



# WPI

## **Design of a Tunneling System for Endoscopic Neurosurgery**

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## Abstract

Endoscopic neurosurgery is a minimally invasive technique used for intraventricular procedures. Typically, a small stainless steel working channel is introduced into the brain to create an opening for the endoscope and microsurgical tools to be inserted during the procedure. Although widely used, surgeons desire greater access and intermittent pressure relief. This project designed and evaluated a flexible sheath and tunneling system to allow for a larger working channel into the brain. Various designs were tested using finite element analysis and a novel *in vitro* gel model. The final proposed design increased the working area by 500% in its expanded state, while not significantly exceeding the pressure on the brain tissue caused by the current system.

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## **Authorship**

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## Chapter 1: Introduction

The brain is a very complex organ that controls most vital functions in the human body, including cognition, speech, movement, organ regulation, and homeostasis. These critical neurological functions are threatened upon the occurrence of various brain conditions or diseases, such as tumors, cysts, trauma, hydrocephalus, aneurysms, and stroke, among others. Statistically speaking, approximately 23,000 malignant brain tumors will be diagnosed in 2014, half of which will be fatal (American Cancer Society, 2014). Additionally, hydrocephalus, or excess fluid on the brain, is the most common reason for brain surgery in children. Although it affects every 2 out of 1,000 newborns, it also occurs in hundreds of thousands of other Americans (Hydrocephalus Association, 2014).

In order to restore and maintain healthy brain function, these conditions must be addressed quickly. The preferred approach to treatment for most of these conditions is surgery. Although common, craniotomies, or open brain surgery, remove substantial amounts of cranial bone to reach deep regions of the brain, exposing large areas of tissue. For conditions that occur in these deep regions, endoscopic neurosurgery is the preferred, less invasive, alternative. In this procedure, a small stainless steel working channel is introduced into the brain, creating an opening for a fiber-optic endoscope and microsurgical tools to be inserted. When feasible, a minimally invasive approach is the desired choice of neurosurgical procedure. Many surgeons prefer to “use minimally-invasive treatments whenever these techniques can achieve comparable or better results compared to standard open surgical procedures” (UCLA Neurosurgery, 2014).

Karl Storz™, the gold standard for endoscopic neurosurgical equipment, is used in approximately 70% of all endoscopic neurosurgical procedures according to Dr. Cataltepe, UMMC Neurosurgeon. To access the ventricles of the brain, a stainless steel multi-part tunneling system is used to push aside brain tissue using an obturator, or blunted-tip stylus. The obturator is placed in a rigid outer guide, and together, this system is pushed through brain tissue to create a tunnel to the affected area. Once the tunneling system reaches the ventricles, the obturator is removed, leaving the rigid outer guide to serve as a channel for the endoscope and instruments. This working channel exerts constant pressure on the brain tissue for the duration of the surgery,

which can last up to two hours. The rigid and small diameter of this working channel also restricts surgeons to parallel tool and endoscope motion in a surgery where angular motion would be beneficial. Although this system is widely used, surgeons desire greater access and intermittent pressure relief. The collapse and flexion of the working channel between insertions of the microsurgical tools and endoscopes would minimize tissue damage when using a larger tunnel. Therefore, a flexible and semi-collapsible sheath design provides the solution to the current limitations of the rigid system.

This project designed and evaluated a flexible sheath and tunneling system to allow for a larger working channel into the brain, while simultaneously relieving pressure on brain tissue. Evaluation of design alternatives with increased diameters and resulting pressures was done with FEA software. A novel *in vitro* viscoelastic gel model was used to provide validity to the results gathered through FEA model. The gel model was also beneficial in helping select the proper working channel material using image analysis. The final design increased working area by approximately 500% without exceeding stresses of the current system in critical regions.

## Chapter 2: Literature Review

### 2.1 Anatomy of the Human Brain

The brain is a major vital organ that controls every function of the body. It is housed in the bone structure called the cranium and is part of the central nervous system, which also includes the twelve cranial nerves and spinal cord. Between the skull and the brain are three layers of tissue called the meninges. The outermost layer is called the dura mater, which consists of two layers of white non-elastic membrane. The outer part of this is the periosteum and the inner part is the meningeal layer. The subdural space separates the dura mater from the next layer, called the arachnoid. This arachnoid consists of a thin, elastic membrane with blood vessels. Separating the arachnoid and the innermost layer is the subarachnoid space, where the cerebrospinal fluid flows. Next, the innermost layer, called the pia mater, follows the folds and contains blood vessels that run deep into the brain surface ("American Association of Neurological Surgeons," 2006).

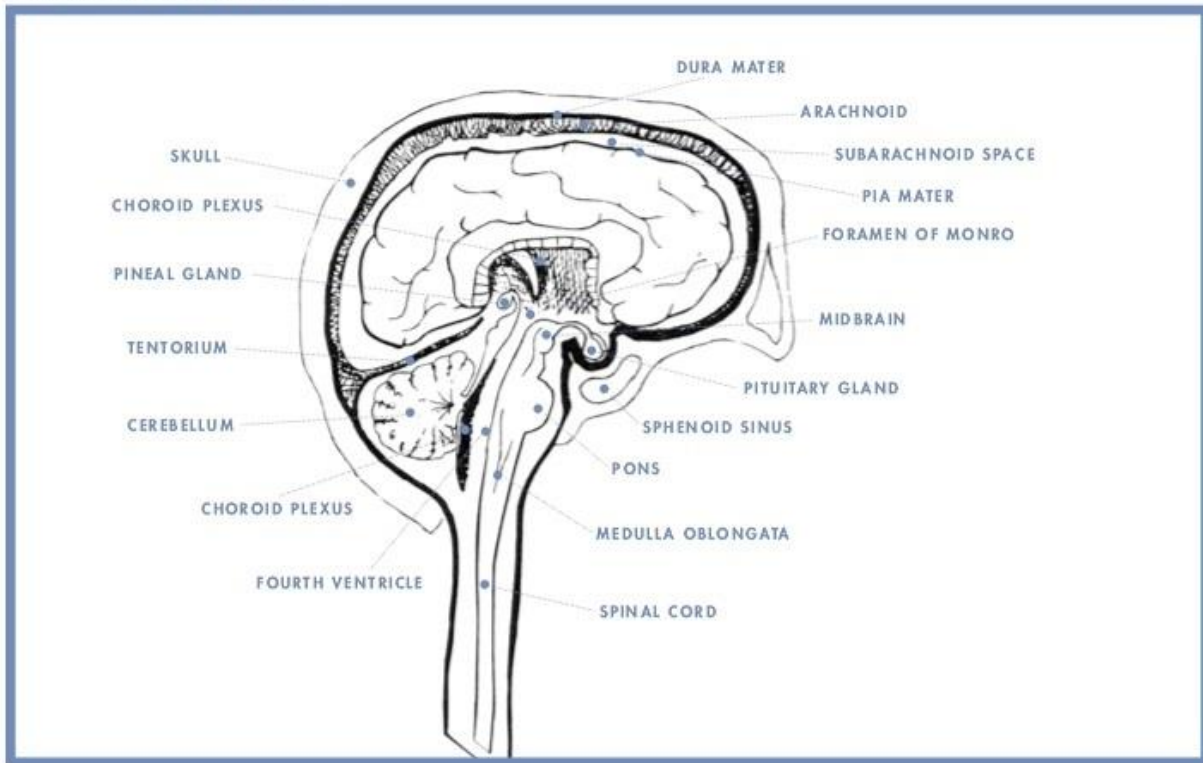
The brain contains small grooves called sulci and large grooves called fissures. It is separated into the left and right hemispheres by the longitudinal fissure, yet still connected by the corpus callosum, allowing it to relay messages in between. The brain cells are called neurons or glial cells, and send and receive impulses or signals to and from the rest of the body. Glial cells are non-neuronal cells that outnumber neurons 50:1, and provide bodily support, nutrition, homeostasis, and signal transmission. These cells also form myelin ("American Association of Neurological Surgeons," 2006).

Cerebrospinal fluid (CSF), as mentioned above, surrounds the brain and spinal cord. It is a clear and watery liquid that provides cushion from injury and is constantly being absorbed and replenished by the body. Specifically, CSF is produced in the hollow ventricles of the brain, a region named the choroid plexus ("American Association of Neurological Surgeons," 2006).

Foramen, or holes, and tubes connect the four ventricular cavities in the brain. The lateral ventricles enclosed in the cerebral hemispheres communicate with the third ventricle located at the center of the brain through the Foramen of Munro. This third ventricle is connected to the

fourth ventricle below it through a tube called the Aqueduct of Sylvius. The third ventricle is housed at the base of the brain with the walls being the thalamus and the hypothalamus (Busey).

#### SIDE VIEW OF THE BRAIN



**Figure 1: Parts of the Brain (American Brain Tumor Association, 2014)**

Different parts of the brain shown in Figure 1 perform different functions. Communication on the right side of the brain causes function on the left side of the body, and vice versa. Disruptions of these pathways from injury, conditions, or disease can greatly affect communication of the brain, leading to loss of function.

For medical terminology purposes, the brain can be broken up into planes. The median plane runs lengthwise through the middle vertically; the sagittal plane runs parallel to the median, but off the main axis; the coronal plan is perpendicular to the median, running between the ears; and the horizontal plane runs parallel to the ground if the person is standing ("American Association of Neurological Surgeons," 2006).

## 2.2 Diseases of the Brain

Endoscopic neurosurgery is a surgical technique used in treating various brain conditions including tumors, cysts, and hydrocephalus. The location and other factors of these conditions determine if endoscopic surgery can be a treatment option. Brain tumors are an abnormal growth of tissue in the brain that can be either benign or malignant. There are two types of brain tumors; primary tumors and secondary tumors. A primary tumor is one that originates in the brain, whereas a secondary tumor, which is four times more common, occurs when cancer starts somewhere else in the body and spreads into the brain. Secondary, or metastatic tumors, typically spread from breast cancer, colon cancer, kidney cancer, lung cancer, or skin cancer according to John Hopkins Medicine ("About Brain Tumors," 2013). Brain tumors are the second leading cause of death due to cancer in children under the age of 20 and males ages 20-39 as of March 2012 ("Central Brain Tumor Registry of the United States: Fact Sheet,"). In 2014 more than 23,000 malignant brain tumors will be diagnosed (American Cancer Society, 2014). These statistics show how improving the treatment of brain tumors can help doctors treat patients in need.

Brain tumors found in children are different from tumors often found in adults, as they typically start in different parts from different cells. Common symptoms of brain tumors are headaches, seizures, personality or behavior changes, vision changing, and memory loss, along with other symptoms ("About Brain Tumors," 2013). Additionally, these symptoms are more prominent in children, so tumors are detected earlier. These effects allow children a better chance of surviving a brain tumor than adults. The most common type of tumors in children are gliomas that come from glial cells found in the supportive tissue in the brain. The first choice of treatment for these pediatric gliomas is removal using endoscopic neurosurgery.

A cyst is another condition that is treated with endoscopic surgery. Cysts are similar to tumors because they are a mass found in the brain; however, instead of a mass of tumor cells, a cyst is filled with fluid and can vary in size and location. For example, a colloid cyst occurs in the third ventricle. The symptoms can vary by the location of the cyst and although cysts are not



cancerous, they oftentimes affect vital functions of the brain and can cause serious tissue damage (Schiff, 2010).

Another condition, called hydrocephalus, occurs when excess cerebrospinal fluid accumulates within the ventricles. There are three different types of hydrocephalus known as Normal Pressure Hydrocephalus, Obstructive Hydrocephalus, and Congenital Hydrocephalus. Normal Pressure Hydrocephalus (NPH) occurs when there is an imbalance of cerebrospinal fluid in the brain. This can cause gait and balance problems, urinary incontinence, and dementia. NPH is usually found in older people and can be caused from a traumatic fall, injury, or illness. Obstructive Hydrocephalus is caused by an obstruction of the communication between the ventricles. This type can be found in all ages and common symptoms are vision problems and headaches. Congenital Hydrocephalus is often found at birth and the reasons are unknown as to where it comes from. The symptoms are similar to NPH, such as balance problems, urinary incontinence, and cognitive memory impairment ("Hydrocephalus Center: Diseases and Conditions," 2013).

### **2.3 Surgical Approaches for Brain Conditions**

There are several different types of brain surgery techniques used by surgeons. The choice of the procedure is based on both preference and purpose. The two most common techniques compared for design purposes are craniotomies and neuroendoscopic procedures. Although both procedures can utilize endoscopic surgical cameras and intraoperative image monitoring, a craniotomy is highly invasive. Unlike endoscopic neurosurgery, where only a small hole is bored through the skull, a craniotomy requires the removal of a large portion of the bone, exposing great amounts of brain tissue. This piece of the skull, known as the bone flap, is restored after the surgery is complete. Although risks of both craniotomies and neuroendoscopic approaches are similar, with potential causes of infection, bleeding, blood clots, brain swelling, unstable blood pressure, etc., since the craniotomies are more invasive, their risk potential is much higher (What is a Craniotomy: Johns Hopkins Comprehensive Brain Tumor Center, 2013). Neuroendoscopy induces less pain, with a quicker patient recovery and minimal scarring. It also allows surgeons' access to parts of the brain unreachable by traditional surgery. For those reasons, surgeons prefer to use the least minimally invasive approach possible (UCLA Neurosurgery, 2014).

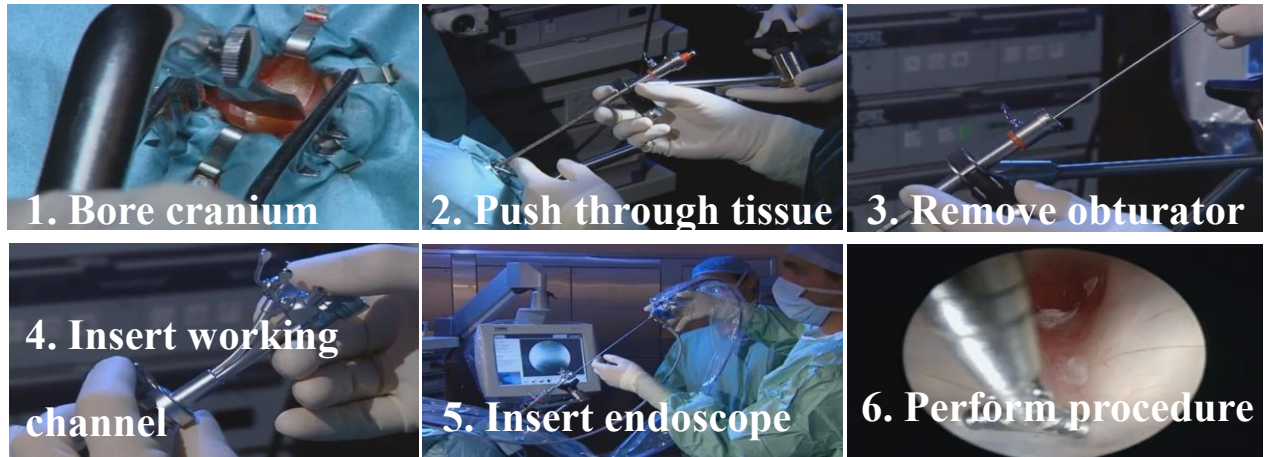
## 2.4 Effect of Pressure in the Brain

The maintenance of a net pressure gradient in the brain, the cerebral perfusion pressure (CCP), is a critical aspect of brain cell health and function. When cranial pressures drop below the recommended 70 mmHg, tissue becomes ischemic due to insufficient blood flow. The opposite condition, high ICP, or pressures above the normal 7-15 mmHg range, can be equally detrimental because in either case, blood flow is restricted to brain tissue (Sperry, 1992).

Restricting blood flow results in lower metabolic function of cells since oxygen and nutrients are not readily available. If the ischemia persists and the oxygen supply is continually dwindled, the cerebral hypoxia leads to brain tissue death, or cerebral infarction. The recommended dose of oxygen for brain tissue is 3.3 mL per 100g of tissue (Butterworth, 1999). When oxygen levels drop, short-term memory and the ability to perform learning tasks is affected, followed by a reduction in motor capabilities, blue-tinted skin, fainting, loss of consciousness, seizures, and finally brain death ('National Library of Medicine'). Increased ICP can also compress cells to the point of rupture, alter structures within the brain, and lead to reflex bradycardia, a potentially lethal heart rate disease. Therefore, maintaining an intracranial pressure (ICP) is critical in ensuring tissue health and function.

## 2.5 Endoscopic Neurosurgery Procedure

Endoscopic neurosurgery is used to treat various conditions through a variety of approaches. The most commonly performed endoscopic neurosurgery, however, addresses conditions within the ventricles of the brain, endoscopic third ventriculostomy. In order to grasp the extent to which the endoscopic surgical tools dictate the surgical procedure, a detailed understanding of the procedure is necessary.



