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DESIGN OF A MULTI-DEGREE OF FREEDOM MICROVASCULAR CLIP APPLICATION SYSTEM

A Major Qualifying Project Report:
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by

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1. Microvascular Surgery
2. Clip/Clamp
3. Forceps
4. Vessel Occlusion

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Abstract

Microvascular clips and their applying forceps are crucial in microsurgery in order to provide a bloodless operating field. The design of these clips, however, has not changed in almost 100 years. The current clips successfully occlude blood flow, but are not ergonomic and are difficult to use. The current interface between the clip and forceps is a tongue-and-groove design, which does not allow the surgeon any degrees of freedom of motion. We have designed a clip-forceps system which will give the surgeon the ability to rotate the clip both horizontally and vertically in relation to the forceps, eliminating the need for uncomfortable wrist contortion and reducing the risk for error during surgery. Our novel design consists of a half-spherical interface on both sides of the currently used clip. One side of the forceps is the inverse of the sphere, while the other is a flat, rectangular track that allows room for vertical rotation. A mockup of this design was built and evaluated using a microsurgical training model. The design idea was assessed via surveys completed by ten surgeons. Results from the surveys showed that the new design was rated better than the current design in terms of functionality and ease of use and nine out of ten surgeons said that they would use the new design. Actual sized prototypes of the current design and proposed new design were also manufactured and subsequently tested on an isolated artery of a rat model. The proposed design further proved the new interface design was functional in eliminating ergonomic issues such as stability of the wrist while applying the clip. Overall, this novel multi-degree of freedom microvascular clip application system has high potential to be adapted into common practice during surgical procedures.

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1. Introduction

Within the medical industry, billions of dollars are spent yearly on research and development of new medical equipment, methods, and materials to enhance the way healthcare is practiced. With a large focus on the evolution of new technologies to change the face of current practice, not much effort is made to improve already existing, commonly used surgical equipment. This is largely the case with microvascular clips and their applying forceps, whose design has not been altered in almost 100 years.

Microvascular clips are very small devices that are used in microsurgery to occlude blood flow through arteries and veins. These clips are necessary to provide a bloodless operating field. The clips are generally picked up from the surgical table, held, and applied to blood vessels using a forceps that interfaces at the end of the clip. One major problem with the current design is that the shape of the interface between the clip and the applying forceps, a tongue-and-groove interface, does not allow any degrees of freedom of motion. That is, any motion needed to achieve various application angles must be achieved through wrist motion. Due to the delicate nature of microsurgery where small surgical spaces are the norm, the surgeon ideally wants to limit wrist and hand motion. Thus, maneuvering the clip and applying it to the vessel at the appropriate angle becomes difficult and uncomfortable for the surgeon and can jeopardize the success of the surgery. An additional problem faced when using this device is that if no locking mechanism is present to lock the clip into the forceps, the clip can easily fall out of place. This is problematic should a nurse or surgical aide need to hand the clip-forceps system to the surgeon during a procedure.

Considering the limitations of the current clip-forceps system, this project focuses on redesigning the interface between the microvascular clips and applying forceps in an effort to make the device more ergonomic and practical for surgeons to use. This will be accomplished by designing an interface that allows for both lateral and vertical rotation of the clip relative to the forceps so that multiple application angles can be achieved if the clip is pushed against the surrounding tissue.

The project will be completed in sequential manner, beginning with a thorough background and literature review of applicable topics, including the history and use of these clips, the current design and attempts at improving the device, and the importance of ergonomics in surgery. This background research will frame the project space, from which a list of design objectives, constraints, and desired functions will be developed. Conceptual designs that comply with these requirements will then be generated. Once a final design is selected based on a series of criteria, it will be drawn in CAD, prototyped, and tested. Reassessment of the design based on feedback from the client and medical professionals who would potentially use the device will be an important aspect in design optimization. This report contains a clear summary of all stages of the design process.

2. Background and Literature Review

2.1. History and Use of Vascular Clamps

During surgery, a bloodless operating field is necessary in order to perform a successful procedure (Goh, et al. 1999, Sauer, et al. 2002, Trobec and Gersak 1997, Walia and Kole 1998). Originally, this was accomplished through ligation, or the tying off of the artery or vein (Dalton, Connally and Sealy 1993). Today, a variety of occluding clamps are used. The application of these clamps spans many types of surgeries including coronary artery bypass, orthopedic and plastic surgery, and microsurgery (Walia and Kole 1998).

The first successful arterial clamping during a vascular procedure was performed in 1882 (Dalton, Connally and Sealy 1993). In 1906, bulldog clamps, which are now widely used, were developed by Carrel and Guthrie. These clamps are spring loaded and can be applied manually to larger vessels. A significant problem that had to be overcome was determining the appropriate clamping pressure that would effectively occlude the vessel without damaging the tissue (See Appendix E). Since their development, small modifications have been made to the bulldog clamps in order to optimize the design, but the overall device has not changed. Examples of these modifications include locking mechanisms and the presence of teeth on the jaws of the clamp to distribute and minimize clamping pressure (Dalton, Connally and Sealy 1993). Today, clips and clamps are available in several shapes, sizes, and curvatures so that they can be applied to a variety of vessels. However, the smallest clips which are used in microsurgery must be applied with forceps, which can be difficult in small surgical spaces.

2.2. Current Designs Used in Surgery

Vascular clamps and clips are used in many different types of surgeries and therefore are available in many different shapes, sizes, and forms. Even though there are many different bulldog clamps and microvascular clips available with small variations based on the manufacturer, there are several basic designs on the market that are most commonly used by surgeons.

Bulldog clamps are generally used on larger vessels, and thus not used in microsurgery. They are approximately three inches in length. The clamps are composed of two criss-crossed arms that allow them to be opened and closed and applied by hand. Several types of bulldog clamps are available, each with a different cross-sectional area and curvature to account for different vessel diameters, locations in the body, and tissue strengths. Some brands are also serrated with "teeth" to improve the grip on the vessel and distribute clamping force. Several versions, such as Dietrich/DeBakey, Johns Hopkins, Dieffenbach, and Glover bulldog clamps, can be seen in Figure 2.1a-d respectively.

Microvascular clips, as seen in Figure 2.2, are similar to bulldog clamps in that they perform the same function. However, the clips are used on a much smaller scale to occlude very small vessels, such as in microsurgery. The clips are approximately 8-14 mm in length and are available in single or double clips, as well as angled clips. Double clips are held parallel to each other by a small wire to occlude two parts of a vessel, allowing for the area in between to be operated on. These microvascular clips are available in a variety of materials. Stainless steel clips are sterilizable and reusable, while plastic clips are disposable. More information on surgical materials can be viewed in Appendix B.

Figure 2.1. (from left to right): a) A Dietrich/DeBakey, b) Johns Hopkins, c) Dieffenbach, and d) Glover Bulldog Clamp (Roboz: The Surgical Instrument Experts 2008, AA Instruments 2008).

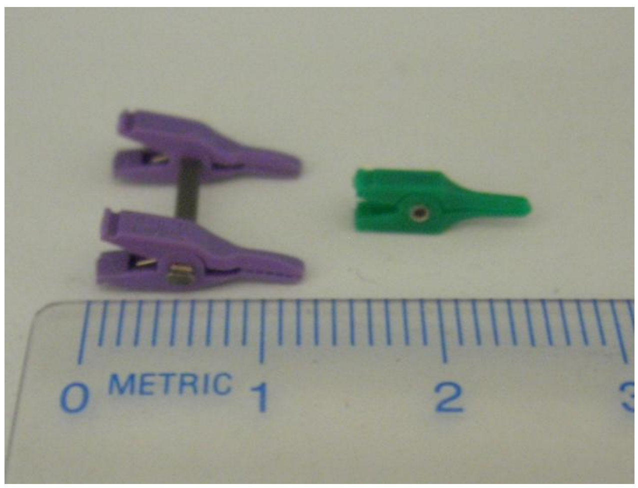

Figure 2.2. An S&T disposable plastic double microvascular clip (left) and single microvascular clip (right).

2.2.1. Tool Component Interfaces

2.2.1.1. Forceps to Clamp Interface

Currently, the interface between microvascular clips and their applying forceps is a tongue-and-groove connection. As seen in Figure 2.3, a groove is located horizontal to the jaw of the clip into which the raised tongue portion of the forceps can fit. Although this design is commonly used in surgery, there are many problems associated with this interface. Due to the small size of the clip, it is very difficult to align the tongue-and-groove in order to properly grip the clip. In addition, many forceps lack a locking mechanism to keep the clip in place. It is easy for the clip to fall out of place, and thus the device requires a constant force in order to hold and maintain grip of the clip in the forceps. This is not only tiring for the surgeon, but can be problematic should a nurse or surgical aide need to pass the system to the surgeon during a procedure. The most significant problem with the currently used clip-forceps system is that the shape of the interface allows no degrees of freedom of motion between the forceps and clip, requiring the surgeon to manually manipulate the clip-forceps system with his/her hand and wrist to properly apply the clip to the vessel. Due to the delicate nature of microsurgery and the small surgical space, it is not ideal for the surgeon to move his/her wrist (R. Dunn 2007). It is evident that surgeons could benefit from a design that allows multiple degrees of freedom of rotation of the clip relative to the forceps to limit fatigue and discomfort and reduce risk for error.

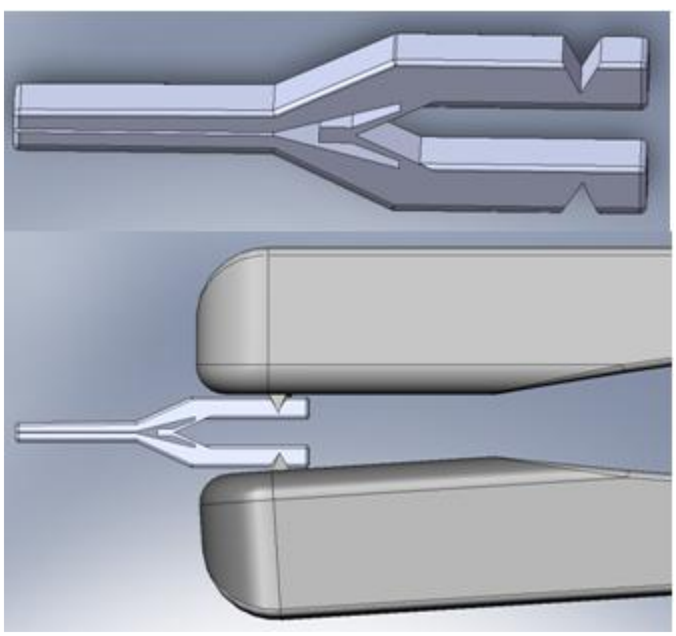

Figure 2.3. Diagram depicting the groove interface of the currently used clips (top) and the tongue-and-groove interface of the currently used microvascular clip-forceps system (bottom).

2.2.2. Forceps User Interface

The current applying forceps are specially designed to be held much like a writing utensil to maximize comfort and maneuverability. In most cases, the stainless steel forceps contains a laterally grooved portion which is designed to decrease the amount of slippage between the forceps and the fingers. As previously stated, forceps may or may not contain a locking mechanism to hold the forceps closed. When a locking mechanism is present, the pressure applied by squeezing both sides of the forceps together in a pinch grip in order to hold the clamp in place is reduced, minimizing hand fatigue.

2.3. Market Research

2.3.1. Vascular Clamp Manufacturers

A variety of companies, both national and international, manufactures and distributes vascular clamping devices. Some companies focus specifically on bulldog clamps, while others manufacture microvascular clips. Appendix A displays a table listing the major companies that currently manufacture vascular clamps and clips. It includes the company name, location, and type of clamp that is manufactured (Register 2007).

2.3.2. Current Prices

Table 2.1 displays the average price range for the different types of bulldog and vascular clamps. As can be seen, the price for each type of clamp varies. This can be attributed to the differences in manufacturers, materials, sizes, serrations, curvatures, sterilization and packaging methods, etc.

Table 2.1. Current Price Ranges for Bulldog and Vascular Clamps

(A1 Medical Sales 2008, Surgical Instrument Professionals 2008)

Type of Clamp	Price Range
Disposable Clips	~$70
Reusable Microvascular Clips	~$70-120
DeBakey Bulldog Clamp	~$120-160
Glover Bulldog Clamp	~$140-190
Dietrich Bulldog Clamp	~$180-200
Applying Forceps	~$180

2.3.3. Percentage of the Surgical Device Market

Although it is difficult to say precisely what percentage of the medical device market vessel occlusion clamps and applying forceps comprise, some estimation can be made. The surgical instrument market was estimated to be approximately $3.8 billion in 2002, where approximately 27% of the market was composed of non-powered surgical equipment (Research Buy 2007). The non-powered category is comprised of scalpels, scissors, and closure devices to which vessel occlusion clamps and forceps belong.

More estimates can be made to determine the exact percentage of the market that is comprised solely of the sales of vessel occlusion clamps and forceps. According to multiple sources, the number of surgeons in America has been fairly steady, ranging between 80,000 and 100,000 surgeons currently practicing in the United States (Rosenthal 1989, JACS 2000). Information provided by one plastic surgeon interviewed stated that hospital administrations are responsible for purchasing surgical equipment, but the surgeons themselves tell the administration what to purchase. He also disclosed that although surgeons may not have their own instrument sets, it is fairly common for hospitals to have multiple sets of clamps and forceps (R. Dunn 2007). Since the vessel occlusion clamp industry is international, surgeons in other countries can also be expected to factor in to the total number of clamps sold. Based on these estimates, it can be concluded that these instruments comprise a significant portion of the surgical device market and are very widely used. Thus it can be deduced that a great number of surgeons could benefit from a new, more ergonomic clip-forceps interface design.

2.4. Ergonomics

Ergonomic comes from the Greek words "ergon" for work and "nomos" for law or knowledge (Dul and Weerdmeester 1993, Patkin 1981). Also called "human factors engineering", it is the study of the interaction between humans and their work environments (Berguer 1997, Stone and McCloy 2004). Ergonomics takes into account the physical and psychological limitations of human beings in order to increase safety, health, comfort, and efficiency (Dul and Weerdmeester 1993).

The focus of this project is on the ergonomics of surgical devices in order to maximize comfort and efficiency during surgery. The most important components of ergonomics in relation to this topic are as follows (Dul and Weerdmeester 1993, Stone and McCloy 2004):

- optimization of system performance and elimination of error;
- maximization of human comfort and reduction of stress and fatigue;
- consideration of body size (anthropometry) and body posture.

2.5. Importance of Improved Ergonomics in Surgery

In microsurgery, the margin for error is extremely small (Patkin 1981). Therefore, as the scale of surgery decreases, considerations such as easy instrument manipulation, good posture, and comfort of the surgeon become increasingly important, yet increasingly difficult to accomplish (Berguer 1997, Berguer 1999, Bhatnager, Drury and Schiro 1985). Most surgical instruments were designed to be mass-producible, universal, and rapidly sterilized; ergonomics were not taken into account. As a result, many surgeons complain of stiffness and discomfort in the neck, arms, wrists, and hands resulting from the prolonged awkward body and hand positions required during microsurgery (R. Dunn 2007, Mirbod, et al. 1995). These positions can lead to inefficient performance and fatigue causing an increase in the cost of procedures, number of injuries, and error (Berguer 1996, Berguer 1999).

"…A recent report by the Food and Drug Administration estimates poor design of medical instruments may account for half of the 1.3 million unintentional patient injuries in US hospitals each year," (Berguer 1999). Despite the criticality of good ergonomics in surgery, there has been minimal research done on improving efficiency and minimizing errors during surgery. The surgical world could benefit greatly from such research leading to improved ergonomics so that patient safety can be improved and the comfort and performance of surgeons can be increased, as well as long-term disabilities avoided (Bhatnager, Drury and Schiro 1985).

2.6. Ergonomics in Hand Tool Design

Ergonomics in hand tool design is very important, especially in surgery. Proper tool design can allow the user to remain comfortable, avoid injury, and precisely manipulate the instrument. The use of non-ergonomic tools can lead to irritation of nerves, pressure areas that can cause prolonged damage/pain, and muscle exhaustion in the hand (Matern, Eichenlaub, et al. 1999, Matern and Waller 1999). These stresses can be attributed to unaccustomed use, excessive use against resistance, and use in abnormal positions. Several other injuries and diseases, such as carpal tunnel syndrome which often requires surgical repair, are quite common as well and thus ergonomics should not be ignored in tool design (Tichauer and Gage 1997). The optimal design of hand tools takes into consideration anatomical, mechanical, physical, and anthropometric principles. Tools should be designed to optimize forces, distribute contact pressures, promote good posture, and conform to common hand sizes (Tichauer and Gage 1997).

2.6.1. Consideration of Common Hand Movements

There are several types of hand motions that are desired in the operating room: fine manipulation, fast movement, frequent movement, and forceful activities. These hand motions can produce accuracy, strength, and displacement (Kroemer, Kroemer and Kroemer-Elbert 1994). Hand tool design should take into consideration that certain motions can and cannot be performed while the hand/arm is in certain anatomical positions. For example, the hand cannot grasp firmly when the wrist is flexed, while when extended it cannot manipulate accurately (Tichauer and Gage 1997).

2.6.2. Types of Hand Grips

There is a wide variety of hand grips that can be used to manipulate a hand tool. In microsurgery, the palmar, side pinch, and external precision grip are most common. When using the thumb-fingertip or palmar grip, the thumb and fingers oppose each other while gripping the object. Similarly, during the thumb-forefinger side grip, lateral grip or side pinch, the thumb opposes the side of the forefinger (Matern and Waller 1999, Kroemer, Kroemer and Kroemer-Elbert 1994). The external precision grip is the most important grip to consider for this project. It is similar to holding a pen, where the thumb and index finger hold the instrument, and the other 3 fingers are used for support (Patkin 1981).

2.6.3. Tool Selection

According to Radwin and Haney (1996), tool selection is based on several criteria. First, the tool should be selected based on whether or not it is capable of performing the desired task. Human operator limitations must also be considered. These include strength, anthropometry, and manual capabilities. The user must be able to apply the necessary force to the tool; in the case of this project, the forceps should be able to open and close easily. The user must also be able to properly hold the tool, so appropriate dimensions should be used (Radwin and Haney 1996). Form fitting handles that conform to the contours of the hand are most effective because the tool can be held securely and with good posture (Kroemer, Kroemer and Kroemer-Elbert 1994). Shape and weight are also taken into consideration as they can affect posture (Radwin and Haney 1996). Keeping joints in neutral position is critical to avoiding discomfort and injury. For example, curved tools could be chosen instead of using a straight tool that requires bending of the wrist (Dul and Weerdmeester 1993, Kroemer, Kroemer and Kroemer-Elbert 1994). This will all be considered in the new design.

