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Development of a New Guidewire Torque Device

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Development of a New Guidewire Torque Device

by

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of the requirements for the degree of
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DEDICATION

This thesis is dedicated to my loving parents, Luis and Nuris, my sisters, Leslie and Clarissa Rigaud, my nephew, James Luis, my grandfather Luis Rigaud Sr., and my supportive and caring fiancé, Jared Sanders. You all have given me the support and guidance I have needed to get through these difficult times. There are no words to express my gratitude and appreciation. I love you all dearly.

I would also like to dedicate this thesis to my beloved grandparents who are no longer here to share in all my success, but who I know are always watching and guiding me from Above, Evaristo Frias, Maria Estrella, and Gladys de Rigaud.

Last but not least, my Lord and Savior Jesus Christ, through You all things are possible. You have paved my way and opened doors for me that I never though possible. Thank you for Your Forgiveness, Your Sacrifice, and Your Love.

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In addition I would like to thank my parents for standing by me and believing in my ability to succeed and for their prayers, support and love through out my educational career. I would especially like to recognize my father who has demonstrated the benefits of hard work and dedication. They have both molded me into the woman I am today and have set the standard of where I hope to be.

Finally, I would like to recognize my loving fiancé, Jared, who has been a consistent driving force in my success. It is due to his loyalty, constant encouragement, direction and love that has gotten me through some of the more difficult times in this process. I attribute much of my success to his support and patience.

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ABSTRACT

Guidewires have been used in many operating rooms by vascular surgeons to assist them in positioning and maneuvering through a tortuous stenosis or lesion to a desired location, and to be used as a guide for the implantation of a catheter. Surgeons are tasked with having to insert a guidewire inside a small cavity, which requires a high level of skill and patience. The insertion of the guidewire is controlled by a torque device, which allows a surgeon to advance, rotate and grip the wet hydrophilic coating of the guidewire. Despite its many advantages, the torque device does, in fact, give rise to many time consuming issues that results in delays to the surgical procedure. One main problem in the use of the torque device is that it is introduced through the proximal end of the guidewire. Therefore, it requires the assistance of another individual, the surgical technician, to advance the torque device from the furthest point away from the patient. Once the torque device is in position, it is up to the surgeon to attempt to control the tightening, advancing and loosening of the device all with one hand. The other, free hand is used as a placement hand to secure the positioning of the guidewire within the patient. Another issue arises in the removal of the torque device, which must be loosened with one hand and slid off the same end it was introduced, often resulting in the unwanted ejection of the guide wire tip from within the patient's body. The process must then commence from the start, resulting in loss of valuable time, and be repeated until the distal tip of the guidewire is secure in the desired location and the catheter can now be introduced.

The main purpose of this research is to investigate, design, and develop a new guidewire torque device to facilitate in a more controlled manipulation of a guidewire by vascular surgeons. Through in-depth interviews with both surgeons and surgical residents alike, direct observational time in the vascular surgery OR (operating room), and I obtained knowledge used as a design basis for the development of the product. For example, observations of relevant medical procedures were also accomplished at Tampa General Hospital to establish a basis for the design, and to assess current vascular surgery medical procedures. Initial design concepts where created using SolidWorks CAD software. After a period of researching and understanding user needs, an assortment of non-slip adhesives where found to be a viable solution to the problem. A characterization analysis was done on the highest rated non-slip adhesive to further define design parameters, and pave the way for FDA approval and product commercialization.

CHAPTER 1

INTRODUCTION

This chapter introduces the motivation behind this body of work and the current challenges faced with the use of a guidewire torque device in vascular surgeries. This chapter then goes on to describe the research objectives and thesis outline.

