Tissue Retractor for Distal Radius Fracture

A Major Qualifying Project Report:

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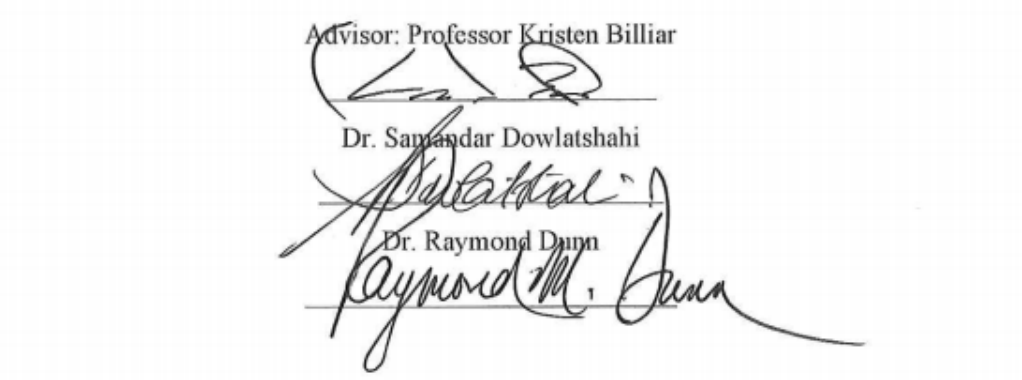

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Retractor
Self- Retaining
Distal Radius Fracture

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Authorship

The following paper was completed with equal contribution between all group members. Each group member was present at meetings, designed prototypes, performed testing, and contributed to the paper.

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Abstract

As distal radius fractures continue to be a common operating room procedure, the need for a self-retaining retractor for surgery is prevalent. Currently, the self-retaining retractors on the market lack in functionality and efficiency. The alternative to using self-retaining retractors requires additional personnel in the operating room to hold the incision open, requiring time and money. The team proposes a self-retaining retractor that is able to expose the incision site, is adjustable and replaces the need for additional surgeons.

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1. Introduction

A distal radius fracture is one of the most common hand and wrist surgeries that are treated by physicians each year with over 640,000 new cases each year. Each year there are approximately 21,000 cases of hand and wrist injuries each year with about 44% of those cases being distal radius fractures [1]. For each distal radius fracture surgery, the tissues and muscles need to be moved so that the bone can be exposed. Retractors are used to retract tissue and organs during surgery. However, most retractors are not self-retaining, and there are many limitations with the current designs. The main constraint is the retractor's lack of stability when placed within the incision, which is associated with the biasing forces caused by the anatomical features of the incision site. These insufficiencies often lead to the retractor slipping out of the patient and landing onto the floor, causing the device to be unsterile and unusable. The use of these retractors frequently requires nurses, interns, and medical students to hold the incision open, which requires resources and time for all involved. Another restriction of the current model is that the retractor's retaining elements can be too sharp which can tear the skin or puncture important arteries [2]. As a result, there is unnecessary bleeding and the incision is compromised. The average cost of a self-retaining retractor varies from $100-260 [3]. However, the current retractors have been deemed unsatisfactory by many surgeons and the client has expressed a need for an innovative, self-retaining retractor.

The purpose of this project is to design a novel, versatile, economical, self-retaining retractor for use in distal radius fracture surgery that has ideal mechanical properties and a competitive edge over existing products. The device must expose the incision site and retract surrounding tissues, skin, and organs in order for surgeons to access the target areas on the patient. This device must also be able to withstand tensile, compressive, and shear forces that are applied on the device from the tissue and muscles of the patient. It must resist mechanical failure and expand and contract surrounding tissue, skin, and organs based on surgeon's needs.

Most importantly, the self-retaining retractor must be safe and cause no harm to the patient or user. There should be no exposed sharps, and it must be biocompatible. Next, the device must be easy-to-use and operable by one user. It should require minimal training and should not extend or delay the surgical procedure time. Moreover, the device should be adjustable and cater to the client and patient need. It should also be versatile consisting of interchangeable retaining elements with the potential to be used in similar procedures. Lastly, the retractor should be marketable and consist of unique design components that addresses the client need. All these objectives will be considered when creating a self-retaining retractor for extremity surgeries, specifically surgeries in the wrist.

A fracture of the distal radius, is one of the most common fractures observed by surgeons today. However, the surgery to address this type of fracture can be complicated due to the amount and proximity of muscles, ligaments, tendons, and blood vessels that surround this area [4]. For this reason, the type and number of retractors chosen for a crucial decision can directly impact the surgeon's success and patient's outcome. Typically, there are only two or more retractors used for distal radius surgery for the purpose of holding open the incision open; however, other retractors may be needed in order to move additional surrounding tissue so that the surgeon can locate the fracture.

Each retractor chosen for this surgery has several drawbacks. Sharp retractors that are used to hold open the incision often puncture the skin or even worse, a nearby blood vessel further complicating the surgery. Choosing a blunt retractor could lead to the retractor slipping out of the incision which could extend the surgical procedure. The handle on each retractor is also problematic. Handles that contain a circular hole to put a finger through often prove to be difficult to maneuver and readjust.

Beyond the handles there are several other elements of the retractor that have received negative feedback from surgeons. One element is the retaining elements, which are located on the end of the retractor that is in contact with the skin. These retaining elements can be sharp or blunt and as previously

mentioned both options can cause surgical complications. However, one aspect of the retaining elements that was not discussed was that blunt objects tend to be more dangerous in the operating room than sharp ones. Sharp objects can make straight incisions while blunt objects can make jagged cuts that become more harmful.

Another aspect of the retractors, especially self-retaining retractors, that has created challenges for surgeons is the ratcheting system. This system allows for the self-retainer to be opened in small increments depending on the width of the surgical incision. When the surgeon needs to lessen the width of the incision, current ratcheting systems require the retractor to be completely closed and then opened to the correct width. There is no effective system in place that allows the retractor to close in small increments.

All the challenges discussed above can cause surgical complications to extend the procedure time. In addition, retractors that are not self-retaining require nurses, assistants, and interns to hold these retractors in place for over an hour which can prove to be both difficult and expensive.

Additionally, surgeon interviews and observations will provide a greater understanding of the current gaps in retractor function and establish potential areas for improvement. Since surgeons are the direct clients, their input will lead to the best possible design. As users, doctors will communicate their needs to the team who will research and create design alternatives. These will be brought back to the doctors for more feedback. In order to create a self-retaining retractor that truly fulfills the needs of the user and client, the team will adopt an iterative approach where everyone involved is updated constantly. Other than interviews, observing surgical procedures will be another method to collect data and understand the current need for a self-retaining retractor. Combining this feedback from surgeons, observing the need first-hand in the operating room, and researching patents on the current market will allow for well-rounded brainstorming and designs. Ultimately, alternative designs will lead to prototyping and the creation of proofs-of-concept that will advance the project.

Once preliminary designs have been established, CAD (Computer-aided Design) models will be created in order to communicate these designs to the client. The specific software used for 3D modeling for this project was Solidworks. Several models will be developed in order to provide the client with a wide-range of options. Specifically, different ratcheting systems, handles, and retaining elements will be created and analyzed using CAD software. Once these proofs-of-concept are reviewed and revised, 3D prototyping will be used to produce final designs. The 3D printed models will allow the team to elicit feedback from surgeons pertaining to the retractor for ease-of-use and functionality. Material considerations will also be discussed during this stage of the design process.

The need for a self-retaining retractor for extremity surgeries is evident. Designing this novel retractor will prove to be beneficial for surgeons and patients. Surgeries will be more efficient, safe, and pleasant for the users. Documenting the iterative design process, communicating this procedure to all the stakeholders involved, creating a computerized model, prototyping the best design, and testing its mechanical properties will lead to a revolutionary self-retaining retractor for extremity surgery.

2. Literature Review

2.1 Medical Significance

Distal radius fractures are on the rise in the United States with over 640,000 new cases each year. The current retractors used for repair of the radius are inadequate in exposing the surgical site for the duration of the procedure. A distal radius fracture is one of the most common hand and wrist surgeries treated by physicians each year. Out of the 1.4 million ER visits each year in the United States, there are approximately 21,000 cases of hand and wrist fractures. Of these 21,000 cases, 44% of are distal radius fractures [1]. These types of fractures are also ubiquitous in orthopedic practices. They account for 8-15% of all bone injuries in adults.

There are two peak age divisions that are affected by these types of fractures. Young people are involved in high impact injuries account for a large number of distal radius fractures, while older patients are affected by low impact injuries report for the remaining population. Most of the time, intra-articular component in distal radius fractures represent high-energy traumas in young adults. These injuries cause impacted and shear fractures of the articular surface of the distal part of the radial bone. The elder group of patients usually portray extra-articular patterns of fractures [5]. The spread of distal radius fractures has increased drastically for three main reasons. The baby boomer generation is now entering the osteoporotic years of their lives, the surge in a more active elderly generation, and the increase in sport related activities have all lead to an increase in the prevalence of distal radius fractures in the United States.

With the breakthrough in cases of distal radius fractures in recent years, the need for more efficient procedures is evident. The current standards may have sufficed in the past; however, the increasing number of patients has heightened the demand for a self-retaining retractor to improve the efficiency and quality of distal radius fracture surgery.

2.2 Retracting the Anatomy of the Wrist

2.2.1 Musculature, Vascularization, Nerves, and Other Soft Tissues

The anatomy of the wrist can lead to complications while in surgery, especially due to the limited space for an optimal incision size. The vascularization and nerves that run along the forearm make wrist surgery a delicate procedure while the tendons, ligaments, and muscles require strong stabilization from the retractors.

Performing distal radius fracture surgery requires the complete exposure of the radius. Consequently, the surgeon must work around 15 ligaments and tendons, 10 muscles [6], critical vascularization and nerves. In this particular surgery, the brachioradial tendon, seen in Figure 1, needs to be removed in order to repair the fracture. In addition, the musculature has to be retracted and held in place to allow for better bone visualization. For instance, the pronator muscle in Figure 1 has to be moved the right as seen in Figure 1. Regardless of the small incision as seen in Figure 1, and width of the patient's wrist, the surgeon works layer by layer until the fractured bone is fully visible. This step-by-step approach requires a versatile retractor that can adjust and stabilize the incision. Currently, this exercise requires several retractors such as rake or army retractors, which makes the surgery less efficient and costly. Evaluating these steps and the biasing forces caused by muscles and soft tissues will be vital while designing a self-retaining retractor.

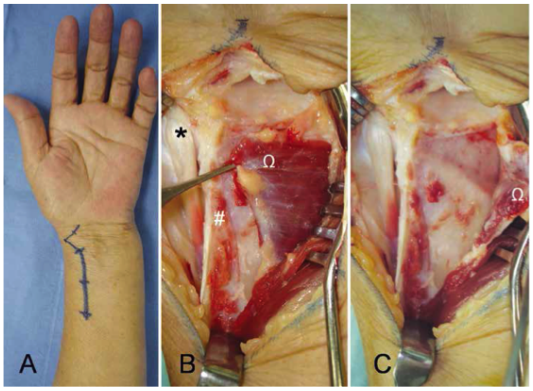


Figure 1: Brachioradial Tendon (#), Pronator Quadratus Muscle (Ω), and First Extensor Component (*) [7]

Furthermore, there are three major anatomic components that will affect the design of the self-retaining retractor. The first one is the vascularization of the forearm. Surgeons have emphasized the fragility of the radial artery (see Figure 2) [8]. Figure 1

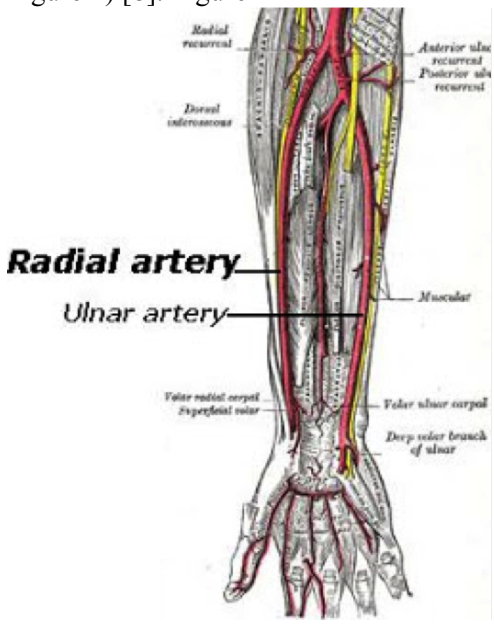


Figure 2: Forearm Vascularization which shows the placement of the Ulnar and Radial Artery [8]

The second major anatomic component is the nerves that travel along the arm. More specifically, there are three main exposed nerves during distal radius fracture surgery: the median, ulnar, and radial nerves (see Figure 3). The median and radial nerves are of particular interest since they are in the main incision space. The surgeons must be careful while maneuvering such nerves; however, these are not as fragile as the vasculature. Therefore, sharp retaining elements can be incorporated into the ulnar side of the incision [9].

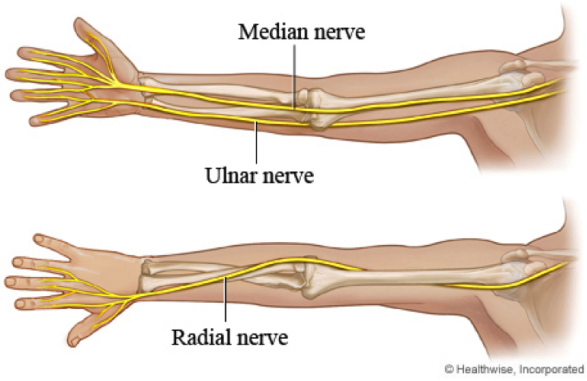


Figure 3: Nerves Along the Arm: Median, Ulnar, and Radial Nerve [9]

Finally, the skin properties are the third main anatomical component. This novel retractor must hold the skin incision open for the entirety of the procedure, all while preserving the skin's integrity. The skin's response to mechanical stress is important because it affects the biasing forces that act against the retractor; however, the skin forces that act on the retractor depend on many factors including the age of the patient. Therefore the design of this novel retractor has to take into account all the factors that could make the skin more or less resistant. Distal radius fracture patients can be categorized into two groups based on age: young patients with high impact injuries and elderly patients with osteoporosis. The elasticity of the skin depends heavily on the age of the patient. This elasticity is dependent on the elastin composition of the skin. Skin elasticity lessens as age increases, which means that it loses the ability to retain its shape after being stretched. Consequently, younger people's skin will create a greater biasing force than the skin of an older patient.

Another factor that affects the skin biasing forces is its thickness, which depends on the skin's location. The skin on the underside of the wrist is thinner when compared to the skin on other parts of the body. The blood vessels in the wrist are also located closer to the skin than in other parts of the body. This means that the retaining elements of this retractor must have the correct depth. The thickness of the skin can also be dependent on how often it is exposed to friction. If skin is exposed to friction on regular occurrences, then the skin can form callouses which would increase its thickness. This thickening of the skin can affect the required depth that the retaining elements on the retractor must meet. In short, the skin biasing forces depend on many variables that need to be considered throughout the design process [10]. Understanding these features will protect the skin will allow for a better and faster recovery of the patient. The surgeon will also feel more comfortable while retracting the skin and adjusting the retractor throughout the procedure.

2.2.2 Targeted Bones of the Hand and Wrist

Once the surgeon is able to retract the soft tissues surrounding the bone, the fractured wrist is finally exposed. The targeted bone is the radius, which is closely related to the ulna and the carpal bones. The ulna and radius are the two major bones of the forearm, which connect to 8 carpal bones on the base of the hand (see Figure 4) [11].

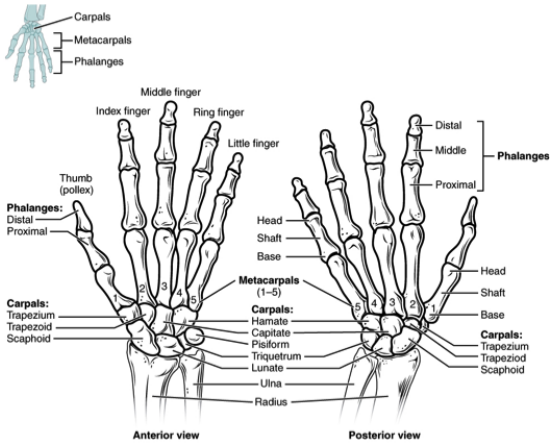


Figure 4: Bones of the Wrist and Hand showing the Ulna, Radius, and Carpal bones [11]

2.3 Distal Radius Fracture Procedure

Distal Radius fractures are one of the most common fractures seen today by surgeons; however, there are several different approaches to fixing these fractures and all require the use of different retractors [4]. One of the most common approaches used by surgeons is the Volar approach because this approach can be used to implant a plate on the tensile side of the radius. The implantation of the plate in this part of the radius allows for there to be less irritation because there is greater soft tissue coverage. The volar approach can further be broken down into three different types of surgeries: the Henry approach, the Trans- FCR approach, and the volar extensile approach. The first two approaches mentioned allow for the volar surface of the radius to be easily exposed making the implantation of the plate easier. The third approach that was mentioned allows a carpal tunnel release to be performed as well making this approach beneficial to those who also need this surgery. However, there are some disadvantages to some of these approaches as well. One disadvantage to the Henry approach is that it requires dissection of the radial artery. A dissection of this artery means that the surgeon is less likely to use a sharp retractor for fear that it may tear open the radial artery, causing more of an issue and possibility elongating the time spent in surgery.

The radial approach can be used to implant a radial plate as well as implant other pins and wire if needed. This approach requires the surgeon to approach the radius near the radial border which requires the surgeon to identify and protect the radial nerve. If the nerve is near the incision then the type of retractor used to move that nerve out of the area that the surgeon needs to work in needs to be considered. The retractor needed to move this nerve cannot harm the nerve but if the retractor slips and releases the nerve into the space that the surgeon is working in then the nerve could still be damaged. This specific nerve has a predilection towards irritation therefore special needs to be taken when performing surgery near and retracting this nerve.

The dorsal approach allows for the implantation of a dorsal plate and other fragment specific fixation of certain fractures. There are several different approaches that can be chosen once the dorsal approach is chosen. The Trans-EPL Approach requires the surgeon to be able to identify a particular tendon and nerve that need to be safely cleared from the area that the surgeon needs to work in. The type of retractor needed to retract both a tendon and a nerve cannot harm either of these tissues but it also cannot risk the tendon or the nerve slipping into the area that the surgeon needs to work in. If this happens then extensive damage could be done to both the tendon and the nerve which would cause the surgery to become elongated. The Dorsal-Ulnar approach also requires the surgeon to have contact with several ligaments that require similar care in order avoid unnecessary damage to these body parts [4].

Figure 5 and Figure 6 show the distal radius fracture plate after it has been implanted into a patient.

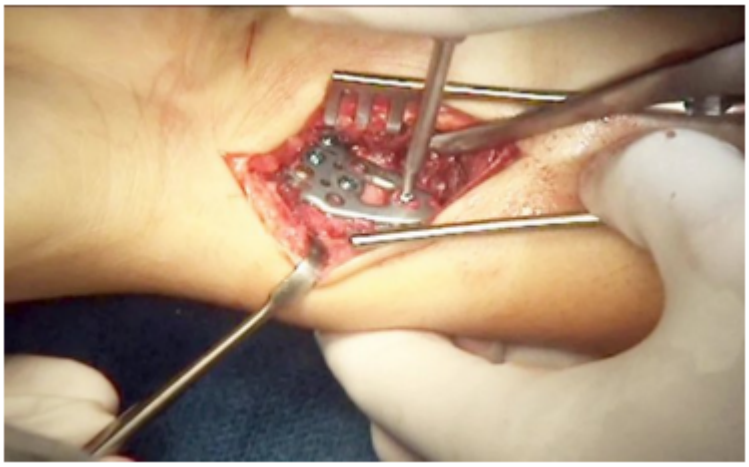


Figure 5: Distal Radius Fracture Plate Insertion with multiple types of Retractors [7]

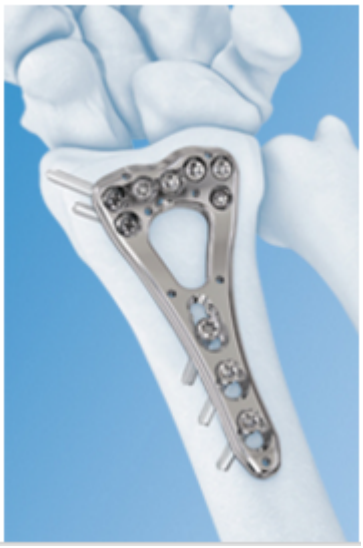


Figure 6: Distal Radius Fracture DRF Plate in the Radial Bone [12]

2.5 Patent Search

There are over 16,000 patents that have been field in the United States with over 3,000 of those patents being filed in the last five years. These numbers reveal that there is still a gap in knowledge and room for improvement, despite the number of retractors currently available. In order to create a novel device there needs to be an understanding of the current technology available to surgeons [1].

Before discussing each patent, it is important to define the nomenclature that will be used. The following are definitions that will be used throughout the remainder of the paper.

Self-retaining: The word self-retaining in the context of this paper will refer to retractors that can keep the incision open without outside help using a type of ratcheting system. For this paper, the word self-retaining will not refer to ring retractors. If ring retractors need to be referred to, then such wording will be used.

Ratcheting system: The ratcheting system of a retractor is the part of the retractor that controls the distance between the retaining elements. The ratcheting system is outlined in red in Figure 7.

Grip/Handle: The grip or handle of the retractor refers to the part of the retractor that the surgeon's hand is in contact with and how the surgeon maintains control of the instrument. The handles or grip are outlined in yellow in Figure 7. More information on the ergonomics of the handles and grips can be found in Chapter 2.6.

Retaining elements: The retaining elements are the part of the retractor that comes in contact with the skin, muscles, nerves, and vasculature in the arm and are placed in the incision. The retaining elements of the retractor are outlined in blue in Figure 7.

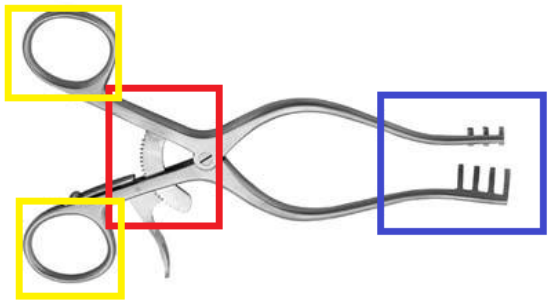


Figure 7: Components of a Retractor: Handles are outlined in yellow; ratcheting system outlined in red; retaining elements outlined in blue [13]

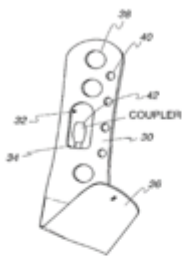
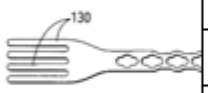
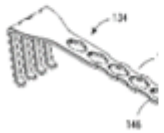
In order to design a novel soft tissue retractor it is important to understand the current devices that are available in the market. Each device lacks certain elements that allow the device to be ideal for a distal radius fracture surgery. One major device that is available to surgeons is the Cricket Retractor. This retractor contains an auto-locking mechanism which allows the ratcheting system to lock into place once the desired distance between the retaining limbs is achieved. The problem with this device is that the ratcheting mechanism limits the geometric area that the surgeon are allowed to work in. Another major device currently in the field is the Weitlaner or Gelpi retractor. A small or medium sized Gelpi retractor is slightly too short to effectively retract the necessary parts of the wrist that need to be moved in order to perform the surgery [14]. An Army Navy retractor is a retractor that has a shorter blunt retaining element on one side of the device and the other side has a longer retaining element for use in retraction of tissues down to the bone. The client has noted that this device is slightly too short to reach the necessary elements, while the longer end is slightly too long and forpasses the bone for use in distal radius fracture surgery. The current devices that are on the market are inadequate for distal radius surgeries. Considering the high number of existing patents, the team must research and reverse engineer existing devices to conceptualize a novel design.

For the purpose of the project, a self- retaining retractor will be split up into three basic parts; the grips or handles, the ratcheting system, and the retaining elements, as seen in Figure 7. The retaining elements are often characterized as being sharp or blunt, however any variation between is also possible. Both types of retaining elements have issues by association. The ratcheting system is another component of the retractor that can be a cause for concern. There are many variations of ratcheting systems but there are three types that are commonly used in retractors. These include a bar system, the ratcheting system, found in the Gelpi Retractor, as well as the ratcheting system found on the cricket retractor. Lastly, the handle or grip of the retractor has an impact on the effectiveness of the retractor as a whole. The handles

on retractors have a wide range. The handle can be a hole that the surgeons put their finger through, or grooves in the middle of the retractor to improve the grip on the device [13].

The retaining elements of the retractor are the part of the retractor that come in contact with the patient's tissue. Most retaining elements are classified as blunt or sharp but any variation is possible. Blunt retaining elements are typically used during surgeries where there are major blood vessels near the incision site [15]. If sharp retaining elements are used near an incision site that has major blood vessels, the surgeon runs the risk of the retractor slipping and puncturing the blood vessel. This type of incident would elongate the procedure time and further complicate the surgery [16]. However, blunt retractors are more likely to slip out of the incision whereas sharp retractors are likely to remain securely in place unless removed. If sharp retractors are moved or excessive force is used to hold open the incision, the sharp retractor may tear the skin at the incision site. This could cause an unsightly scar as well the need for extra stitches that can cause pain and unnecessary surgical procedures for the patient [15]. Another consideration is the length of the retaining element. The length of the element contributes to the depth that the retractor can reach in the incision, which is important when the retractor needs to move muscles, tendons, and blood vessels. All of the issues discussed will be considered when prototyping and testing the retaining elements of our novel tissue retractor. Some types of retaining elements along with pros and cons can be seen in Table 1, shown below.

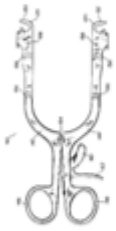
Table 1: Current Retaining Elements on the Market with Pros and Cons of each

Retaining Elements		
	**Type:**	Blunt
	Pros:	decrease risk of causing excessive tramua
	Cons	increase chance of slipping during surgery
	Other Info:	Example: Army Navy Retractor [15]
	**Type:**	Rake
	Pros:	decreased chance of slipping during surgery
	Cons	increase risk of causing excessive tramua
	Other Info:	risk of tramua depends on sharpness of retaining element [16]
	**Type:**	Rake
	Pros:	more depth for retracting deeper tissues
	Cons	increase risk of causing excessive tramua
	Other Info:	risk of tramua depends on sharpness of retaining element [16]

The ratcheting system refers to the part of the retractor that controls the distance between the retaining elements. The most popular form of ratcheting systems is called an ALM or auto-locking mechanism. This mechanism allows the retractor to be locked at a particular distance that is chosen by the surgeon. This helps to reduce the chance of the retractor slipping and closing the surgical site during the procedure. One common ratcheting system is the bar system. This system consists of a bar with holes that

connect to the retractor and hold them in place. The distance between the retractors can be adjusted in increments that are proportional to the distance between the holes in the first bar which allows for the device to be adjustable. However, this device does not allow for small incremental changes and this can be a potential problem with small scale extremity surgery [17]. However, the Gelpi retractor and the cricket retractor allow for smaller incremental changes in the distance between the retaining limbs. The Gelpi retractor has a ratcheting system that allows for small incremental changes as the distance been the retaining limbs increases but the distance between the limbs cannot decrease in increments. In order for the distance between the retaining limbs to decrease, the release needs to be pressed and the device has to be brought back to its original starting position [18]. However, the cricket retractor has the ability to both open and close in small increments. This retractor poses a separate issue that the ratcheting system is quite large compared to the rest of the retractor. The size of the ratcheting system decreases the already small area that the surgeon has to work in [19]. When designing a novel soft tissue retractor, the increments by which the device can be opened and closed will be a considered as an important element of the retractor. Some ratcheting systems along with the pros and cons of each can be seen in Table 2, shown below.

