METHODS, DEVICES, AND APPARATUS FOR PERFORMING A VASCULAR ANASTOMOSIS

by

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A thesis submitted to the faculty of
The University of Utah
in partial fulfillment of the requirements for the degree of

Master of Science

Department of Mechanical Engineering

The University of Utah

August 2012

The University of Utah Graduate School

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ABSTRACT

During reconstructive and free tissue transfer surgeries it is often necessary to cut and reattach multiple vessels. The current method of vessel anastomosis is traditional hand suturing. The scope of this venture is to create a commercially available vascular coupling device (VCD) that would allow surgeons to quickly attach vessels together. The VCD is designed to increase reliability and reduce the amount of time spent on connecting two vessels. Hand suturing a vessel is time consuming (20-30 minutes) and difficult (requires a skilled surgeon). The method that has been developed can reduce the amount of time in the operating room by 75% and provides a superior anastomosis. In order to reach this level of improvement a set of installation tools was developed. These tools compliment the VCD and perform the necessary functions to consistently anastomise vessels. These tools were developed using laser machining techniques developed for this project. The laser manufacturing techniques allowed for the rapid development of the VCD and its supporting tools. With further development the VCD will become an important tool for the microsurgical community.

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ACKNOWLEDGMENTS

This project would not have been possible without the help of multiple people. I would like to thank my advisor Dr. Bruce Gale for his unprecedented patience and support. The inspiration for this project came from Dr. Jay Agarwal who has been a constant guide throughout this process and has played a critical role in its success. I would also like to thank Dr. Himanshu Sant for his day to day efforts on this project.

Most importantly, I would like to sincerely thank my wife Michelle. She believed in me in times that I couldn't believe in myself.

CHAPTER 1

INTRODUCTION

1.1 Medical Devices

The use of implantable medical devices is increasing in popularity. It is expected that the use of these devices will continue to increase in the future [1]. The FDA describes a medical device as a product that is intended for use in the diagnosis of disease, or in the cure, mitigation, treatment, or prevention of disease. The device does not achieve any of its primary intended purposes through chemical action and it is not dependent upon being metabolized for the achievement of any of its primary intended purposes [2]. New medical devices are making their way into the market each year. These devices can help reduce the cost or care and patient recovery time. In some cases these devices can help make a difficult procedure more manageable.

1.2 Microsurgery

One area of medicine that has benefited from increasing medical device technology is surgery. Without the aid of microscopes and delicate tools many types of operations are not even possible. Through the use of these devices the relatively new field of microsurgery was developed [3]. Some of the more common microsurgical procedures are replantation and free tissue transfer. Replantation is the reattachment of body parts such as fingers and thumbs [4]. Free tissue transfer is a reconstructive procedure that takes a section of tissue from a healthy part of the body and transfers it to an area that needs to be repaired [5-9]. During this type of surgery, the arteries and veins from the donor tissue are cut and then reattached at the reconstruction site.

In both replantation and free tissue transfer, vessels need to be reconnected. Connecting the vessels is necessary because they are what provide the blood flow to keep the tissue alive. Two types of vessels need to be connected: arteries and veins. Veins are smaller in diameter and have very thin walls. Arteries are larger in diameter and are thick and muscular. They have some stretch to them, but not nearly as much as veins. Arteries can be stretched up to 80% of their original size without significant damage [10, 11] . A vein, on the other hand, can stretch up to several times its original diameter without significant damage [12].

1.3 State of the Art

The current method of anastomising two vessels is hand suturing [13-16]. This technique requires complex microscopes and very skilled surgeons to efficiently perform the operation. Multiple vessels need to be reattached during replantation and free tissue transfer procedures [8, 17-19]. Each of these connections requires a microscope, a skilled surgeon, and around 30 minutes in the operating room.

Over the past 30 years there have been many devices created to connect vessels. However, the vast majority of surgeons are still hand sewing vessels. The suture is still used partly due to the fact that the current coupling devices either work well for veins or for arteries, but not both. During a routine surgery, where both a vein and an artery have to be connected, a surgeon has to perform two completely different techniques if the coupler does not work well for both types of vessels. Instead of dealing with the hassle of learning and practicing two different techniques, surgeons opt to hand suture the vessels.

A good example of a device that works well with one type of vessel and not the other is the “GEM Microvascular Anastomotic Coupler”. This device is designed to attach vessels using a set of tools and two coupling rings [5, 6, 12, 19-26]. It is commonly used in reconstructive surgery for veins, but not for arteries. The GEM Coupler is prescribed for both veins and arteries but it is used less on arteries because it requires multiple steps that negate the benefits of using the device. Difficulties arise because the arterial wall’s elasticity and thickness cause the artery to slip off of the spikes during the installation process. This difficulty has been overcome by using rubber bands to secure the artery to the individual spikes [22]. The process has proven to work, but it is not widely used because of its complexity and time requirements.

There are also devices used to connect arteries. Most of these devices are used on coronary arteries during heart surgery. The coronary arteries are much larger and various methods have been employed to provide anastomosis [10, 11, 27-40]. These arterial connection methods include staples, magnets, clips, and glues. Due to the larger sizes of the applicators and connecting devices they do not work well with the smaller arteries utilized in reconstructive surgery. These types of arterial coupling devices are not prescribed for use with veins.

1.4 Vascular Coupling Device

The Vascular Coupling Device (VCD) is designed specifically to efficiently connect veins and smaller arteries found in reconstructive surgeries (Figure 1.1). The VCD will allow surgeons to quickly reattach vessels in a safe and convenient manner.

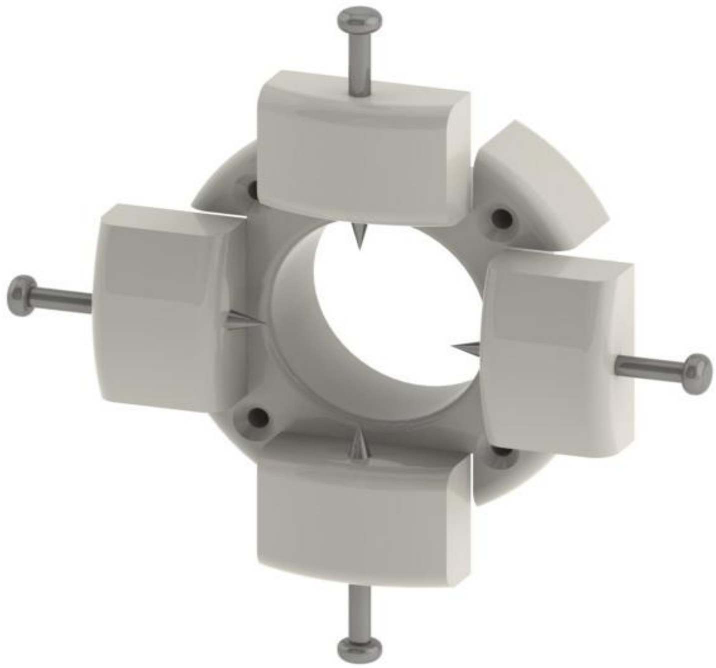

Figure 1.1: Image showing the VCD ready to be installed on a vessel

The vascular coupling device is designed to reduce the amount of time it takes to connect two veins or arteries. The method that has been developed reduces the amount of time in the operating room, can be done by less skilled hands, works for both types of vessels, and provides a better seal than a standard hand sutured anastomosis.

Using the VCD, the lumens of the vessels are the only surface that comes into contact during the anastomosis. Once the couplers are pressed together the device provides an intima-to-intima anastomosis and the blood flow only contacts the inner surfaces of the vessels. This reduces the risk of thrombosis since the blood flow is not exposed to any foreign material [7, 24, 41]. Another advantage is that the couplers are designed to keep the vessels open. This reduces the chance of blockage or collapse at the point of coupling.

1.5 Manufacturing

The VCD and its supporting installation tools were created using rapid prototyping methods. Rapid prototyping techniques were developed in the 1980s. It is an automated process that ads material to create a desired form [42-45]. Rapid prototyping is used to create physical object from drawings. The rapid prototyped parts can be used for a range of purposes. On one end, the parts can be created as a physical representation of a design. The parts can be prepared and painted to create nearly exact visual replicas of the final part. These parts are mainly for show and rarely have the material properties and function of a final product. On the other end of the scale, parts can be made to function properly, but may not have the appearance of the final part. With recent advances, some final products can be made using rapid prototyping. In general, rapid prototyped parts are either visual replicas or functioning parts. Both of these types of parts were created using rapid prototyping for this project.

Initially the parts needed for the VCD were created using a 3D printer. This method is a popular and effective way of making custom products rapidly. The use of this technology has grown by leaps and bounds in the last decade. In fact, CNN reported that custom 3D printed glasses were the hottest accessory on the runway at Fashion Week 2012. Within a few years, many homes across America are projected to have their own 3D printers [46]. This method has become so popular with consumers and designers because it is easy to use. A 3D design is created and then simply printed out using an additive process [47]. The printer lays down a bead of material which gradually builds up to form the desired part. There are currently printers that are able to create features with accuracy range of only a few micrometers.

Laser machining was used extensively in the manufacturing process of the couplers and installation tools [48-53]. Easy access to a laser cutter allowed for development of unique manufacturing processes. The first process creates plastic hinges by laser obliteration and the second is a method of backside alignment which leaves very little room for error. The third and final technique in referred to as 3D assembly. It creates parts that are stronger and in less time than a 3D printer. All three of these techniques were created out of necessity specifically for the VCD project but can be adapted to a wide variety of applications.

1.6 Chapter Outlines

The following chapters discuss the creation and evaluation of the VCD and its installation tools. Chapter 2 was written as a paper that will be submitted to medical device journals and is an overview of the project. Chapter 3 describes and evaluates the tools used to install the coupler and Chapter 4 presents manufacturing techniques used in this project. The fifth and final chapter describes future work and a summary of this document.

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CHAPTER 2

METHODS, DEVICES, AND APPARATUS FOR PERFORMING A VASCULAR ANASTOMOSIS

2.1 Abstract

In microsurgical operating room environments, it is often necessary to cut and reattach arteries and veins multiple times during surgery. The current method of vessel anastomosis is traditional hand suturing. This technique requires complex microscopes and very skilled surgeons to efficiently perform the operation. The scope of this venture is to create a commercially available vascular coupling device (VCD) that would allow surgeons to quickly attach vessels together. The VCD is designed to increase reliability and reduce the amount of time spent on connecting two vessels. Hand suturing a vessel is time consuming (20-30 minutes) and difficult (requires a skilled surgeon). The method that has been developed can reduce the amount of time in the operating room by 75% and provides a better seal. Once the couplers are pressed together, the device provides an intima-to-intima anastomosis and the blood flow only contacts the inner surfaces of the vessels. This reduces the risk of thrombosis since the blood flow is not exposed to any foreign material. Another advantage is that the couplers are designed to keep the vessel open which reduces the chance of blockage or collapse at the point of coupling.

2.2 Introduction

The goal of this project is to create a vascular coupling device (VCD) that will allow surgeons to quickly reattach vessels in a safe and convenient manner. The vascular coupling device is designed to reduce the amount of time it takes to connect the two vessels. The method that has been developed reduces the amount of time in the operating room, can be done by less skilled hands, and provides a better seal than a standard hand sutured anastomosis.