**Figure 2: Endoscopic neurosurgery procedural steps (Performing a neurendoscopic procedure, 2012)**

Preoperative magnetic resonance imaging (MRI) is required to determine the extent of the condition and to visualize various anatomical landmarks. The placement of the bur hole is then planned accordingly. The patient is anesthetized and the head is fixed at a 30-degree angle and dressed for surgery in sterilized dressings. Normally, the access hole is made along the coronal suture and the medial pupillary line, about 2cm from the midline and 10cm from the eyebrows. An incision is made and the cranium is bored. Bone dust is collected to maximize tightness of the closure upon the conclusion of the procedure, and the dura matter is reached and coagulated. The obturator, a stylus with a blunted tip, is placed within the ridged outer guide, a stainless steel sheath, and locked in place. The system is secured to the articulating arm and the sheathing system is introduced to the ventricles through the hole under visual aid. Location in the ventricles is confirmed when cerebral spinal fluid is ejected through the obturator's inner hole from the distal tip to the proximal end. The obturator is removed and the working channel is inserted into the sheath. An irrigation channel is attached to the working channel to flush the cerebral spinal fluid. Next, the fiber optic endoscope is inserted through a passage in the working channel, and the brain tissue is visualized on a monitor. The movement of the system is very slow and controlled, with constant visual direction. Once the Foramen of Munroe is located on the top of the third ventricle to once again confirm location, the articulating arm is adjusted for optimal view. After consensus of location has been reached and the surgical approach is decided, micro-tools are inserted through the working channel to the distal end of the sheath to create an opening in the floor of the third ventricle. Balloon catheters are placed in the working channel to

expand openings. The sheath can be spun around the endoscope to get panoramic views, and the entire articulating arm and endoscope can be adjusted to change camera view. Varied visualization is challenging due to the rigidity of the sheath and the delicate nature of brain tissue. Once in the third ventricle, the condition (tumor, cyst, hydrocephalus, biopsy, etc.) is treated with surgical micro-tools through resection. The system is removed upon satisfaction of treatment and the hole is closed with an absorbent hemostat, along with the previously gathered bone dust and skin grafts. Although endoscopic neurosurgery is effective and has overall low complication rates compared to open brain surgery, or craniotomies, the procedures are lengthy and tedious, lasting up to two hours with over hundreds of tool insertions.

## 2.6 Current Technology in Use

Current tunneling and sheathing systems for endoscopic neurosurgery offer a spectrum of options for neurosurgeons to use in treating ventricular diseases. Although patents and commercial products range in complexity, the fundamental components of the tunneling and sheathing systems span all designs. Apart from preparatory tools, such as bone drills and cranial stabilization mechanisms, the first tool in endoscopic neurosurgery is the tunneling system comprised of two main stainless steel components (Cohen, 1993). The typically hollow center stylus is the axis of the design, known as an obturator. Its 0.5cm-diameter hemispherical tip is manufactured to be very smooth since it is the tool that pushes away cerebral tissue (Gaab & Schroeder, 1998). When displacing brain tissue, any surface roughness may induce injury, which is why this simple tip must be precisely made. Before entering the brain, the obturator is placed within a hollow cylinder called the rigid guide. This is a removable steel guiding system that temporarily maintains the integrity of the tunnel, and with which the surgeon controls cerebral navigation, with the help of magnetic resonance and infrared imaging. The distal junction of the obturator and rigid guide must be continuous and smooth to further avoid brain tissue injury during insertion (Hellwig & Bauer, 1992). Since no endoscopes are used in the first stage of the surgery, the obturator hole is vital in assuring surgeons that the fluid-filled ventricles have been successfully reached. Correct navigation is ensured when cerebrospinal fluid begins to spout from the proximal end of the obturator, as previously mentioned. Once this is achieved, the surgeon may continue onto the second phase of the procedure.

The second phase begins when the obturator is removed and the rigid guide is secured outside the brain using an articulated arm for the duration of the surgery ("Karl Storz Endoscope Product Catalog: 9<sup>th</sup> Edition," 2013). Appendix A and B contain dimensions and products for endoscopic neurosurgery made by Karl Storz™. The surgeon can proceed to use endoscopes and an array of stainless steel micro-tools to execute the procedure. Two types of endoscopes are used. A diagnostic fiber-optic endoscope with excellent resolution is first inserted into the sheath to explore the area of interest. Its width fills the entire sheath, so it is only used at the beginning of the procedure when no micro-tools are needed alongside it. A lower-resolution endoscope with fewer fiber optics and a smaller diameter is used after the diagnostic endoscope is removed.(Schurr et al., 1999). This is known as the working endoscope. Its 0.3 centimeter diameter is small enough to allow for the use of up to two micro-tools at once ("Karl Storz Endoskope Product Catalog: 9<sup>th</sup> Edition," 2013). These micro-tools are typically one millimeter wide, 5 millimeters long, and are situated at the end of 30-centimeter long tubes. These tools perform numerous functions, controlled with spring-operated, finger hole handles and thin inner rods (Schroeder, Wagner, Tschiltshcke, & Gaab, 2001). For example, grasping forceps are used to clamp tissue in order to create a fenestration or pull away excess material. Balloon catheters are used to widen existing holes or passages created in ventricular membranes. Biopsy forceps remove material from within the ventricles and are the primary mechanism in tumor removal. Suction catheters are used to remove excess fluid from operating areas, and coagulation electrodes are essential in stopping hemorrhaging during the procedure. Common suture and dressing materials are used to close the surgical opening.

Among the many tunneling and sheathing system patents in existence, two commercialized systems the most commonly used are Karl Storz™ and Aesculap™. Karl Storz™ endoscopic neurosurgery sets are considered the “gold standard,” and are used by the consulting doctor. They come equipped with all of the aforementioned surgical devices. All of this project’s designs are based around endoscopes, fixation devices, and tools from the Karl Storz™ system ("Karl Storz Endoskope Product Catalog: 9<sup>th</sup> Edition," 2013). Appendix A includes images and dimensions for all items in the Karl Storz™ endoscopic neurosurgery set. Non-commercialized patents include plastic sheath systems, interlocking components, and other minor amendments to the basic systems. A list of these patents can be found in Appendix B.

## 2.7 Limitations of Current Technology

Although the Karl Storz™ system is the current standard in endoscopic neurosurgery technology, limitations exist within the system that the consulting doctor must work with during the procedure. The rigid stainless steel sheath with a mere 6.5 millimeter diameter allots only enough room for either just a diagnostic endoscope, or a working channel endoscope with up to two micro-tools as seen in Figure 3. Since the working channel endoscope is of a lower resolution than the diagnostic endoscope, the surgeon must infer information from the blurrier image. Ideally, a high-resolution endoscope should be used for the entirety of the procedure to allow for optimal visual assessment. Additionally, the narrow passageway maintained by the rigid sheath restricts the surgeon to parallel tool and endoscope movement (Vougioukas, Hubbe, Hochmuth, Gellrich, & van Velthoven, 2003). This means that a tumor or membrane can only be contacted from one narrow angle. No visuals to the side or behind the tumor are available. Additionally, if a surgeon is using two tools, they must be used side by side. This parallel motion makes maneuverability within the ventricles increasingly difficult and nearly impossible for a surgeon to grasp tissue and reach the same area of tissue with the other tool (Bauer & Hellwig, 1994). The endoscope provides light and a visual output for the surgeon, so it must remain in the working channel for the duration of the surgery. Ideally, the surgery would be completed most effectively if two micro-tools, the diagnostic endoscope and suction catheters, could all enter into the ventricles, and if greater angular movement could be allotted.

Limitations of the current technology also affect the health of brain tissue. The viscoelastic nature of brain tissue means that time is a factor when stress and strain are applied to it. The rigid sheath maintains shear stress and pressure on the surrounding brain tissue for the entire surgery, which again, can last up to two hours (Prat & Galeano, 2009). Some flexibility in sheath design is optimal because it could relax when the micro-tools are removed from the brain. This relaxation would alleviate pressure on the surrounding tissue, allowing some degree of individual cell geometry restoration and function (Baumhauer, Feuerstein, Meinzer, & Rassweiler, 2008). The current technology makes for a long and monotonous procedure where the surgeon must insert very small tools into tiny openings up to hundreds of times. The rigid nature of the current sheath maintains constant pressure on the brain tissue, increasing the chance of tissue damage

and surgical complications (Baumhauer et al., 2008). The narrow diameter limits the quality of endoscope the surgeon can use as well as the degree of motion of the micro-tools.



**Figure 3: Karl Storz stainless steel working channel which is about 6.5mm in diameter allowing for two tools and an endoscope to be used at a time**

A less widely used tool exists in the neurological field, equipped with limitations of its own. Another rigid working channel, manufactured by Vycor Medical™, as seen in Figure 4 It is a polished polycarbonate that comes in varying lengths and widths. An inner channel is used in conjunction with a wider outer channel during insertion. The inner channel is then removed, providing a surgeon with a hollow, transparent working channel in which to conduct the procedure.



**Figure 4: Vycor Medical VBA is an elliptically shaped rigid polycarbonate brain retraction system (Vycor Medical - Targeting Solutions in Neurosurgery, 2013)**

While the transparent material lends itself well to passageway hemorrhage detection, its rigid nature still induces a constant pressure on the immediate brain tissue. However, the selection of sizes allows the surgeon to customize the working channel to accommodate their endoscope and tool use needs. While this provides a slight advantage over the Karl Storz™ working channel, brain tissue displacement must always be considered and accounted for. The major limiting factor of this working channel is the rigid polycarbonate used in the manufacturing process, which, like the Karl Storz™ working channel, produces a constant pressure on brain tissue the device displaces.



## Chapter 3: Project Approach

### 3.1 Client Statement

Design and prototype a multi-component tunneling system for endoscopic neurosurgery surgery, which includes a flexible sheath and a securing mechanism to allow for a larger passageway to the intracranial fluid spaces and afford surgeons a greater range of motion when using multiple instruments simultaneously while also reducing pressure on the brain tissue to avoid further tissue damage.

### 3.2 Design Goals

The design of the endoscopic neurosurgery tunneling system device was aimed to achieve certain goals for both the surgeon and the patient. The main goal was to use an alternative material to create a larger working channel without exceeding the pressure exerted on the brain tissue by the current technology. By increasing the working channel diameter, the design was geared towards allowing the surgeon larger angular movement, effectively decreasing surgery time. This increased range of motion of the tools and endoscope leads to a larger working area, exposing access to different portions of the ventricles, and leading to better patient outcomes.

### 3.3 Objectives

The objectives for the design of the tunneling system were ranked using a pairwise comparison chart seen in Appendix C. The pairwise comparison chart represents the six objectives, with the highest score being the most important.

The following objectives are ranked starting with most important:

- 1) **Sustain a passageway:** In order for the device to be used throughout the duration of the surgery, it must not fully collapse, but maintain an opening for the surgeon to go in and out with different tools with ease.

- 2) **Match pressure to current technology:** One of the main goals is for the device to be able to be semi-collapsible so that when the tools are not in the working channel, pressure on the brain can be reduced or matched to the current technology to allow for more blood flow and exhibit lower the risk of tissue damage.
- 3) **Increase diameter:** The current tunneling system designs used by the surgeon only allow for parallel movement with minimal amount of tools due to the small size of the working channel. The new design should allow for more angular movement and the ability to use multiple tools simultaneously with ease in the working channel.
- 4) **Maintain durability:** The material of the tunneling system should also be durable enough to not tear under the shear stresses of the tools move across the surface of the device as they are moved and pulled in and out of the working channel.
- 5) **Securable at proximal end:** Lower on the importance of the ranked objectives is that the system does not shift from or in the brain tissue. This requires the sheath to be securable at the proximal end. There are a variety of mechanisms that can be explored for this objective.
- 6) **Suitable for pediatric and adult procedures:** Since the surgeon performs both pediatric and adult endoscopic neurosurgery procedures, the device should be able to be made suitable for all ages. This can occur through manufacturing incremental diameters of sheath sizes or designing the system with a material that can be cut to different lengths to adjust for different depths to the ventricles in the brain.

### 3.4 Constraints

**Biocompatible:** The tunneling system must be biocompatible as to not cause reaction with surrounding brain tissue for the duration of the surgery (up to two hours).

**Non-adhesive:** The material chosen for the design of the tunneling system must be non-adhesive to the brain tissue. Since the device will be in contact with the brain for the entire surgery, it

must not adhere to it so that when it's taken out, it does not stick and tear brain tissue with it, causing damage and complications.

**“Sterilize-able”:** The device must be sterile to be used in a surgical setting with medical grade materials.

**Dimensional Constraints:** The size of our device must not exceed the amount of pressure on the brain tissue that the current technology exerts. The limitations of the size of our device will be measured through ANSYS modeling.

### 3.5 Functions and Specifications

**Table 1: Functions and Specifications**

<b>Function</b>	<b>Specification</b>
Introduces rigid inner/outer guide (trocar) and sheathing system into the brain tissue. Trocar or rigid guide is removed vertically, leaving in place the sheath/working channel	Rigid guide or trocar must small enough pore size (<4nm) as to not damage surrounding tissue upon removal
Maintains an enlarged opening <ul style="list-style-type: none"> <li>• Expands to maximum diameter without exceeding pressures the current stainless steel sheath applies to the surrounding tissue</li> <li>• Allows multiple tool access (up to 3 at a time) with the endoscope</li> </ul>	Approximately D=1cm (with a wall thickness of 1mm)  Deformation over 2 hours is less than the current system
Collapses but maintains minimum opening	Minimum D=5mm  (Diameter of the endoscope is 3mm, tools 1mm each)
Secures to the head at proximal end	Securing mechanism does not come above head to reduce range of motion for tools and keeps system in place so doesn't slide down into working channel
Maintains longitudinal length inside brain	7cm (average, adjustable length for pediatric and adult) without cinching up or pushing too far into the ventricle of the brain to obstruct tool access

Maintains structural integrity throughout procedure and does not cause tissue ingrowth or entrapment	~0% tissue adhesion within 6 hours Porosity <4nm
Withstands forces from tool insertion <ul style="list-style-type: none"> <li>• High Puncture Strength</li> </ul>	Use material that has either a known puncture strength or is used in applications with high or similar loads
Flexible sheath can be removed without causing tearing to brain tissue	Flexible sheath must have a low friction coefficient as to not damage surrounding tissue upon removal and must be non-adhesive to brain tissue for up to 3 hours

## Chapter 4: Design

### 4.1 Clinical Need

Endoscopic neurosurgery is very a complex, yet minimally invasive, neurosurgical technique used to treat many conditions in the brain. For this reason, it is critical to make constant improvements to the technology used in these types of procedures in order to decrease patient time under anesthesia, relieve cranial pressure, and increase ease of use for surgeons. While the current tool technology used in endoscopic neurosurgery is highly advanced, there are limitations in the flexibility and collapsibility of the working channel or trocar system. The most commonly used technology, Karl Storz™, employs a rigid stainless steel tunneling system with an obturator and trocar working channel, which remains completely stationary and maintains pressure on contacted brain tissue for the entirety of the surgery (Karl Storz Endoskope Product Catalog: 9<sup>th</sup> Edition, 2013). Another commonly used system is the Vycor Medical ViewSite Brain Access System two-cup design. The VBA is a brain retraction system that allows 360° access to the targeted site through the use of an elliptical rigid polymer (Vycor Medical - Targeting Solutions in Neurosurgery, 2013). Each system is very effective in maintaining the required working channel or tunnel, but none allow both range of motion and relief of pressure.

The design of the new tunneling system was targeted at increasing range of motion for surgeons, while not exceeding the pressures exerted by the current system, allowing for better surgical outcomes. This system is based on an idea presented by a neurosurgeon seeking a new device to use in endoscopic neurosurgeries, and was aimed to counteract the limitations of the existing commercial technology, while simultaneously meeting the objectives, functions, and constraints established by the team and client. For the design to meet the needs for an effective endoscopic neurosurgery tunneling system, the following criteria was obtained:

- Introducing the flexible sheath
- Maintaining open access for tools at the proximal end of the sheath
- Maximizing the diameter of the sheath, while semi-collapsing to maintain low stress on surrounding tissue

- Being safe, sterilize-able, and durable

## 4.2 Generation of Design Alternatives for the Tunneling System

Design of any mechanical or medical device requires various cycles of establishing need, overall design objectives, and brainstorming. The design of the tunneling system for endoscopic neurosurgery is no different. In addition to background research, Dr. Cataltepe established the need by presenting the various limitations of the current system and the ways in which he saw potential improvements. In response to this need, the doctor conceived a preliminary design of the tunneling system. The design included a 4-part system consisting of a generally flexible biomaterial for the working channel and a 3-part stainless steel rigid outer guide system for introducing the working channel into the brain. A preliminary patent was filed to distinguish that the idea was in fact novel. While this preliminary patent provided a basis to begin further technical design, the overall tunneling system was not limited to conform to this original design.

In the initial stages of design generation, the focus revolved around the design provided by the doctor. Various alternatives involving multi-part rigid outer guide systems were considered, while the inner working channel had few design alternatives. Iterations were both hand drawn, and modeled in computer aided design software, SolidWorks. After an extended period of time, it was determined that limiting the design to a multi-part system was holding back innovation in design, and the direction of the design aspect of the project shifted.

Various companies were quoted for material samples and the process of generating design alternatives for the flexible working channel began. It was crucial for the sake of design to grasp the tactile material properties of materials, which account for the delay in design generation of the working channel. Along with the working channel, methods to secure the entire system to the cranium were considered. Like the multi-part rigid outer guide, many different designs were developed. Some of the designs were based purely on geometry, and could utilize various materials, while others were based entirely on the material choice and geometry was assumed after. Inspiration was gathered from the desire to increase ease of use of the sheath for surgeons, the overall ability of the material to collapse/flex, and general brainstorming sessions. Some of the designs were deemed unfeasible, but three working channel and attachment mechanism were

considered and optimized for the final design. Two of the multi-part outer rigid guides were considered for the insertion mechanism, as well as a simple one-piece obturator.