1.1 Rationale and Motivation

The use of catheters and other endovascular devices, whether diagnostic or interventional, are rarely maneuverable without the aid of a guidewire. Guidewires serve the purpose of creating a pathway to a target point through a tortuous vascular system. Their associated length may be dependent on the requirements of the surgical procedure, yet their intended use of achieving and maintaining critical access across a target lesion is universally expected. Figure 1.1 shown below, depicts a small calcified tortuous iliac artery which is considered one of the most difficult cases seen in a patient. As noted in this figure, calcified arteries are extremely small and very difficult to navigate through. Without proper training or exposure, the force required to navigate through highly compacted arteries could accidently rupture an arterial wall. Calcified arteries tend to get worse over time if not properly treated. This calcification accumulates in a laminar way, inhibiting surgical devices from reaching target organs. The use of guidewires to effectively create a pathway through these systems is highly

desirable and is of great importance to effectively diagnose and treat a patient. Calcification of arterial walls can lead to other complications such as decreased blood circulation, which, if left unattended, could result in a fatality due to high blood pressure, embolism development or blood clot formation.

Figure 1.1 Calcified Iliac Artery [drawing]. Retrieved January 07, 2014 from www.wiley-vch.e-bookshelf.de/products

Access into the vascular system is attained by one of two ways: either through natural orifices or through incision points. One of the more common points of entry is an incision point done on the femoral artery located in the groin/abdomen or upper leg area of the patient. As shown in Figure 1.2, a 3-5 mm incision is made as an entry port into the vascular system. This entry point is made on either the right side or left side of the groin. Most points of entry are located on the right side of the patient due to ease of access for most right-handed surgeons.

However, choice of entry is completely dependent on surgical preference. Two incisions are sometimes done as a precautionary tactic in case there is some sort of occlusion or blockage, which inhibits further use of a particular artery. Having the other incisions open and prepped for entry allows the surgeon to easily transition to the other access port without wasting any time.

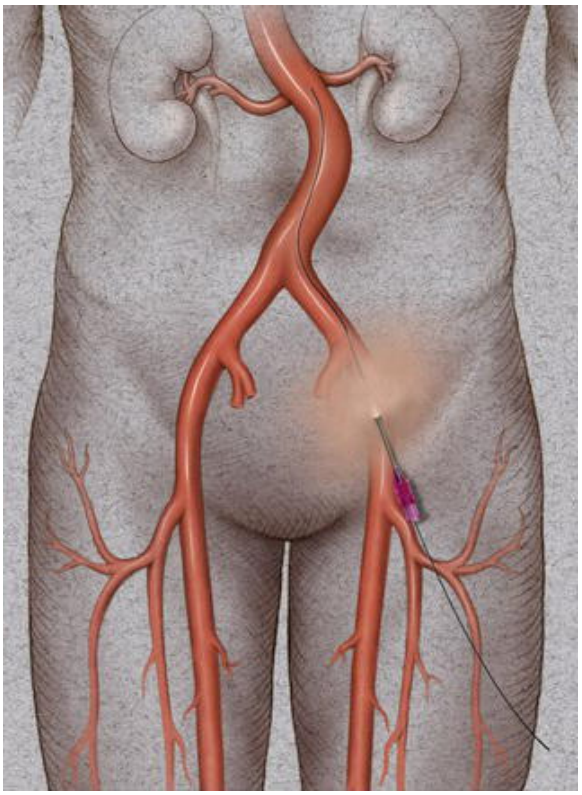

Figure 1.2: Introduction of an Angled Guidewire through Needle [drawing]. Retrieved January 07, 2014 from www. wiley-vch.e-bookshelf.de

There is an assortment of medical/surgical procedures that require the assistance of medical guidewires. For example, in procedures, such as a thoracic endovascular aortic repair, guidewires are required to facilitate and maintain access throughout the entire aorta, sometimes reaching as far as the aortic valve (Khoynezhad, 2009). Guidewires' variation in length is a direct result of its intended use. Target organs are not always close within a reasonable distance to the arterial puncture point, therefore requiring a guidewire that can accommodate for relatively

long distances. Table 1.1 below displays a brief overview of surgical procedures and medical specialties that are recognized for their dependency on guidewires.