Table 2: Current Ratcheting Systems on the Market with Pros and Cons

Ratcheting System		
	**Type:**	Bat-to-Bar
	Pros:	adjustable; can be locked into
	Cons	obstrusive to surgeon, adjustability limited to precut holes [17]
	Other Info:	
	**Type:**	Locking Teeth
	Pros:	useful in small incisions, can be locked into
	Cons	must be fully released to readjust [20]
	Other Info:	
	**Type:**	ALM (auto-locking mechanism)
	Pros:	useful in small incisions, easy to adjust
	Cons	lack of easy grip, screw mechanism is hard to sterilize [19]
	Other Info:	

There are many different types of handles and grips that can be found on retractors. These include rings for the surgeon's fingers, an expanded part of the retractor, or small grooves for easier grip. The main points of interest for the grip of each retractor is how easily the surgeon can adjust their grip and how likely the retractor is to slip from the surgeon's hand. One example of a simple grip can be seen in the Army Navy Retractor. The grip for this retractor is an expanded part in the middle of the retractor. This retractor is easily adjustable in the surgeon's hand, however it is also likely to slip due to the lack of grips and specific holes for the surgeon's fingers [21]. To combat the problem that some surgeons have

with the retractor slipping, some retractors have a circular gap that allows the surgeon to insert a finger in the hole which allows for a better grip. The issue that this solution poses is that the surgeon cannot easily adjust the position of the retractor in their hand [22]. Another idea to improve the grip on a retractor can be found in a Volkmann Rake Retractor which has a series of grooves in the middle of the retractor. These grooves are meant to improve the surgeon's grip on the retractor while also allowing the surgeon to easily adjust the position in the hand. Unfortunately, these grooves do not always prevent slipping [23]. The team will take all the positive aspects of the current retractors into consideration when designing a grip for the novel retractor. Some handles/grips along with the pros and cons of the each can be seen in Table 3, shown below.

Table 3: Current Handles/Grips on the Market with the Pros and Cons of Each

Handles/Grips		
	**Type:**	Expansion Handle
	Pros:	easily adjust grip
	Cons	becomes slippery when introduced to bodily fluids [21]
	Other Info:	
	**Type:**	Handles with a Hole
	Pros:	hole allows for less risk of slipping
	Cons	not easily adjustable in surgeon's hand, may not fit all surgeon's fingers [24]
	Other Info:	
	**Type:**	Grooved Handle
	Pros:	easily adjustable in surgeon's hand
	Cons	grooves become slippery when in contact with bodily fluids [23]
	Other Info:	

2.6 Retractor Ergonomics

Ergonomics, in regards to medical devices, is defined as the process of altering the tangible device to improve the physical requirements and limitations rather than having surgeons and assistants adapt to devices that over time can cause harm on their physical well-beings [26]. Surgeons in the medical device field can have a strong opinion on ergonomics of the instruments they use each and every day. Examples of this can be seen through the accommodating finger hole in the army navy retractor and the handles of the Gelpi and Weitlaner retractors. In Figure 8 we can see the rounded shape of the scissor grips in the Weitlaner retractor and how easily a surgeon can fit their fingers into these handles. The locking release mechanism is located precisely below the grip and closest to the surgeon's thumb for easy release of the retractor. In Figure 9 below we see an Army Navy retractor that has an added piece in the

middle of the part. This piece is added to increase the weight distribution of the part and for ease of repositioning by the surgeon. Both designs incorporate the desires and needs of surgeons that have developed over many years of testing and uses of medical devices.

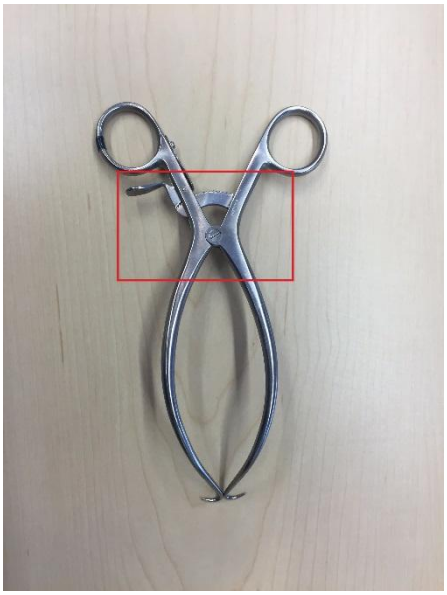


Figure 8: Gelpi Retractor often used in distal-radius procedure with ratcheting system highlighted in red

Figure 9: Army Navy Retractor with one short retaining element that is 21mm long and a long retaining element that is 42mm long

During surgery, if more time is needed to accommodate physical discomfort of the surgeon or the surgical procedures are lengthened, the chance of infection and other postoperative problems increases dramatically. According to the Canadian Centre for Occupational Health and Safety, the tool design is very important when considering safe and effective measurements. The weight, shape, and fit to the user

and the task are all conditions to be considered in the design of a novel tissue retractor. Ideally, the surgeon should be able to handle the tool with one hand. In standard, if the tool will be used away from the body or above shoulder height then it should weigh approximately 5 pounds maximum. One pound is ideal for precision tools to allow for good control of the device.

Moreover, the center of gravity in any tool is necessary to achieve counterbalance. The handle shape can be altered to execute an efficient design. Tools with angled handles or pistol-grips are useful when force is exerted in a straight horizontal line parallel to the forearm and wrist as seen in Figure 10. For forces exerted perpendicular to the straightened forearm and wrist a tool with a straight handle to pull vertically on the tissue would be more efficient as seen in Figure 11.

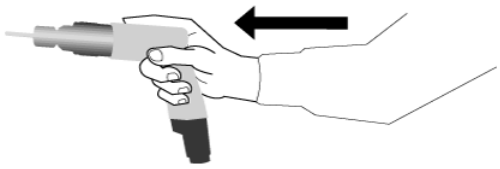


Figure 10: Tool with Angled or Pistol Grips [27]

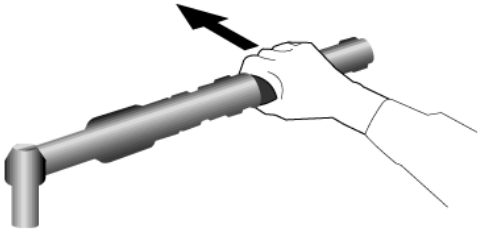


Figure 11: Forces exerted perpendicular to forearm [27]

Understanding the surgery and the layout of the operating room will be vital for selecting the right design for distal radius fractures. Choosing a design that requires no wrist flexion, extension, or deviation and allows the surgeons to be in a neutral and relaxed position will be important. Below, Table 4 shows specific guidelines for an ergonomic design:

Table 4: Guidelines for Ergonomic Design [27]

Guidelines - Summary		
Description	**Guideline**	**Reason**
Tool shape	Slightly contoured	Easy grip
Direction of force is in-line with forearm and wrist (typically horizontal)	Bent handle	Minimal wrist deviation
Direction of force is perpendicular to forearm and wrist (typically vertical)	Straight handle	Minimal wrist deviation
Separation distance between handles (for crushing, gripping or clipping tools such as pliers or tongs)	65-90 mm (separation distance)	Maximum grip strength
Handle length	> 100 mm	Keep contact out of palm
Handle diameter (power grip)	30-50 mm	Greater force and stability
Handle diameter (precision task)	8-16 mm	Greater control
Material and texture of handles	Non-slip non-conductive materials	For comfort and reduces effort required to use tool

A study done was done in 2012 on the evolution of minimally invasive surgical approaches and how surgeons favor certain instrument handle designs. An analysis of the surgeons' preferences on device handles was performed to identify the ideal grips. 49 surgeons completed a survey about physical discomfort and working conditions in their hospitals: 28% of surgeons complained about finger and neck pain during robotic surgery. However, three instrument handles received the highest scores for most criteria: conventional needle holder, da Vinci wrist, and joystick-like handle. Figure 12 below shows where and what percent of surgeon's had pain in open surgery, laparoscopic surgery, and robotic surgery [28].

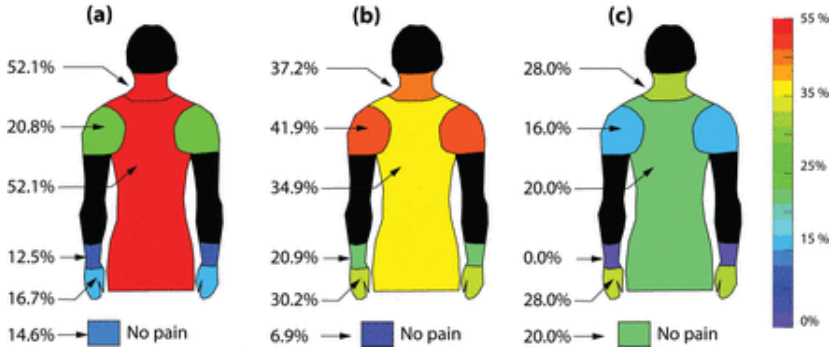


Figure 12: (a) Open surgery (b) Laparoscopic (c) Robotic surgery [28]

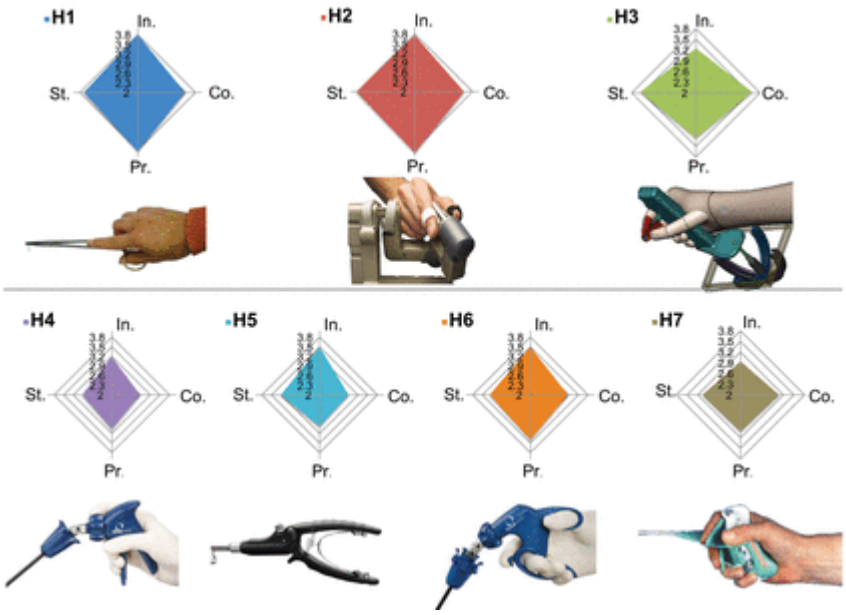


Figure 13: Rankings of Surgical Instrument Handles [28]

Figure 13 above shows the rankings of handles and grips preferred by surgeons starting with the conventional needle holder, the da Vinci wrist, and joystick-like handle. This study shows an insight into the desires and physical necessities of surgeons in the operating room. Understanding the limitations of the ergonomics and the interactions between the human and the working environment is a crucial part of designing an innovative product. To avoid errors and reduce unpredicted complications, one must consider all the ergonomics of existing self-retaining retractors.

2.7 Regulations

The FDA or Food and Drug Administration classifies retractors as a Class I medical device, meaning the device is considered to have low risk of harm to the patient or user [30]. In order to develop a tissue retractor for use in distal radius fracture repair, it is critical that the team complies with FDA standards. The FDA has a clear set of requirements that must be met to be considered a medical device. There are three different classes of medical devices. The first class has the lowest risk whereas the third class has the highest. Manual surgical tools, including tissue retractors, are treated as Class 1 medical devices. This class of device is subject to general controls and possess a history of safe use.

Device classification determines the type of premarketing submission and application required by the FDA in order to be cleared as a medical device. Class I devices may be exempt or nonexempt from a 510K submission. In order to be exempt from a 510K submission, the device must not exceed the limitations of exemption stated in the Code of Federal Regulations (CFR) Title 21. According to this section, tissue retractors are within Part 878 named “General and Plastic Surgery Devices.” They are present in Subpart E under the category of “Manual surgical instruments for general use.” According to the CFR, these devices are defined as a “non-powered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various surgical procedures. Some additional devices in this category include forceps, needles, clamps, and suture needles. Devices within this category are exempt from a premarket notification and subject to the limitations in section 878.9. These limitations can be summarized as devices that are intended for a different use than the legally marketed devices. It also includes devices that are used for monitoring or diagnosis of life-threatening or genetic diseases. Since the

novel, self-retaining tissue retractor for distal radius fracture repair surgery is intended to replace existing retractors on the market, it will be used in a similar manner as the existing devices. That said, the team's device is exempt from a premarket notifications according to FDA regulations.

3. Project Strategy

Introduction

The team developed a detailed project strategy in order to successfully design a novel tissue retractor that meets the client's needs. Planning each stage of the design process was necessary to ensure that all tasks were completed within the timeframe. The first step in the project strategy consisted of reviewing the initial client statement provided by the UMASS sponsors. The team was then able to determine the design space through background research as well as identifying the gaps in the current devices. Through several group discussions, specific objectives and constraints were chosen and ranked based on priority. After consulting with the UMASS sponsors, the initial client statement was revised in order to better fit the scope of the project.

3.1 Development of Initial Client Statement

3.1.1 Client's Needs

The team recognizes the importance of extensive background research and patent reviews in order to build a solid foundation before transitioning into the design phase. In addition, it is critical that the team is fully aware of the medical significance relating to the device and is able to convey the need for a novel tissue retractor for distal radius fracture repair. Once the team had a greater understanding of the client need and relevant subject matter, the objectives and constraints were defined to narrow the project scope and develop a more feasible client statement.

3.1.2 Initial Client Statement

Design an effective, simple, adjustable, economical retractor for use in surgery, specifically in extremity surgery.

3.2 Technical Design Requirements

3.2.1 Design Objectives

After several team discussions with the sponsor, four main objectives were determined which include easy-to-use, versatile, compatible, and economical. The objectives of the novel device represent the aspects that should be optimized. Figure 14 below is an objective tree that portrays the four main objectives and their descriptions.

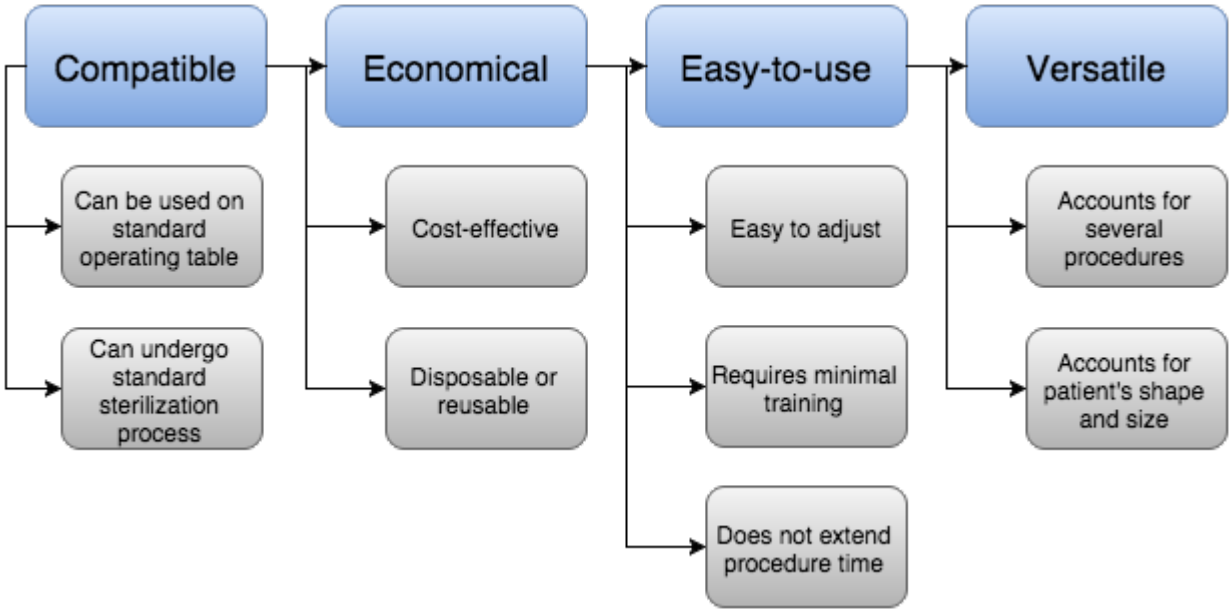


Figure 14: Objective Tree used to organize objectives for device design

Each primary objective is discussed in detail below:

Easy-to-use: One of the most crucial aspects of the device is that it can be easily handled by the surgeon. The device should be able to adjust during the surgery based on the surgeon's need. The device should also require minimal training, and not extend the procedure time.

Versatile: Versatility is an important component for the novel retractor since it will ideally be used for a wide-range of patients undergoing extremity surgery. It is important that the novel tissue retractor accounts for several different shapes and sizes of patients. Although the intent of this retractor is to assist in distal radial fracture surgery, its design will allow for future modification in order to aid in other extremity surgeries.

Compatible: The compatibility of the device refers to its ability to be used in a standard operating room. It is essential that the novel tissue retractor can be used alongside the common resources found within the operating room. Another consideration is the sterilization and/or disposal of the device. A reusable retractor should be able to use common sterilization processes, for example, being autoclavable. A disposable retractor should fit inside a standard biohazard waste bin.

Economical: There is a need for the novel tissue retractor to be cost-effective. The novel tissue retractor should be inexpensive relative to existing retractors on the market. If the device is disposable, the packaging and sterilization procedures should be taken into account when determining the market price. A reusable device should exhibit durability and wear resistance throughout the procedure and sterilization processes. This objective was classified by our sponsors as being the least important objective for our project because if this device eliminates the need to pay interns and nurses to hold the retractors then the device has a high probability of being cost-effective.

3.2.2 Design Objective Evaluation

The team first ranked the primary objectives. The groups consisted of easy-to-use and versatile, as Group 1 and compatible and economical as group 2. The team decided that easy-to-use was ranked highest followed by versatile. Economical and compatible were tied and far less objectives for this project. The rankings were determined using a Pairwise comparison chart that can be seen in Figure 15, below.

Pair-wise Comparison Chart

Objectives	Easy-to-Use	Economical	Versatile	Compatible	Total Score
Easy-to-Use	X	1	1	1	**3**
Economical	0	X	0	1/2	**1/2**
Versatile	0	1	X	1	**2**
Compatible	0	1/2	0	X	**1/2**

Figure 15: Pair-wise Comparison Chart used to rank objectives

The team met with the client to rank the objectives from the client's perspective. Both Dr. Dowlatshahi and Dr. Dunn were in agreement that the rankings were as follows: easy-to-use, versatile, compatible, and economical. It is also important to keep in mind that each objective can easily affect the rest. Easy-to-use was ranked first and the client stressed the need for a novel device that was effective and could also be inserted and adjusted with ease. Easy-to-use was followed by versatility because the client preferred a retractor accommodate different patient's shape and size. Compatible was ranked third and finally economical. Dr. Dunn specifically ranked economical last since addressing the first two objectives (easy-to-use and versatile) would indirectly enhance the cost effectiveness of the device. He also stated that if the novel retractor was a significant improvement from current devices, money would not be major consideration. More specifically, a self-retaining retractor (easy-to-use and operable by one person) would reduce the expenses from hiring staff or buying additional retractors.

3.2.3 Design Requirements, Functions, and Specifications

A functions and specification table was created to display the specific functions of the tissue retractor along with the associated specifications. The functions and specifications are outlined in Table 5, seen below.

Table 5: Functions and Specifications

Functions	**Specifications**
The novel tissue retractor should retract surrounding tissue and skin. The tissue retractor should be able to withstand the biasing forces and should remain stable within the incision site.	The tissue retractor must withstand the biasing forces of the surrounding tissue and skin which is approximately 1.32lbs to 3.75lbs.
The novel tissue retractor should open the incision to expose the distal radius. The retractor should be minimally obtrusive to the surgeon's operation field.	The retaining elements of the retractor must be less than 3 inch in length.
The novel tissue retractor should be able to adjust the incision site by expanding and contracting easily in order to accommodate for the patient's wrist size and different surgical stages.	The tissue retractor should be adjustable in at least one direction in increments <1cm.
The retaining elements on the retractor must retract surrounding tissue with minimal slipping in the incision. The retaining elements should function at an equal or better standard than the current retractors.	The length of the retaining elements should be 21-42mm. The width of the retaining elements should be 15 mm plus or minus 5mm.
The retractor should remain stable and the retaining elements should not rotate within the incision site.	The retractor should not rotate more than 20 degrees plus or minus 5 degrees.

3.2.4 Design Constraints

The team came up with four major constraints, described below in Figure 16. These constraints define the design parameters of the novel device.

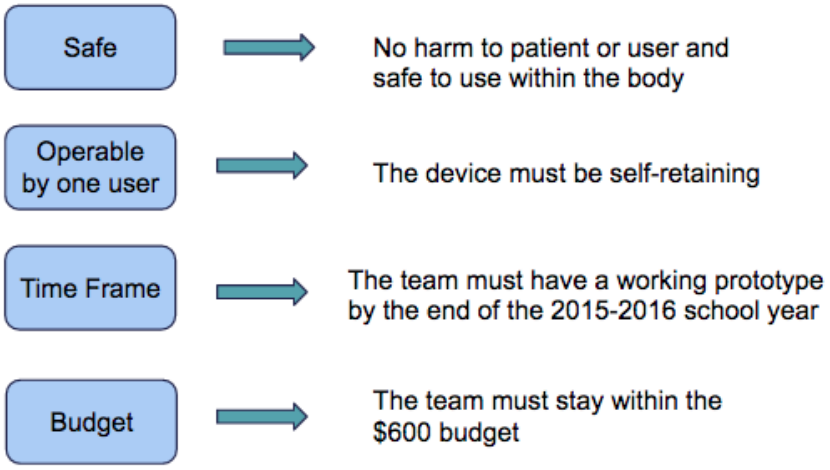


Figure 16: Design Constraints that need to be considered when designing the device

Safe: The novel tissue retractor must be safe. It must pose no harm to the patient or user. The material chosen for the retractor needs to be biocompatible, and one that will not elicit an inflammatory response when placed inside the patient. Additionally, if the device has puncturing features, these must be properly concealed for safe handling.

Operable by one person: The novel tissue retractor must be operable by one person. It is imperative that the tissue retractor is self-retaining, meaning it does not require additional people to hold the retractor in place. It must also require only one surgeon to place the retractor inside the patient and adjust it accordingly.

Time frame: The novel tissue retractor must be designed and tested within the 2015-2016 academic school year. It is required that the project team addresses all aspects of the client statement by the conclusion of the school year. This includes creating different design alternatives as well as completing proof of concept testing. In order for this project to be considered successful, a working prototype must be proposed and validated by the end of the school year.

Limited Budget: The novel tissue retractor design must stay within the designated budget. The project team must not exceed the allotted budget of $600.

3.3 Design Requirements-Standards

Tissue retractors are defined as Class I medical devices, meaning they are subject to general controls and are considered low risk with a history of safe use. Since tissue retractors are categorized as medical devices, there are certain safety and regulatory standards that must be met in order to be a viable product.

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. Several standards have been developed that apply to the tissue retractor product design. Described below are the general requirements surrounding ISO 13485 and ISO 11737:2009.

ISO 13485 refers to the quality management system (QMS) that is required for the manufacture of medical devices. This standard is based off of ISO 9001 and is applicable on a voluntary base. ISO 13485 is used by organization that are involved with the design, development and production process for

medical devices and related services. In order to achieve an ISO 13485 certification written policies for the following functions must be developed:

- Document and record controls
- Internal auditing procedures
- Controls for non-conformance
- Corrective and preventative actions
- Process and design controls
- Record retention
- Accountability and traceability

It is important to receive ISO 13485 certification in order to be recognized in the medical device market and maintain an accredited quality system.

ISO 11737:2009 was developed to produce standards for the sterilization of health care products. It discusses the tests for sterility that must be performed when defining, validating and maintaining a sterilization process. A sterile medical device is defined as one that is free from viable microorganisms. The purpose of sterilization is to inactivate these microbiological contaminants [31].

The biocompatibility standard for medical devices can be followed through ISO 10993-1 Biological Evaluation and Biocompatibility Testing of Medical Devices. Considering this device will be used in an operating room it is imperative that this device be biocompatible with human tissues and blood.

The team will also look into manufacturing and software standards such as those associated with CAD files for CNC and other machining when the time comes to start designing and prototyping. Moreover, there are ASTM International standards for testing of materials which the team will further explore and evaluate throughout the prototyping process.

3.4 Revised Client Statement

Once the objectives and constraints of the project were determined, the project scope was narrowed based on feasibility. After speaking with the team advisor and client, the broad terms were eliminated from the client statement after being deemed ambiguous. The initial client statement was revised and reviewed with the client to develop a clear understanding and agreement. Throughout the entirety of the design process, the team will refer back to the revised client statement to ensure the project is on track. The revised client statement is as follows:

Design a soft tissue retractor for use in distal radius fracture surgery that is self-retaining, in order to expose and stabilize a 3 inch incision site by applying a biasing force to the targeted tissue for the entirety of the procedure (60-90 minutes). The retractor must be operable by one user and should be easily adjustable.

3.5 Management Approach

The team must have a complete, working prototype at the end of the 2015-2016 school year. In order to stay on track and address all aspects of the design process, several management tools have been implemented. A work breakdown structure, seen in Figure 17 was created in order to break up designated design stages with their associated tasks. It is important to note that during the entirety of the design process, the team will communicate ideas and elicit feedback from both the client and the advisor. The

Gantt chart is shown in Figure 18 below. The structures show the major design stages followed by their associated tasks. The Gantt chart portrays precise dates and time frames to keep the team on track for the duration of the project. To start, the team must build a solid foundation of the client needs that will assist in establishing the design specifications and therefore lead to design alternatives and a final design.