During replantation and free tissue transfer surgeries, vessels need to be reconnected. The current method of attaching two vessels is hand suturing [1-3]. This technique requires complex microscopes and very skilled surgeons to efficiently perform the operation. Multiple vessels need to be reattached during replantation and free tissue transfer procedures. Each of these connections requires a microscope, a skilled surgeon, and around 30 minutes in the operating room [1].

Using the VCD, the lumens of the vessels are the only surface that comes into contact during the anastomosis (Figure 2.1). Once the couplers are pressed together the device provides an intima-to-intima anastomosis and the blood flow only contacts the inner surfaces of the vessels. This reduces the risk of thrombosis since the blood flow is not exposed to any foreign material [4-6]. Another advantage is that the couplers are designed to keep the vessels open. This reduces the chance of blockage or collapse at the point of coupling.

There are currently devices that are used to attach veins to each other in a simple process [4, 6-11]. This device may also be used to connect arteries but is used less because it requires multiple steps that negate the benefits of using the device. Difficulties

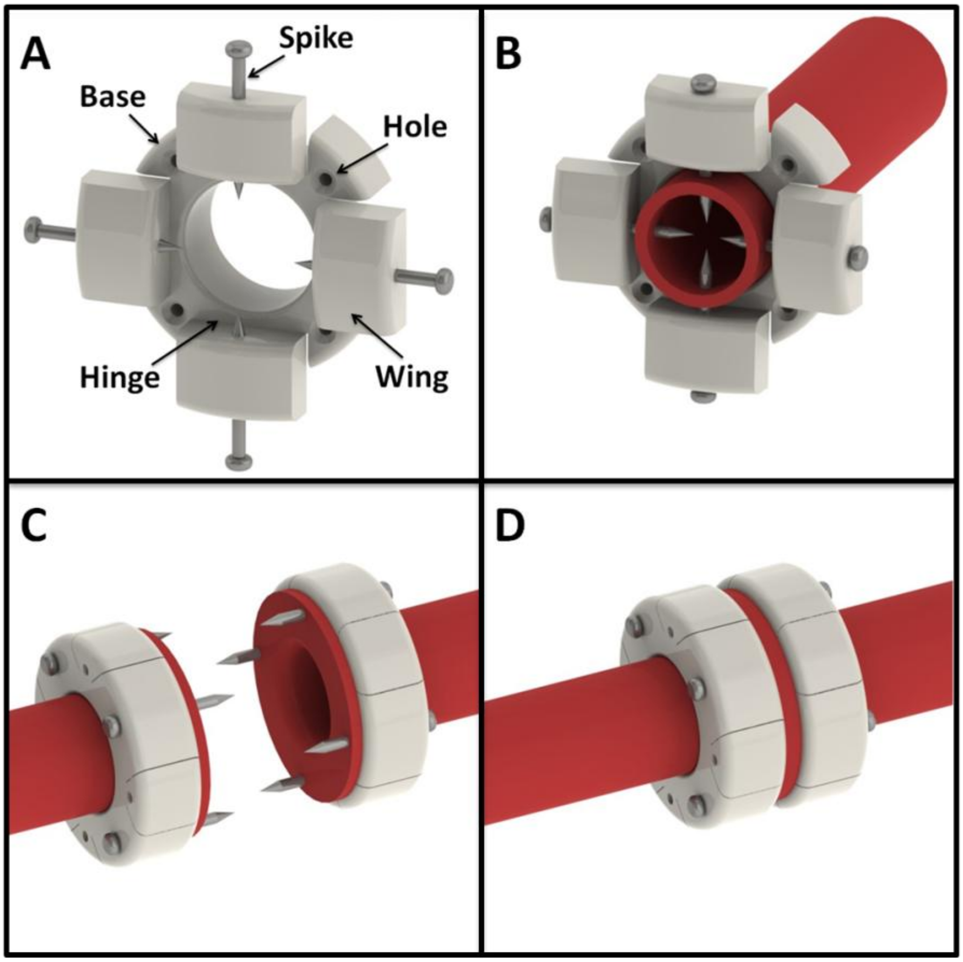

Figure 2.1: Overview of VCD. (A) Open position (B) Punctured vessel (C) Wings are folded back and couplers are ready to install (D) Coupled vessel

arise because the arterial wall's elasticity and thickness cause the artery to slip off of the spikes during the installation process. This has been overcome by using rubber bands to secure the artery to the individual spikes [12]. The process has proven to work but it is rarely used because of its complexity and time requirements. The VCD allows both veins and arteries to be connected by nonsurgeons. It provides a better seal and requires less than half the time it takes a specialized surgeon to connect a vessel.

2.3 Modeling

2.3.1 Coupler

The design of the device is divided into two major parts: the vascular coupler and its installation tools. The vascular coupler has a ring shaped base that is sized appropriately for the vessel it is installed on (Figure 2.1). The base ring is made of biocompatible materials, such as polytetrafluoroethylene (PTFE) or high density polyethylene (HDPE), and will stay in the body indefinitely. The base has a smooth inner surface that allows the distal end of the vessel to be passed through without damage. Stainless steel spikes are attached to the base via hinged wings (Figure 2.1). The wings allow the spikes to be pressed perpendicularly though the vessel wall using an installation instrument. The wings are attached to the base by a plastic hinge which allows the wings to rotate the 90° needed for proper installation. Using the installation instrument, the vessel wall is evenly stretched open as the wings are rotated and lock into place when the spikes are parallel to the vessel. The same procedure is performed on the opposite vessel with another coupler. At this point the two couplers are brought together and the inside walls of the vessels are aligned and pressed together (Figure 2.1). The spikes of each coupler imbed in corresponding press-fit holes on the opposing coupler. The couplers are held in place by the friction created by the press-fit holes of the bases on the couplers' spikes.

Since there are different sized vessels that typically range from 1.5mm to 5.0mm, the VCD will be produced in several sizes[8, 11, 13]. In order to quickly match the vessel diameter to an appropriate coupler size, a special tool can be used as a measuring gage. This gage is used to measure the outside diameter of the vessel so that an appropriate coupler can be chosen. The outside diameter of the vessel must be approximately that of the inside diameter of the coupler base structure. The elasticity of the vessel wall will allow the vessel to be stretched to the nearest size of VCD. This method conveniently allows for vessels of different diameters in an allowable tolerance to be joined together while keeping the center of the vessels aligned with each other.

2.3.2 Installation Tools

The coupler is held during the installation process using the base tool. This tool provides the base which the cam tool rotates around. The cam tool inserts the spikes perpendicularly into the vessel. This is done by rotating the tool about the axis of the vessel 90°. As the tool rotates, the spikes are pressed into the vessel by the inner cams of the tool. If the vessel walls are too thin to support themselves during the spike installation, the anvil tool should be used. The anvil is inserted into the end of the vessel before the cam tool is rotated so the vessel does not collapse when the spikes are pressed through it. The anvil tool is especially useful for veins and thin walled arteries. Once the spikes are inserted the cam tool is removed by opening the tool similar to a pair of pliers. The wing tool is used once the cam tool is removed. This simple tool is pressed over the wings to simultaneously rotate the wings 90° and hold them in place while the couplers are pressed together. Tweezers may be used to pull the vessels though the coupler and for various adjustments throughout the installation process. Currently the tools are designed to provide specific tasks. In the future, the functions of the tools will be combined into one or two instruments.

2.3.3 Vessels

Fresh cadaver arteries were used to determine what type of tubing would be best suited for bench testing the device. Two types of tubing were used during testing. The most readily available tubing was made of latex (McMaster-Carr, Santa Fe Springs, CA). The tubing could be acquired in sizes similar to the range of arteries in both diameter and wall thickness. Its limitations were that it was much more difficult to puncture than vascular tissues and that it stretched quite a bit. The second type of tubing used was expanded-polytetrafluoroethylene (ePTFE) (Zeus, Orangeburg, SC). This tubing is currently used in vascular grafts and has similar material properties to arteries. It was used as a substitute for cadaver arteries for coupler assembly tests because it behaves most similar to an artery. The weakness of using ePTFE is just that, it is weak and fragile compared to actual tissues. It was not used in the strength tests because it would tear under a very minimal load compared to the cadaver vessels.

2.4 Methods

2.4.1 Fabrication

The couplers are made from PTFE, which is commonly referred to by the trade name Teflon. PTFE was selected because of its high melting point and its compatibility with laser machining. When struck by a CO2 laser (VLS3.60, Universal Laser Systems, Scottsdale, AZ) the PTFE is obliterated and can be accurately shaped[14]. This was not the case with other polymers that were tested; polypropylene (PP), acrylonitrile butadiene styrene (ABS), poly(methyl-methacrylate) (PMMA), HPDE, and various forms of nylon. The PTFE reacted consistently to laser exposure. Though a trial and error process, a defined depth of cut could be reached. This was utilized to create the plastic hinges necessary for the wings to rotate.

The couplers were cut from the PTFE using three different drawing layers. One layer was a through cut. The other two layers were used to create a cross-hatch of 20µm. One layer consisted of horizontal lines; the other was used for vertical lines. The cross-hatching was used to create the cuts used for the plastic hinges. The cuts for the plastic hinges were created first using two passes of the laser. Once these were completed the through cuts were made using a single pass. The couplers were then cleaned with a brush and compressed air to remove PTFE dust created by the laser machining. The spikes were created by cutting pins to length and sharpening them with a small abrasive wheel attached to a rotary tool (Dremel, Mount Prospect, IL). They are then pressed into the holes cut by the laser.

The tools were also created using the CO2 laser. The drawings were made in AutoCAD 2010 (Autodesk, San Rafael, CA) and were used to create the tools using different layers of acrylic (McMaster-Carr). The layers were then glued together using acrylic specific glue (Weld-On 4, IPS, Compton, CA). The layers were aligned though the use of small alignment holes created when the layers were cut out. A sewing needle was then pressed though the holes during assembly to line up the various parts of the tools. The pivot point of the installation tool was created by cutting out a smaller than needed hole with the laser. It was then drilled to the final size and treaded using a tap.

2.4.2 Mechanical Testing

The coupler was first tested to prove that the concept behind it was viable. In the initial stages, this was done without the use of any supporting installation tools. A basic leak test was performed by blocking the one end of a cadaver artery and applying a low pressure (3-7 psi) air source to the opposite end. The coupler was submerged in a beaker of water to observe if the air was leaking from the anastomosis. Any leaks could easily be identified by air bubbles leaving the vessel.

Once the coupler proved to work, specialized support tools were developed. A basic application process was determined for the tools and was used to install the couplers on fresh cadaver arteries and large veins. The coupling process was then timed to determine how the coupler and tools compared to traditional hand suturing.

The force required to separate the couplers was tested by applying a tensile force to the VCD. The couplers were hung from a clamp. They were pulled down gradually by adding weight at a slow rate so strain hardening would not be an issue. Originally ePTFE tubing was joined using the couplers and tested. The tubing was clamped and pulled to determine the separation force. This method did not work because the tubing tore out before the couplers separated. Another method was derived to determine the separation force. Small diameter wires were placed around each of the couplers to simulate the tubing and provide a much stronger interface for the separation test. Once the couplers were separated the required weight was measured using a digital scale (SR-20 Hanging Scale, American Weigh, Norcross, GA).