Table 1.1: Medical Procedures and Professions that Require the Assistance of Guidewires. Retrieved: April 24, 2014 from: http://www.medicalguidewiremanufacturer.com/guidewire-procedures/

Procedures/Professions	**Description**
Vascular Surgery, Cardiology: Angioplasty, Coronary and Peripheral	Repair or unblocking of a blood vessel
Vascular Surgery: Atherectomy	Removal of plaque from a within a blood vessel
Interventional Nephrology	Improve vascular access to patients undergoing hemodialysis. http://www.medicine.wisc.edu/nephrology/interventional
Interventional Radiology	Employ image guidance methods to gain access to deep interstices of most organ and organ systems. http://www.medterms.com/script/main/art.asp?articlekey=8654
Vascular Surgery: Thoracic Endovascular Aortic Repair (TEVAR)	Treatment of thoracic and aortic diseases, repair embolisms

As can be seen in the table above, each medical procedure and/or profession requires a particular guidewire that is independent from one another. However, selections of such guidewires are not solely contingent upon the surgical procedure. Factors such as a patient's condition and the surgeon's own professional preference must be taken into account when selecting the appropriate guidewire characteristics such as length and diameter (Shannon Micro Coil, 2014).

There are many benefits in using a guidewire before introducing a catheter. One of them being that it is used as a direct guide to a surgical target point. The guidewire, composed usually of a tightly coiled grade 304 stainless steel, is easily maneuvered with the use of a *torque device*.

This torque device provides the following necessary functions such as advancing, rotating, and gripping the hydrophilic coating of a guidewire; therefore, allowing the surgeon to advance, retract and rotate the wire as needed through the desired path. Catheters are composed of a tougher material, usually a plastic material such as polyurethane, which cannot be easily rotated or guided. Thus, by introducing the directional guidewire initially it allows for the surgeon to quickly locate the area of interest more rapidly. The placement of the catheter precedes the guidewire by being threaded over until secured in the desired location.

Guidewire torque devices that are currently used in the medical industry serve their intended purposes by providing an increased level of tractability. However, their design flaws significantly limit their efficiency. The skill level required to be able to use such devices accurately and efficiently takes years to master. Time that could be put to much better use on other more complex aspects of the procedures and not spent on accessory tools such as attempting to manipulate the guidewire torque device efficiently.

For incoming first-year residents, the challenge of gaining knowledge while working in a fast-paced highly demanding environment can be overwhelming to say the least. With many time demands, including regular fourteen-hour workdays, a typical first-year resident does not have the capacity or capability to spend excessive time on training modules. Currently-marketed torque devices require a high skill level in order to be able to tighten, loosen, advance and torque the guidewire with just the use of just one hand. This severe learning curve for incoming first year residents is very daunting, so a new device to allow easy manipulation of guidewires would be quite advantageous.

Another design flaw that contributes to surgical inefficiency is the need for the assistance from a surgical technician in order to thread the current torque devices over the guidewire. The

addition of another individual to aid in the handling of a medical device interferes with the overall surgical time efficiency by not allowing the technician to carry out other important tasks such as the organization, cleaning and preparation of surgical instruments.

As with most medical/surgical devices, a certain level of training is required to ensure proper handling. After a period of adequate exposure, mastery of the skill should be attained. However, despite the surgeon's level of expertise, situations in which the guidewire falls from its desired position are common when attempting to slide the torque device on or off the guidewire. Most guidewire torque devices that are currently used are required to be introduced and removed through the proximal end of the guidewire. There are, however, a few new designs that allow for guidewire torque devices to be attached sideways along any point on the guidewire. These other devices that incorporate a side mounting design, have limitations in that such torque devices must still be tightened, loosened and advanced with the use of one hand, while the other free hand must be used to secure the guidewire's placement from within the patient; therefore, limiting both the diligence and efficiency of the surgical procedure. The market of success of these newer options has yet to be determined.