### 4.3 Material Alternatives

Research was conducted to determine possible materials for the application of the flexible sheath device. Through contact with several companies and examining several material properties such as biocompatibility, elastic modulus, porosity, etc., the team came up with three final options. In order to properly gauge the material properties Samples of these options were obtained to get the overall feel of each selection.

The first was a medical grade, polyether polyurethane (PE-PU) with a brand name of Tecoflex®. This material was found be already used inside the body for short-term implant applications. Compared to several other extruded polymer materials, this material was selected mostly by feel. The material is highly compliant and has a very smooth surface. It is proven to be able to be sterilized by either EtO or gamma radiation, and can be made into durometers as low as 72A to achieve high flexibility. The extrusion process would also allow the team to create the exact wall diameter, length, and thickness desired.

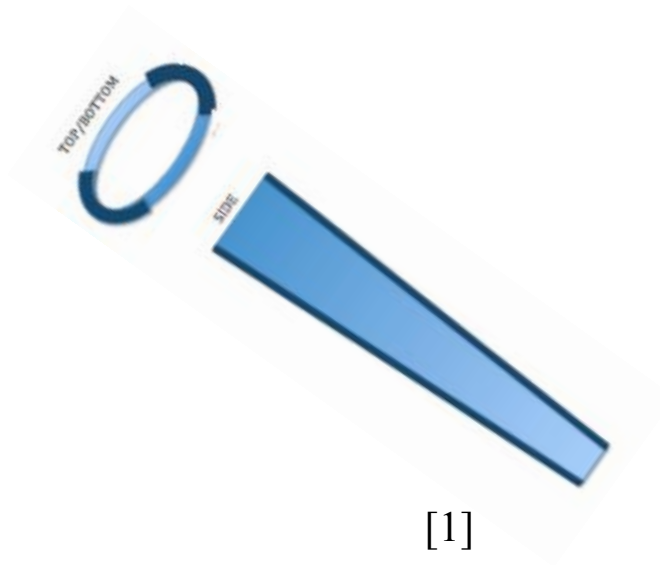
The second material was polytetrafluoroethylene (PTFE). This material was also determined to be very biocompatible and durable, as it is used in applications such as ligament replacement. Another advantage of the PTFE is that it can be woven into different configurations to achieve the desired porosity, modulus, and durability for the given application. Additionally, other materials can be woven into the construct for additional support, as the material is fabric-like and flimsy. This material can be sterilized by ethylene oxide technique.

The third option was a woven nylon material. This material configuration is currently used in orthopedic applications to stabilize limbs during the healing process. The woven nylon is essentially folded over itself and secured together on one end. In this way, a finger can be inserted into the device and when pressure or load is applied, the finger is trapped in position. It was conceived that this material configuration could be adapted to be used as the working channel sheath. Although nylon is used in the medical industry, this material was quickly

dismissed for our project because of its high porosity when woven into a stent-like configuration. It required extensive remanufacturing, and an additional coating to protect the porous surface.

#### 4.4 Flexible Sheath Designs

The first flexible working channel design alternative [1] seen in Figure 5 is an extruded medical grade polymer, PEPU. The design features thin vertical strips of greater shore hardness extruded continuously along the sides of the length, with a lower shore hardness in the center to allow for collapsing. While the sheath would collapse partially in the center, it will maintain its structural elliptical shape, remaining slightly open at all times.

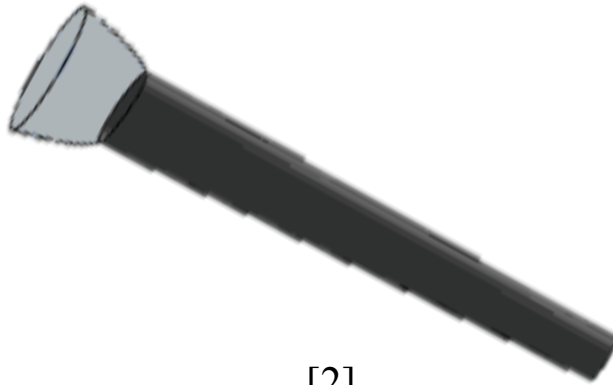


**Figure 5: PEPU Working Channel Design Alternative**

This design alternative would require co-extrusion of two type's plastics. This design addressed the desire of Dr. Cataltepe to have an elliptically shaped working channel, while maintaining vertical rigidity. It does not, however, address the issue of substantial collapse because the plastic may not be compliant enough.

The second [2] design seen in Figure 6 is simply a woven medical grade PTFE textile sheath body. The top of the working channel is held open with a rigid polymer cup piece to maintain access for the surgeon to go in and out of the tunnel with tools and the endoscope.

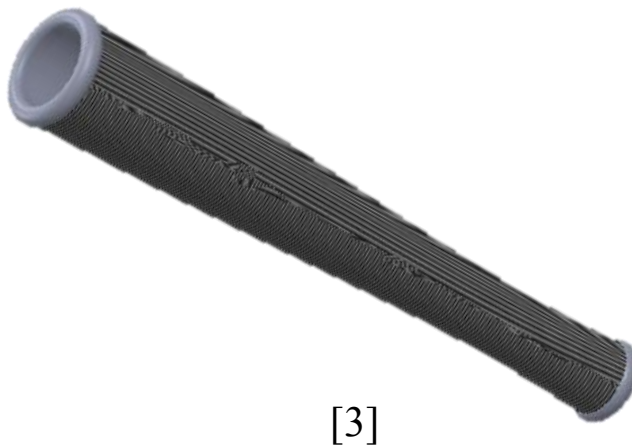




**Figure 6: PTFE Working Channel Design Alternative**

This design would come with a rigid “emergency channel” that can be inserted by the surgeon if a complication occurs to quickly obtain a permanent rigid channel to the ventricles in the brain. Unlike the previous design, this material is highly compliant due to its textile nature, but it does not have vertical rigidity.

The final design alternative [3] in Figure 7 represents a finger-trap/woven mesh design, which allows for circumferential expanding and collapsing of the tunnel.

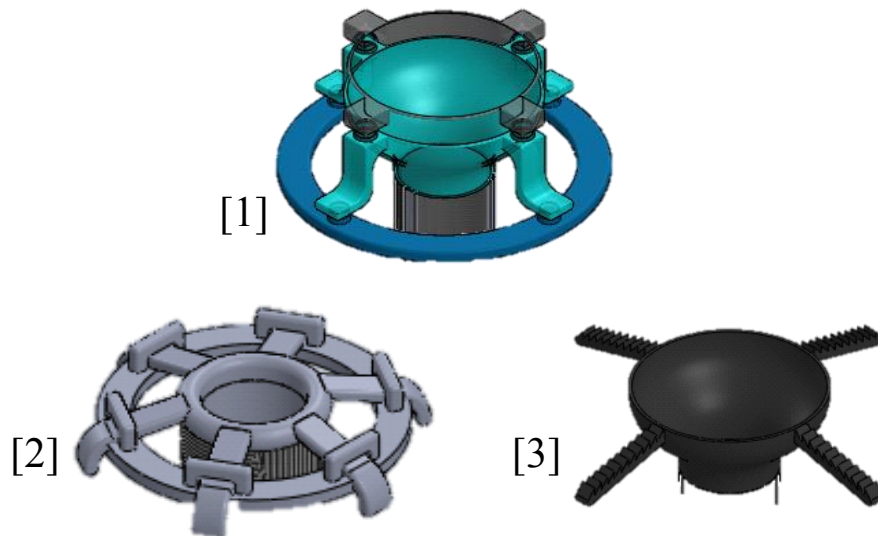


**Figure 7: Woven Nylon Working Channel Design Alternatives**

The design would be secured with a silicone type ring material at the proximal and/or distal ends to make sure that the length does not significantly shrink when the nylon circumferentially expands.

## 4.5 Attachment Mechanisms

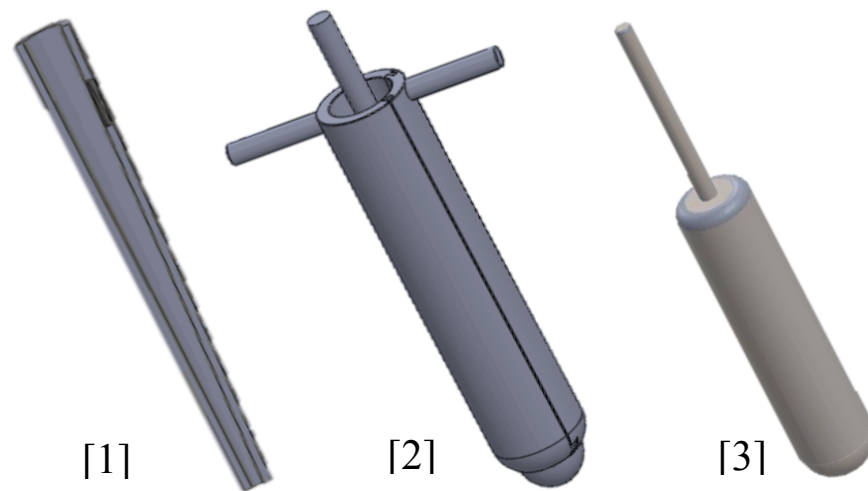
In designing the flexible sheath component of the endoscopic tunneling system for neurosurgery, the mechanism of attachment was also considered. Figure 8 depicts the three design alternatives for the attachment mechanism component of the tunneling system that were initially generated.



**Figure 8: Attachment mechanisms for the tunneling system**

The first mechanism [1] features an attachment ring that can be surgically secured to the cranium. A rigid polymer cup, attached to the flexible sheath, can then be secured to the ring with snaps. The second design [2] also features a surgical attachment ring. But instead of snaps flexible metal tabs fit into the loops on the attachment ring secure the sheath. The final attachment mechanisms [3] utilizes a zip tie design that locks into a surgically secured attachment ring

## 4.6 Insertion Mechanism Design Alternatives



**Figure 9: Rigid Insertion Guide Design Alternatives**

Figure 9 shows the rigid insertion guide design alternatives to place the flexible working channel sheath in the brain. The first design alternative [1] shows half of the design of the first alternative as if it were cut vertically down the middle. The other half has a hooked piece that locks into the socket shown. This was presented to Dr. Cataltepe, and rejected, as the act of pulling the two pieces horizontally apart to take them out of the brain puts unnecessary excess pressure on the brain. The desired movement of the rigid guide was vertically in and out of the brain to reduce compressive forces. The second picture [2] represents the design created from this feedback. In this design, the three-piece system can be pushed through the brain tissue all together, as shown, and once in the ventricular space, the middle portion is removed leaving a hollow tunnel. The flexible sheath can then be inserted. The rigid guide would be removed by vertically sliding out the small panel, making sure the flexible sheath is secured properly to the head, and then removing the larger portion of the tunnel. The last design for the rigid guide system is a simple obturator that can be inserted into the flexible sheath and fits flush. This would allow for one insertion and one removal to limit the amount of shear on the tissue.

## Chapter 5: Methodology

In order to properly execute the aforementioned project objectives and evaluate the various design alternatives, the following technical approach was developed. A firm understanding of the mechanical properties of brain tissue was determined through research to develop a model to analyze designs for the flexible sheath. The numerical forces and pressures required to injure brain tissue and the cascading complications that result from injury were also established.

### 5.1 FEA Testing Using ANSYS™

Once sufficient technical understanding of the brain tissue and potential biomaterials were met, the modeling and design was the next stage of the project. A detailed model of brain tissue was created in finite element analysis (FEA) software, ANSYS™, to mimic the mechanical properties of the brain. The model was built to simulate surgical forces on the brain from tunneling through the tissue. From this model, the normal pressures and stresses in the brain without puncture were calculated and compared to the research-obtained values, as well as to an *in-vitro* gel model that was created for validation of FEA. First, a representation of the current technology was developed in ANSYS™ by modeling a stainless steel tunnel with the same radius of 3.25mm. This was created by making a cylinder of brain tissue containing a small hole of 6.50mm throughout using a displacement. A stainless steel tube was then modeled next to the tissue to show how the brain compressed on the stainless steel tube, which allowed analysis of the forces that the current technology exerted on the brain. Flexible materials from the design alternatives then replaced the stainless steel to show how the brain relaxed on the flexible tube and reduced the stress on the brain tissue.

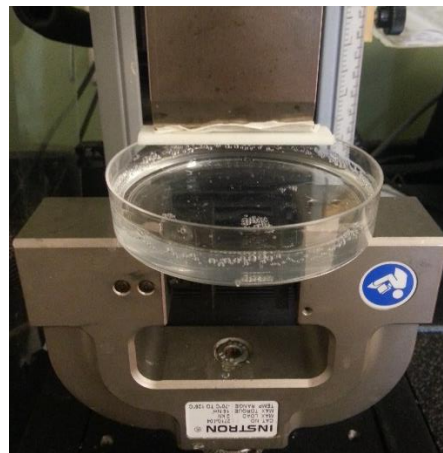
### 5.2 In Vitro Validation of FEA

The finite element analysis and calculations provided a great deal of data regarding the reduced pressure and flexibility of the designs, in comparison to the standard stainless steel working channel currently used. To validate the values generated by the FEA model, and *in vitro* test method was developed. A gel and testing container were created. The gel was manufactured to simulate brain tissue and the container was designed to monitor displacements in a single

direction. Sheaths of different sizes and materials were inserted into the gel model to mimic insertion in brain tissue. Markers were suspended in the gel to display gel displacement. A camera captured the displacements as the sheaths were inserted. The displacements, in conjunction with known gel modulus values were used to calculate stresses and strain generated in the gel material.

### 5.2.1 Gel Manufacture and Testing

In order to develop an effective material that can simulate the brain tissue during testing, a PVA based gel was synthesized. PVA and sodium borate were combined in different ratios until a gel that exhibited an elastic modulus of 3500 Pa was chosen as the closest match to the modulus of brain tissue, 3400 Pa, found in literature (Miller, 2000). The successful combination mixed 1.5 mL of 8% aqueous sodium borate solution in 50 mL of 4% aqueous PVA solution. Both solutions were heated to 70°C. The sodium borate was added to the PVA solution using a micropipette and the mixture was stirred vigorously. The gels were placed in Petri dishes and left to settle overnight. In that time the majority of air bubbles exited the gel. The gel was then compressed in the configuration displayed in Figure 10 using a screw operated INSTRON® machine.



**Figure 10: Gel Compression Testing Configuration**

A rectangular compressive head, 61.5 mm long and 12.5 mm wide, was manufactured and secured to an existing INSTRON® head. The test was programmed to lower the head at a set rate of 0.5 mm per second to match in vivo swine brain compressive testing procedure. The gel was

compressed to 0.6 strain in accordance with ASTM F2900-11 for hydrogel characterization. Each gel sample was compressed five times. The results were analyzed to isolate the strain in the third region of the graph, most accurate to the inherent properties of the gel.

### **5.2.2 *In Vitro* Material Testing**

More gel was made to fill the gel testing container. While a cylindrical testing container was considered, the opacity of the gel provided a measurement accuracy problem, in that the gel refracted light which skewed the results. The final testing container design was a Plexiglas rectangular prism 14 cm wide, 3 cm deep, and 5 cm high to reduce light refraction. The open-top container was filled with gel and allowed to sit overnight to allow for the escape of air bubbles. Two strings were marked with 0.5 cm graduations and were placed 1 cm away from the central axis of the container. Their purpose was to visually represent gel displacement cause from the introduction of a sheath. A camera was mounted on a tripod in front of the container to capture string movement and relaxation during and after sheath insertion.

## Chapter 6: Design Selection

The main objectives were met with the final chosen design. The diameter of the working channel was increased to optimal size without significantly exceeding the pressure that the current technology induces on the brain tissue. This larger diameter proved to allow greater range of motion and free working area space for the surgeon's micro tools. These objectives were achieved by incorporating a flexible material in the design of the working channel sheath, enabling it collapse when tools are not in use. Achieving these objectives and functions were accomplished using a Finite Element Analysis (ANSYS™) model and an *in vitro* viscoelastic gel model.

### 6.1 Optimizing Working Channel Diameter

Optimizing the diameter was accomplished by finding the resultant stress the current channel creates in the brain tissue. This stress was then compared to channels using alternative polymer materials. The optimum size was chosen by finding the size that most closely matching the stress caused by the current stainless steel channel.

#### 6.1.1 Develop FEA Model (inputs and outputs)

ANSYS™ Finite Element Analysis software applied displacements to simulated brain tissue to generate resultant stresses and displacements. The results from different size cross sectional areas and materials were compared in order to further narrow down the best design. The main goal of the FEA ANSYS™ analysis was optimize the diameter of the new working channel sheath. This was done by matching the stress exerted on the brain tissue from the current stainless steel working channel to the new working channel made of a different material.

The modeled system consists of brain tissue, the current stainless steel working channel, and the newly designed working sheath of a flexible material. The simulation was completed in a 2D plane because of its symmetry. The 2D model allowed the program to run the complicated analysis faster. The inputs of the model include; material properties, geometry, applied forces, and boundary conditions.

### 6.1.1.1 Material Properties

The materials modeled in this system are brain tissue, stainless steel and a flexible polymer. For the purpose of this model, the brain tissue system was assumed to be a uniform, isotropic, hyperelastic material. The material properties of brain tissue have been well documented in scientific research. Further research has been completed on how to properly model brain tissue in a finite element analysis model. Karol Miller, from the department of Mechanical and Materials Engineering at the University of Western Australia conducted research to model brain tissue that is suitable for finite element analysis of surgical procedures. The Miller model was confirmed using experimental in-vivo data. Miller's research was used as the ideal model because as he stated;

“A number of constitutive models of brain tissue...have been proposed in recent years. The major deficiency of most of them, however, is the fact that they were identified using experimental data obtained in vitro and there is no certainty whether they can be applied in the realistic in vivo setting” (Miller, 2000).