The amount of fluid allowed to leak from the anastomosis was also tested. A parallel plate apparatus was created to determine the leak rate of the couple at different separation distances. Holes were created in the plates to allow a coupled test vessel to be held securely by the plates. Three screws on the apparatus were adjusted to allow for different separation distances of the plates. The vessel was simulated using 3/16" latex tubing. Pressurized water was applied to one end of the test vessel and the other end was plugged. See Figure 2.2. The water was pushed though the gap in between the couplers. The water was pressurized to three different levels corresponding to an extended range of acceptable blood pressures (3, 5, 7psi). The amount of water was measured and then pushed through the gap in the couplers. This process was timed to determine the flow rate of the water coming out of the gap.

A flow test was done to determine how the coupler would affect blood flow though a vessel. The vessel was again simulated using 3/16" latex tubing. A coupled length of tubing was compared to an uncut piece of tubing of the same length. The couplers were pressed shut so that the couple would not leak. Pressurized water at 3, 5, and 7 psi was pushed though the simulated artery. The difference in pressure before and after the simulated artery was determined using a pressure gauge. This was done using both the coupled and control tubing.

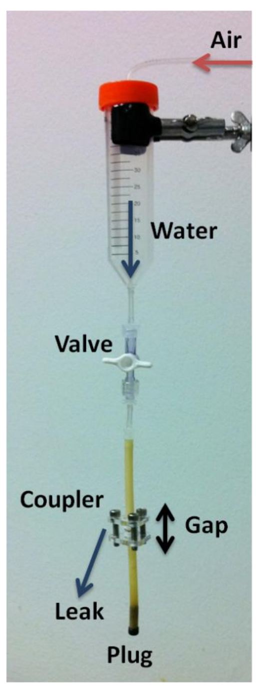

Figure 2.2: Separation test setup

The tensile strength of the hinges that connect the wings to the base was found to determine if they would break before couplers would separate. The base of the coupler was clamped in a vise and weigh was hung from the wing until failure. The weight was then measure to determine the force required to separate the hinge.

2.4.3 Medical Testing

Coupled cadaver arteries were examined using micro-CT, micro-MRI, and histology. The samples were delivered to the specialists located at the University of Utah Hospital's research facilities. They were examined by the experts and the results were reported. Basic testing was done on cadaver pigs to determine the ease of use and functionality of the couplers and support tools. These tests were done on pigs that were euthanized for other research projects.

2.5 Results

2.5.1 Fabrication Results

Multiple versions of the VCD were successfully fabricated. Figure 2.3 shows a set of five winged couplers ranging from 1.5-7 mm inner diameter fabricated using a CO2 laser. The tools were also created using a CO2 laser. The 3D shapes of the tools were created by stacking cut layers of acrylic and gluing them together. This method allowed for multiple tool iterations in a relatively quick timeframe.

Figure 2.4 shows the application sequence of the coupler on a section of latex tubing. The tools and coupler would be handed to a surgeon as a single unit (A). The base tool and cam tool are combined and the coupler is loaded onto the base. The tubing

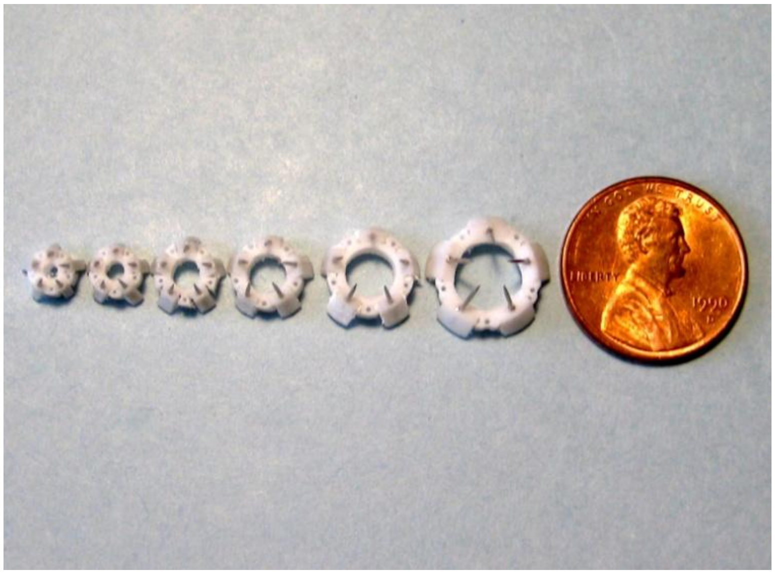

Figure 2.3: Set of five winged couplers for vessels ranging from 1.5-7 mm

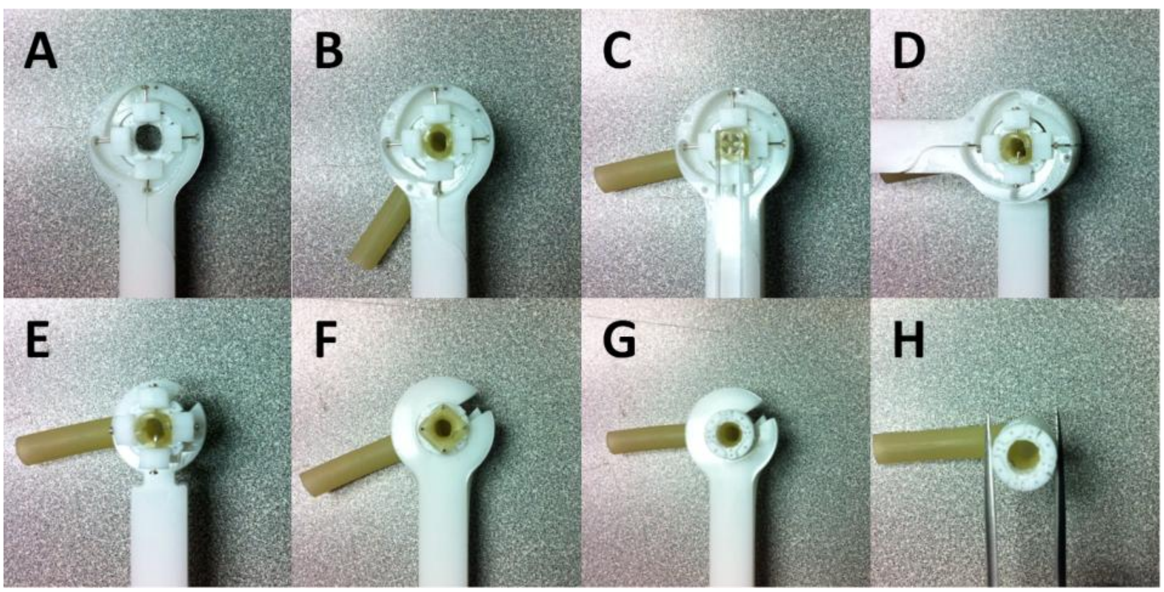

Figure 2.4: Application sequence of the coupler and tools using latex tubing

is inserted though the coupler (B). The optional anvil tool (C) can be installed if the vessel wall needs to be supported. At this point the cam tool is rotated and the spikes are pressed though the tubing (D). The cam tool is removed (E) and the wings are depressed using the wing tool (F). The second coupler is installed and pressed onto the first coupler (tubing was removed to show internals) (G). The tools are then removed and the couple is complete (H).

2.5.2 Mechanical Testing Results

Figure 2.5 shows a 5mm fresh cadaver artery that was cut and reconnected using the VCD. The basic leak tests demonstrated that the VCD was able to securely attach the arteries together and provide a tight seal. In all four trials the arteries failed under high pressure and the couple stayed intact. The coupling process was timed for various sized vessels and the connections were all completed in less than ten minutes. The tests were performed by engineers who had no prior surgical experience.

The separation test was done using both PTFE and HDPE couplers. An average pull test of four devices resulted in 4.6 pounds for PTFE couplers and 7.4 pounds for HDPE couplers.

The data gathered from the leak test is provided in Figure 2.6. It is shown as the flow rate of the water verses the gap between the couplers. The test was performed three times at each gap length and at three different pressures.

The flow test results are plotted in Figure 2.7 as the pressure difference across the test vessel versus the fluid pressure. The results show a coupled piece of tubing and an uncut control piece.

Figure 2.5: Fresh 5mm cadaver artery with VCD installed

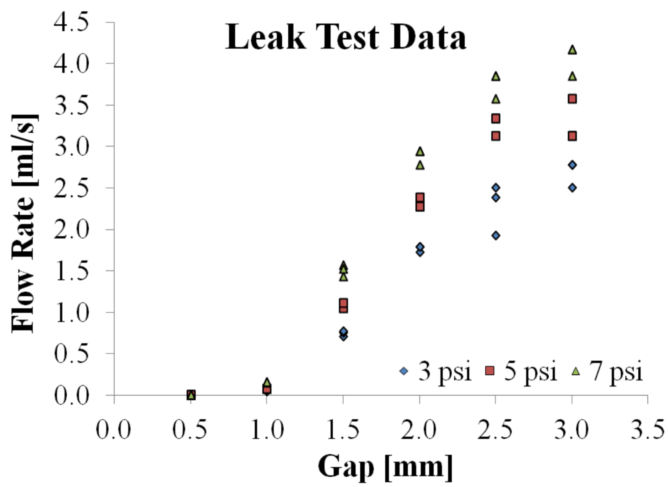

Figure 2.6: Plot of the leak test data showing flow rate versus gap size

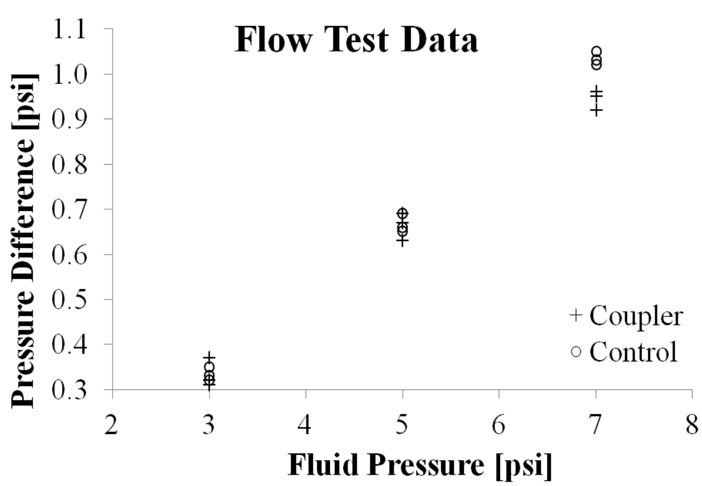

Figure 2.7: Plot of the flow test data showing the relationship between pressure difference versus fluid pressure over coupled and control vessels

The hinge test was performed only on HDPE couplers. The resulting average failure force of six individual hinges was 3.9 pounds.