1.2 Thesis Objectives and Contributions

The purpose of this thesis arose after discovering the need for a new, improved medical/surgical device to better manipulate hydrophilic directional guidewires, trade marketed by Cook Medical to be known as glidewires, during the course of a cardiovascular procedure. So, the main goal was to examine, design, and develop a new medical torque device for improved manipulation of guidewires, having a number of design advantages over what is currently in the market.

Major objectives:

1. To investigate and design an innovative torque device to be employed in cardiovascular surgical procedures involving the use of guidewires in order to improve efficiency as well as effectiveness. In particular, this device will focus on decreasing the time taken compared to existing torque devices, as well as eliminate inefficiencies associated with current devices.
2. To develop an actual prototype of the design in order to evaluate through the use of multiple tests.
3. To determine the market value and estimate the risk of starting a business focused on the manufacturing, distribution, and sale of the developed torque device.

In addition to the above objectives, this Masters work focused on understanding what goes on behind the scenes in the operating room. Specifically, how surgeons and other medical professionals cooperate together, how procedures are performed, and what improvements can be made to benefit both patient and surgeon. The development and application of new devices and processes not only decrease the time in the operating room, but they can also improve outcomes and decrease the time a patient spends recovering.

1.3 Thesis Outline

Chapter 2 discusses, in detail, the types and composition of guidewires, catheters and access needles in order to gain an understanding of the importance of torque devices. Chapter 3 presents many of the current torque devices out in the market along with their limitations and advantages. Chapter 4 discusses the initial work done in the development of the new torque device and how that led to the final stages of development; and describes the comparative

advantages of the newly developed torque device and why it can be considered a superior design. Chapter 5 introduces a feasibility analysis for a startup of a business focused on manufacturing and selling the new torque device. Chapter 6 summarizes the accomplishments made as well as describes the next steps to be taken in the process of developing the new torque device and commercializing it.

CHAPTER 2

LITERATURE REVIEW

This chapter provides a detailed description regarding the basic instrumentation for the use of guidewire torque devices along with addressing the initial steps for arterial access. It also gives an overview regarding the material specifications of a guidewire, catheter and the access needle.

2.1 Vascular Access

There are basic rudimentary steps usually taken to gain access into the vascular system of a patient. The body is composed of three major types of blood vessels: arteries, capillaries and veins. Each one of these vessels connectively contributes to the complex inner workings of the vascular system. Arteries are tasked with carrying highly oxygenated blood and distributing it to different parts of the body. There are larger arteries that stretch out to the extremities and are centrally located within the body which have walls that are thicker, more elastic, and more muscular than those of other vessels in order to withstand high levels of blood pressure (Taylor, 2014). Smaller networks of blood vessels are known as capillaries, which is the most common type of blood vessel in the body, providing the connecting links between arteries and veins.

Capillaries are very small, thin blood vessels that perfuse almost every tissue of the body, connecting arterioles on one end and venules on the other. The primary function of a capillary is to carry blood very near the cells of bodily tissues to exchanges gases, nutrients, and waste

products (Taylor, 2014). Contrary to arterial action, which carries blood away from the heart, veins function to do just the opposite.

Veins are very large vessels that return deoxygenated blood back into the heart to be re-cycled and converted into oxygenated blood, which is then distributed to the body in the arteries. Veins are subjected to lower blood pressures that allow them to be much thinner, less elastic, and less muscular than the walls of arteries (Taylor, 2014). With the assistance of gravity, inertia, a valve system, and the force of muscle contractions, veins are able to push blood back to the heart (Taylor, 2014). Specifically, many veins have small one-way valves that prevent the back flow of blood. With skeletal muscles working in conjunction with this venial system, blood is effectively transported to the heart with ease.