Miller's research has been widely cited in the research since 2000 when it was completed and was therefore used as the basis for the FEA model.

The Young's Modulus was found in literature which obtained the values through experimental data. The elastic modulus was found experimentally using compression testing. The process of this compression testing was used in the creation of *in vitro* gel model. Figure 11 explains how the Young's Modulus was estimated in the experiments done by Miller and comparing it to the viscoelastic and hyper-viscoelastic analysis in the FEA model.



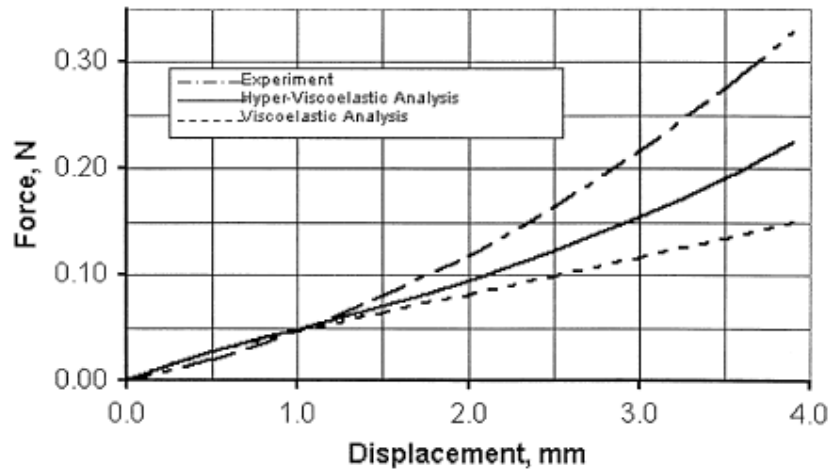


Fig. 7. Force versus displacement relationship for  $1 \text{ mm s}^{-1}$  indentation speed and  $10 \text{ mm}$  indenter diameter: (a) experiment; (b) hyper-viscoelastic analysis results; (c) linear, viscoelastic analysis results (for small strains the linear, viscoelastic model used had the same properties as the non-linear, hyper-viscoelastic model (Miller and Chinzei, 1997), instantaneous Young modulus  $E = 3240 \text{ Pa}$ , Poisson's ratio  $\nu = 0.499$ ).

Figure 11: Experimental data to obtain Young's Modulus (Miller, 2000)

For the purpose of this project, a hyperelastic model was applied to the simulated brain tissue. Elastic data that was used was from Figure 11 of  $E=3240\text{Pa}$  and Poisson's Ratio=0.49. The Table 2 shows the hyperelastic properties used in this model.

Table 2: Material Properties to Model Brain Tissue (Miller, 2000)

Hyperelastic Properties of Brain Tissue	
(Mooney-Rivlin Model)	
Instantaneous Response Constants	
$C_{100}=C_{010}$	263 Pa
$C_{200}=C_{020}$	491 Pa
$C_{110}$	0
Mooney-Rivlin Equation	$W = C_{100}(\bar{I}_1 - 3) + C_{200}(\bar{I}_2 - 3)$

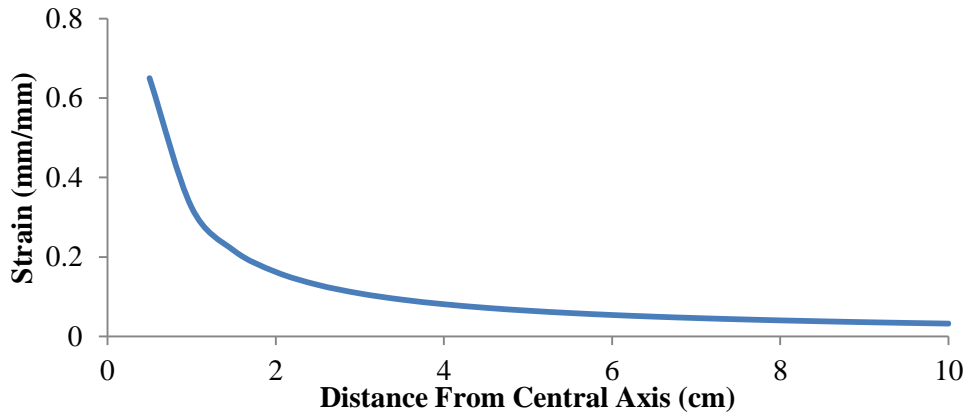
The last row of Table 2 contains the Mooney-Rivlin equation. This equation was developed to model hyperelastic materials and is used to express mechanical strain energy. Constants  $C1$  and  $C2$  are derived from experimental data using curves using best fits. They are unique to each material tested. When the Mooney-Rivlin equation is inputted into an FEA model, these

constants are indicative of material stiffness. Stretch ratios are plotted against engineering stress to obtain curves whose slopes produce the variables  $\bar{I}_1$  and  $\bar{I}_2$ , called Invariants. These variables take into account forces and deformation gradients. The C and  $\bar{I}_1$  variables combined in the Mooney-Rivlin equation above produce a hyperelastic material's mechanical strain energy. (Miller, 2000) The constants experimentally determined by Miller from Table 2 are inputted into the material property section of the ANSYS™ model settings.

The model is not only made up of brain tissue, but also the material of the working channel. The current technology consists of a stainless steel tunnel. The material properties used for stainless steel were the given properties in ANSYS™ with young's modulus  $E=200\text{GPa}$  and a Poisson's Ratio  $\nu=0.3$ . The material properties of the flexible material were acquired from specifications provided by the respective manufacturers. The Young's moduli of the ideal PU-PE and PTFE materials were averaged to produce a Young's modulus of  $2.86\text{MPa}$ . The Poisson's ratios of both flexible materials were also averaged to produce a value of  $0.46$  (Miller, 2000). These values were used in the material input section for the flexible material ANSYS™ models.

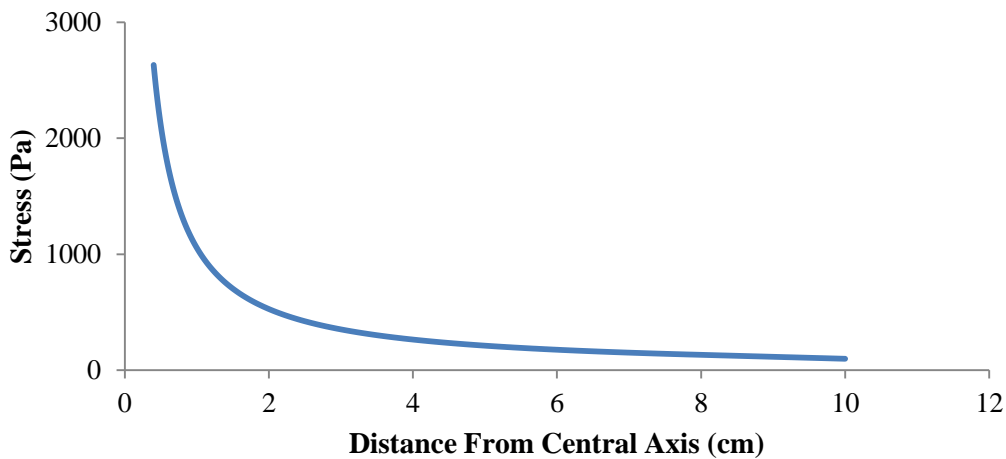
#### 6.1.1.2 Geometry

The dimensions of the FEA and *in vitro* models were determined in two parts. The width was determined using linear elastic average strain calculations. The technology considered was the rigid stainless steel working channel. Equal displacements on both sides of the working channel were assumed and a symmetrical model was devised. The symmetrical nature allowed for analysis on only one side of the system spanning from the central axis where the probe was inserted to  $10\text{cm}$  away from that axis. The outer diameter was  $6.5\text{mm}$ , and the radius was  $3.25\text{mm}$ . The radius was considered the change in length of the of the brain gel. The distance away from the central axis was considered the total length. The change in length value was divided by the total length values which ranged from  $5\text{mm}$  to  $100\text{mm}$  to calculate strain. Figure 12 displays the average strains as a function of distance from the central axis. The strain decreases as the distance from the central axis increases.



**Figure 12: Average strain as a function of distance from central insertion axis**

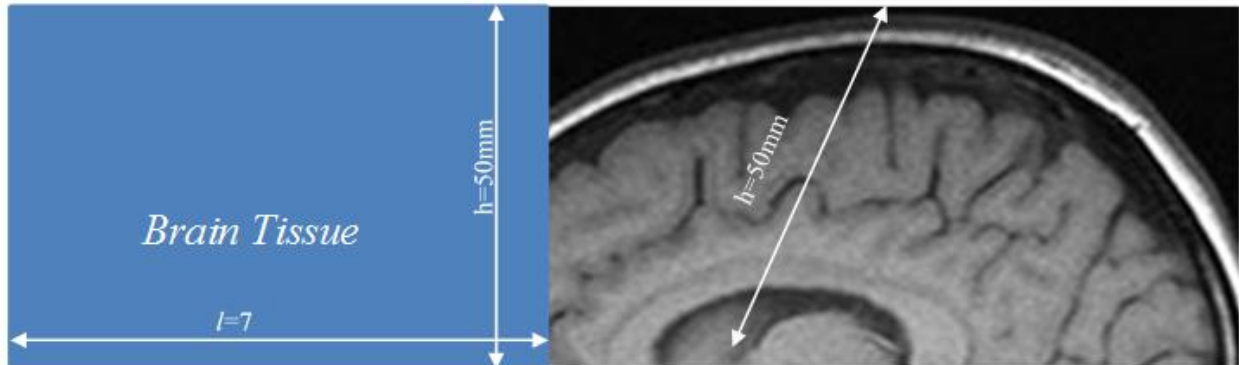
Using strain values from the theoretical calculations, stress at each point distance from the central axis was calculated. This was accomplished using the Young’s modulus equation and the documented modulus of brain, 3240 Pa (Miller, 2000). Figure 13 displays the stresses at different points in the brain tissue along the positive x-axis after stainless steel working channel insertion. The stress also decreases as distance from the central axis increases, as does the strain.



**Figure 13: Theoretical stress at increasing differences from the central axis**

The greatest theoretical stresses and strains significantly decrease by a distance 7cm away from the central axis. This is the reason the FEA and *in vitro* models were made 7cm wide from the central axis.

The depth of the models was based on skull geometry. The distance from the typical entrance point for a third ventriculostomy, the coronal suture, to the ventricles differs with each subject. According to Dr. Cataltepe, the average working channel distance required to reach the ventricles is 5cm. This average distance was used as the model depth for both FEA and *in vitro* applications. Figure 14 displays the dimensions of the model, and its depth correlation to average brain anatomy.

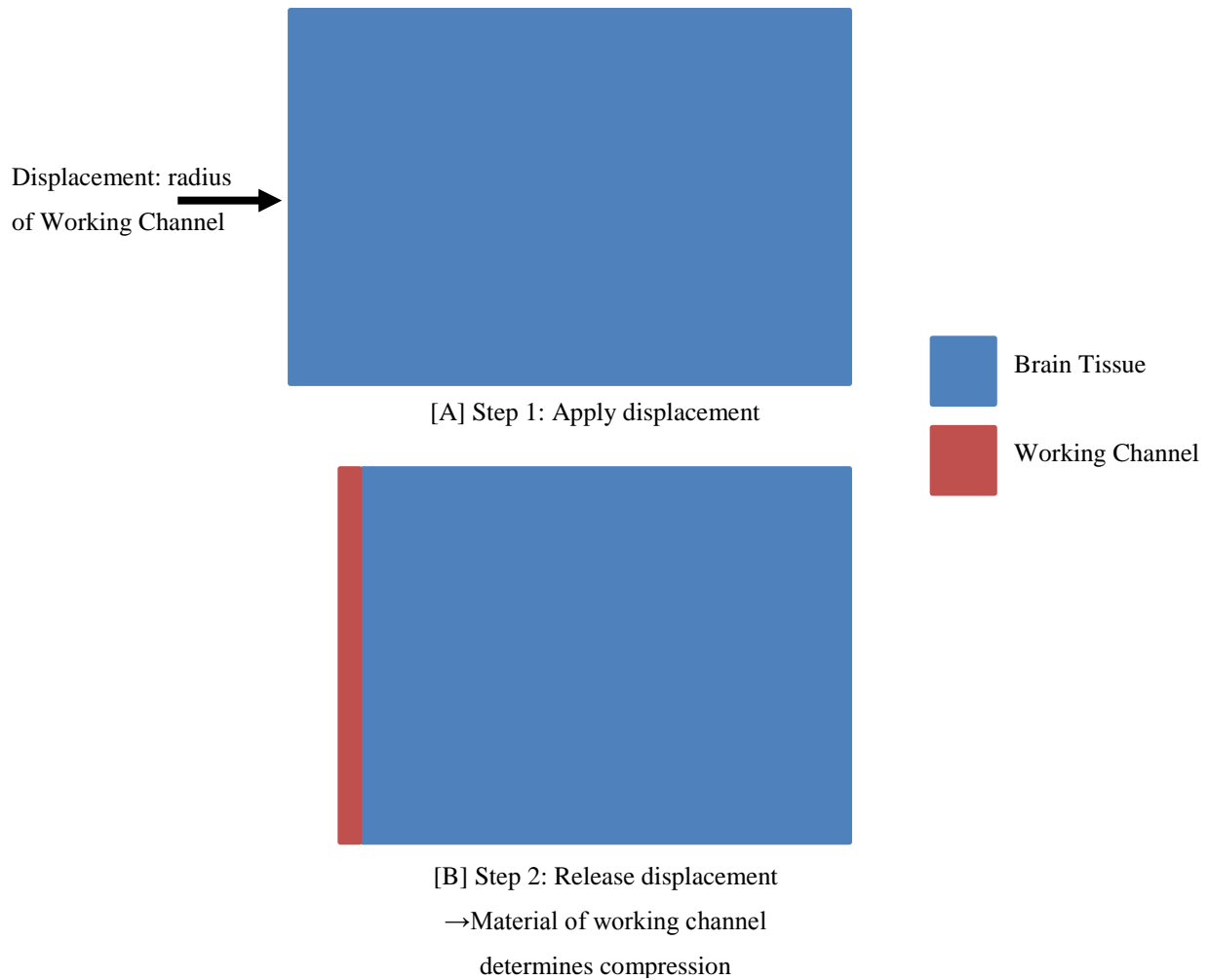


**Figure 14: Diagram of the geometry modeled in ANSYS™ paralleled with typical third ventriculostomy surgical path. The Blue area is the brain tissue and the red area is the wall of the working channel.**

Theoretical strain and stress calculations coupled with brain anatomy were the basis in deciding model dimensions.

### 6.1.1.3 Applied Forces and Boundary Conditions

The inputs of the applied forces on the tissue were used to determine the resulting stress and displacement. Figure 15 shows the compression force the working channel exerts on the brain tissue and how it was modeled. A two-step process was used in the analysis settings to run the model's results. This process simulated the compression force applied by the channel material on brain tissue. The first step applied a displacement to the brain tissue equal to the radius of the channel. The channel wall was aligned to be flush to the compressed brain tissue.

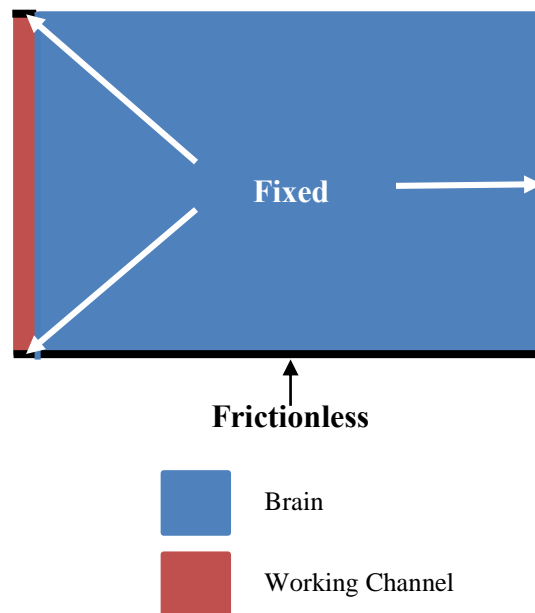


**Figure 15: Diagram showing how the compression force the channel exerted on the brain tissue was modeled by using a two-step process**

Figure 15 has two images on top of each other showing the two step process; [A] and [B] respectively. This two-step process was completed in the analysis settings. The first step, shown

in image [A], was to apply a displacement equal to radius of the working channel in the positive x-direction. This displacement models the compression caused by the channel when it is secured in the brain tissue. This displacement generated the hollow passageway through which the surgeon conducted the procedure. This marked the completion of the first step. In the second step, a no separation connection was added to the edge of the brain tissue in contact with the edge of the channel wall. This connection allowed each body to exert forces on the other. Once this connection was added, the initial displacement on the brain tissue from step 1 was released. The release of the initial displacement allowed tissue displacements to be a result of the channel wall material. Finally, a pressure in the negative-x direction was applied to model intracranial pressure present in the brain. This pressure amounted to 1500Pa (American Assoc. of Neurological Surgeons, 2004). This allowed the model to show the comparison of stresses caused on brain tissue between stainless steel and a flexible material.

Lastly the boundary conditions were added. Two different boundary conditions were used in this model. There were three edges where a fixed support was used as shown in Figure 16.



