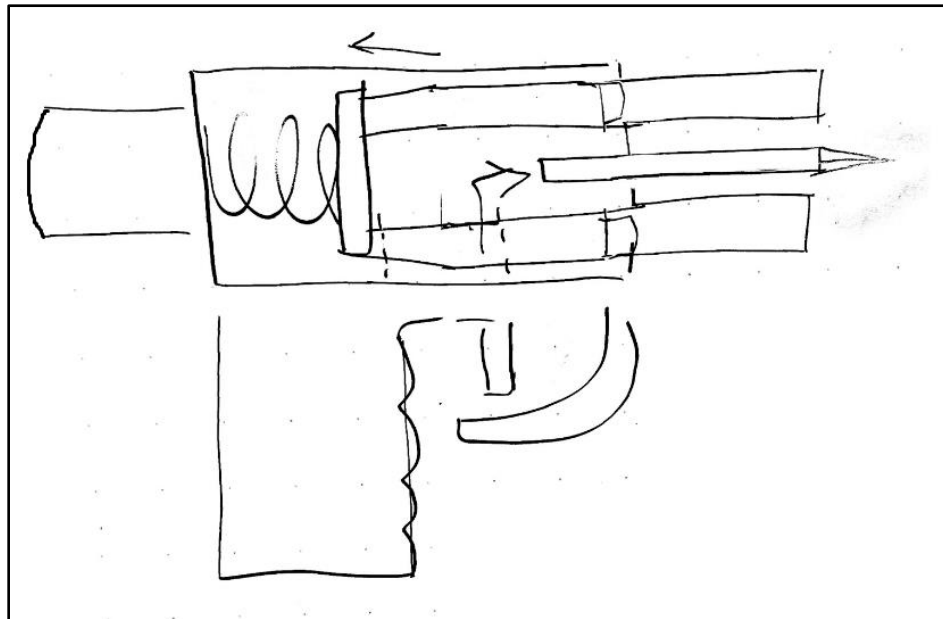


Figure 9: Trigger and push-button mechanisms

4.3 Preliminary Designs

The team began by creating a proof of concept, demonstrating the ability of a push button mechanism to extend a flexible wire and blade outside a catheter-like sheath. This was made with common materials bought at a hardware store. This prototype demonstrated that the push button mechanism works with our design. The prototype uses materials at least ten times the scale of the maximum size allowed for the tool, which can be observed in Figure 10. Therefore, additional manufacturing assistance is necessary to create a tool at such a small scale. From this point forward, designs were primarily modeled in SolidWorks.



Figure 10: Proof of Concept made with pen mechanism, outer plastic tubing, and inner wire, and a small blade

4.3.1 Interchangeable Blade Models

The simplistic Interchangeable Blade design was modeled in SolidWorks, as shown below in Figure 11 with a sample blade.

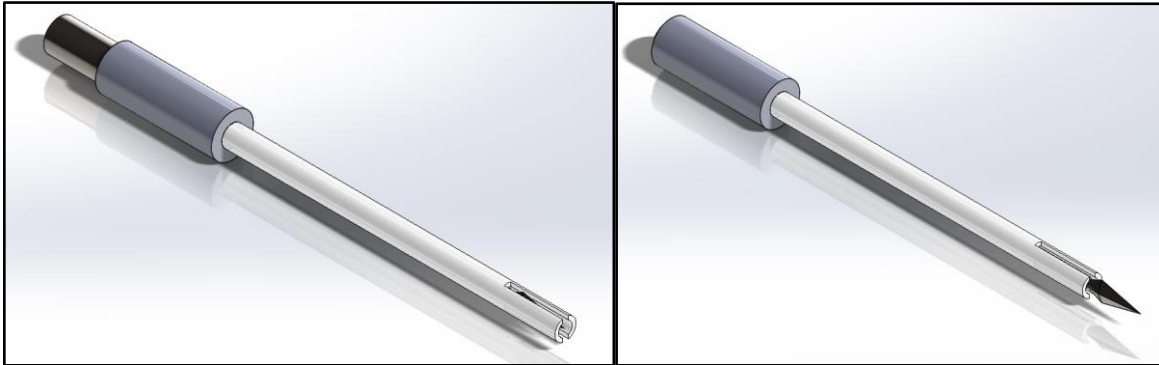


Figure 11: Retracted (left) & Extended (right) Interchangeable Blade Design as designed in SolidWorks

This design also involves sheathing and the push button mechanism, as shown below, in combination, in Figure 12.

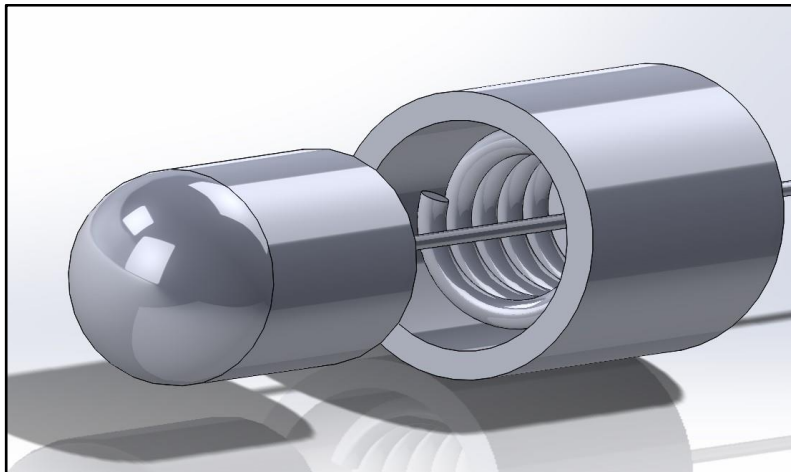


Figure 12: Push-button mechanism as designed in SolidWorks

A scaled prototype of the Interchangeable Blade design was made by rapidly prototyping the push button mechanism and the arrowhead blade. Polyurethane tubing was used for the outer tubing (acting as the outer sheathing in this case), and silicone tubing was used as the inner tubing. A spring was used with the 3D-printed push button in order to complete the actuation mechanism.

A slot was cut out of the end of the tubing so that the blade could fit into the sheathing. This scaled prototype can be seen in Figure 13 below.



Figure 13: Proof of concept of Interchangeable Blade design at 10X scale with 3D printed push button mechanism and blade, an internal spring, polyurethane outer tubing, and silicone inner tubing cut to size

This scale prototype provided a good model for what we are attempting to manufacture, but the 3D-printed arrowhead blade needed to be exchanged with an actual blade in order to be able to test our prototype.

In order to attach the blade to the silicone tubing, a slot was cut out of the tubing, and super glue was used to attach the blade to the tubing. The only additional adjustment that needed to be made was obtaining a spring with a lower spring constant, such that the actuation mechanism would require less force in order to extend the blade. The original spring had a spring constant of 55 pounds per inch. A spring with a spring constant approximately one third of the original spring was ordered and implemented into the prototype. As compared to the original spring, the blade extends by approximately three times the distance. The difference in elongation can be observed in Figure 14 below.



Figure 14: Close up view of the difference in elongation of inner tubing and scalpel blade for the Interchangeable Blade proof of concept

Initially, the shape of the outer tubing made it difficult for the silicone tubing and knife to extend smoothly. In order to help the inner tubing and blade propagate in a smoother fashion, the polyurethane tubing was heated up via a heat gun. This made the outer tubing more flexible, allowing it to be straightened. This adjustment allowed the blade to move freely and extend easily.

4.3.2 Reverse Scissor Models

The two knife designs were modeled in SolidWorks. The Reverse Scissor and Scissor designs are shown in Figure 15 below.

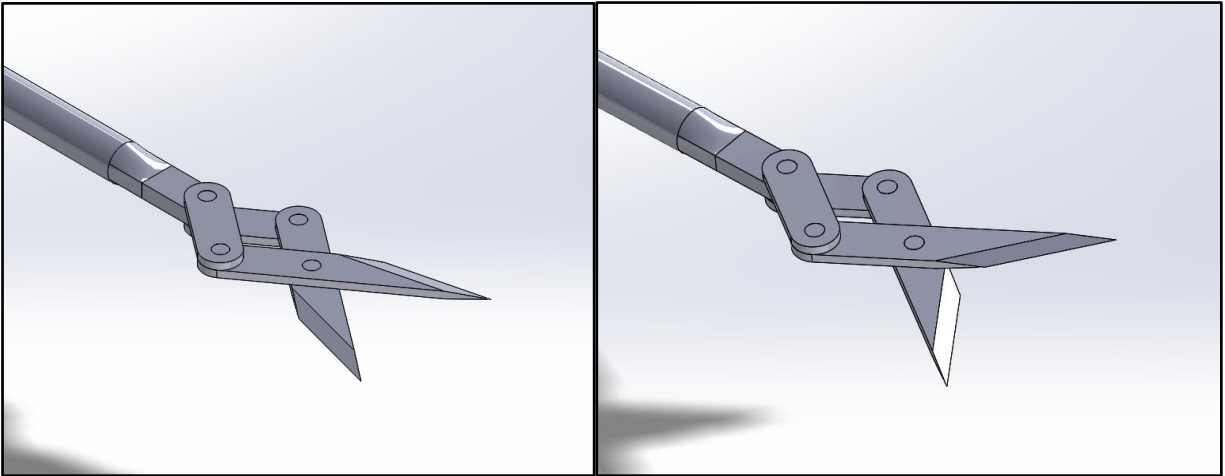


Figure 15: Reverse Scissors (left) & Scissor (right) 3D models

The design of the knife influenced the type of sheathing the team designed. The sheathing was created in two parts, an interior and exterior sheath. The interior sheath is composed of metal, and its primary purpose is to fix the scissor mechanism in place, allowing for the blades to extend. The exterior sheath is designed to be similar to a 5 Fr. catheter and to shield the ear canal from damage. The interior and exterior sheathing is displayed in Figures 16 and 17, respectively.

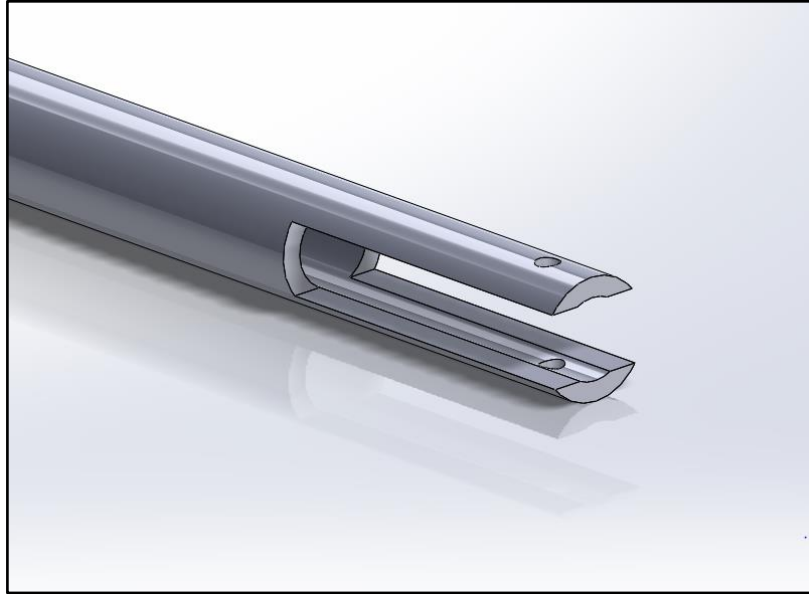


Figure 16: Inner sheathing covering blade mechanism

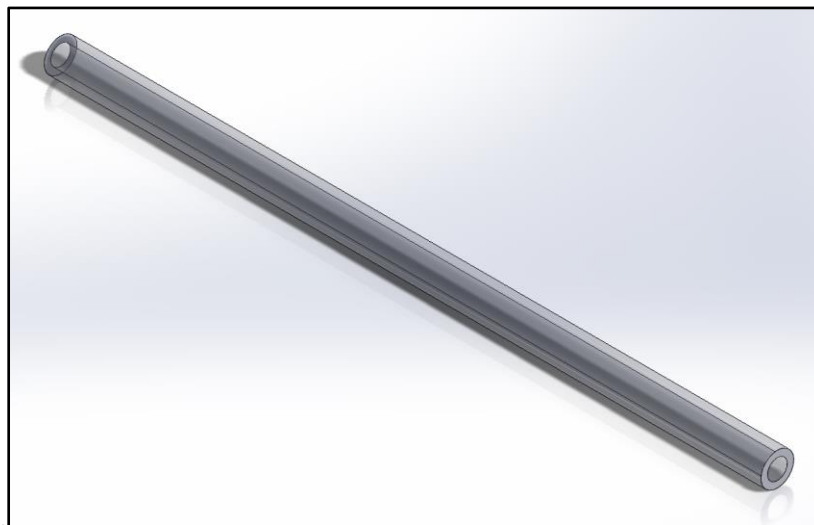


Figure 17: Outer sheathing enclosing blade mechanism and inner sheathing

The design in Figures 18-20 encompasses the knife and sheathing designs, forming a tool which can create an incision in the tympanic membrane without damaging the ear canal. Figure 16 shows the sheathed Reverse Scissor and Scissor designs. When fully extended, the two blades in both designs would create an incision over 3mm, which is larger than the required 1.66 mm.

The two designs are shown with the catheter retracted in Figure 19, and blades extended in Figure 20.

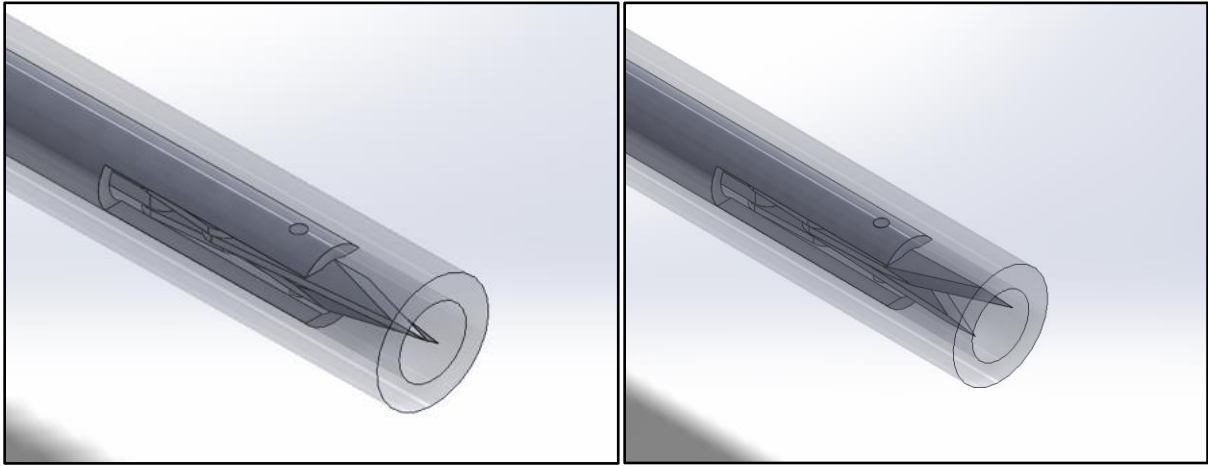


Figure 18: Reverse Scissor (left) & Scissor (right) fully closed with sheathing

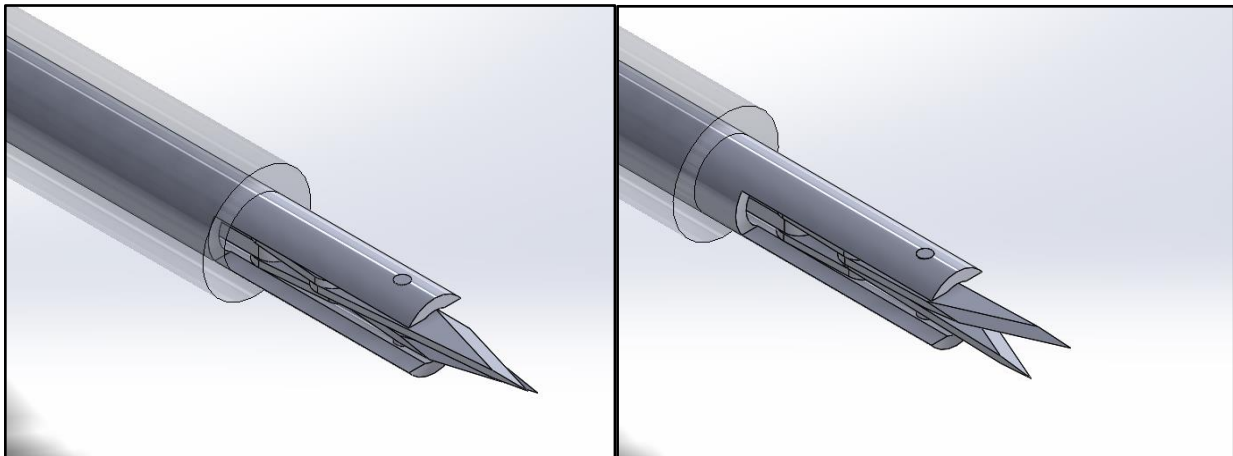


Figure 19: Reverse Scissors (left) & Scissor (right) with exposed blades and sheathing retracted

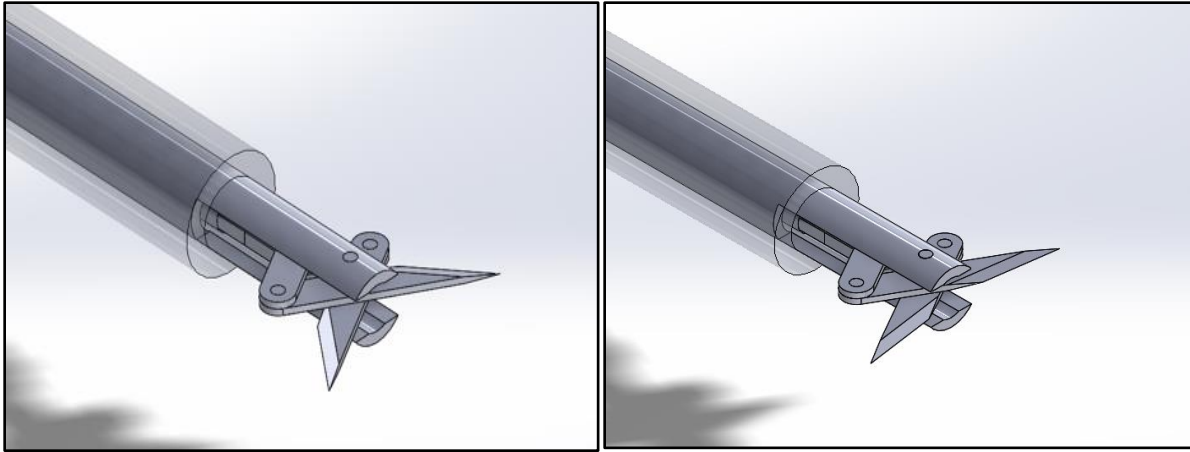


Figure 20: Reverse Scissor (left) & Scissor (right) with fully extended blades and sheathing retracted

When researching patents, the team discovered a flexible scissor device used for minimally invasive surgical applications, shown in Figure 21. While this instrument does not function in the same way as the team’s Scissor design, it is very similar (Spivey, 2011). Therefore, the team decided not to pursue the Scissor design further. However, the team continued with prototyping the reverse scissors design, as shown in the section below.

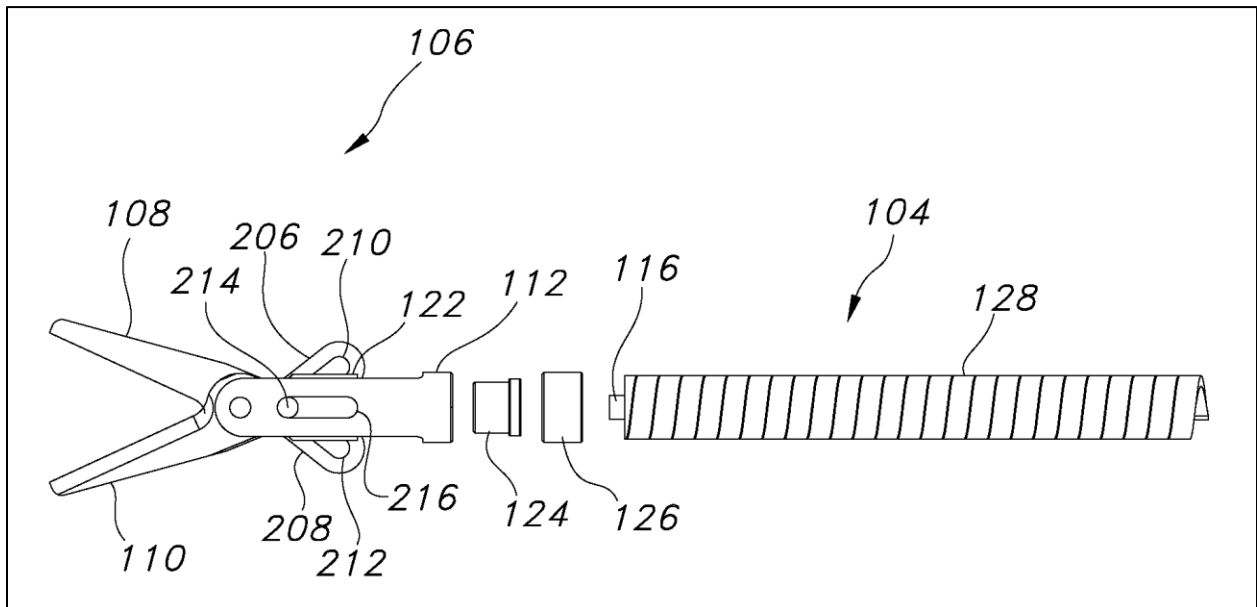


Figure 21: Flexible surgical scissor design used for minimally invasive surgical applications

To address the issue of complexity and the lack of manufacturing capabilities on campus, the team consulted with Boston Scientific to validate the feasibility of manufacturing under realistic scaling and conditions. With the precedent of manufactured devices on the same scale, Boston Scientific confirmed that the proposed design could be manufactured with similar resources and equipment. For this reason, the team chose not to pursue the simplified design, as it would not perform as well as the complicated design, and would only be marginally easier to manufacture.