Access to the vascular system is typically preferred through the femoral arteries located in the groin area. As stated by Curtis Bakal, author of *Vascular and Interventional Radiology*, "the large caliber of the femoral vessels allows placement of relatively large-diameter catheters with a low risk of vessel thrombosis." (Bakal, 2002 Pg. 10) In other words, attaining access through the femoral arteries is an ideal option because of its size, which allow multi-sized catheters to be easily inserted. When assessing the correct puncture site of the femoral artery, the most desired area is located below the inguinal ligament [ILL], as shown in Figure 2.1 below, but above the profunda femoral artery [PFA] also shown in Figure 2.1 (Bakal, 2002). However, in obese patients the inguinal crease is not always the appropriate location for femoral puncture due to the fact that the inguinal crease may be located much lower than the actual inguinal ligament (Bakal, 2002). Therefore in such cases, other methods are required in order to determine the location of the common femoral artery such as: fluoroscopic imaging, pulse identification, and the use of surface landmarks.

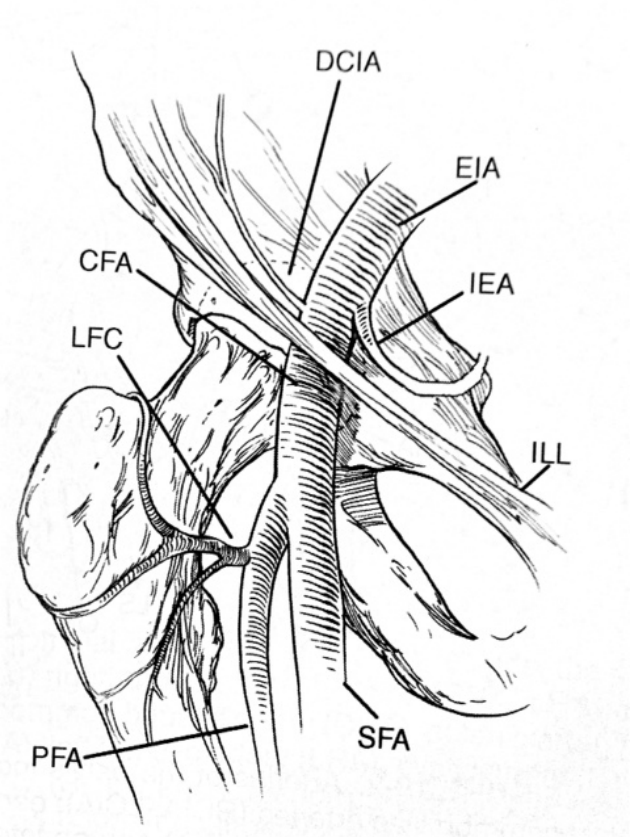

Figure 2.1: Lower Body Extremity [drawing]. (Bakal, 2002)

As stated above, there are many techniques for locating the femoral artery according to the patient anatomy and surgical procedure. However, there is only one technique, known as the Seldinger's Technique that is used to attain arterial access. Such technique involves the use of a puncture needle and a guidewire.

2.1.1 Seldinger's Technique

In 1953, Seldinger described a technique that allowed for access into the vascular system. Such methods required the use of certain tools such as a puncture needle and a guidewire. However, it was not until the 1960s when "interventional" procedures surfaced in the medical industry, and Seldinger's Technique then transformed arterial access from the 1960s to the present day. Vascular surgeons and radiologists alike refer to this technique as the principle

method to perform diagnostic and therapeutic procedures on target organs from a specific puncture point (Bakal, 2002). There are basic rudimentary steps required for accurate execution of Seldinger's Technique. The steps will be explained below according to *Vascular and Interventional Radiology* written by Curtis Bakal (2002).

After a patient's skin is sterilized and draped with a medical adhesive slip, bone structures and the abdomen are visualized under fluoroscopy. This fluoroscopic visual ensures a clear puncture site for the access needle and verifies that there is no fluid in the abdomen that could interfere with the area that is under examination. At this point, the tip of a needle is placed within a vessel using either a single- or double-wall technique. The choice of piercing the first wall versus both walls is dependent on operator preference. However, there are advantages and disadvantages to each which require an adequate examination and assessment of such risks before proceeding with either one.