**Figure 16: Diagram showing the edges where the boundary conditions were applied**

A fixed support secures the edge in both the X and Y direction. This means that the fixed support edge cannot move when a force is applied. A frictionless support was applied to the bottom edge

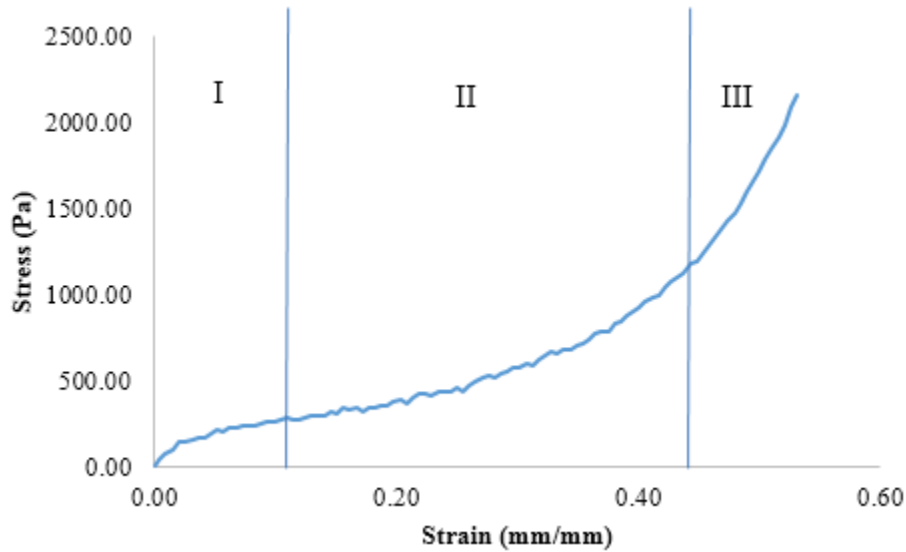
of the brain tissue. A frictionless support can be compared to a rolling pin, where the edge can move in only one direction. In the case of this model, the tissue can move side to side (x-direction) but cannot move up and down (y-direction). Figure 16 displays which edges the boundary conditions were applied to.

### 6.1.2 Model Current Technology and *In Vitro* Validation

The first step of the analysis was to model the current working channel as a basis of comparison. The current working channel is made of stainless steel and has a radius of 3.25mm. The material properties of stainless steel were used to model the working channel wall (the red area shown in Figure 15 and Figure 16). The displacement that was added was equivalent to the radius of the channel of 3.25mm. The analysis was run using the two-step process and boundary conditions discussed in section 6.1.1.3. To verify the validity of the FEA model, the results of FEA and *in vitro* testing of the current technology was compared to show that the measured stresses at the same location in the brain tissue were in an acceptable error range.

The results generated by the finite element analysis model required validation. The *in vitro* model devised to accomplish this involved a gel mimicking the mechanical properties of brain tissue, whose formulation can be found in Section 4.3.1. Displacements caused from sheath insertion and gel modulus were the basis for stress calculations. The probe used in the gel model was made of stainless steel and had a 6.5 mm diameter. The ANSYS™ model displaced the simulated tissue using a stainless steel material with the same properties as the probe used in the *in vitro* model. The displacement in the ANSYS™ model was equal to the diameter of the *in vitro* probe. The stresses generated from the *in vitro* model were compared to the stresses generated from the ANSYS™ model.

The gel compression data was analyzed to determine the gel which best matched brain tissue mechanical properties. Figure 17 is representative of the typical three-region curve generated by the compression testing.



**Figure 17: Trial 4 stress and strain graph of successful gel sample**

The modulus was calculated for the third region of the graph and averaged from five compression trials as seen in Appendix E. This region was used because it was most indicative of the true nature of the gel. The PVA/sodium borate gel formulation described in Section 4.3.1 had a modulus that closely matched brain tissue modulus found in literature. For this reason, it was manufactured on a larger scale and use in the *in vitro* model.

Suspended in the gel were two strings marked with 0.5 cm graduations. The strings were placed 1 cm away from the central axis of the container. This distance was chosen because the ANSYS™ model analyzed stresses at this location. The ANSYS™ model that matched the *in vitro* model produced an average stress at 1cm away from the central axis of 167Pa. Figure 18 displays a typical set up of the testing rig. A stainless steel probe was inserted in alignment with the central axis of the container. The stainless steel probe displaced gel as it was inserted. The suspended strings made these displacements observable.



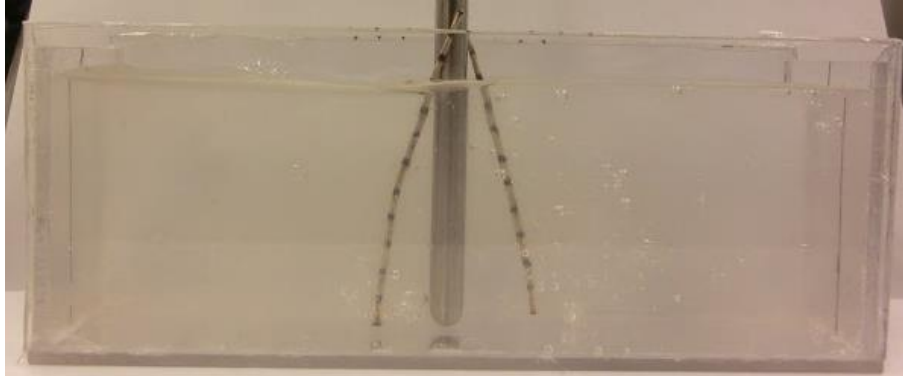


Figure 18: Gel testing set-up

Multiple displacements were recorded at three positions: The initial position of the string, the position of the string at the middle of insertion and the position of the string once the probe was fully inserted. Differences in those distances, known as displacements, were used to calculate strain. Incorporating the known modulus gel, stresses were calculated on either side of the probe as shown in Table 3.

Table 3: In Vitro Gel Stress Calculation

		Middle of String (2cm from bottom)			
Current Working Channel		Distance from Wall		Displacement	
	Time	R String	L String	R String	L String
	(s)	(mm)	(mm)	(mm)	(mm)
PreInsert	0	61.3	58.4	0	0
MidInsert	5	61.2	57.8	0.07	0.61
Full Insert	10	58.0	54.9	3.27	3.51
		Full Insert	0.053	0.06	STDV
		Stress	<b>186.79</b>	<b>210.32</b>	<b>16.6</b>

The *in vitro* stresses at full insertion were compared to the stresses generated by the FEA model. The average *in vitro* stress was  $197 \pm 16$  Pa. This was comparable to the FEA stress, 167 Pa. The stress values of the FEA and *in vitro* model were within a 16% error. This served as a validation of the FEA model and the results it produced. The lack of manufacturing capabilities resulted in

heavy reliance on finite element models, so proving their validity was paramount in basing any design decisions off FEA results.

### 6.1.3 Model New Material Compare to Current Technology

The FEA model was used to analyze the stress caused by the current technology compared to the flexible material sheaths. The flexible sheaths were analyzed at incremental increasing diameters and an optimum size was chosen.

The current technology working channel was run using in the FEA model. The resultant stress was measured at 5mm into the brain tissue from the edge of the working channel. Figure 19 shows the stress distribution throughout the entire height of the channel caused by the current stainless steel technology.

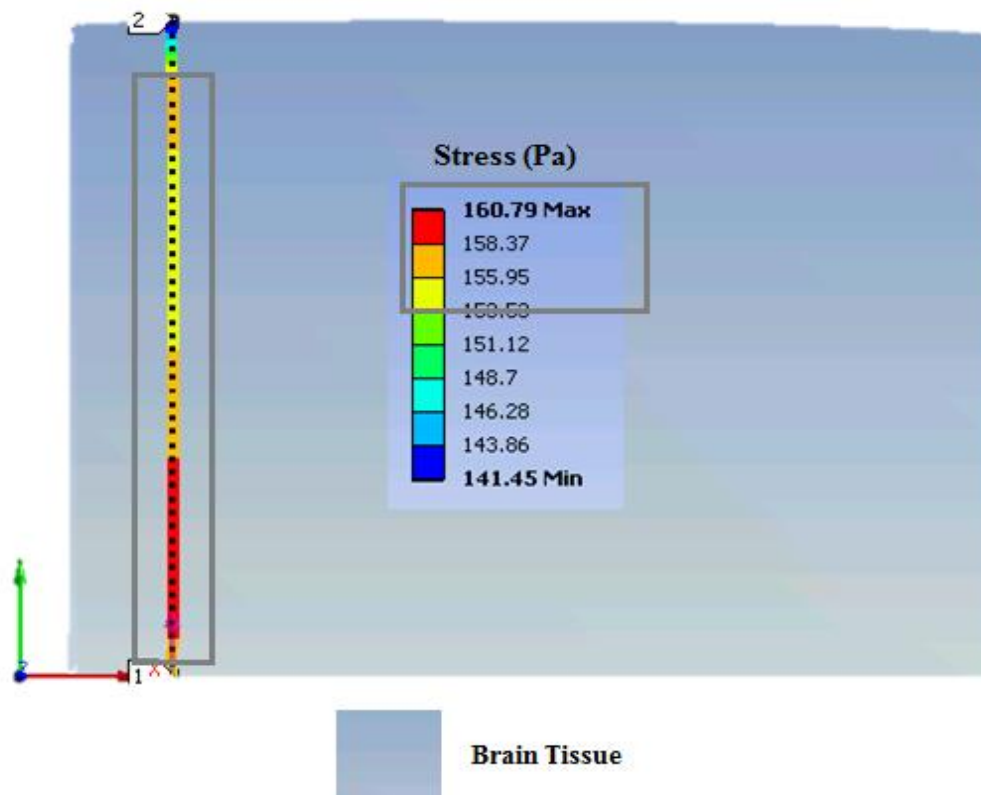


Figure 19: Stress distribution throughout the height of the channel caused by the current stainless steel working channel

As the color key shows Figure 19, in the center of the blue brain tissue, the stress ranges from 161Pa to 141Pa. The stress is less at the top of the tunnel because the tissue at the top is unconstrained and is free to move upwards. The brain tissue being unconstrained at the top is why there is a larger stress concentration at the bottom of the channel. These results were used to be compared to varying diameter sizes of the flexible material to determine the optimum size.

### 6.1.3.1 New Material of Same Size

Modeling the new flexible materials was first analyzed using the same diameter of the current working channel of 3.25mm. The flexible material was able to relax at the middle section of the channel, greatly reducing the stress. Figure 20 shows the stress distribution through the height of the channel using the flexible material at 5mm into the brain.

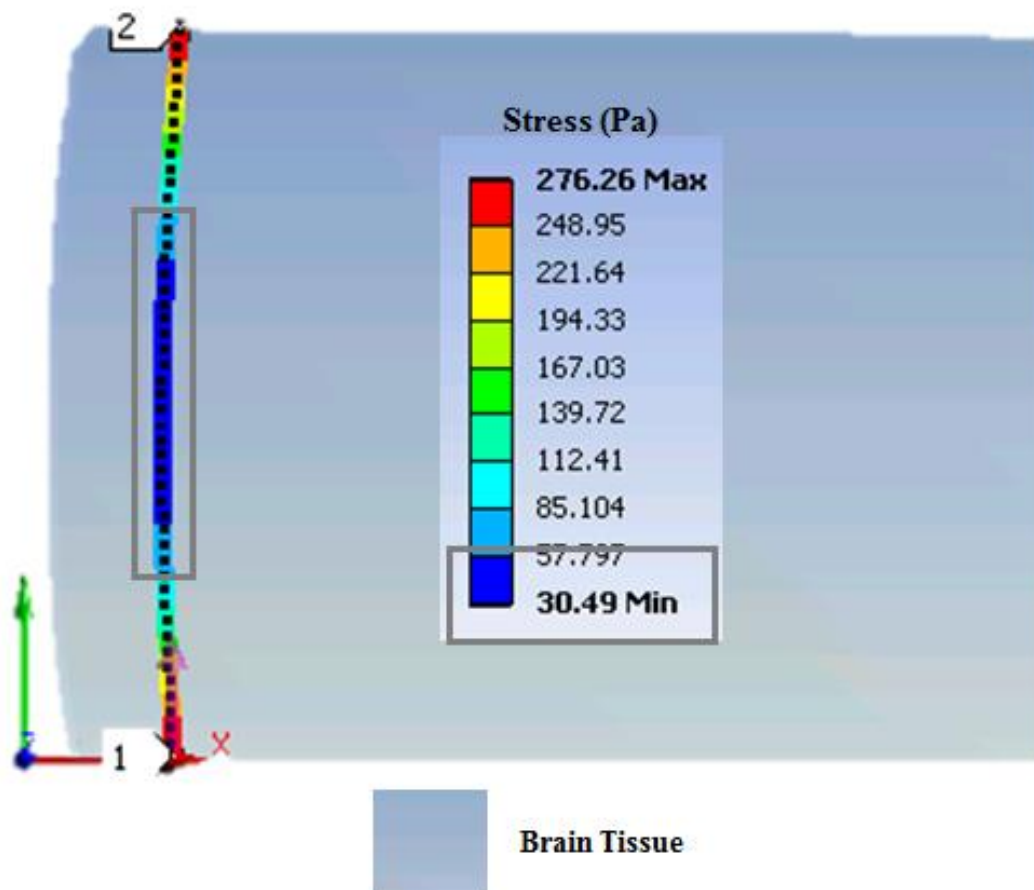


Figure 20: Stress distribution throughout height of channel using flexible material with radius of 3.25mm

The channel wall was constrained at the top and bottom as discussed when describing the boundary conditions in section 6.1.1.3. This boundary condition did not allow the edge of the material to move in the x direction which created a larger stress at the top and bottom of the channel. These boundary conditions were chosen to simulate the opening that needs to be created at the proximal and distal end of the channel. The curvature seen in this image in the brain tissue is due to the relaxation of the tissue from the material collapsing. The maximum displacement, or collapse, of the channel for this size radius was 1.8mm. This displacement was observed in the middle section of the channel. The radius size of the flexible channel was increased until the stresses matched that of the current stainless steel technology.

### 6.1.3.2 New Material with Increased Diameter

According to our specifications, the minimum size of the new channel should be 5mm radius as requested by Dr. Cataltepe, UMMC neurosurgeon. Varying sizes were tested starting with a 5mm radius and increasing by 2.5mm radially. Four different size flexible channels were tested including the current technology size of 3.25mm and incrementally increased the specification of 5mm, 7.5mm, and 10mm. Figure 21 shows the comparison of the stress distribution at the same location throughout the height of the tunnel.

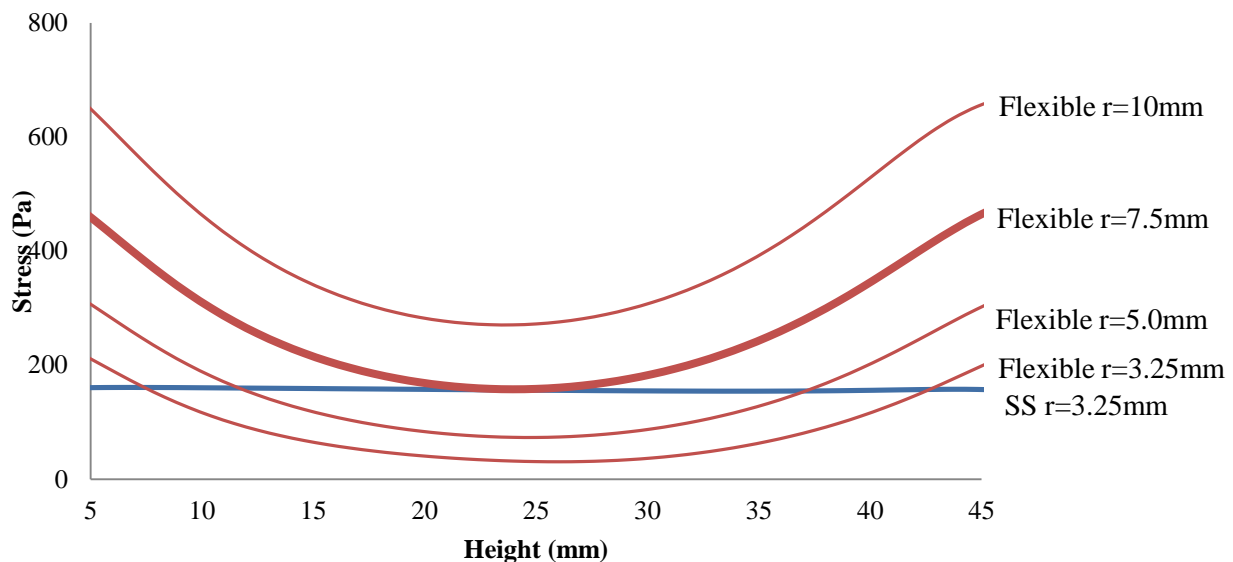
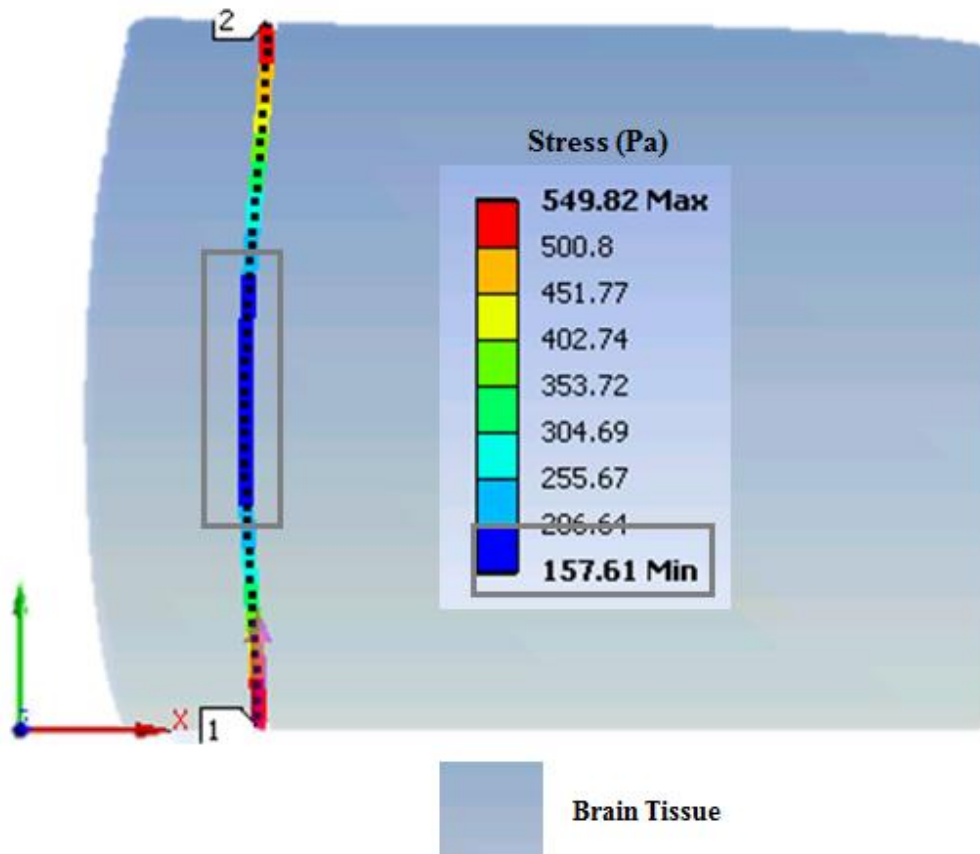