After the CAD models were completed, the team scaled the models up to about ten times and had the parts 3D printed. The assembled blade can be seen in Figure 22 below. The entire blade system, along with the push button mechanism and flexible tubing can be seen in Figure 23.



Figure 22: Fully assembled Reverse Scissors mechanism closed (left) and open (right)



Figure 23: Fully assembled prototype with reverse scissor mechanism, flexible sheathing, and push button mechanism

The prototype was an effective representation of the opening mechanism for the Reverse Scissors Design. The mechanism worked mostly as intended, opening the blades repeatedly with minimal effort. However, the linkages tended to shift out of alignment with the pull wire. This caused the device to jam in an improper orientation and be unable to retract. Another downside to this prototype was its inability to extend the blades forward. A second, entirely separate mechanism would be required to allow the blades to extend before opening.

4.4 Development of Final Prototype

Due to accuracy and size constraints of on campus manufacturing equipment, the team could not manufacture a scale prototype using WPI resources. Instead, to demonstrate the working kinematics and effectiveness of the design, the team created a 3D printed ABS plastic model scaled up to approximately 11 times the original dimensions. The factor of approximately 11 was selected based on linkage pin sizes. The team was concerned that plastic pins that were any smaller than 1/8 inch would be susceptible to breaking.

4.4.1 Clevis Design

Based on discussions with Boston Scientific and other manufacturing experts on campus, the team updated some components of the design for ease of manufacturing and assembly. The most notable change was the inner sheathing, referred to in the industry as a “clevis”. In manufacturing, a clevis is a U-shaped connector by which other components may be fastened using a pin. The team designed three variations of a clevis, which were evaluated for ease of assembly.

4.4.1.1 Single Pin, Single Slot Clevis

The single pin, single slot clevis design was based on the previous prototype to address the linkages from coming out of alignment by adding the slot to the back half of the clevis. The slot forced the movement of the pins to be completely linear. This can be seen in Figure 24.

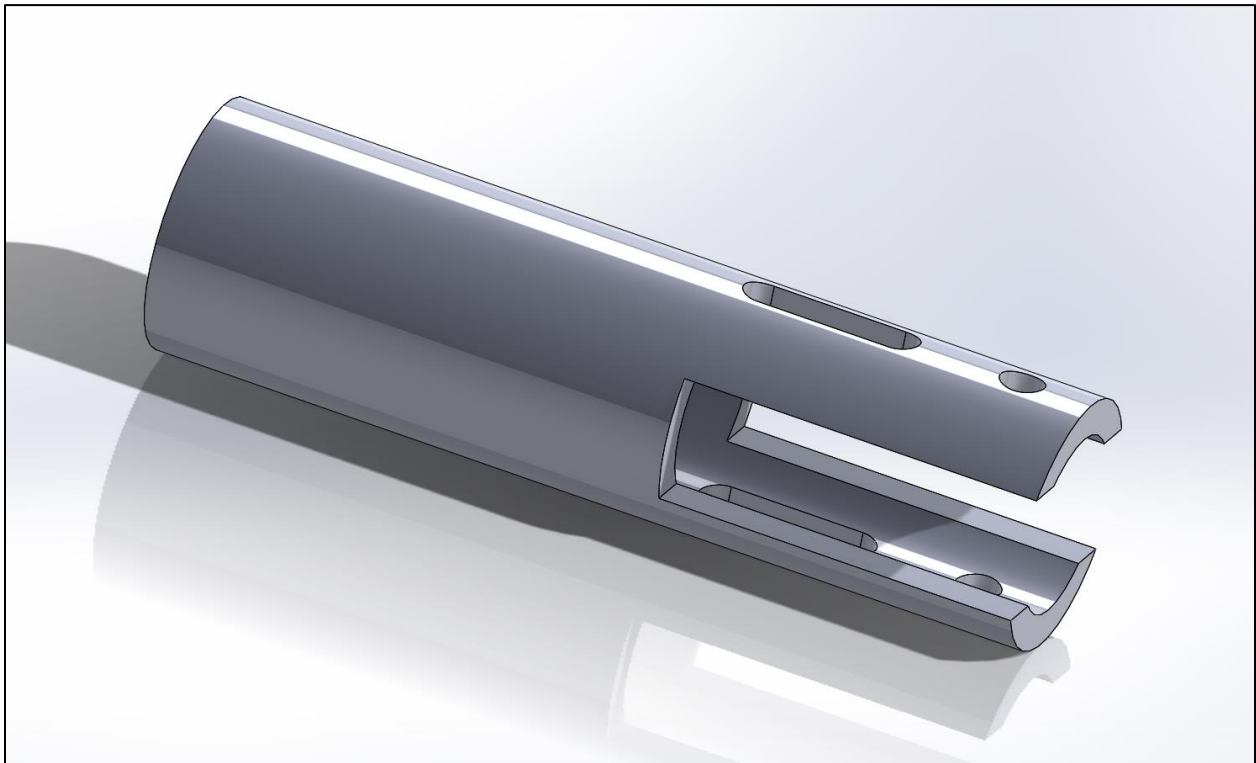


Figure 24: Pin-Slot Clevis design

4.4.1.2 Single Slot Clevis

The single slot clevis is similar to the single pin, single slot clevis, but it is not fixed at its extension length. The front pin can slide freely, allowing extension and retraction. The device operates as designed in four stages: extending, opening, closing, and retracting. When the button is pushed, both pins move forward until the front pin touches the front edge of the slot. At full extension, the front pin remains stationary and the back pin continues moving forward to open the blades. The entire four stage operation of the device can be seen in section 4.4.5. When the button is released the device is retracted, with the sides of the clevis forcing the linkages to close. This iteration of the clevis utilized a smaller cutout on the sides to address the issue of the blades remaining open upon retraction, which is a safety hazard. This prototype proved that our new clevis design solved this issue and worked as intended. The device can be seen in Figure 25 below.

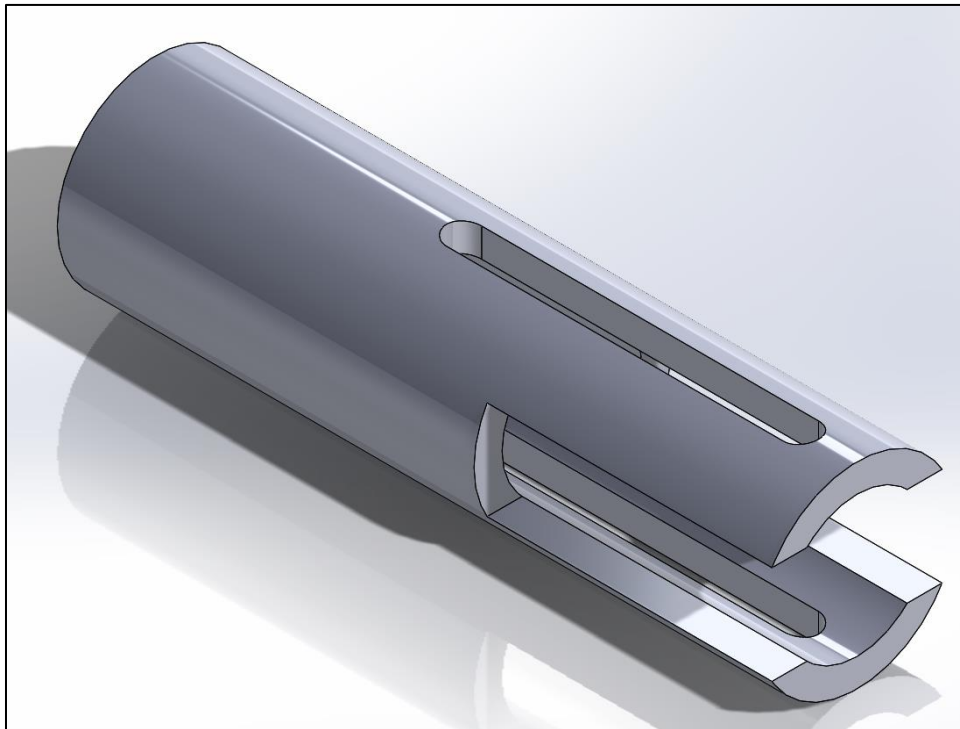


Figure 25: Slot Clevis design

4.4.1.3 Two Piece Clevis

Previous designs did not take into account the feasibility of manufacturing the device. The single slot clevis was divided into two pieces to accommodate the blade assembly. Fasteners were included in the design to attach the two pieces without dramatically increasing the overall diameter of the clevis. This design is shown in Figure 26.

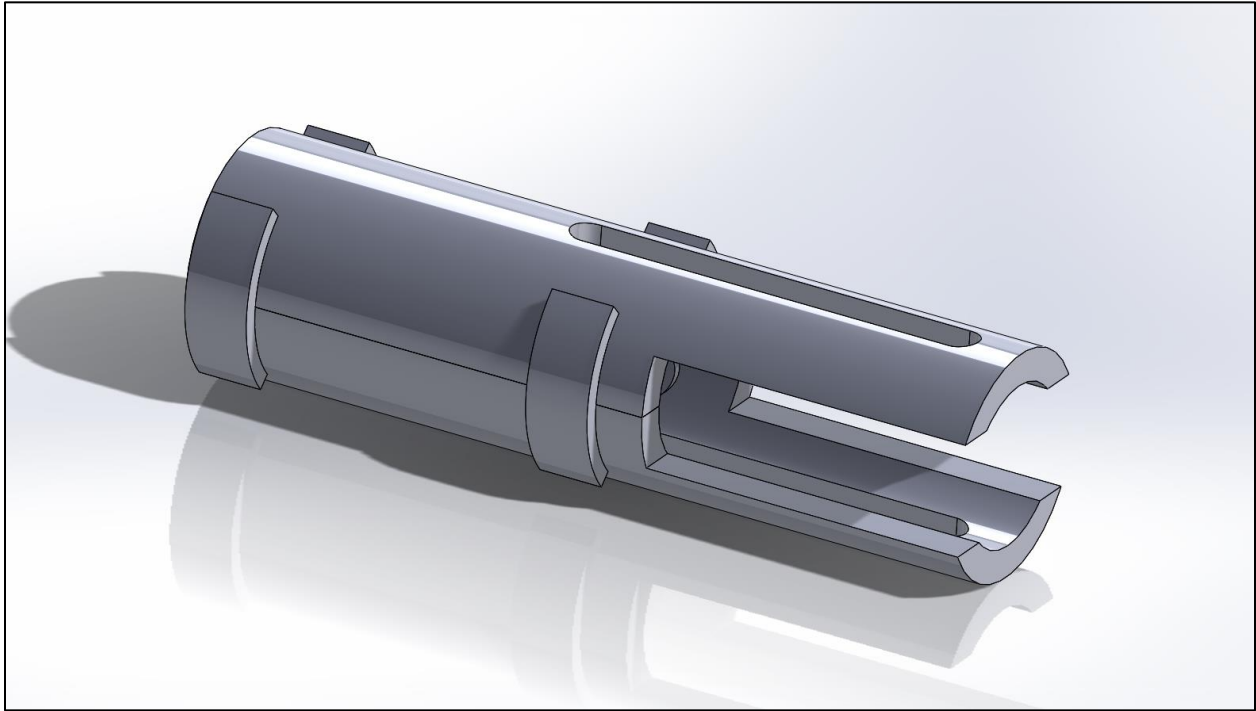


Figure 26: Half Clevis with attachment straps

4.4.2 Sheathing

The sheathing design was updated to a coiled wire, which is a standard in the industry. Coiling a thin wire allows for the use of a stainless steel sheathing that remains flexible and acts similarly to a spring. The sheathing can be seen in Figure 27.

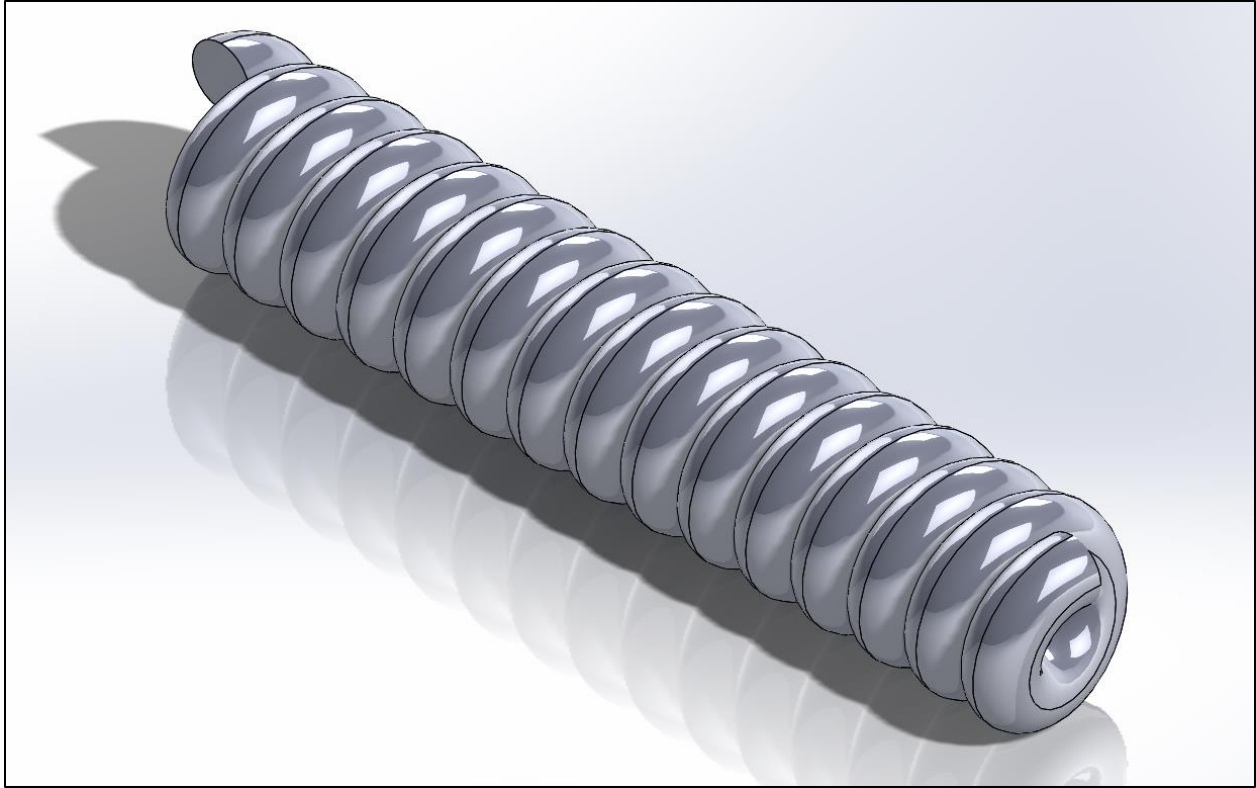


Figure 27: Segment of spiral sheathing

4.4.3 Spacers and Pins

In order to keep the pins, blades and linkages aligned properly, spacers were added between the interior of the clevis and the surfaces of the linkages at both the front and back pins. The team found that spacers allowed the linkages to slide more smoothly, and prevented misalignment in the blades. These spacers can be seen as part of the assembly in Figure 28.

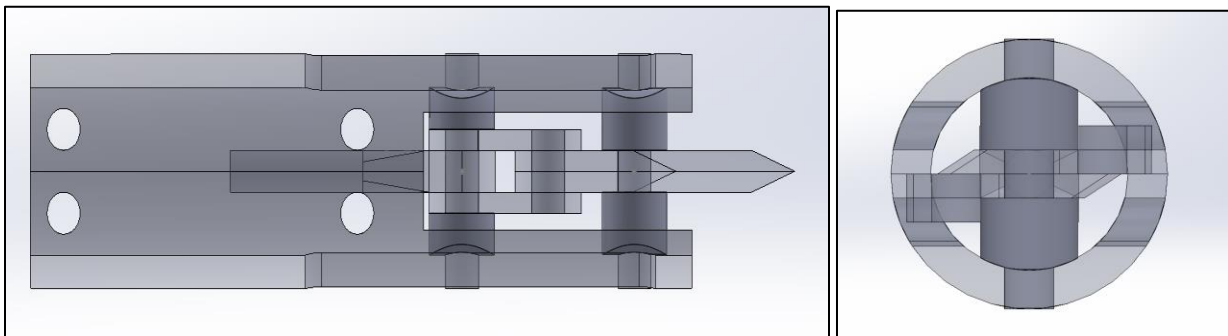


Figure 28: Side view of the spacers (left) and front view of the spacers (right) in the assembly

The team designed a new pin shape, as seen in Figure 29. This pin would be peened to keep it from falling out of the clevis, blades and linkages.

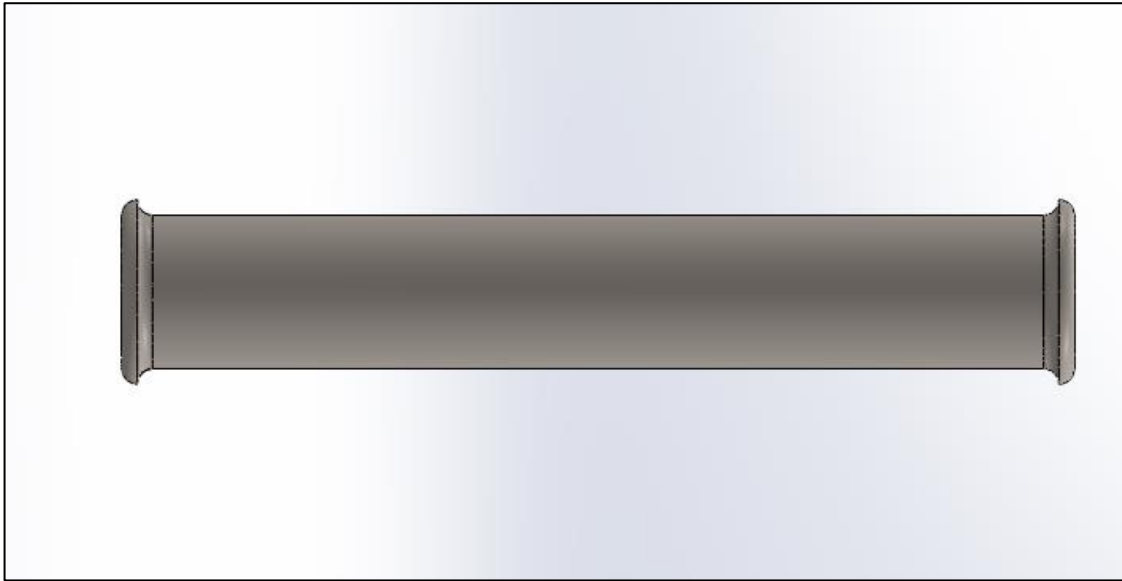


Figure 29: Flared pins used to hold the linkages and blades together in the assembly

4.4.4 Final Prototype with Compiled Components

For manufacturing purposes, the material assignments for all assembly components were changed to type 316 stainless steel. The final CAD design is shown below in Figures 30-32, including all chosen components. The maximum incision depth is 1.3mm, and can be seen in Figure 31. When fully opened, the blades expand to a total width of 3.2mm, which can be seen in Figure 32.