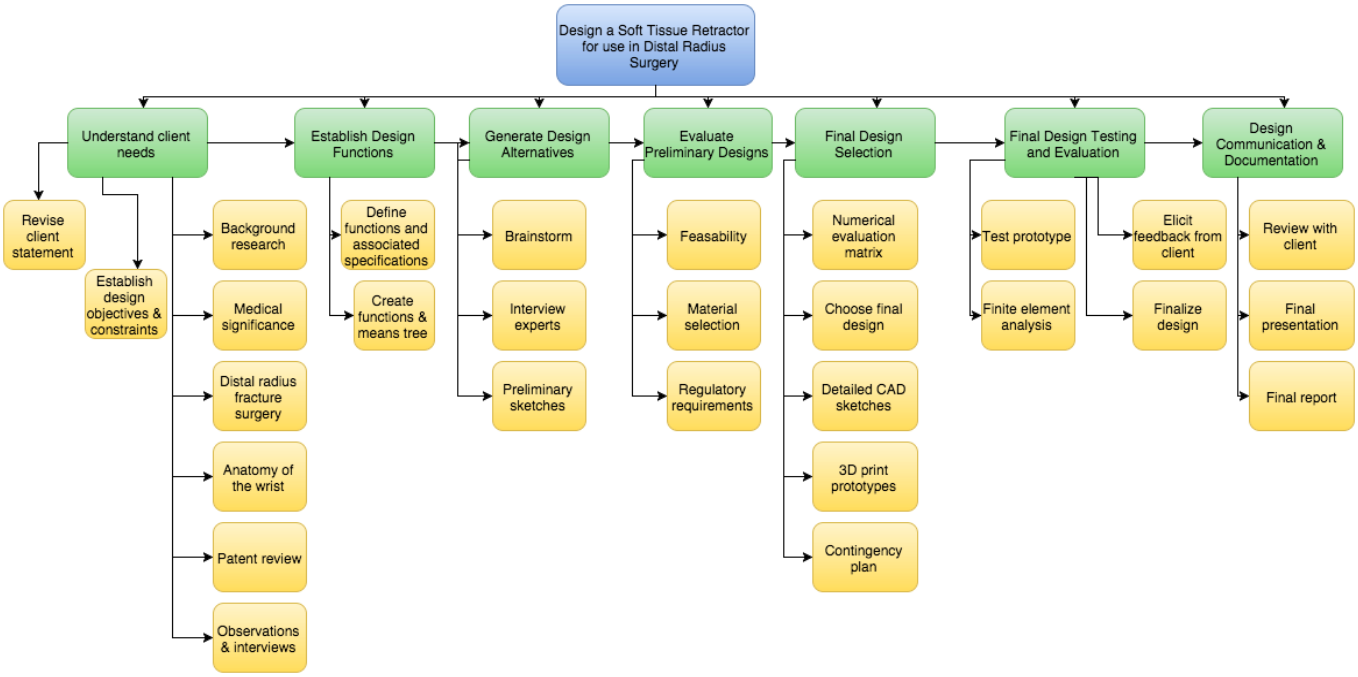


Figure 17. Work Breakdown Structure

	Task Name	Duration	Start	Finish
1	Meet Umass Representatives	7 days	Thu 8/27/15	Fri 9/4/15
2	Meet with Professor Billiar	7 days	Thu 8/27/15	Fri 9/4/15
3	Initial Client Statement	9 days	Thu 8/27/15	Tue 9/8/15
4	Research Medical Significance	14 days	Thu 8/27/15	Tue 9/15/15
5	Research Existing Patent Designs	14 days	Thu 8/27/15	Tue 9/15/15
6	Define Project Objectives	14 days	Thu 8/27/15	Tue 9/15/15
7	Define Project Constraints	14 days	Thu 8/27/15	Tue 9/15/15
8	Chapter 1: Introduction	36 days	Thu 8/27/15	Thu 10/15/15
9	Chapter 2: Backgound	36 days	Thu 8/27/15	Thu 10/15/15
10	Chapter 3: Project Strategy	36 days	Thu 8/27/15	Thu 10/15/15
11	Preliminary Designs with CAD	20 days	Thu 10/15/15	Wed 11/11/15
12	Design Communication to UMass	20 days	Tue 11/3/15	Mon 11/30/15
13	3D Prototyping	39 days	Mon 11/23/15	Thu 1/14/16
14	Testing Prototypes	30 days	Thu 1/14/16	Wed 2/24/16
15	Decide on Final Prototype	15 days	Wed 2/17/16	Tue 3/8/16
16	Machine Final Retractor Device	10 days	Fri 3/4/16	Thu 3/17/16
17	Test Final Product	12 days	Sun 3/13/16	Mon 3/28/16
18	Deliver Final Product to UMass	4 days	Mon 5/2/16	Thu 5/5/16
19	Finalize Paper	37 days	Mon 3/14/16	Tue 5/3/16

Figure 18. Gantt Chart

The client needs are closely related to the current gap in the retractor industry. Even though there are several retractors available none fulfill the client needs when it comes to distal radius fracture complications. The team must communicate with the client to further understand the current limitations and brainstorm alternative designs. This process will allow the team to create a set of tangible goals that would ultimately lead to a device that can improve the distal radius fracture procedure. The goals of this project were condensed into a concise client statement and design functions that expand this client statement by providing specifications that can be achieved through an iterative design process.

3.5.2 Establish Design Functions:

It is crucial that the team establishes specific functions of the novel tissue retractor before entering the design stage. The team will create a function and means tree in order to brainstorm possible ways to achieve the given function. In addition, precise specifications will be associated with each function. During all future design stages, the team will refer back to the functions and specifications to ensure that the novel retractor meets the given criteria.

3.5.3 Generate Design Alternatives:

This stage of the process will mainly focus on utilizing all of the information from background research and interviews with surgeons to create preliminary design sketches. The team will start by drawing schematics by hand and keep an open mind about possible solutions. The team plans to break up the parts of a self-retaining retractor by prongs, ratcheting system, and handles/grips, focusing each component separately.

3.5.4 Evaluate Preliminary Designs:

The team will thoroughly evaluate each preliminary design before moving forward with more detailed, CAD sketches and prototyping. Each design will be evaluated based on its feasibility. In addition, possible materials, regulatory requirements, and costs will be examined during this stage. By incorporating these considerations in the early design stages, the team anticipates to minimize complications in the later stages.

3.5.5 Final Design Selection

The team will develop a numerical evaluation matrix to assess each possible design based on how well they optimize the defined objectives and meet each constraint. Based on the results of this evaluation, chosen designs will be created via CAD software and 3D printed. During this stage, a contingency or “back-up” plan will be established.

3.5.6 Final Design Testing and Evaluation

The 3D printed designs will be analyzed using Finite Element analysis. In addition, the effectiveness of each design will be tested using various methods including using pork skin as a model for human tissue. Each prototype will be given to the client and the team will elicit feedback regarding its effectiveness and feel. Once each design component is chosen, a final design that encompasses all three components will be drawn and 3D printed.

3.5.7 Final Design Communication and Documentation

After establishing a final design, the team communicated the reasoning to the client. The team documented the results and analysis of the testing in the final MQP paper. The final findings were communicated to the client for approval and the team moved to the iterative design and production phase.

4. Design Process

4.1 Introduction to Approach

After establishing the objectives with the clients and researching the current market, the team began to conceptualize various alternative designs. This design process started with a top to bottom approach and the team began by focusing on the general retractor structure. Once the team selected the best alternatives to pursue, the team focused on developing retractor components stated above: the grips or handles, the ratcheting system, and the retaining elements.

As the team iterated designs, data was collected to make further improvements and to take into account the challenges that surgeons face with current retractors. The team observed a distal radius fracture surgery, performed a cadaveric study, and met with the clients to collect device specifications.

4.2 Observing Surgery

In order to fully understand the current complications in distal radius fracture surgery, the team observed and outlined the procedure while recording details that would affect the overall design of the retractor. It is important to note that the surgical procedure varies according to patients and the severity of the fracture. For instance, there are several sizes of volar plates that can be used according to the patient's preoperative state, see Figure 19 and Figure 18. According to a Trimmed representative, a volar plate of 240 mm is used 90% of the time.

Figure 18: Assortment of Trimmed Volar Plates which depend on the fracture and patient size

Figure 19: Sterile Equipment for Distal Radius Fracture Surgery which includes retractors

Prior to surgery, doctors analyze the x-rays to select a plate size and to visualize the location of the fracture and its fragments. However, securing the bone fragments and the plate requires imaging and decision making alongside the surgical procedure. To accommodate this, the operating room needs to be equipped with several types of retractors, screws, screwdrivers, and additional surgical tools that are sterilized and ready to be used, see Figure 20. As the team designs a novel retractor, it is important to make sure it is compatible with the other tools involved in the procedure. There are three steps in no particular order that must be noted to account for tool compatibility.

The first step is the placement and clipping of Kirschner wires (K-wires), which are used to secure the bone fragments in place prior to plate implantation. Once the fragments are aligned, the plate is introduced into the incision and secured in place with more K-wires as seen in Figure 21. The number of K-wires needed varies based on the state of the fracture, however, the surgeon's noted the current retractors used make obstruct the incision site making the insertion of k-wires more difficult. After insertion, the K-wires are also cut before the permanent securing of the plate with screws. This tool, seen in Figure 22, is relatively large, and could also interfere with retractors.

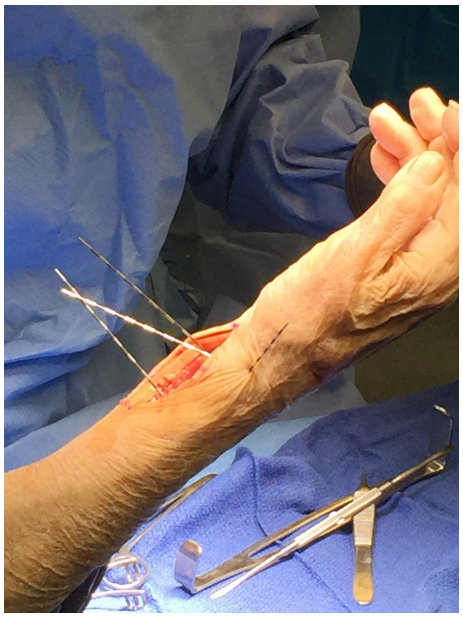


Figure 20: Reduction of the fracture and positioning of the plate relative to the radius, radiocarpal joint, and distal radioulnar joint Placement of K-wires

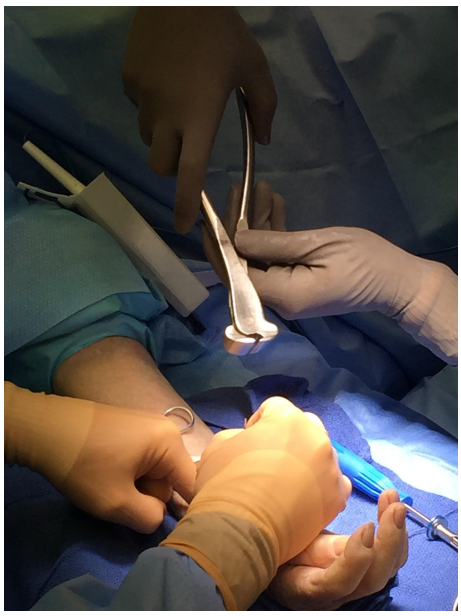


Figure 21: Wire cutter used to trim K-wires

The second step involves taking multiple X-ray images. As the surgeons readjust the plate and insert the K-wires, they use an HD Orthoscan to confirm the proper location of the K-wires (see Figures 23, 24, and 25). This is a repetitive process, and the number of X-rays varies according to patients. In this case, there were six X-rays taken, starting with the initial K-wire insertion for bone fragment alignment and ending with the confirmation of plate implantation. The retractor design must be able to either be removed easily prior to X-ray imaging or it must be undetected by the X-rays. In the interest of getting an entire view of the K-wires and the screw placement, the forearm is rotated to get a well-rounded view of the plate placement, see X-ray examples in Figure 24 and Figure 25. In case the retractor cannot be easily removed, it must be secured well enough for surgeons to be able to rotate the forearm and take the necessary X-rays.

Figure 22: Mobile Orthoscan HD used for X-ray imaging

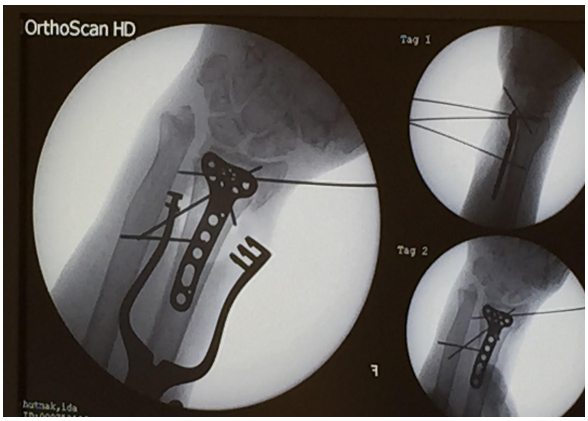


Figure 23: Volar view of plate insertion into the right wrist, K-wires, and the position of the Gelpi retractor inside the incision

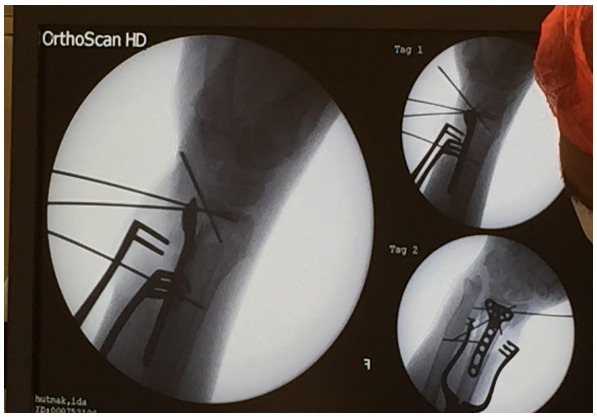


Figure 24: Lateral view of plate insertion in the right wrist, K-wires, and Gelpi retractor

The third step the fracture fixation plate to the radial bone. After the initial K-wire is placed to hold the fractured bone fragments, the surgeons begins the drilling process. The holes are drilled as seen in Figures 26 and 27. After the holes are drilled, a screwdriver used to secure the screws in place. The surgeons drilled the holes from different angles, which leads to another design consideration. This retractor should not interfere with the mobility of the surgeon as he/she repositions based on the screw location.

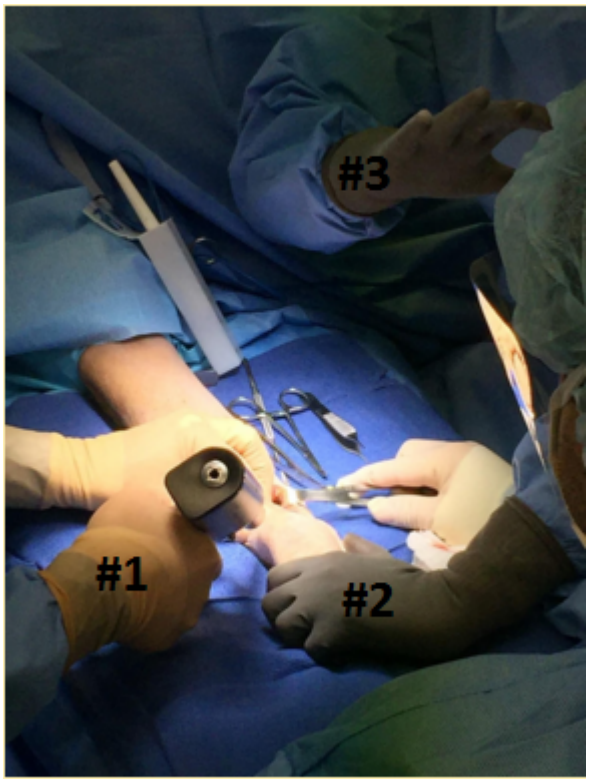


Figure 25: Drill used for the holes for screw insertion and insight into the number of surgeons present during this procedure

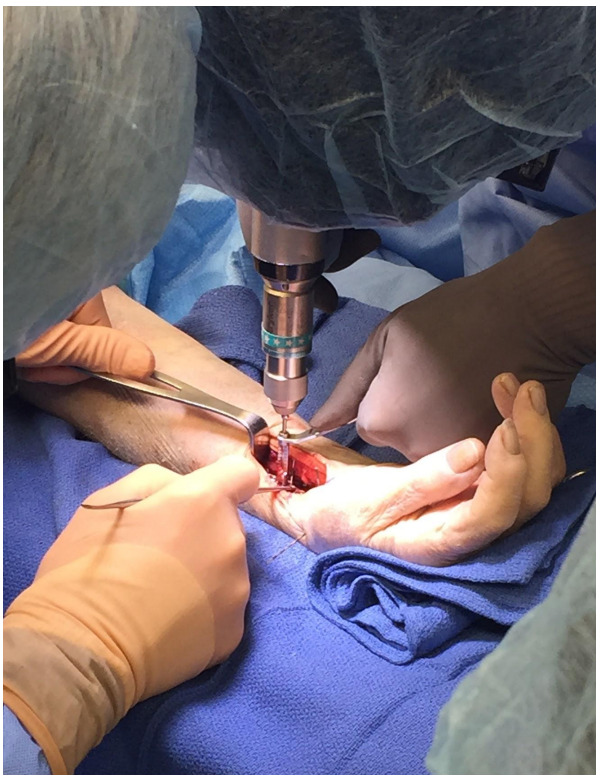


Figure 26: Drilling the holes for screw insertion

These three steps led to design considerations that would contribute to a retractor that is compatible with the distal radius fracture procedure and can be used with existing surgical tools. From a more general standpoint, two army navy retractors are used for the majority of the procedure to retract in opposing sides, see Figures 28 and 29. There were a total of three medical staff involved in the procedure. Two surgeons hold the opposing army navy retractors, while an assistant holds the hand to keep the whole forearm in place. Ideally, this novel tissue retractor will only require one surgeon.

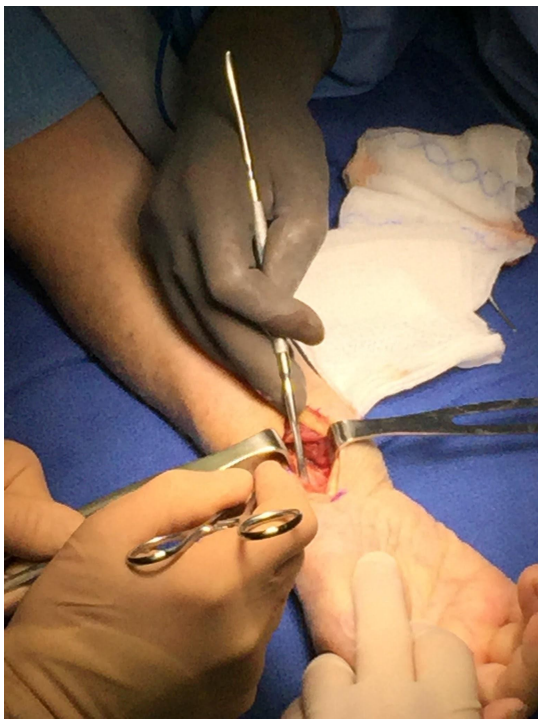


Figure 27: Use of Army Navy Retractors and insight into the number of surgeons needed to perform procedure (View A)

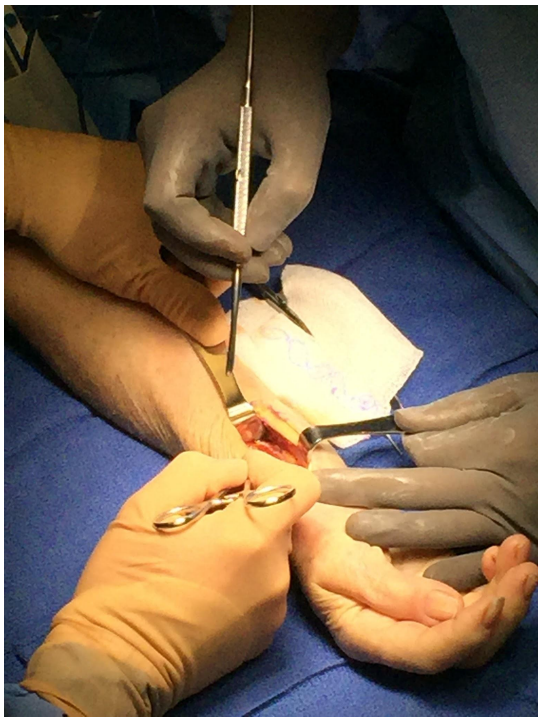


Figure 28: Use of Army Navy Retractors and insight into the number of surgeons needed to perform (procedure (View B)

4.5 Client Design Specifications

4.5.1 Range of Forces for Retraction

In order to gain a better understanding of the forces that the retractor design would have to withstand, a small experiment was conducted to obtain the minimum, average, and the maximum force that the surgeons exert on the retractor in order to retract the skin and muscle the required amount. To obtain this data, a model was created as shown in Figures 30 and Figure 31.

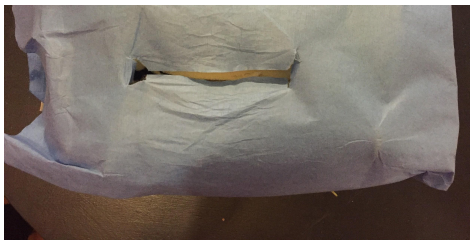


Figure 29: Top View of Model Incision used to obtain forces needed to retract during procedure

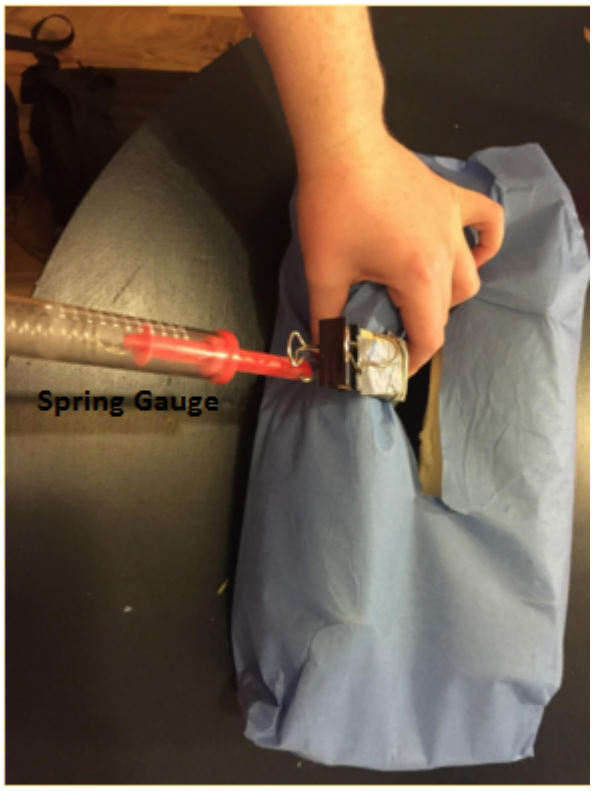


Figure 30: Retraction of Model using a spring force gauge

This model consisted of an incision which was surrounded by padding in the inside of the incision. A makeshift retracting element was then inserted into the incision. The retaining element was attached to a spring-dashpot that would be used to measure the force. The surgeon was then asked to pull on the force transducer which the least amount of force used to retract the muscle and skin. The forces from the force transducer were recorded. The process was repeated but for the average amount of force required to retract during that surgery. That response was recorded. Lastly the surgeon was asked to

retract will the maximum amount of force required during surgery. This entire process was repeated with another surgeon in order to obtain different results. The surgeons were not informed of force that they used to ensure that the results were not bias. The results of this experiment are shown below in Table 6.

Table 6: Forces Exerted on Retractor during Distal Radius Fracture Surgery

	Surgeon 1	**Surgeon 2**
Minimum Force	5.87N	5.87N
Average Force	9.79N	9.79N
Maximum Force	11.79N	16.68N

It should be noted that Surgeon 2 is a resident and has more recent experience holding retractors and retracting the skin and muscle during surgery. When asked about the maximum force required during surgery, the second surgeon stated that there was a particular screw that was hard to reach and required much more force to retract.

4.6 Design Alternatives

Various design alternative were created by the team and assessed based on the established design functions and objectives. At the beginning of the design stage, the team welcomed creativity and did not limit designs to recommendations from the client. In order to create several, very different designs, team members brainstormed individually. Once each team member created a design, they presented their idea to the rest of the team in order to receive feedback. These preliminary designs led to several iterations and also inspired new alternative designs. Initial designs were drafted in Solidworks in order to better conceptualize how the device will work and have a detailed drawing to present to our advisor and client.

Once the preliminary design concepts were established, it was noted that several of the team's design alternatives were based on existing retractors. The team was advised to explore different mechanisms and ratcheting systems rather than just focusing on the existing systems. To draw inspiration for future designs, the team took a trip to Home Depot and explored different tools and mechanisms. Specifically, the team looked at several different clamps, turnbuckles, wrenches, and their associated ratcheting systems. New designs were drafted in Solidworks and presented to the client. Based on feedback, it was decided that the team would move forward with one specific design. Once this was established, the team worked to design several iterations of this design.

4.6.1 Design Alternatives Tree

Figure 32 is a design tree that displays all of the retractor design alternatives and how the final design was selected. From this design tree, the evolution and iterative process of the cuff design can be followed. More detailed pictures and descriptions of each design alternative can be found in Appendix A.