2.5.3 Medical Testing Results

The results from the CT scan and histology work are shown in Figure 2.8. The MRI did not provide any usable results. The image created by the machine was a white orb without any distinguishable features. This was due to the metal spikes in the VCD. The CT scan also had severe artifacts created by the metal spikes, but provided some useful data. The scan revealed that the metal spikes from the joined couplers correctly form a concentric ring. This shows that the spikes are correctly bedded into the press-fit holes and pose no threat of puncturing the vessel or surrounding tissue. However, the artifacts hide any data that could be gathered on the patency of the anastomosis.

The histology work provided the most valuable information. It confirmed that the anastomosis was patent. The artery was not constricted by the couplers and held the artery open. A sectioned sample of a 5mm cadaver artery coupled using the VCD is shown in Figure 2.8.

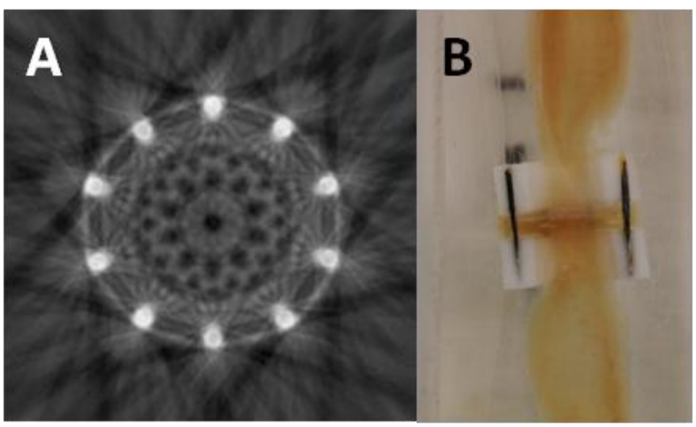

Figure 2.8: Medical testing results. (A) Results from the CT scan and (B) a section of the histology sample

2.6 Discussion

The couplers' design went through much iteration. The number of spikes on the coupler was varied from four to six. The higher the number of spikes the more difficult alignment of the couplers was. Four spikes were decided on for the final design because they sufficiently held the vessels open and allowed for the easiest alignment. The majority of the couplers were made from PTFE. This material was used because it was compatible with laser machining and prototypes could be made quickly. The PTFE is not the ideal material for the couplers as it is too soft and does not work well with press fit holes.

HDPE seems to be the most promising base material. It has been used in similar devices and has shown good results in our testing. The HDPE couplers that we tested were made by traditional machining. This process was time consuming and expensive so only a few of this type of couplers were made. Once a final design has been selected an injection mold will be used to create the couplers.

The concept behind the tooling design proved to be solid. Having the spikes pressed into the vessel at a 90° angle consistently gave good results. The cam design pressed the spikes in easily and at a uniform position relative to the end of the vessel. This is important because the uniformity allowed the vessel to open evenly when the coupler wings were depressed. The tools worked well in a laboratory setting but be need to be refined for use in surgery. With a little work the base and cam tools could be combined into a single instrument. The wing and anvil tools could also be combined into a second instrument. This would simplify the application sequence and reduce operator error. Work is currently being done to combine all of the installation tools into a single unit that actuates with a single motion.

The method of laser cutting and assembling layers of acrylic worked well. This allowed for multiple iterations of the tools to be made quickly. A 3D printer was used in the early development of the tools but lacked the strength to support the coupler. Once refined, the tools will be machined from medical grade steel.

The coupler proved to be a viable method of performing end-to-end anastomosis. The first couplers that were created were assembled by hand. Even performing the anastomosis by hand proved to be faster than hand suturing. The basic leak test showed that the coupler was strong enough to withstand any fluid pressure that could be applied by the body. It also showed that the VCD sealed the anastomosis.

Once the tools were made it was clear that the VCD was much faster than other methods of anastomosis. With practice a couple could easily be made in less than five minutes. With further refinement of the tools the process is expected to take less than three minutes. The times were based on tests done by engineers, showing that with a small amount of training even nonsurgeons could perform this normally difficult procedure.

The separation test was done on two different material types of couplers. The HDPE couplers required 61% more force than the PTFE couplers. This result was not surprising as the PTFE is a much softer material. The VCD will most likely be mass produced using an HDPE injection mold. The force required to separate both types of couplers is more than adequate to secure a vessel under normal conditions.

The results from the leak test data show that even with a gap of 1mm between the couplers there is virtually no leak. Fluid pressures as high as 7 psi were used in this test. The high pressures demonstrated that the anastomosis would not leak at exceptionally high blood pressures. In order to keep the couplers within the acceptable sealing gap, radial grooves will be created on the spikes. The spikes will still be pressed into the opposing coupler, but the radial grooves will cause the couplers to snap into place when they are pressed together.

The flow test showed that the coupler did not restrict the artery significantly different than a complete vessel would. This was tested multiple times at various pressures and the coupled vessel showed little difference from the intact vessel. In fact the test showed that there was a slight decrease in pressure drop with the coupler installed. This could be due to the coupler stretching open the radius of the vessel at the anastomosis which would allow the fluid to flow with less resistance. The differences that were measured were minimal and it can be concluded that the VCD has little effect on the flow.

The strength of the hinges on the HDPE couplers was tested to predict if the hinges would fail before the press-fit spikes would separate. The hinges provided more than enough strength to stay intact while the couplers were separated.

The CT scan provided some useful data on the orientation of the spikes in the installed VCD. This information could also be gathered by visually inspecting the device. This method will not be used in further testing. The MRI provided no useful data and will not be used again. The histology work provided the most useful data and will be used in the future to determine the state of anastomosis performed using the VCD.

2.7 Conclusion

The VCD has shown that a vascular anastomosis can be performed in a safe and rapid manner and that a relatively difficult microsurgery can be performed by non-surgeons. The application of the current device requires less than five minutes with minimal operator training. The installation instruments are currently being refined down to one or two multifunction tools. With these improvements, the application of the VCD could require less than three minutes. The device will save valuable operating time during reconstructive surgery. The VCD is in the process of becoming a valuable tool for the medical community.

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CHAPTER 3

COUPLER INSTALLATION TOOLS

3.1 Introduction

The purpose of the coupler tools is to provide an easy method of attaching and coupling the VCD. While it is possible to attach the VCD with basic tools like tweezers, the VCD loses its advantages over hand suturing without the support of specialized tools. The tools need to be simple and intuitive so they do not complicate the anastomosis and be easier to work with than a typical suture. The tools will obviously come with a set of instructions, but the tools themselves need to be intuitive. The functions of the tools need to be simple to use but may be complex in actuation. The more the tools can do, the more consistent the procedure will be.

Multiple tool designs were considered and created in this work. To include each design would be counterproductive; however, two tool sets proved to be functional. The design and function of these sets is described in this chapter. The first set is referred to as the Basic Tool Set. In this set, the coupler is held by the hold tool and its wings are at a 45° angle. The artery is installed by pressing the install tool into the coupler and depressing the wings. The second set uses cams as part of its actuation. This set is referred to as the Cam Tool Set. The cam tool presses the spikes in at a 90° angle. Both methods have their advantages and disadvantages. The tool sets are discussed below in the order they were created.

3.2 Basic Tool Set

The Basic Tool Set requires four basic tools. The tools are solid and have no moving parts. There are two hold tools, one for the left and another for the right. There are also two installation tools. They each serve the same purpose, but are also left and right specific. Figure 3.1 shows the complete Basic Tool Set.

3.2.2 Basic Coupler

The coupler that is used with the Basic Tool Set is slightly different than the coupler used with the Cam Tool Set, referred to as the VCD. The coupler used with the Basic Tool Set is referred to as the Basic Coupler. The main difference of this coupler is

Figure 3.1: From top to bottom: Right hold tool, right installation tool, left installation tool, left hold tool

that the spikes are fixed in the wings and do not slide like the spikes in the VCD. Another slight difference is that there are grooves around the outer diameter of the base which correspond to the pillars of the Basic Hold Tool. A picture of the Basic Coupler is provided in Figure 3.2.

3.2.3 Hold Tool

The purpose of the hold tool is simply to hold the coupler. The coupler is installed onto the tool and is held in place by a set of pillars (see Figure 3.3). The tool must not block the inner diameter of the coupler base, because the vessel is fed through the inner diameter of the coupler while it is installed on the hold tool. The base of the hold tool has a pinned hinge that connects to the installation tool when needed. Figure 3.1 shows the right tool set coupled and the left tool set uncoupled using the pinned hinge. When the installation tool is needed, it is connected at its base by inserting the pin of the hold tool into a hole in the base of the installation tool. When connected, the heads of the tools properly align and allow for precise movement. The lengths of the tools

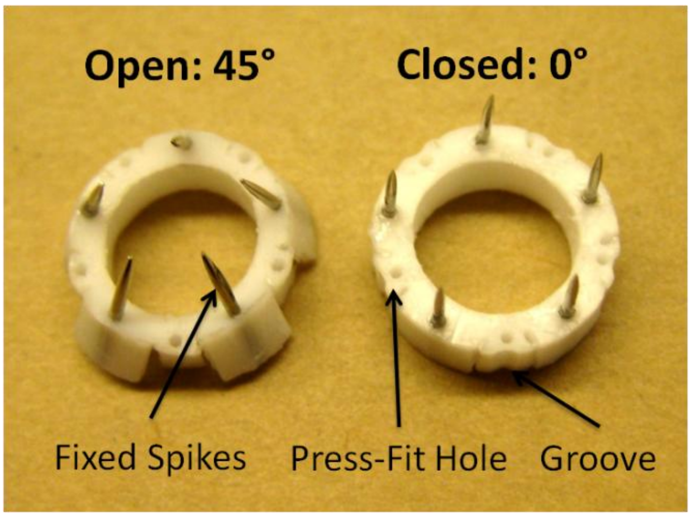

Figure 3.2: Picture showing the basic coupler in its open and closed position

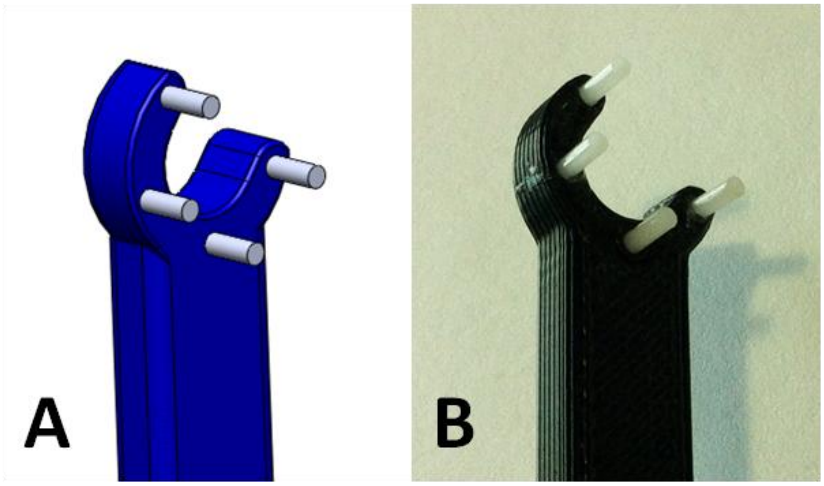

Figure 3.3: Images of hold tool. (A) 3D model showing the tool head of the hold tool. Blue parts are 3-D printed, white are premade pillars (B) Hold tool created using 3D printer

create a sufficiently large radius so that the motion of the heads of the tools is nearly linear in the range of operation. The linear motion is crucial to the installation process because of the precise interaction between the installation tool, the coupler base, and the spikes.