As shown in Figure 2.2 below, the needle is inserted through the vessel and it is adjusted approximately to a 60-degree angle parallel to the skin. Following the readjustment of the needle, a guidewire is then inserted through the lumen of the needle allowing for a more secured and stable access. Once the guidewire is in position and it has reached its desired location the needle is removed leaving the guidewire in position for a catheter to slide over easily. With tension placed securely upon the guidewire the catheter is advanced until it reaches the target lesion, at that point the guidewire is removed and access is maintained through the catheter. It is imperative to maintain a constant flush of heparinized saline solution through the catheter every 2 to 3 minutes in order to prevent formation of clots within the catheter.

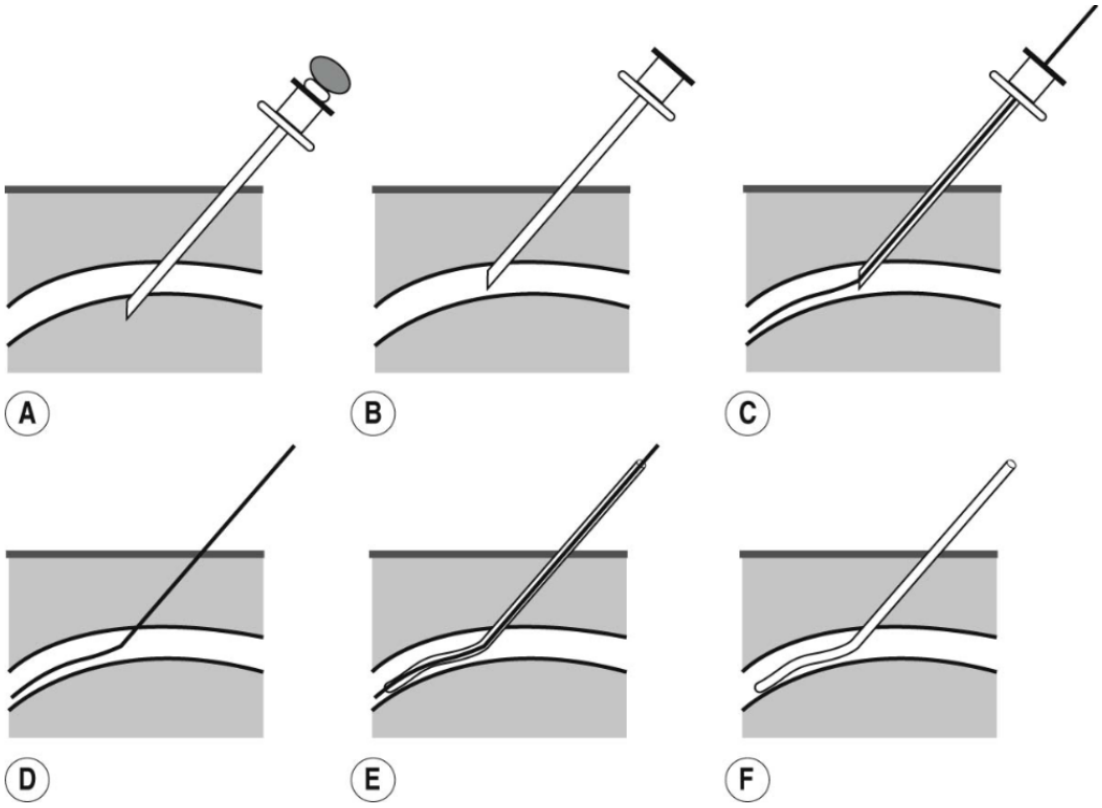

Figure 2.2: Seldinger's Technique [drawing]. Retrieved January 24, 2014 from: https://www.inkling.com/read/watson-chapman-nakielny-guide-radiological-6th/chapter-9/femoral-artery-puncture

Seldinger's technique holds true to its initial description and since then has only been modified to provide access to virtually every organ through a distant percutaneous site (Bakal, 2002). Such modification and advancement through the years has allowed for greater uses of this technique and has even expanded upon its capabilities. However, the basic instrumentation remains unchanged: a guidewire, an access needle, and a catheter.