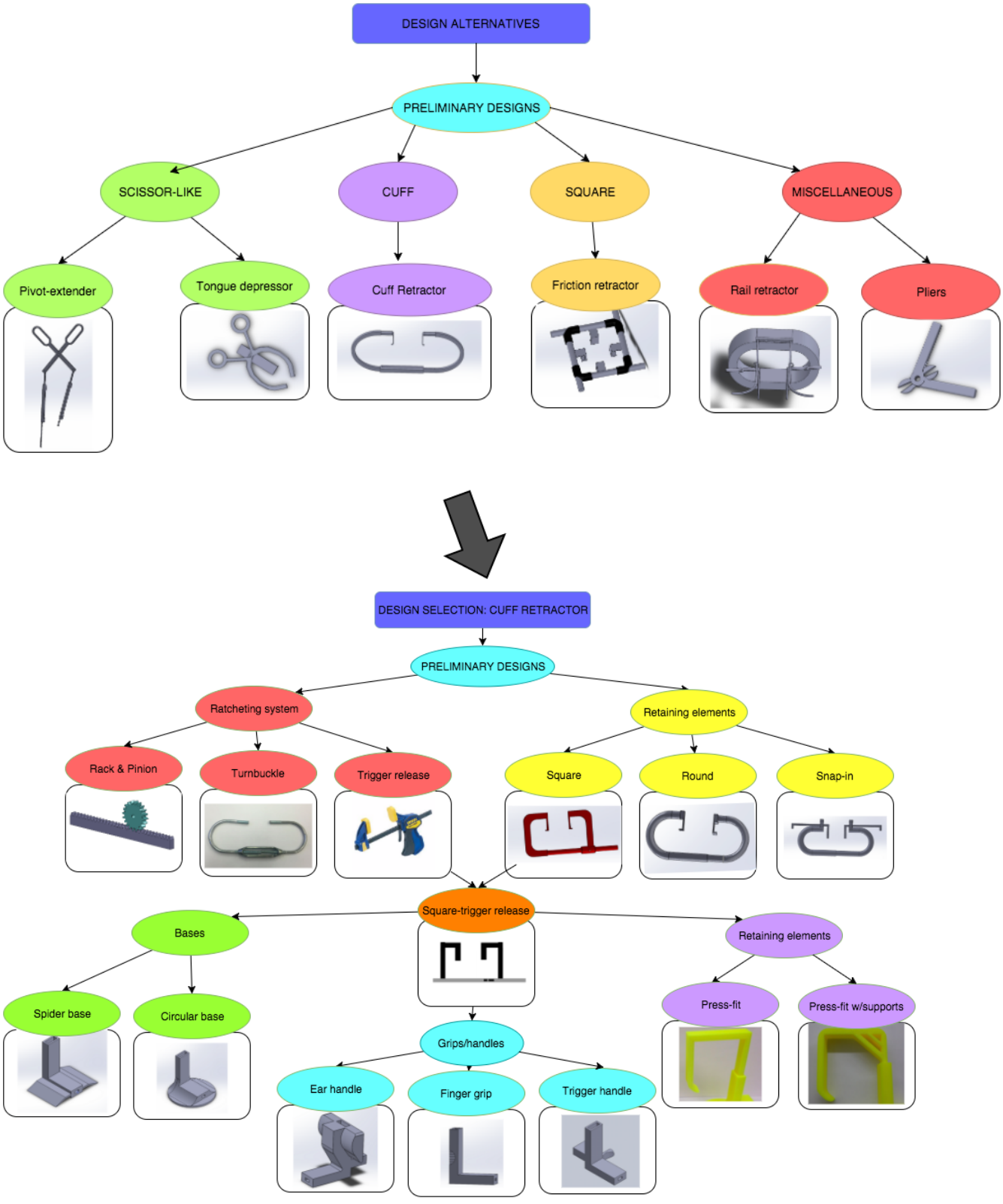


Figure 31: Design Alternative Tree with a yellow square highlighting the design that lead to the final design

4.7 Design Selection

The team conceptualized the cuff design after observing a distal radius fracture surgery. During the surgery, the team noticed that two or more plastic surgeons used army navy retractors on opposite ends of operating table. The surgeons used one hand to hold the army navy retractors while using their other hand to perform other aspects of the surgery such as dissection and inserting K-wires. The cuff design aims to replace the opposing army navy retractors used during the surgery.

4.7.1 Reason for Cuff Design

The cuff design was chosen as the team's final design because it is a simple solution that aligns with the team's objectives. The cuff design can be used on a standard operating table and remains stable on that table during the procedure. The cuff design can also be sterilized in an autoclave, which is the standard sterilization procedure for UMass Medical School. The device is easy to use, requiring minimal training and can be adjusted in small increments.

4.7.2.1 Bar Handle Design (Trigger Handle)

The bar Handle design shown in Figure 33, below, has a handle on the base of the retractor where the surgeon can place their thumb, while the pointer finger presses down on the trigger. The bar itself adds little material to the retractor and does not overcomplicate the design.

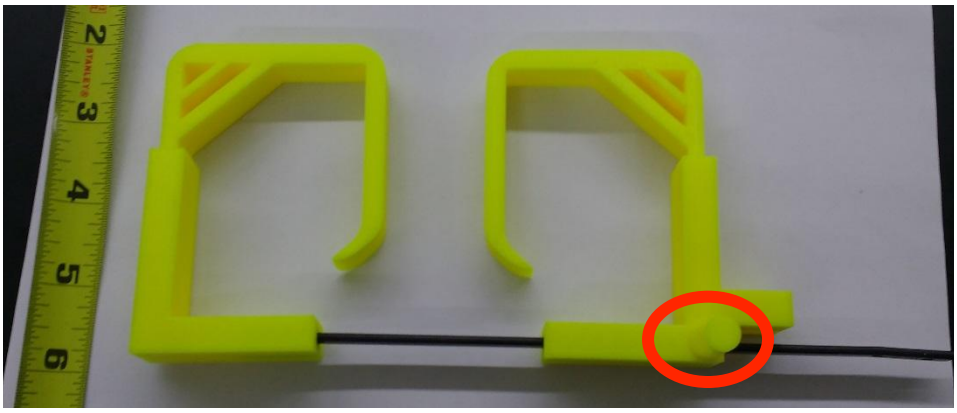


Figure 32: Trigger Handle highlighted in the red circle

4.7.2.2 Ear Handle Design

The Ear handle design shown in Figure 34 below, provides the surgeon with an ergonomic grip where two fingers can be placed over the ear shaped handles. One bent finger is placed in each handle and the surgeon can use the thumb to press down on the trigger to adjust the retractor horizontally. The ear handle allows for single-handed control of the retractor. However, this design is not intuitive enough which could affect its appeal to surgeons who are accustomed to using the Army Navy retractor.

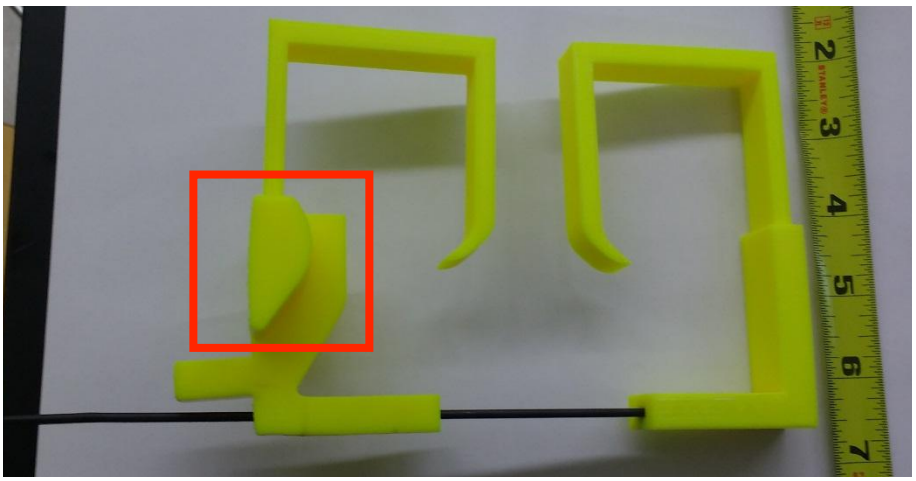


Figure 33: Ear Handle highlighted in the red square

4.7.2.3 Grooved Grips Design

The Grooved Grips design is based off of a design that can be found in an Army Navy retractor, shown in Figure 35 below.

Figure 34: Grooved Grip of Army Navy Retractor that design was based off [23]

The grooves in this retractor improve the surgeon's grip and decrease the likelihood of slippage, especially in the presence of bodily fluids. The team's version of this design, shown in Figure 35 below, is based off the Army Navy design and consists of a grip where the surgeon can place their thumb and pointer fingers. These grips create more traction between the surgeon and the retractor, reducing the possibility of their hand slipping when adjusting the device.

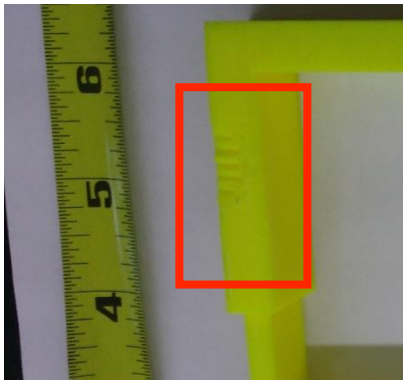


Figure 35: Grooved Grips highlighted in the red square

4.7.3 Ratcheting System

The ratcheting system allows the retractor to be adjusted in the horizontal and vertical directions based on the surgeon's need throughout the surgical procedure. The ratcheting system can also be used to accommodate different patient sizes by providing adjustability. The team explored four different options for ratcheting systems which included a screw mechanism, a scroll mechanism, a clamp mechanism, and a press-fit mechanism.

4.7.3.1 Screw Mechanism

The screw mechanism is used as a locking mechanism in current retractors. A common example is the Dingman retractor, which is used for cleft lip repairs. The bars of the retractor are adjusted to hold the cheeks at adjustable position. Figure 37 below shows the screw mechanisms on the left and right of the retractor. Even though this mechanism provides a strong hold, it can be tedious and time consuming for the surgeons secure the retractor in place. The screw mechanism also includes loose parts of the retractor which can complicate the assembly of the retractor.

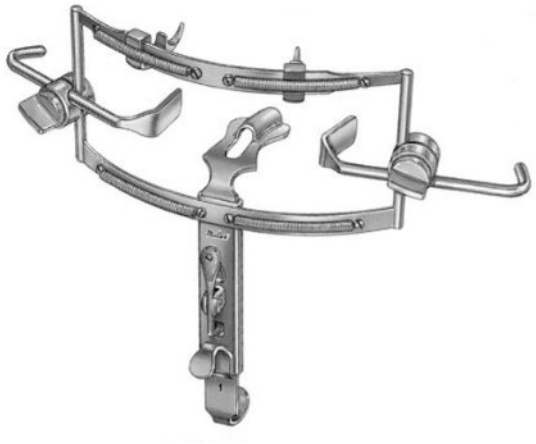


Figure 36: Dingman Retractor used as an example of screw mechanism [43]

4.7.3.2 Scroll Mechanism

A scroll mechanism involves a rack and pinion to make horizontal or vertical adjustments. In this case, the pinion is translated into the shape of a wheel which aligns with the rack. Turning this wheel will make the device expand or contract in small increments as seen below in Figures 38 and 39. This mechanism is intuitive because it is used in several tools, a common example being the wrench. The advantages consist of adjusting in fine increments, and ease of adjustment. However, a major disadvantage is difficulty of sterilization.

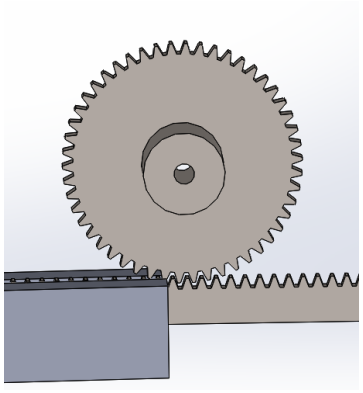


Figure 37: Scroll Mechanism created in Solidworks View A

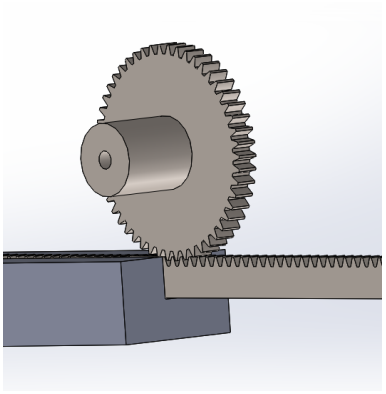


Figure 38: Scroll Mechanism created in Solidworks View B

4.7.3.3 Clamp Mechanism

The clamp mechanism is based off the mechanism that is found in household trigger clamps used for woodworking. This mechanism contains a rail in which the entire system operates on, a trigger that when pressed allows for free movement in one direction down the rail, and a stop at the other end of the rail. When the trigger is pressed, there is less friction because the hole in the trigger and the rail line up which allows the trigger to slide down the rail in one direction. A small amount of force is required to move the mechanism down the rail. The entire mechanism, shown in Figure 40 below, can be used to control how and when the trigger moves down the rail.

Figure 39: Example of Clamp Mechanism [32]

4.7.3.4 Press-Fit Mechanism

A press-fit mechanism is based on friction between two pieces which allows for adjustment between the two parts. Manufacturing these pieces with a low tolerance creates a tight fit that secures the moving elements.

4.7.3.5 Selected Ratcheting Systems for Final Design

After exploring options for the ratcheting systems, the team decided that two ratcheting systems would be used. One ratcheting system would allow for adjustability in the horizontal direction and the other would allow for adjustability in the vertical direction. The press-fit mechanism was chosen for vertical adjustability for several reasons. One of the main reasons was that this mechanism is relatively simple and is limited to two parts. This ratcheting mechanism is ideal for the vertical components of this design since once horizontal forces are applied to the retaining elements, more friction will be generated causing the retaining elements to stay in place. The team was concerned, however, that the presence of bodily fluids could possibly deteriorate the components off the cuff, which would reduce the friction holding the parts in place. After discussing this concern with Dr. Dowlatshahi and Dr. Dunn, it was decided that there were other factors that would allow for the mechanism to remain in place. One major factor that was discussed was using static equilibrium equations. Static equilibrium equations can be used when an object is not moving which is the case when the cuff has been placed into the incision. If the cuff remains in place, then the sum of the forces in all directions must add up to zero. What this means for this design is that the forces exerted by the incision should be enough to keep the press fit mechanism from sliding down or changing position. Figure 41 shows this press-fit mechanism between the black retaining elements and the yellow base. In this case, the retaining elements have a 0.05 cm difference in thickness which created enough friction for the retaining elements to stay in place while still allowing vertical adjustments.

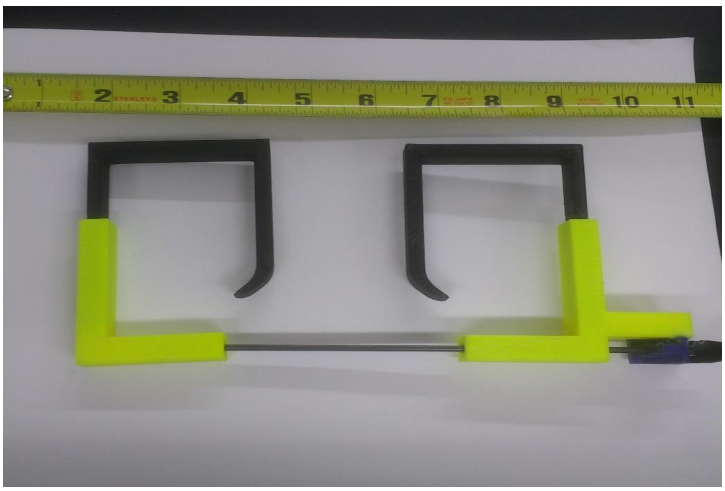


Figure 40: Press Fit Mechanism where the black pieces fit inside the yellow pieces

The clamp mechanism was chosen as the ratcheting system to adjust the cuff in the horizontal direction. This mechanism is advantageous for the cuff retractor because it is relatively simple and allows for adjustment in small increments. The ability to adjust in the horizontal directions also accommodates different patient's wrist sizes, as long as the wrist is smaller than the length of the rail. In addition to being easily adjustable, the clamp mechanism is a ratcheting system based on friction. This is advantageous for the cuff application because it does not require threading and several moving parts. For sterilization purposes, this is beneficial because threading and small parts have a shorter sterilization lifecycle and could deform in the autoclave machine. Also, in terms of operating room compatibility, it is better to have fewer parts to reduce the risk of the nurses loosing parts during the sterilization process. Finally, since the clamp mechanism is based off a trigger clamp, which is a common household item, the mechanism is intuitive increasing the devices marketability.

4.7.4 Retaining Elements

There are two major types of retaining elements used in distal radius fracture surgery: blunt and sharp retaining elements. The team evaluated the advantages and disadvantages of both of these retaining elements and made the decision to use an element that was a combination of both. A serrated retaining element, as seen in Figure 42Figure 41 below, has small protrusions on the inside of the element that increases traction. This serrated element is not as extreme as a sharp edge which reduces the risk of tearing.

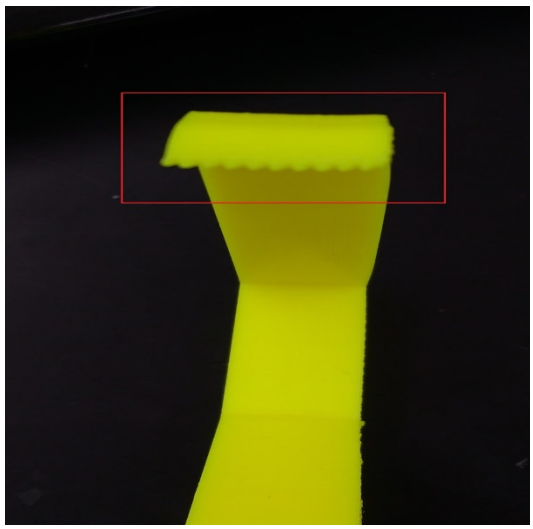


Figure 41: Serrated retaining element for increased traction

4.7.5 Stability

Based on conversations with the surgeons, the team identified a need to stabilize the device. Stability of the cuff design is important because it will help hold the wrist in place during surgery. At first, the team explored ways in which the device could be attached to the operating table. However, after discussing this preliminary concept with the surgeons, it was decided that attaching the cuff to the table would be inconsistent since not all operating rooms are the same. It was also noted that attaching the cuff to the table would overcomplicate the device. This feedback led the team to establish two different base designs for stability, the circular base and the spider base.

4.7.5.1 Circular Base

The circular base depicted in Figure 43 below was designed for increased stability and traction. This design is aesthetically appealing and functions properly to improve surgical site exposure.

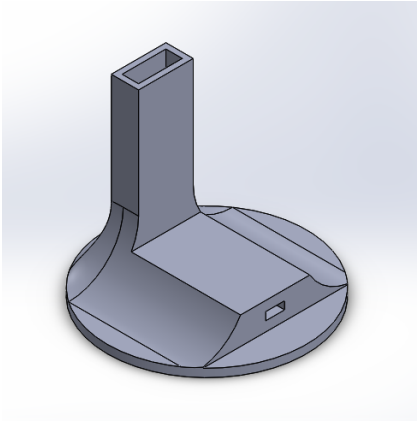


Figure 42: Circular Base that Improves Stability

The 3D printed base seen in Figures 44 and 45, improved the stability of the cuff design.

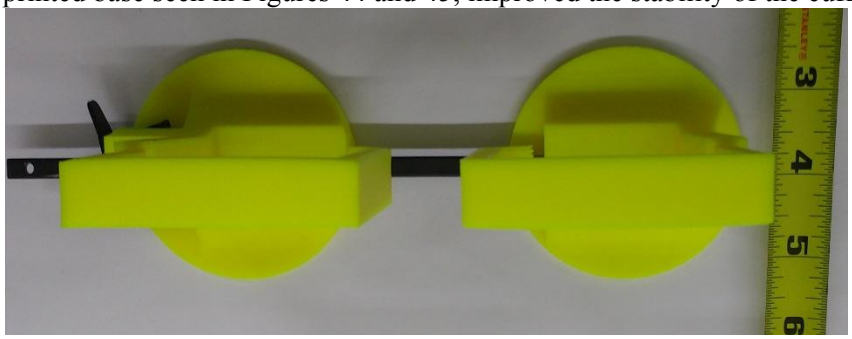


Figure 43: Top View of the 3D printed circular base

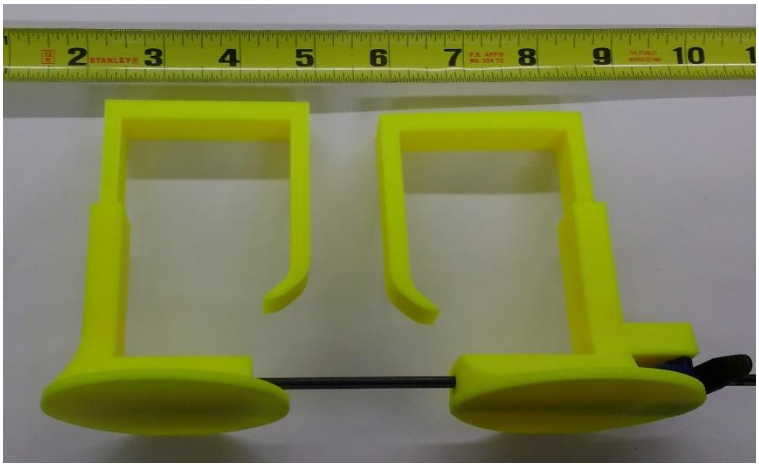


Figure 44: Side View of the 3D printed circular base

4.7.5.2 Spider Base

The spider base shown in Figure 46 below, is an iteration of the base component of the cuff designed to improve stability.

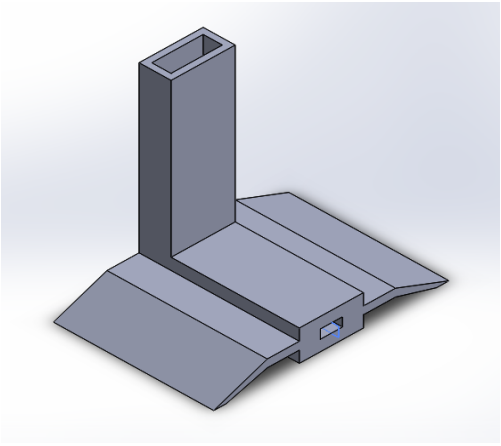


Figure 45: Spider Base that Improves Stability

The 3D printed spider base can be seen in Figure 47 and 48 below.

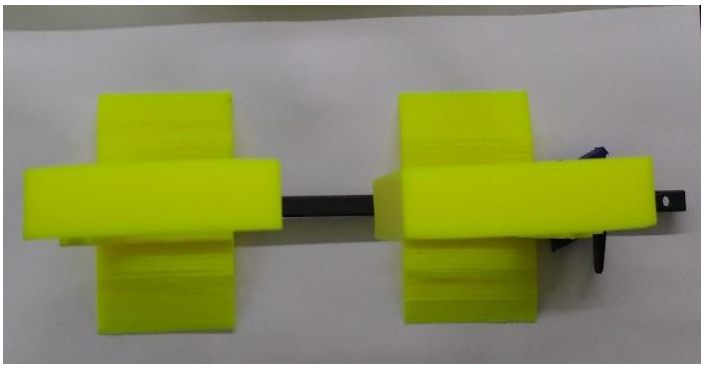


Figure 46: Top View of the 3D printed Spider base

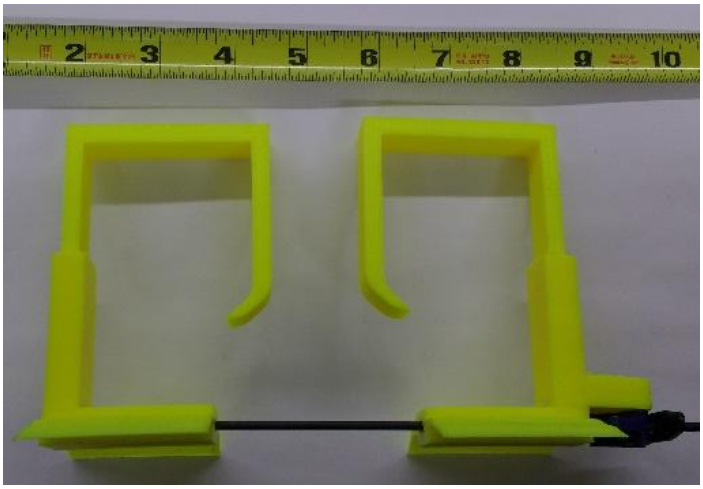


Figure 47: Side View of the 3D printed Spider Base

4.7.5.3 Supporting Bars

The team identified a need for stabilizing the retaining elements of the cuff design. After testing the 3D printed prototype, the team realized that the corner closest to the sliding component of the retaining element is subject to high stress. Figure 49 below shows the corner where the highest stress point occurs.

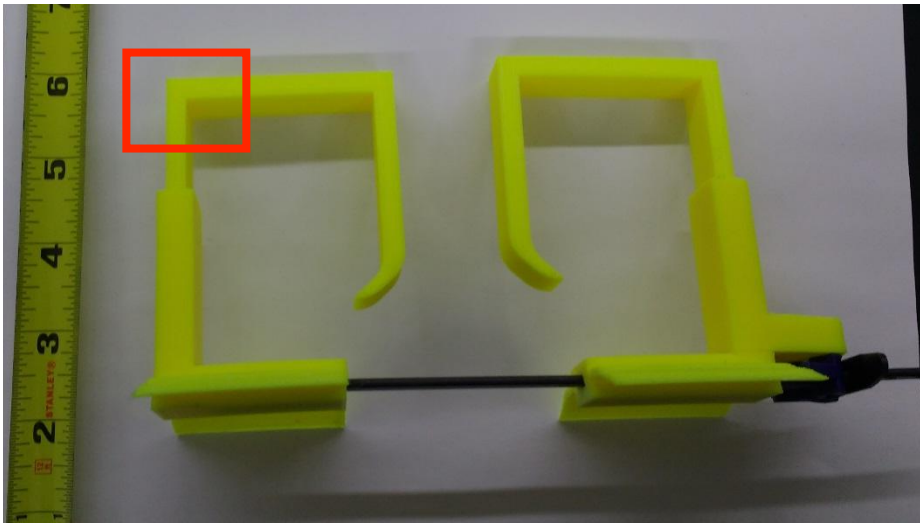


Figure 48: Cuff Iteration: highest stress point shown in red box

To ensure the stability of that part of the cuff design, an iteration was created with supporting ribs as seen in Figure 50, seen below. The supporting ribs distribute the stress throughout the retaining arm to reduce the risk of the device breaking during retraction.

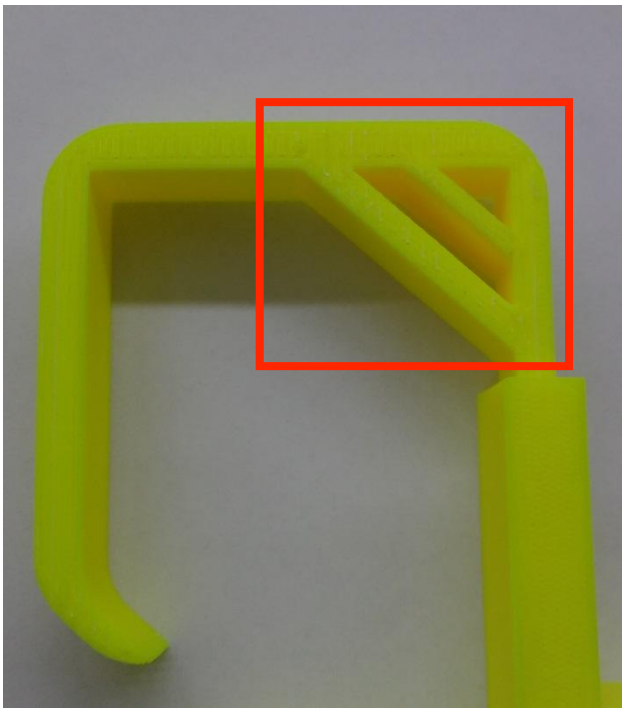


Figure 49: Supporting bars highlighted

4.7.6 Analysis of Final Design

Exploring the different elements of the design and comparing the alternatives led the team to conceptualize a final design which can be seen in Figures 51 and 52. This includes smaller retaining elements (see Appendix A1.11 for specific dimensions) with a curved end in order to minimize slipping. Similarly, the serrated elements increase the traction within the incision. There are two ratcheting systems that contribute to the adjustability of the retractor. In the vertical direction, the press-fit mechanism allows for adjustment of the retaining elements and also makes it easier for the surgeon to insert the retaining elements during the procedure. The second ratcheting system is trigger clamp that allows for horizontal adjustment in small increments. Finally, the bases are circular to improve stability, and the overall ergonomics of the design. Some of the minor changes to the final design were obtained as a result of the cadaveric study and surgeon feedback (see Chapter 5).