2.7. Patent Review: Attempts at Improving Technology

Since the invention of microvascular clamps and clips, there have been many attempts to improve the technology to take into account ergonomics and the technical needs of the surgeon. Some attempts have been better than others in terms of function and practicality, but still, none of these attempts have successfully made it to the market or the operating room.

In microsurgery, the commonly used vascular clips are composed of spring-loaded opposing jaws which close down onto a vessel to occlude blood flow. There are many types of clamps that have been patented over the last 100 years. Simple clamp designs that have made small changes to the currently used design are showcased in several different patents, such as patent # 3,805,792 issued to Cogley in 1974 and patent # 7,144,402 issued to Kuester in 2006. Graphics of these designs can be seen in Figure 2.4. These patents change the angle and shape of the clamp to a set value, but do not change how the clamp and forceps interface.

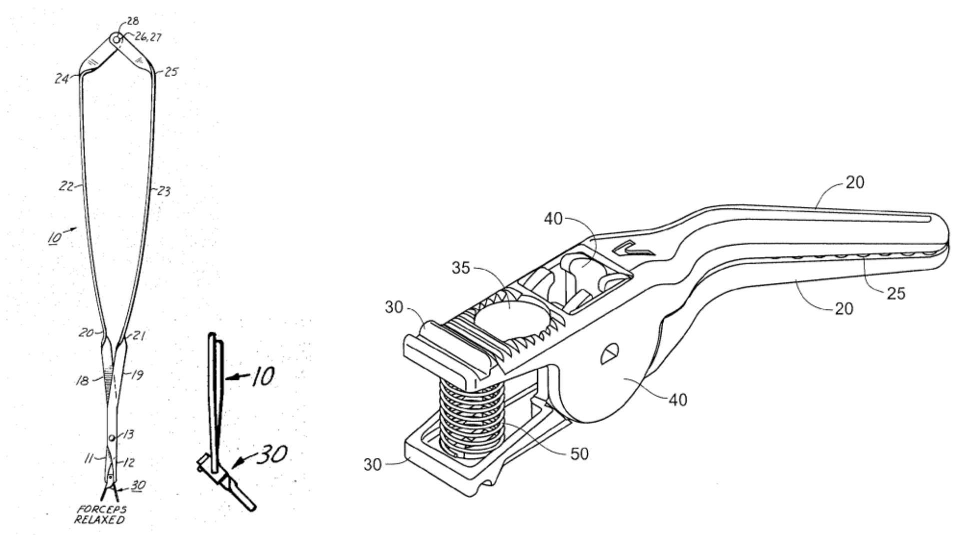

Figure 2.4. a) Schematic of a new spring-loaded forceps that incorporates a pivoting arm (left) (Cogley 1974) and b) a clip with angled jaws (right) (Kuester 2006)

In the past years people have been attempting to make the vessel clamp/forceps system more ergonomic and easier to use. So far none of these new designs have revolutionized the clamp/forceps market due to complex and/or impractical designs, but there are many patents that showcase these novel designs.

In an attempt to make the clamps easier to apply, many people have designed specialty forceps. Failla et al. (1994) have designed an applier to apply bulldog clamps endoscopically. This design consists of a long, rigid handle which enables the surgeon to open and close the clamp as well as rotate it in all directions. The surgeon controls the movements by either squeezing the handle or rotating a knob on the end, as seen in Figure 2.5. In this design there are no structural changes to the bulldog clamp. The only change is in the way the clamp interfaces to the applier. There are two circular cut-outs in the clamp which allows the clamp to be secured to the applier by two teeth. The benefits of this design are that the clamp can move in all directions and the applier can reach deep into the body. The disadvantages of this device are that it is difficult to manufacture and sterilize, it is not ergonomic, and it would be potentially difficult to apply clamps at short distances (Failla, Hildwein and Lau 1994).

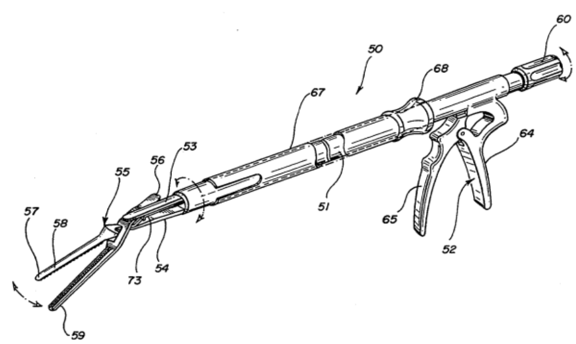

Figure 2.5. Schematic of endoscopic bulldog clamp (Failla, Hildwein and Lau 1994)

Similarly, Stevens and Rapacki (1996) designed a clamp/forceps system which uses a long, rigid rod that can be extended or retracted. The clamp is rotated in all directions via a turn button on the end of the rod. This design alters the clamp itself as well as the interface between the forceps. The clamp is secured to the rod by means of two hooks which grab the clamp and secure it into the applier, as seen in Figure 2.6 (Stevens and Rapacki 1996). This device has similar advantages and disadvantages as the previous design; however this design also requires a completely different clamp design which adds to its complexity.

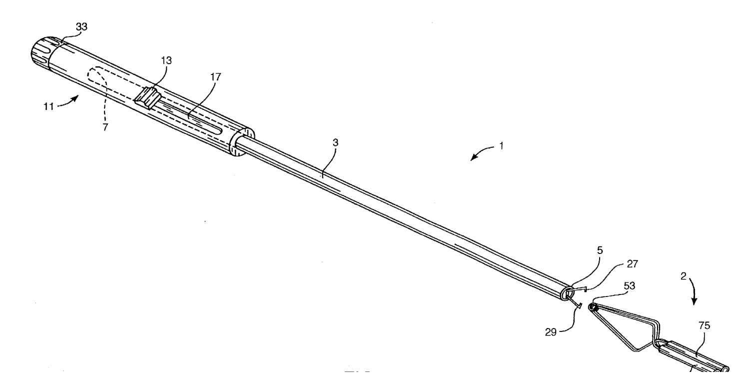

Figure 2.6. Schematic of hook bulldog clamp applicator (Stevens and Rapacki 1996)

Another attempt in making it easier to apply the clamps involves a flexible applicator. Glines et al. (2000) designed a bendable shaft which can be elongated and moved by the surgeon. There is also a pulling device to open or close the clamp when necessary, which can be seen in Figure 2.7. This design does not have the ability to use the standard, commonly used clamps. The advantage of this design is that the clamp can be adjusted to many different angles. However, the disadvantages of this design are that it may be difficult to manufacture and sterilize, it may difficult to control the clamp and keep it in a precise location, and a different clamp needs to be used (Glines, Morejohn and Septeka 2000).

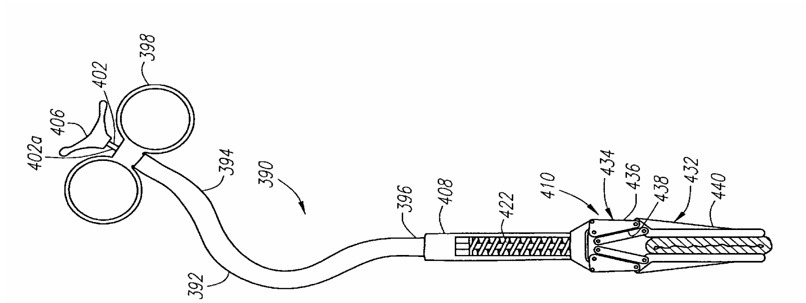

Figure 2.7. Schematic of flexible clamp applicator (Glines, Morejohn and Septeka 2000)

In the effort to change the vessel clamps, some designs have removed the clamp altogether in exchange for a different method of occlusion. One such method, shown in Figure 2.8, involves a flexible tube which is looped around a vessel and then filled with air. By inflating the tube, the blood flow is occluded (Dunn and Scarrow 1985). Advantages of this design are that the device can be used on different sized vessels and the tubing is flexible so it can get into tight spaces. Disadvantages of this design are that it may be difficult to control the tubing and loop it around the vessel. Also, the vessel can be easily damaged if it is inflated too much.

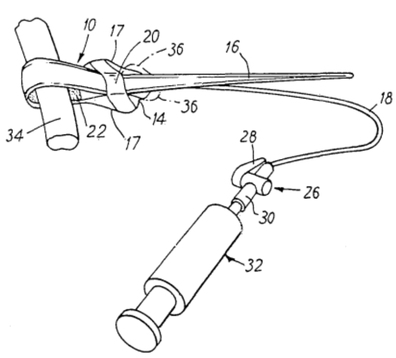

Figure 2.8. Schematic of inflatable tube application (Dunn and Scarrow 1985)

Another design to remove the need for a clamp was created by Matern and Der (1998). Their device uses a spring-loaded loop which is extended around a vessel and tightened to occlude it, as shown in Figure 2.9. This device is useful because it can fit around many different sized vessels and could also be used on different tissues. Disadvantages of this design are that it may be difficult to thread the loop around the vessel and also may be too tight and damage the vessel (Matern and Der 1998).

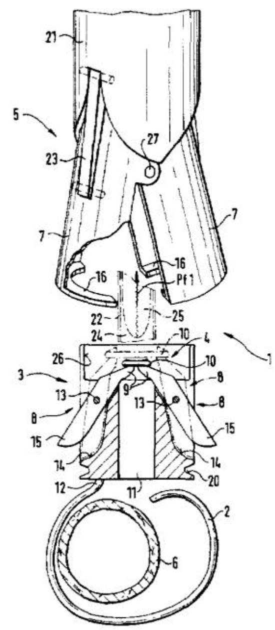

Figure 2.9. Schematic of a spring loaded clamping device (Matern and Der 1998)

All of these designs that have attempted to improve the functionality of vascular occluding clamps are radically different from what is used currently by surgeons, and therefore may not be easily accepted. Also, these designs are not well-suited for microsurgery where very fine, controlled, movements are necessary. By thoroughly searching through the current patents we have determined that there is a gap in technology that our proposed device can fill. Our design attempts to take a new approach by allowing the angle of the clamp to be changed “on the fly” relative to the forceps in both the lateral and vertical direction by changing how the clamp and forceps interface.

2.8. Conclusion

As stated, the purpose of vessel occlusion clamps is to keep the operating field free of blood so that the surgeon can visualize the procedure as best as possible. Every year billions of dollars are spent on purchasing different types of clips and clamps which accomplish this task. Although the current clamp designs are successful in occluding the blood flow, there are several limitations that affect the comfort and ability of the surgeons to appropriately apply the clamps to the vessels. Thus, the goal of this project is to use the basic principles of hand-tool ergonomics discussed in this chapter in combination with the knowledge of operating room conditions to design a more comfortable, more ergonomic, and more easy to use clip and forceps system. Specifically, the focus will be on redesigning the interface between the clamp and the applying forceps to allow for multiple degrees of freedom, which in turn will aid the surgeon in comfortably manipulating the clamp and applying it to the vessel more easily. The upcoming chapters of this report will discuss the specific aims of the project, the methods and approach to designing the new device, a summary of the design process, results of testing, and justification for the final design of the clip-forceps interface.

3. Project Approach

The design of a new microvascular clip/forceps system was inspired by the need for an easier to use, more ergonomic device. Through background research on the importance of ergonomics, it has been concluded that a more comfortable and easy to use device will allow for more accurate surgical procedures and less fatigue and discomfort for the surgeon. In the past, many individuals have attempted to create new devices to help alleviate the issues at hand, but so far very few have been successful and none are used in surgery today because they are still too difficult, awkward, and complex to use.

The main limitation of the current device is the fact that no degrees of freedom of motion can be achieved by the clip while in the forceps. This impedes the surgeon from adjusting the angle of the clip before applying it to the forceps, which can be necessary in small, crowded surgical spaces. Another issue with the current design is that maintaining the clip within the forceps without dislocation of the clip is difficult. This is due to difficult alignment of the tongue-and-groove interface. Additionally, most forceps do not have a locking mechanism, requiring the surgeon to apply constant pressure to hold the clamp open and in place between the forceps. This constant pressure can cause hand fatigue and make the forceps uncomfortable to use. It seems that these problems could be easily solved, but there are several practical and complex engineering considerations.

In consideration of the problem just stated, our design approach was to create a new, simple interface between the microvascular clip and applying forceps that would make the system more ergonomic and easier to use than the previous designs. The specific goals of the project are listed below:

I. Design a system that is easier to use and more comfortable than the current, commonly used system.

II. Design a system that is similar to the current design so that surgical technique does not need to be altered.

III. Design a system that allows the angle of the clip to be adjusted, both laterally and vertically in relation to the forceps, by pushing the clip against the tissue surrounding the vessel to be clamped.

IV. Design a method for evaluating and validating the need for this new device.

V. Design a mock surgical scene so that clinicians can test and evaluate the comfort and ease of use of the new device.

VI. Send drawings of the new device to a microsurgical company for prototype manufacturing.

VII. Obtain a patent for the new design ideas.

4. Design

4.1. Needs Analysis and Design Criteria

4.1.1. Design Parameters and Specifications

There are several requirements and constraints that the prototype must meet. They are listed below:

- Cost of final design is less than $50 to manufacture;
- Chosen material is able to be sterilized, if not disposable;
- Clamp is able to rotate 180° horizontally and 45° vertically in both directions;
- Applying forceps has a mechanism to prevent hand fatigue;
- No change in basic clamp design or clamping pressure;
- Forceps are similar size and shape to what is currently used by surgeons;
- Forceps must accommodate different sized clamps;
- Interface must allow the surgeon to adjust clamp angle “on the fly”.

4.1.2. Design Objectives and Functions

Before generating design alternatives, it was important to generate a list of objectives that each conceptual design would have to meet in order to be considered. A complete objectives tree which includes main objectives and sub-objectives can be viewed in Appendix F. Table 4.1 below displays the pairwise comparison chart that rates the importance of each main objective. Each objective was given a value of 1 if the objective in the vertical column was considered more important than the objective in the horizontal column, 0 meaning the opposite, or 0.5 if the importance was equal. The results of the comparison chart revealed that ease of use and comfort were the two most important objectives and durability and universal interface were the two least important objectives.

Table 4.1. Pairwise Comparison of Design Objectives

	Ease of Use	Durability	Safety	Comfortable	Universal Interface	Manufactur-ability	Total
Ease of Use	-----	1	1	0.5	1	1	4.5
Durability	0	-----	0	0	0.5	0	.5
Safety	0	1	----	1	1	.5	3.5
Comfortable	0.5	1	1	-----	1	1	4.5
Universal Interface	0	0.5	0	0	-----	0	.5
Manufacturability	0	1	.5	0	1	-----	2.5

Next, the functions of the design were determined for both the clip and the applying forceps. Table 4.2 displays the means for accomplishing each function. The functions of the forceps are seen in blue, and the functions of the clip are seen in orange. This morphological chart enables the determination of the size of the design space, as each means can be combined with any other means for a given function. The table lists all possible means for achieving each specific function and at this point none of the means were ruled out because of feasibility. In Appendix G, the functions-means tree can be viewed. This chart also facilitates the viewing the possible means for each function.

Table 4.2. Morphological Chart of Functions and Means

Functions/means	1	2	3	4	5	6	7	8	9
Open and close	Tweezers	Lock	Scissor						
Interface with clamp	Magnet	Notched end	Clip into forceps	Standard clamp design	Socket-like button				
Hold Clamp in Place	Inverse/ Indent	Magnet	Claw						
Apply a constant force to hand while holding	Lock	Reverse forceps	Large surface area						
Enhance ergonomics	Pencil-like	Fist grip	Pinch grip	Ring/talon grip	Hammer grip				
Apply correct force to vessel	Spring	Reverse clamp							
Open and close	Spring	Reverse clamp							
Move with multiple degrees of freedom	Swivel	Ratchet	Gears	Flip button	Flexible applicator	Scroll wheel	Rotate forceps over nipple	Angled clamps	Angled forceps

4.2. Conceptual Designs

Drawings of the initial conceptual designs that were developed using the means determined through the morphological chart can be viewed in Appendix H. Each of these designs was rated on how well it met the objectives laid out in the previous section. A weighted score was then determined using a Design Selection Matrix, which can be viewed in Appendix I. Several of the proposed conceptual designs did not meet the required constraints. They were not considered for prototyping despite their weighted scores. Conceptual Design 6 met all of the constraints and had the highest weighted score. This design was chosen as the initial design.

4.3. Preliminary Prototype Designs

As seen in Figure 4.1 (see Appendix J for full drawings), CAD drawings were made in Solidworks® of the initial design (Conceptual Design 6). The interface on the clip itself features a half sphere on one side and a cylinder on the other. These shapes allow the clip to rotate laterally, with the cylinder providing extra support for the clip to stay in place. The interface on the forceps is the inverse of the spherical and cylindrical shapes. On the spherical side of the forceps, a sliding mechanism is present. Pushing this sliding mechanism in or out allows the clip to rotate vertically in either direction. This design was made into a crude mock-up to test proof of concept. But it was determined that the sliding mechanism would be too complex for use in surgery based on the technique used to hold the forceps and apply the clip to the vessel.

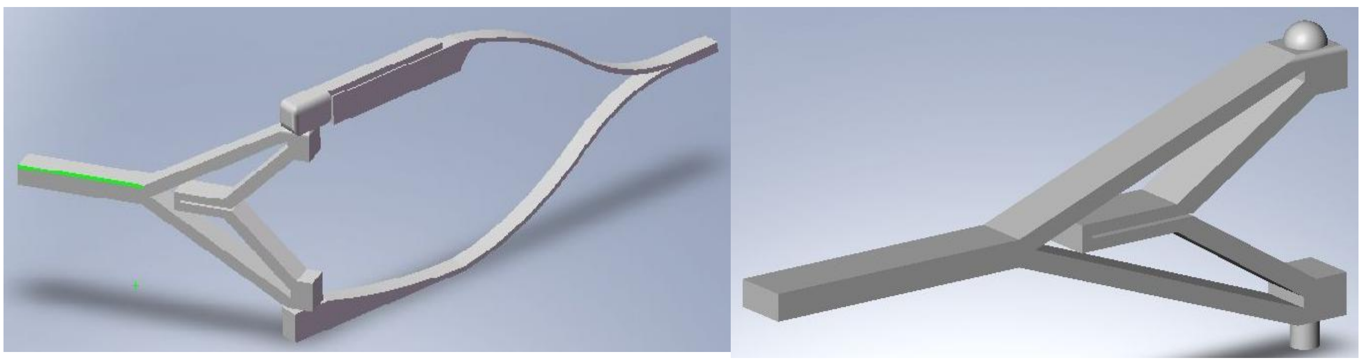

Figure 4.1. Preliminary design featuring spherical and cylindrical clip interfaces (right) and a sliding mechanism on the forceps (left).