3.2.4 Install Tool

The install tool has two major functions. The first function is to press the vessel onto the spikes of the coupler. The second function of the installation tool is to depress the wings of the coupler (Figure 3.2). First, the vessel is pressed onto the coupler's spikes by a cone in the center of the tool head. This cone is referred to as the anvil. The anvil has grooves that run from its tip to its base that correspond to the spikes of the coupler (see Figure 3.4). The grooves allow the spikes to penetrate the vessel wall as the anvil advances into the inner diameter of the vessel. Once the spikes have engaged the vessel, the installation tool begins to depress the couplers wings. This action is performed by a ring of pillars that are concentric to the anvil. As the installation tool is

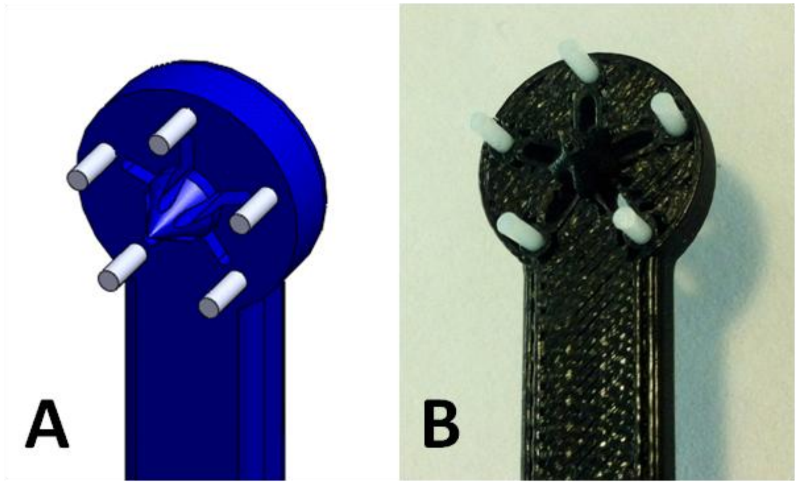

Figure 3.4: Images of installation tool. (A) Drawing of tool head of the install tool showing center anvil and wing closure pins (B) Manufactured device

advanced further toward the coupler, the pillars cause the wings to rotate the spikes. The wings rotate from their initial open position of 45° to their closed position of 0° (see Figure 3.2). The 0° position means the spikes are parallel to the vessel wall and the center axis of the coupler. The pillars on the installation tool contact the face of the hold tool once the wings have fully rotated.

3.2.5 Manufacturing

The tools were designed using SolidWorks 2010 (Dassault Systèmes, Waltham, MA) and created by a 3D printer. The 3D printer was a convenient method of creating the tools because a complete set could be printed in less than three hours. This convenience allowed for multiple designs to be tested in a relatively short period of time [1]. However, the 3D printer has its limitations [2, 3]. Features smaller than 0.010" were unable to print, or were greatly distorted. An example of this is the installation tool's anvil. The anvil required multiple attempts for the printer to properly create its grooves. Another disadvantage of the 3D printer is that the material was not very strong. Thin features are very brittle and would often fail. Because of the brittleness, the pillars on the hold and the installation tools were created using solid HDPE pins. The pillars were removed from the tool drawings and replaced by pilot holes. Once the part was printed the holes were drilled to the proper size and the HDPE pins were glued into place. The pins were much stronger than the thin features created by the printer. The added strength allowed the tools to function properly.

3.2.6 Application Sequence

The application sequence of the basic coupler is shown in Figure 3.5. The steps for completing a vascular anastomosis using the basic tool set are given below:

(A) The coupler is inserted into the hold tool, which is connected to the installation tool. The vessel is then pulled so that it protrudes past the sharp end of the spikes a distance of 1.5 times the radius of the vessel. The vessel is held in place by the coupler spikes.

(B) The installation tool is then used to press the vessel onto the anvil causing the spikes to engage the vessel. As the installation tool is advanced the spikes puncture the vessel and the wings are depressed. The wings rotate from their initial position of 45° to being fully closed.

(C) The installation tool is removed and the same process is completed on the other artery using the second set of tools.

(D) Once both couplers are installed, the hold tools are connected as the base pivot.

(E) The hold tools are brought together and the couplers' spikes are pressed into their corresponding press-fit holes on the opposing coupler.

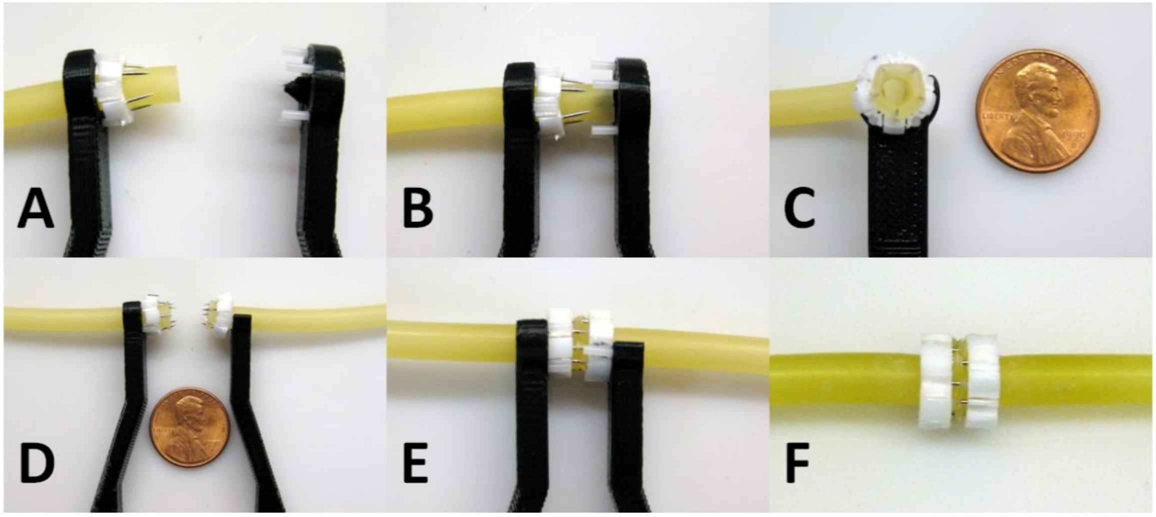

Figure 3.5: Composite photo showing the application sequence of the basic tool set

(F) Once the couplers are fully mated, the hold tools are removed and the couple is complete.

3.2.7 Results

The basic coupler and tool set required less than 15 minutes to complete an anastomosis. While the process worked, it did not complete the task easily. There were many factors that kept the process from functioning smoothly. The first issue was that the coupler would fall out of the hold tool when the vessel was introduced into the coupler. The coupler would then have to be removed from the vessel and reinstalled in the hold tool until the vessel was properly positioned. Another issue came about during the installation process. The angled spikes slid down the vessel wall and did not engage at an equal distance from the end vessel. This slippage caused the vessel to stretch unevenly when the wings were rotated. The uneven stretching would often cause the vessel to be pulled from one or more of the spikes. Another major issue was that there was nothing to keep the wings in the closed position. The spikes were difficult to align and required a great deal of manual manipulation to fit into the press-fit holes.

3.3 Cam Tool Set

3.3.1 Introduction

The cam tool set was designed to alleviate the issues of the basic tool set. It consists of six tools: right and left base tools, the cam tool, anvil tool, and the right and left wing tools (see Figure 3.6). While the number of tools grew from four to six, the installation process was simplified and improved. The tools were created to perform a specific part of the anastomosis. The base tool holds the coupler more securely than the hold tool. The basic installation tool was split up into three separate tools, the cam tool, anvil tool, and the wing tool. The cam tool allows the spikes to be pushed directly into the vessel wall which keeps the spikes at a consistent distance from the end of the vessel. The anvil tool became optional due to the improvement of the spike penetration. The wing depressor tool was separated so it could be kept in place while the couplers were pressed together. Even though there are more tools in the cam tool set, they perform their basic functions better. By breaking each part down, the steps to complete the

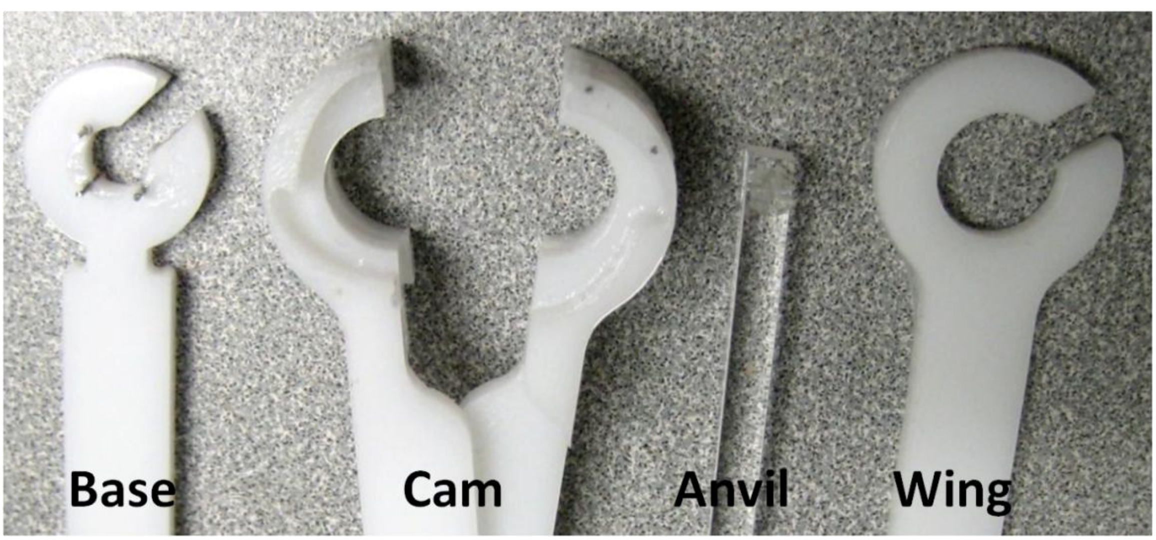

Figure 3.6: The cam tool set showing the right base, cam, anvil, and right wing tools

anastomosis can be streamlined. As these tools evolve they will be recombined into one or two tools that perform all of the proper functions determined by the cam tool set.

3.3.2 Cam Coupler

The cam coupler is known as the VCD (Figure 3.7). It is similar to the basic coupler except for a few differences. The open position of the wings is 90° instead of 45°. This position allows the spikes to penetrate the coupler perpendicular to the vessel wall. The spikes on the VCD are allowed to translate through the wing. This action is necessary to allow the vessel pass though the coupler while the wings are at a 90° angle. When the cam tool rotates it pushes the spikes through the wings and into the vessel. The number of spikes was reduced to four. This reduction was done to decrease the amount of spikes that need to be aligned when the couplers are pressed together. These changes were made out of necessity to address the issues found with the basic coupler.