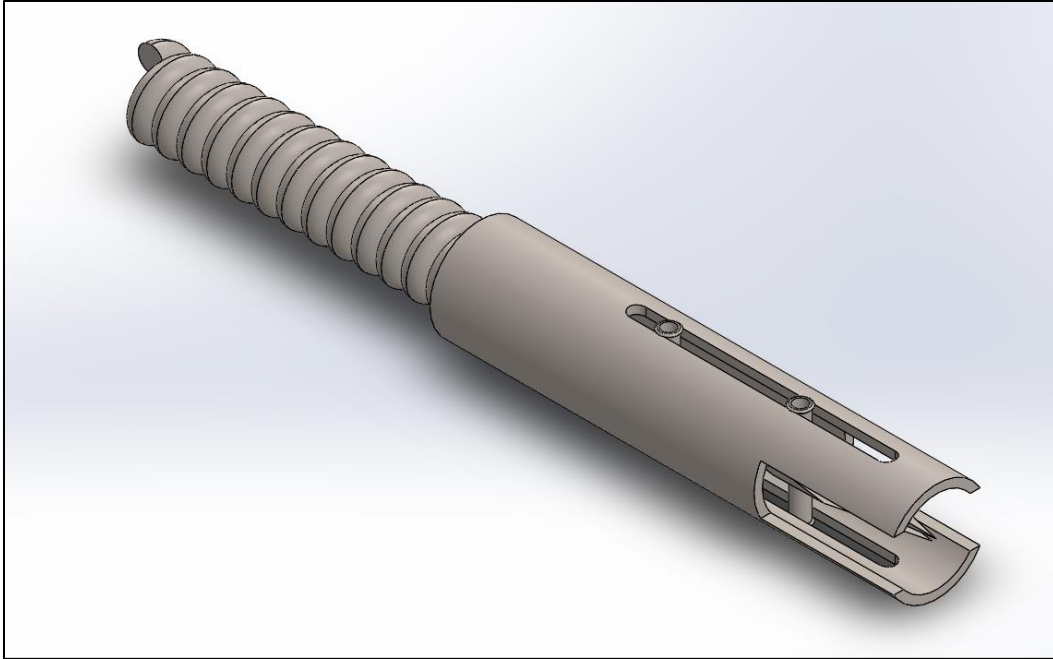


Figure 30: 3D model of the final design in the fully sheathed position

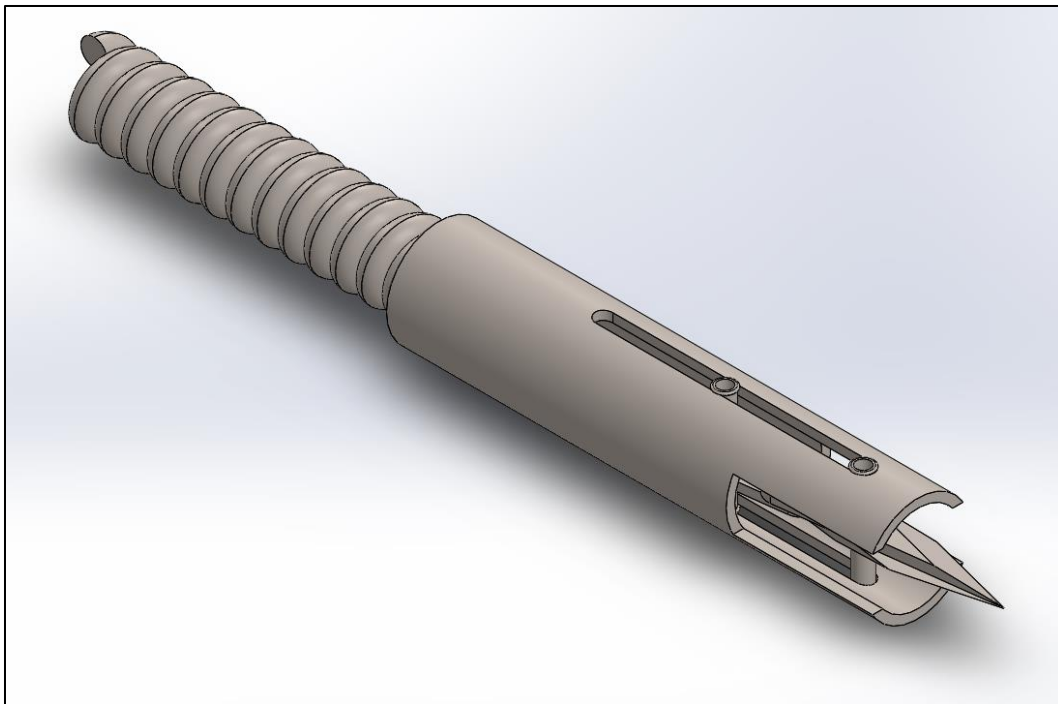


Figure 31: 3D model of the final design in the puncture position

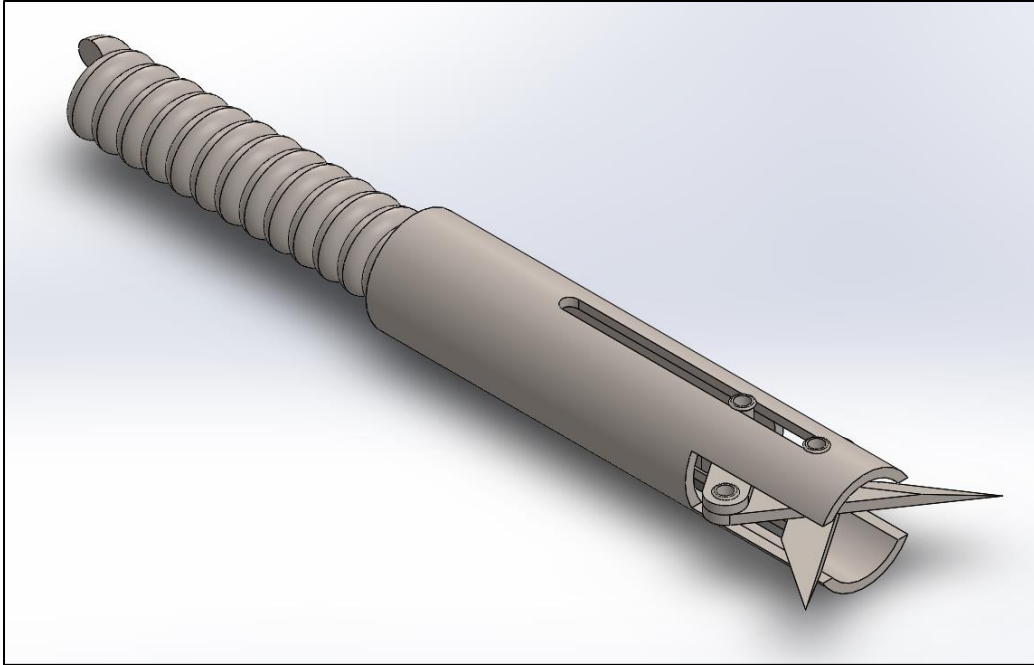


Figure 32: 3D model of the final design in the fully expanded position

4.4.5 3D Printed Prototypes

A physical representation of the device's operation using 3D printed ABS plastic components can be seen in Figures 33-35 below.

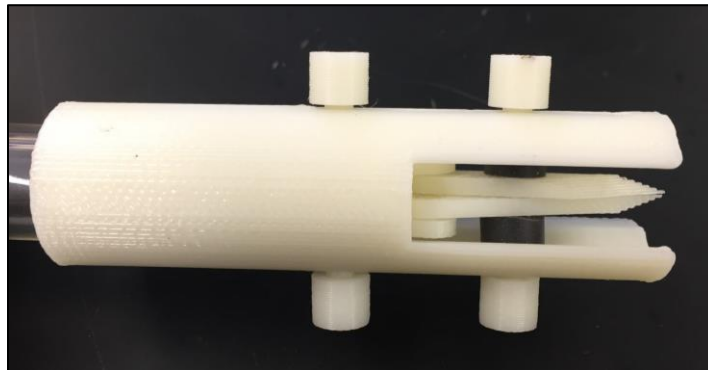


Figure 33: Final 3D printed prototype in the fully sheathed position

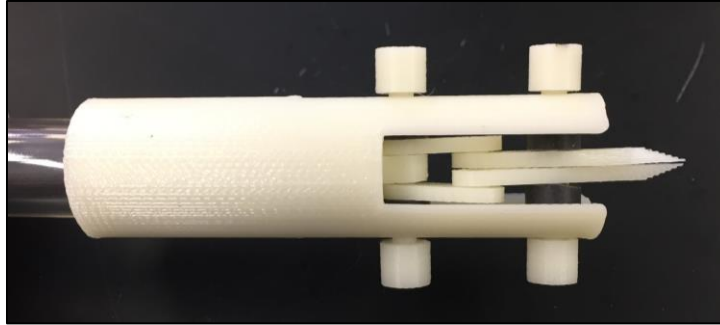


Figure 34: Final 3D printed prototype in the fully extended puncture position

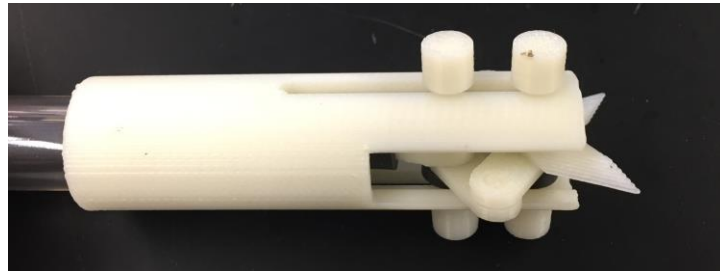


Figure 35: Final 3D printed prototype in the fully expanded position

4.5 Manufacturing

Boston Scientific, as a leading OEM, has the ability to manufacture the device on a five times scale. Using their equipment, the team was able to assemble the five times scale model in their facility.

4.5.1 Cost Analysis

The five times model was selected for manufacturing due to the team's budgetary constraints. This prototype cost less than \$50 for materials, and the cost of labor was donated by Boston Scientific. A prototype on the true scale would cost an extra \$1,400 in materials due to the need for external vendors (Pfizenmaier, 2017). Labor cost would be comparable, even on the smaller scale.

4.5.2 Linkages and Blades

An Electric Discharge Machine was used to cut the linkages and blades. The linkage and blade cutouts can be seen in Figure 36 below.



Figure 36: Sheet of metal from which the blade and linkages were cut

The pins were made by cutting miniature stainless steel tubing to the specified length, shown in Figure 37. An iWeld micro laser welder was used to join the pins to one face of the blades. The welded blade and pin can be seen in Figure 38 below. Once the linkage and blade were threaded onto the miniature stainless steel tubing, the tubing was cut to size, as shown in Figure 39.



Figure 37: Cutting the miniature stainless steel tubing to size using a rotary tool with a cut-off wheel attachment



Figure 38: Blades with miniature precision stainless steel tubing laser welded flush to one end



Figure 39: Blade and linkage assembled with peened miniature stainless steel tubing

4.5.3 Clevis

The clevis was made by extruding steel stock through a stencil. An electric discharge machine cut both the slot for the pins and the openings for the linkages on both sides. The clevis can be seen below in Figure 40.



Figure 40: Clevis, showing the top slot for pins, and side slot for linkages

4.5.4 Sheathing and Pull Wire

The sheathing for the five times scale was limited by accessibility of properly scaled components within a limited time frame. Therefore, the team was unable to include the correct sheathing in the final prototype. Additionally, the team was unable to procure a wire of sufficient flexibility. In order to demonstrate the mechanism, the team opted to use a rigid stainless steel tube that was laser welded to the linkages.

4.5.5 Assembly

In order to comply with Boston Scientific's manufacturing capabilities, the team had to use a standard handle that was manufactured in house. The pull wire was crimped at both ends in order to fix both the S wire to the handle and the pull wire attachment in the clevis. In order to keep the pins held within the device, the ends had to be peened, or gently widened using a hammer and center punch. Additionally, rubber spacers were added within the clevis to keep the blades aligned. On a five times scale, these spacers were used solely for proof of concept and would be made of stainless steel on the true scale. Figure 41 shows the S wire, and Figure 42 shows the clevis with peened pins.



Figure 41: Back handle of the device showing the S wire bend



Figure 42: Clevis of the device showcasing the peened pins and linkage assembly

5.0 Experimental Designs

A variety of experiments were designed to determine if each design component would satisfy the device's functional requirements. These involved testing the clients' applied forces during a myringotomy procedure, capabilities of various types of blades, and the kinematic mechanism by which our device will operate.

An appropriate substitute for a tympanic membrane was necessary to conduct testing. The material needed to have similar mechanical properties to that of the tympanic membrane of human cadavers. The team investigated a variety of materials to mimic the tympanic membrane consistency. The properties of a tympanic membrane are similar to type II collagen, which has a Poisson's ratio roughly equivalent to that of the membrane and a slightly larger elastic modulus (Sun, 2002). Apple skin is partially composed of collagen and has similar mechanical properties, so it could be used to mimic the tympanic membrane (Masoudi, 2007). The elastic modulus of bovine tendon falls within the range of the tympanic membrane's elastic modulus, and has a similar fiber orientation as the pars tensa quadrant of the tympanic membrane (Cheng et al., 2009). Additionally, the Poisson's ratio of a bovine tendon is nearly equivalent to that of the tympanic membrane (Kim, 2013). Intestinal submucosa has an elastic modulus only an order of magnitude lower than tympanic membrane; however it is composed of much of the same natural components as the tympanic membrane (Lin, 2013). The intestinal submucosa was measured to be 150 μm in thickness, whereas the tympanic membrane is approximately between 30 and 120 μm (Decraemer & Funnell, 2008).

The elastic modulus of 184 PDMS (Polydimethylsiloxane) is slightly lower than the range of the tympanic membrane's modulus; however, the Poisson's ratios are very similar (Johnston et

al., 2014). PAM (polyacrylamide) has a range for Poisson's ratio that is very similar to the tympanic membrane, but PAM's modulus is significantly smaller than the tympanic membrane (Gautreau, 2006). A comparison of the mechanical properties of these materials can be found in Table 12, below (Decraemer & Funnell, 2008).

Table 12: Mechanical properties of various materials used to mimic the tympanic membrane

Material	Elastic Modulus	Poisson's Ratio	Density
Tympanic Membrane	20-70 MPa	0.30 - 0.50	1000-1200 kg/m ³
Collagen II	72-468 MPa	0.50	N/A
Apple Skin	1-4 MPa	0.04-0.25	N/A
Bovine Tendon	50-600 MPa	0.453-0.461	N/A
184 PDMS	1.32-2.97 MPa	0.45-0.50	N/A
PAM	4-30 kPa	0.35-0.50	N/A
Intestinal Submucosa	3-8 MPa	N/A	N/A

Potential drawbacks of testing substances include cost and feasibility of obtaining or producing these materials for the experiment. Apple skin, for example, is difficult to separate from the rest of the fruit. Type II Collagen is too expensive for the budget of this project. PAM lacks the required stiffness to serve as an accurate representation. 184 PDMS was tested and deemed unrepresentative of the fibrous nature of the membrane. It was decided that intestinal submucosa and the bovine tendon would be used to mimic the tympanic membrane in future experiments because they have similar mechanical properties and are feasible for use in the team's desired testing.

5.1 Catheter Force Experiment

The team decided that the clients would use 5 Fr. catheters and a force transducer to determine the amount of force applied to the tympanic membrane during a myringotomy procedure. The two clients mimicked puncturing the tympanic membrane ten times each. Based on the results of the experiment, the team was able to incorporate this variable into future testing and influence the final design. The overall setup for the experiment is shown below in Figure 43. The in depth procedure can be found in Appendix J. The Arduino code can be found in Appendix K.

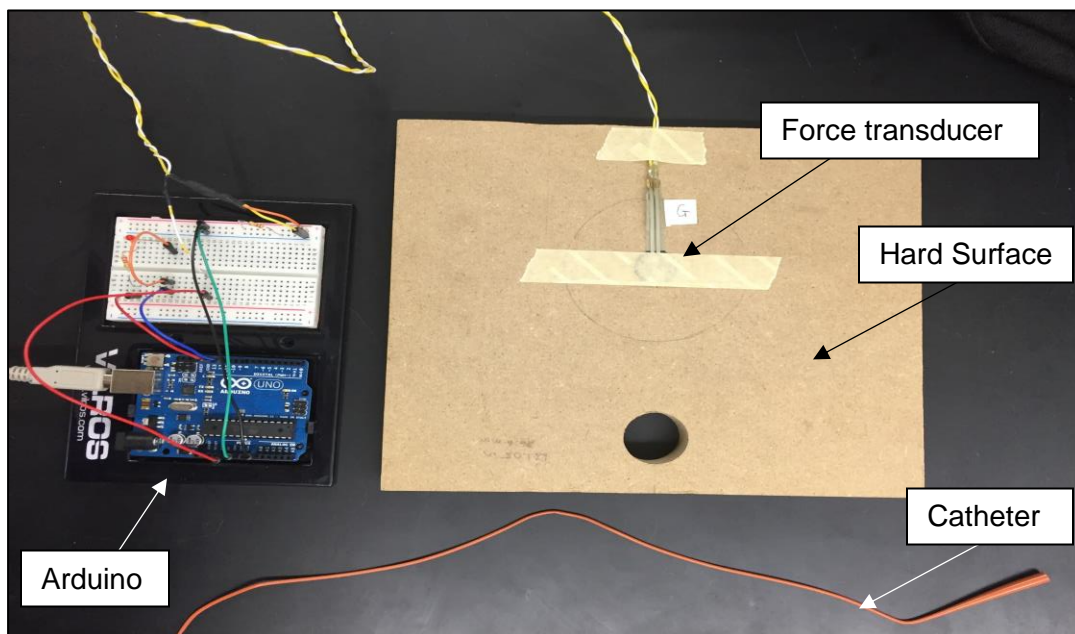


Figure 43: Setup for the force experiment using an Arduino Uno and force transducer

5.2 Blade Experiment: Bovine Tendon

The team chose to use bovine tendon to mimic the tympanic membrane since it has similar mechanical properties. It can also be cut to thicknesses that fall in the range of the tympanic

membrane by using a cryostat machine. The overall setup of the experiment is shown below in Figure 44. The in depth procedure can be found in Appendix L.

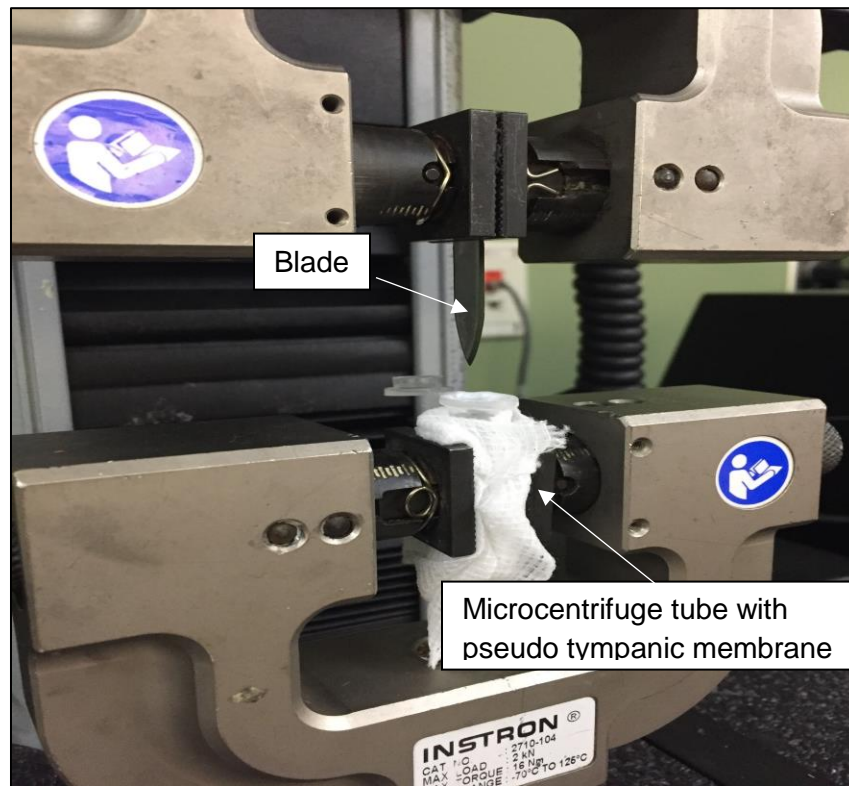


Figure 44: Setup for Blade Experiment

Surgical blade designs are diverse in shape, material, and size. The team chose three different types of surgical blades: lancet, triangular, and curved (scalpel blades 2, 22, 23); these can be seen in Figure 45.



Figure 45: Blade types used for testing

5.3 Blade Experiment: Force to Puncture Membranes

Using the human myringotomy knife, samples of intestinal submucosa were punctured to determine the amount of force required to make an incision. Additionally, tympanic membranes dissected from cat and dog cadavers were also tested. These two materials were compared to determine if the intestinal submucosa had similar properties to the tympanic membrane. The experimental setup can be seen in Figure 46. The procedure and detailed setup can be seen in Appendix M through Q.

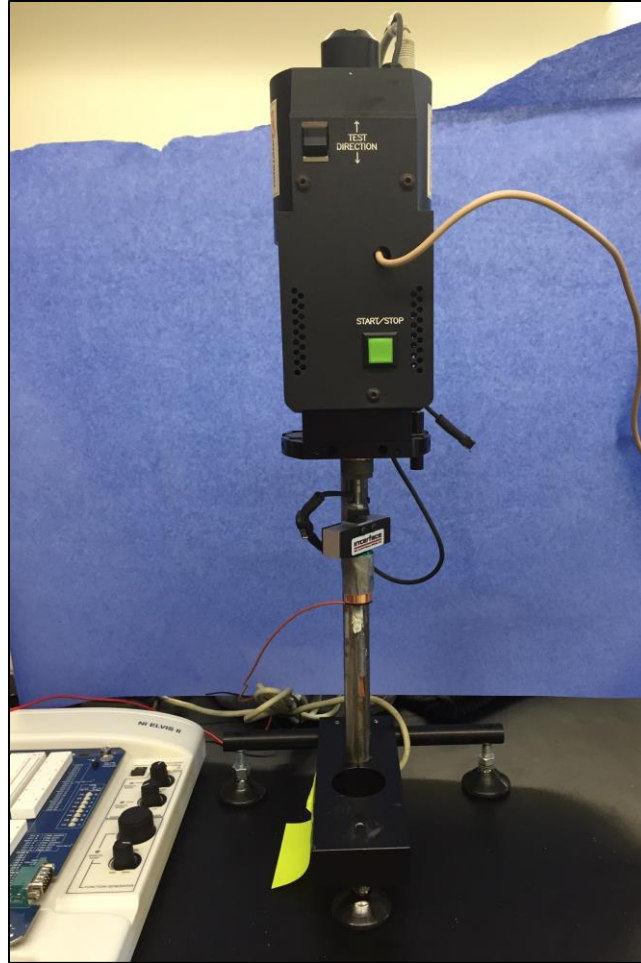


Figure 46: Set up of the In-Spec 2200 Instron for the force to puncture experiment

5.4 Blade Experiment: Effect of Blade Shape on Membrane Incision

Three different blades were used to puncture intestinal submucosa to qualitatively determine which blade shape cuts with the least amount of additional tearing. The team chose three different types of surgical blades: lancet, triangular, and curved (scalpel blades 2, 22, 23) to test. The blade that provides the cleanest cut will reduce the amount of trauma inflicted on the tympanic membrane during surgery. The experimental setup can be seen in Figure 47. The procedure and detailed setup can be seen in Appendix R.