4.4. Design Optimization

After obtaining feedback from the client regarding the preliminary design, differently shaped protrusions and mechanisms for rotation were considered. Examples of such protrusions consisted of half and full spheres, hexagonal balls i.e. ball-end hex key designs, cylinders surrounded with inclines, spheres with surface irregularities, and different combinations and orientations of these protrusions. Appendix K displays CAD drawings of other designs that were considered. Some designs were ruled out because achieving both types of motion was difficult. Others were ruled out for complexity.

4.5. Final Preliminary Designs

After reviewing the design parameters and necessary device functions and comparing them to feedback from the client, we chose two final designs to evaluate and test clinically. The first design "Design 1", consisted of a smooth sphere on either side of the clip that would interface with a spherical depression in the top half of the forceps and a flat, rectangular track on the bottom of the forceps. The track would allow the clip to rotate vertically and the spherical depression would hold the clip stable while rotating horizontally. The second design, "Design 2", was essentially the same as the first with surface irregularities added onto the clip interface, with inverse irregularities on the forceps interface. These bumps would allow the clip to be "locked" into different angles. Figure 4.2 displays these designs. Using basic trigonometry, it was determined that the track length would need to be a minimum of 6mm in order for the clamp to be able to rotate ±45 degrees vertically. This was also incorporated into the forceps design. The crude prototypes were evaluated by surgeons, the methods of which will be discussed in the next chapter, and further alterations were made to optimize the design. The results of the evaluation and the final design selection will be discussed in the results chapter of the report.

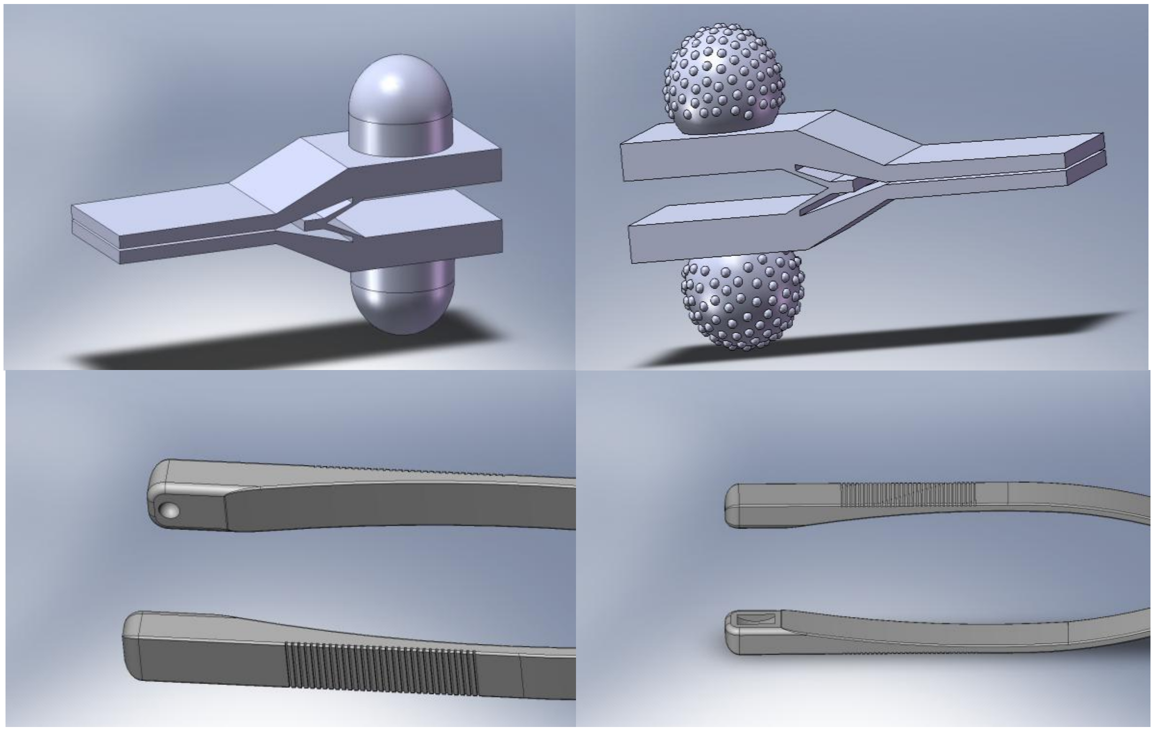

Figure 4.2. CAD drawings showing the smooth spherical interface on the clip (top left), the spherical interface with surface irregularities (top right), and the spherical inverse (bottom left) and track (bottom right) interfaces on the forceps.

4.6. Final Design

After evaluating and testing the two preliminary designs, a final design (Design 1), was selected. As stated, the design consisted of a half-sphere and collar on either side of the clamp that interfaced with an inverse spherical cutout on the top half of the forceps and a flat, rectangular track on the bottom half of the forceps. These interfaces successfully allow for two degrees of freedom of rotation in the horizontal and vertical planes. Figure 4.3 displays a close-up view of these interfaces, as well as the new clip design. Detailed dimensioned drawings can be viewed in Appendix L.

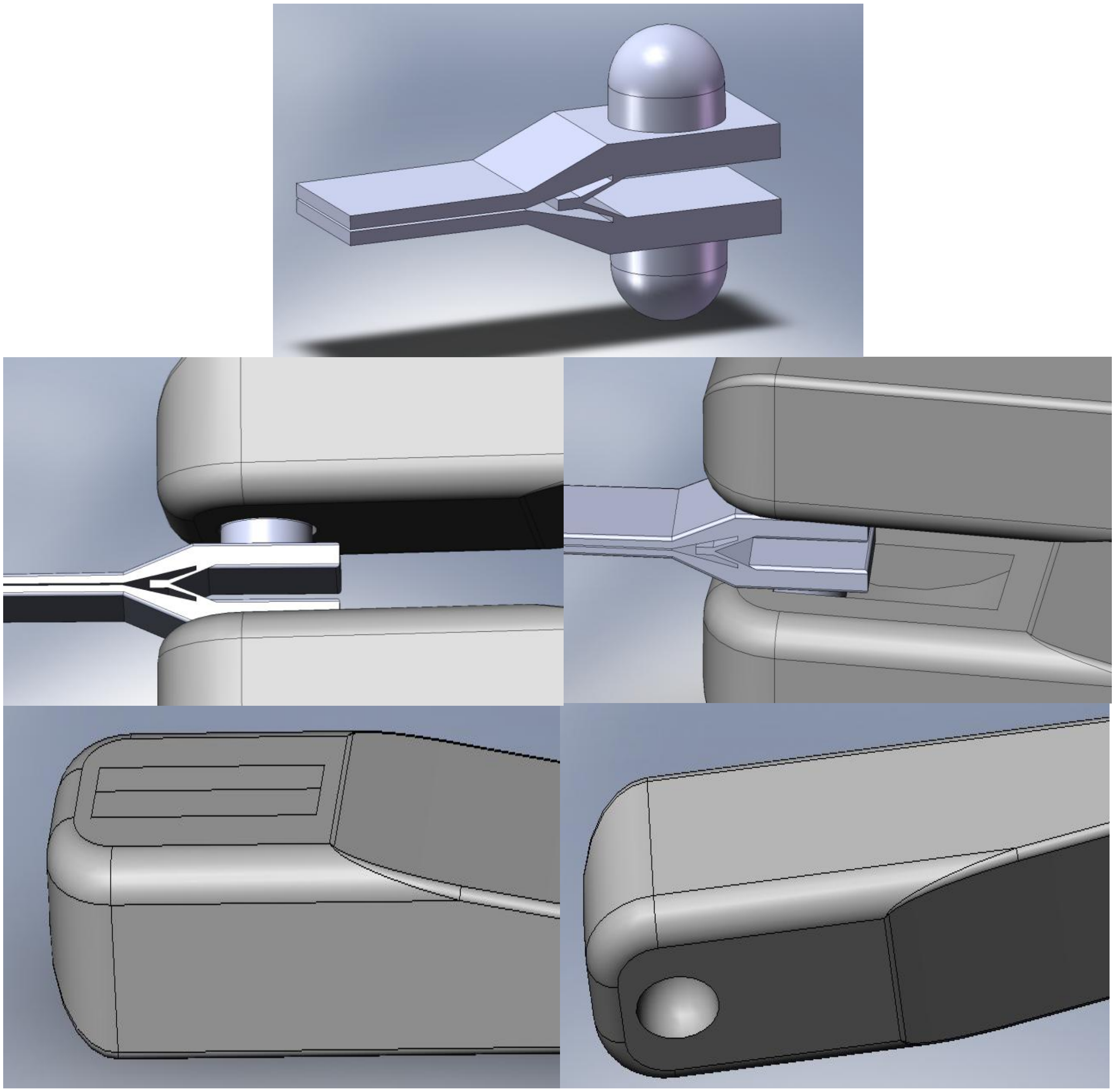

Figure 4.3. CAD drawings of final design

5. Methods

In order to complete this project, the design process as outlined by Dym and Little (2004) was followed. A complete list of project tasks can be viewed in the Work Breakdown Structure in Appendix M. The first task for this project was to understand the user requirements for the device. This was accomplished through an interview with the client. Based on the feedback received, an objectives tree, functions-means tree, and morphological chart were developed to aid in visualizing the design space. These charts can be seen in Appendix F and G and Table 4.2 respectively. Next, design alternatives were generated through individual and team brainstorming sessions. Each design was evaluated based on the design objectives, and two preliminary designs were chosen as described in the previous chapter. After further testing and validation, a final design was selected (Dym and Little 2004).

5.1. Validation of Concept

As with any design project, it is important to validate both the need for the product as well as the design choice. This validation is necessary to assure the design satisfies the outlined objectives and functional requirements before time and money is spent to manufacture an actual prototype. Concept validation is also useful in determining whether or not the design is more appealing to the user compared to the current design and if it could be successful in the market.

5.1.1. Survey of Surgeons

In order to validate the need for this project, a survey was administered to ten surgeons at the University of Massachusetts Medical School. The survey, which can be viewed in Appendix O, asked the surgeons to provide feedback on how they currently use the clip-forceps system and important criteria that they felt a clip application system should possess. As part of the survey, the surgeons were also asked to rate mock-ups of the two proposed designs against the currently used design in terms of the project objectives.

The design of the survey was simple to use because it consisted of multiple choice answers that required the surgeon to check boxes or circle answers. More information and rationale on survey design can be found in Appendix N.

5.1.2. Design Mockups

To validate the chosen conceptual designs, 1.5X large scale mock-ups were constructed using readily available materials to serve as a proof of concept. The mock-ups can be seen in Figure 5.1. These mock-ups were evaluated in terms of ease of use, comfort, functionality, and safety by ten surgical residents, in combination with the survey that was just described. The surgeons were first given an overview of the problem and given instruction on how to use the device. They were then able to experiment with the device on a mock surgical scene, which can be seen in Figure 5.2. The scene was made from a shoe-box draped in black cloth. Vessels were represented by thin surgical tubing on which the surgeons could use the applying forceps to practice placing the clips at different angles. Reasons for designing the mock field in this way are described in Appendix Q.

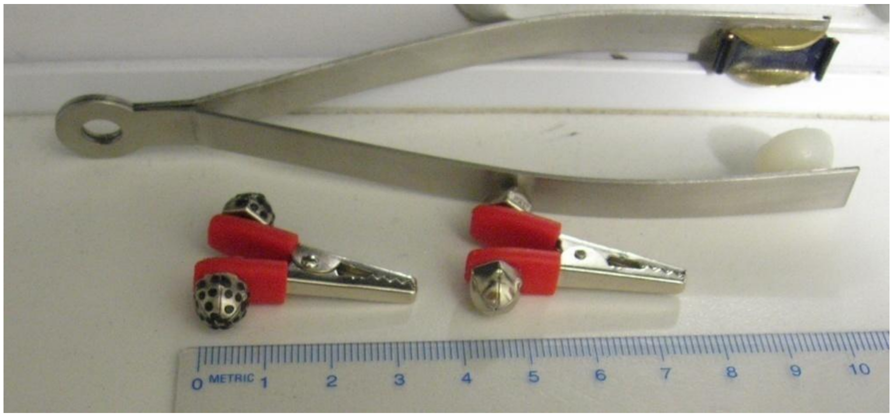

Figure 5.1. Forceps with cap and track interfaces (top), clip with spherical interface with surface irregularities (bottom left), and clip with smooth spherical interface (bottom right).

Figure 5.2. Mock surgical scene used for evaluating mock-ups.

5.2. Advanced Prototyping

After validation of concept testing was completed, a final design was chosen and the design was modified slightly based on feedback received. CAD drawings were then sent to S&T Microsurgical Instruments so that to-size prototypes could be manufactured and further tested for functionality. However, the time scale for receiving these mock-ups was not soon enough for completion of our project. Investigation into local companies with SLA prototyping capabilities also lead to time-wise problems for obtaining the prototypes. It was then decided that actual scale prototypes of the clamp-forceps interface would be manufactured with use of the WPI machine shop.

Two forceps were obtained from the BME department to be modified; one was used in conjunction with an unmodified clip to represent the current design since it already had a groove portion on the end that fit into the clip, and the second forceps and clip were modified to include the interface of our proposed design. Refer to Figure 5.3 for photo depicting the actual size prototype of our proposed design. A sphere was affixed to either side of the clip to provide this portion of the interface. Plastic was cut into very small pieces and the inverse sphere and track forceps interfaces were machined.

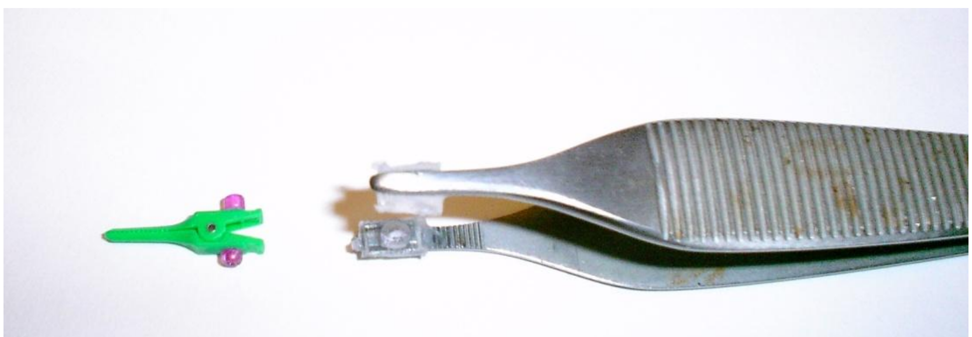

Figure 5.3. Actual scaled prototype with new interface design

5.3. Validation of Actual Scaled Prototypes

After prototypes of the correct size where manufactured, they were tested on a rat model. The rat was laid on top of an operating table. An incision was made to isolate the Carotid artery to which the clips would be applied. Both the current design and improved interface design were applied repeatedly to this vessel to determine how the new interface design compared to the project objectives. The ease of use and ergonomics of each design were also noted and compared to one another.

6. Results

6.1. Survey Results

The results from the survey validated the need for this device. Of the surgeons who regularly use the vascular clips, half said they apply them with the appropriate forceps. The other half simply used their fingers to apply the clips, but still complained that because the clips are so small, this is difficult. In regards to the type of motion that the surgeons desired a new design to achieve, 7 out of 10 surgeons commented that they required both lateral and vertical motion. Table 6.1 shows the ratings of importance of several design criteria, the results of which stressed the importance of our design objectives.

Table 6.1. Ratings of Important Design Criteria

PLEASE RATE THE FOLLOWING FEATURES OF CLAMP-FORCEPS DEVICES ON IMPORTANCE TO YOU	Not Important	Neutral	Very Important
Ability to change the angle of the clamp while it is locked into the forceps	0	4	6
Simple, easy to use design	0	1	9
Similarity of surgical technique to current design	1	4	5
Ergonomic, comfortable forceps	0	2	8
Presence of a locking mechanism, such as a Castroviejo, to secure clamp in place	2	2	6
Presence of the same interface on both sides of the clamp so that there is no wrong orientation	0	3	7

6.2. Mock-up Validation

Based on initial inspection, the mock-ups met the basic functional requirements for the device. The spherical interface on the clip in combination with its inverse on the forceps allowed the clip to rotate laterally. The elongated track allowed the spherical interface extra room for vertical rotation.

The results of the mock-up evaluation done by the surgeons also showed that the mock-ups did indeed show proof of concept.

Table 6.2 shows that the number of surgeons who rated our designs above average in terms of the objectives was greater than the number of surgeons who rated the currently used design above average.

Table 6.2. Number of Above Average Ratings for Conceptual Designs Based on Design Objectives

PLEASE RATE THE CURRENT CLAMP-FORCEPS DESIGN IN REGARDS TO THE FOLLOWING PARAMETERS	Number of Above Average Ratings
Ease of Use	1
Functionality	2
Comfort	1
Safety	1
PLEASE RATE DESIGN 1 (SMOOTH SPHERICAL INTERFACE) IN REGARDS TO THE FOLLOWING PARAMETERS	**Number of Above Average Ratings**
Ease of Use	3
Functionality	5
Comfort	2
Safety	2
PLEASE RATE DESIGN 2 (SPHERE WITH SURFACE IRREGULARITIES) IN REGARDS TO THE FOLLOWING PARAMETERS	**Number of Above Average Ratings**
Ease of Use	4
Functionality	8
Comfort	3
Safety	3

When asked if they would use one of the new designs, all but one surgeon said they would use at least one of the new interface designs yet preference between the smooth spherical interface (Design 1) and the interface with surface irregularities (Design 2) was approximately equal. The main reason that surgeons chose the interface with surface irregularities was that it "stayed in place well" because the irregularities provided extra friction and a tighter fit in the forceps, not necessarily because they liked the ratcheting concept, which is a drawback of the rough construction of the mock-ups. There were concerns that the ratchet might provide too much friction. Surgeons liked the smooth spherical interface because it was easy to use and provided unlimited rotation in all directions. The responses for reasons for design choice can be seen in Table 6.3. All in all, responses to the two new interface designs were positive; each of these designs received a better rating than the current design. The full survey data can be viewed in Appendix P.

Table 6.3. Reasons for Preference of Conceptual Designs

WHY DID YOU MAKE YOUR DESIGN CHOICE FOR DESIGN 1?	Number of Responses
Simple and easy to use design	2
Provides unlimited rotation in all directions	2
Clamp stays in place well	1
No major changes in surgical technique	0
WHY DID YOU MAKE YOUR DESIGN CHOICE FOR DESIGN 2?	
Simple and easy to use design	1
Provides unlimited rotation in all directions	2
Clamp stays in place well	5
No major changes in surgical technique	1

Due to simpler manufacturing techniques, Design 1 was chosen as the final design. Detailed drawings can be viewed in Appendix L.