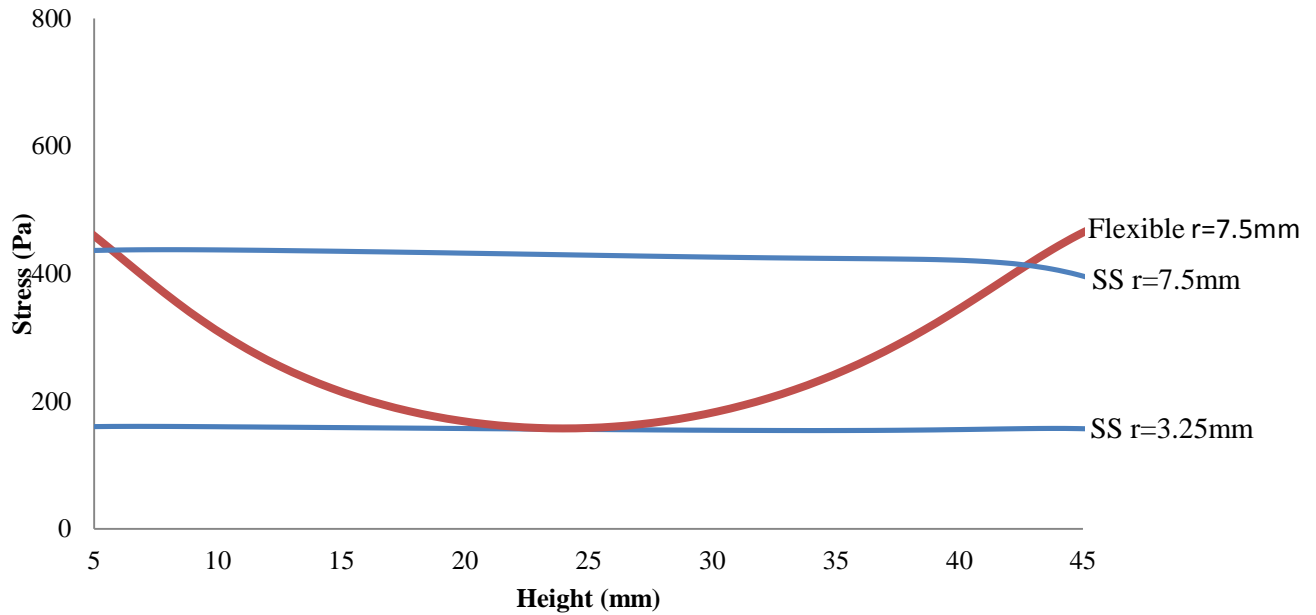
Figure 21: Stress distribution throughout the height of the channel, comparing the current stainless steel technology and varying sizes of flexible channels

This graph in Figure 21 compares the four different radii of the flexible channel. The stress distribution with the radius of 7.5mm closely matches the current stainless steel channel at the middle region of the channel. This size was chosen as the optimum size radius and more analysis was conducted to prove this finding. Figure 22 shows the model results of the stress distribution of the 7.5mm radius.



**Figure 22: Stress distribution throughout the height of the channel when using a flexible material with a radius of 7.5mm**

Figure 22 shows that there is an approximate stress of 158Pa in the middle region of the channel. This stress is very close to the stress produced by the current stainless steel channel. The curvature in the brain tissue is caused by the deformation, or collapse, of the channel material. This material deformed 3mm. This deformation was caused by the relaxation by the brain tissue. Figure 23 compares the optimized diameter of 7.5mm to the current stainless steel channel to a stainless steel channel of 7.5mm.



**Figure 23: Comparison stress distribution of the current technology to the optimum size diameter flexible channel with a radius of 7.5mm**

Figure 23 shows that not only does the optimum size of the flexible channel match the current stainless steel channel in the middle region of the channel, but it is also consistently less than the stress the same size tunnel would produce if it were made from the rigid stainless steel. The ability of the flexible channel to collapse reduces the stress caused on the brain tissue.

The results of the FEA analysis showed that 7.5mm radius was the ideal size channel, and was incorporated in the new design. The stress caused on the brain tissue from this newly sized flexible material channel does not significantly exceed the stress caused by the current stainless steel channel. The middle 3cm of the height of the channel only produces an average percent stress increase of 39%. The average percent stress increase in the same region using the larger channel made of stainless steel is 174%.

### 6.1.4 Increasing Range of Motion

The larger size diameter of the working channel sheath allows for a greater range of motion with the ability to use larger tools and devices. Figure 24 compares using the current technology with

existing micro tools to using the larger flexible sheath with the same micro tools and then with larger ones.

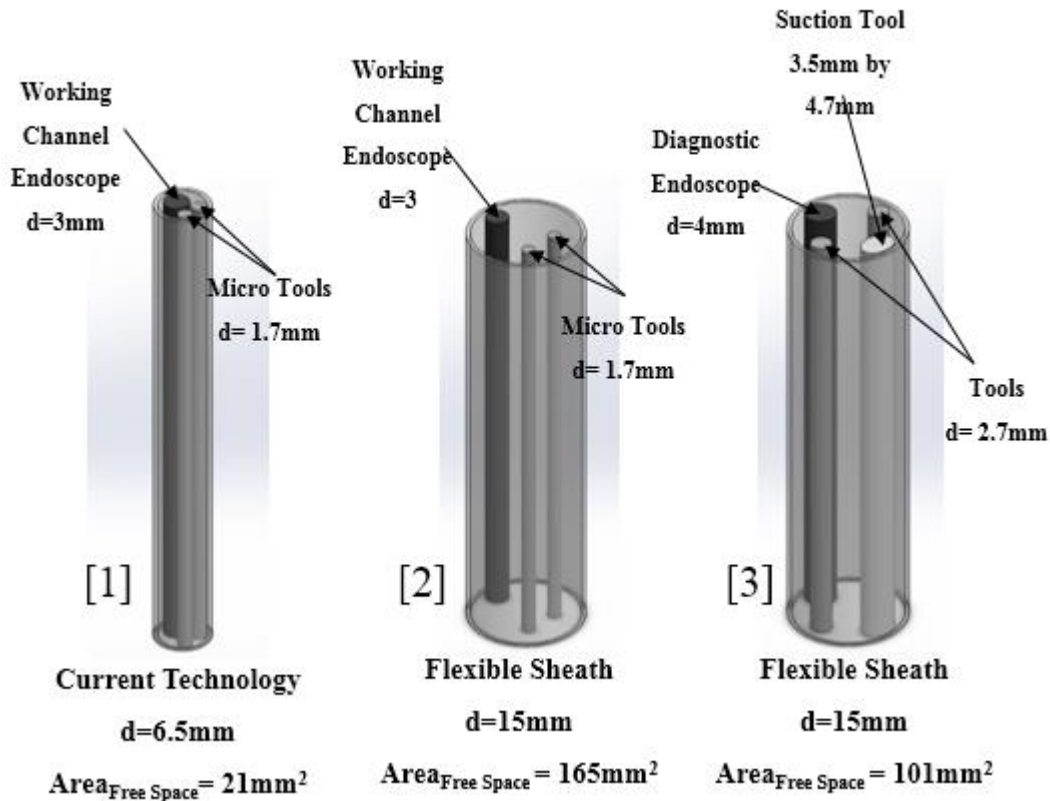


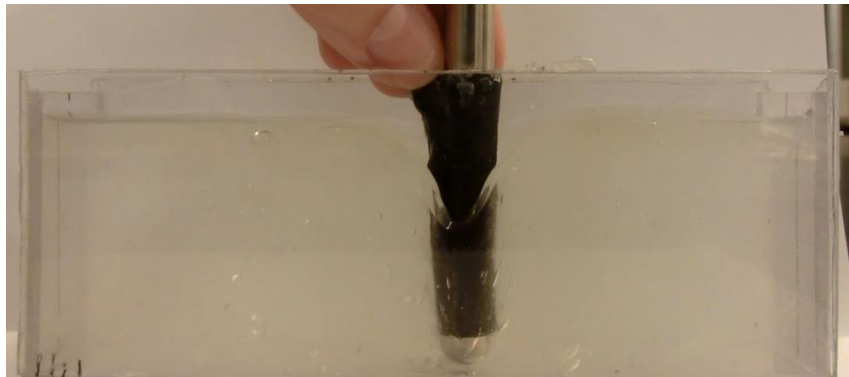
Figure 24: Comparing Size of Working Channel

In Figure 24, image 1 shows the endoscope and two micro tools used in the current procedure. Two different endoscopes are required for surgery. First, the diagnostic endoscope, of larger diameter and higher image quality, is used to initially gain vision of the affected area. The smaller, working channel endoscope is then inserted, which produces a lower quality image, but allows for tools to be inserted next to it. Although the area of the working channel allows for a maximum of two micro tools in conjunction with the working channel endoscope, this takes up almost the entire tunnel, leaving only  $21\text{mm}^2$  of free space, which highly limits angular movement. Image 2 in Figure 18 represents the larger size flexible material with the same working channel endoscope and micro tools. This image shows how the increase in size of the tunnel allows for a greater range of tool motion. The free space in the flexible sheath, with the

same tools as the rigid working channel in image 1, leaves  $165\text{mm}^2$  of free space, almost eight times greater than the rigid current technology. Image 3, to the far right, is the same larger flexible sheath in image 2, but represents the ability of using the larger, better quality, diagnostic endoscope for the duration of the surgery, along with the larger tools and a suction device. These larger tools are generally utilized by the surgeon in open brain surgeries and are desired for all surgeries because of their ease of usability. Additionally, in talks with Dr. Cataltepe, the ability to also fit the suction device was found to be important in the ventricle visibility during surgery to complete the procedures with fewer complications. This image shows that even with the use of these larger tools, range of motion is still increased in the flexible sheath, having almost five times greater working area than the current technology. Therefore, these results satisfy previous stated project objectives.

## 6.2 Choosing Material for Working Channel Sheath

Testing was conducted with a flexible material sample to ensure collapse in fact occurred in brain gel substitute. A 1.1 cm diameter PTFE sheath was manufactured for this experiment. The sheath was introduced into the gel using a blunted stainless steel probe as shown in Figure 25.



**Figure 25: PTFE Sheath Insertion into Gel**

The stainless steel probe was then removed and the material collapsed towards the central axis. The initial diameter of the PTFE sheath 1.1 cm. Immediate inward collapse occurred as soon as the probe was removed which was recording using image analysis. The initial collapsed diameter of the sheath was 0.96 cm. After 15 minutes, the sheath collapsed to its smallest diameter as seen in Figure 26. The final collapsed diameter was 0.35 cm, a 68% reduction. These positive results



confirmed the hypothesis that a flexible material (PTFE) would decrease in area in brain gel substitute. Therefore conclusions can be drawn about the potential for collapse in an *in vivo* brain setting, and thus partially alleviating pressure in the surrounding brain tissue.

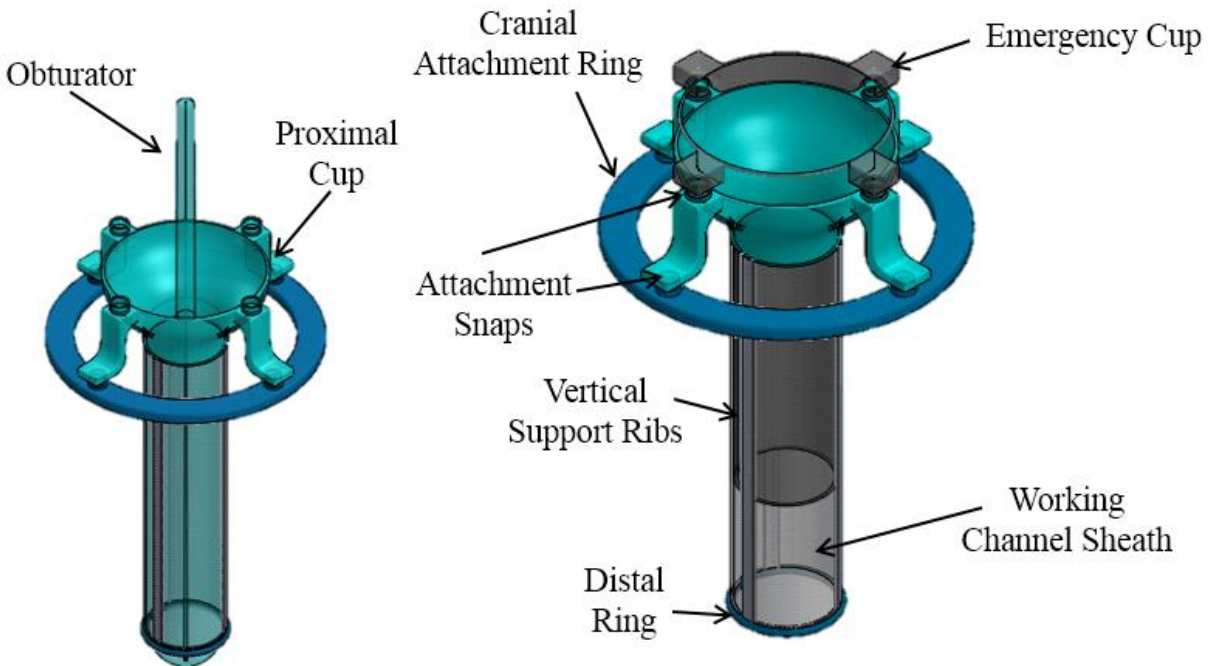


**Figure 26: Collapsed PTFE Sheath in Gel**

Although PEPU was considered strongly for the final design, the promising results of the PTFE collapse in the *in vitro* model showed that this material was superior for the design application. Samples of the ideal durometer PEPU were not able to be obtained due to cost constraints of the project, so therefore the material was ruled out.

### **6.3 Final Design Selection**

A design evaluation matrix, shown in Appendix D, was used to compare the design alternatives against the design's major functions, constraints, and specifications. Based on the matrix, the nylon finger-trap design was not predicted to significantly reduce pressure on the brain for the duration of the surgery. The design could not be easily manufactured to secure at the proximal end, and its large pore size ( $>4\text{nm}$ ) made it inadequate for this application. Additionally, the design shortened in length when it expanded circumferentially. The PEPU and PTFE alternatives had similar benefits; however, the main advantage of the PTFE over the PEPU is that the PTFE would have the ability for greater range of motion of tools because of its high flexibility and collapse. The idea of vertical rigidity in the PEPU design was preferred, and was therefore included in the final design.



**Figure 27: Final Tunneling System Design**

For the aforementioned reasons, the PTFE material was chosen for the flexible sheath. Although the team was only able to attain PTFE samples, it was determined through research that ePTFE was more applicable for this application. Specifically Gore Preclude PDX/MVP Dura Substitute GORE-TEX® material is currently used in neurosurgery to act as a temporary brain dura mater. The material is biocompatible, bioinert and causes minimal tissue adhesion and damage when removed, all properties that are preferable in our chosen working channel material. As this material is already used in neurosurgical applications, it would likely work well for the flexible working channel in this design. Unfortunately, samples of this material and other composites could not be attained due to proprietary restrictions. Figure 27 details the optimized final design. The design combined the main advantages of most every design alternative. It features a single nylon 6 obturator that fits inside the ePTFE working channel sheath. Nylon was chosen because of its common use in medical devices, it is also light weight compared to stainless steel and it has a wide range of material properties. The sheath itself is reinforced vertically with nitinol strips for support. Nitinol can be extruded into thin strips and woven into textiles. It also has the unique ability to have shape memory if this property is desired. The sheath is attached to a nylon proximal cup that can be snapped securely to a surgically stapled attachment ring, stabilizing the

whole system to the brain. In case of an emergency situation during surgery, for example hemorrhaging, a rigid nylon 6 emergency cup can be slid and snapped into place within the proximal cup and sheath, giving open access. A snap fit attachment mechanism was chosen for its ease use and its ability to conform to overall design changes. The design is also very stable and has only one way to attach correctly, eliminated placement error. The diameter of the working channel is 1.5cm, and the length can be varied depending on its use in both pediatric and adult endoscopic neurosurgery. For further detail on design dimensions, refer to Appendix F. The final design was 3-D printed, but was not manufactured for prototyping in the exact materials that were selected for the device.