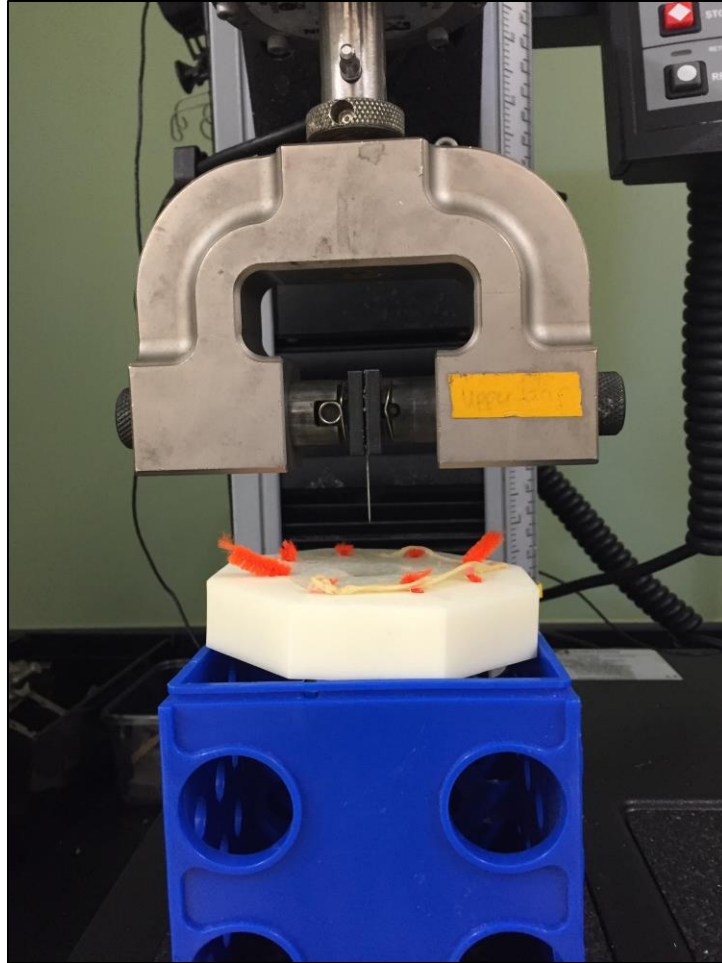


Figure 47: Set up of the Instron 5544 with intestinal submucosa for the blade shape test

6.0 Results

6.1 Force Experiment Results

The data from the experiment is represented below in Figure 48. As Table 13 shows, the maximum force from Dr. Zewe was 6.4 N while the maximum force from Dr. Lam was 3.4 N.

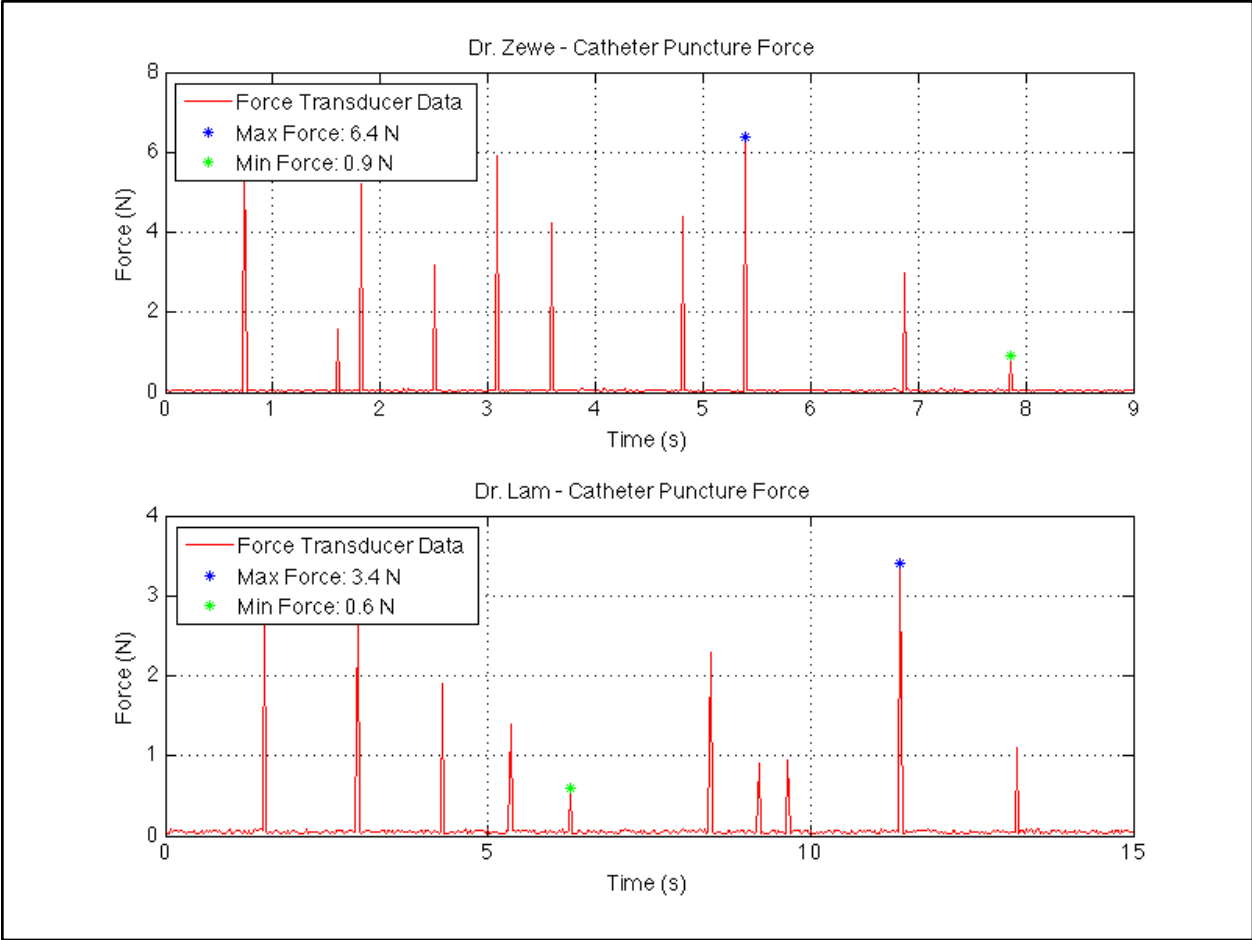


Figure 48: Transducer data demonstrating the force applied with the catheter by each doctor

Table 13: Maximum puncturing force for both doctors

Doctor	Max Force (N)
Christine Zewe	6.4
Andrea Lam	3.4

From the data above the team concluded that the maximum force achieved varies significantly depending on who is performing the procedure. This significant discrepancy between the doctors' maximum forces shows that the rubber catheter method is measurably inconsistent.

The team took this information into account during the initial design phase of the project, which ensured the design would minimize the force required to successfully operate the tool.

6.2 Blade Experiment Results (Bovine Tendon)

Representative data from the 2000N load cell is shown below in Figure 49.

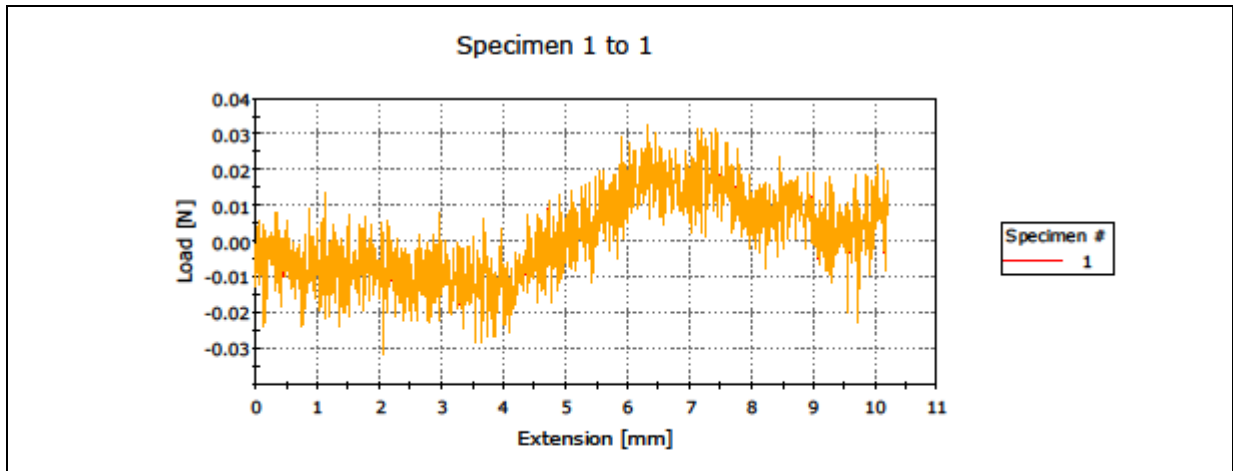


Figure 49: Triangular blade force over time test graph

Due to the amount of noise present in the graph, the team decided to further experiment with a more sensitive Instron load cell. The team also determined that the bovine tendon data was inconclusive due to the lack of material uniformity and integrity. The thin tendon cross sections were perforated by the cryostat slicing process, leaving the samples compromised prior to testing. This can be seen in Figure 50 below.



Figure 50: Bovine tendon lacking uniformity and integrity

After this experiment, the team determined that the bovine tendon was an inaccurate representation of the tympanic membrane, and therefore would no longer be tested. Instead, the team continued testing with intestinal submucosa, because it was both repeatable and reproducible as a testing medium.

6.3 Blade Experiment Results: Force to Puncture Membranes

Figures 51 and 52 show the forces that were required to puncture the tympanic membrane and intestinal submucosa with the human myringotomy knife. The force to puncture is represented by the peak on each of the curves; this corresponds to approximately 2 Newtons for the tympanic membrane, and 0.2 Newtons for the intestinal submucosa. The team also attempted to puncture the intestinal submucosa with a 5 Fr. catheter using the same test method as the human myringotomy knife. However, the catheter was unable to puncture the membrane, and no force data was recorded.

Figure 53 shows the average force to puncture for each blade type. This data shows that the triangular blade and the curved blade require less force to puncture, and are therefore less traumatic.

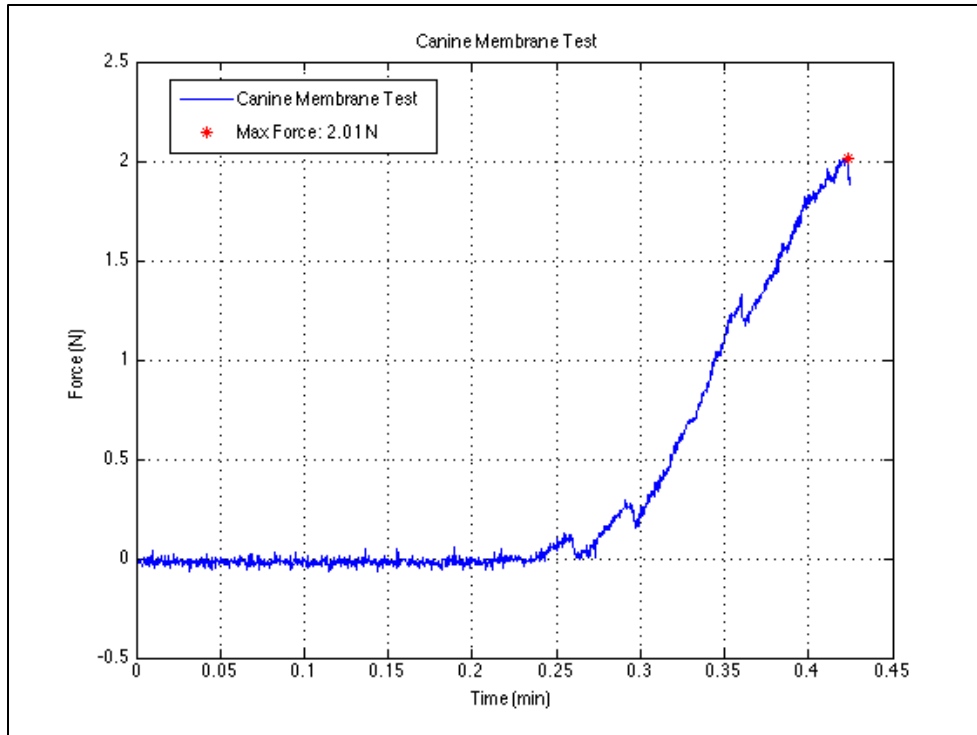


Figure 51: Force required to puncture tympanic membrane

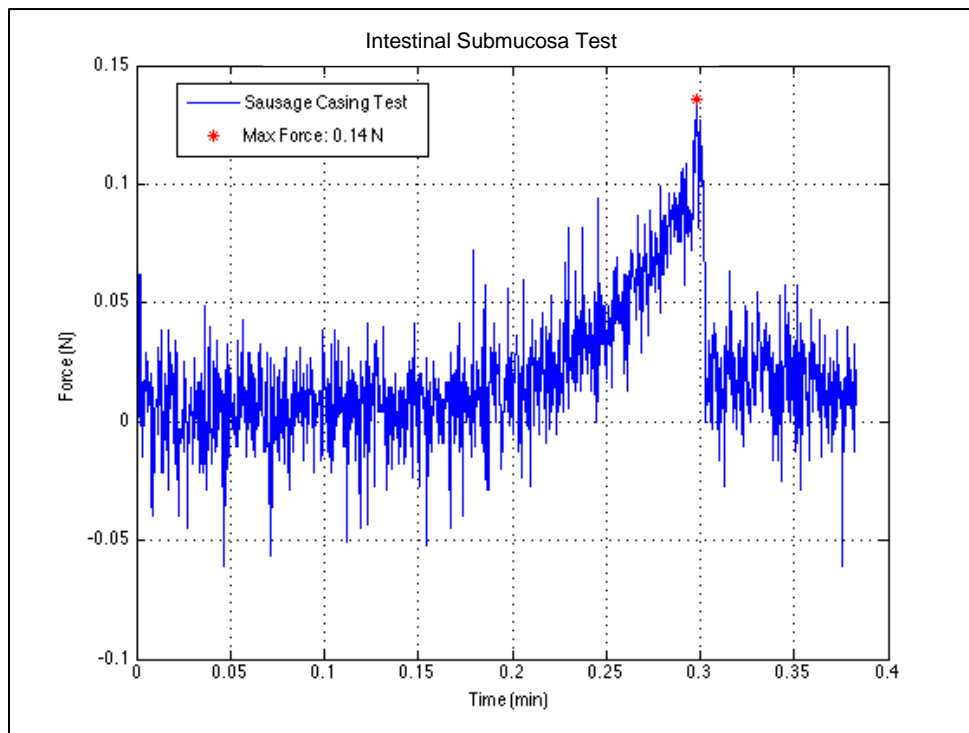


Figure 52: Force required to puncture intestinal submucosa

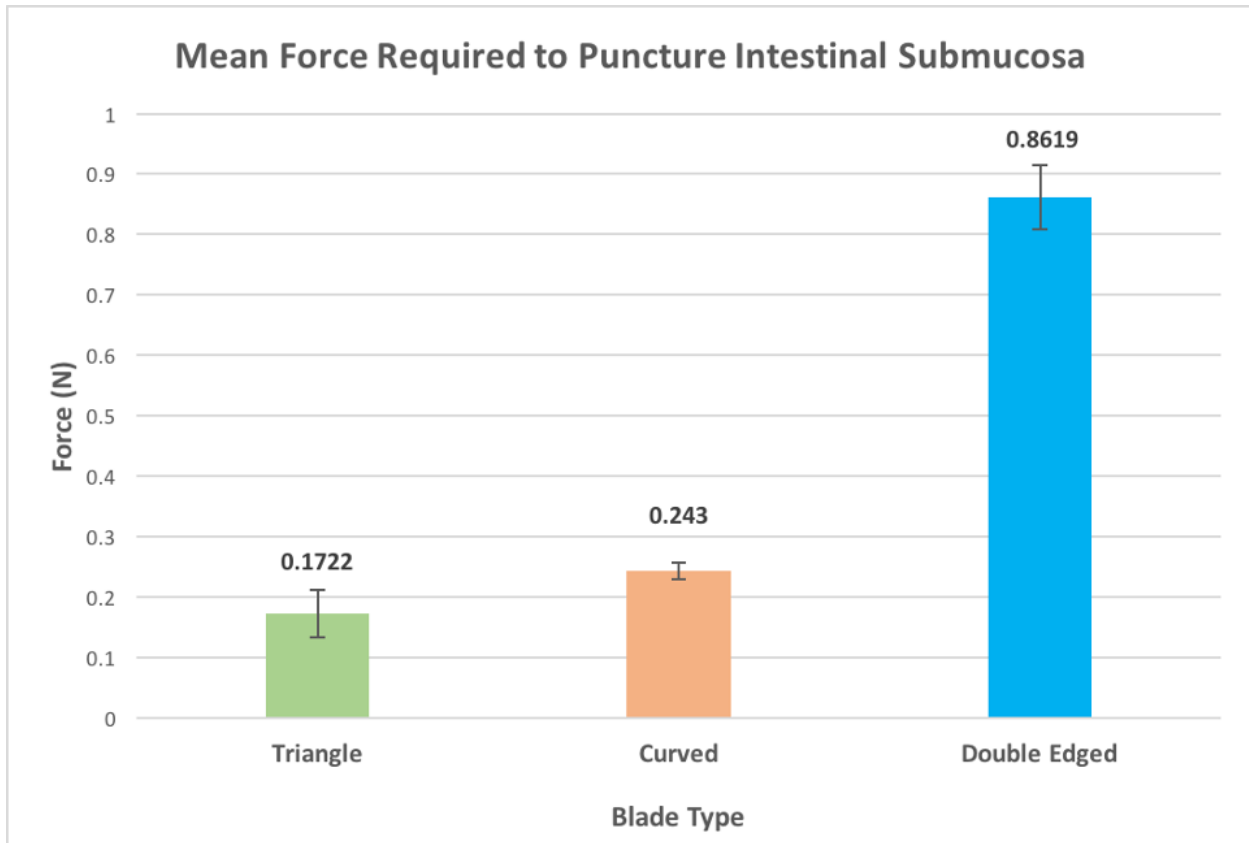


Figure 53: The mean force required to puncture the membrane, using 3 different blade types, with standard deviation

6.4 Blade Experiment Results: Effect of Blade Shape on Incision Size

In order to determine the blade shape that cuts best, it was necessary to standardize the data. The team did so by dividing the average incision length by the length of the blade. This can be seen in Figure 54 below.

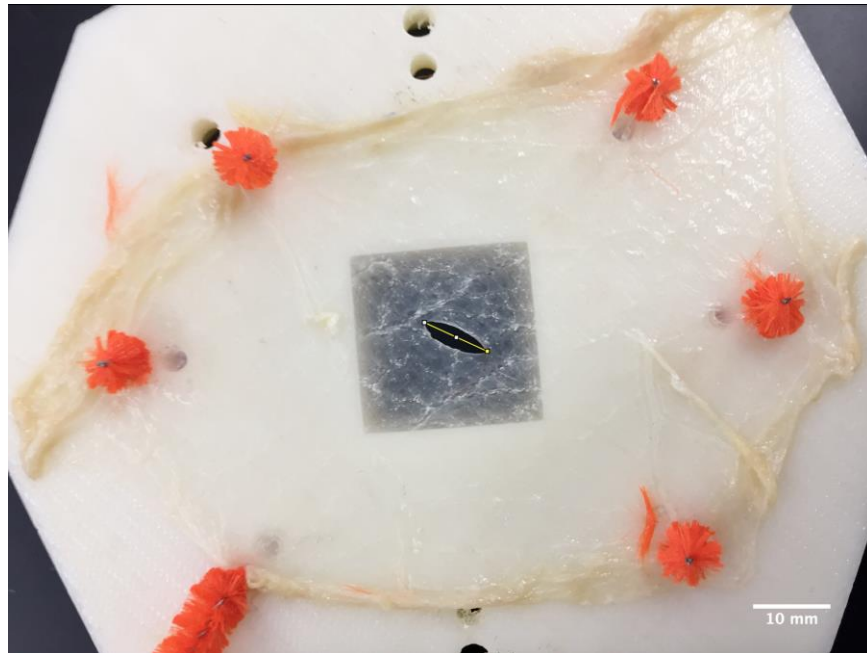


Figure 54: Experimental intestinal submucosa fixed and punctured with scale bar for reference

The blade shape with the highest percent cut was determined to be the optimal blade to use.

Table 14 shows that the curved blade had the highest “percent cut.” The width of the incision was also noted.

Table 14: Percent Cut of Different Blade Types

	Blade length (mm)	Incision length (mm)	Incision width (mm)	Average incision length (mm)	Percent cut
triangular	7.5	5.81	2.6	6.30	84%
triangular	7.5	6.8	2.03		
curved	9.98	9.89	2.81	9.04	90%
curved	9.98	8.19	6.24		
lancet	9.7	6.65	2.33	7.16	74%
lancet	9.7	7.68	3.3		

Using the 2000 N Instron 5544 in Goddard Hall, samples of intestinal submucosa were used as a testing media to further differentiate our blade selection. Ramping at 100 mm/min, samples of the intestinal submucosa were punctured with each of the three blade shape types (triangular, curved, and lancet). The load vs. extension data recorded for each case was plotted on one graph (Figure 55, below) to compare the force required to puncture the intestinal submucosa for each blade.