6.3. Actual Scaled Prototype Validation

Testing of the proposed interface between the scaled forceps and clip showed positive results. As seen in Figure 6.1, the current interface design is being used to occlude blood flow of the vessel using a rat model. When using the current device, the wrist had to be contorted and rotated into both an uncomfortable position and unstable position in order to apply the clip to the vessel because all of the accommodation had to come from the wrist. The wrist also had to be moved from the wrist rest, which is very poor surgical technique and the lack of stability could be harmful to the patient.

Our new interface design had much greater ease of use and comfort in applying the microvascular clip to the vessel as compared to the current interface design. Using the new design, the clip could be gently pressed against the surrounding tissue to easily rotate the clip in the forceps, requiring absolutely no uncomfortable wrist contortion or movement of the wrist from a stationary position on the wrist rest which is very important in the delicate field of microsurgery. Figure 6.2 depicts our proposed design where the clip is able to rotate within the forceps. Application of the microvascular clip with this design was much more ergonomic than the current design. In the photo, the wrist remains in a stable, comfortable position on the wrist rest without undergoing any contortion to apply the clip at the proper angle.

Figure 6.1. Current microvascular clip being applied to vessel in rat model while wrist is uncomfortably contorted to achieve proper application angle

Figure 6.2. New interface design where clip is being applied to vessel while wrist is in a stable and comfortable position since the clip is able to rotate in the forceps to achieve proper application angle

7. Analysis and Discussions

As discussed in the previous chapters, we have designed a new interface between microvascular clips and their applying forceps to allow for 180º of rotation in the horizontal direction and 90º of rotation in the vertical direction. Our device solves the 100 year old problem of a lack of ergonomics in microvascular clip design, making using the clips more practical, comfortable, efficient, and accurate without drastically altering the basic surgical technique used to apply the vascular clips to a vessel during surgery. The design is easy to use because it is very simple, and thus it is also easily manufacturable.

7.1. Design Criteria

Our list of important design criteria was validated through surveying ten surgeons at the University of Massachusetts Medical School. As seen in Table 6.1, the majority of surgeons rated criteria such as similarity of technique, ability to change the clamp angle on the fly, simple and easy to use design, and comfort, as being very important to a successful design. In Table 6.2, the ratings of the current design and our two preliminary designs can be seen. Each design was rated based on our objectives, which included comfort, ease of use, and functionality (ability to rotate and change application angle on the fly). As can be seen in the table, our designs were rated above average approximately three to four times more often than the currently used design. These results suggest that the surgeons responded positively to our new designs, and since nine out of the ten surgeons reported that they would use at least one of our designs, we feel that our design has great market potential.

7.2. Design Specifications

Additionally, our design has met all of the design constraints, specifications, and functions set up at the beginning of the design process. The following is a list of these parameters and a description of how it was ensured that each specification was met:

7.2.1. Chosen material is able to be sterilized, if not disposable;

We plan to manufacture our product out of a disposable polymer, such as polycarbonate. After communicating with several manufacturing experts, we determined that plastic molding would be the easiest and most cost-effective manufacturing method. Polycarbonate is commonly used as a medical plastic. The advantages of using a disposable plastic such as polycarbonate are that it does not retain tissue debris from the procedure and is not susceptible to rust. Polycarbonate is also radio-opaque and can be detected by fluorescence or MRI, but does not reflect microscope light making it easily detectable and removable. The pins that hold the clamp together will be made of titanium, which is also commonly used in medical devices (Aro Surgical 2008). The forceps will be made of surgical grade 420 stainless steel, which is the same material as the currently used forceps. We currently have a preliminary agreement with S&T Microsurgical Instruments to manufacture the new device for our client. S&T currently manufactures disposable, single-use plastic microvascular clips, and would be able to modify their molds and manufacturing techniques to accommodate the new interface.

7.2.2. Cost of final design is less than $50 to manufacture;

Disposable clips are available on the market for approximately $70. In order to make a profit, this cost is much higher than the actual manufacturing cost. Since our design simply modifies the interface between the clip and forceps, and since the design is very simple with minimal new parts, manufacturing the new device will not significantly raise the cost of production. Since S&T currently manufactures disposable clips and forceps, they have the means to manufacture the new clips efficiently and cost effectively. Once the initial molds are modified, the clips simply need to be injection molded. The only cost for this would be the cost of the plastic itself. So after the initial cost, the clips will be very inexpensive to manufacture. Also, the forceps will be sterilizable and made out of surgical grade 420 stainless steel. These would also be easily manufacturable after initial setup.

7.2.3. No change in basic clip design or clamping pressure;

The clip design itself has not changed. We have simply added a protrusion to the edge of the clip on either side in place of the groove that is present on the currently used clips. Therefore, no change in clamping pressure is incurred.

7.2.4. Forceps are similar in size and shape to what is currently used by surgeons;

No drastic change in basic forceps design was made, and thus the forceps will fit in the surgeons' hands and can be held in the same manner as before.

7.2.5. Clip is able to rotate 180° horizontally and 45° vertically in both directions;

The spherical shape of the new clip interface allows unimpeded motion in the horizontal direction, which well exceeds the 180° requirement of the client. To obtain the appropriate range of vertical rotation, a basic calculation was performed to determine the necessary dimensions of the interfaces on the forceps, for example the appropriate length of the rectangular track. Also, basic visual observation and angular measurement using a protractor were performed on the 1.5X mockup to verify proof of concept that the clip did meet the 45° vertical rotation requirement.

7.2.6. Interface must allow the surgeon to adjust clamp angle "on the fly";

The smooth interfaces allow the clip to be pushed gently against the surrounding tissue while in the forceps. Friction is minimal enough to allow the clip to move uninterruptedly, but large enough to hold the clip at the desired angle while no force is applied. This was verified in both the 1.5X mockup and the 1X prototype.

7.2.7. Applying forceps has a mechanism to prevent hand fatigue;

We have incorporated a preliminary locking mechanism into our design that is similar to a Castroviejo lock, which will clamp the forceps together to better hold the clip in place. This locking mechanism eliminates the need to apply a constant force with the hands to hold the clip in place, thus eliminating hand fatigue.

7.2.8. Forceps must accommodate different sized clamps;

The spherical clip interfaces will be the same size on every clip, and thus can be used by the same pair of forceps.

7.3. Data Limitations

Although all of the preliminary testing and evaluation showed positive results, there are some limitations to the methods used. Due to the small scale of the device, it was difficult to produce as accurate mock-ups as we would have liked. However, we feel that all of the calculations and testing that were performed are indicative that to-size prototypes would be functional. Obtaining these prototypes is a future recommendation that will be discussed in the upcoming chapters. Also, due to time and personnel constraints, we obtained a small sample size of ten surgeons who evaluated our designs. This made it difficult to get definitive results. The way in which we designed our survey questions also did not allow for statistical analysis, so we had to rely on observation of the ratings of the design to determine if there was a numerical difference rather than statistically significant responses. However, based on the qualitative feedback, we feel that this point is trivial and that the positive feedback we received on our designs is legitimate and compelling.

8. Conclusions

Every year the quality of many surgeries is compromised by poor ergonomics and lack of precision from common surgical hand tools. Much time is spent on creating new, advanced technologies, but often the problems with older, more basic surgical tools are neglected. The current tongue-and-groove design of microvascular clips is one example of this issue. The overall design of this device has not changed in around 100 years. The current tongue and groove interface between the clips and the forceps does not allow for any rotation of the clip within the forceps and therefore all of the rotation needs to come from the surgeon's wrist. During microsurgery, the operating field is very small and very delicate and the movement of the surgeon's wrist may lead to fatigue and inaccurate placement of the clip, therefore jeopardizing the procedure.

The goal of this project was to change the clip-forceps interface in order to make the system more comfortable and easier to use. The final design needed to not alter clamping pressure of the clip, be made of sterilizable material, and be able to rotate ± 90 degrees horizontally and ±45 degrees vertically. Also, the new device could not alter the surgical technique currently used.

Initially many complex designs were created to achieve this goal, but in the end a simple smooth sphere placed on the ends of the clips was chosen as the final design. The spheres interface with a cut-out sphere in the top side of the forceps and a shallow, flat track on the bottom side. The cut-out sphere tightly holds the clamp in place and allows for horizontal rotation. The track allows the bottom sphere to slide back and forth, theoretically changing the length of the forceps and allowing for vertical rotation. This design allows the surgeon to alter the horizontal and vertical angle of the clip while the clip is secured in the forceps.

Because of the rotational ability of the new design, vascular clips will be easier to apply and will improve quality of surgery.

9. Recommendations

The device created successfully meets all functions and complies with all specifications and constraints set at the beginning of the design process. However, there are several issues to be addressed in the future to make improve the device.

The first of these is to incorporate a locking mechanism into the forceps. One major issue with the current tongue-and-groove design is that the clip does not stay in the forceps and is awkward to handle or pass off from surgical aid to surgeon. Because of the spherical interface on the new design the clip naturally holds tighter in the forceps, but a locking mechanism would ensure that the clip stays in the forceps. A simple Castroviejo type lock would be a good fit for this application. This lock would allow the aid to place the clip in the forceps, lock the system, and easily hand the unit to the surgeon without the clip falling out. Then, because of the spherical interface, the surgeon could rotate the clip and easily release the lock and apply the clip to the vessel.

The patent for this type of lock was issued in 1953 under patent # 2,652,832 and can be viewed in Figure 9.1 (Castroviejo 1953). Devices with patents over 20 years old are considered to be "common knowledge" and therefore we would be able to add this type of lock to our device without infringement.

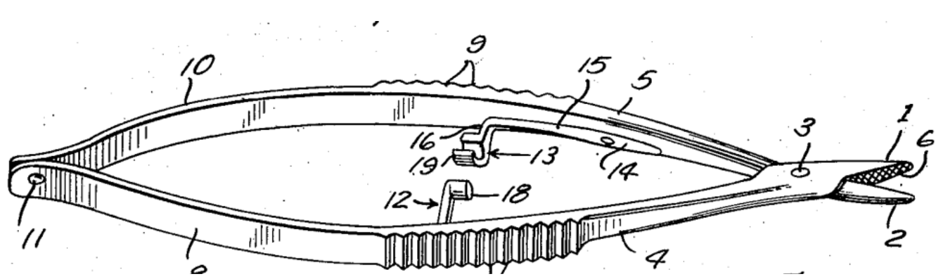

Figure 9.1 Schematic of Castroviejo Locking Mechanism (Castroviejo 1953)

We have investigated this locking mechanism and included a CAD drawing of the lock in Figure 9.2, however, due to time and resource constraints we were not able to build and test a mockup of the lock design.

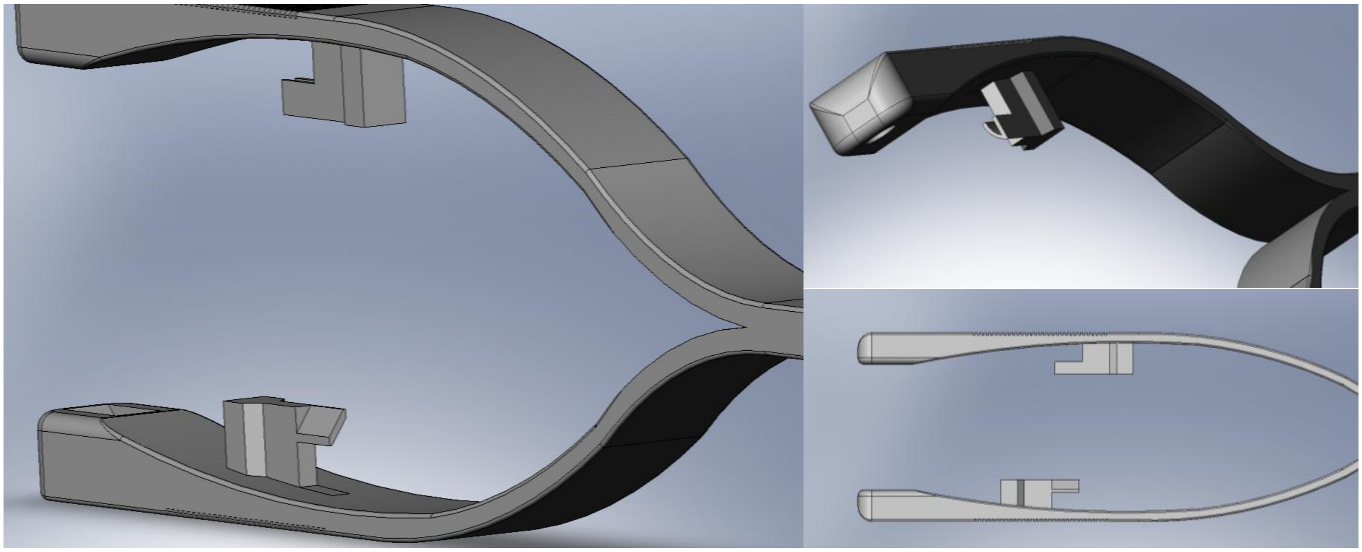

Figure 9.2. CAD drawing of proposed locking mechanism for forceps device

Another recommendation is to manufacture to-scale prototypes of the device to test for full functionality. Both the 1.5X scale mock-up and the to-scale rough mock-up have shown the proof of concept, however, manufactured prototypes are necessary for more thorough testing and a full evaluation of the device's capabilities.

The new design allows for vertical and horizontal rotation (two degrees of freedom), however, the clip cannot rotate vertically and horizontally at the same time (three degrees of freedom). It would be optimal the have a design that enables the clip to be rotated in all directions. One potential way to achieve this would be to use a circular track instead of a flat, rectangular track. A mock-up of the device with a circular track was created, but there was no stability and the clamp did not stay in place at the correct angle. Surface modifications (such as the irregularities on Design #2) made to the sphere on the clip which could be mated with the negative on circular track would potentially hold the clip in place and allow for three degrees of freedom. This concept would be much more difficult to manufacture and the trade off between manufacturability and functionality would have to be evaluated.

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11. Glossary

Applying Forceps – Forceps that are used to hold and manipulate microvascular clips in order to apply them to a blood vessel.

Bulldog Clamp – A 5-8 cm long clamp that is applied to large blood vessels to occlude blood flow during orthopedic or similar surgeries.

Clamping Pressure – A value determined through extensive testing that can successfully occlude blood flow through a vessel without damaging the vessel tissue.

Design Selection/Evaluation Matrix – A design tool used to evaluate and score design alternatives based on how well they meet design objectives.

Ergonomics – The practice of maximizing efficiency and productivity, while reducing discomfort and fatigue, through appropriate equipment and instrument design.

Function – A task that the device must do or be able to do.

Functions-Means Tree – A design tool that pictorially represents each design function and different methods or means for accomplishing that function.

Horizontal Rotation – Movement in the left to right direction.

Interface – The common boundary between two objects that allows them to interact to perform a function.

Microvascular Clip – A small 1-2 cm long stainless steel or plastic disposable clip that is applied to a small caliber blood vessel, using forceps, to occlude blood flow.

Microvascular Surgery – Surgery that is performed on vessels 3-5 mm in diameter using special tools and instruments.

Objective – A consideration for developing a new design or product.

Pairwise Comparison Chart – A design tool used to rank and weight the importance of design objectives.

Specification – A performance characteristic that the design must meet in order to be successful. It must be measurable or able to be evaluated.

Tongue-and-Groove Interface – An interface that consists of a shallow groove and a corresponding protrusion that fits into the groove.

Vertical Rotation – Movement in the up-down direction.

12. Appendix

A. Companies Currently Manufacturing Vascular Clamps *(Register 2007)*

Company	Location	Type of Clamp
Aesculap, Inc	PA	Vascular clamps
Alpha Industries, Inc	FL	Vascular clamps
Applied Medical Resource Corp	CA	Stealth low profile bulldog clamps, vascular clamps, Disposable inserts
Argon Medical Devices Inc	TX	Vascular clamps
Aspen Surgical Products, Inc.	MI	Vascular clamps
Boston Scientific	CA	Vascular clamps
Cardiva Medical, Inc.	CA	Vascular clamps
Clinimed, Incorporated	DE	Vascular clamps
Codman and Shurtleff, Inc.	MA	Vascular clamps
Depuy Codman	MA	Vascular clamps
Deroyal Surgical	VA	Vascular clamps
Edwards Lifesciences Corporation of Puerto Rico	Puerto Rico	Vascular clamps
Edwards Lifesciences Research Medical	UT	Vascular clamps
Edwards Lifesciences, LLC.	CA	Vascular clamps
Fehling Surgical Instruments	GA	Vascular clamps
Guidant Cardiac Surgery	CA	Vascular clamps, Coronary Shunt
Health and Hospital Services	CA	Vascular clamps
Integra Lifesciences/Plastic and Reconstructive Products	NJ	Bulldog clamps
International Hospital Supply Co.	CA	Vascular clamps
Interventional Hemostasis Products, Inc.	OR	Vascular clamps, mobile clamps, hand held clamps
Kelsar S.A.	Tijuana Mexico	Vascular tourniquets
Lamitre Vascular	MA	Cardiovascular occluders
Lifestream International, Inc	TX	Vascular clamps
Mcpherson Enterprises, Inc.	FL	Vascular clamps, carotid shunts
Miltex Inc.	PA	Bulldog clamps, vascular clamps
Novare Surgical Systems, Inc.	CA	Bulldog clamps, vascular clamps
Novosci Corp.	TX	Vascular clamps
Pilling Surgical	PA	Vascular clamps
Pilling Surgical, Teleflex Medical	PA	Micro anastomosis clamp

Princeton Medical Group, Inc.	SC	Vascular clamps
Prosurge Instruments, Inc	NJ	Vascular clamps
Roboz Surgical Instrument Co., Inc	MD	Bulldog, vascular clips
Scanlan International, Inc.	MD	Disposable bulldog
Sontec Surgical Instruments	CO	Vascular clamps
Sterion Incorporated	MN	Bulldog, parallel clamping jaws
Synovis Surgical Innovations	MN	Vessel occluders
Synovis Surgical Innovations, A Division of Synovis Life Technologies, Inc.	MN	Internal vessel occluders, vascular occluders, shunts
Tuzik Corporation	MA	Vascular clamps
TZ Medical, Inc.	OR	Vascular clamps
Vascular Solutions, Inc.	MN	Vascular clamps
Voss Medical Products	TX	Coronary clamps
Walter Lorenz Surgical, Inc.	FL	Vascular clamps

B. Materials

Materials for manufacture of applying forceps and clamps play a major role in the sterility and durability of these surgical instruments. Commonly used materials include stainless steels for forceps, as well as stainless steel and titanium alloys for vessel occlusion clamps. Choice of materials is mostly limited to materials stated suitable in various standards to which these surgical tools must conform.