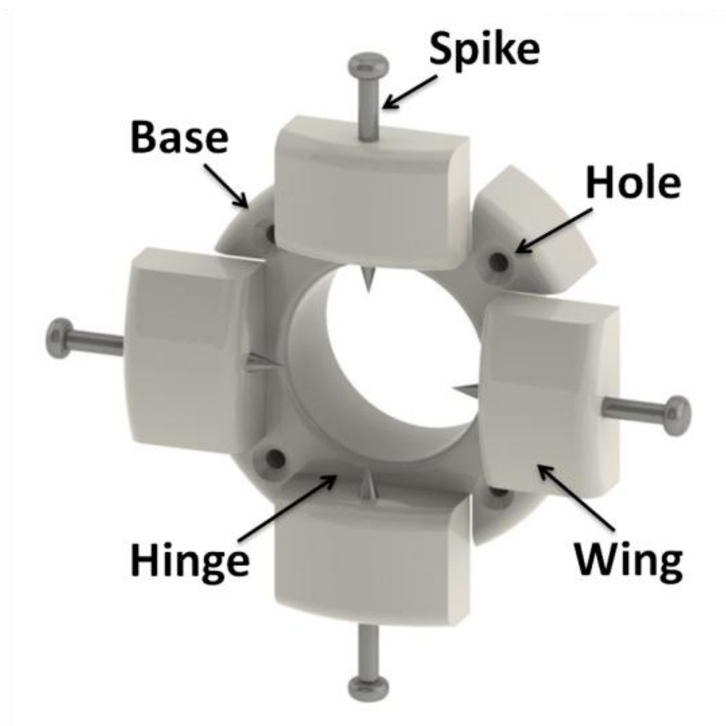

Figure 3.7: Image identifying major parts of the VCD

3.3.3 Base Tool

The base tool holds the coupler during installation (Figure 3.6). The base tool is a relatively simple device that provides the base for all of the other tools. It holds the coupler in place by having four small pillars that are pressed into the back of the coupler, which hold it securely. The vessel is allowed to pass through the coupler when it is mounted in this tool. It has a cutout section which allows the vessel to exit the tool when it is removed.

3.3.4 Cam Tool

The cam coupler uses four cams to press the spikes through the vessel wall at a 90° angle. The spikes are inserted by clamping the cam tool around the base tool and rotating it 90°. The tool also supports the wings and keeps them perpendicular to the vessel wall. The cam tool fits around the base tool. This step is done by opening up the cammed head like a pair of pliers (see Figure 3.8). They are then closed around the circular head of the base too. The base tool provides the axis of rotation for the cam tool. Once the cam tool has been rotated and the spikes have penetrated the vessel wall the cam tool is removed. The cam tool is removed by simply opening the tool.

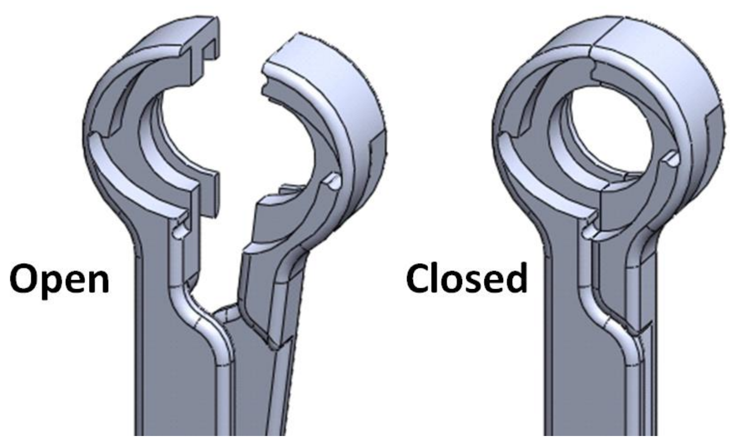

Figure 3.8: The tool head of the cam tool is shown in its open and closed positions

3.3.5 Anvil Tool

The anvil tool is optional. It is used if the vessel is not rigid enough to support itself while the spikes are pressed through the vessel. It is especially useful for veins and thin walled arteries. The tool itself is very simple (Figure 3.6). The head of the tool is a cylinder that is about the same diameter as the inner diameter of the vessel. The cylinder has grooves cut out of it which allow the spikes to stick through the vessel.

3.3.6 Wing Tool

The wing tool performs the basic function of pressing down the wings (Figure 3.6). The inner diameter of the tool head is the same size as the diameter of the VCD. The inner ring has a slight chamfer which helps center the tool on the coupler. Once centered, the tool is simply pressed on the coupler. This step rotates the wings to the closed position and secures them until the tool is removed.

3.3.7 Application Sequence

The application sequence for the cam tool set is shown in Figure 3.9. The steps for completing a vascular anastomosis using the cam tool set are given below:

(A) The base and cam tools and are handed to a surgeon as a single unit with the VCD mounted on the hold tool.

(B) The vessel is inserted though the coupler until one-half of the vessel diameter protrudes past the face of the coupler.

(C) The anvil tool is installed by aligning its handle with the handle of the base tool and pushing the anvil into the lumen of the vessel. This step is optional and should be performed if the vessel wall needs to be supported.

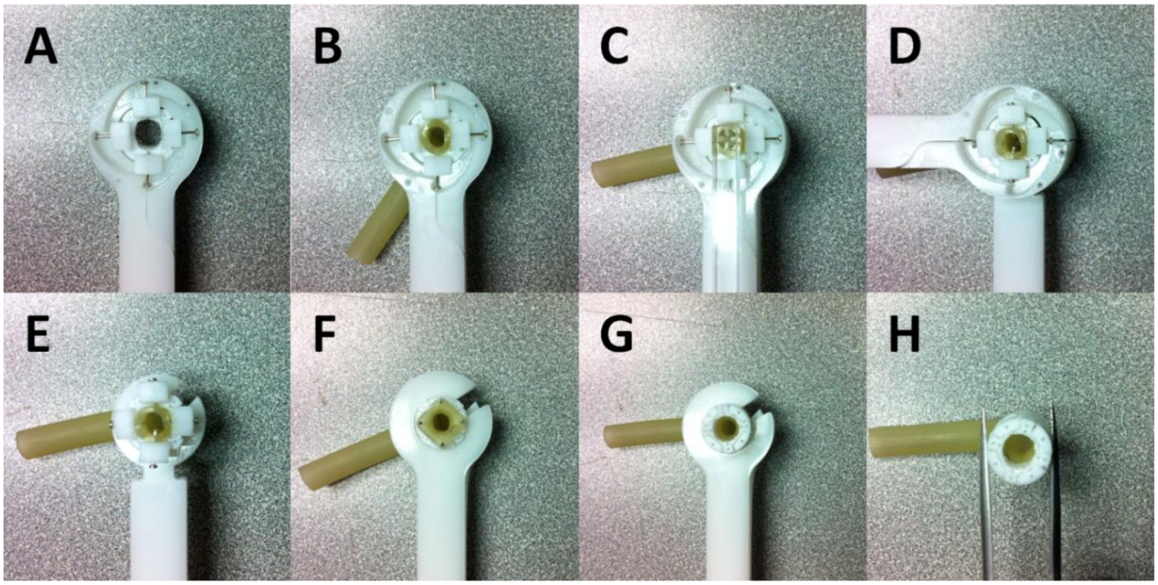

Figure 3.9: Composite photo showing the steps of the cam tool application sequence

(D) At this point the cam tool is rotated clockwise 90° which presses the spikes through the vessel wall.

(E) The cam tool is removed by opening it like a pair of pliers

(F) The wings are depressed by pushing the wing tool over the coupler as it is still mounted to the base tool

(G) The second coupler is installed using the process above. Once installed the couplers are pressed together to form an intima-to intima anastomosis (vessel was removed to show internals).

(H) The tools are then removed and the anastomosis is complete.

3.3.8 Results

The cam tool set has many advantages over the basic tool set. With only a few practice runs the cam tool set was able to perform an anastomosis is under five minutes. While there are more tools involved in this set than the basic set, they perform their functions with better accuracy and consistency. The steps of the anastomosis are more defined using the cam tool set. By having each step separated, the characteristics of each step can be improved. Once they are functioning properly and consistently, work will be done to combine the steps into a single apparatus.

3.4 Discussion

The basic tool set went too far, too quickly. While it completed the same functions as the cam tool set with fewer tools, it did not provide good results. It required 15 minutes to perform an anastomosis if the tools and couplers functioned properly. This amount of time did not provide much of an advantage over hand suturing, and any advantage that was left was diminished by the inconsistency of the tools. However, the basic tool set provided a good base for the design of the cam tool set and is a vast improvement over the previous design work.

The main issues with the basic tool set were that coupler was not held securely by the hold tool, the angle spikes did not penetrate the vessel in a consistent manner, and the alignment of the spikes with the press-fit holes was extremely time consuming. These issues were addressed with the cam tool set. The coupler was held in place by the base tool using press-fit pillars that were inserted in the back of the coupler. This method of securing the coupler was just a temporary solution but it proved to be effective for the time being. In future designs the coupler will likely be held by clips that surround the outer diameter of the coupler. This feature will be easier to create when the tools are machined from metal. The tools' features will be more accurate and smaller features will be incorporated. The metal will also provide enough material strength for the smaller features to function properly.

The penetration of the angled spikes was the biggest concern with the basic tool set. The other issues were solvable with simple fixes. With the angled spikes there was no sure way of puncturing the vessel. The spikes seemed to catch at random, if they caught at all. This problem is most likely due to the variability of the vessels. Tests done on tubing were much more consistent than tests on cadaver vessels. On the vessels, some areas are soft and sticky while others are tough and slippery. The soft areas were easily punctured by the spikes while the hard areas tended to slide past the spikes. This discrepancy caused the spikes to engage unevenly or to not engage at all.

The spike penetration issue was addressed by the cam coupler and tool set. The spikes now enter the vessel at a 90° angle. This method ensures that the spikes are inserted at a consistent distance from the cut end of the vessel. The variability of tissue structure or thickness is taken out of the equation. The down side to the cam coupler is that it is more complex than the basic coupler. Since the spikes move there is a chance that they will fall out and be lost in the operating room; however, this issue has never happened during testing. The advantages of the pins entering the vessel at 90° seem to outweigh the concerns with the moving spikes.

The alignment of the spikes and press fit holes was addressed by two means. The number of spikes per coupler was reduced from five to four. This reduction eliminated the alignment of two of the spikes. The second method was accomplished by the wing tool. It pressed the wing closed and then held them in place. This addition made it much easier to align the couplers and press them together. It is expected that couplers made from harder materials like HDPE will be easier to align than the soft PTFE couplers that are currently being used. The soft couplers allow for a significant amount of spike movement. The harder couplers should eliminate this movement and allow for easier alignment.

3.5 Future Work

Work is currently being completed to consolidate the number of tools used in the installation process. Two approaches are being taken. One is an extension of the cam tool set and the other from the basic tool set. The basic tool set is being integrated into a linearly actuated device. The coupler is pushed from behind through a series of steps that mimic the functions of the basic tool set. The biggest concern with this method is that the spikes will still be entering the vessel at a 45° angle. While adjustments to the anvil have been made, further testing will determine if the angled spike will still be an issue.