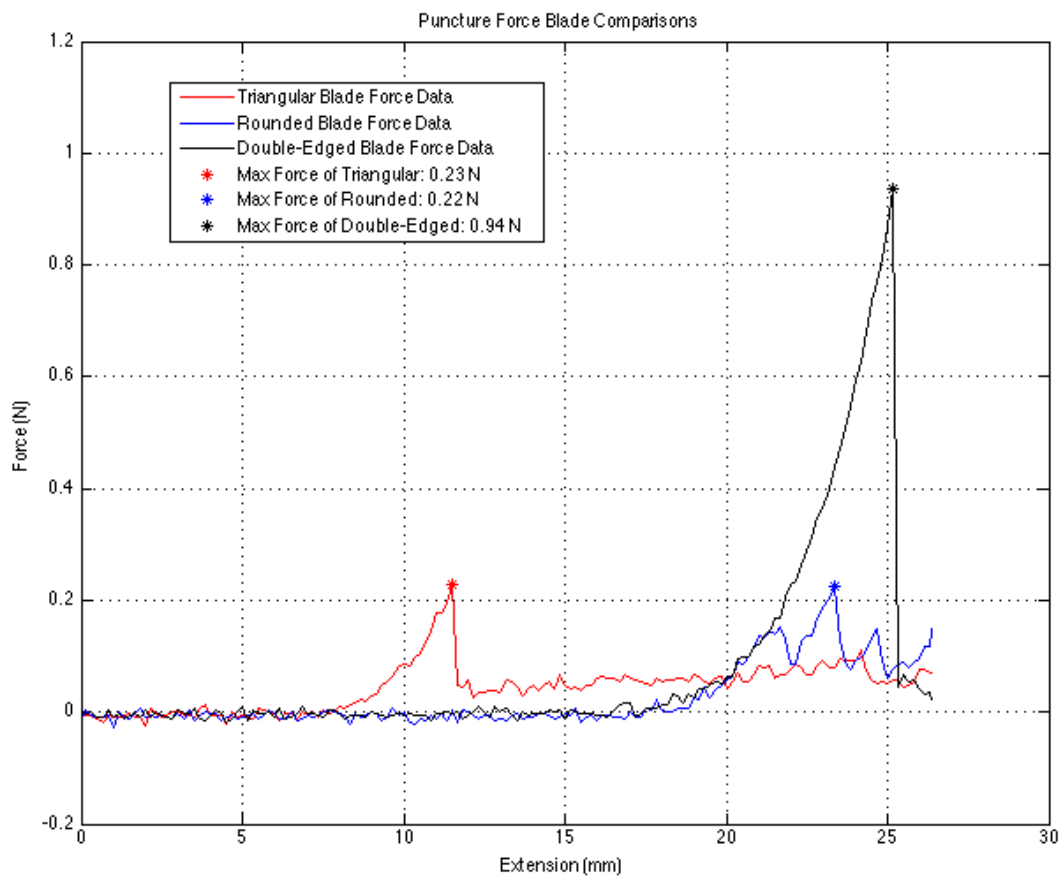


Figure 55: Graph comparing puncture forces vs. extension of each of the 3 blade types. The puncture force of each dataset is indicated with a star

The double-edged spear blade required 0.94 N to puncture, which is notably more force than the triangular blade and rounded blade, which required 0.23 and 0.22 N to puncture,

respectively. This shows that either a rounded blade or a triangular blade requires less force to puncture a membrane.

6.5 Verification and Validation

6.5.1 System Constraints

Simple Finite Element Analysis (FEA) was conducted on the SolidWorks final design model in order to determine the effects of loading on the device during intended use. Static structural stress analysis and component deformation were simulated using system constraints and boundary conditions for applied force, direction of loading, and fixed support location and geometry. Axial compression was considered for the case of the overall assembly. Since the clevis pins are the smallest, weakest components in the assembly, bending of the pins was considered as the weakest point in the system. For the calculation of bending of the pin, both end faces were treated as fixed supports in order to mimic the way the pin is physically held in place. In the case of the entire assembly, the front face of the clevis was treated as a fixed support, mimicking the device's actual contact with a tympanic membrane. One-directional forces were applied at the center of the pin along its axis and at the back end of the pull wire. Boundary conditions and constraints for the assembly can be seen in Figure 56 below.

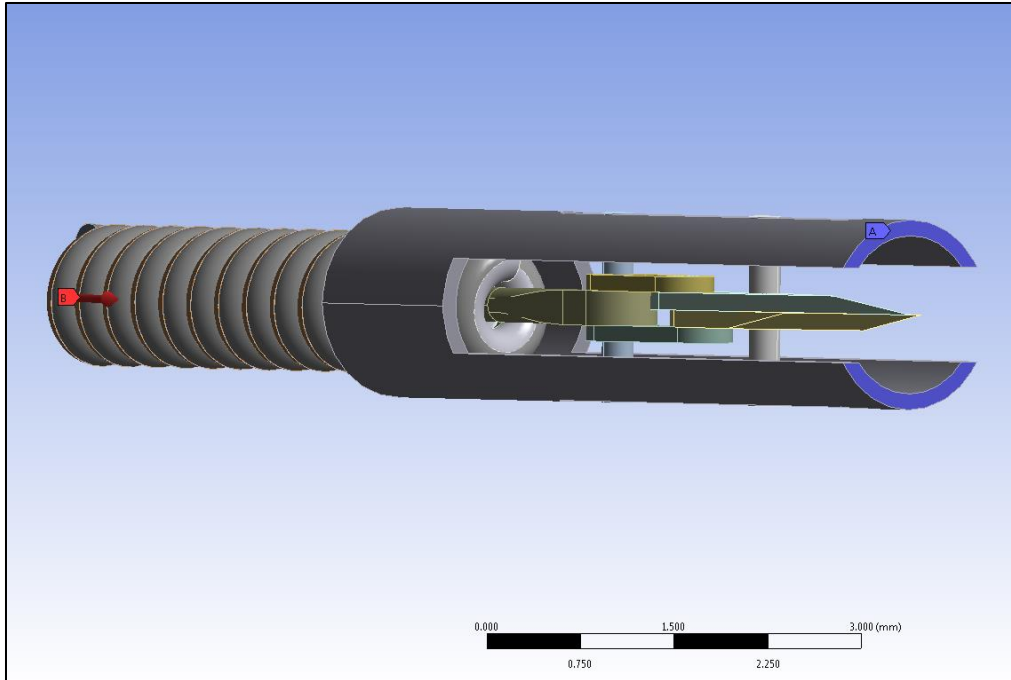


Figure 56: Boundary conditions and constraints of device assembly

Using the simulation results, the measured maximum stress and deformation were compared to failure criteria based on the material properties of type 316 stainless steel.

6.5.2 Stress Analysis

Bending stress is the primary loading on the pin due to the way it is fixed in the device. It is important to note that due to the limitations of the Finite Element Analysis software, a realistic result was unobtainable for the case of the pin. The calculated maximum bending stress in the pin, which occurs equally at both ends, was approximately 17 MPa. This was calculated using the equation for normal stress in a simply supported beam ($\sigma_{bend} = \frac{Mc}{I}$). The highest bending stresses are present at the fixed ends of the pin.

In the case of the entire assembly, a more realistic result could be obtained through simulation due to a more realistic set of constraints. The maximum stress in the simulation was

17.51 MPa, which occurs in the long pins. This is within a reasonable range of the previously calculated stress in the pins, 17 MPa. The maximum stress occurs at the center of the pin, at the points where it comes into contact with the blades and linkages. This system was more realistic because it accounted for multiple contact surfaces on the pins and dissipation of the applied force amongst all system components. The stress distribution can be seen in Figure 57.

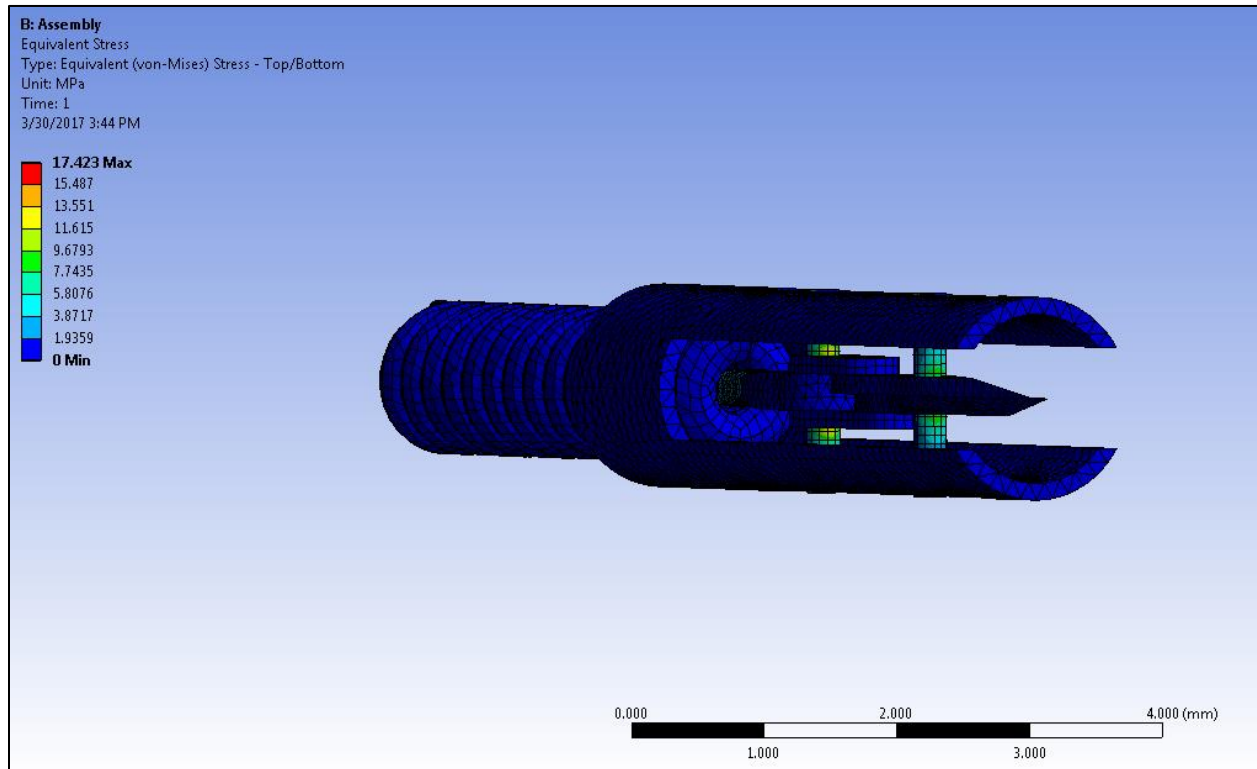


Figure 57: Stress distribution of the pins calculated by ANSYS

The team is very confident in the simulation accuracy due to how similar the results are to the theoretical values calculated by hand.

6.5.3 Deformation Analysis

Both hand calculations and 3D simulation results yielded maximum deflections of less than 10 μm , so deformation of assembly components was effectively negligible. Screenshots of the resulting deformation of the system can be seen in Figure 58 below.

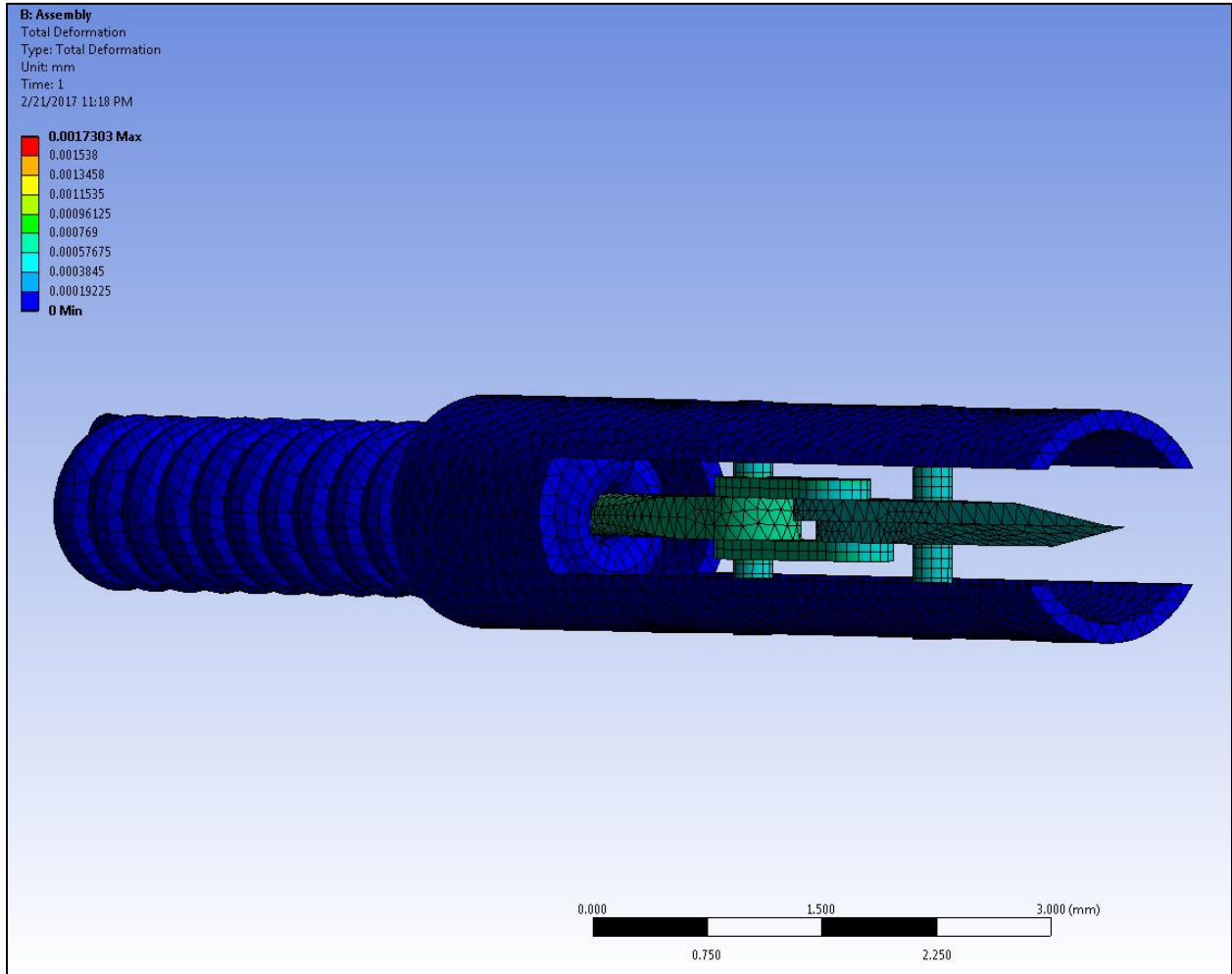


Figure 58: Calculated total deformation of system in mm

Even though both the calculated value and the simulation value for deformation were negligible, this simulation provided a more realistic depiction of how the component deformation would actually occur during use. Each of the moving linkage components and pins would

experience similar deformations because they are all in contact and are all moving together in the same direction.

6.5.4 Failure Criteria

Yield strength, or the point where a component experiences plastic deformation, for type 316 stainless steel is about 205 MPa, or 30 ksi. Tensile strength, or the point of failure, is about 515 MPa, or 75 ksi (316/316L Stainless Steel, n.d.). Compared to the actual applied stress in the case of the pins (170.1 MPa), the factor of safety for yielding and failure in this analysis are 1.21 and 3.03, respectively. This was calculated by dividing the failure criteria (yield and failure stress) by the actual applied working stress.

In the case of the full assembly, the factor of safety for yielding and failure are identical to those in the pins, because those are structurally the smallest and weakest components. It is important to note that these simulation values are for the worst-case scenario of the operation of our device. For ease of analysis, the simulation was treated as a static structural analysis. In reality, the system is a dynamic system involving cutting mechanics that are too complex to model accurately in the Finite Element Analysis software. Since the device will not actually be subjected to these magnitudes of loading, it will most likely never experience these levels of stress.

There is a substantial difference in the mechanical properties between stainless steel and the biological membrane material, so a more realistic factor of safety would be considerably higher for the device. Even in a worst-case, static scenario the device still operates with an acceptable factor of safety, so the team is confident in saying that the device will not fail due to applied stress during its intended use.

6.6 Summary of Results

6.6.1 Summary of Force Tests

In order to puncture the intestinal submucosa, approximately 0.2 N of force was required by the human myringotomy knife. It took one order of magnitude more force to puncture the tympanic membrane. These results match what the team found in literature, since the Young's modulus of the tympanic membrane (20-70 MPa) is approximately ten times the Young's modulus of the intestinal submucosa (3-8 MPa).

Bovine tendon was not an adequate representation of a tympanic membrane. In order to prepare the samples so that they were a relatively similar thickness to a tympanic membrane, the bovine tendon needed to be frozen and then sliced with a cryostat. The freezing and cutting weakened the aligned fibers, which were larger than those found in a typical membrane. These features combined to yield results that were inconsistent and inconclusive. So no further testing with bovine tendon was done.

The catheter was unable to puncture the intestinal submucosa when going at the same speed as the blades. In order for the catheter to be able to puncture the intestinal submucosa, it requires more speed and energy than the blades.

6.6.2 Summary of Membrane Test

The curved blade had the highest percent cut, but the triangular blade had a percent cut that was very close (90% compared to 84%). Even though the percent cut was higher, the team decided to use triangular-shaped blades for the device because they are easier to sharpen, and therefore are easier to use for this particular procedure.

7.0 Discussion

7.1 Compare to Current Devices

The team developed a device that is retractable and works via a dual-linkage mechanism. A medical device previously patented by Ravi Nallakrishnan involves a retractable surgical blade that has the capability to control its depth of cut (Nallakrishnan, 1997). The team's device utilizes a similar mechanism during the initial extension and retraction portion of operation, broadening functionality to include widening of the initial incision.

The team also developed a mechanism with inverse blades that works similarly to a flexible scissors patent that is used in minimally invasive surgical applications (Spivey, 2011). However, Spivey's device was only capable of expanding the blades, and did not have a mechanism for puncturing. Additionally, Spivey's device involves the linkages being exposed throughout expansion and closing of the blades.

Another similar design, medical biopsy forceps designed by Boston Scientific, used pull wires instead of secondary linkages (Bales, 2006). The device is able to extend linkages outwards; however, it does not have a mechanism to extend forward. The device is used for microsurgery, but still exceeds the 5 Fr. restriction of the team's device.

There is a needle on the market, manufactured by Karl Storz, made specifically for veterinary myringotomy in small animals (Otoscope, 2016). However, the incision is too small and requires multiple punctures to complete the procedure (Zewe, 2016). In comparison, the team's device only requires a single pass, which is less traumatic and more efficient.

7.2 Achieving Objectives & Limitations

At the start of the project, the team defined four objectives that device would need to maximize. The device must be versatile, compatible, safe, and inexpensive. It is versatile and can be used on any cat or dog breed. Due to its flexibility and length it can traverse an ear canal of any size or shape. The device can also puncture tympanic membranes of varying thicknesses, as an animal's membrane thickness can vary greatly depending on the condition of their ear. The device is also symmetrical, which allows for any surgeon to use it regardless of their hand dominance.

The device is also compatible with the current processes and tools used by the Tufts veterinarians. The device can be used with one hand and therefore can be used with current equipment, such as a handheld otoscope. Additionally, the device is compatible with current sterilization protocol since it is made of surgical steel, which is important because the device components are too small and complex to be made using a disposable material such as plastic.

Delicate and technical surgical work, such as a myringotomy procedure, often requires more advanced and reusable instruments (Smith, 2011). Though the initial cost for manufacturing this device is more expensive due to the complexity of the design, the high quality of surgical steel allows the device to be sterilized repeatedly. Since myringotomy procedures are performed fairly often, it is more ideal to have a specifically designed, reusable device that is always available which allows for maximized cost-effectiveness.

The blades are ensheathed to protect both the ear canal of the patient as well as the veterinarian performing the procedure. The blades are only unsheathed and expanded at the veterinarian's discretion.

Since it was not possible to perform clinical testing, the team performed testing on tympanic membranes from dog cadavers. The tympanic membrane provided useful results to validate the effectiveness of our device; however, additional clinical testing would be necessary to simulate a realistic surgical scenario before the device can be used in myringotomy procedures.

A prototype on the exact scale of the design was considered but was not feasible for the project team due to insufficient project funding, and therefore a five time scale model was manufactured. While the scaled prototype allowed for an accurate visualization of the device actuation and proof that the device operates as intended, without a fully accurate sized model, it is impossible to begin clinical testing of the device. The device could still be tested for sterilizability by autoclaving and durability by operating the device in a non-Newtonian fluid.

The final limitation of the team's device is its marketability. Currently there are only a few hundred board certified veterinary dermatologists in the world, each performing only one or two myringotomies per month (Zewe, 2016). In order to mass-manufacture the device an alternative application would need to be identified. This would increase the market need for the product, providing manufacturers with incentive to license the device.

7.3 Ethical Concerns

This device is currently meant to be used by trained professionals who are performing myringotomy procedures on dogs or cats. The device is made from surgical grade stainless steel which will be sterilized before each use and will not release byproducts during the operation. The purpose of our device is to relieve discomfort and aid in healing of small animals with ear infections. Through verification and validation the device has achieved a high degree of repeatability and accuracy. Therefore, when in use by a trained veterinarian, it poses minimal risk

to the patient and the user. The device replaces the current procedure with a more effective and efficient process.

7.4 Health and Safety Concerns

A key design feature of the myringotomy knife is sterilizability. The device was designed to withstand the temperatures of an autoclave, and in turn, can be reused safely and without risk of spreading disease. When the device is properly handled, veterinarians would not come into contact with the device's sharp blades. The training and sheathing mechanism would mitigate potential safety risks to the veterinarians using the device.

7.5 Compliance to Industry Standards

Although there are no FDA/ISO standards for veterinary medical devices, this device would be considered an FDA Class II device if it were to be used on humans. With that guide, the device sterilization principles were assessed with comparison to the standards that would apply to a typical Class II. The doctors at Tufts Veterinary School informed indicated their primary sterilization method was moist steam autoclave. ISO 17665:2006 refers to moist heat, and dictates that a device is considered sterile of microbiologics after being immersed in 121°C steam for at least 15 minutes. Should a device be sent to market, FDA Premarket Approval 510(k) guidelines for a Class II steam certify the same requirement for sterility.

In addition to sterilization, the team assessed the device against general requirements of scissors and shears in surgical devices, using ISO 1774:1986 as the primary reference. This voluntary standard outlines the general requirements and testing methods for surgical instruments that incorporate scissors or shear blades. A large portion of the standard involves material

selection, as outlined further in ISO 7153/1, 'Instruments for Surgery - Metallic Materials' and ISO 683/13, 'Heat-treated steels, alloy steels and free-cutting steels'. Since the material chosen for the device was 316 Stainless Steel, also known as Surgical Stainless Steel, adherence to the material requirements of these standards is easily achieved. The cutting ability of the shear blades requires testing with a sample media. The blades in the final design are categorized as micro-spring instruments, and therefore must be able to cut through wetted tissue paper to be accepted as successful blades in accordance with ISO 1774:1986. This test, as well as corrosion testing outlined in the same standard (1774:1896), cannot be completed until the final prototype is fully manufactured. The corrosion test requires submersion in boiling, distilled water for at least 30 min and cooling in a colder water solution for at least an hour, followed by air drying for 2 hours. Corrosion is then determined by examining the surface for blemishes.