## Chapter 7: Project Considerations and Discussion

### 7.1 Client Feedback

The final design was selected based on both the technical testing and the client feedback. The design alternatives were presented to the surgeon for his opinion on which one would be most suitable for his applications. Although the nylon finger-trap design was thought to be good design for increased range of motion, there was concern that there was no vertical support and there was a negative correlation with the diameter and length (as the diameter increases, the length decreases). The doctor expressed that it may not be reasonable to manufacture. There was positive feedback for the PE-PU material; however, the surgeon was concerned it would not provide enough difference in range of motion from the current stainless steel device. The ePTFE design was the favored design by the doctor. He favored the extremely flexible design, as it allowed for a larger diameter that could collapse when tools are not in the channel. The nitinol woven down the sides of the ePTFE tube would provide the vertical support needed to maintain a channel into the ventricles, and the ring at the bottom would allow for easy insertion and removal of tools in and out of the channel. The proximal end at the skull would also be able to be maintained open with the use of the fixation system.

### 7.2 Cost Comparison

The team was unable to do a full cost comparison of the design alternatives and final prototype. In talking with the companies that would provide the various manufactured materials, they were not able to give a quote without pursuing manufacturing steps. The baseline manufacturing cost for a bulk of prototypes started at \$1500, which made this step impossible. However, this was not a significant problem for the conclusion of our project, since it was stated in the beginning that cost was not a major factor in designing this device. The team realizes that there will be several different manufacturing techniques that will affect the cost, including the extrusion of the plastic pieces, metal molding for the obturator, and weaving of the ePTFE sheath. Although this may cause the cost to elevate for the device, the anticipated benefits of a decrease in complications and healthcare costs should provide justification for this design.

## **7.3 Impacts**

The team analyzed the various impacts the project and device may have in the following sections.

### **7.3.1 Economic**

While it is crucial to keep health care products cost effective, it is more important that the quality of the device is maintained above all else. When cost of the device was discussed with the client, it was established that cost was not a major factor if the product was better than the existing technology and it improved patient outcomes.

In designing a more effective tool for endoscopic neurosurgical procedures, economic costs are taken into consideration. By offering greater range of motion to surgeons and increased tool size, time in surgery may significantly decrease. Along with decreased time in surgery, comes decreased risk of surgical complications and infection for patients. When time of surgery decreases and patient outcomes are more positive with faster postoperative healing times, cost of healthcare also decreases.

### **7.3.2 Environmental**

There were no large environmental considerations to be addressed during this project. Overall, the goal of this project was to design a tunneling system for endoscopic neurosurgery to facilitate endoscopic neurosurgery. The limited environmental considerations include the cost and environmental impacts of manufacturing the various materials that will be used in the finished device.

### **7.3.3 Social Influence**

This particular research and design project was intended to provide information to the medical community, and specifically those interested in neurosurgical procedures, about endoscopic neurosurgical technology. The system does not implicate social concerns or influences.

Scholars, as well as neurosurgeons and patients, can utilize this research in the further development of devices and advancement of patient care.

#### **7.3.4 Ethical**

There are few ethical concerns with this design project in its current research stage. There were no *in vivo* tests conducted and very little interaction with sensitive test subjects. Gel was used in substitute for testing biological brain tissue, but there are still significant improvements that must be made to the testing medium. If this project is to continue, testing much progress to more sensitive subjects. Once real prototypes can be manufactured, testing will progress through advanced *in vitro* studies, then to animal and cadaver models. However, these considerations lie outside the scope of the project.

#### **7.3.5 Health and Safety**

The design of the tunneling system for endoscopic neurosurgery has not yet been approved by the FDA and is therefore not safe for use in humans. There is a very extensive process that medical devices must go through to gain approval for both testing in humans and then commercial use in the US and other parts of the world. This research project is the first step in the process of design and proof of concept of the device. The concepts demonstrated in this project show that flexible and semi-collapsible materials in this device would decrease pressure on surrounding tissue preventing greater injury and facilitate surgeons, decreasing surgical time and expediting healing time for patients.

#### **7.3.6 Manufacturability**

By the conclusion of this project, it was determined that the manufacturing of this device by the team would be out of scope, and future approach would also deem to be difficult. Basic 3-D prototypes of the design have been generated, but the design has not been manufactured with the ideal materials due to time and money constraints. While it is beneficial to have a novel design idea, it makes initial manufacturing of the design very challenging. Baseline costs for manufacturing this device begin at about \$1,500 minimum. Further complicating the approach is

the need for multiple manufacturing techniques for the device's various components. For instance, the cup, emergency cup, bottom ring and attachment ring require injection molding, while the sheath requires weaving of PTFE (Teflon), and the inner obturator requires either injection molding of a rigid polymer or casting of stainless steel. Various methods of attaching each component including heat and laser welding and adhesives must also be considered. Additional information regarding manufacturing processes as well as sterilization techniques is required before decisions are made.

### **7.3.7 Sustainability**

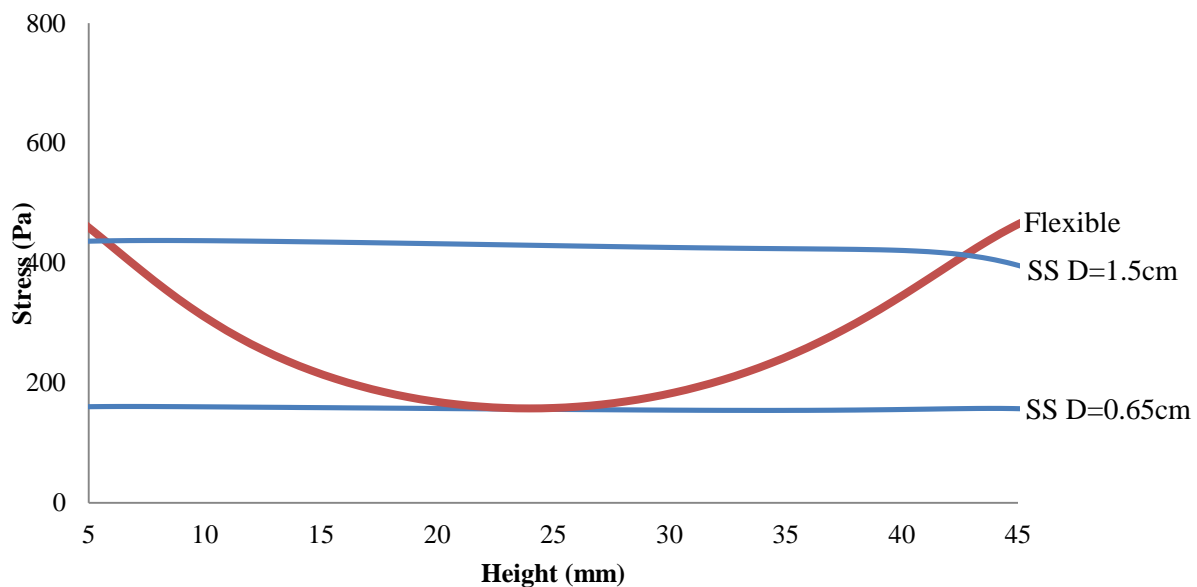
The entire device can be manufactured using existing methods. All chosen materials are commonly used in medical device applications; in combination the device is highly sustainable.

## Chapter 8: Conclusions

### 8.1 Design

Design alternatives were generated and optimized based on results of the FEA modeling, *in vitro* modeling and surgeon preference. The chosen design features a nitinol reinforced ePTFE working channel and a nylon cup opening. Its diameter is 1.5cm and the manufacturing of the working channel length can be varied based on its use for pediatric and adult endoscopic neurosurgery.

The final design was able to increase the working channel by 500%, but only increased the average stress induced on the simulated tissue by 40%. Figure 28 shows the resulting stress of both the new flexible working channel and the stainless steel working channel. The flexible working channel diameter was increased to 1.5cm, and the resulting stress was on average equivalent to the current 0.65cm stainless steel working channel.



**Figure 28: Comparison of the current technology to the flexible channel with an optimum size diameter of 1.5cm**

By increasing the working channel, the working area for surgeons was 5 times larger, even with the use of larger and greater numbers of surgical tools. Figure 29 is a diagram of the current



0.65cm diameter stainless steel channel with micro-surgical tool and an endoscope, in comparison to the new 1.5cm diameter ePTFE working channel with larger tools and endoscope.

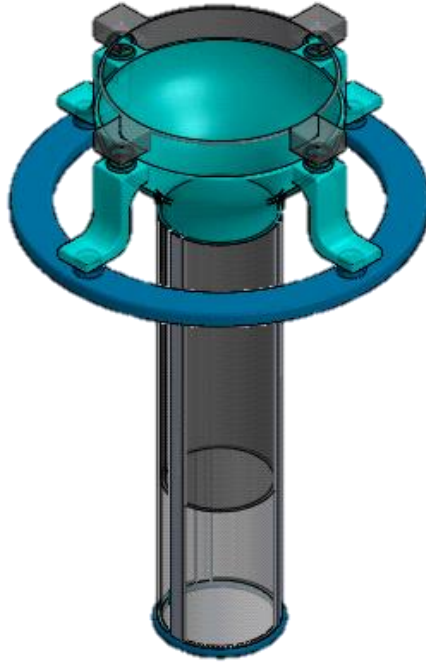


**Figure 29: 5x increase of free working space with new design and use of larger surgical tools**

Based on these factors, the final chosen design was ePTFE material sheath with nitinol vertical support. PTFE was tested in place of ePTFE, the desired material. The *in vitro* testing confirmed the collapse-ability of the PTFE shown in Figure 30.



**Figure 30: Collapsed PTFE Sheath in Gel**



**Figure 31: Final Design**

In conclusion the final design, shown in Figure 31, optimized the size of the working channel creating many advantages for both the surgeons and the patients. The larger size sheath allows surgeons increased range of motion, better visibility, and the ability to use larger tools. These benefits result in ease of use for the surgeon, decreased surgery time, and overall leading to better surgical and patient outcomes.

## **8.2 Recommendations**

After finishing the project, some project improvements were recommended, including testing various shapes of the sheath or using different FEA software to analyze the design alternatives.

### **8.2.1 Change in Design**

The first recommendation in the design of the neuroendoscopic tunneling system is in the design alternative process. Although this project worked in collaboration with a single neurosurgeon, it is recommended to gather feedback from other doctors in the same specialty to come to a

consensus on the most important factors that should to be considered in creating such a device. Diversity of expert feedback would allow for creation of a more universally acceptable device.

The second recommendation, relating to the design itself, is to explore the possibility of an elliptical-shaped sheath design rather than a circular one. This design may induce less pressure on the brain tissue with its ability to more readily collapse uni-directionally in between the gyri, or in the center of the sulci of the brain. In this way, the ellipse could be oriented in such a way to allow maximum angular motion of tools along one axis, with minimal pressure applied to the surrounding brain tissue. Extensive FEA analysis of this elliptical design would need to be conducted to determine whether or not this hypothesis is correct.

Further continuation of this project could include more official industry prototyping of the device. Without testing the final prototyped design, it is difficult to determine ease of use and effectiveness. This testing could be performed with an *in vitro* animal or cadaver model and then with *in vivo* user validation. It is also recommended to do an extensive cost analysis. Because it was impossible to get a quote for the final chosen design of this project, the cost per device was not determined. Doing a cost analysis may lead to a different material selection for the final design, as some materials or manufacturing processes may prove to be unfeasible.

### **8.2.2 Change in Testing**

Several improvements to the testing were considered. A more physiologically accurate *in vitro* model could be developed to better simulate the brain tissue and environment for testing the designs. The model used in this project did not consider intracranial pressures and therefore was not the most accurate at determining what materials induced the most displacement and stress on the tissue. A container with the exact brain geometries and physiological pressures could be constructed to simulate the endoscopic surgery.

The other component of the testing was the finite element analysis. Recommendations for this portion include imputing more sheath sizes by evaluating them at smaller increments. This would give more accurate trend lines for a given material. Additionally, a higher computing power and laboratory setup is recommended, as solving this model proved to be tedious on normal

computers and required extensive time and storage. Although ANSYS™ FEA software was used in this project because of previous knowledge, it may not be the most effective software package to analyze the complexity of the hyper-elastic material of brain tissue. Through further research, it was found that ABAQUS™ is commonly used to model brain tissue and other biological materials. This is why using ABAQUS™ FEA software in the future is advised to further analyze the size and material choices for the sheath.

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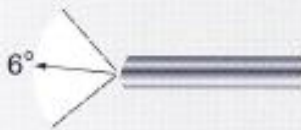
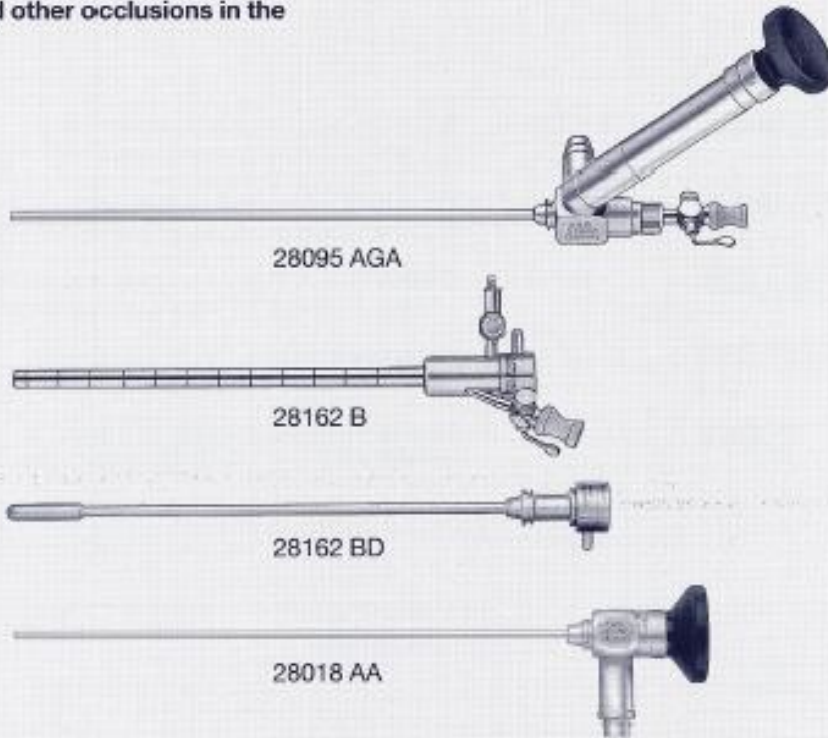
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## Appendix A: Karl Storz Endoscopes

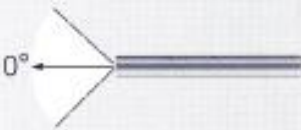
removal, tumors and other occlusions in the ventricular region.