Figure 50: Final Design Front View Fully Assembled

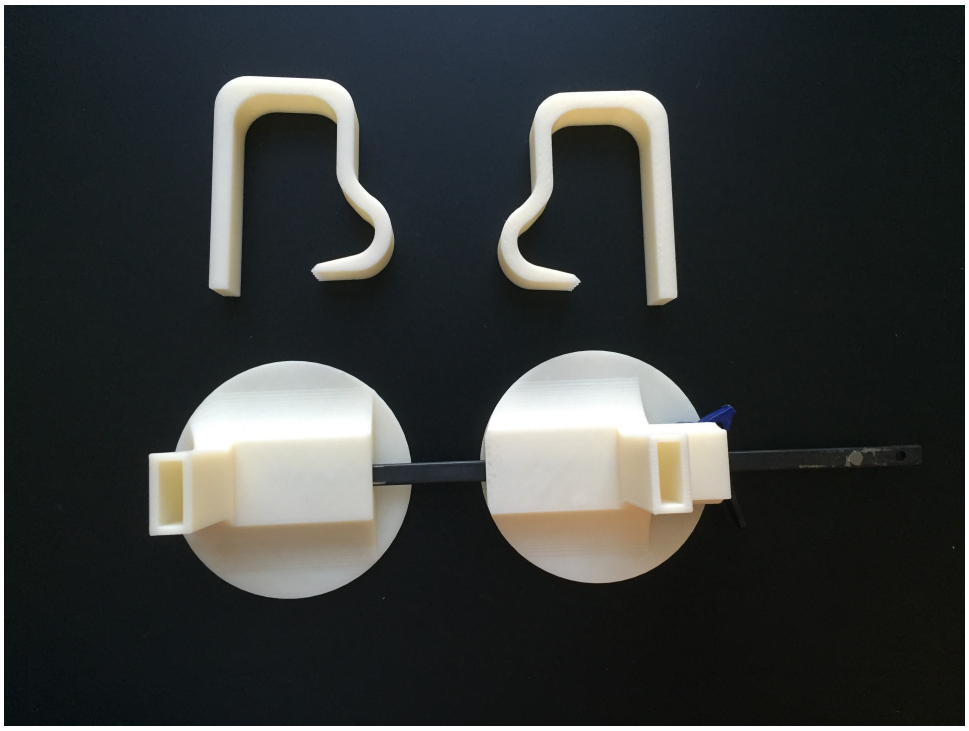


Figure 51: Final Design Top View

5. Final Design Verification

The team created several prototypes with various ratcheting mechanisms, handle/grips, retaining elements, and bases for stability. Each of these design alternatives were 3D printed using Solidworks computer aided design. To assess the functionality of each prototype, a series of design verification methods were used. The team elicited feedback from the surgeons through a client survey and determined the usability of the device through Finite Element Analysis and a cadaver study. These different forms of verification led to the development of the final design.

5.1 Surgeon Feedback

Throughout the design process, the team elicited feedback from our clients at UMASS in order to gain their expertise on the devices. In the final stages of the design process, the team created several 3D printed prototypes with various bases, grips, handles, and retaining elements. A client survey was created so the surgeons could give a quantitative ranking to each iteration. This survey (see Appendix B) focused on assessing each component of the device on its functionality, ergonomics, and aesthetic appeal.

5.2 Cadaver Study

Note: All team members completed Blood Borne Pathogen Training prior to conducting this study. Team members were under the supervision of WPI faculty throughout the duration of this study.

The team conducted a cadaver study in order to verify the functionality of the final device. Before beginning the surgery, the cadaver arm was removed from the freezer and allowed to thaw completely. Once the arm was ready for surgery, it was placed on the table with palm facing upward in order to perform an incision using the Volar Approach. A 4-5 inch incision was made in the wrist using a 20in scalpel. It was ensured that the incision was made so that the distal end of the radius was exposed. The

team used blunt dissection until the bone was reached. Once the bone could be seen, an the first prototype was inserted into the incision. The method of insertion consisted of first removing both retaining elements and placing the rail underneath the cadaver wrist. Next, the retaining elements were secured in the incision one at a time and placed back into the base of the device. Finally, the device was retracted by gripping the ends of the base and pulling the device apart. A preliminary prototype inside the cadaver arm can be seen in Figure 53.

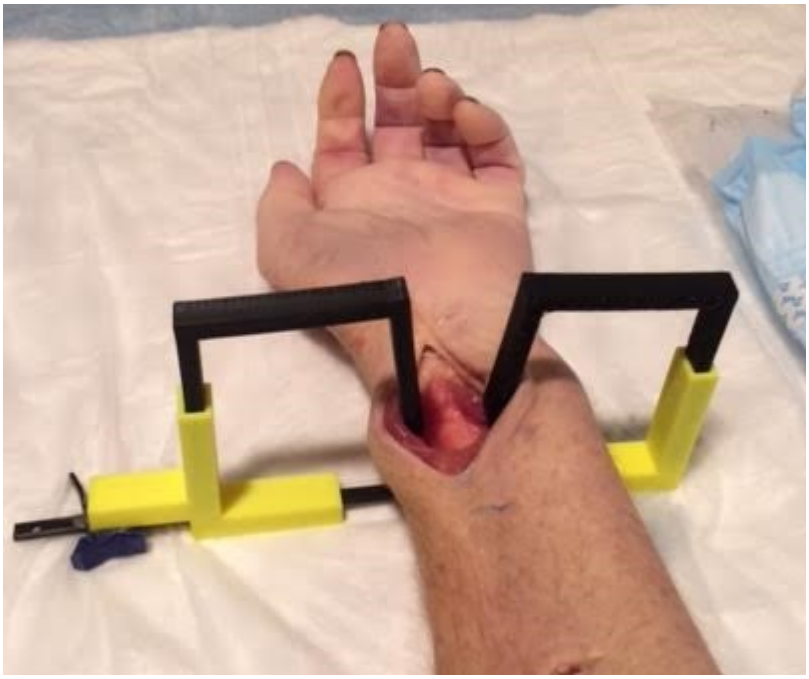


Figure 52: Alternative Design #1 during the Cadaver Study

The team noticed several issues with this prototype, specifically in regard to its retaining elements. When the device was retracted, the retaining elements bent and started to crack. The retaining elements were also too long and obstructed the surgical sight. The team believed that it would be difficult for the surgeons to access the radial bone and use the necessary tools throughout the surgical procedure due to the lack of space above the incision.

Next, the team inserted a second prototype into the incision using the same method as described above. This prototype can be seen in Figure 54 below.

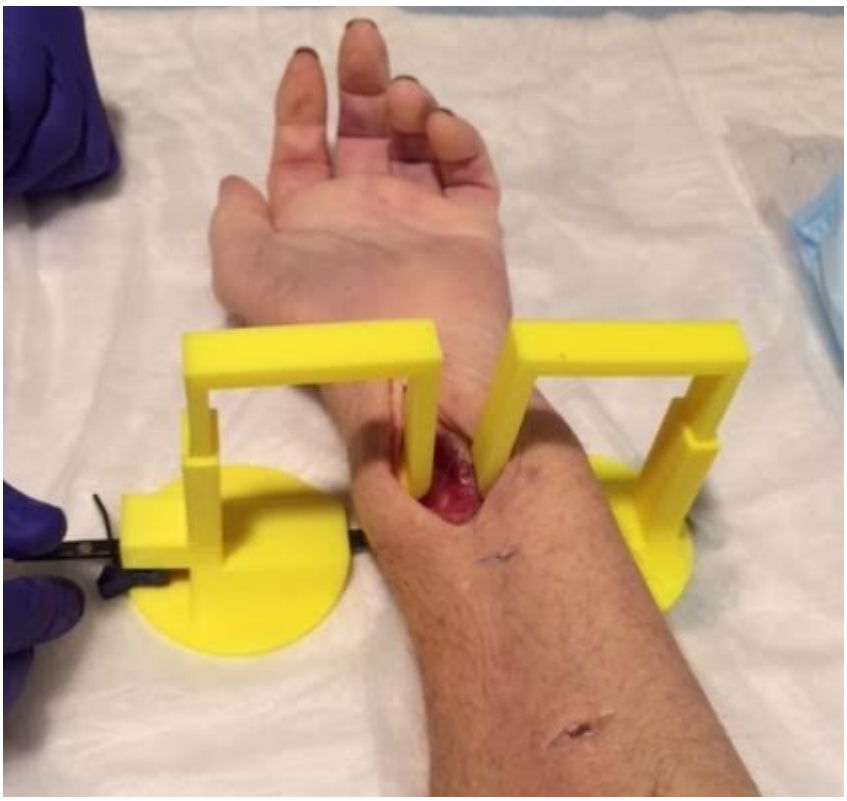


Figure 53: Alternative Design #2 during the Cadaver Study

This prototype showed less displacement than the previous one which could be due to its thicker retaining elements. This prototype also obstructed the surgical site in the same way as the previous prototype.

The next prototype tested was the same prototype described previously but with supporting bars located and the corners of vertical and horizontal intersections as seen in Figure 55 below.

Figure 54: Alternative Design #3 during the Cadaver Study

When this prototype was placed into the cadaver and retracted, it cracked when exposed to the biasing forces of the surrounding tissue. The team hypothesized that while the supporting bars were helpful for eliminating stress concentrations on one part of the retractor, the bars actually created more stress concentrations in other places that caused the retractor be less stable than the previous retractors.

The team tested the final design prototype and it can be seen in Figure 56 below.

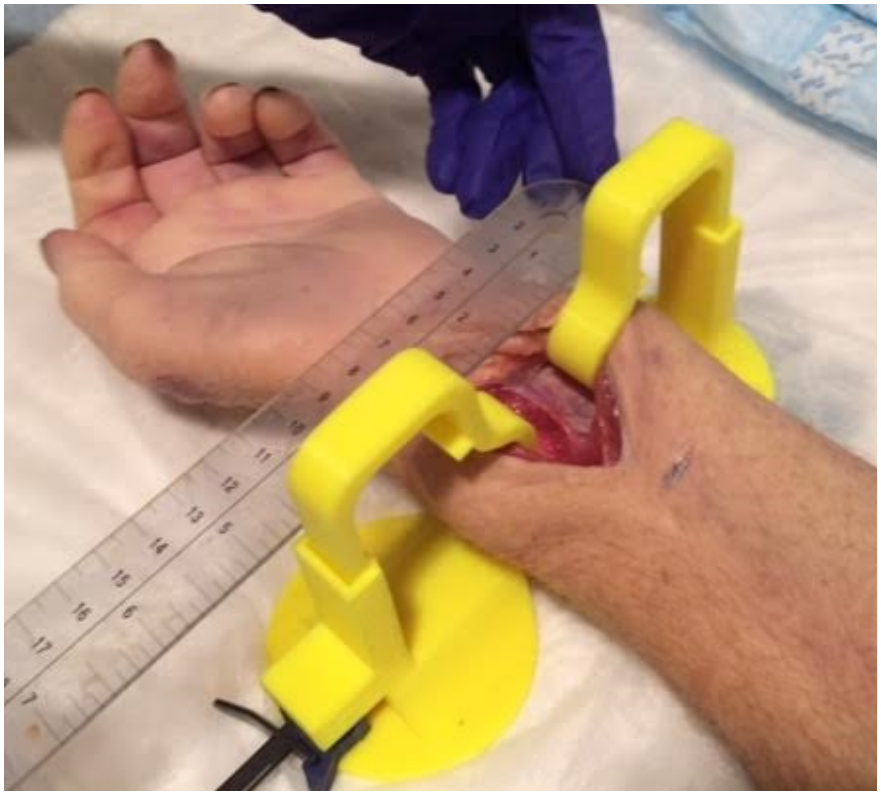


Figure 55: Final Design View #1 during the Cadaver Study

The final design prototype worked best in the cadaver arm. The curved retaining elements grasped the surrounding tissue and also allowed for more area around the incision. The curved retaining elements are advantageous to the straight ones because they are unobtrusive to the surgical sight. A top view of the final design prototype in the cadaver can be seen in Figure 57 below.

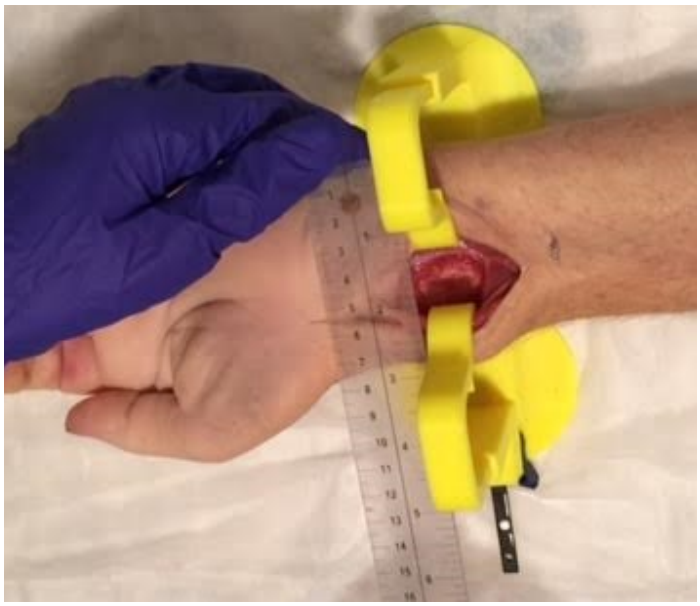


Figure 56: Final Design View #2 during the Cadaver Study

Overall, the final design prototype can be securely inserted into the incision and is able to retract the surrounding tissue. The curved retaining elements are able to effectively grasp tissue, muscle, and skin and expose the surgical site. The trigger clamp mechanism allows for easy incremental adjustment and can hold open the incision site for the duration of the procedure. Despite its overall success, there were some minor problems with this design. The main problem was that it was difficult to insert the retaining elements into the incision and then back into the base of the retractor. In order to do this, the team member had to lift up the arm. In addition, the stopper, located at the end of the curved portion of the retaining elements, was not beneficial to the device and was not needed to stop the tissue from slipping. The team used the results of the cadaver study to improve the dimensions of the device. The team shortened the bases and the length of each retaining element. The team also removed the stopper from the final design.

5.2 Finite Element Analysis

Finite Element Analysis (FEA) was conducted on two cuff iterations to show the stress, strain, and displacement of the different designs. A early cuff design and the final cuff design were tested through Solidworks Simulation Package to demonstrate the various forces of distal radius fracture surgery on the self-retaining retractor. Acrylonitrile Butadiene Styrene (ABS) was used for the base and retaining elements. The force that was applied to the device during FEA was 16.7N which was the highest force that the retractor would have to withstand during surgery (See Section 4.5.1 Range of Forces Retraction for details). The areas that have the highest stress concentrations, the highest strain, and the highest displacement are shown in red, while the areas that have the lowest stress, strain and displacement are shown in blue. On the right hand side of all the figures shown below there is a color scale and the value that each color corresponds to.

FEA was conducted on an early alternative design in order to determine the places that mechanical failure was most likely to occur. That data was then analyzed in order to create a design that could withstand greater forces exerted in surgery. Figure 58 seen below shows the stress concentrations on this device design. The figure below shows the highest stress concentrations are located on the horizontal part of the retaining elements. The locations that contain the highest stress concentrations on the device are the areas that are most likely to break when the device is being exposed to forces. It should be noted that the maximum tensile strength of ABS is around 42 MPa and the maximum stress concentration that can be seen in the figure below is about half of that tensile strength. This leads to the conclusion that this device will not suffer mechanical failure due to stress concentrations of distal radius fracture surgery [40].

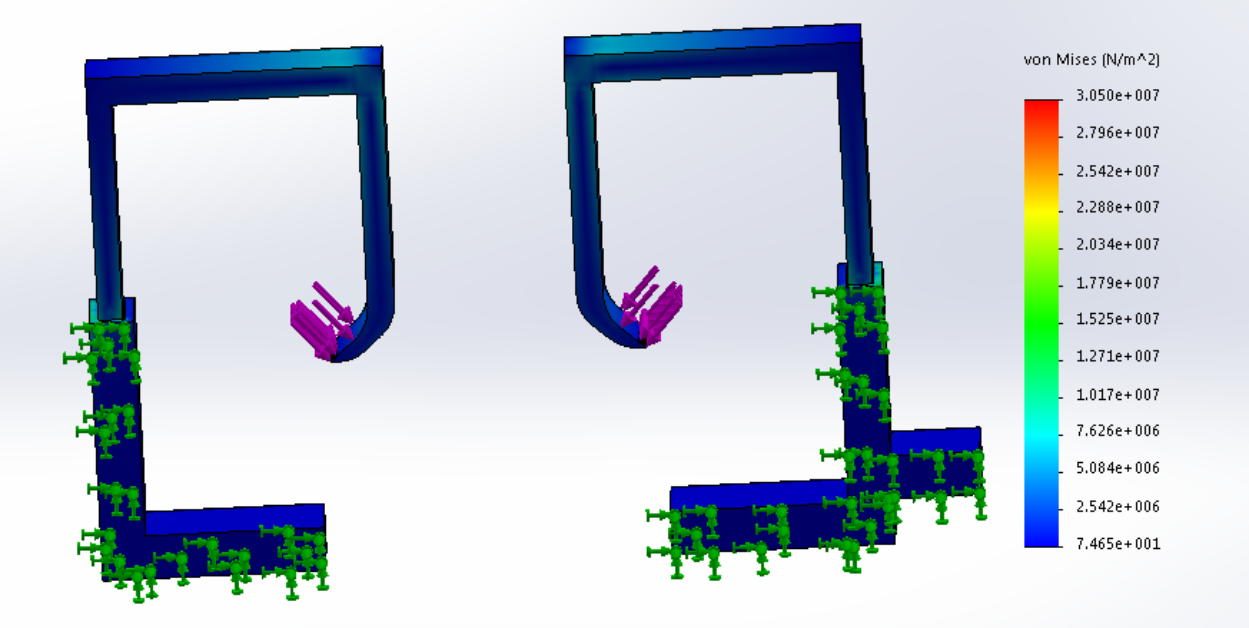


Figure 57: Stress Concentrations on Alternative Design

Figure 59 below, shows the strains that device experiences when forces are applied to the retaining elements during surgery. The areas that have the highest strain are in yellow and green while the areas that have the lowest strain are in blue. From this analysis it can be seen that the areas of high strain are located on the horizontal part of the retaining elements. The areas that show the highest strains are areas that could fail if put under enough strain.

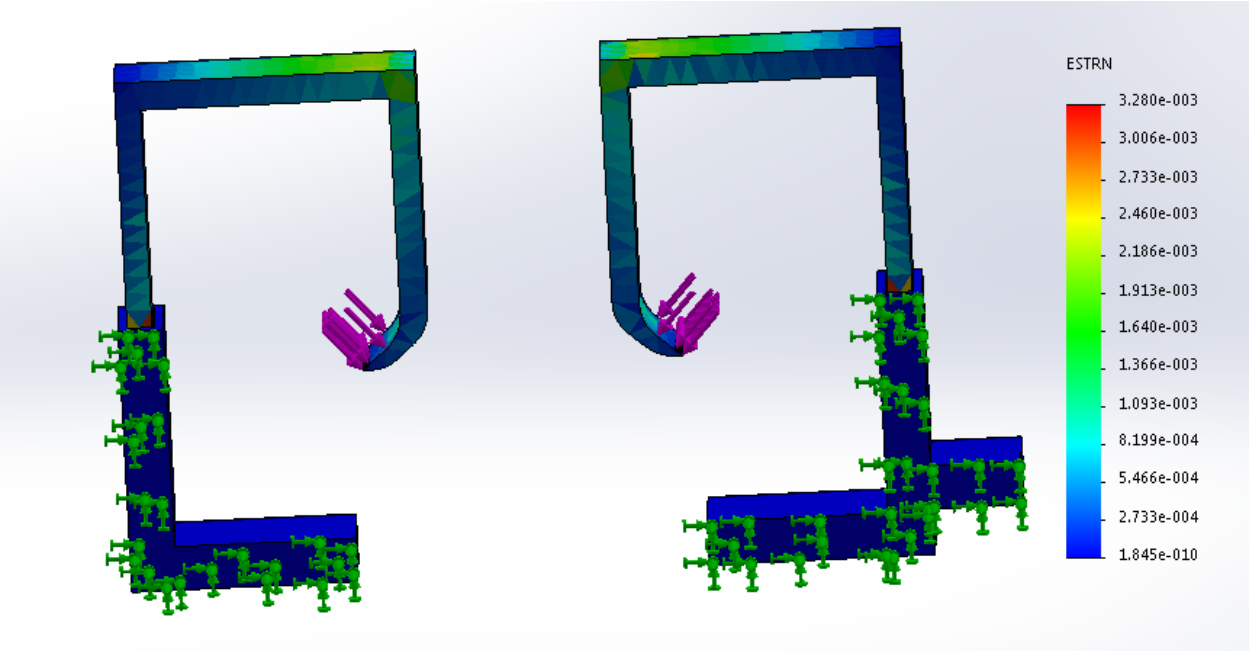


Figure 58: Strain Concentrations for Alternative Design

Figure 60 below, shows the displacement or the change in shape that the device undergoes when being exposed to maximum surgical forces. The red areas shows the area with the largest displacement which was near the end of the retaining elements and the areas in blue show the areas of the lowest displacement which are located near the base. This study was used to alter the design to distribute displacement more evenly throughout the device.

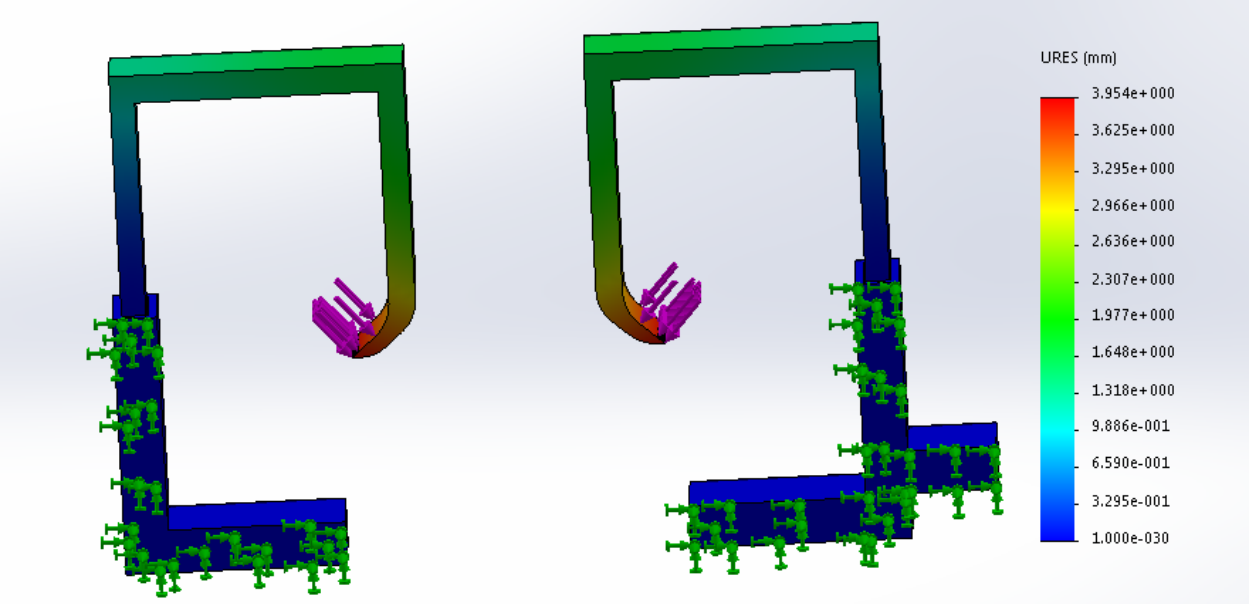


Figure 59: Displacement for Alternative Design

FEA was then conducted on the final design in order to compare the stress and strain concentrations as well as the displacement to the early cuff iteration. Figure 61 below, shows the stress concentrations in the final design when FEA was conducted using the same force (16.7N) that was used on the alternative design. This figure shows that the highest stress concentration can be found in the horizontal portion of the retaining elements. However, it should be noted that in this design there was no instances were red can be seen and there are many areas where blue can be seen. This result indicates that there are little to no areas that have a high stress concentration and there are many areas that contain little to no stress concentration. This analysis helped the group to verify the final design of the device.

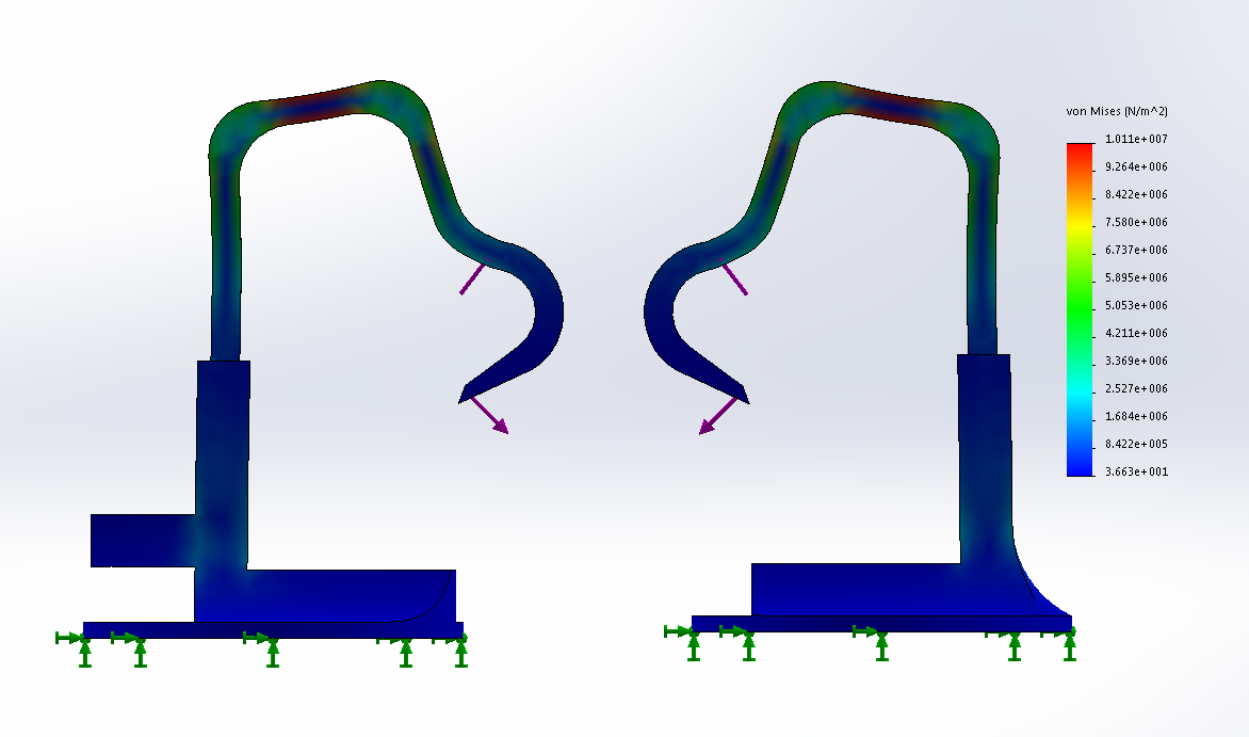


Figure 60: FEA showing Stress Concentrations on Final Design

Figure 62 below, shows the strain concentrations that can be seen in analysis of the final design. The highest strains can be observed on the vertical portion of the retaining element. It should be noted, however, that there are minimal areas that are red and there are many areas that are blue. This results in confirmation that the final design of the curved retaining elements have minimal areas of high strain concentrations and many areas of low strain concentrations when used in this surgery.