7.6 Economics and Manufacturability

Our device is composed entirely of surgical grade stainless steel, which is a widely available and well known material in biomedical applications. Typically, this would be type 316 high-strength austenitic stainless steel, which can be purchased at low cost, roughly \$3-4 per kilogram. The prototype of the final design took only a few days to manufacture, which is a relatively short prototype turnaround. On a production scale our product could be manufactured at a fraction of the cost and with much less labor input. Current endoscopic devices from medical device manufacturers range from approximately \$20 to \$350, so due to the device's similarity its price would most likely fall within that range. A lot of the time spent by machinists on the prototype was regarding design intent and small manufacturing details that would not be present in a large scale production of the product. On a production scale, the device assembly would

require automation for accuracy and repeatability. Additional fixturing would also add to the ease of assembly, particularly in lining up components for pin placement.

The design of our device included a manufacturing strategy that could be achieved using pre-existing machinery and processes at Boston Scientific, so as to minimize the cost of the prototype. Therefore, we determined that despite the product's complexity it would be economically viable for a medical device manufacturer, such as Boston Scientific, to incorporate this product into their product line.

While the large scale manufacturing of our device could be achieved at minimal cost, the market for this type of device in small animal surgeries is severely limited. Currently there are only a few hundred board certified veterinary dermatologists in the world, each performing only one or two myringotomies per month (Zewe, 2016). For this reason, an alternative use for the device would need to be determined in order to be profitable.

7.7 Societal & Political Concerns

The main societal concern that is associated with our project involves animal rights. The team needed to ensure that the device would be safe for all animals that it would be used on. The team performed extensive research on the sizes of different dog ear canals and the variability of tympanic membrane sizes before beginning to design the device. The size of the sheathing was chosen based on these numbers such that the device would fit through any dog's ear canal and not cause damage on the way to the tympanic membrane. In addition, our device will hopefully benefit society by improving the efficiency of the current myringotomy procedure. Our device will be able to make a 5 French sized cut in one pass, whereas the current procedure required multiple punctures due to the inefficiency and size of the rubber catheter that was being used. This device

will improve the Veterinarian's ability to perform the procedure quickly and efficiently, and therefore lowering the risk of any trauma that could occur from a myringotomy.

If the device were to be used in human surgeries in the future, the FDA would play an important role in the review and analysis of the device. Due to increasing complexity of medical devices, such as this device, it could potentially play a role in shaping policy of medical device regulation.

7.8 Environmental Concerns

Our device will mainly be used in veterinary surgeries and primarily in veterinary hospitals. Therefore, the device will have minimal environmental impact. The device is made from 316 surgical stainless steel, which is recyclable and has little to no impact on the environment (Stainless Steel, n.d.). The device will be cleaned by autoclaving, a process which involves high steam pressure at very high temperatures, effectively killing any bacteria present. The steam by-product of autoclaving is condensed to water and recycled. The biological waste is minimal and biodegradable. Once autoclaved, the device must be sealed inside a sterile package.

8.0 Conclusions

8.1 Project Success

The goal of this project was to design a flexible, one-handed myringotomy tool to cut the tympanic membrane in one pass and not damage the ear canal. The tool accommodates a large variety of patient and surgeon needs, including incision size and different patient sizes. It is compatible with current surgical processes and equipment. On a production scale, the tool will be cost-effective and safe for patients, surgeons, and equipment.

8.2 Summary of Final Design

For the final prototype material, the team chose Type 316 surgical grade stainless steel, which is highly corrosion resistant and durable while being relatively low in cost. The slots on the sides of the clevis were made smaller to force the linkages closed during retraction, and the pins were hollowed out to more realistically represent rivets. In addition to being hollow, the ends of the pins have also been flared out to keep them from falling out of the linkages. The final device is autoclavable by moist steam autoclave, which is the primary sterilization process available on the Tufts campus. Using ANSYS, the final design was simulated and verified with the forces measured in the blade testing. In a simplified static analysis, the simulation results yielded a maximum stress of 17.5 MPa resulting in a minimum factor of safety of 12.

8.3 Future Suggestions

Small modifications to the design may include spacers to contain the pins within the clevis and keep the linkages aligned horizontally with respect to the clevis.

The team also recommends that clinical studies be conducted to test the sterilizability and durability of a prototype on the proper scale. As a resterilizable device, the team recommends that the testing be done according to ISO 17664:2004, which outlines the tests and procedures for assessing the sterilizability of reusable medical devices in depth. Before studies are conducted on live animals, it is additionally necessary for sufficient testing to be performed on canine cadavers. Although scaled prototypes were tested on cadaver tissue and pseudo tissues, this is recommended to properly gauge the usability of the final device in the target tissue.

Veterinary myringotomy devices fall within a very niche market. In order for this device to be marketable, it is necessary to identify another possible application such as further veterinary

surgery or human procedures. This additional application will increase the incentive for a company to license and manufacture the device.

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Appendices

Appendix A: Tympanic Membrane Variability

TABLE 1. Signalment and Measurements of the Tympanic Membrane, Annular and Auricular Cartilage of the Horizontal Ear Canal in Dorsoventral Canalography

Breed(n)	Mean of Body Weight(kg)	Mean of Diameter(mm \pm SD)			Mean of pa/da
		Tympanic Membrane	Proximal Annular Cartilage(pa)	Distal Annular Cartilage(da)	
Pug (12)	6.9 \pm 2.6	not found	1.4 \pm 0.9	3.4 \pm 0.4	0.4
Pekignese (8)	4.3 \pm 0.5	4.1 \pm 0.2	3.1 \pm 0.1	4.1 \pm 0.2	0.8
Shi-Tzu (10)	4.0 \pm 1.0	4.9 \pm 0.2	3.2 \pm 0.1	4.3 \pm 0.3	0.7
Cockerspaniel (12)	8.6 \pm 2.0	6.1 \pm 0.3	3.5 \pm 0.4	4.1 \pm 0.3	0.9
Pomeranian (10)	3.3 \pm 0.5	5.3 \pm 0.4	3.9 \pm 0.6	4.3 \pm 0.3	0.9
Chihuahua (10)	2.4 \pm 0.7	5.0 \pm 0.3	4.0 \pm 0.4	4.1 \pm 0.4	0.9
Maltese (8)	3.8 \pm 0.5	5.4 \pm 0.4	4.1 \pm 0.4	5.0 \pm 0.2	0.8
Poodle (11)	3.1 \pm 1.0	5.6 \pm 0.4	4.3 \pm 0.4	5.4 \pm 0.3	0.8
Yorkshire terrier (12)	2.7 \pm 0.6	5.5 \pm 0.3	3.5 \pm 0.3	4.5 \pm 0.3	0.8
Large breeds (15)	16.9 \pm 0.8	8.2 \pm 1.2	5.7 \pm 1.0	6.9 \pm 1.3	0.8

Appendix B: Copyright Permission

Email correspondence

11/3/2016

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Re: FW: Request for Copyright permission



Jacqueline Gimmler <jacqueline.gimmler@gmail.com>
Mon 10/31, 2:57 PM
Mindy Valcarcel <Mindy.Valcarcel@ubm.com>; Quintal, Nicole F

Reply | ...

Inbox

You forwarded this message on 10/31/2016 3:21 PM

Action Items

Hi Nicole,

I'd be happy to give you my permission to use the photo for your project. Can you credit me at the bottom of presentations or in publications? Your work sounds very exciting! Best of luck!

Mindy, thanks for connecting us!

-Jacqueline Gimmler, DVM, MS
Diplomate of the American College of Veterinary Dermatology
Animal Dermatology Referral Clinic- Grapevine, TX

On Fri, Oct 28, 2016 at 12:45 PM, Mindy Valcarcel <Mindy.Valcarcel@ubm.com> wrote:

Hello Dr. Gimmler,

We received the following request on our website from someone wanting to reuse one of your photos from this article (I'm connecting you to the fifth page, which contains the figure she'd like to reuse):

<http://veterinarymedicine.dvm360.com/skills-laboratory-how-perform-myringotomy?pageID=5>

The copyright for all the photos from this article remains with you, so just checking if you'd like to contact her and let her have permission. Up to you!

Thanks!
Mindy

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1/4

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--

Mindy Valcarcel | Medicine Channel Director & Editor, *Veterinary Medicine*

UBM Life Sciences, Veterinary

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From: "Quintal, Nicole F" <nfquintal@wpi.edu>

Date: Thursday, October 27, 2016 at 5:54 PM

To: DVM360 <dvm360@ubm.com>

Subject: Request for Copyright permission

October 27, 2016

Nicole Quintal

Worcester Polytechnic Institute

100 Institute Road –Box 3101

Worcester, MA 01609

Re: Image of the caudoventral quadrant of the pars tensa under Step 4 of Skills Laboratory: How to perform a myringotomy by Jenise Daigle, DVM, DACVD, and Jacqueline Gimmler, DVM

Dear Advanstar Veterinary:

I am a student at Worcester Polytechnic Institute where I am completing an undergraduate degree requirement called a Major Qualifying Project. My team and I are in the process of creating a myringotomy knife tool for myringotomy procedures while working with Tufts Veterinarians. For this

<https://outlook.office.com/owa/projection.aspx>

2/4

11/8/2016

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our project report which will be eventually posted in the online archive of student project reports at <http://www.wpi.edu/E-project-db/E-project-search/search> for world wide access as well as given to the Tufts Veterinarians that we are working closely with. My project team would like your permission to include the following material in our Major Qualifying Project report:

Daigle DVM, J., & Gimmler, J. (2012, July 1). Skills Laboratory: How to perform a myringotomy. Retrieved September 23, 2016, from

<http://veterinarymedicine.dvm360.com/skills-laboratory-how-perform-myringotomy>

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Sincerely,

Nicole Quintal

11/3/2016

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Appendix C: Table of Patents Relating to the Tool

Patent No.	Patent Title	Filing Date	Purpose	Assignee
EP19900313800	<i>Device for extended delivery of pharmacologically active agents to the ear</i>	1990-12-18	Device that releases active chemical agent to inner ear for myringotomy.	3M Innovative Properties Co
US09390229	<i>Bio-erodible Myringotomy Tube</i>	1999-09-03	Insertable tube for myringotomy that bio-erodes	Acoustic Technologies Inc
US3913584A	<i>Combination Myringotomy scalpel, aspirator, and otological vent tube inserter</i>	1974-06-28	Trigger system for myringotomy and draining fluid in humans.	Xomox Corporation
US08372849	<i>Surgical Knife with Retractable Blade and Depth of Cut Control</i>	1995-01-13	Rigid knife with sheathing ability for atraumatic maneuvering.	Nallakrishnan, R
US06405843	<i>Sheath and retractable surgical tool combination</i>	1982-08-06	Tubular sheathing of blade, optimal for small canals.	Zimmer Orthopaedic Surgical Products Inc
US10873021	<i>Surgical Instruments particularly suited to severing ligaments and fibrous tissues</i>	2004-06-21	Blunt tip surrounding sharpened blade; intended for spinal surgeries/tight vessels.	Ferree Bret A.
US09707641	<i>Retractable Micro-Surgical Tool</i>	2000-11-06	Spring-loaded push mechanism. Similar to a ballpoint pen. Rigid.	ESCALON IP HOLDINGS, INC.
US10071056	<i>Device for sealing a vessel during coronary artery bypass surgery</i>	2002-02-08	Thin, flexible device for sealing blood vessels. Easily maneuverable.	Fogarty Thomas J Maquet Cardiovascular LLC
US08885064	<i>Delivery System and Method for Surgical Laser</i>	1997-06-30	Flexible tube-like device with topical surgical laser on the end.	Clinicon Corporation
US08640542	<i>Contact Laser Surgical Endoscope and Associated Myringotomy Procedure</i>	1996-05-02	Rigid endoscope for pediatric procedures.	BEAVER-VISITEC INTERNATIONAL Inc

US3768482 A	<i>Surgical cutting instrument having electrically heated cutting edge</i>	1972-10-10	Device electrically heated for cutting, cauterizing and sterilization, leading to faster surgical procedures.	Shaw, R
US1813902 A	<i>Electrosurgical apparatus</i>	1928-01-18	Device used to cut tissue and cauterize capillaries using a high frequency electric discharge	Liebel Flarsheim Co
US20060184198A1	<i>End effector for surgical instrument, surgical instrument, and method for forming the end effector</i>	2006-01-31	Endoscopic surgical tool design with opening jaw. The jaw opens using a hand-held mechanism and two pull wires.	KMS Biopsy, LLC
US20120116397 A1	<i>Electrosurgical apparatus with retractable blade</i>	2010-11-08	Electrosurgical device intended to use cold plasma cutting techniques on a surgical scale	Bovie Medical Corporation
US3384085 A	<i>Surgical cutting tool</i>	1964-07-03	Flexible dental drill for clearing hard and soft tissues within the mouth	Robert M. Hall

Appendix D: Individual Pairwise Evaluation Charts & Total

Dr. Zewe's Objective Rankings

Objectives	Adaptable	Compatible	Inexpensive	Safe	Score:
Versatile		1	1	1	3
Compatible	0		1	1	2
Inexpensive	0	0		0	0
Safe	0	0	1		1

Nicole's Objective Rankings

Objectives	Versatile	Compatible	Inexpensive	Safe	Score:
Versatile		0.5	1	1	2.5
Compatible	0.5		0	0	0.5
Inexpensive	0	1		0.5	1.5
Safe	0	1	0.5		1.5

Dr. Lam's Objective Rankings

Objectives	Versatile	Compatible	Inexpensive	Safe	Score:
Versatile		1	1	1	3
Compatible	0		1	1	2
Inexpensive	0	0		0.5	0.5
Safe	0	0	0.5		0.5

Connor's Objective Rankings

Objectives	Versatile	Compatible	Inexpensive	Safe	Score:
Versatile		0.5	1	0.5	2
Compatible	0.5		1	0	1.5
Inexpensive	0	0		0	0
Safe	0.5	1	1		2.5

Jack's Objective Rankings

Objectives	Versatile	Compatible	Inexpensive	Safe	Score:
Versatile		0	1	1	2
Compatible	1		1	0	2
Inexpensive	0	0		0	0
Safe	0	1	1		2

Mike's Objective Rankings

Objectives	Versatile	Compatible	Inexpensive	Safe	Score:
Versatile		0.5	1	1	2.5
Compatible	0.5		1	1	2.5
Inexpensive	0	0		0	0
Safe	0	0	1		1

Kaitlin's Objective Rankings

Objectives	Versatile	Compatible	Inexpensive	Safe	Score:
Versatile		1	1	1	3
Compatible	0		1	0.5	1.5
Inexpensive	0	0		1	1
Safe	0	0.5	0		0.5

Appendix E: French Catheter Scale

French Catheter Scale by Key Surgical. (n.d.). Retrieved October 12, 2016, from <http://www.medline.com/product/French-Catheter-Scale-by-Key-Surgical/Z05-PF91571>

French Gauge	Circumference (mm)	Diameter (mm)	Diameter (inches)
3	3.14	1	0.039
4	4.19	1.333	0.053
5	5.24	1.667	0.066
6	6.28	2	0.079
7	7.33	2.333	0.092
8	8.34	2.667	0.105
9	9.42	3	0.118
10	10.47	3.333	0.131
11	11.52	3.667	0.144
12	12.57	4	0.158
13	13.61	4.333	0.170
14	14.66	4.667	0.184
15	15.71	5	0.197
16	16.76	5.333	0.210
17	17.81	5.667	0.223
18	18.85	6	0.236
19	19.90	6.333	0.249
20	20.94	6.667	0.263
22	23.04	7.333	0.288
24	25.13	8	0.315
26	27.23	8.667	0.341
28	29.32	9.333	0.367
30	31.42	10	0.393
32	33.51	10.667	0.419
34	35.60	11.333	0.445

Appendix F: Tufts Doctor Interview

Hi guys,

I listed my answer below in red. I will have my technicians look for some good images of the procedure for you guys. We definitely have some. I can also have them look into the cost of that puncture tool.

I have attached the latest paper reporting the use of experimental ear tubes in a small group of dogs.

Christine

- Have you used the Karl Storz tool? “I have not used this tool, so I can only comment based on the description from the company. I think the size of the tool is too small. Following the myringotomy, I have to then thread a 5 french catheter into my incision in order to flush the ear. If the incision is larger, it makes this process considerably easier. Some of the exudate I flush from ears is very viscous, so I need a relatively large incision. This tool would require me to puncture the ear drum multiple times, and manage to do this in a linear fashion so my puncture connect, in order to make a large enough opening. The tympanum is vascularized and does bleed profusely when we puncture it, so the ability to do this in one pass is very helpful”
 - What about this tool doesn’t work for you?
 - Just the puncture aspect or the overall tool?
- Can you use ear tubes in dogs? “This has been done experimentally, though not but us. The process requires the use of an operating microscope, which we do not have”
 - Has this ever been tried or considered?
- Purchasing department “I don’t know but I can ask my technicians to get this information”
 - How much do these tools cost? We’ve had difficulty ascertaining this information without a proper PO system
- What is the corporate relationship between Tufts and Karl Storz? “We purchase endoscopy equipment from them for Dermatology and Internal Medicine. It is possible the surgery service also purchases equipment from them”
- Do you have pictures or videos of the procedure? “Yes we do”
- How many myringotomy procedures do you perform a month? “Probably average 1-2”
 - About how many dogs about how many cats? “I would say 80% dog, 20% cats”
- How do you prep your patient? “The patient is under general anesthesia for the procedure. If possible, they have a CT exam of their bullae prior to the procedure. I usually will flush sterile saline into the ear canal to remove any exudate or debris prior to the myringotomy, but no other prep is involved”
- What supplies do you have in the room with you? “We have multiple sizes of red rubber catheters (we usually use 5 Fr), sterile syringes, sterile saline, some ear cleaner, biopsy forceps that are scope compatible, and multiple implements for myringotomies (including tom cat catheters of stiff plastic, and a flexible wire with a blunt end, human myringotomy knives)”
- How long does the process typically take? “The ear flush procedure is usually 15-30 minutes per ear, depending on the condition of the ear canal. The myringotomy itself takes just a few minutes (or seconds), followed by several more minutes of flushing and cleaning”
- How long is the recovery period? Do you require a follow up appointment? “Patients will recover from anesthesia under supervision in our wards. The procedure is an outpatient procedure and most will go home at the end of the day. Recovery from the myringotomy itself is minimal. The owners will often be required to clean and treat the ears at home following the procedure to manage infection, as the procedure is unable to completely sterilized the ear canal or bulla. For the reason of monitoring infection, we usually

recheck our patient about 2 weeks post-procedure, and then anywhere from every 2-4 weeks until their infection is resolved”

Appendix G: Other Cutting Techniques

Type of Cutting Technique	Description	Pros	Cons
Needle	<i>Myringotomy Needle, with outer tube including: Flexible Needle, outer diameter 0.7 mm Outer Tube, outer diameter 1.5 mm</i> https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/A_SSETS/2165700.pdf	A needle used for puncturing the eardrum of a small animal	Tufts doctors do not like the design, it does not provide a large enough incision for the interior to be rinsed
Drilling	<i>Mechanized drill bit that punctures and tears the membrane</i>	Fast,	Too harsh.. Could tear the membrane, reduce ability to heal. Drilling typically used for bone, not tissue
Chemical	<i>Chemical substances on the tip of a knife,</i>	Dissolve the membrane and reduce need for a cut, could create a cut larger than 5 Fr.	Feasibility - difficult to procure the right chemicals, would need sufficient testing to ensure the safety of the animals/no long term damages/safety of the vets
Surgical Knife	<i>Double edged knife for piercing</i>	Creates a puncture	Simplistic
Scalpel	<i>General types of scalpel blades to investigate</i> https://vetmed.tamu.edu/files/etc/modules/CSS/02_Scalpels/18/CSS_Scalpels.pdf	Creates a puncture, but moreso used for cutting than puncturing.	Simplistic, only cuts with one edge
Micro laser for cauterizing/incisions	<i>Small laser designed for dermatology, can be focused from a distance to create a larger incision</i>	Small, flexible, can cut large incisions	Extremely out of budget

Appendix H: Individual Design Matrix Charts & Total

Dr. Lam Design Matrix

	Design Idea	Safety	Cost	Compatibility	Versatility	Feasibility	
	Weight (1-10)	5	3	7	9	8	TOTALS:
Sheathing	1-Catheter	10	10	10	4		
	Final Value	50	30	70	36	0	186
	2-Frog Tongue	10	4	10	10		
	Final Value	50	12	70	90	0	222
Knife	1-Fixed	5	1	5	7		
	Final Value	25	3	35	63	0	126
	2-Interchangeable Blade	5	3	6	6		
	Final Value	25	9	42	54	0	130
	3-Phillips Head	5	5	8	8		
	Final Value	25	15	56	72	0	168
	4-Plastic	5	10	8	5		
	Final Value	25	30	56	45	0	156
Retracting Mechanism	1-None	1	8	8	3		
	Final Value	5	24	56	27	0	112
	2-Ball point	10	5	10	6		
	Final Value	50	15	70	54	0	189
	3-Trigger	10	5	10	6		
	Final Value	50	15	70	54	0	189
	4-Reverse Scissors	5	2	10	6		
	Final Value	25	6	70	54	0	155

Dr. Zewe Design Matrix

	Design Idea	Safety	Cost	Compatibility	Versatility	Feasibility	
--	-------------	--------	------	---------------	-------------	-------------	--