28095 AGA **HOPKINS® Wide Angle Straight Forward Telescope 6°**, with angled eyepiece, with instrument channel diameter 3 mm, length 15 cm, **autoclavable**, fiber optic light transmission incorporated, color code: green

28162 B **Operating Sheath**, outer diameter 6.5 mm, working length 13 cm, with graduated scale, with lateral stopcock and inlet for catheter, with obturator 28162 BO and obturator 28162 BB for stereotactic positioning

28162 BD **Optical Obturator**, for positioning of operating sheath 28162 B under visual control, for use with **HOPKINS®** telescope 28018 AA

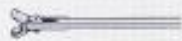
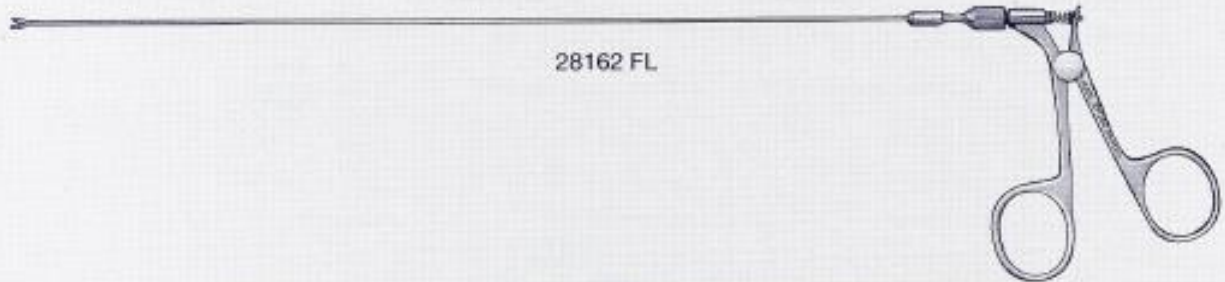


28018 AA **HOPKINS® Straight Forward Telescope 0°**, diameter 2.7 mm, length 18 cm, **autoclavable**, fiber optic light transmission incorporated, color code: green



## Appendix B: Karl Storz Tools

### Rigid instruments for use through the central channel Diameter 1.3 mm, working length 30 cm



28162 FL

**Biopsy Forceps**, double-action jaws, semi-rigid, diameter 1.3 mm, working length 30 cm



28162 FK

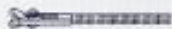
**Grasping Forceps**, double-action jaws, semi-rigid, diameter 1.3 mm, working length 30 cm



28162 FP

**Scissors**, single-action jaws, pointed, diameter 1.3 mm, working length 30 cm

### Flexible Instruments for use through the lateral channel Diameter 1 mm, working length 60/53 cm



11161 KA

**Biopsy Forceps**, double-action jaws, flexible, diameter 1 mm, working length 60 cm



11161 KB

**Grasping Forceps**, double-action jaws, flexible, diameter 1 mm, working length 73 cm



28160 KA

**Coagulating Electrode**, unipolar, flexible, diameter 1 mm, working length 53 cm



## Appendix C: Pairwise comparison Chart

Objectives	Sustains a passageway	Match Pressure	Securable to proximal end	Durable	Increase diameter	Suitable for all ages	Score
Sustains a passageway	X	1	1	1	1	1	5
Match Pressure to CT	0	X	1	1	1	1	4
Securable to proximal end	0	0	X	0	0	0.5	0.5
Durable	0	0	1	X	0	1	2
Increase diameter	0	0	1	1	X	1	3
Suitable for all ages	0	0	0.5	0	0	X	0.5

## Appendix D: Design Alternative CAD Drawings and Selection Matrix

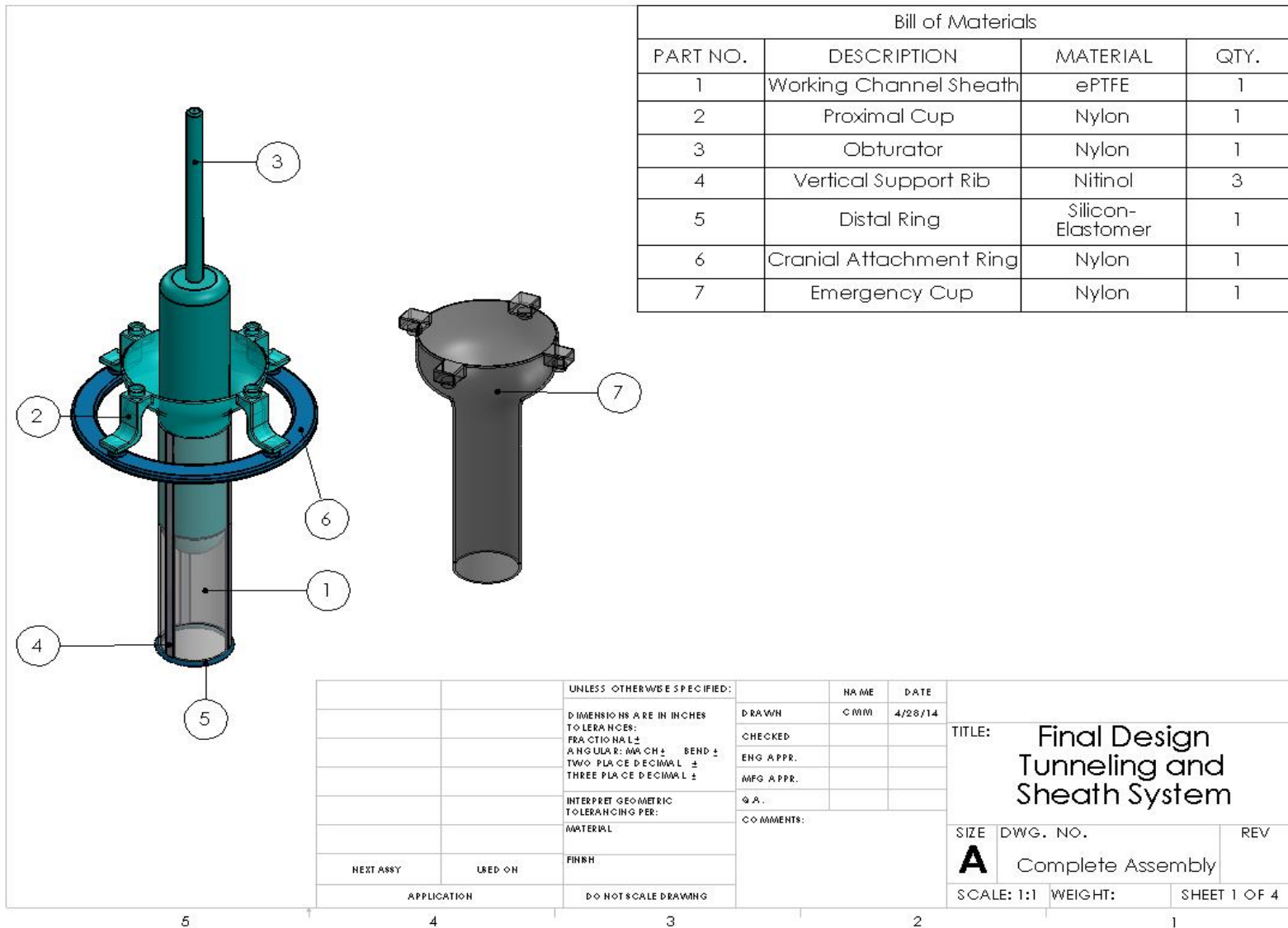
<i>Design Alternative Evaluation Matrix</i>				
	Woven ePTFE with Nitinol Support	Extruded Tecoflex with Vertical Ribs  (Polyether Polyurethane)	Extruded Tecoflex  (Polyether Polyurethane)	Nylon “Finger Trap”
<u>Constraints</u>				
• Biocompatible	√	√	√	√
• “Sterilize-able”	√ EtO	√ EtO	√ EtO	√
<u>Objectives</u>				
• Sustains Passageway	√	√	√	√
• Reduces Pressure	√	√	√	X
• Securable at Proximal End	√	√	√	X
• Increase Range of Motion	√	X	X	√
<u>Functions/Specs</u>				
• Max Diameter/ 1.5cm	√	√	√	√
• Collapsed Min. Opening/ .5cm	√	√	√	X
• High Puncture Strength	√	√	√	√
• Pore Size <4um	√	√	√	X

<ul style="list-style-type: none"> <li>• Maintains Longitudinal Length/ <math>L=7\text{cm}</math></li> </ul>	√	√	√	X
<ul style="list-style-type: none"> <li>• Minimum Wall Thickness</li> </ul>	√	√	√	X
<ul style="list-style-type: none"> <li>• Low Friction (Coefficient)</li> </ul>	√	√	√	X

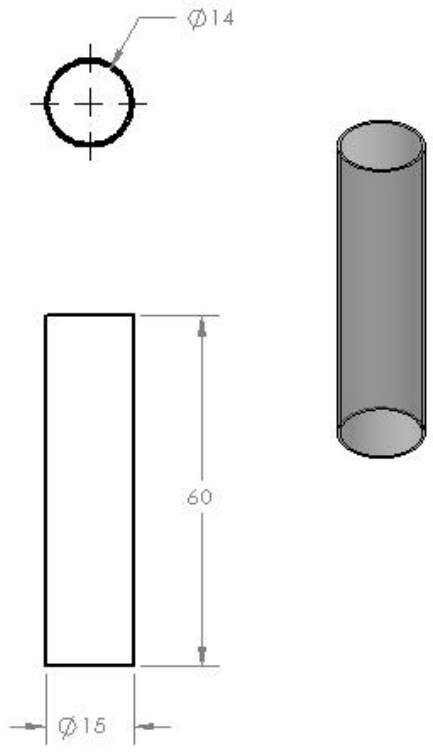
## Appendix E: Gel Model In vitro Testing Results

<b>3.14.14 1.5 mL B Gel</b>	<b>Phase 3</b>	<b>STDEV</b>
Sample 1	2407.2	238.8
Sample 2	4132.2	660.2
Sample 3	3393.9	511.8
Sample 4	3136.1	480.9
Sample 5	3539.8	589.4
AVG	<b>3321.8</b>	
STDEV	628.6	

## Appendix F: Final Design Drawing

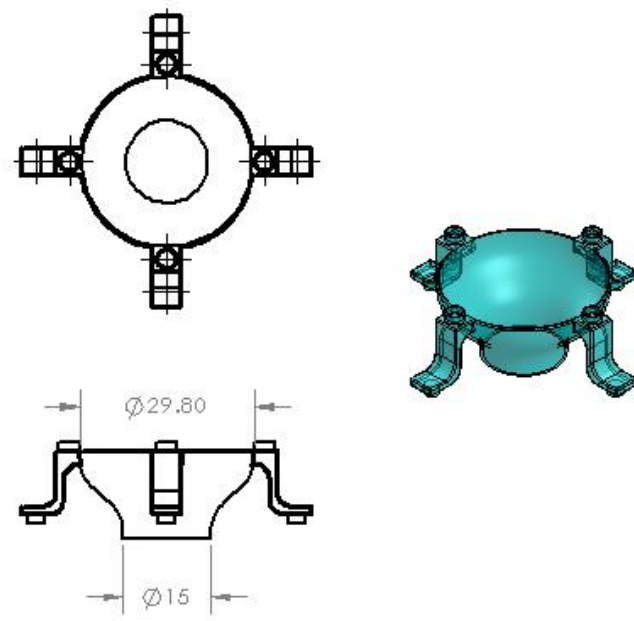


Wall Thickness=0.5mm



Part No. 1

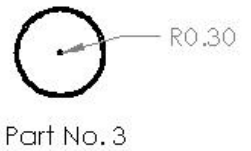
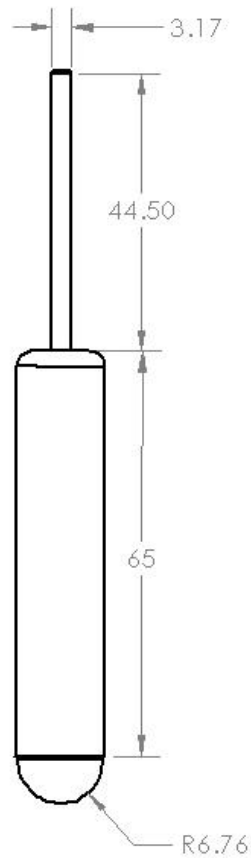
Wall Thickness=0.5mm



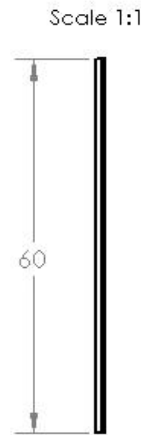
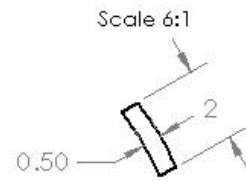
Part No. 2

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		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	TITLE: Working Channel Sheath and Proximal Cup	
		DIMENSIONS ARE IN INCHES		DRAWN			
		TOLERANCES:		CHECKED			
		FRACTIONS: ±		ENG. APPR.			
		AND DECIMALS: ±		MTC APPR.		SIZE DWG. NO. REV	
		THREE PLACE DECIMAL: ±		Q.A.		A Part No. 1,2	
		NEEPTRE GEOMETRIC		COMMENTS:		SCALE: 1:1 WEIGHT: SHEET 2 OF 4	
		TOLERANCE PER:					
		MATERIAL:					
		FINISH:					
		DO NOT SCALE DRAWING					
5	4	3	2	1			

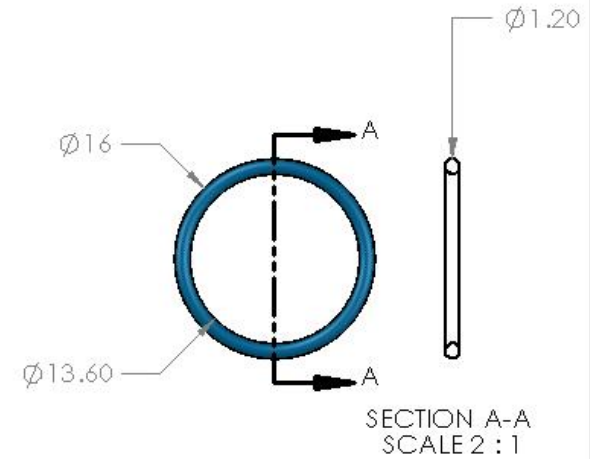


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Part No. 3

Scale 2:1



Part No. 4

		UNLESS OTHERWISE SPECIFIED:		NAME	DATE		
		DIMENSIONS ARE IN INCHES		DRAWN		TITLE:	
		TOLERANCES:		CHECKED		Obturator, Vertical Support Rib,	
		FRACTIONAL ±		ENG APPR.		and Distal Ring	
		ANGULAR: MA CH ± BEND ±		MFG APPR.		SIZE	DWG. NO.
		TWO PLACE DECIMAL ±		Q.A.		<b>A</b>	Part No. 3,4,5
		THREE PLACE DECIMAL ±		COMMENTS:		SCALE: 1:2	WEIGHT:
		INTERPRET GEOMETRIC				SHEET 3 OF 4	REV
		TOLERANCING PER:					
		MATERIAL:					
NEXT ASSY	USED ON	FINISH					
APPLICATION		DO NOT SCALE DRAWING					

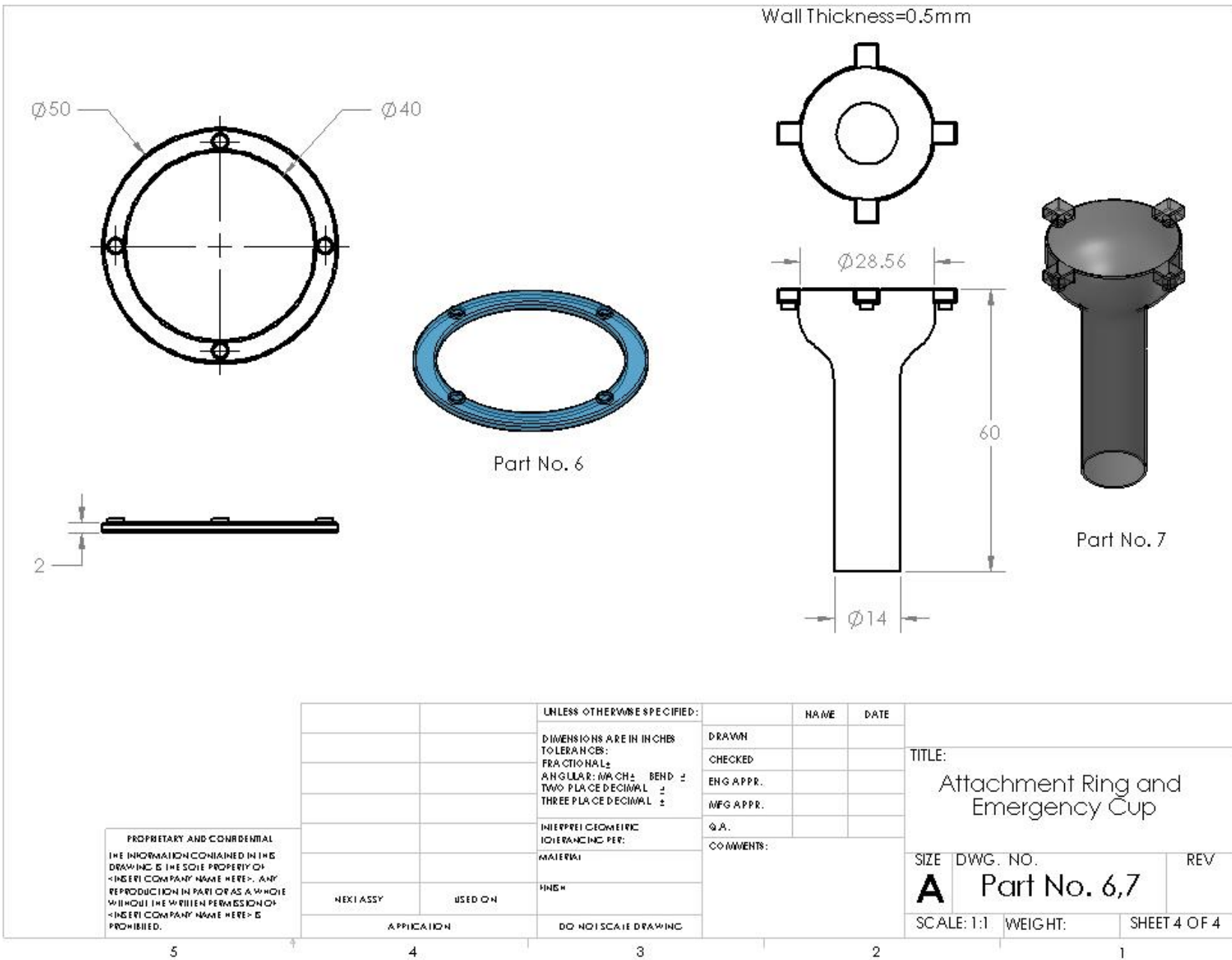
5

4

3

2

1



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		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	TITLE: Attachment Ring and Emergency Cup
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONALS		DRAWN		
		ANGULAR: MATCH BEND ± TWO PLACE DECIMAL ±		CHECKED		
		THREE PLACE DECIMAL ±		ENG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:		MFG APPR.		
		MATERIAL		Q.A.		SIZE DWG. NO. REV
NEXT ASSY		USED ON		COMMENTS:		<b>A</b> Part No. 6,7
APPLICATION		FINISH				SCALE: 1:1 WEIGHT: SHEET 4 OF 4
		DO NOT SCALE DRAWING				