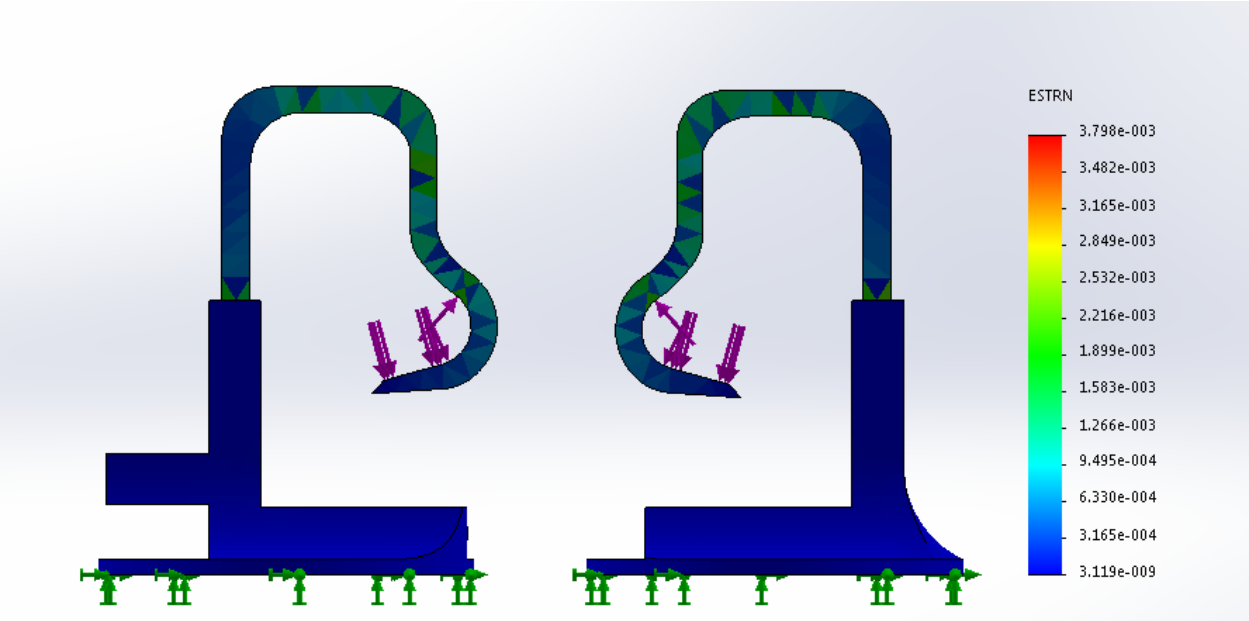


Figure 61: FEA showing Strain on Final Design

Figure 63 below, shows the maximum displacement that can occur when the device is subject to the maximum forces during surgery. This figure shows that the most displacement occurs in the end of the curved part of the retaining elements. This result was to be expected because the end of the retaining elements are the thinnest part of the retractor and therefore would be the most likely to displace under this concentrated stress. The amount of displacement that the end of the retaining elements undergoes is a positive aspect to our retractor because if the retaining elements were too stiff then the retaining elements would be more likely to cut or rip part of the soft tissue that it is retracting. One negative aspect of this result is that once the retaining elements undergo a certain amount of displacement, they are more likely to fail under mechanical loads if used multiple times. Therefore, a solution to this problem is to dispose of the device once surgery is complete.

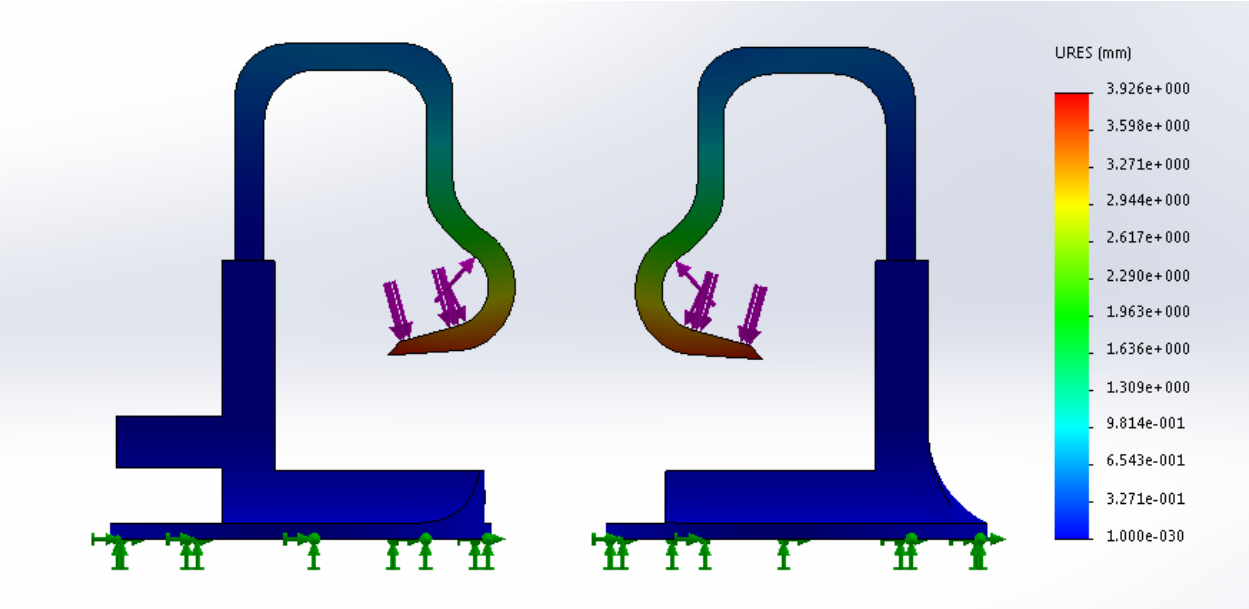


Figure 62: FEA showing displacement on Final Design

Overall, based on the FEA it was determined that our final design had slightly more areas of higher stress and strain concentrations than the early alternative design. It was determined that this was acceptable because all of the maximum stresses, strains, and displacements are less than the mechanical failure values of ABS [40]. The curved retaining elements performed better than in the cadaver study and therefore it was determined that despite the results, the curved retaining elements would remain in the final design.

6. Final Design and Validation

6.1 Surgeon Feedback on Final Design

Throughout the design process the team elicited feedback from the clients at UMass to gain expertise on each design iteration. This insight allowed the team to move forward with the final design. Overall, the surgeons believed that the device was functional and easy-to-use, however, they provided the team with suggestions in order to optimize certain design features. One aspect of the final design that the team needed to improve upon was the serrations at the end of the retaining elements. It was recommended to conduct an experiment that would assess how these serrations affect the surrounding tissue. Based on

this test, the depth of the serrations as well as the sharpness could be altered accordingly. The surgeons recommended to explore different shapes for the base to ease manufacturability and increase stability. The last suggestion included looking into the specific dimensions of the device and proving that these measurements are ideal. The surgeons wanted the team to look into potentially making the width of the retaining elements as small as possible without impairing the design's ability to withstand the biasing forces. The clients provided crucial feedback and provided the team with direction to advance the project.

6.2 Economics

The medical device field includes a broad variety of technologies and has over thousands of new products marketed every year. The economics is as widespread as the products. Prices range from very low for disposable bed pans and clamps, to very high for PET scanners at $2.5 million. In order to be competitive on the market, the soft tissue retractor must be economical and be affordable for hospitals. This device will not increase the overall cost of distal radius fracture surgery. The device will be efficient and practical for daily use. The device should be near current retractor costs and not exceed the allotted budget for this surgery. The different parts of the retractor must be mass produced in order for it to be affordable.

6.3 Environmental Impact

The environmental impact of medical devices is an influential part of the design process when creating instruments for today's market. The Commonwealth of Massachusetts released "The Environmental Guide for the Medical Device Industry" in December of 2006. This guide stresses the importance of designing for the environment and minimizing environmental impacts when manufacturing products. Another part of the guide is for environmental performance improvements in the medical device manufacturing field. Companies look for links between design for the environment, pollution prevention, and implementation of: quality management systems, lean manufacturing, and Six Sigma. There are numerous materials that the environmental advocacy community suggest, such as: mercury free, PVC-free, latex-free, products free of bio-accumulative toxins and reusable products. Another key improvement environmentalists are advocating is the use of recycled materials and extension of product life cycles. These considerations will be beneficial when designing an innovative medical instrument that will be competitive on the market as a sustainable device [33]. In the case of a disposable device, it will be important to use the least amount of material possible. Further Finite Element Analysis and mechanical testing can minimize the amount of material needed which would make the whole production system more environmentally-friendly.

6.4 Societal Impact

Often times, the advancement of medical technology can have a societal impact and affect not only medical professionals but also the general population. The creation of novel medical devices has the ability to change current healthcare practices and significantly affect patient outcomes. A self-retaining tissue retractor for distal radius fracture would remove the need for additional personnel in the operating room to retract the surgical site. This is especially helpful in emergency room procedures where surgeons tend to operate alone. In this case, having an easy-to-use self-retaining retractor will shorten the overall procedure time and allow the surgeon to focus on dissection and securing the fracture fixation plate on the radial bone. By using the self-retaining retractor for distal radius surgeries, one of the most common hand and wrist surgeries, the overall procedure will be faster and easier. This will ultimately result in surgeons being able to see more patients thus improving the efficiency of emergency room cases.

6.5 Political Ramifications

The creation of a novel tissue retractor for distal radius fracture could potentially lead to some political ramifications. Under the Affordable Healthcare act, medical device manufacturers must pay an excise tax of 2.3%. This tax makes it difficult for medical device companies, especially small start-ups to be innovative and develop new products. The novel tissue retractor for distal radius fracture has the potential to revolutionize common surgical procedures, however, the required taxation may hinder the success of the device. That said, it may be necessary that this act is repealed in order to manufacture the novel tissue retractor.

6.6 Ethical Concerns

One of the major goals for this retractor is to be self-retaining in order to reduce the number of surgeons and assistants required to be in the operating room. As a result, introducing this retractor to the industry may eliminate existing jobs. It is important to consider the possible reduction of employment and how many employees this would affect. Additionally, this device is meant to reduce the surgery time, which could reduce the cost of the surgery. If the surgery time is reduced, then it would be ethical to reduce the cost of the procedure as well.

6.7 Health and Safety

The majority of retractors in the market are reused after being sterilized. Even though sterilizing retractors reduces the overall expenses in equipment, it presents potential dangers for the patient's health. Devices with kinematic features lead to greater challenges in the sterilization process. In this case, the sliding bar, the spring, and the press fit components of the device must be carefully autoclaved. Close cooperation between the hospital and the sterile service providers is crucial to prevent risky infections in patients [34]. Considering disposable materials may be a safer and better option to guarantee the health of patients. This would not require sterilization processes and would protect patients from possible cross-contamination.

6.8 Manufacturability

Designing for manufacturability is a crucial part of the design process of a medical device. The material of a medical device must be evaluated based on whether the device will be a reusable or disposable. Most medical devices are made of metal, can be sterilizable, and reusable. According to the FDA ISO 9001 for Design Control Guidance for Medical Device Manufacturers, the FDA follows examples of verification methods such as worst case analysis under overstress during handling and use, thermal analysis, failure modes, biocompatibility testing, bioburden testing of products to be sterilized, and comparison of designs to a previous product that has an established history of successful use [29].

In regards to the design of the soft tissue retractor for distal radius fracture, the major decisions revolve around material considerations. Advantages of metal materials, specifically Stainless Steel 304 and 316/316L are high corrosion resistance, rust proof, antibacterial properties, reusable, non-magnetic, high heat resistance, and once work-hardened stainless steel 304 will keep its shape [25]. On the other hand, plastic medical devices also have numerous assets such as lightweight, cost effective, ease of processing, flexibility, non-ferrous properties (MRI safe), superior biocompatibility, less hospital acquired infections. Different materials for manufacturing are seen below in Figure 64 from "Product Design for Engineers" by Devdas Shetty. Each material is ranked as excellent, good, or seldom for each manufacturing process. Based on this chart, extensive research, and the expertise of Dr. Paul Cotnoir (Director of Design Program at Becker College) the soft tissue retractor will be created using Acrylonitrile Butadiene Styrene or ABS which is a thermoplastic polymer.

Material	Casting (die)	Casting (Centrifugal)	Injection Molding	Sand Casting	Investment Casting	Milling	Grinding	Electrical Discharge Machining (EDM)	Forging	Rolling	Extrusion	Powder Metallurgy	Sheet Metal working	Blow Molding
Low carbon steel	–	E	–	E	E	G	E	E	G	G	G	E	G	–
High carbon steel	–	E	–	E	E	G	E	E	G	G	G	E	G	–
Low alloy steel	–	E	–	E	E	G	E	E	G	G	G	E	G	–
Stainless steel	–	G	–	E	E	–	–	E	G	G	G	E	G	–
Malleable iron	–	E	–	E	E	G	E	E	S	S	S	E	G	–
Alloy cast iron	–	E	–	E	E	G	E	E	S	S	S	E	G	–
Zinc alloys	E	–	–	G	S	–	S	E	S	S	G	E	E	–
Aluminum alloys	E	E	–	E	E	E	G	E	E	E	E	E	E	–
Titanium alloys	–	–	–	–	S	–	S	E	G	S	S	E	–	–
Copper alloys	G	E	–	E	G	E	G	E	E	E	E	E	E	–
Nickel alloys	–	E	–	E	G	–	S	E	S	G	G	E	G	–
Tungsten alloys	–	–	–	–	G	–	S	E	S	–	–	E	–	–
Acrylonitrile butadiene styrene (ABS)	–	–	–	–	–	G	G	–	–	–	E	–	–	G
Nylons	–	–	E	–	–	G	G	–	–	–	G	–	–	G
Polystyrene	–	–	E	–	–	G	G	–	–	–	E	–	–	G
Polyvinyl chloride	–	–	–	–	–	G	G	–	–	–	E	–	–	G
Polyurethane	–	–	–	–	–	G	G	–	–	–	G	–	–	G
Polyethylene	–	–	E	–	–	G	G	–	–	–	E	–	–	E
Acrylics	–	–	–	–	–	G	G	–	–	–	S	–	–	–
Epoxies	–	–	E	–	–	G	G	–	–	–	S	–	–	–
Silicones	–	–	–	–	–	–	–	–	–	–	S	–	–	–
Polyester	–	–	–	–	–	G	G	–	–	–	S	–	–	–
Rubbers	–	–	E	–	–	–	–	–	–	–	S	–	–	–

E = Excellent; material is most suitable for the process.
G = Good; material is a good candidate for the process.
S = Seldom used in the process
– = Unsuitable; material is neither suitable nor used for the process.

Based on Ashby, M.F., 1992, *Material Selection in Mechanical Design*, Oxford, UK, Pergomon Press.

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TABLE 7.2 Data to Use in Matching Materials and Manufacturing Process

Figure 63: Data to Use in Matching Materials and Manufacturing Process [35]

The process of manufacturing the retractor could be done through injection molding. Injection molding produces parts by injecting material into a mold. Materials such as metals or polymers are heated and forced into a cavity where it cools and hardens into the configuration of the mold. More recent research has been done on the use of 3D printed polymer devices in the operating room and the advantages with cost, sterilizability, and ease of manufacturing. There are three main processes of manufacturing medical devices: investment casting, forging, and powder metallurgy. As seen in Figure 65 below, different manufacturing processes are compared based on manufacturing process attributes for example dimensional accuracy, complexity, relative cost, and size.

	Attributes						
Process	Surface	Dimensional Accuracy	Complexity	Production Rate	Production Run	Relative Cost	Size (Projected area)
Pressure die casting	L	H	H	H/M	H	H	M/L
Centrifugal casting	M	M	M	L	M/L	H/M	H/M/L
Compression molding	L	H	M	H/M	H/M	H/M	H/M/L
Injection molding	L	H	H	H/M	H/M	H/M/L	M/L
Sand casting		M	M	L	H/M/L	H/M/L	H/M/L
Shell mold casting	L	H	H	H/M	H/M	H/M	M/L
Investment casting	L	H	H	L	H/M/L	H/M	M/L
Machining	L	H	H	H/M/L	H/M/L	H/M/L	H/M/L
Grinding	L	H	M	L	M/L	H/M	M/L
Electrical Discharge Machining	L	H	H	L	L	H	M/L
Sheet metal working	L	H	H	H/M	H/M	H/M/L	L
Forging	M	M	M	H/M	H/M	H/M	H/M/L
Rolling	L	M	H	H	H	H/M	H/M
Extrusion	L	H	H	H/M	H/M	H/M	M/L
Powder metallurgy	L	H	H	H/M	H	H/M	L
Units	millimeters	millimeters		Parts/hour	Parts		m^2
High (H)	>0.064	<0.13	High	>100	>5,000	High	>0.5
Medium (M)	>0.016	>0.13	Medium	>10	>100	Medium	>0.02
	<0.0064	<1.3		<100	<5000		<0.5
Low (L)	<0.0016	>1.3	Low	<10	<100	Low	<0.02

Based on Ashby, M.F., 1992, *Material Selection in Mechanical Design*, Oxford, UK, Pergomon Press.

TABLE 7.3 Manufacturing Process Attributes

Figure 64: Manufacturing Process Attributes [35]

From this chart, the best choice for manufacturing the base of the retainer would be injection molding. It is primarily the most viable, economic and would be the most ideal manufacturing method for this application. Injection molding is a technique for manufacturing small, complex castings by injecting a material into a mold. This process is mostly used with thermoplastic or thermoset polymers. After the mold is formed, the wax is removed by melting and filled with the appropriate material. Advantages of injection molding consist of making many intricate forms with undercuts, a smooth finish with no parting line, and accurate dimensions. This aspect of injection molding would be particularly helpful for creating the curved retaining elements of our retractor. The material used for investment casting would be ABS polymer. [41]

The team has also looked into 3D printing all the parts of the retractor except for the small spring that is used in the trigger clamp. There has been research conducted on the advantages of 3D printing disposable medical devices due to the fact that that ABS can be 3D printed. Moreover, the cost of 3D printing is relatively inexpensive. 3D printed devices in operating room are on the rise due to efficiently reducing infections during surgery with disposable devices. Since the 3D printed prototype could withstand the forces necessary for a distal radius fracture, it is economical to manufacture this device with injection molding or 3D printing.

Sustainability of the medical device field has recently gained momentum. Sustainability is vital to the long-term success of our medical system. Traditionally, safety, efficiency, and cost are the classic triad of medical device design. In recent studies, it has been observed that hospitals are not willing to pay premium for sustainable devices. However, along with environmental conservation, the concern for sustainable, long-lasting products has increased. Along with long-term medical devices comes increase in infections. The autoclave process is a crucial sterilization process that is necessary to prevent spread of disease. There is a huge gap in the market and an opportunity for medical device designers and manufacturers to meet the demand of products re-envisioned through the lens of sustainability [36].

7. Discussion

The proposed device design has been proven to be successful through the measurement of forces, FEA, and mostly importantly a cadaver study. The cadaver study allowed to the team to ensure that the overall device functioned properly as well as meeting the objectives that were set forth in the onset of this project. This study also allowed the device to be compared to current retractors that are on the market in order to highlight some of the aspects of this device that gives it at a competitive edge. However, there are still considerations that need to be looked into before this device can be market as a trusted medical device.

7.1 Achieving Objectives

At the onset of this project, the team defined four major objectives for the device. The objectives are as follows; compatible, economical, easy-to-use, and versatile. The device is compatible with the standard operating room and does not require any external attachments. It can also be easily removed from the incision which is ideal since the surgeons are constantly moving the arm throughout the distal radius fracture procedure. In addition to being compatible with the operating room, the device accounts for various patients wrist size since it can be adjusted in the vertical and horizontal directions.

In terms of being economical, the device eliminates the need for additional trained professionals in the operating room to hold open the incision. Physician assistants are typically paid around $47.20 [37] per hour, increasing the overall cost of the procedure. The device can also be considered economical because ABS plastic is relatively inexpensive and injection molding is one way to mass produce this product with minimal costs.

Based on the cadaver study as well as surgeon feedback, it was validated that this device is easy-to-use. The removable retaining elements allow for easy insertion into the incision and the ratcheting system on the bottom is simple and effective. According to surgeon feedback, the device is intuitive and would not require special training or elongate the procedure time.

Finally, the device is versatile because it has the potential to be used in other extremity surgeries such as the forearm and the ankle. The team believes that by scaling up the dimensions and slightly altering the shape of the retaining elements, the device could be easily modified for similar surgeries.

7.2 Comparison to Other Devices

The proposed soft tissue retractor for distal radius fracture surgery is different than any device currently on the market. Unlike existing self-retaining retractors, the novel device does not contain sharp retaining elements. This limits the risk of excessive trauma from puncturing surrounding vessels or arteries during surgery. Another key feature of the device is its curved retaining elements. These retaining elements are able to grasp the surrounding tissue and keep the retractor stable inside the incision. The retaining elements in the novel retractor are very similar in shape and dimension to the Army Navy retractors. This is because the surgeons indicated that the Army Navy retractors are able to go deep into the incision and their blunt ends are favorable in the distal radius fracture procedure.

In addition, the novel retractor is advantageous over existing self-retaining retractors because it comes from under the patient's wrist. Existing self-retaining retractors such as the Weitlaner and the Gelpi are "scissor-like" and are inserted above the incision. The novel device is less obtrusive to the

surgical site making it easier to insert the fracture fixation plate and use other surgical tools throughout the procedure.

Finally, the ratcheting component of the novel device allows for incremental adjustment in both directions. In comparison, existing retractors such as the Gelpi and the Weitlaner can be incrementally adjusted in one direction, but must be fully released in order to contract the retractor. Overall, the novel device is very different from the retractors currently being used for distal radius fracture procedures.

7.3 Limitations

Although the final design was proven to be fully functional with the cadaver study, there are some limitations with the data collection and verification processes. The cadaver study was not conducted by a physician, but the surgical procedure was followed as close as possible to a professional incision. Since a plastic surgeon was not present during the cadaver study, there could have been some additional steps that went unnoticed. Additionally, it would be ideal to test the device in a patient in order to get a better understanding of how the device affects the vascularization and surrounding tissues. A gap in the design verification is observed in the serrated ends of the retaining elements. These were not adequately tested to ensure surrounding veins would not be punctured during surgery. However, with minimal forces acting on the ends of the retaining elements this is not a major area of concern.

After completing the cadaver study, the team made minor changes to the dimensions of the device so that it could be easily inserted into the bases. As a result, a new study should be conducted to test how these dimensional changes affect the device. The device that was tested in the cadaver was a PLA prototype instead of ABS plastic since PLA was cheaper to 3D print. The final design was printed using ABS, but it was not tested in the cadaver study. This was an acceptable use of materials because ABS and PLA have very similar mechanical properties.

The Final Element Analysis also exposed some limitations with the final design as it was compared to previous iterations. The design with straight retaining elements showed minimal areas of high stress concentration when compared to the final design. Nevertheless, these areas of concentration were acceptable since they did not exceed the maximum concentration that ABS is capable of handling without mechanical failure. Further Final Element Analysis can lead to a better design that would minimize the areas of stress as well as reduce the amount of material being used.

In order to address all of these limitations, it is essential to test the final prototype in a patient with the help of plastic surgeons. Collecting their feedback throughout this process will lead to a final round of iterations that would result in a fully functional device.

8. Conclusions and Recommendations

Although the device is successful in completing a distal radius fracture surgery, the limited amount of time that the team had to complete the project lead to some aspects of the design being neglected. Suggestions for future work as well as the conclusion for this project will be discussed in this chapter. These suggestions are to improve sterilization, optimize mechanical properties, and develop a manufacturing strategy.

8.1 Conclusions

In conclusion, the soft tissue retractor that was created for distal radius fracture surgeries is novel, self-retaining, and eliminates the need for additional personnel in the operating room. It is able to hold the incision open while allowing enough room for other tools and equipment necessary to complete the surgical procedure. This retractor was designed using information from an extensive patent search as well as observing distal radius fractures. Based on the team's findings, many design alternatives were 3D printed and improved based on surgeon feedback. The final design was chosen and validated using FEA to ensure that the device wasn't subject to mechanical failures when exposed to the biasing forces of surrounding tissues. Further validation was achieved by testing the retractor on a human cadaver. Based on the information gathered and the results from testing, the team believes that this self-retaining retractor successfully eliminates the need for additional surgeons to be present in the operating room and provides a competitive edge over existing retractors on the market.

8.2 Sterilization

The team intends for the novel device to be completely disposable and made from ABS plastic. The device must be sterilized once before use and then will be disposed at the conclusion of the surgery. For the initial sterilization, either ethylene oxide sterilization or gamma or electron beam irradiation. Overall, sterilization isn't an overlying concern, since the device is not reusable and only one sterilization process is required before use.

8.3 Optimizing Stress concentrations, Strain concentrations, and Displacements

Based on the FEA described in Section 4.4, there are some areas of stress and strain concentrations as well as some areas of high displacement. In order to minimize any stress or strain concentrations that may lead to mechanical failure, the team recommends a further examination of the dimensions and the shape of the device. In addition, the team needs to conduct further research on the potential manufacturing methods that could be used to mass produce this device. Specifically, the team should look into cost-saving initiatives to improve the devices marketability.

8.4 Other Recommendations

If more time was allotted for this project, the team suggests further research and testing this retractor for its use in other extremity surgeries. Some potential alternatives where this device could be applied include forearm surgery and ankle surgery. In order to see if the device would work in these surgeries, the team recommends for more cadaver studies to be conducted. Other suggestions for further recommendations include scaling the device in size in order to accommodate for larger surgeries.