The second tool set being developed is an extension of the cam tool set. It still uses cams to press the pins through the vessel at a 90° angle, but it reduces the number of tools needed. The cam has been modified to close the coupler wings as well as insert the spikes. The anvil tool has been incorporated into the cam tool as well. With further development this tool could insert the spikes at a 90° angle with the use of only two tools. Both methods look promising and it is expected that the final tool set will be a combination of the two emerging sets.

3.6 Conclusion

The tool sets described in this chapter allowed an anastomosis to be competed in less time than traditional hand suturing. The limitation of the basis tool set provided enough information to create the cam tool set. This set was able to perform an anastomosis in less than 3 minutes. With further refinements it is expected that only one or two tools will be needed during to perform the operation. In any case, the tooling needs to be attractive to its potential users, mainly micro-surgeons. It has to be on par with currently available surgical tools. As a final design is approached the tools will need to be made out metal that can be properly cleaned and prepared for human trials. The cost of manufacturing these tools will be much higher than the rapid prototyping methods that are currently being used. The manufacturing will need to be outsourced and the base material cost will be much higher. The next chapter explains in detail the manufacturing processes that have been used and what will need to be done in the future.

3.7 References

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CHAPTER 4

MANUFACTURING TECHNIQUES

4.1 Introduction

Manufacturing played an important role in the success of the VCD. New parts and tools had to be created in ways that have never been done before. Design changes were common due to the trial and error approach used to create the VCD. Parts needed to be made quickly and often. Rapid prototyping was used extensively to create a large quantity of couplers and tool sets. At first, the parts were created using a 3D printer. The parts provided physical feedback, but lacked the strength needed for testing. This issue led to the development of new laser machining techniques that were used to create stronger prototypes in less time than 3D printing [1].

4.2 Plastic Hinges

The couplers were first created using a 3D printer. The shape of the larger couplers was acceptable for early proof of concept testing, but the material properties of the parts were not acceptable. The 3D printer used ABS plastic to create the parts. The parts were much more brittle than typical ABS [2-5]. The narrow hinges created by the printer failed in only one or two cycles. Different 3D printers were outsourced, but the parts were still brittle and creating a plastic hinge that lasted longer than a few rotations could not be made. The hinges needed to be made and injection molding was not financially possible. Another method had to be used.

The second method of creating the couplers was done by modifying premade parts. The base of the coupler was made from ABS plastic spacers (Ace Hardware, Salt Lake City, UT). These were available at a local hardware store in a wide variety of sizes that corresponded nicely with the range of base sizes needed. The plastic spacers were cut by hand using a razorblade to resemble couplers. Hinges were created by pressing the blade though spacers until the desired hinge thickness was reached. The plastic hinge created using this method was much better than the hinges created by 3D printing. The hinge would function for 10-20 cycles before failure. The cut spacers functioned properly because the bulk material properties of the plastic were maintained.

The CO2 laser cutter VLS3.60, Universal Laser Systems, Scottsdale, AZ) was first used to cut holes for the spikes in the handmade couplers. This method was a great advantage over drilling the holes. The laser allowed the design to simply be drawn in AutoCAD (Autodesk, San Rafael, CA). The only issue with this method was aligning the spacers with the laser. To help with this issue a template was created that held six spacers at a time. This template made it so the set could be aligned instead of each individual spacer. The template saved a lot of time but it still required precise alignment that was difficult to establish. This method was imprecise and was not acceptable beyond a very basic proof of concept.

After having some success using the laser to cut the holes, the idea or creating the entire coupler using the laser arose [6]. This thought led to a trial and error approach that ended in success. A method of using the laser was developed to create complete couplers without the need for alignment. The convenience, speed, and price at which the couplers could be created were much better than any other method that was available. The key to using this method is material selection.

In order to use the laser to create an entire coupler, a sheet of ABS plastic (McMaster-Carr, Santa Fe Springs, CA) was obtained. The sheet was the same thickness as the spacers. The idea was to cut out the coupler from behind starting with the spike holes and wings. Once these features were created the coupler would cut from the ABS sheet by a through cut. This cut proved to be difficult as the ABS material would melt and become brittle from the heat of the laser. Many attempts were made using various speeds and powers to improve the cuts but the couplers never reached an acceptable level.

Multiple different materials were tried, such as: HDPE, Acrylic, Polypropylene, Nylon, and PTFE (McMaster-Carr, Santa Fe Springs, CA) [7-9]. PTFE was the only material that produced a consistent cut. The other materials would melt and reform once the laser had passed. The difference with the PTFE is that the laser obliterates it. It never reaches the liquid phase. As the laser hits the PTFE it changes from a solid to a gas. This transformation helps the machining process because it does not melt and refill the cut areas like other materials. The PTFE material is simply obliterated by the laser. Another difference that the PTFE had while being cut was that it left a film of PTFE dust at the material removal site. This dust was the material that had been obliterated by the laser and then had reformed once it had passed. The surfaces of the parts made from PTFE would be covered with this dust and would require cleaning. The parts were cleaned using a brush and compressed air. Once the dust was removed, the surfaces of the PTFE parts were smooth and consistent.

Since the laser cut the PFTE so precisely, a method of creating the entire coupler using the laser was developed (Figure 4.1). The most innovative part was creating the plastic hinges. These parts were created blind cuts into the material that stopped at a specified depth (Figure 4.2). By varying the speed and power of the laser, a specific depth could be reached [10, 11]. Areas that needed to be cut were crosshatched in AutoCAD with a line separation of 20µm. The crosshatch consisted of horizontal and vertical lines that were on two separate layers. During the machining process the horizontal and vertical crosshatches were cut separately. With proper settings the laser machining of the blind cuts was very accurate and could be used to create the thin plastic hinges for the wings.

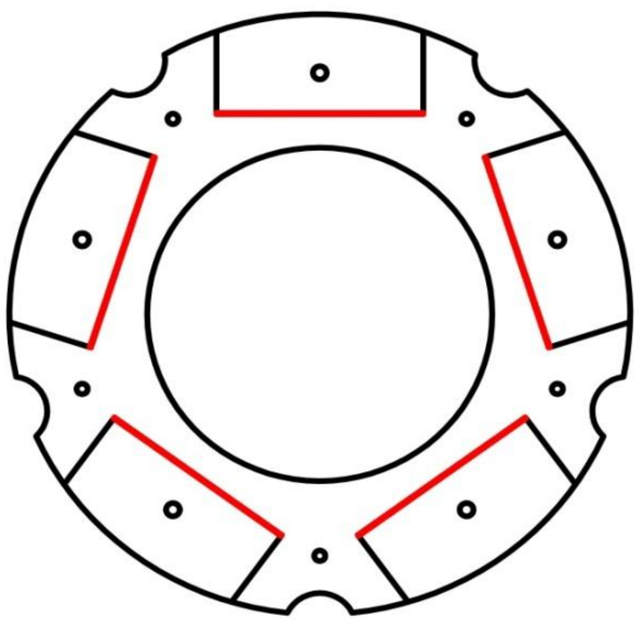

Figure 4.1: Drawing file used to create an entire coupler using a laser. The red lines are blind cuts and the black lines are through cuts

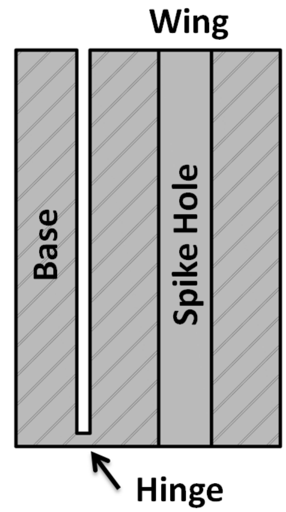

Figure 4.2: Cross-section of the plastic hinge created by a blind cut of the CO2 laser

The couplers were cut out from behind using the laser. The blind cuts were done first so that the coupler would be held stable by the bulk material. Using two passes the material was removed to create the plastic hinges. A typical 3mm thick bulk piece of PTFE could be consistently machined down to 30µm or less in a matter of seconds. The accuracy of the laser allowed only the area directly behind the material to be removed with very little variation of cut thickness. The walls of the cut were nearly vertical. Once the blind cuts were created the through cut was performed. This final cut was done as a single pass and was perfectly aligned with the blind cuts since the bulk material could be left in its original position. The heat from the laser did not affect the surrounding material and left it with the bulk properties.

The process of creating an entire coupler from a sheet of material takes less than one minute. Multiple couplers can be cut at that same time which reduces the manufacturing time even further. A single 12 by 18 inch sheet of PTFE can make hundreds of couplers. Various sizes of couplers can be cut at the same time. Basically any shape consisting of blind and through cuts can be designed and created in a matter of minutes. This method was a huge advantage over the other processes that were previously used to create the couplers. The turnaround time was nearly zero, and since the infrastructure was already in place the cost was extremely low.

4.3 Doubled Sided Technique

This technique was developed to create blind holes on the front of the coupler for the spikes to be mounted in. Originally the holes were cut all the way through from the back side of the coupler. The spikes were inserted and glued into place. The glue did not hold the spikes well enough to prevent them from breaking free during installation. To solve this problem holes were cut only partially though the coupler. The holes had to be on the face of the coupler so it required the couplers to be flipped and realigned with the laser. The issue with machining both sides of the coupler was the alignment. This obstacle was overcome by using the double sided technique developed for the laser.

The first step is to cut out blind holes from the bulk piece of material which is securely mounted in the bed of the laser by tape. The holes are cut out along with any other blind feature desired for the front side of the specimen (Figure 4.3). Small holes with diameters comparable to needles are created in the space between the part and a perimeter. The perimeter surrounds the part and the alignment holes. After the necessary machining has been completed on the front side of the part, the perimeter is then cut out. Another layer is used to create corresponding holes in a new location on the mounted bulk material. The original part is then flipped over and mounted onto the bulk material using pins. The pins are placed through the alignment holes and hold the part in place.

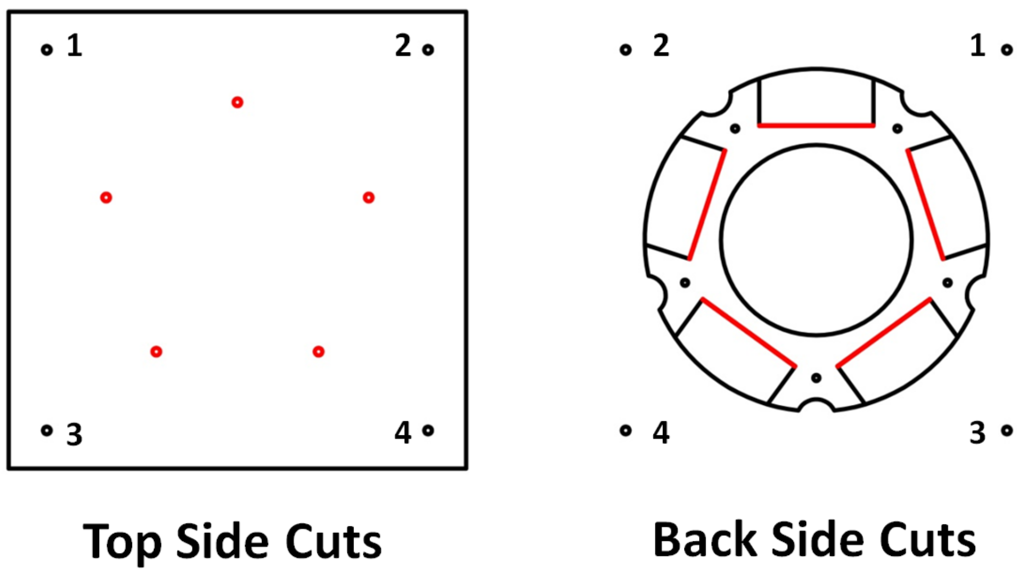

Figure 4.3: Drawing file showing the top and bottom cuts and their alignment holes. Through cuts are black, blind cuts are red.