	Weight (1-10)	5	3	7	9	8	TOTALS:
Sheathing	1-Catheter	7	10	10	4		
	Final Value	35	30	70	36	0	171
	2-Frog Tongue	7	5	10	8		
	Final Value	35	15	70	72	0	192
Knife	1-Fixed	7	10	6	2		
	Final Value	35	30	42	18	0	125
	2-Interchangeable Blade	3	5	7	7		
	Final Value	15	15	49	63	0	142
	3-Phillips Head	9	5	7	6		
	Final Value	45	15	49	54	0	163
	4-Plastic	7	10	5	5		
	Final Value	35	30	35	45	0	145
Retracting Mechanism	1-None	3	10	7	5		
	Final Value	15	30	49	45	0	139
	2-Ball point	8	5	8	8		
	Final Value	40	15	56	72	0	183
	3-Trigger	7	5	5	5		
	Final Value	35	15	35	45	0	130
	4-Reverse Scissors	7	4	8	10		
	Final Value	35	12	56	90	0	193

Kaitlin Design Matrix

	Design Idea	Safety	Cost	Compatibility	Versatility	Feasibility	
	Weight (1-10)	5	3	7	9	8	TOTALS:

Sheathing	1-Catheter	10	10	10	10	10	
	Final Value	50	30	70	90	80	320
	2-Frog Tongue	8	4	8	8	6	
	Final Value	40	12	56	72	48	228
Knife	1-Fixed	8	6	10	9	10	
	Final Value	40	18	70	81	80	289
	2-Interchangeable Blade	7	7	10	9	10	
	Final Value	35	21	70	81	80	287
	3-Phillips Head	5	3	8	8	6	
	Final Value	25	9	56	72	48	210
	4-Plastic	9	9	10	4	8	
	Final Value	45	27	70	36	64	242
Retracting Mechanism	1-None	7	10	10	10	10	
	Final Value	35	30	70	90	80	305
	2-Ball point	9	9	8	8	8	
	Final Value	45	27	56	72	64	264
	3-Trigger	9	7	9	8	8	
	Final Value	45	21	63	72	64	265
	4-Reverse Scissors	8	6	9	9	7	
	Final Value	40	18	63	81	56	258

Nicole Design Matrix

	Design Idea	Safety	Cost	Compatibility	Versatility	Feasibility	
	Weight (1-10)	5	3	7	9	8	TOTALS:
Sheathing	1-Catheter	10	10	9	10	9	
	Final Value	50	30	63	90	72	305

	2-Frog Tongue	9	3	7	9	6	
	Final Value	45	9	49	81	48	232
Knife	1-Fixed	7	8	7	9	9	
	Final Value	35	24	49	81	72	261
	2-Interchangeable Blade	4	8	7	10	7	
	Final Value	20	24	49	90	56	239
	3-Phillips Head	6	3	5	8	5	
	Final Value	30	9	35	72	40	186
	4-Plastic	8	9	8	8	8	
	Final Value	40	27	56	72	64	259
Retracting Mechanism	1-None	5	10	8	6	6	
	Final Value	25	30	56	54	48	213
	2-Ball point	8	6	7	6	8	
	Final Value	40	18	49	54	64	225
	3-Trigger	8	6	7	8	6	
	Final Value	40	18	49	72	48	227
	4-Reverse Scissors	7	4	7	8	6	
	Final Value	35	12	49	72	48	216

Connor Design Matrix

	Design Idea	Safety	Cost	Compatability	Versatility	Feasibility	
	Weight (1-10)	5	3	7	9	8	TOTALS:
Sheathing	1-Catheter	7	8	7	8	8	
	Final Value	35	24	49	72	64	244
	2-Frog Tongue	6	3	6	6	3	

	Final Value	30	9	42	54	24	159
Knife	1-Fixed	7	4	3	3	7	
	Final Value	35	12	21	27	56	151
	2-Interchangeable Blade						
		5	8	6	7	8	
	Final Value	25	24	42	63	64	218
	3-Phillips Head	4	4	4	4	4	
	Final Value	20	12	28	36	32	128
	4-Plastic	7	9	6	4	8	
	Final Value	35	27	42	36	64	204
	5-Reverse Scissors	6	4	8	8	4	
Final Value	30	12	56	72	32	202	
Retracting Mechanism	1-None	2	10	3	3	10	
	Final Value	10	30	21	27	80	168
	2-Ball point	6	6	8	8	7	
	Final Value	30	18	56	72	56	232
	3-Trigger	7	4	7	6	5	
	Final Value	35	12	49	54	40	190

Mike Design Matrix

	Design Idea	Safety	Cost	Compatibility	Versatility	Feasibility	
	Weight (1-10)	5	3	7	9	8	TOTALS:
Sheathing	1-Catheter	9	9	8	7	10	
	Final Value	45	27	56	63	80	271
	2-Frog Tongue	8	4	8	7	6	
	Final Value	40	12	56	63	48	219

Knife	1-Fixed	8	8	7	4	9	
	Final Value	40	24	49	36	72	221
	2-Interchangeable Blade	8	7	7	9	6	
	Final Value	40	21	49	81	48	239
	3-Phillips Head	6	5	6	5	6	
	Final Value	30	15	42	45	48	180
	4-Plastic	9	10	7	4	9	
	Final Value	45	30	49	36	72	232
Retracting Mechanism	1-None	3	9	8	4	10	
	Final Value	15	27	56	36	80	214
	2-Ball point	8	7	8	6	8	
	Final Value	40	21	56	54	64	235
	3-Trigger	8	5	8	6	7	
	Final Value	40	15	56	54	56	221
	4-Reverse Scissors	5	2	7	6	5	
	Final Value	25	6	49	54	40	174

Jack Design Matrix

	Design Idea	Safety	Cost	Compatibility	Versatility	Feasibility	
	Weight (1-10)	5	3	7	9	8	TOTALS:
Sheathing	1-Catheter	8	9	7	5	9	
	Final Value	40	27	49	45	72	233
	2-Frog Tongue	6	3	4	8	6	
	Final Value	30	9	28	72	48	187
Knife	1-Fixed	7	3	5	6	7	
	Final Value	35	9	35	54	56	189

	2-Interchangeable Blade	6	9	4	5	8	
	Final Value	30	27	28	45	64	194
	3-Phillips Head	6	6	5	6	6	
	Final Value	30	18	35	54	48	185
	4-Plastic	6	8	5	4	8	
	Final Value	30	24	35	36	64	189
Retracting Mechanism	1-None	2	10	7	3	9	
	Final Value	10	30	49	27	72	188
	2-Ball point	7	8	3	3	9	
	Final Value	35	24	21	27	72	179
	3-Trigger	6	7	8	4	6	
	Final Value	30	21	56	36	48	191
	4-Reverse Scissors	3	8	5	8	8	
	Final Value	15	24	35	72	64	210

Appendix I: Pictures of Initial Designs

Design 2: "Trigger Shank"

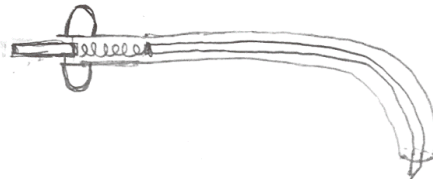
- Think biopsy forceps, but with a knife



Design 1: "Ballpoint Shank"

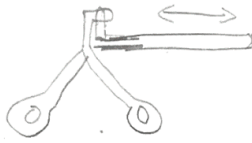
Think of a pen - spring mechanism w/ flexible wire

- Blade is sheathed and extends with push of a button
- Automatically retracts



Design 2: "Trigger Shank"

- Think biopsy forceps, but with a knife



Design 3 "Reverse Scissors"

- outside edges are sharp

closed

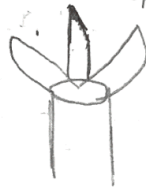
open



Design 4: "Frog Tongue"

closed

open



Fixed knife & Exacto (simple knife)

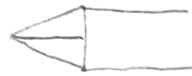


Phillips head knife

Front



Side



Isometric

Appendix J: Force Experiment

Materials:

- Force-Sensitive Resistor
- Arduino UNO microprocessor
- Relevant components
 - Red LED
 - Wire connectors
 - 2.2K Ω resistor
 - 10K Ω resistor
- 5 Fr. Catheter

Procedure:

1. Gather all materials.
2. Connect one lead of the Force Sensitive Resistor (FSR) to the 5V port of the Arduino UNO board.
3. Connect the other lead of the FSR to the empty row of the breadboard.
 - a. Connect into this row:
 - i. A wire from GND (port adjacent to 5V out).
 - ii. A wire from the A0 (analog serial monitoring port 0).
 - b. Between the GND and A0 wires, connect the 10K Ω resistor.
4. Connect a wire from the Digital -11 port of the Arduino UNO to an empty row on the breadboard.
5. Connect the red LED to this row, with the polarity oriented according to the diagram, Figure A below.
6. Connect the 2.2K Ω resistor from the open end of the LED into the GND port on the Digital side of the Arduino UNO board.
7. Connect USB wire from an external computer to the Serial port of the Arduino UNO board.
8. Open MQP_Final.iso (this is a custom-written sketch for the serial processor. This code can be found in Appendix K).
9. Re-compile the sketch to scan for potential errors, then upload the sketch to the board. The small LEDs near the Serial port of the Arduino UNO should change orientation, and begin to flash as the device fetches data from the analog port.
10. Open the Serial Monitor in the Tools menu of the Arduino program.
 - a. This should give readings of the resistance recorded from the FSR, as well as the conversion to Newtons.
11. Lay out all the materials (Figure B).

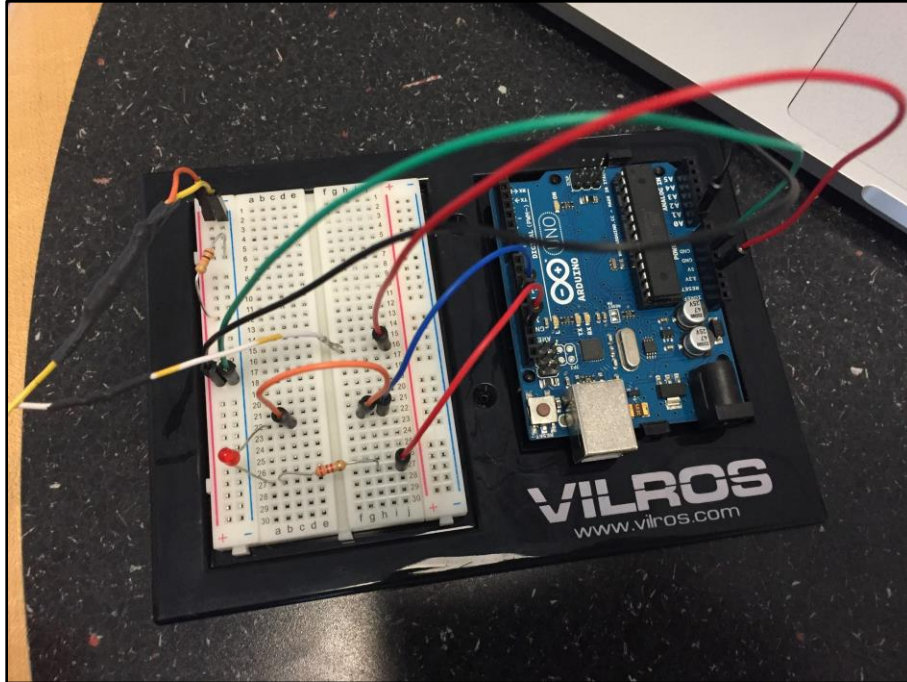


Figure A: Arduino circuit setup

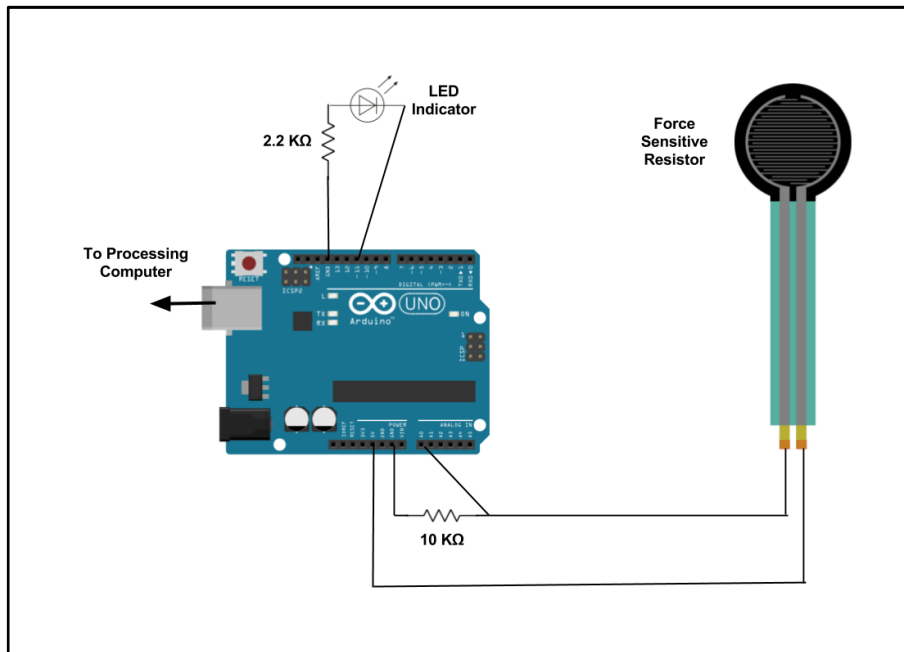


Figure B: Total assembly of force transducer circuit with indicator LED and Arduino UNO microprocessor

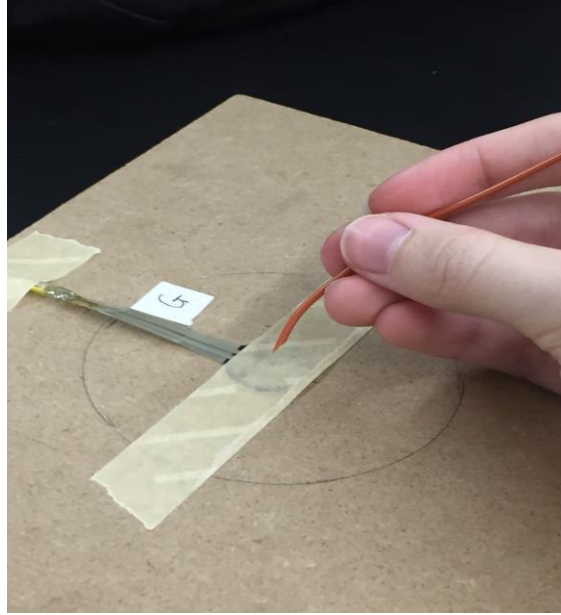


Figure C: Testing the force applied by a catheter

12. Using a blade, cut the 5 Fr. catheter at a 60 degree angle while the catheter is still inside the packaging.
13. Mimic the puncturing force used when performing myringotomies (x10 each)
14. Determine the maximum force from all the trials and record the data.

Appendix K: Experiment 1 Arduino Code

```
/* FSR testing sketch.

Author: Connor Tower
Code constructed with Free assistance from:
For more information see www.ladyada.net/learn/sensors/fsr.html */

int fsrAnalogPin = 0; // FSR is connected to analog 0
int LEDpin = 11;      // connect Red LED to pin 11 (PWM pin)
int fsrReading;      // the analog reading from the FSR resistor
                    divider
int LEDbrightness;

void setup(void) {
  Serial.begin(9600); // We'll send debugging information via the
Serial monitor
  pinMode(LEDpin, OUTPUT);
}

void loop(void) {
  fsrReading = analogRead(fsrAnalogPin);
  Serial.print("Analog reading = ");
  Serial.println(fsrReading);

  // we'll need to change the range from the analog reading (0-1023)
down to the range
  // used by analogWrite (0-255) with map!
  LEDbrightness = map(fsrReading, 0, 1023, 0, 255);
  // LED gets brighter the harder you press
  analogWrite(LEDpin, LEDbrightness);

  delay(100);
}
```


Appendix L: Bovine Tendon Blade Experiment



Figure D: Blade types used for testing

Materials:

- Lancet Blade
- Triangular Blade
- Curved Blade
- Bovine tendons
- 5Fr catheter
- Instron 5544
- Cryostat
- DPBS (without calcium and magnesium)
- Uncharged microscope slides
- Micro centrifuge tubes
- Forceps
- Scalpel blade (for cutting tendon)
- Saline
- Scissors
- Gloves

Procedure:

1. Gather all materials
2. Obtain and prepare the bovine tendons

- a. Obtain a bovine tendon from the grocery store.
- b. While wearing gloves, clean the tendon by removing fat with scissors and scalpel blade such that the tendon is isolated. Dispose of the fat and other waste in a biohazard bag.
- c. Cut off a piece of the tendon that is approximately the size of your thumb (1.5-2.5 inches) with the scalpel blade.



Figure E: Cleaned bovine tendon

- d. Cut this resulting piece into fourths by using a scalpel blade.



Figure F: Frozen piece of bovine tendon

- e. Place one of these pieces of bovine tendon in Tissue-Tek O.C.T Compound gel, and freeze it for 15 minutes at -80 degrees Celsius.
- f. After 15 minutes, place the frozen sample on the chuck, the tissue holder component of the cryostat (can be seen in the figure below)

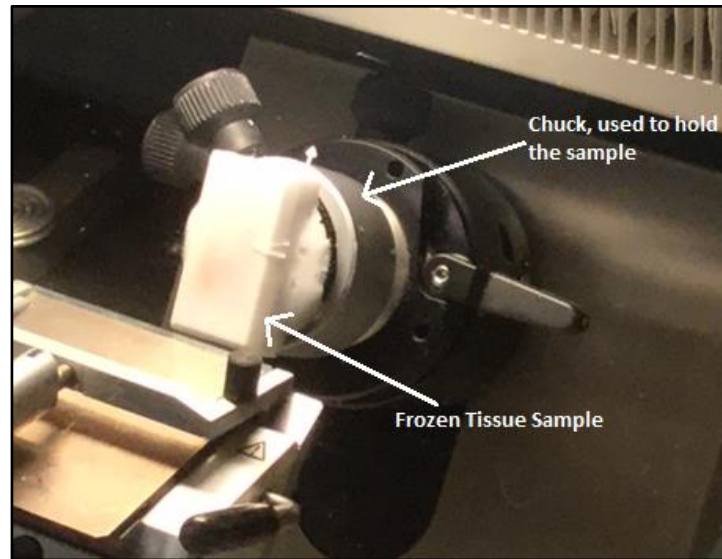


Figure G: Cryostat and tendon setup

- g. Place a polytetrafluorethylene (PTFE) blade on the cryostat and use it to cut the tendon at various thicknesses by changing the settings on the cryostat (50, 100 and 150 micrometers).



Figure H: Tendon/knife setup

- h. Place the samples on uncharged slides so that the samples could be removed more easily for further testing. The slides were warm compared to the frozen sample so that the sample would stick on them initially, but could be removed from the slide once the samples reached room temperature.



Figure I: Cut bovine tendon on uncharged slides

- i. Make a bath of DPBS that does not include calcium or magnesium.
- j. Submerge the samples into the DPBS to detach the samples from the microscope slides.
- k. Place the samples over the tops of the microcentrifuge tubes such that they look like the figures below.



Figure J: Bovine tendon samples on microcentrifuge tubes

- l. If you do not want to test all of the samples immediately, they may be stored overnight in a humidity tray set to 4 degrees Celsius.
- m. The samples on the microcentrifuge tubes may then be brought to the Instron 5544 for testing.
3. Create a Test Method in BlueHill to use the Instron 5544 on membrane samples.
 - a. The method is a simple compression test, with a few key parameters.
 - i. Set the test to ramp at 5 mm/min. This speed guarantees visibility as the blade enters the membrane, and allows time to observe the membrane/blade interaction when contact is made.

- ii. Do not precycle or set a preload. The samples are extremely fragile, and experience forces of less than 1 Newton at the point of failure in some instances.
 - iii. The sample shape is set to a cylinder. This is important, as the samples are stretched over a microcentrifuge cylindrical tube.
 - iv. The End of Test criteria can vary, but in this instance an extension-based restriction was put into place to keep the blade from puncturing far beyond the membrane. Given the thickness of the membrane, the length of the blade, and the depth of the microcentrifuge tube, the extension restriction was set to 50 mm. A second EOT criteria added was a force stopper. Should the measured rate of load experience a 40% change, the test would be stopped.
4. The Instron 5544 is used in tandem with BlueHill to formulate a method for testing.
 - a. First load the tissue sample on a centrifuge tube into the bottom grips of the Instron 5544 and load the top grips with the blade. Adjust the grips so that the blade aligns with the center of the centrifuge tube.
 - b. Open the method on BlueHill.
 - c. Set the physical safety stops on the Instron 5544 to prevent damage to the sample and to the machine. Double check the method safety stops to make sure they are accurate for the test.
 - d. Your sample is ready to test. Click start on the selected BlueHill method. Name the sample so that the results can be saved at completion.
 - e. Once the individual test is complete. Save the results by selecting “Stop.”
 5. Puncture bovine tendon with lancet blade.
 6. Analyze the puncturing forces of the various types of blades and the catheter.

Appendix M: In-Spec 2200 Instron Set-up and Calibration

Materials:

- In-Spec 2200 Instron
- Elvis board
- NI ELVISmx Instrument Launcher-Data logger program
- 2 standard alligator clip leads (red and black)
- MATLAB program

Set up procedure:

1. Turn on the computer, plug in the In-Spec 2200 Instron and Elvis board into the power socket
2. Connect the red lead to the center oscilloscope pin and insert the the other end to the AI0+ on the Elvis Board
3. Connect the black lead to the center oscilloscope pin and insert the other end into the AI0 on the Elvis Board. The Elvis board is shown in Figure L.
4. Make sure both machines are on, and open the NI ELVISmx Instrument Launcher computer program and choose the Data logger application.
5. Select channel ai0 as the chosen data channel.
6. Change the sampling rate to 20 samples per second.
7. Calibrate the In-Spec 2200 Instron (shown in Figure M) by creating a standard curve using a set range of weights. Start with 50gs and add increments of 20g up to 250g.
8. Analyze the data and create a standard curve in MATLAB, an example of which is shown in Figure N.