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Appendix A: Design Alternatives

A1.1 Pivot and Extender Retractor

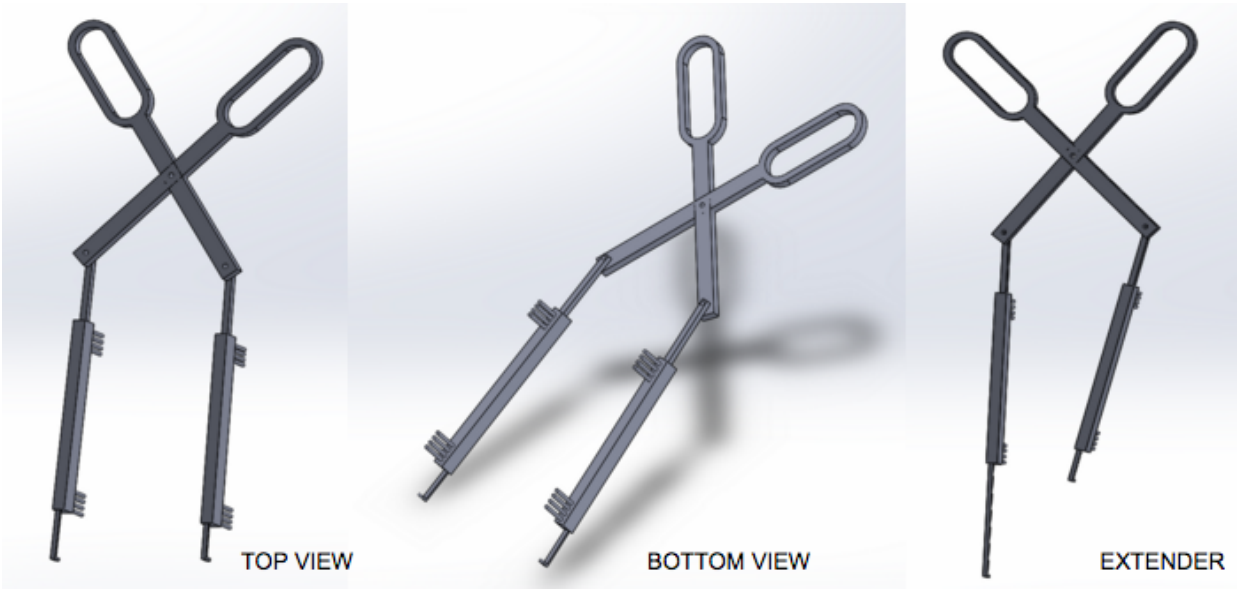


Figure 65: Top, Bottom, and Extender View of Pivot and Extender Retractor

The idea for the Pivot and Extender Retractor as seen in Figure 66, originated from the limitations of the Gelpi retractor extension and elongation. The ergonomics of the top of the retractor where the surgeon would have control of the device is ideal. This is due to the mobility and range of motion available with the scissor grip mechanism. However, the hinge between the scissor handles provides a limited angle of rotation and therefore there is a restriction on how wide the retractor can retract the tissue.

The extender or bottom half of the retractor was the main focus of this design. It would be agile and easy to move but once in place the surgeon could screw the pivot arm into a fixed position using the wing nut. The retaining elements could either line the entire extender or just the tips which allows the design to be flexible. Furthermore, the extender also incorporates a blunt army navy retractor that can be easily slid in and out of the exterior pivot arm. This piece can be detached and only used in surgeries when necessary which can be a crucial advantage of this design. This design has the potential to be practical in surgical applications that require the addition of a blunt retractor to be extended to expose necessary parts of the distal radius fracture. Complications with this design can include uncontrollability and fixing the device into the correct position may extend procedure time. Moreover, the mechanism to slide the additional blunt retractor inside the extender part could be difficult to clean in the autoclave process.

Table 7, below outlines the key advantages and disadvantages of the pivot and extender design:

Table 7: Advantages and Disadvantages of the Pivot and Extender Retractor

Advantages	**Disadvantages**
● Adjustable blunt retractor add-on ● Range of motion through pivot mechanism is versatile	● Controllability could be difficult at large, unsecure angles ● May prolong time and procedure set-up to position retractor in optimal orientation

A1.2 Friction Retractor

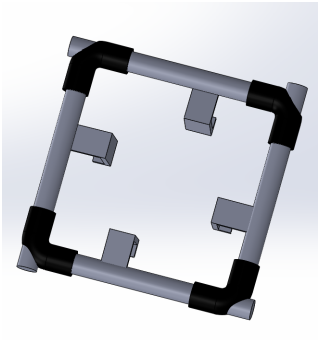


Figure 66: Top View of Extended Friction Retractor: retracted for larger patients

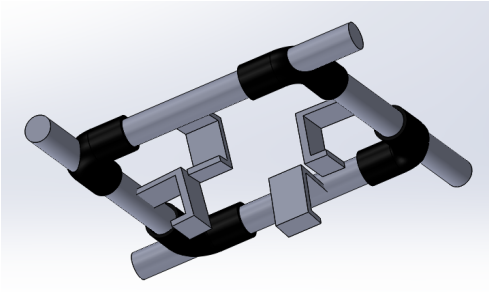


Figure 67: Bottom View of Friction Retractor: shows retaining elements

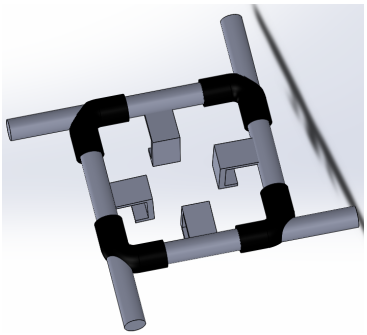


Figure 68: Top View of Friction Retractor Shortened: for use in smaller patients or incisions

This design is based off a picture frame maker as seen in Figures 67, 68, and 69. This design is made of 4 separate rods that are connected using rubber pieces on each corner of the device to connect the rods. The idea behind this idea is that friction will keep these rods together and when the rods are pulled to accommodate a larger wrist as seen in Figure 66, then the friction from the rubber will cause the rods to stay in place. Some force may be required to get the rods into the formation that is needed for surgery. The retracting elements are attached to the rods. There were several different ways that the retracting elements can be attached to the rods. One way that was discussed was to just have the retracting elements welded to the rod but they would not be adjustable and that could cause a problem for patients that are different sizes. Another idea included retaining elements that could slide along the side of the rod; however the issue arose of how to secure the retracting elements once they are in the proper place.

This design did not strictly follow the three distinct elements of a self-retaining retractor. This retractor has no distinct handles because this device is meant to stay in the incision without having to be held in place by a surgeon. This retractor does have several retracting elements, four to be exact. These elements may or may not be adjustable but they are designed to retract deep into the incision so that they can retract muscle. This system also has four ratcheting systems as opposed to a Gelpi retractor which only has one.

Due to its originality, there are several unique advantages and disadvantages to this product that are outlined in Table 8 below.

Table 8: Advantages and Disadvantages of the Friction Retractor

Advantages	**Disadvantages**
● designed to stay in the incision without the need to be held in place ● would not obstruct the surgeon's view of the incision in any way ● reusable	● when bodily fluids come in contact, friction mechanism may not work ● many materials that would need to be put together ● may require force to ratchet the system to the proper dimensions ● may be hard to change the dimensions by small increments

Overall, it was decided that this design had too many limitations that could not be overcome.

A1.3 Cuff Iteration 1

The cuff design is consists of a two-part cuff that will be placed around the patient's wrist. The bottom of the cuff will contain a ratcheting system to allow the retaining elements to easily adjust based on the surgeon's need. Several different iterations of the cuff design were explored in with varying shapes and adjustment systems. Figures 70 and 71, below shows the preliminary cuff design. This design consists of two semi-circle that fit together in a rectangular prism.

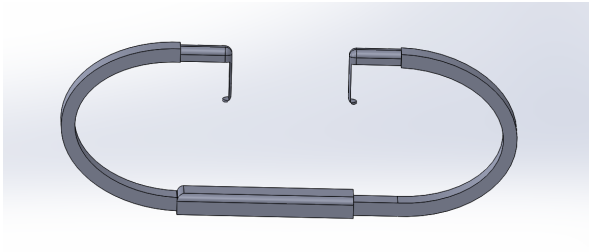


Figure 69: Cuff Retractor Iteration 1 in collapsed position for retraction in small incisions

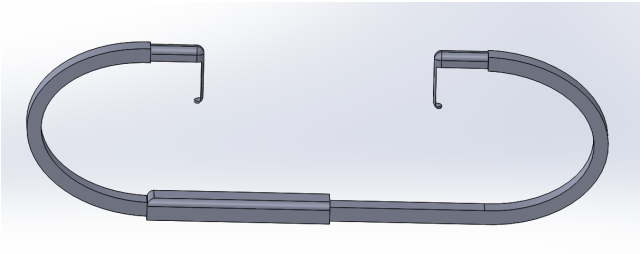


Figure 70: Cuff Retractor Iteration 1 in extended position for retractions in larger patients

A.1.4 Tongue Depressor Retractor

The tongue depressor retractor is based off of the Gelpi retractor with one major modification. The tongue depressor retractor contains an additional retaining element that is attached at the vertex of the scissor-like model. The idea for this retractor originated from the need to access the upper right and left hand corners of the distal radius fracture fixation plate. The access point on the left side of the fixation plate is shown in Figure 72 below. The yellow circles represent the where the plate will be drilled in order to secure the plate to the distal radius.

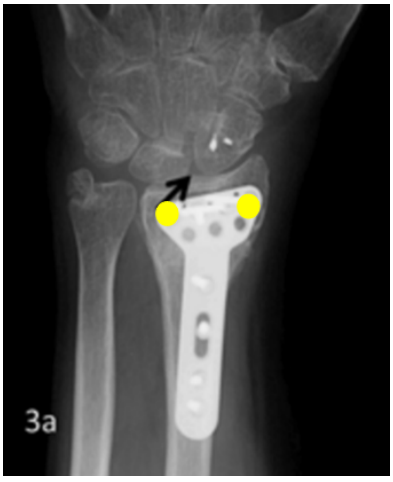


Figure 71: X-ray Image of Fracture Fixation Plate

The tongue depressor retractor as seen in Figures 73, 74, and 75, works like a Gelpi retractor during most of the surgery. The scissor-like design allows for lateral retraction of the incision site. This type of retraction leads to a diamond shape opening. However, when the surgeon needs to access specific areas of the fracture fixation plate, the tongue depressor component of the retractor can be inserted into a sleeve which is attached to the vertex of the retractor. When the tongue depressor component of the retractor is being used, the Gelpi part of the retractor would be in the collapsed position so that skin is loose and can be retracted in the opposite direction. The figures below displays and various view of the tongue depressor retractor.

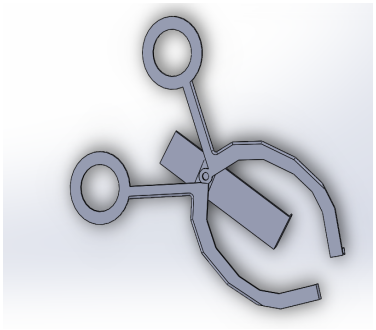


Figure 72: Top View of Tongue Depressor Retractor

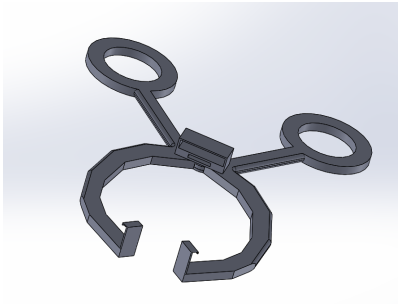


Figure 73: Bottom View without Depressor Component

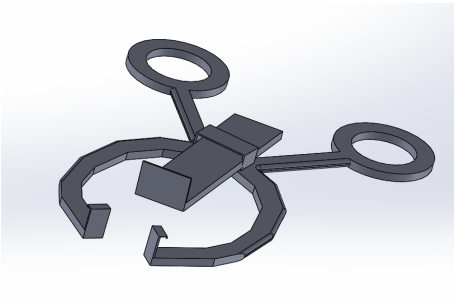


Figure 74: Bottom View with Depressor Component

Table 9, below, outlines key advantages and disadvantages of this design:

Table 9: Advantages and Disadvantages of Tongue Depressor Retractor

Advantages:	**Disadvantages:**
● Simple, based off Gelpi retractor ● Tongue depressor component can be used to reach upper right and left hand corners of radius fixation plate ● Tongue depressor component is removable so it will not interfere with surgical procedures when not needed	● Depressor is not able to retract in all four directions

A1.5 Pliers

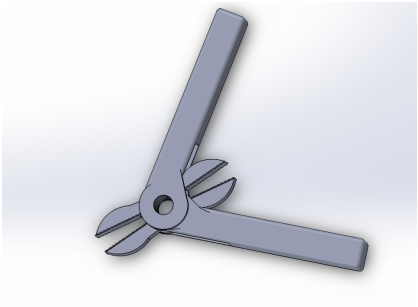


Figure 75: Pliers Retractor Closed: not retracting

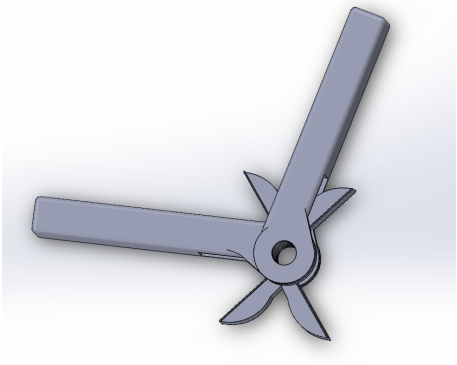


Figure 76: Pliers Retractor Open and Flipped: retracting

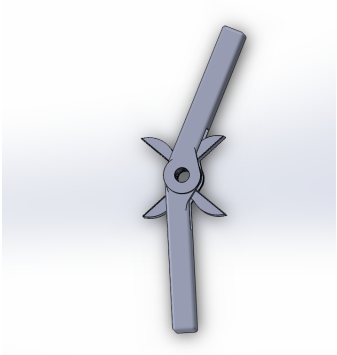


Figure 77: Pliers Retractor Open: retracting with extension shown to get the hard to reach areas

The Pliers design as seen in Figures 76, 77, and 78, was based on the idea of Flip Pliers that were found at Home Depot. The idea behind this design was that the incision would be held open by the retracting elements that are located in left hand side. The handles could then be used to adjust the retracting elements to the correct size. After the retaining elements were adjusted to the needed size, the handles could then be flipped the other side. The handle could then be used as a retractor to retract the skin that is in the higher part of the incision that is closer to the wrist. The idea was also thought of to have a separate retractor that would actually extend from the handle in order to provide an option for the parts of the plate that were closer to the wrist and in hard to reach places.

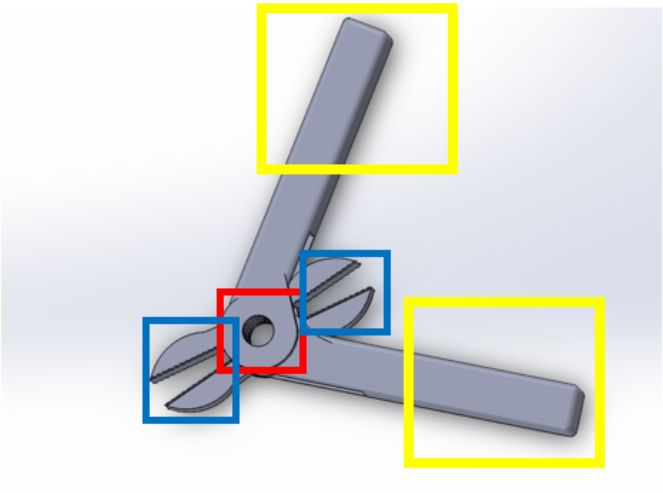


Figure 78: Elements of the Pliers Retractor highlighted in blue, red, and yellow boxes

As you can see in Figure 79, this design contains the three parts of a self-retaining element that are outlined in the background of this paper. The blue boxes show the retracting elements, while the yellow boxes show the handles of the retractor. The red box shows the ratcheting system. However, the handles also double as retaining elements when needed. It is also important to note that there are two different sets of retaining elements.

There are several reasons that this design was not chosen as a final design. The ratcheting system was incredibly complicated because there were many moving parts that all connected to one place. There also needed to be a stop in the ratcheting system that wouldn't allow the retaining elements to open too wide and tear the incision. Other concerns about this device included that the retaining elements themselves contained teeth in order to keep the retractor in place. It was brought to the team's attention that the best type of retaining elements needs to be able to retract muscle and therefore must have some depth to them. The handles of this retractor are also a simple rectangle shape which is not preferable to

the surgeons and therefore may cause this retractor to fall out of the surgeon's hand. A full list of advantages and disadvantages can be found in Table 10 below.

Table 10: Advantages and Disadvantages of the Pliers Retractor

Advantages	**Disadvantages**
• can reach areas that are closer to the wrist and toward the end of the incision • versatile • reusable	• complicated • handles are not ergonomically designed • requires many small parts • may interfere with tools needed to complete the procedure

Overall, it was decided that this design had too many limitations that could not be overcome.

A1.6 Rail Retractor

This retractor was designed in order to provide an alternative to scissor-like models. It is based on two rails that are attached to a cuff. The rails are suspended over the incision, and they curve closer to the distal radius in order to reach the top drilling points of the volar fracture plate. Two opposing blunt retractors move up and down each rail, and they have a circular ring grip so that the surgeon can adjust them easily, see Figures 80 and 81. Additionally, the retaining elements are longer since the rails are elevated over the incision.

The cuff is located closer to the proximal radius to provide stability for the entire retractor. Further iterations of this design would include a cuff that is adjustable to fit different patients. The rails are adjustable in order to adapt to the width of the incision. As seen in Figure 80 the top of the cuff has different insertion points for the rails to be adjusted. These insertion points must be able to withstand the biasing forces from tissues since they are the only contact between the rails and the cuff.

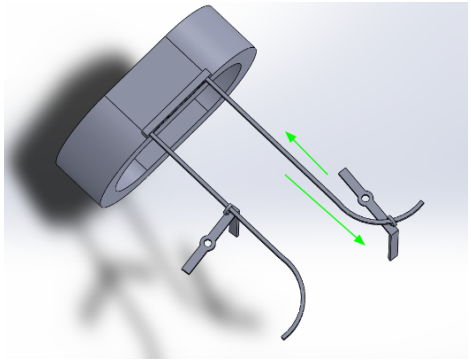


Figure 79: Top View of Rail Retractor with arrows that show the motion of the retractor

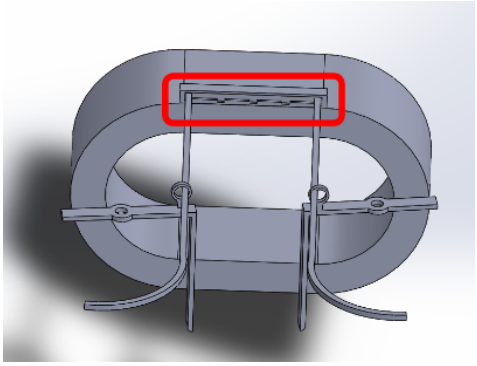


Figure 80: Top View of Rail Retractor

The advantages and disadvantages of this design are summarized in Table 11 below.

Table 11: Advantages and Disadvantages of the Rail Retractor

Advantages	**Disadvantages**
• Rail structure outside of incision allowing increased area for surgeon to work • Cuff is adjustable to allow for various size and shape of patients • Adjustable blunt retractors	• Different pieces - may elongate the procedure time • Brace attachment • Might interfere with drilling

A1.7 Cuff Iteration 2

A second cuff was designed in a cylindrical shape. The team decided to create this design iteration so a different ratcheting system could be applied. Specifically, the team wanted to implement the shower curtain ratcheting in order to adjust the retaining elements. Figures 82 and 83, below displays this cuff retractor design iterations.

Figure 81: Cuff Retractor Iteration 2 in collapsed position for retraction in small incisions

Figure 82: Cuff Retractor Iteration 2 in extended position for retraction in larger patients

A1.8 Cuff Iteration 3

A third cuff as seen in Figures 84 and 85 was designed in a square shape. This modification was based on feedback from our client. The retaining elements in this design adjust on a sliding rod and can be secured in place using a screw on the side of the rod.

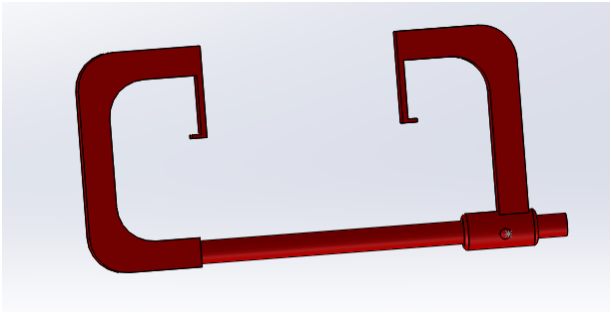


Figure 83: Cuff Retractor Iteration 3 in collapsed position for retraction in small incisions

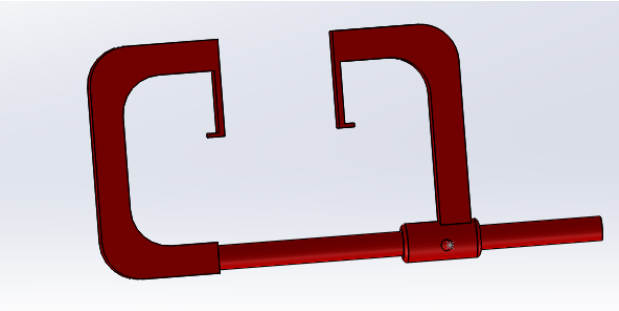


Figure 84: Cuff Retractor Iteration 3 in extended position for retraction in larger patients

After creating this retractor in Solidworks, this retractor was 3D printed in order to be able to complete further analysis and testing. Pictures of the 3D printed prototypes can be seen in Figure 85 86 and 87.

Figure 85: 3D printed square cuff design in extended position for retraction in larger patients

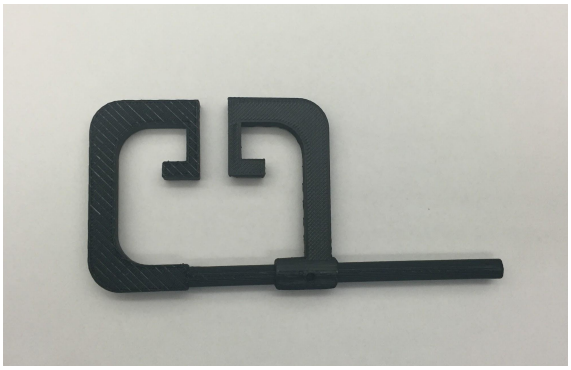


Figure 86: printed square cuff design in collapsed position for retraction in smaller patients

A1.8 Cuff Iteration 4

An additional cuff was created that is made up of a malleable metal. The purpose of this design was to explore if a cuff could be created that is bent by the surgeon to the desired position. This cuff was created by twisting two strands of galvanized stainless steel. The twisted stainless steel was inserted into a plastic tube. The retaining elements consisted of shelf fasteners. This design can be seen in Figures 88 and 89.

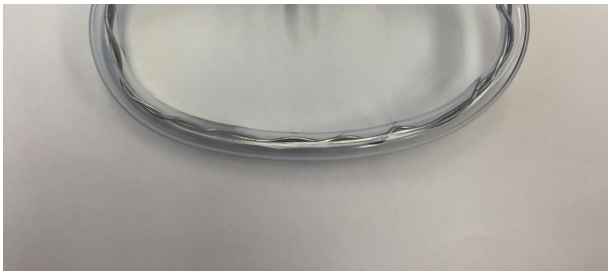


Figure 87: Cuff Retractor Iteration 4 collapsed for retraction in smaller patients

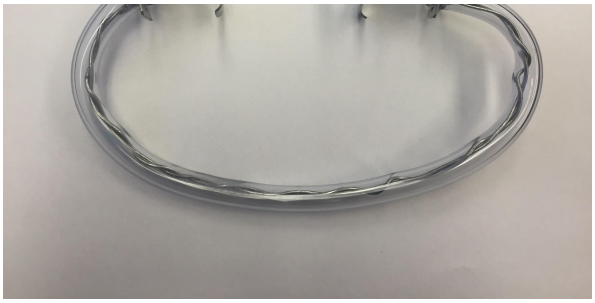


Figure 88: Cuff Retractor Iteration 4 Extended for retraction in larger patients

A1.9 Cuff Iteration 5

Lastly, another cuff prototype was created using a turnbuckle ratcheting system as seen in Figures 90 and 91. This prototype design is comprised of two semi-circle zinc-plated U-bolts and a zinc-plated turnbuckle. This cuff is able to adjust by rotating the turnbuckle clockwise or counterclockwise.

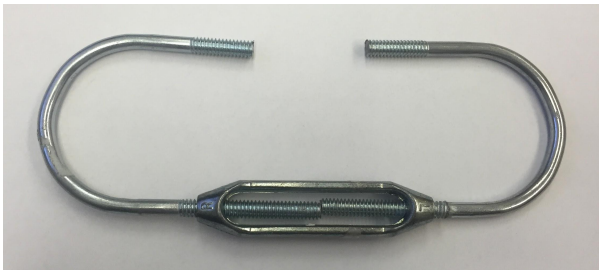


Figure 89: Cuff Retractor Iteration 5 collapsed for retraction in smaller patients

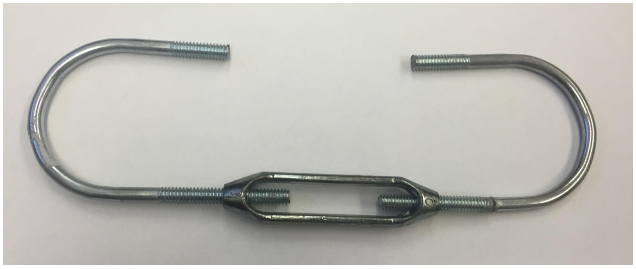


Figure 90: Cuff Retractor Iteration 5 Extended for retraction in larger patients

A1.10 Snap- In Design

This design is based on the cuff but there is a frame that can hold two retractors, specifically Army Navy retractors. This design can be seen in Figure 92 below. Instead of retaining elements, this iteration features clips that allow an Army Navy retractor to be inserted into, which can be seen in Figure 93. This design would allow for the retractors that surgeons are familiar with to still be used while also eliminating the need for these retractors to be held.

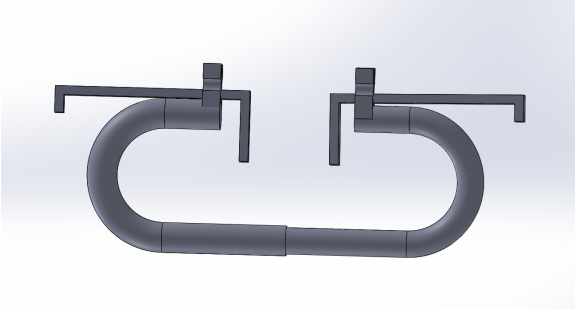


Figure 91: Cuff Retractor Iteration 6 with Army Navy Retractors that snap into the device using the attachment mechanism

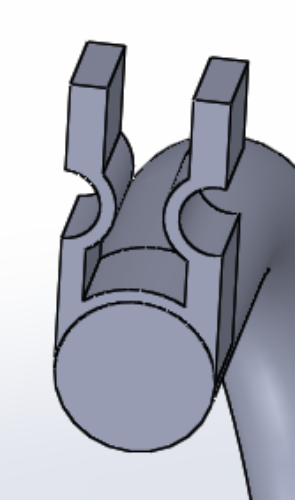


Figure 92: Attachment Mechanism for Army Navy Retractors to the retractor

A1.11 Chosen Standard Cuff and Dimensions

The standard cuff design that was chosen consisted of two main parts; the top part and the base part. The top part of the cuff and all the associated dimensions can be seen in the Solidworks drawing depicted in Figure 94, below.