The laser is then raised the thickness of the material. All the blind cuts are made followed by the through cuts. At this point the part is complete.

The front side machining of multiple parts can be accomplished at the same time. Once the front side is complete, only one set of alignment holes can be made in the bulk material. The parts can then be flipped over individually and mounted to the alignment holes using the pins. After one part is finished another part can be flipped over and mounted to the bulk material the using the same holes. This method provides an extremely accurate method of laser machining both sides of a part. The double sided technique combined with the bind cuts allow for complex parts to be made very quickly and in large quantities.

The main limitation of this method is the choice of materials. In testing, only PTFE performed favorably with laser machining. The material is soft and has a low coefficient of friction. It deforms easily and is not compatible with press-fit holes. Once the PTFE is compressed it tends to stay there due to its low modulus of rigidity. The benefits of using PTFE include the ability to rapidly create devices using laser machining and its biocompatibility. The PTFE parts are not ideal for long term use as couplers, but other medical devices could be created using this method. Parts could potentially be created and cleaned as they were needed. This possibility could allow custom parts to be made while a patient is in the operating room.

4.4 3D Assembly

A third technique for creating 3D shapes with the laser cutter was developed. This method is more versatile and can be used with any material that the laser will cut. This type of rapid prototyping is referred to in this paper as 3D Assembly. One major advantage of using this method is that it provides better material properties than other methods, such as 3D printing. Using 3D printers, the material is usually weaker than what would be expected from a part that was molded from the same material. The material properties of the prototype created by laser cutting and assembly are very similar to the bulk material from which the parts were cut.

The 3D printer that was used to create the early prototype tools used ABS plastic; however, the parts were much more brittle than typical ABS. This brittleness caused the tools and couplers that were printed to be too weak to function correctly. Different 3D printers were outsourced, but the parts were still brittle. Another method had to be used. A method of using the laser cutter was also developed for the tools. The tools were created out of acrylic sheets. The thickness of the sheet depended on how thick a specific part needed to be. Thinner parts were cut out of thinner material, and thicker parts used thicker sheets. The variable thickness of the sheets and the complex patterns created with the laser tool allowed for intricate tools to be made. The tools could be cut out and assembled in minutes. They were also more robust than any of the tool created by the 3D printers. The bulk material kept its superior material properties rather than degrading them with the printing process.

The tool shapes were cut out of the acrylic. Included in these shapes were alignment holes. The holes would allow for pins to be placed through the stack of materials in order to align the different layers of the tools. The pins provided excellent part alignment and could either be removed after the layers were glued together or left in to provide extra strength. The glue was acrylic specific glue which softens the acrylic and bonds it together as it dries. The joints created with the glue were stronger than the bulk material.

The acrylic parts were much stronger than similar parts created by the 3D printer. The strength of the laser machined parts allowed for smaller features to be used. It also allowed the tools themselves to be thinner. In order for the printed tools to be useful for testing, the thickness of the tools had to be increased greatly. The laser cut tools could be much thinner and were a better representation of the final tools. They were much more convenient to use because their sized could be reduced.

The greatest advantage of the laser cut part was the ability to create them rapidly. Designs could be drawn in AutoCAD, cut out, and assembled in less than 15 minutes. If a design did not work right, it could be modified and a new part could quickly be made. This convenience allowed for a rapid succession of design improvements to the tools. Instead of waiting around for mail order parts, changes could be made immediately. The number of tool iterations was crucial to the success of this project. An exploded view of the layers used to create the cam tool is shown in Figure 4.4. The parts were aligned using pins and glued together with the acrylic specific glue.

4.5 Conclusion

Rapid prototyping machines have proven to be a very cost effective and simple way to create products from virtual designs. The machines allow for parts to me made quickly and with little effort from the user. Three-dimensional printing is a great example of an effective rapid prototyping method. It can be used to create designs that are impossible using traditional machining. The parts can be printed in a large variety of materials; however, the material properties of the parts are inferior to the machined or molded parts. This chapter has discussed three laser machining techniques that were used to create prototype couplers and tool sets. The methods used created parts with superior material properties in less time than a 3D printer. These methods were used to create

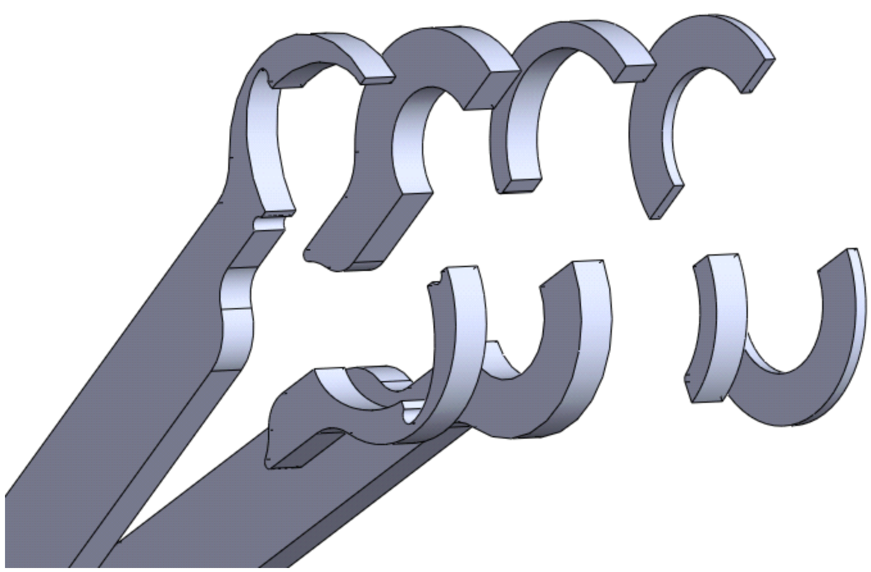

Figure 4.4: Exploded view of the layers used to create a complex cam tool

complete couplers from HDPE with functional plastic hinges in less than a minute. A backside alignment technique was used to machine both sides of the coupler accurately. A large number of tool designs were created and tested using the 3D layering process. A new design could be drawn and created in less than 15 minutes. The processes helped bring the VCD to into reality and cam be used in any project where multiple iterations are needed.

4.6 References

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CHAPTER 5

CONCLUSION

5.1 Conclusion

The VCD has demonstrated that it can perform a vascular anastomosis in a safe and rapid manner. It has also shown that a relatively difficult microsurgery can be performed with relative ease. The application of the current device requires less than five minutes with minimal operator training. The minimal time and training compare favorably against the 30 minutes and advanced skill level required to hand suture vessels.

The tools developed to support the VCD play a critical role in its success. While the tools are not yet fully developed they have captured the key movements needed to accurately and consistently install the VCD. A large amount of time and iteration went into the design and understanding of the requirements of the toolset. This understanding led to the development of a system that accurately performs vascular anastomosis. The installation instruments are currently being refined down to one or two multifunction tools. With these improvements, the application of the VCD could require less than three minutes.

Manufacturing the VCD and its supporting tools required innovation. Originally the parts in this project were created using traditional rapid prototyping techniques such as 3D printing. These parts were weak and did not fulfill the design requirements of the parts. Methods were developed to overcome the shortcomings of 3D printing using laser machining. Through the use of laser machining, fully functional parts were created. These parts required the development of three laser manufacturing techniques. The first technique was used to rapidly create plastic hinges from bulk plastic material. The second technique describes a method of double sided machining and the third is a method of rapidly creating 3D parts by assembling layers of laser cut material. The development of these techniques greatly added to the success of the VCD and has proven useful in additional projects.

The manufacturing techniques developed during this project are useful in a wide variety of future design projects. They allow complex parts to be created efficiently, and in a cost effective manner. The newly developed techniques provide a better option to quickly iterate a design build when a laser cutter is available. In many projects, the design process can become very iterative and time consuming. Using the knowledge gained in this work, such as the ability to rapidly produce plastic hinges, design engineers have a cost effective prototyping advantage over the methods that are currently being used.

This project was most successful when it was considered a system. The coupler and tools were developed separately for a large portion of the project. Advances were made during this time, but the problem was never solved. Once the mindset of treating the problem as a system was applied, the work progressed much faster and the design improved to a fully functioning system. It is recommended to continue to develop future designs as a system and not as individual parts. This mindset can also be applied to many other engineering problems. Parts are made to function as a system, and they should be designed as such. Focusing on one part of the design without considering the rest will result in a system that will not function properly.

The difficulty of the tooling design was underestimated at the beginning of the design process. The problem needed to be considered a system. Once a systematic approach was taken, a functional design was established. The design came from multiple iterations and evaluations. Future VCD designs should be based on this work to avoid unnecessary repetition. Following the manufacturing innovations discovered in this project will provide a good method to further advance the design. The coupler and installation tools will be successful when considered as a system.

5.2 Contributions

The work that was accomplished during this project will have a lasting effect on those who follow. It provides a solid design that provides a strong base for future products. The current design of the VCD has all of the necessary functions to provide a safe and effective vascular anastomosis which compares favorably to all existing methods. With further refinement, the design will become a valuable tool for micro surgeons. The intellectual property developed at the University of Utah has pending patents that will provide useful funding for future projects.

The VCD design is not the only gem being left behind. The rapid prototyping techniques developed during this project have been used on many different projects since their development and will continue to be an asset to the engineering community. Using a laser cutter to create plastic hinges, 3D features, and complex 3D parts is an innovation that will continue to be developed for this project and for projects in the future.

5.3 Future Work

Three areas are in need of greater focus for the VCD: tool refinement, device testing, and mass manufacturing design. The installation tools for the VCD need to be combined into one or two simple tools that are superior to other devices on the market. Along with mechanical design superiority, the VCD and installation tools need to be aesthetically and financially appealing to hospitals and doctors. These considerations are crucial for the future success of this device.

The second area of focus is testing. In order for the VCD to be used in the medical field it will need to thoroughly verified and validated. The device currently proves that its concept is valid by reducing the amount of time and effort required to perform an anastomosis. The VCD needs to be tested and developed further in order for it to become an asset to the medical community.

The third area that will need to be addressed is mass manufacturing design. Once basic testing has been completed, a large number of units will need to be created. This will most likely require the development of injection molds and advanced machining procedures. The spikes will need to be made quickly and consistently. The installation tools will need to be machined and assembled. Once these manufacturing methods are established, the VCD will be ready to provide the world with a safe and efficient method of performing vascular anastomosis.