Stainless Steel

Stainless steels are iron based alloys predominantly used in many surgical and dental applications, popular due to good mechanical properties and great corrosive resistance. Although there are many different classes of stainless steel, they all have a minimum of about 10.5% chromium, which forms a protective self-healing oxide film which attributes to "stainlessness" characteristics. Interestingly, the categorization of stainless steel is based upon atomic arrangement of the grains of steel, creating five basic groups of stainless steel: martensitic, precipitation hardening, austenitic, ferritic, or mixture of both austenitic and ferritic (termed duplex) (AZoM 2007).

Of the five classes on stainless steel, type 420 martensitic stainless steel is used in the manufacture of most forceps due to restrictions stated in ASTM and ISO standards. Martensitic refers to the process of manufacture of this stainless steel, in which it is oil quenched at high temperatures and then cooled to make it stronger yet still corrosive resistant (Ludlum 1998). Type 420 martensitic stainless steel is mostly selected for this application due to its material properties. Type 420 differs from other type 4 stainless steels in that it has higher carbon content and can be hardened by heat treatment which is uncommon for stainless steels. This type is a minimum of 12 percent chromium which provides good corrosive resistance important in the application of surgical equipment although a smooth surface finish aids in non-corrosive performance. One drawback of this type is that when hardened above a set value, machining becomes more difficult (Ludlum 1998).

Other Metals

In addition to stainless steel, commercially pure titanium (CP-Ti) is used in the manufacture of many of the occlusion clamps. The major advantage of using CP-Ti instead of stainless steel for occlusion clamps is due to its great biocompatibility since the clamps themselves come in contact with biological tissues unlike the forceps. The superior biocompatibility is from the thin titanium oxide layer that forms naturally on the surface of the CP-Ti when exposed to air at normal room temperature conditions (Kuromoto 2007)**.** This material still has suitable mechanical properties for this application.

Plastics

Plastics such as polycarbonate are commonly used in medical devices. Polycarbonate is advantageous because it has excellent material properties, such as rigidity, strength, biocompatibility, and low water absorption, which are important criteria for devices that come in contact with human tissues. It will not retain tissue debris, making it safe to discard. Also, polycarbonate can be radio-opaque, allowing the clamps to be easily detected by fluorescence or MRI. The material does not reflect light making it easily detectable for removal (Aro Surgical 2008, AZoM 2007, Powell 1998).

Polycarbonate also offers variety in the ways it can be manufactured. The most common technique is injection molding and other methods include blow molding, thermoforming, or machining (AZoM 2007, Powell 1998).

C. Sterilization Methods

According to ASTM standard F 1744 titled "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments", there are three methods noted suitable for the sterilization of stainless steel equipment. The three methods listed are steam sterilization, dry heat sterilization, and chemical vapor sterilization (ASTM 2002).

Steam Sterilization

Although steam sterilization is a widely used means of sterilization, it is less commonly used in the medical device industry. Steam sterilization is typically done in an autoclave where steam temperatures ranging from 100C to 135C are used. Commonly in hospital settings, temperatures of 134C for approximately 3 minutes are used to sterilize surgical equipment, although exposure times can be as long as 3 hours for certain applications. Steam is a very simple, inexpensive method of sterilization with little waste in the form of heat energy. This method is capable of killing highly resistant spores and prions that other methods are not effective at destroying (Rogers 2006).

Steam sterilization is very practical for use in sterilizing stainless steels and other metals since there is little concern with heat of temperatures from 100C to 135C changing any properties of the metals. As noted in ASTM 1744, care should be taken to reduce spotting and staining by completely rinsing the instruments of any residual chemicals before being subject to steam sterilization. Following proper drying cycles determined by the device manufacture will also reduce water spotting (ASTM 2002).

Dry Heat Sterilization

Dry heat sterilization works much like steam sterilization although this method utilizes heat instead of steam to produce temperatures that kill microorganisms. This method produces less heat than steam methods although the use of lower temperature sterilization methods can be very advantageous and more effective in applications involving materials and electronics that are highly susceptible to high heat. In comparison to other methods, dry heat uses no other agents (steam or chemicals) that come in contact with equipment, ultimately reducing corrosion. Although dry heat is much slower at heating than steam, in sufficient time it is capable of penetrating surfaces that steam and chemicals cannot (Rogers 2006).

Chemical Vapor

This method uses a mixture of chemicals, including formaldehyde, alcohol, ketone, acetone, and water to sterilize equipment. This mixture of chemicals is typically heated under pressure to form a sterilizing gas. A typical sterilization cycle exposes the surgical equipment to the sterilizing gas at a temperature of 132C for approximately 20 minutes at 20 PSI although this procedure can vary by manufactures recommendations. Advantages of this technique include no corrosion, rusting, or dulling since the vapor is less than 15% water. In addition, there is not an additional drying cycle. One large disadvantage is that this method requires adequate ventilation. It is common for some chemicals to not be fully removed from the autoclave chamber when the door is opened after the sterilization cycle is completed, releasing traces of chemicals into the air (Rogers 2006).

D. Standards

In the design and manufacture of surgical equipment it is important that the device complies with national and international standards. Surgical equipment is typically governed by FDA under 510k for medical devices within the USA. The American Standard of Materials (ASTM) is also an American organization that produces many standards for mechanical and physical properties as well as testing procedures that must be followed for certain surgical equipment. A similar international organization with much similar standards to ASTM is the International Organization of Standards (ISO).

E. Clamping Force

When redesigning vessel occlusion clamps and the applying forceps it is critical that the clamps still apply the necessary gram force to the tissue to fully stop blood flow. Many studies have been conducted to determine the proper amount of force to stop flow, but not damage the tissues. The minimum amount of force needed to stop flow is known as the minimum occlusive force. Vessel size, age, blood pressure, wall thickness, vessel and clamp shape, blade contact area, and vessel elasticity are a few of the many different factors that influence the minimum occlusive force (Sauer, et al. 2002). Figure 12.1 displays a graph of vessel diameter and force along with the type of clamp that is recommended for use by S&T. Figure 12.2 displays a diagram of variations in clamp shape to accommodate for different vessel sizes and pressures required. The "V" clamp is generally used on veins, while the "A" clamp is used for arteries with thick walls. The curved tip allows for extra security on slippery vessels (S&T 2007).

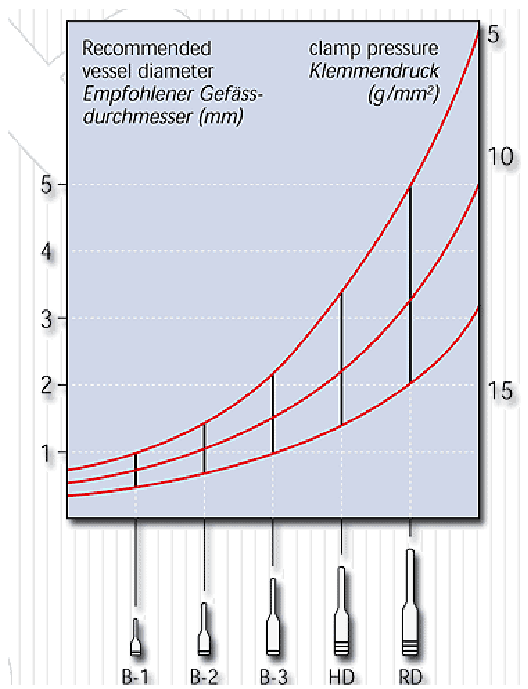


Figure 12.1. Recommended clamps for certain vessel diameters and required clamping pressure (S&T 2007)

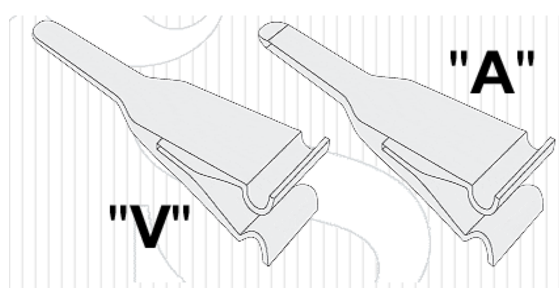
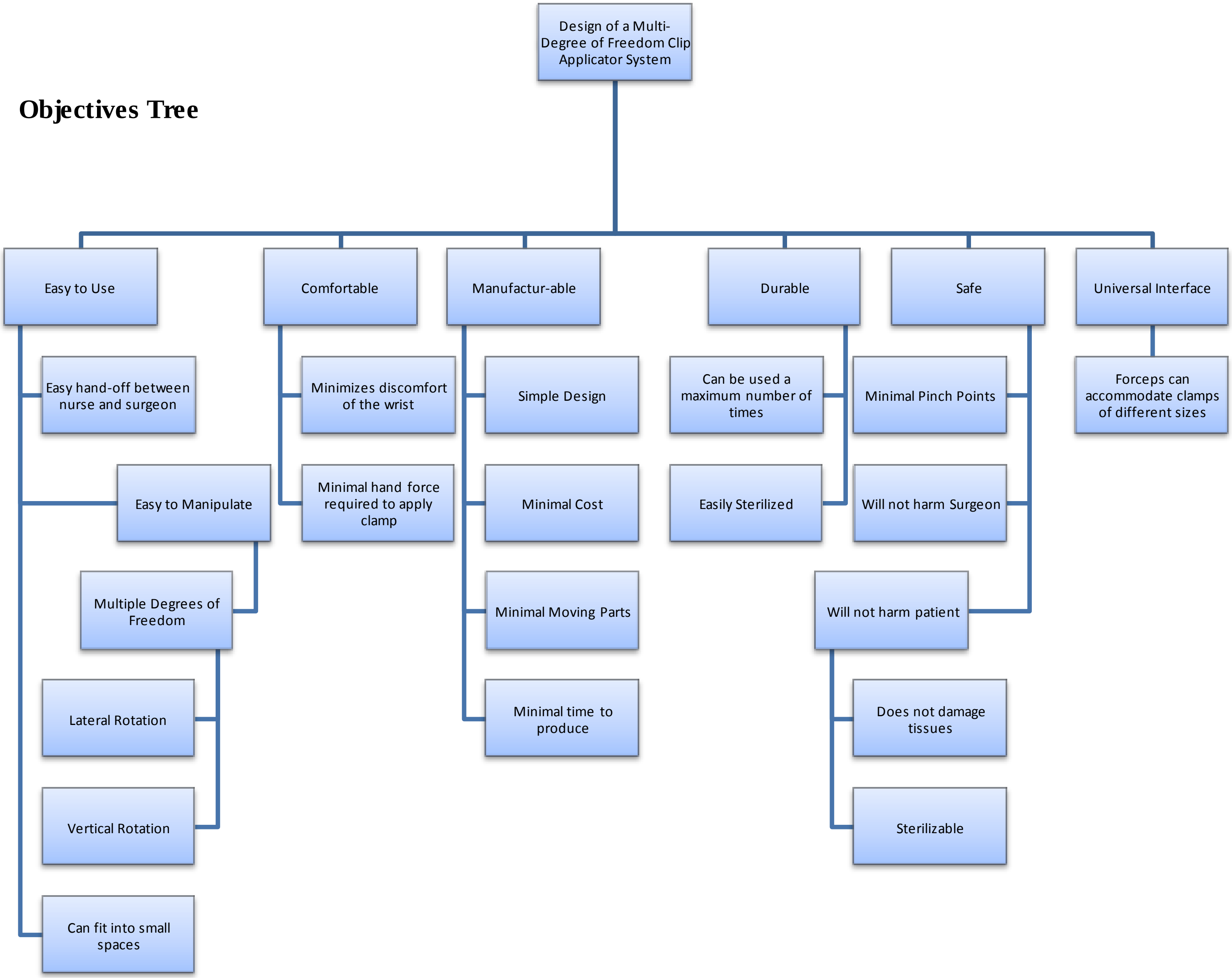


Figure 12.2. Variations in clamp shape to accommodate for different vessel sizes and pressures (S&T 2007)

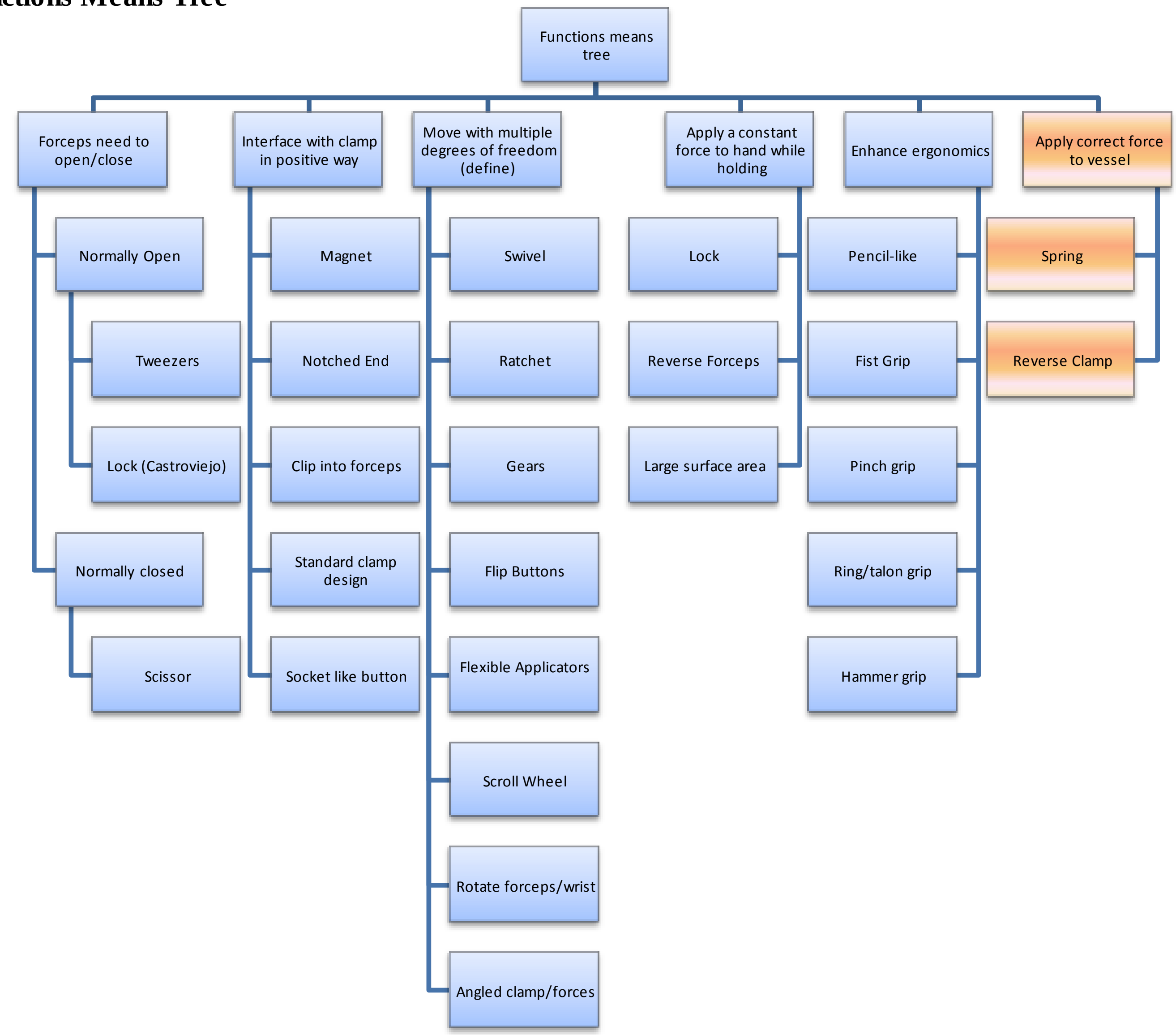
After the clamps are applied it takes time for the vessel to re-equilibrate; once the vessel reaches steady state the vessel is experiences the actual clamping force. It has been found that for safety, the actual clamping force should be only three times greater than the minimum occlusive force (Trobec and Gersak 1997). The minimum occlusive force for the abdominal aorta (1.1 mm in diameter) in Wistar rats was found to be 70.6 mN and 57.3 mN was the force needed to occlude the femoral artery (.6 mm in diameter) (Sauer, et al. 2002).

When the force applied by the clamp is too high the vessel will be damaged. Most often when damage occurs, the endothelium of the vessel is damaged and a thrombus forms. It has been shown that the minimum occlusive force is safe for the vessel and there is little to no endothelial damage. When the clamp force is too high certain types of clamps may 'scissor' and more severe damage results; sometimes the vessel itself may be cut (Sauer, et al. 2002). To prevent scissoring most clamps are designed with flat arms.