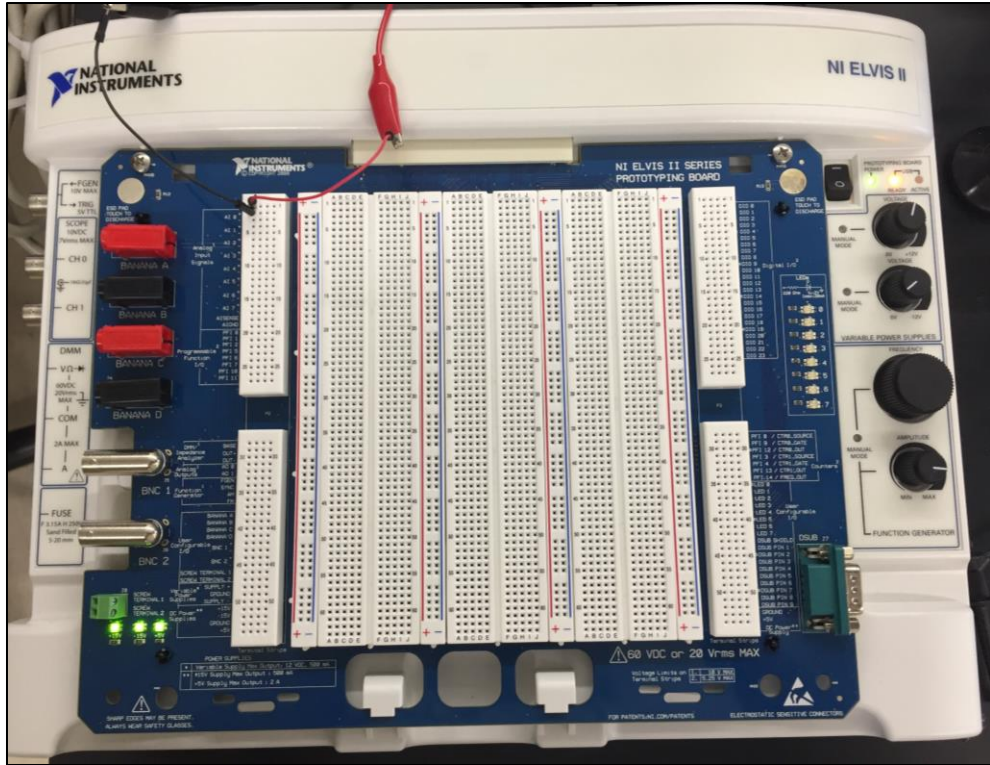


Figure L: Elvis board setup



Figure M: In-Spec 2200

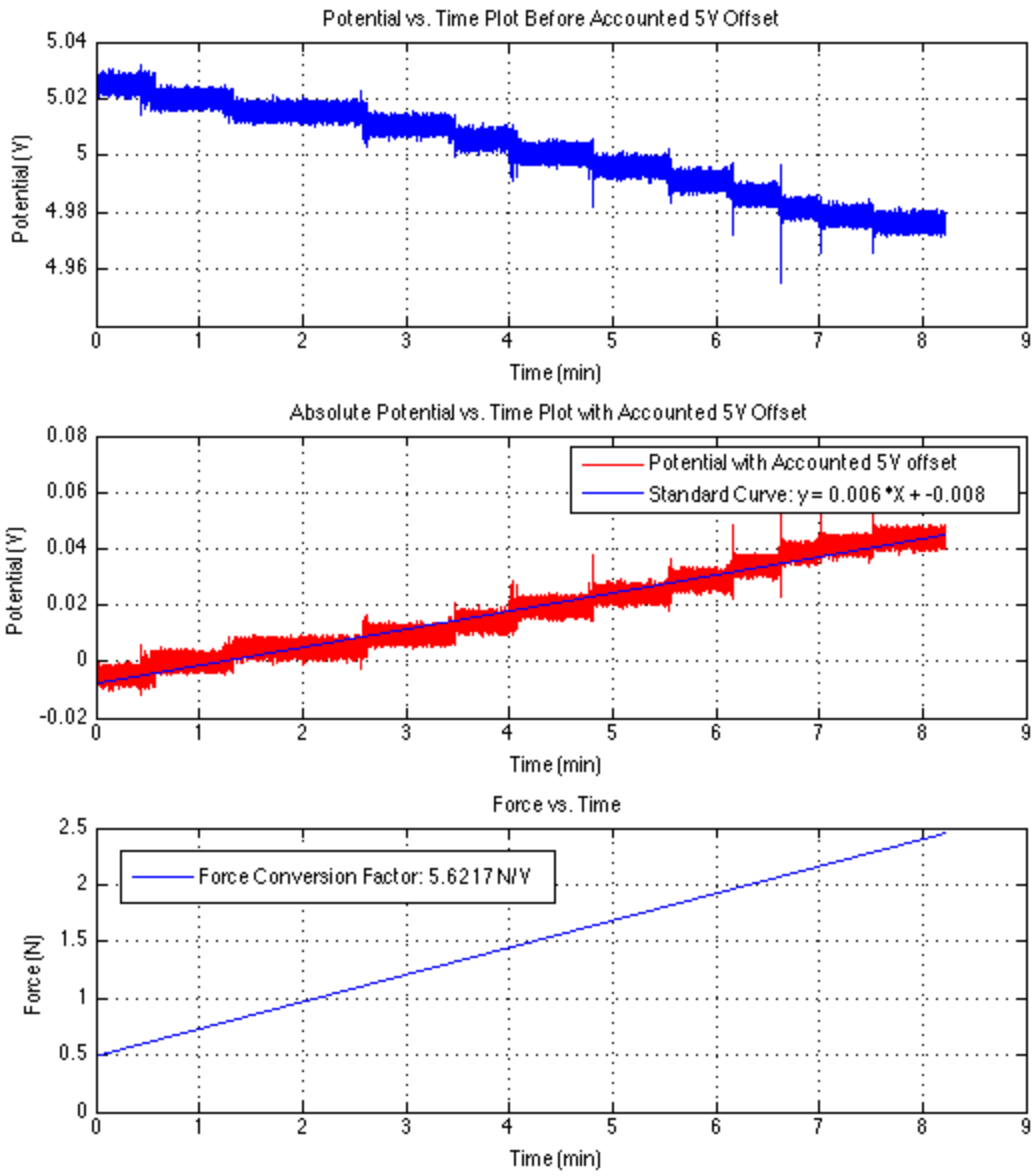


Figure N: MATLAB standard curve

Appendix N: PDMS Curing Protocol

Materials

- Sylgard Silicone Elastomer base (Ellsworth Adhesive #184 SYL ELAST)
- Sylgard Silicone Elastomer curing agent (Ellsworth Adhesive #184 SYL ELAST)
- Gloves (The elastomer reagents are sticky and may be difficult to wash off)

Procedure:

1. Make PDMS
 - a. Weigh 10 parts Sylgard silicone elastomer base and 1 part Sylgard silicone elastomer curing agent. Note: DO NOT MIX THE STOCK SOLUTIONS!!! Use separate weighing materials for each reagent.
 - b. Pour reagents together and thoroughly mix the elastomer base and curing agent.
 - c. Pour the well mixed solution into your mold.
 - d. Degas the PDMS by putting it into a vacuum chamber for at least 1 hour (larger/thicker volumes of PDMS may require more time).
 - e. After degassing, visually inspect the PDMS to ensure that there are no more bubbles. If there are, repeat steps 4 and 5.
 - f. Cure the PDMS by placing the mold into an oven set for 60 °C for at least 1 hour (larger samples may require more time). Cured PDMS can be seen in Figure K.

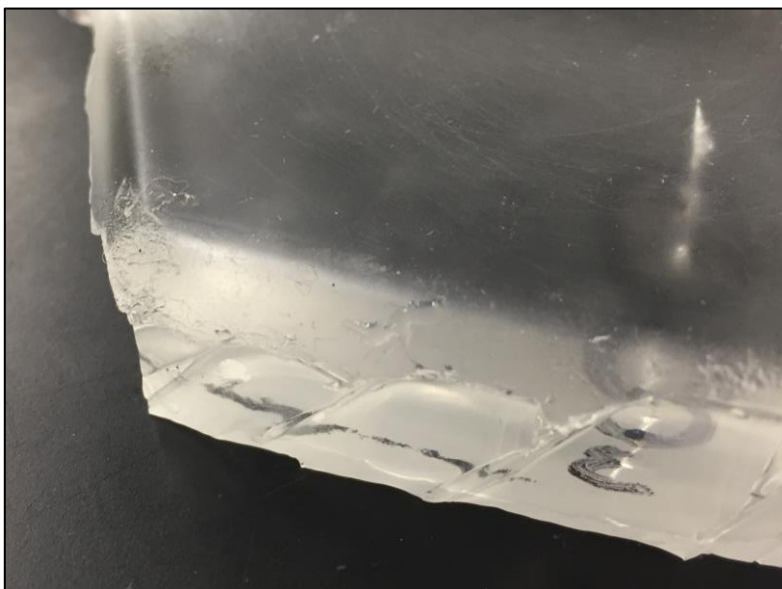


Figure K: PDMS sample

Appendix O: MATLAB Program for Standard Curve

```
%% MQP 50 N Instron Testing
% Author: Connor Tower
clear all; close all; clc;

%% Loading Data, Adjusting Offsets

filename = 'StandardCurveCalibrationTake1.xlsx';
data = xlsread(filename);

% first column of data is just the date, not relevant to this.
time = data(:,2);
volt = data(:,3);

toffset = 3600*time(1);

for i = 1:length(time)
    time(i) = 3600* time(i) - toffset;
end

fig1 = figure;
set(fig1,'position',[50 50 600 800]);

subplot(3,1,1)
plot(time,volt,'b'); grid on;
title('Potential vs. Time Plot Before Accounted 5V Offset')
xlabel('Time (min)'); ylabel('Potential (V)');

% This test was done through pulling on the static transducer.
% Therefore, this data is "negative" what we need it to, and on
the scale
% of 5 V, not 0. So to get true force change data, we'll need
to invert it
% and subtract 5 V

for i = 1:length(volt)
    volt(i) = volt(i) * -1; % Reversing pull data into absolute
force
    volt(i) = volt(i) + 5.02; % Accounting for the 5.02V offset
end

subplot(3,1,2)
plot(time, volt,'r'); grid on;
```

```

title('Absolute Potential vs. Time Plot with Accounted 5V
Offset')
xlabel('Time (min)'); ylabel('Potential (V)');
hold on;

%% Applying Known Force Values to Generate a Force Curve

% KNOWN: 50 g at t = 1, 250 g at t = end
f1 = (50/1000) * 9.8;
fend = (250/1000) * 9.8;

p = polyfit(time,volt,1);
trend = polyval(p,time);
plot(time,trend);

l2 = legend('Potential with Accounted 5V offset',...
    sprintf('Standard Curve: y = %0.3f *X + %0.3f',...
    p(1),p(2)));

subplot(3,1,3)
fline = linspace(f1,fend,length(volt));
plot(time,fline,'b'); grid on;
title('Force vs. Time')
xlabel('Time (min)'); ylabel('Force (N)')

l3 = legend(sprintf('Force Conversion Factor: %0.4f N/V',...
    (fend/volt(end))/10));
set(l3,'position',[0.23 0.27 0.2 0.04])

fprintf('Potential Line Equation: y = %0.4f *X + %0.4f\n',...
    p(1),p(2));
fprintf('Starting Mass: 50g = %0.2f N\n',f1);
fprintf('Ending Mass: 250g = %0.2f N\n',fend);

%% Generation of a Conversion Factor for Potential

force1 = volt(1)/f1;
force2 = 10*(volt(end)/fend);

fprintf('Conversion Factor 2: %0.4f \n\n',force2);

```

Appendix P: Cadaver Form

**Cummings School of Veterinary Medicine at Tufts University
Anatomy Lab Request for Dog/Cat Cadaver Specimens**

CLINICAL SCIENCES USE FORM

All Clinical Sciences requests should be submitted to
Dr. Webster (Cynthia.Leville-Webster@tufts.edu) **3 weeks in advance** of the date needed

Reviewed and approved by _____
Dr. Cyndie Webster, Associate Chair

Priority level: ³ _____ 1 (highest priority) to 5 (lowest priority)

Date: 01-10-2017

Date Required: 01-30-2017

Requestor: Connor Tower

Research or Course/Lab

Species: Canine & Feline

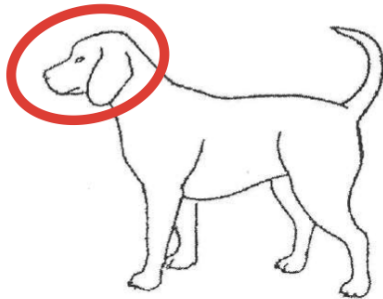
Course name: WPI Major Qualifying Project

Dept. ID/Grant # for research _____

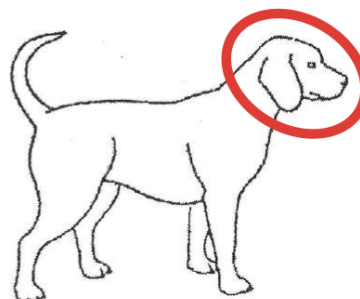
Course director: _____

<u>Anatomic Region</u>	<u>Number of Specimens</u>
1. <u>Canine Head</u>	<u>2</u>
2. <u>Feline Head</u>	<u>2</u>
3. _____	_____

Use the diagram below to indicate the level of transaction of each limb or head requested. Also indicate if sagittal sections are required.



Left Side



Right Side

All specimens are to be used for teaching or research purposes only.

Signature: Connor Tower ext or beeper number _____

Procurement Policy: Department of Clinical Sciences Use

Specimen requests from the **Department of Clinical Sciences** must be sent to Dr. Cyndie Webster, Associate Chair (Cynthia.Leville-Webster@tufts.edu) **3 weeks in advance**. Dr. Webster will review the request, approve it if all of the information is complete, and assign a priority level on a 1 (highest) to 5 (lowest) scale. Student teaching has the highest priority, followed by resident training, Tufts research, continuing education, and collaborator research by outside parties.

Approved requests will be forwarded to Joe Popowski, Lab Coordinator, via email (joseph.popowski@tufts.edu). Joe will only procure specimens after he receives an approved form from the Department of Clinical Sciences office. He will not accept verbal or email requests. A Dept ID or grant number is required, **for all non-teaching accounts only**, to charge a fee for the preparation work and supplies. There is no fee for teaching accounts and student groups. All specimens will be processed by the lab coordinator. Requests should be made in advance and must take into account the regular work schedule and time off of the lab coordinator. Please allow extra time for larger orders, very specific orders or special procedures needed such as defleshing. There will be an extra charge for any requests with less than three weeks' notice or any special procedures required to process the specimen. **Other species are available on a limited basis.**

PRICE SCHEDULE for non-teaching accounts

Canine or Feline Limbs	\$25.00
Canine or Feline Limb w/pelvis	\$35.00
Canine or Feline Head	\$25.00
Canine or Feline Head w/jaws, mandible, maxilla	\$25.00
Canine or Feline Knees	\$25.00
Canine or Feline Ovaries & Reproductive Tract (if available)	\$25.00
Canine or Feline Whole Cadaver	\$10.00
Canine or Feline Embalmed	\$100.00
Bagging charge per specimen	\$ 5.00
Delivery charge	\$10.00
Less than three weeks' notice	add. \$25.00
Special preparation (sawing, defleshing, etc.) priced per specimen	

If delivery is not required, you will be notified when the specimen(s) are ready to pick up. The specimen(s) will be disposed of if not picked up within 5 days of notification.

Appendix Q: Force to Puncture Membranes

Intestinal Submucosa Materials:

1. Intestinal submucosa (Natural casing)
2. Pins (short pipe cleaners)
3. In-Spec 2200 Instron (50N load cell)
4. Blade (human myringotomy blade)
5. Platform to pin the intestinal submucosa
6. Ear from dog cadaver
7. PDMS (used to hold tympanic membrane)
8. 5 Fr. Catheter

Intestinal Submucosa Force Testing Procedure:

1. Soak the intestinal submucosa in lukewarm water for 30 minutes.
2. Cut the intestinal submucosa into 3 inch segments.
3. Open the end of a segment and fill it with water completely by holding the opposite end closed.
4. Make a longitudinal cut down the intestinal submucosa.
5. Stretch the intestinal submucosa completely flat, and pin to a flat surface with an opening in the middle (as seen in Figure O below).
6. Fixture myringotomy blade to the In-Spec 2200 Instron
7. Align the hole with the intestinal submucosa stretched over it under the blade.
8. Run the In-Spec 2200 Instron test.
9. Analyze the results by comparing them to the standard curve created in Appendix O.
10. Repeat steps 1-9 with a 5 Fr. Catheter instead of a myringotomy blade.

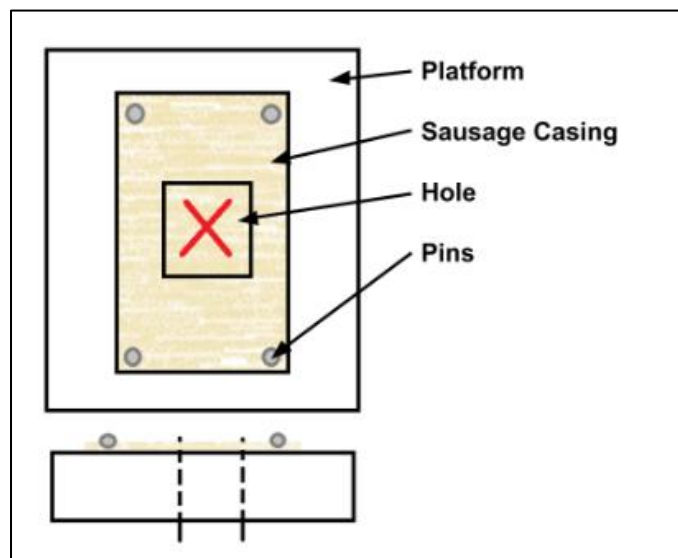


Figure O: Setup for pinning intestinal submucosa to prepare for Instron test

Tympanic Membrane Procedure:

1. Obtain a dog ear from a cadaver
2. Isolate the tympanic membrane by identifying the hammer, as seen in Figure P below.
3. Soak the tympanic membrane in saline for one hour.
4. Fixture myringotomy blade to the In-Spec 2200 Instron
5. Fix the tympanic membrane in place under the myringotomy blade
6. Run the In-Spec 2200 Instron test.
7. Analyze the results by comparing to the standard curve created in Appendix O

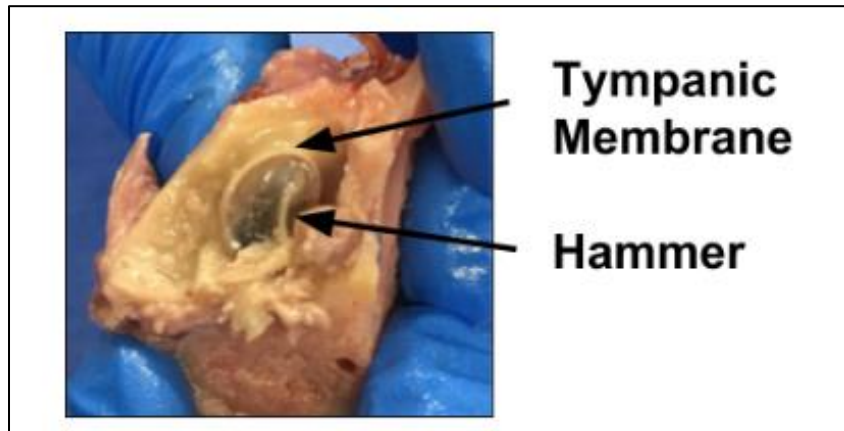


Figure P: Important visual indicators to confirm proper orientation under the Instron

Appendix R: Blade Shape on Tearing

Materials:

- Intestinal submucosa (Natural casing)
- Pins (short pipe cleaners)
- Instron 5544 (2000N load cell)
- Blades (lancet, triangle, curved)
- Platform to pin the intestinal submucosa
- PDMS (used to hold tympanic membrane)

Procedure:

1. Follow steps 1 through 5 in the Intestinal Submucosa Force Testing Procedure to prepare the sample for testing.
2. Using the lancet, triangular and curved blades, puncture the prepared sausage casing using the Instron 5544, as shown below in Figure Q.
3. Qualitatively analyze the holes for size of hole and degree of tearing that occurred during the puncture.
 1. Measure the width of the blade at the desired point of puncture
 2. Measure, with calipers, the incision size
 3. Calculate the percent change of incision size vs. blade width

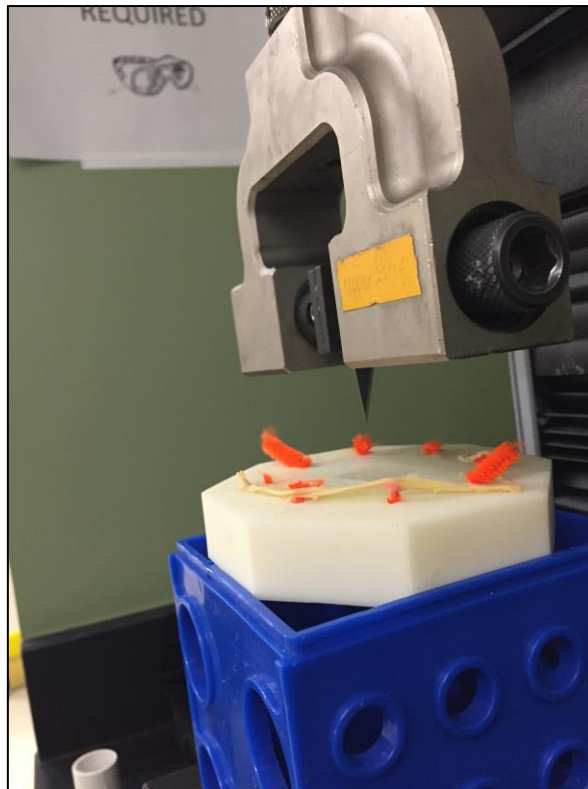


Figure Q: Instron 5544 experimental setup