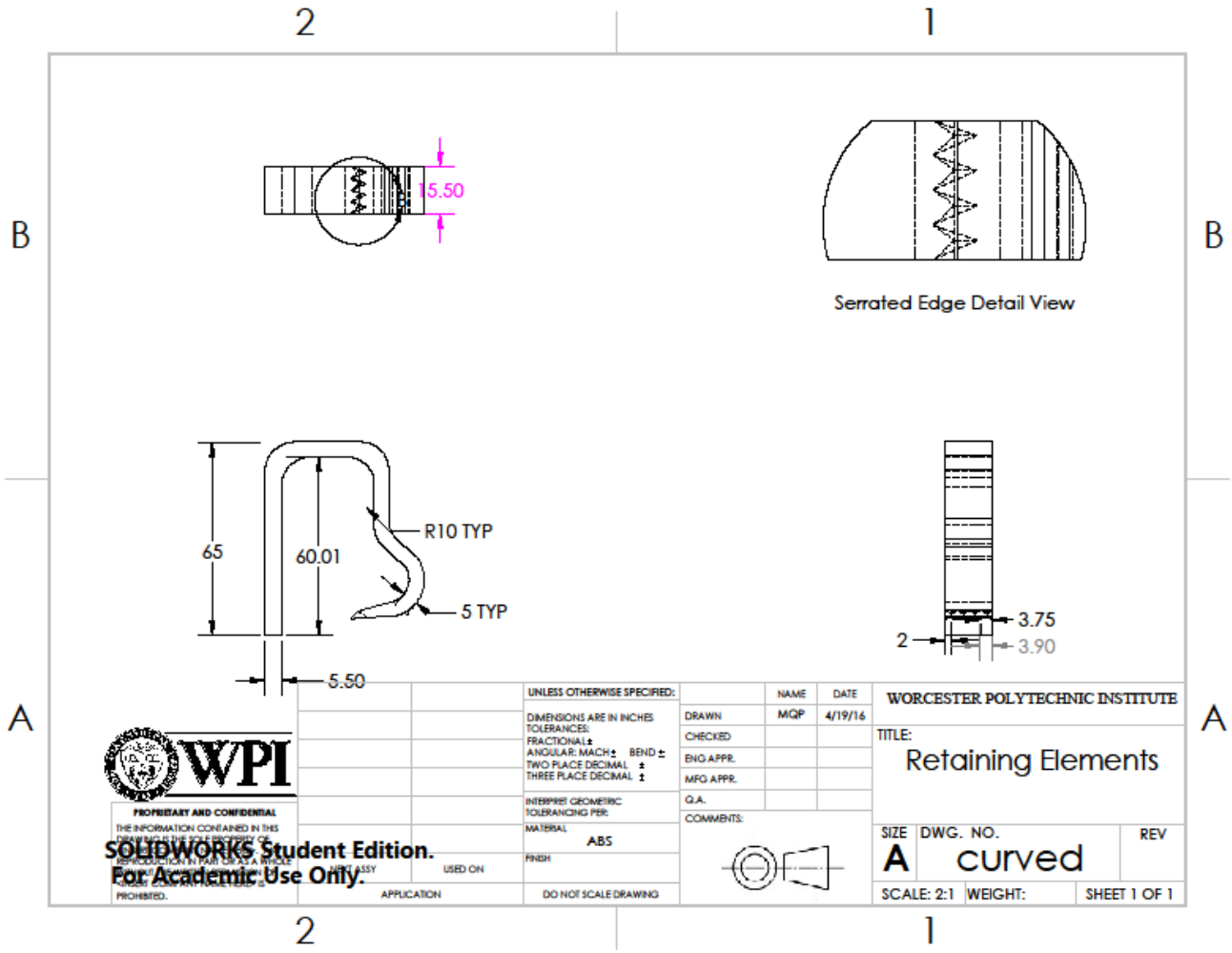


Figure 93: Solidworks drawing for the Retaining Element of Final Design

There are two different bases designed for this device. One base is attached to the ratchetting system and that base is referred to as the trigger side base. This base part of the cuff and all the associated dimensions can be seen in the Solidworks drawing depicted in Figure 95, below.

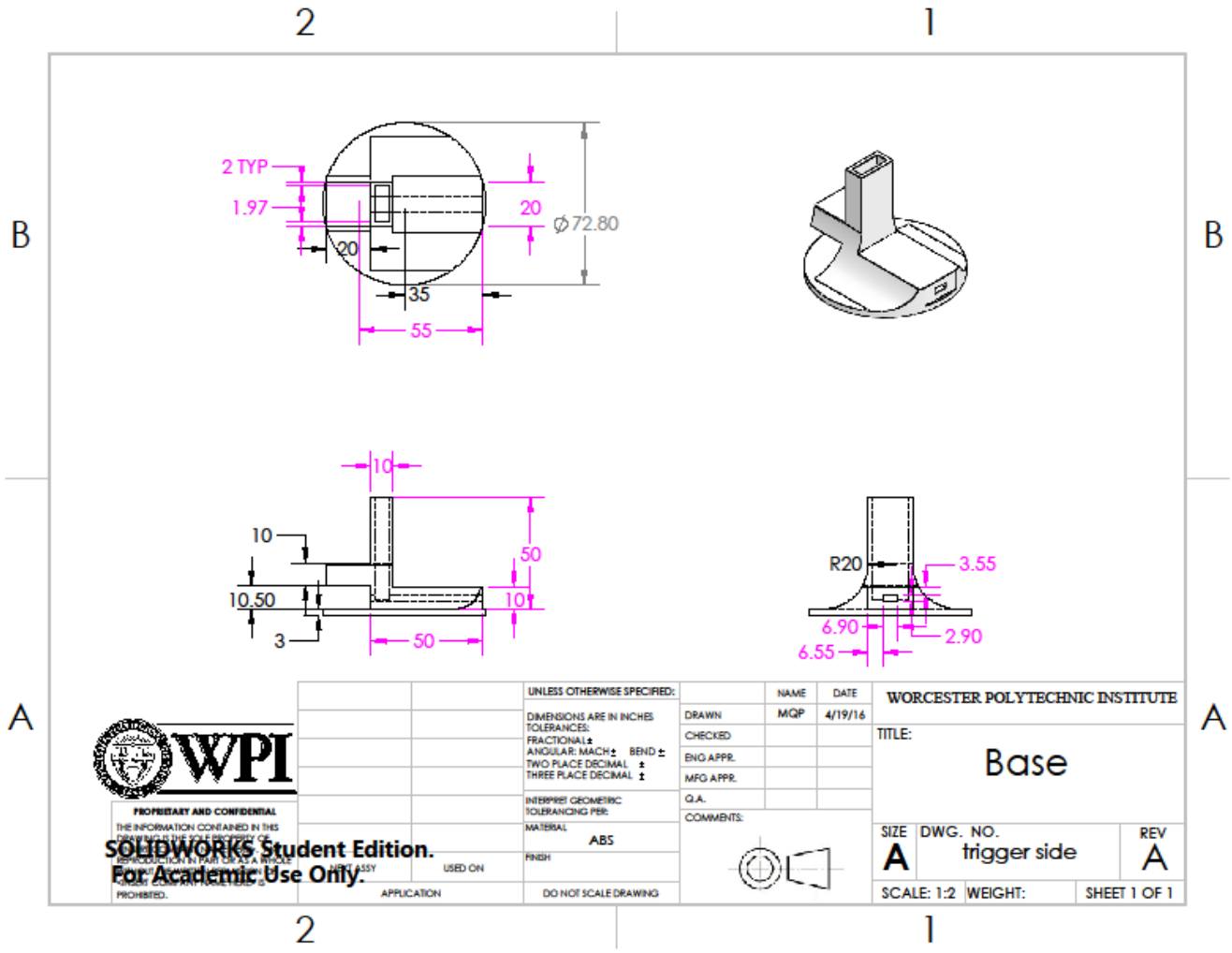


Figure 94: Solidworks Drawing for Trigger Side Base of Final Design

The other base is known as the non-trigger side base or the base that is not attached to the ratchetting system. This base part of the cuff and all the associated dimensions can be seen in the Solidworks drawing depicted in Figure 96, below.

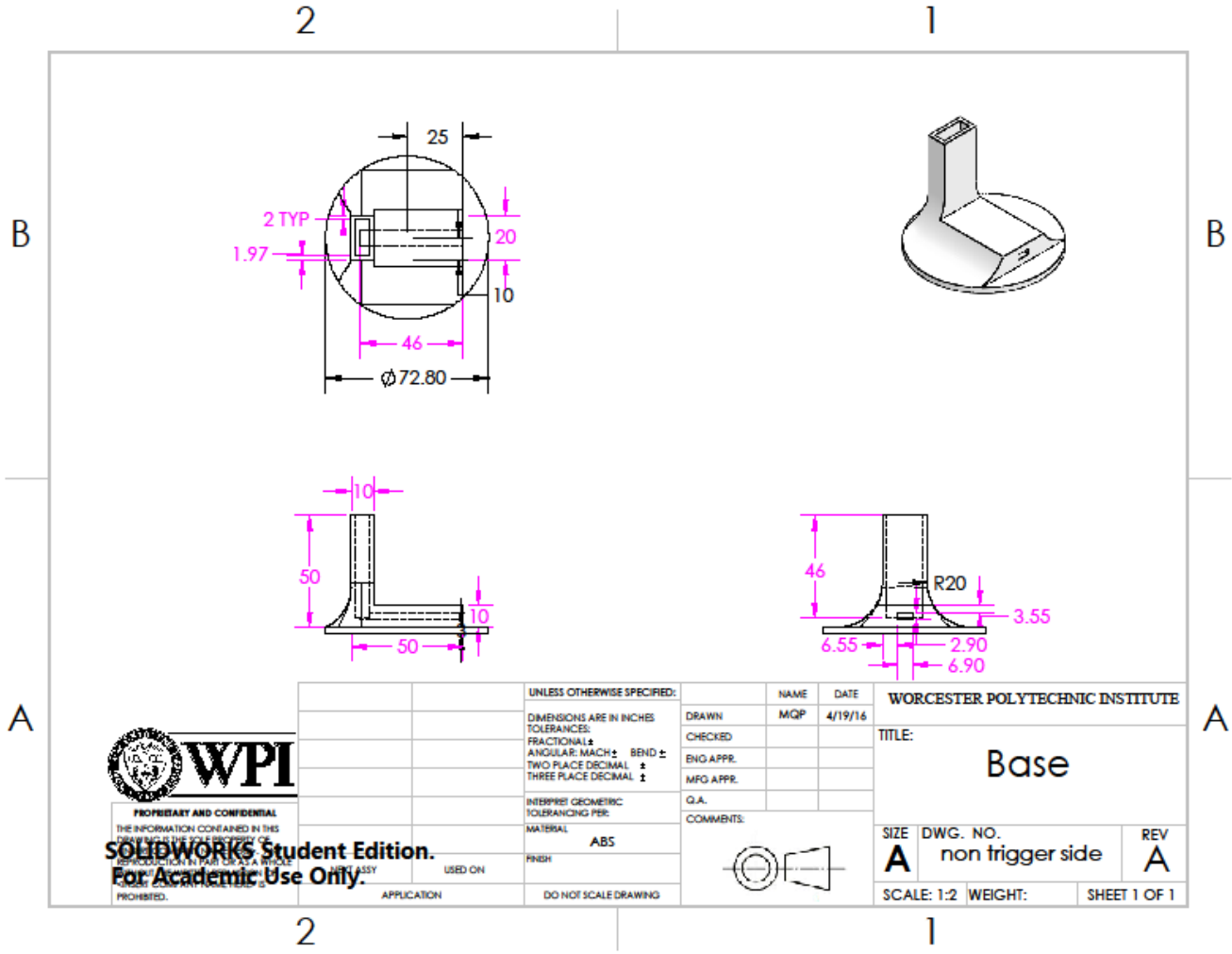


Figure 95: Solidworks Drawing of Non-Trigger Side Base of Final Design

Some of the dimensions that can be seen in the drawing are based off the dimensions of the Army Navy retractor. Some of the dimensions were changed based on the preferences and the feedback from the surgeons at UMass Medical School. Other dimensions were based on the anatomy of the wrist and the parts of the anatomy that need to be retracted in order to perform the surgery. The overall dimensions of the cuff were determined based off the average wrist size but consideration for smaller and larger patients was used in determining the length of certain dimensions.

Appendix B: History of Retractors

Tissue retractors have been an integral part of surgical procedures throughout history. Various shapes, sizes, orientations are available depending on different procedures. These tools originated with very basic shaped tools in the Stone Age to dig and extract food from the ground. Evolution of these tools allowed for the addition of hooks, fingers, and prongs for use in butchering meat and dissecting bodies. Self-retaining retractors were first used for gynecologic surgeries created by the Romans. In the 7th century, there was documented use of a tongue spatula to hold back the tongue while a hook was used to

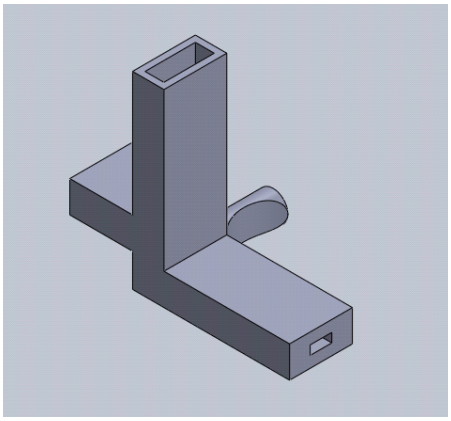
bring the tonsils forward for excision [38]. Moreover, in 1000 CE many surgical techniques and retractors were discussed in an Arabic encyclopedia of medicine and surgery.

In 1885, Dr. Doyen designed an abdominal retractor that could be fixed to a patient's thigh during surgery. The creation of the hinged rib spreading retractor in 1904 prompted a flurry of development of evolving retractors in the early 20th century. The Balfour retractor was designed in 1912 and is still used today in abdominal surgeries. Moreover, John R Bookwalter created the Bookwalter retractor in 1980. This retractor has a ring structure that borders the abdominal incision. The Bookwalter retractor is fixed to the table and has several adaptable components that connect to the major ring structure. This retractor reduced the number of assistants and medical students needed to hold the retractors open during surgery [39]. It is also important to note that the Bookwalter retractor was a successful design because its focus is solely on abdominal surgery. Targeting a specific surgery location will be critical to guarantee the success of this novel self-retaining retractor. Studying current technologies can help with the design process by extracting the best features of existing retractors.

Appendix C: Client Survey for Final Design Iterations

Rate the following criteria for each of the design:

Design Iteration 1: Bar Handle



Functionality:

1 2 3 4 5

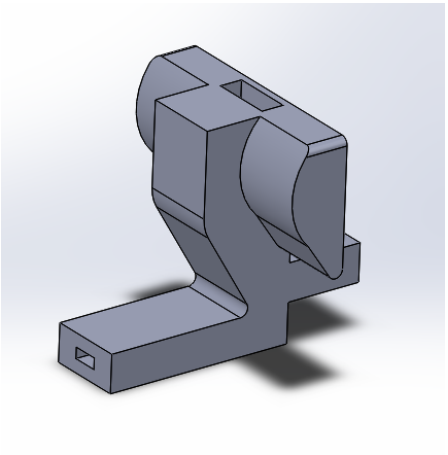
Ergonomics / User-Friendly:

1 2 3 4 5

Aesthetic appeal:

1 2 3 4 5

Design Iteration 2: Ear Handle



Functionality:

1 2 3 4 5

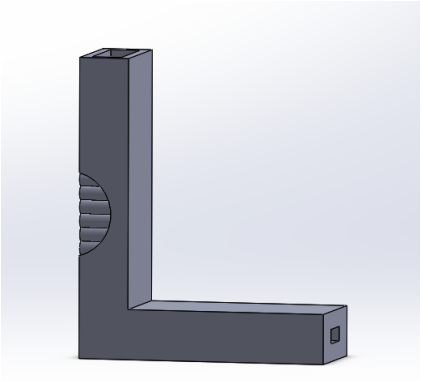
Ergonomics / User-Friendly:

1 2 3 4 5

Aesthetic appeal:

1 2 3 4 5

Design Iteration 3: Grooved Grips



Functionality:

1 2 3 4 5

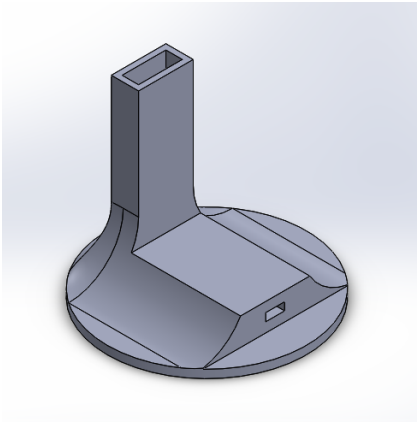
Ergonomics / User-Friendly:

1 2 3 4 5

Aesthetic appeal:

1 2 3 4 5

Base Iteration 4: Circular Base



Functionality / Stability:

1 2 3 4 5

Ergonomics / User-Friendly:

1 2 3 4 5

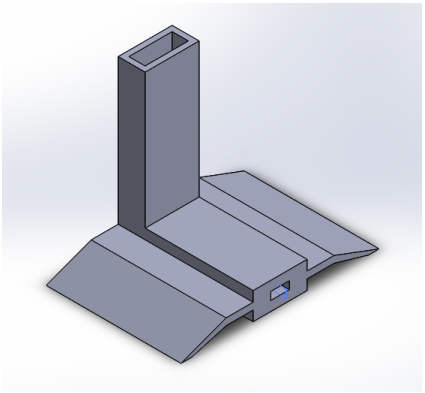
Aesthetic appeal:

1 2 3 4 5

Base Iteration 5: Spider Base

Functionality / Stability:

1 2 3 4 5



Ergonomics / User-Friendly:

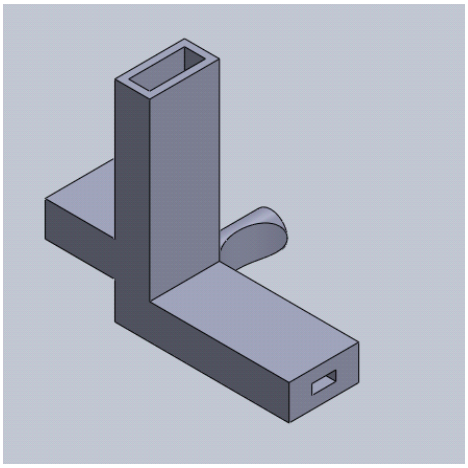
1 2 3 4 5

Aesthetic appeal:

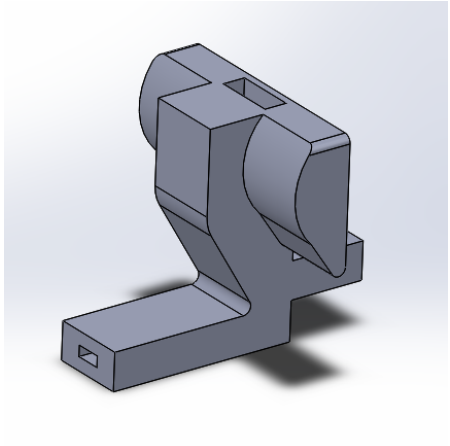
1 2 3 4 5

Rank 3 Grip/Handle Designs:

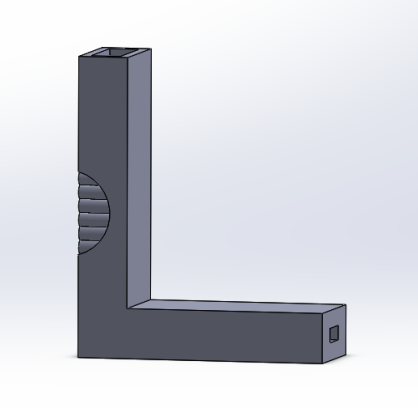
Bar Handle: _____



Ear Handle: _____

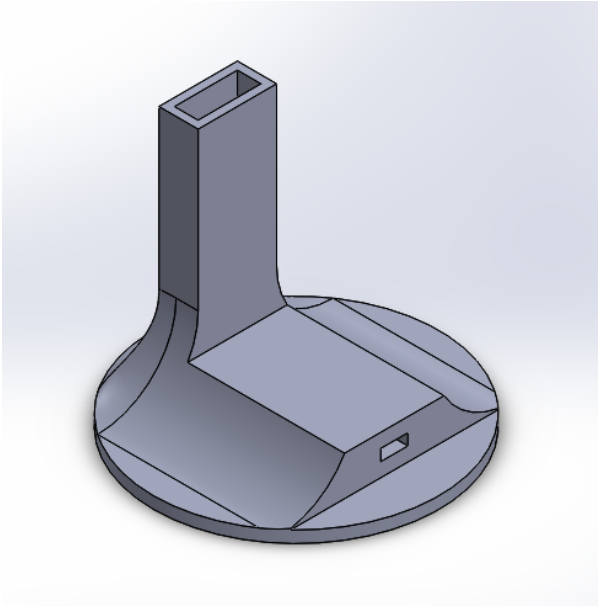


Grooved Grips: _____



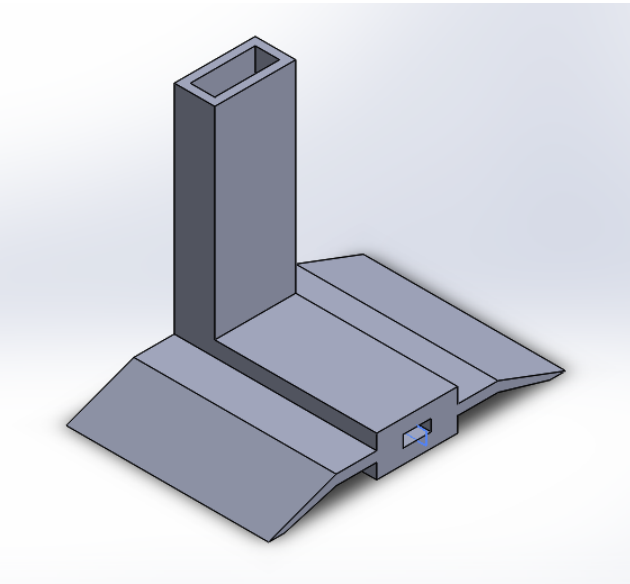
Rank 2 Base Designs:

Circular Base:



_____

Spider Base:



Glossary

Biocompatibility- relative ability of a nonorganic material to interaction favorably with a biologic system depending on the material's chemical stability over time, tendency to cause inflammation, incite disease, or become carcinogenic

Callous- relating to bone callus or epidermal callous; hard

Carpal bones- eight bones arranged in two rows that articulate proximally with the radius and indirectly with the ulnar and distally with the five metacarpal bones

Carpal Tunnel Release- a surgical procedure for treating carpal tunnel syndrome in which the flexor retinaculum of the wrist is cut to release compression of the median nerve

Center of Gravity- point in or near a body at which the gravitational potential energy of the body is equal to that of a single particle of the same mass located at the point and through which the resultant of the gravitational forces on the component particles of the body acts

Code of Federal Regulations (CFR)- list of US government regulations that specify the way certain activities or practices must be carried out and will be enforced

Compressive force- a force that squeezes an object's surfaces together and causes its mass to bulge

Deviation- act of turning aside

Distal- located away from the point of origin or attachment

Distal radioulnar joint- the pivot synovial joint between the head of the ulna and the ulnar notch on the radius, an articular disc passes across the distal part of the joint

Dorsal plate- dorsal plates are designed for complex distal radius fractures that require internal fixation from the dorsal side (see definition of dorsal side)

Dorsal side- located near or toward the upper surface of an animal opposite the lower surface

Ergonomics- a branch of ecology concerned with human factors in the design and operation of machines and the physical environment

Extension: movement by which the two ends of any jointed part are drawn away from each other

Extra-articular- outside a joint

Flexion- a movement allowed by certain joints of the skeleton that decreases the angle between the two adjoining bones

Food and Drug Administration (FDA)- a federal agency in the Department of Health and Human Services established to regulate the release of new foods and health-related products

Forearm- the part of the forearm between the elbow and the wrist which is also called antebrachium

Fracture- the breaking in the continuity of the bone caused by trauma, twisting, or disease

Gelpi retractor- a self-retaining, small spreader suitable for small sites which contains two blades hinged in the middle; the blade separate as the handles are closed and is held open by a ratchet

Impacted fracture- a fracture in which one fragment is firmly driven into the other (see fracture)

International Organization of Standardization (ISO)- a nongovernmental federation of worldwide bodies that publishes international agreements covering a broad range of services and technologies to promote the use of common standards across the world

Intra-articular- within a joint

Median nerve- nerve that supplies all the muscles of the anterior part of the forearm with the exception of the flexor carpi ulnaris and the ulnar half of the flexor digitorum profundus and passes through the carpal tunnel; formed by the union of the medial and lateral roots from the medial and lateral cords of the brachial plexus; most commonly injured through compression in carpal tunnel syndrome

Pronator muscle- muscle that twists the forearm about the longitudinal axis from the neutral position toward one in which the bottom of the hand is directed anteriorly from the anatomical position

Radial border- an imaginary line that runs along the outermost part of the forearm that laterally separate the anterior and posterior surfaces

Radial nerve- supplies the muscles of the posterior compartments of the arm and forearm and overlying skin; most commonly injured by fractures of the middle third of the humerus

Radiocarpal joint- aka the wrist joint; the synovial joint between the distal end of the radius and its articular disc and the proximal row of carpal bones with the exception of the pisiform bone

Radius- one of the three long bones that form the framework of the arm; the outer bone of the forearm

Ratcheting system- part of the retractor that controls the distance between the retaining elements

Retaining elements- the part of the retractor that comes in contact with the skin and are placed in the incision

Retractor- a surgical instrument used for holding back the edges of a surgical incision or organ or part

Self-retaining retractor-a retractor that can keep the incision open without the help of an outside source. Self-retaining retractors usually contain a type of ratcheting system which allows the retractor to remain open.

Serrated- notched or toothed on the edge

Shear angle- the angle between a deformed body and its original position

Shear force- force acting parallel to the surface of a material so as to tend to deform it; usually through shear angle

Shear fracture- a fraction resulting from shear stress (see shear stress)

Shear stress- the force per unit area of cross-section which depends to produce a deformation or fracture induced by parallel planes in a body or assembly slide over one another

Solidworks- a type of 3D Computer Aided Design Software that allows the user to design parts, assemblies, and 2D drawings. Solidworks allows the user to use tools for sheet metal, weldments, surfacing, and mold tools.

Static Equilibrium- Any system in which the sum of the forces, and the torque, on each particle of the system is zero; mechanical equilibrium

Tensile force- a force put on a material which can cause the material to be pulled in opposite directions on either end usually resulting in stretching or tearing

Ulnar bone- long medial bone of the forearm

Ulnar nerve- supplies the hypothenar, interosseous, medial lumbricals, adductor pollicis, and the deep head of the flexor hallucis brevis, and the intrinsic muscles of the hand and skin of the small finger and medial side of the ring finger and adjacent portions of the palm of the hand; when mild injury occurs the "crazy or silly bone sensation" is experienced

Volar- refers to the underside for both the palm and the sole

Weitlaner Retractor- a self-retaining instrument shaped like scissors but the blades open when the ratcheted handles are closed