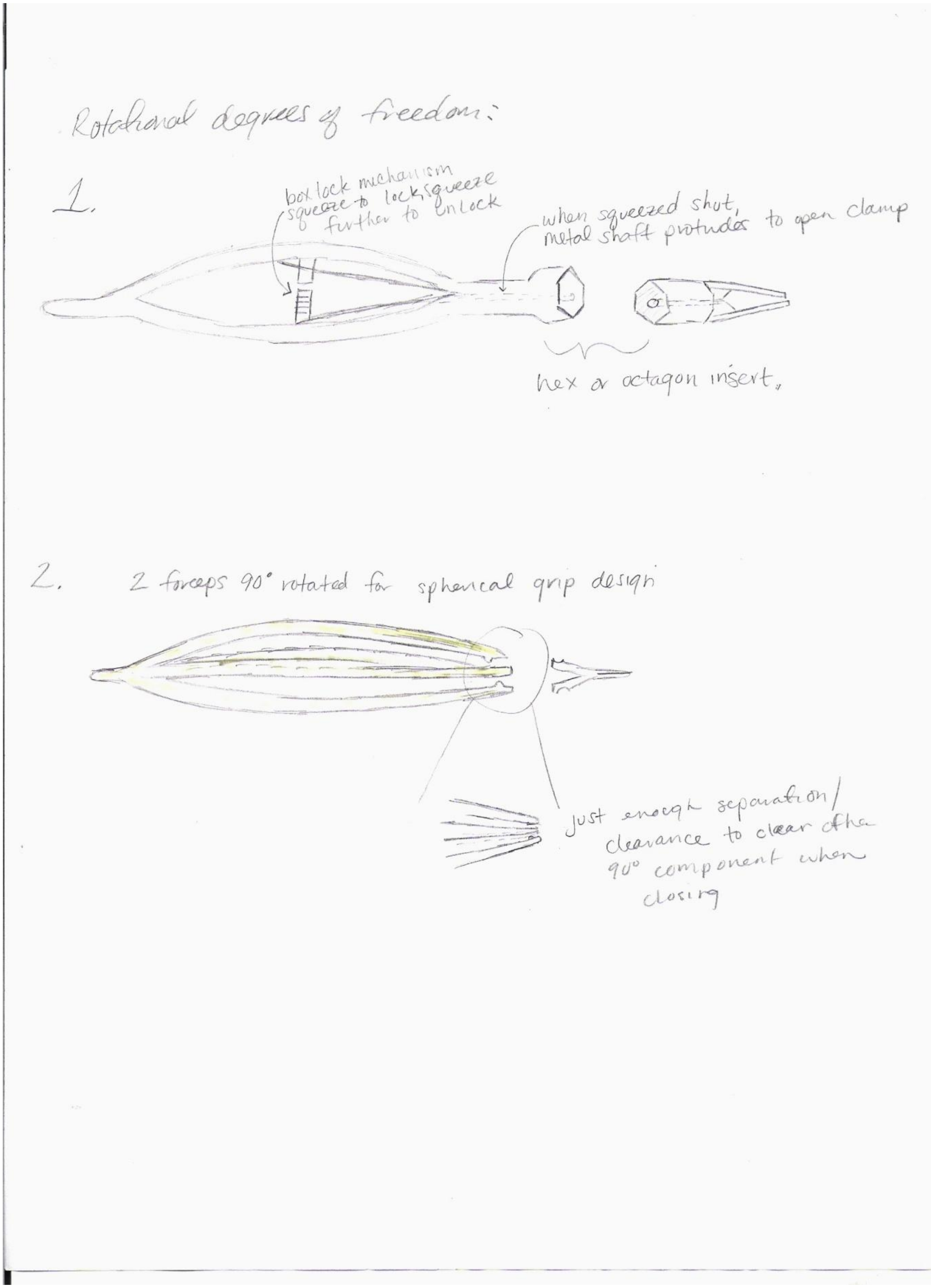
F. Objectives Tree



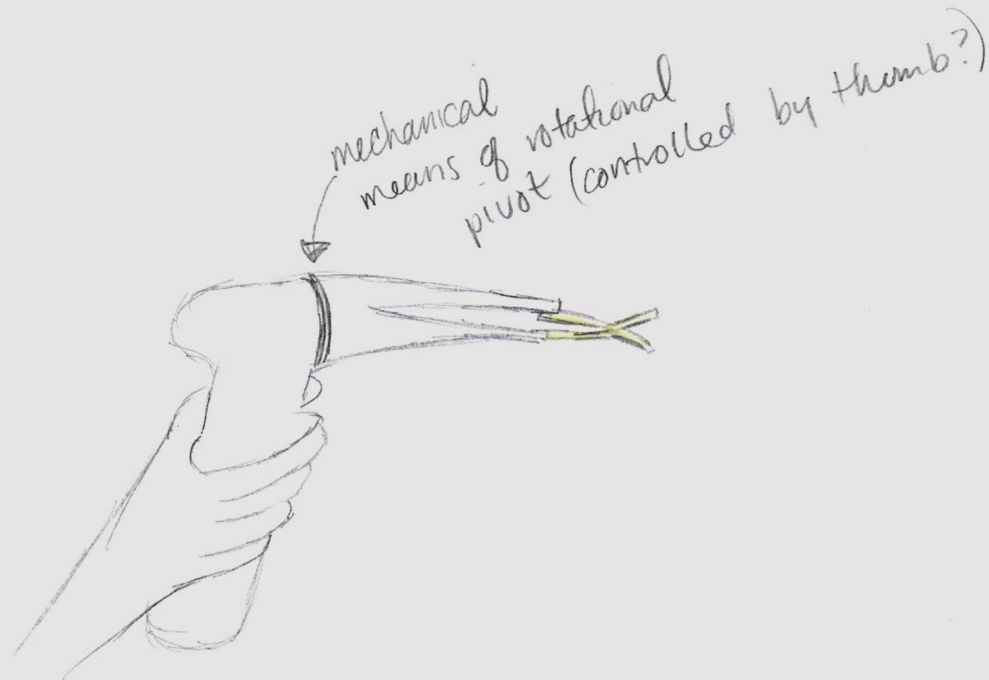
G. Functions Means Tree



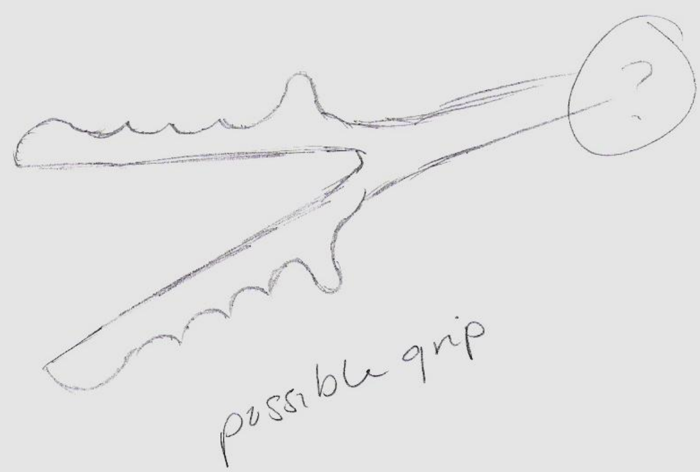
H. Conceptual Designs



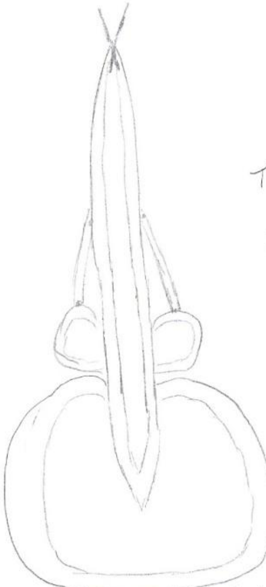
3.


mechanical means of rotational pivot (controlled by thumb?)

4.


?
possible grip

5.



Forceps with circular "anchor" held in the palm. Squeezing the anchor once locks the forceps, squeezing again releases them. There is a ring on each side of the forceps for the pointer and middle finger. The rings operate like a pulley system. Moving one ring moves the forceps horizontally while the other moves them vertically. Clamp and forceps interface in standard way.

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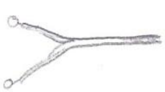
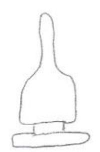
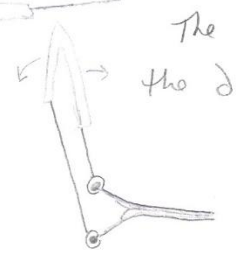
6.

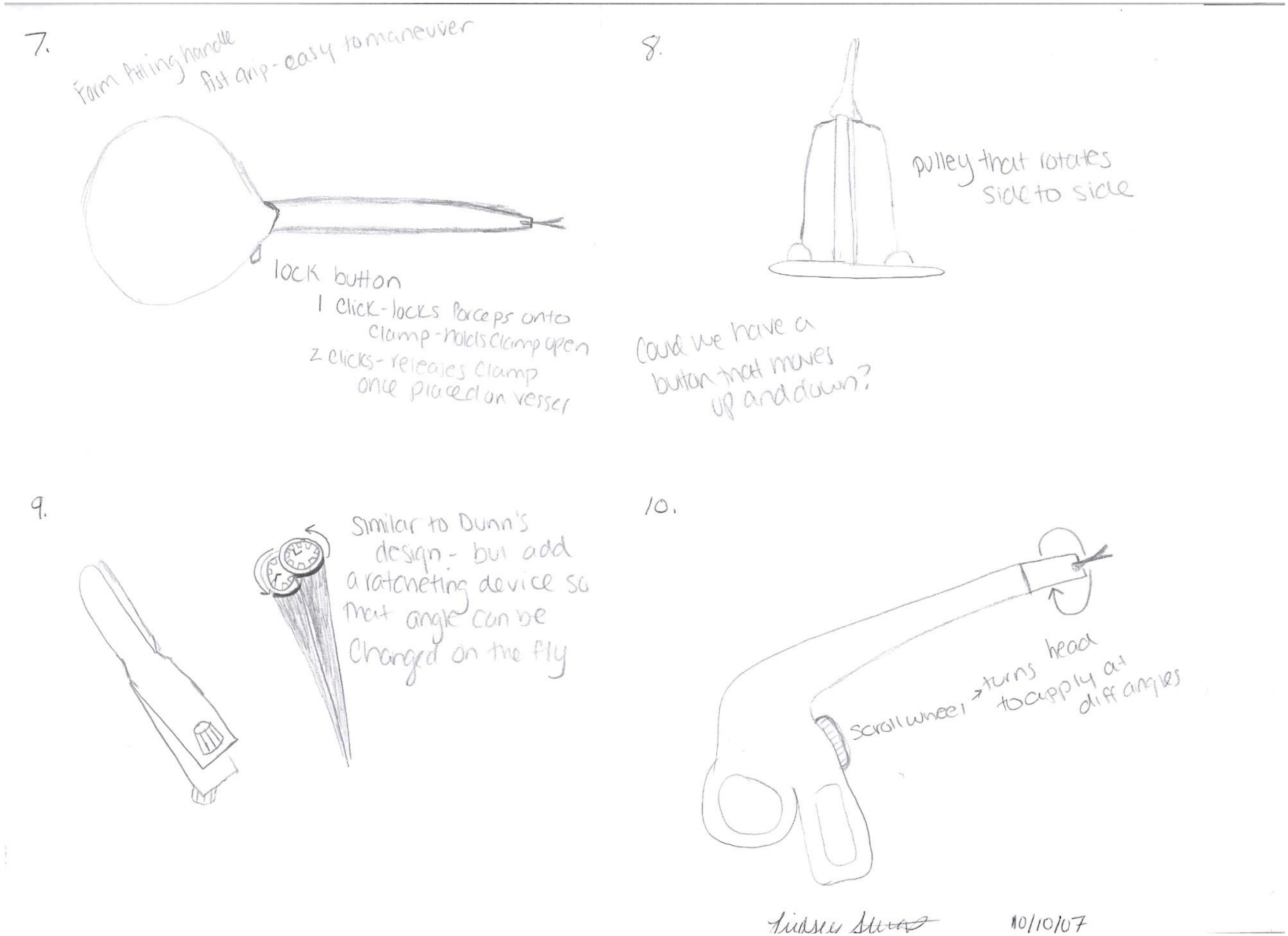




Telescoping forceps with circular end on the tip. The clamps have a cylinder on each end. The circular ends of the forceps slide ~~of~~ over the cylinder to secure the clamp. Since the forceps can telescope they can rotate around the cylinders on the clamp. The forceps can be locked when the desired angle is achieved.



Lesley Bright


7.
Form fitting handle
fist grip - easy to maneuver
lock button
1 click - locks forceps onto clamp - holds clamp open
2 clicks - releases clamp once placed on vessel
8.
pulley that rotates side to side
Could we have a button that moves up and down?
9.
Similar to Dunn's design - but add a ratcheting device so that angle can be changed on the fly
10.
head
scroll wheel → turns to apply at diff angles
10/10/07

I. Design Selection Matrix

		Design 1		Design 2		Design 3		Design 5	
Constraints		"Octagon"		"Double Tweezer"		"Dora"		"Pulley"	
Sterilizable		N		Y		N		N	
Cost effective		Y		Y		N		Y	
Interfaces w/ clamp		Y		Y		Y		Y	
Occludes flow		Y		Y		Y		Y	
	Weight (%)	**Score**	**Weighted**	**Score**	**Weighted**	**Score**	**Weighted**	**Score**	**Weighted**
Objectives			**Score**		**Score**		**Score**		**Score**
Ease of Use	28.1	0.6	16.86	0.5	14.05	0.5	14.05	0.45	12.645
Durability	3.1	0.5	1.55	0.6	1.86	0.75	2.325	0.2	0.62
Safety	22	0.6	13.2	0.6	13.2	0.35	7.7	0.3	6.6
Comfortable	28.1	0.7	19.67	0.7	19.67	0.8	22.48	0.7	19.67
Universal Interface	3.1	0.7	2.17	0.5	1.55	0.9	2.79	0.7	2.17
Manufacturability	15.6	0.1	1.56	0.2	3.12	0.45	7.02	0.1	1.56
Total Score			55.01		53.45		56.365		43.265

		Design 6		Design 7		Design 8	
Constraints		"Cylinder"		"Locking Ball"		"Dunn+Ratchet"	
Sterilizable		Y		Y		N	
Cost effective		Y		Y		Y	
Interfaces w/ clamp		Y		Y		Y	
Occludes flow		Y		Y		Y	
	Weight (%)	**Score**	**Weighted**	**Score**	**Weighted**	**Score**	**Weighted**
Objectives			**Score**		**Score**		**Score**
Ease of Use	28.1	0.7	19.67	0.2	5.62	0.6	16.86
Durability	3.1	0.75	2.325	0.6	1.86	0.6	1.86
Safety	22	0.7	15.4	0.6	13.2	0.5	11
Comfortable	28.1	0.65	18.265	0.7	19.67	0.7	19.67
Universal Interface	3.1	0.9	2.79	0.7	2.17	0.7	2.17
Manufacturability	15.6	0.8	12.48	0.2	3.12	0.1	1.56
Total Score			70.93		45.64		53.12

J. CAD Drawings of Initial Designs

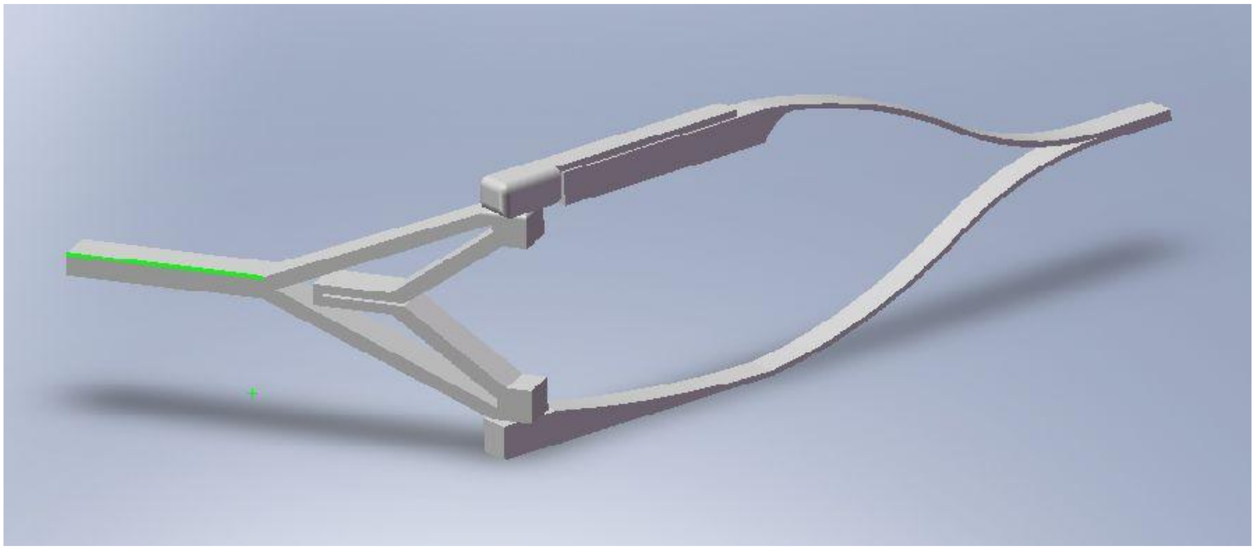


Figure 12.3. This image depicts the full assembly of the initial forceps, sliding mechanism, and clamp design.

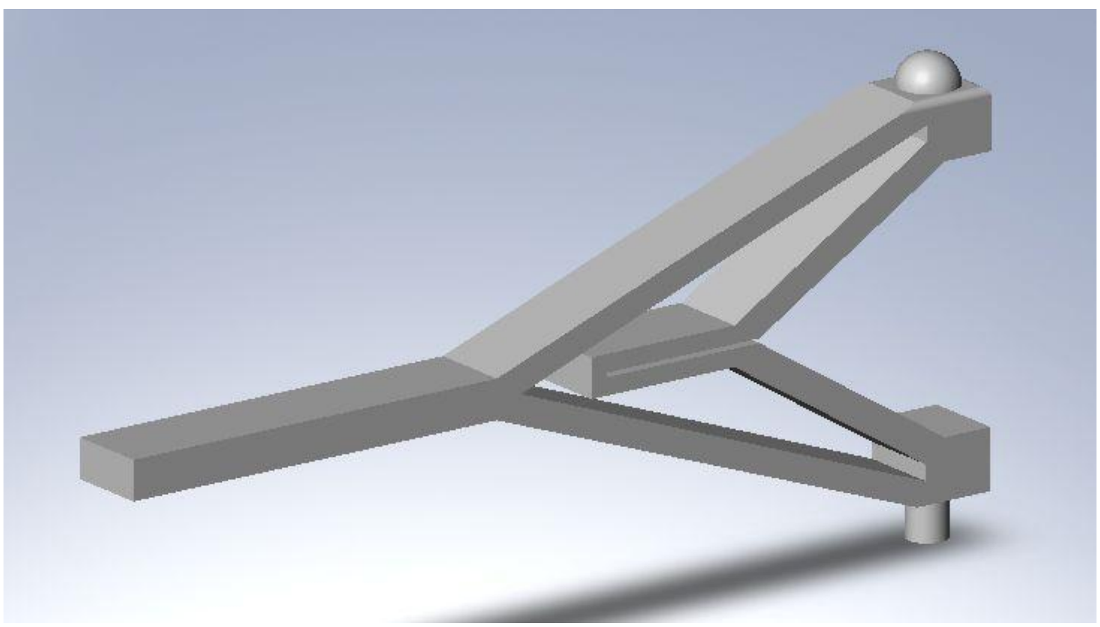


Figure 12.4. CAD drawing of clamp depicting interfaces on both sides of the clamp

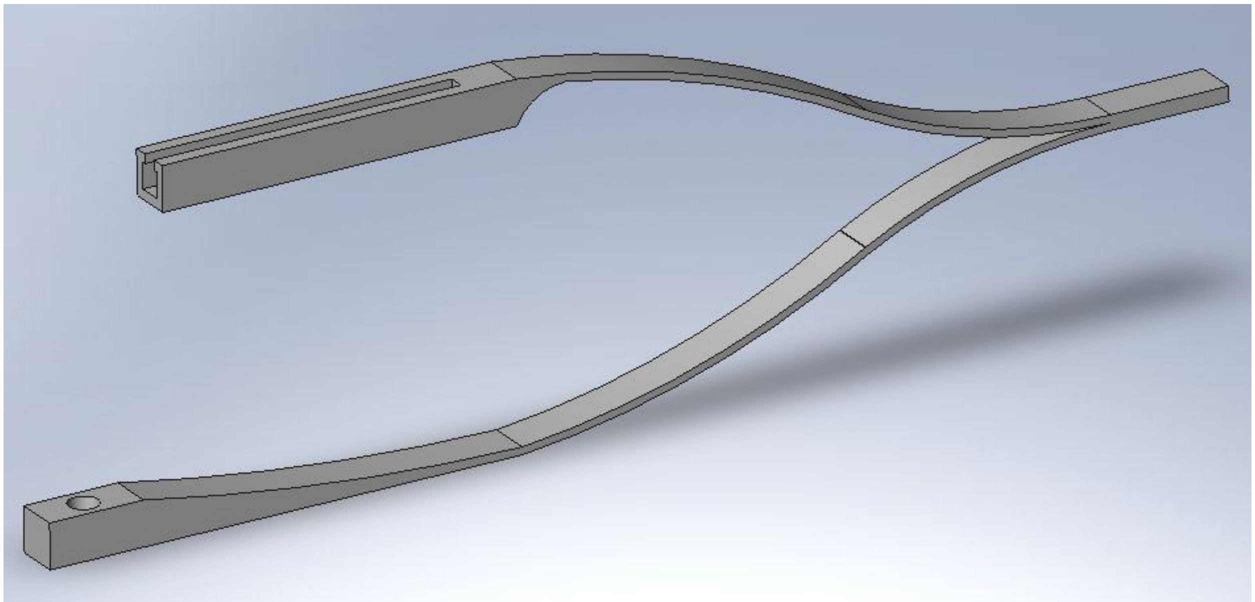


Figure 12.5. CAD drawing of forceps without sliding mechanism

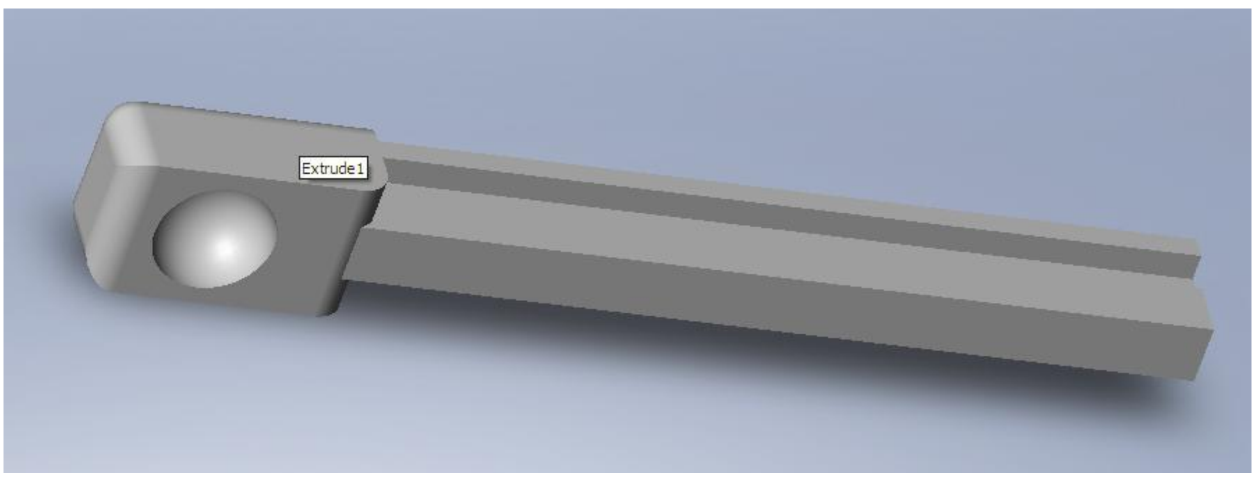


Figure 12.6. Sliding mechanism that fits into top portion of forceps above

K. Alternative Designs

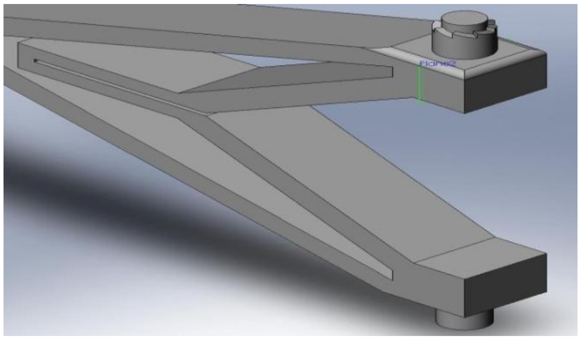


Figure 12.7. Interface featuring inclined cylinder that would function like a ratchet to allow lateral rotation.

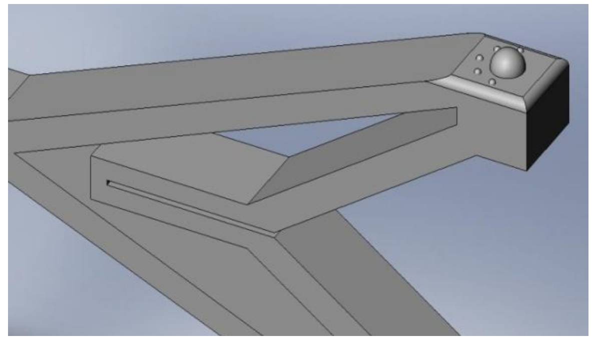


Figure 12.8 A large half-sphere allowing vertical rotation with smaller half-spheres surrounding it to allow the clip to be locked into different lateral angles.

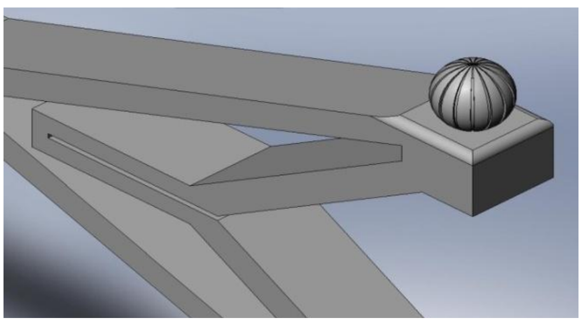


Figure 12.10. A spherical interface with slotted grooves allowing both lateral and vertical rotation, locking the clip into place.

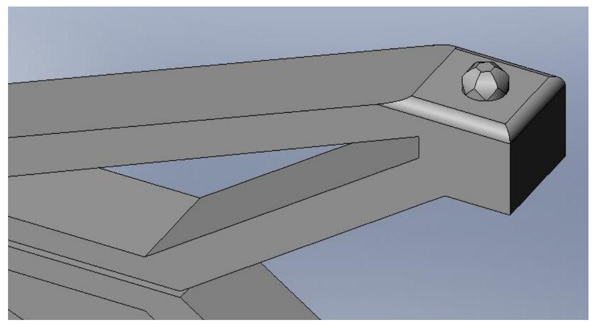


Figure 12.9. Hexagonal half-sphere that would function as a ball-end hex key to lock the clamp into different angles.

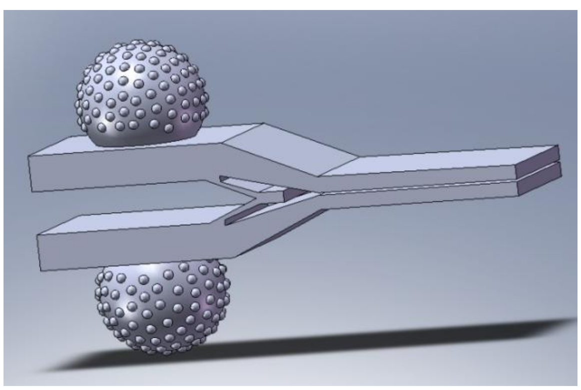


Figure 12.12. Spherical interfaces with surface irregularities to allow the clip to be locked into virtually any lateral or vertical angle.

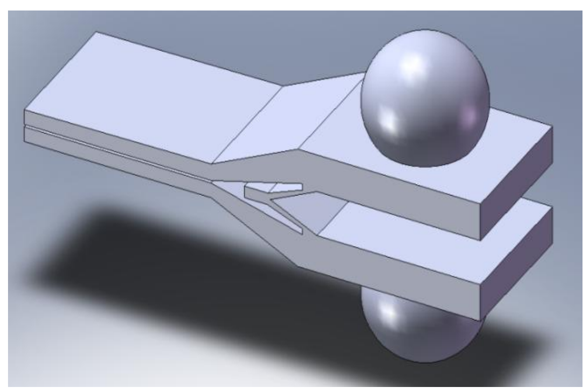
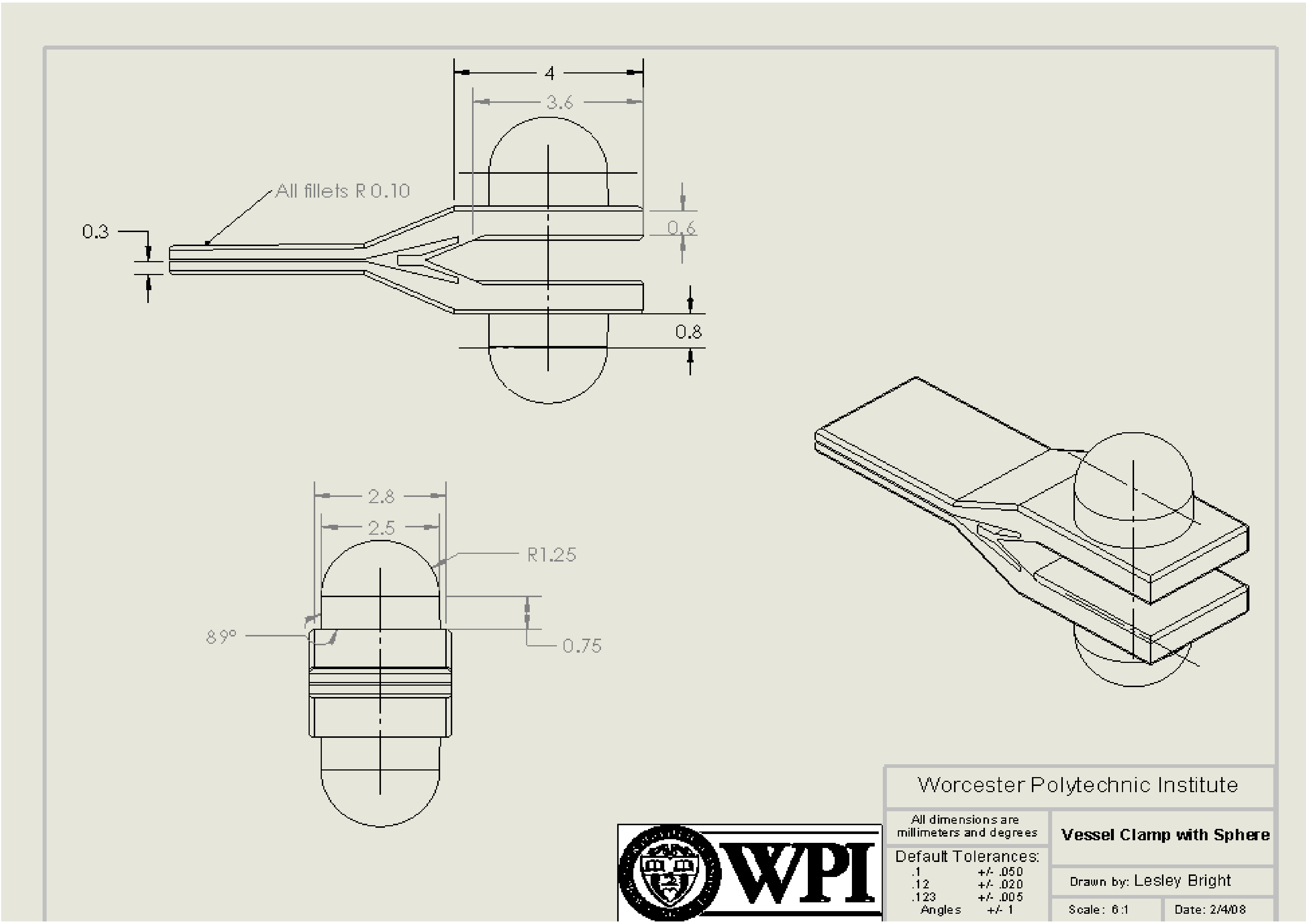
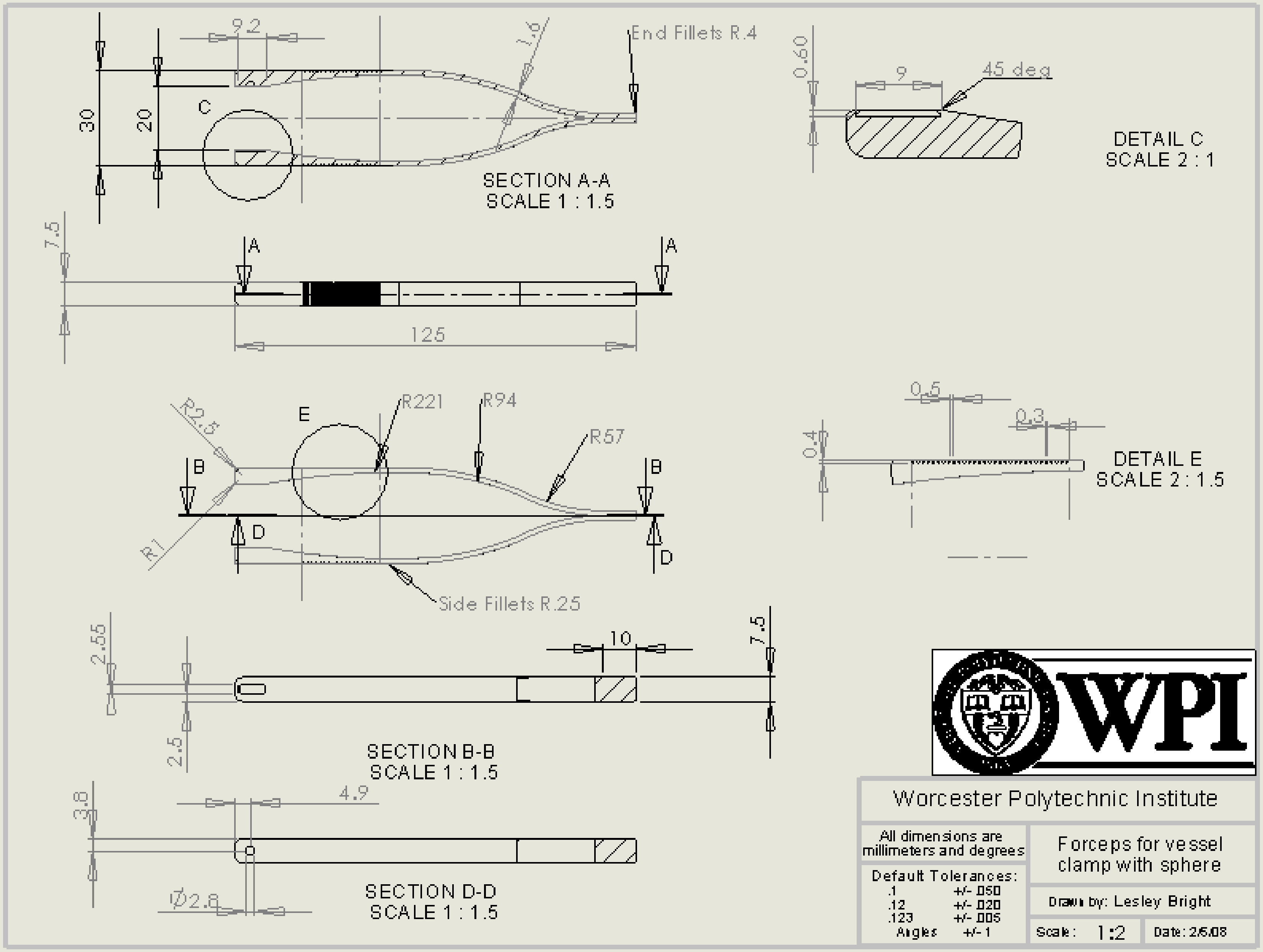


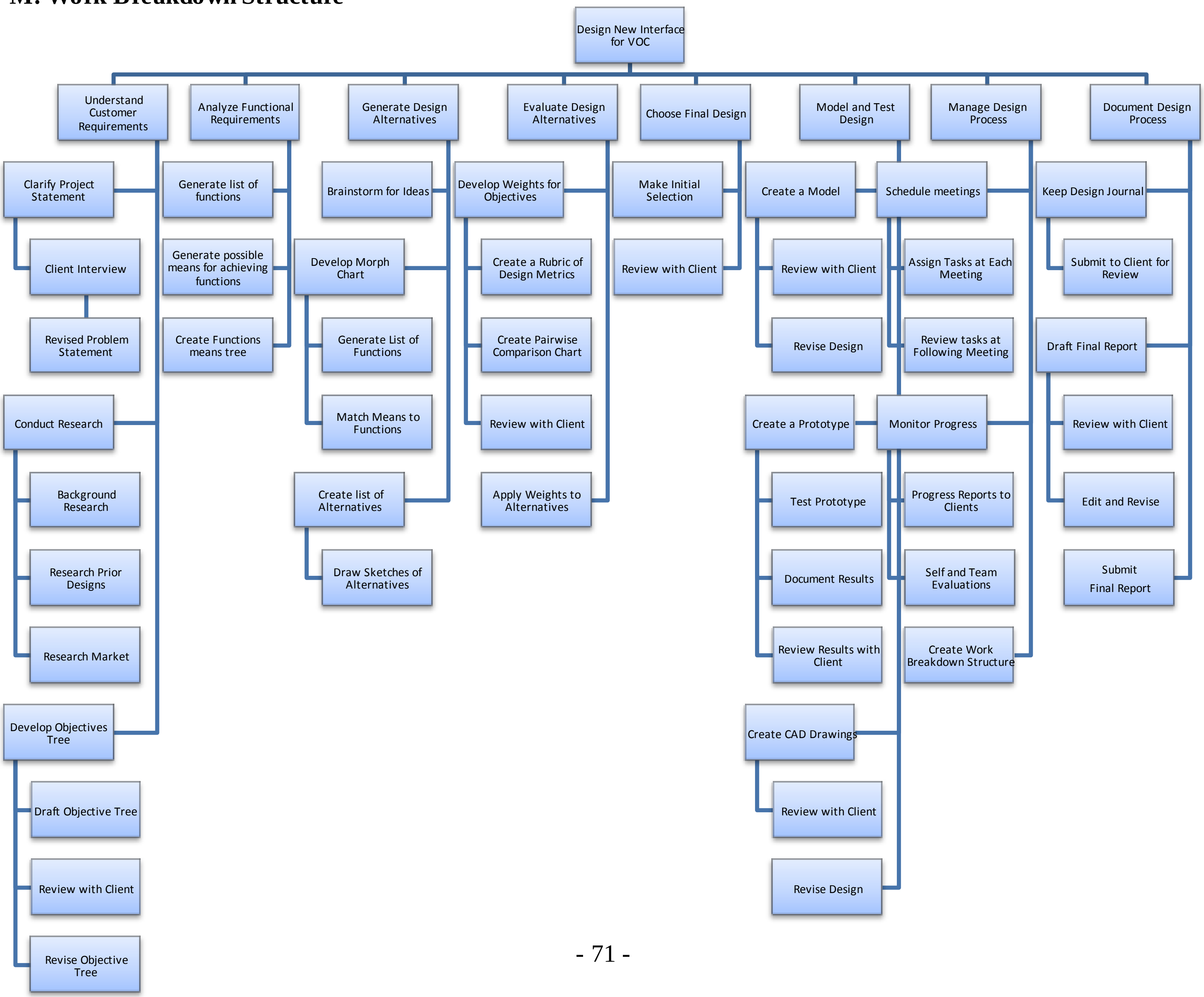
Figure 12.11. Smooth spherical interfaces that would allow unlimited vertical and lateral rotation based on friction.

L. Final Design




9.2
1.6
End Fillets R.4
30
20
C
SECTION A-A
SCALE 1 : 1.5
0.60
9
45 deg
DETAIL C
SCALE 2 : 1
7.5
A
A
125
0.5
0.3
0.4
DETAIL E
SCALE 2 : 1.5
R2.5
E
R221
R94
R57
B
B
R1
D
D
Side Fillets R.25
2.55
10
7.5
2.5
SECTION B-B
SCALE 1 : 1.5
3.8
4.9
Ø2.8
SECTION D-D
SCALE 1 : 1.5
WPI
Worcester Polytechnic Institute
All dimensions are millimeters and degrees
Forceps for vessel clamp with sphere
Default Tolerances:
.1 +/- .050
.12 +/- .020
.123 +/- .005
Angles +/- 1
Drawn by: Lesley Bright
Scale: 1:2
Date: 2/5/08

M. Work Breakdown Structure



N. Validation of Opinions in Focus Groups and Surveys

Surveys

The data collected from surveys differ greatly depending on the method of survey distribution, the types of questions asked, and the overall design of the questionnaire. Quantitative questionnaires and surveys are often written lists of questions with standardized answers. Their purpose is to gather data for statistical analysis. They are useful for collecting data where detailed feedback is not necessary.

Questionnaires can involve two types of questions: open-ended or closed questions. The use of open-ended or closed questions should be determined by the type of research being performed. Open-ended questions allow the respondent to provide their own answer without being influenced by multiple-choice answers. Closed questions provide the respondent with several selections from which to choose or rank their answer. Closed questions are easy to analyze statistically, while open-ended questions leave room for interpretation and are difficult to analyze in a structured way (Berg 2007, Godfrey and Clarke 2000). Closed questions are also quick and easy for the respondent to answer and can maximize the number of survey responses received.

Wording of the questions should be carefully examined. When designing a survey, leading questions and abstract concepts should be avoided so that a simple, non-biased, and easily analyzable responses can be given. The language should also be simple and understandable, avoiding jargon or slang that not everyone may be familiar with, which can help to increase the consistency of responses. People who do not understand slang or who have a limited vocabulary may interpret survey questions differently, skewing the results (Berg 2007, Godfrey and Clarke 2000).

Focus Groups

Focus groups are a useful means for gathering many different opinions, ideas, and pieces of information over a short period of time, such as general background on a topic, research questions, and evaluations of a product or service (Berg 2007). Focus groups are also helpful in providing insight into vocabulary that can be used for improved communication with the intended audience (Milman 1993). This research method can also aid the researcher in determining attitudes and perceptions about a certain topic, as well as understanding why participants feel the way they do (Berg 2007).

Despite their benefits, there are several limitations to using focus groups. First, it is difficult to achieve equal participation among members of the focus group and the quality of participation can be affected by actions of the moderator. It is also difficult to achieve a statistically significant sample size and to obtain answers to all of the necessary questions in the given time period (Berg 2007).

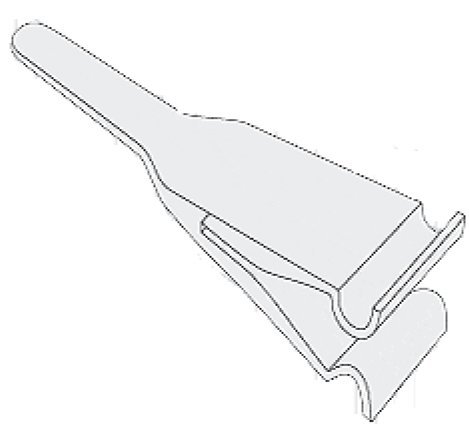
Focus groups generally consist of 6-12 participants led by a moderator and discussions generally last for 1 ½ - 2 hours. They can be audio or video recorded for transcription and analysis purposes (Berg 2007, Milman 1993, Kidd and Parshall 2000, Ritchie, Burns and Palmer 2005, Smithson 2000). Several factors should be taken into consideration when planning a focus group session. First, it is important to minimize distraction to the participants, so the location should be comfortable and free from external stimuli such as noise or traffic. Focus groups should also be conducted at convenient times so that participants are inclined to attend. It is often effective to offer incentives such as a free meal to further encourage participation. It is important to establish ground rules before discussion begins to ensure confidentiality and maintain a safe, constructive discussion environment. Participants should be assured that their input is important and valuable and that there is no right or wrong answer. An effective strategy for promoting discussion is to limit the role of the moderator to simply making sure the discussion stays on track. This will allow the participants to openly share their ideas without too much guidance or influence. After the focus group is complete, a follow up should be conducted and researchers should express their thanks to the focus group members for their participation (Ritchie, Burns and Palmer 2005).

O. Survey

Project Title: Redesign of a More Ergonomic Vessel Occlusion Clamp-Forceps Interface

Project Team: Lesley Bright, Lindsey Sturgis, Jessica Thibideau
Worcester Polytechnic Institute
Department of Biomedical Engineering
Class of 2008

Project/Survey Description: This project is our senior capstone design project for Biomedical Engineering at Worcester Polytechnic Institute. The goal of the project is to redesign the interface between microvascular clips and their applying forceps to allow for multiple degrees of freedom of motion during surgery. The purpose of this survey is to gather opinions on the current clamp-forceps device (as shown below), suggestions for improving this device, and impressions of our new designs. We thank you in advance for taking the time to complete our survey.



Currently used tongue-and-groove microvascular clips and applying forceps from S&T Microsurgical Instruments.

Please check the appropriate box or circle the appropriate answer for each question.

1. Are you a:
   - ☐ Plastic Surgeon
   - ☐ Plastic Surgery Resident
   - ☐ Hand Surgeon
   - ☐ Hand Surgery Resident
   - ☐ General Surgeon
   - ☐ General Surgery Resident
   - ☐ Other (Please specify). ____

2. Do you perform microsurgery?
   - ☐ Yes
   - ☐ No

3. Do you use the current microvascular clips/clamps during surgery?
   - ☐ Yes (Proceed to Question 4).
   - ☐ No (Proceed to Question 7).

4. Do you apply the vascular clips to the vessels with the appropriate forceps?
   - ☐ Yes (Proceed to Question 5).
   - ☐ No (Proceed to Question 6).

5. How do you place the clamp in the forceps?
   - ☐ The nurse/surgical aide hands me the forceps with the clamp in place.
   - ☐ I manually place the clamp in the forceps myself.
   - ☐ Using the forceps, I pick up the clamp off of the table.
   - ☐ Other (Please Specify). ____

6. If you do not use the appropriate applying forceps, what alternative design or method do you use to apply the clips to the vessel?
   - ☐ I apply the clips with a different type of forceps (Please Describe). ________________
   - ☐ I apply the clips by hand using my fingers.
   - ☐ Other (Please Specify). ____

7. Please rate the current clamp-forceps design in regards to the following parameters:

a.	Ease of use:	*Below Average*	*Average*	*Above Average*
b.	Functionality:	*Below Average*	*Average*	*Above Average*
c.	Durability:	*Below Average*	*Average*	*Above Average*
d.	Comfort:	*Below Average*	*Average*	*Above Average*
e.	Safety:	*Below Average*	*Average*	*Above Average*

8. Please rate Design 1: Smooth Spherical Interface in regards to the following parameters:
   a. Ease of use: *Below Average* *Average* *Above Average*
   b. Functionality: *Below Average* *Average* *Above Average*
   c. Durability: *Below Average* *Average* *Above Average*
   d. Comfort: *Below Average* *Average* *Above Average*
   e. Safety: *Below Average* *Average* *Above Average*

9. Please rate Design 2: Spherical Interface with Surface Irregularities in regards to the following parameters:
   a. Ease of use: *Below Average* *Average* *Above Average*
   b. Functionality: *Below Average* *Average* *Above Average*
   c. Durability: *Below Average* *Average* *Above Average*
   d. Comfort: *Below Average* *Average* *Above Average*
   e. Safety: *Below Average* *Average* *Above Average*

10. Please check the statement that is most descriptive of the type of rotational degree of freedom you would prefer the new interface to achieve.
   ☐ I only need to achieve lateral/horizontal rotation when applying a vascular clamp.
   ☐ I only need to achieve vertical motion when applying a vascular clamp.
   ☐ I need to achieve both lateral and vertical rotation when applying a vascular clamp.
   ☐ I do not need to achieve any type of rotation when applying a vascular clamp.

11. Please rate the following features of clamp-forceps devices on importance to you:
   a. Ability to change the angle of the clamp while it is locked into the forceps:
      Not Important *Neutral* *Very Important*
   b. Simple, easy to use design:
      Not Important *Neutral* *Very Important*
   c. Similarity of surgical technique to current design:
      Not Important *Neutral* *Very Important*
   d. Ergonomic, comfortable forceps:
      Not Important *Neutral* *Very Important*
   e. Presence of a locking mechanism, such as a Castroviejo, to secure clamp in place:
      Not Important *Neutral* *Very Important*
   f. Presence of the same interface on both sides of the clamp so that there is no wrong way to place the clamp in the forceps:
      Not Important *Neutral* *Very Important*

12. We have created a "black box" in order to evaluate the functionality and ease of use of our new interface designs. Do you feel that our box model appropriately mimics a microsurgical scene that would require the use of a vessel occluding clamp?
   ☐ Yes
   ☐ No

13. Assuming there were no major changes in application technique, would you use one of our new clamp designs?
    - ☐ Yes (Proceed to Questions 14 and 15).
    - ☐ No (Proceed to Question 16).

14. If you would use one of our new designs, which design do you prefer? Please check one.
    - ☐ Design 1: Smooth Spherical Interface.
    - ☐ Design 2: Spherical Interface with Surface Irregularities.
    - ☐ Either.

15. Please state why you made your choice. Please check all that apply.
    - ☐ Simple and easy to use design.
    - ☐ Provides unlimited rotation in all directions.
    - ☐ Clamp stays in place well.
    - ☐ No major changes in surgical technique.
    - ☐ Other (Please Specify). ____

16. If you would not use one of our designs, why not? Please check all that apply.
    - ☐ I see no problems with the current design and will continue to use it.
    - ☐ The technique is too different from what I am used to using.
    - ☐ The new designs are not comfortable to use.
    - ☐ The new designs are too complex and difficult to use.
    - ☐ Other (Please specify). ____

17. Please provide any additional feedback you may have including comments, limitations, or other suggestions for improvement regarding the current device or our new designs.

Thank you again for taking the time to complete our survey. Your feedback is much appreciated!

P. Survey Results

1. ARE YOU A…				
Plastic Surgeon	1			
PS Resident	0			
Hand Surgeon	0			
HS Resident	0			
General Surgeon	0			
GS Resident	9			
2. DO YOU PERFORM MICROSURGERY?				
Yes	3			
No	7			
3. DO YOU USE THE CURRENT MICROVASCULAR CLIPS/CLAMPS DURING SURGERY?				
Yes	3			
No	7			
4. DO YOU APPLY THE CLIPS TO THE VESSELS WITH THE APPROPRIATE FORCEPS?				
Yes	2			
No	2			
N/A	6			
5. HOW DO YOU PLACE THE CLAMP IN THE FORCEPS?				
The nurse/surgical aid hands me the forceps with the clamp in place.	0			
I manually place the clamp in the forceps myself.	1			
Using the forceps, I pick up the clamp off the table	2			
Other	0			
N/A	7			
6. WHAT ALTERNATIVE DESIGN OR METHOD DO YOU USE TO APPLY THE CLIPS TO THE VESSEL?				
I apply the clips with a different type of forceps.	0			
I apply the clips by hand using my fingers.	2			
Other	0			
N/A	8			
7. PLEASE RATE THE CURRENT CLAMP-FORCEPS DESIGN IN REGARDS TO THE FOLLOWING PARAMETERS.		**Below Average**	**Average**	**Above Average**
Ease of Use		0	9	1
Functionality		1	7	2
Durability		1	8	1
Comfort		1	8	1
Safety		2	7	1
8. PLEASE RATE DESIGN 1 IN REGARDS TO THE FOLLOWING PARAMETERS.		**Below Average**	**Average**	**Above Average**
Ease of Use		0	7	3
Functionality		0	5	5
Durability		1	8	1
Comfort		0	8	2
Safety		2	6	2

9. PLEASE RATE DESIGN 2 IN REGARDS TO THE FOLLOWING PARAMETERS.		Below Average	Average	Above Average
Ease of Use		0	6	4
Functionality		0	2	8
Durability		1	7	2
Comfort		0	7	3
Safety		0	7	3
10. WHAT TYPE OF ROTATIONAL DEGREE OF FREEDOM WOULD YOU PREFER THE NEW INTERFACE TO ACHIEVE?				
I only need to achieve lateral rotation when applying a vascular clamp.	1			
I only need to achieve vertical rotation when applying a vascular clamp.	2			
I need to achieve both lateral and vertical rotation when applying a vascular clamp.	7			
I do not need to achieve any type of rotation when applying a vascular clamp.	0			
11. PLEASE RATE THE FOLLOWING FEATURES OF CLAMP-FORCEPS DEVICES ON IMPORTANCE TO YOU.		Not Important	Neutral	Very Important
Ability to change the angle of the clamp while it is locked into the forceps		0	4	6
Simple, easy to use design		0	1	9
Similarity of surgical technique to current design		1	4	5
Ergonomic, comfortable forceps		0	2	8
Presence of a locking mechanism, such as a Castroviejo, to secure clamp in place		2	2	6
Presence of the same interface on both sides of the clamp so that there is no wrong orientation		0	3	7
12. DO YOU FEEL THAT OUR BOX MODEL APPROPRIATELY MIMICS A MICROSURGICAL SCENE THAT WOULD REQUIRE THE USE OF A VASCULAR OCCLUDING CLIP?				
Yes	8			
No	2			
13. ASSUMING THERE WERE NO MAJOR CHANGES IN APPLICATION TECHNIQUE, WOULD YOU USE ONE OF OUR NEW DESIGNS?				
Yes	9			
No	1			
14. IF YES, WHICH DESIGN DO YOU PREFER?				
Design 1	4			
Design 2	5			
Either	1			
15a. WHY DID YOU MAKE YOUR DESIGN CHOICE FOR DESIGN 1?				
Simple and easy to use design	2			
Provides unlimited rotation in all directions	2			
Clamp stays in place well	1			
No major changes in surgical technique	0			
Other	0			
15b. WHY DID YOU MAKE YOUR DESIGN CHOICE FOR DESIGN 2?				
Simple and easy to use design	1			
Provides unlimited rotation in all directions	2			
Clamp stays in place well	5			
No major changes in surgical technique	1			
Other	0			

16. IF YOU WOULD NOT USE ONE OF OUR DESIGNS, WHY NOT?				
I see no problems with the current design and will continue to use it.	0			
The technique is too different from what I am used to using.	0			
The new designs are not comfortable to use.	0			
The new designs are too complex and difficult to use.	0			
Other	1			
N/A	9			

17. OTHER FEEDBACK.
Irregular interface not as nice as smooth ball
The black boxes suffice for this purpose but they could be improved if they had nearby tissue to push on to direct the clamp rather than having to wait until its clamped on the vessel-which would tear it off in real life
Great idea to be able to rotate to appropriate angle without taking clamp out
It is difficult to judge by these prototypes because they lack accuracy and real time flexibility
Integration of a mechanism to change the angle on the clamp so that it doesn't need to be pushed against the tissue or lounged on the vessel.

Q. Microsurgical Training Models

Microsurgery is an important aspect of many other surgical fields, including orthopedics, reproductive gynecology, ophthalmology, and plastics (Studinger, Bradford and Jackson 2005). Training is important because of the delicate nature and time-dependency of the surgery. Without adequate accuracy and speed, the patient can be injured. A common procedure that needs to be taught is the clamping of a vessel, followed by anastomoses completed within 30 minutes of clamping.

Microsurgical training facilities are located throughout the country. Training models vary from synthetic materials to virtual reality to animal models. Training is most often undergone by surgical residents. Generally, the beginner's training model usually consists of synthetic materials such as silicone or polyurethane sheets, silastic tubing, gauze, or rubber gloves (Studinger, Bradford and Jackson 2005). The trainee can practice handling and manipulating the instruments at this time. After practicing on the synthetic models, the trainees may move to animal models such as chickens or rats to get a feel for the live tissues. All of these training models have been shown useful in improving surgical technique. An additional advantage of training models is that they can also be used for preclinical evaluation of medical devices because they provide a stable and ideal operating environment (Sugiu, et al. 2003).

R. Non-Disclosure Agreements

When parties enter into business alliances, each partner risks exposure of its internal information which can include business processes and strategies, product ideas, etc. It is important that each partner takes appropriate measures to protect is assets regardless of how much trust is placed in the other partner. It is the responsibility of the management and other persons involved in negotiations and business dealings to protect its company's information by not giving away secret information. Legal methods can also be used to protect vital information. These methods include patents and contractual agreements such as non-disclosure agreements (Norman 2001).

Non-disclosure agreements are legal contracts that prohibit the parties involved from disclosing protected information to outside parties, reproducing, or using information for their own benefit. The document generally defines what constitutes confidential information and spells out which processes, product ideas, etc. are not to be disclosed to outside parties. These agreements also specify the time period during which disclosing information to third parties is prohibited. A common length for an NDA is five years (Bellis 2008). Often, penalties for violating the contract are included.