2.2 Basic Instrumentation

2.2.1 Guidewire Specifications

Medical guidewires are manufactured with different dimensions and properties in order to be applicable to a vast array of surgical procedures. Their differences range from tapered cores

for the attachment of a tip to extended cores up through the tip. In some guidewires the tip is composed of an entirely different material allowing for increased flexibility that is desirable for situations in which the vasculature is highly tortuous. However, according to Bakal (2002) except for guidewires that serve highly specific functions, construction of most guidewires are similar in the following ways:

- Length
- Diameter
- Tip
- Shape
- Core Stiffness
- Taper
- Coating

Shown below in Table 2.1, is a list of the different types of guidewires that are currently used. This table also provides a detailed description of each guidewires' characteristics and features.

Table 2.1: Common Guidewires (Bakal, 2002)

Wire	***Core Stiffness***	***Coatings***	***Tip***	***Features***
Newton	Medium	Teflon	J 3-15 mm	All-purpose wire for navigating large to medium vessels, abscess cavities, etc. J tip is atraumatic and lumen seeking. Will not traverse small or tortuous vessels. Typically 0.035-in to 0.038-in diameter
Rosen	Stiff	Teflon	J 1.5 mm (short taper)	Useful for visceral artery exchanges where extra support is needed, e.g. obese patients, tortuous vessels, stiff catheters. Typically, 175 cm to 180 cm long, 0.035-in. to 0.038-in diameter

Table 2.1: Continued

Bentson	Medium	Teflon	Straight with floppy tip	Very floppy, long straight tip good for crossing small, tortuous vessels or stenosis. Unless stifflest portion of the wire is placed into the vessel of interest, may not be able to place the catheter tip into selective position. 0.035-in. to 0.038-in diameter
Amplatz	Very stiff	Teflon	Straight with relatively soft tip.	May be used cautiously to guide large, stiff catheters such as angioplasty balloons, stents, or IVC filters, and for catheter exchanges. 0.035-in. to 0.038-in. diameter
Glidewire	Soft to stiff	Hydrophilic (extremely low coefficient of friction when wet)	Straight or angled	Extremely slippery wire used to pass occlusions, extremely small or tortuous vessels, or stenosis. Will easily dissect though vessel or other wall, so use with caution. 0.014-in. to 0.038-in diameter
"Steerable"	Soft to stiff	Teflon, hydrophilic	Shapeable	Used with low-profile "tibial" balloons or coaxial catheters. 0.010-in. to 0.018-in. diameter, made of steel, platinum, or nitinol

IVC = Inferior vena cava

Standard guidewires are typically seen with a set length of 145 cm and are manufactured with the use of tightly coiled stainless steel that composes the inner body of a guidewire. Likewise, the outer diameter, which is the surface of the coiled stainless steel, has a common width of 0.035 inches but is used in various sizes. Surgical preference and patient anatomy dictate the length, width, and stiffness of the guidewire, which depends on the mandril core. With an outer coating of Teflon or one of many hydrophilic polymer coatings, guidewires are

able to easily travel through tortuous paths and calcified narrow arterial walls. This coating also allows for an easier advancement of a catheter over the top the guidewire. Despite how easily a guidewire is maneuvered through the body, composition of a catheter is also a great determinate of how to maintain vessel integrity.

2.2.2 Catheter Specifications

Catheters serve many functions such as: delivering contrast, inflating a balloon, and passing a wire-based tool. They are defined as the main conduit that allows the interventionist to access a structure deep within the body (Bakal, 2002). Due to the vast array of tasks preformed, catheters vary greatly in size, structure, and composition. Classification of a catheter is determined by the following characteristics:

- Material
- Shape
- Outer Diameter/Wire Diameter
- Number of Side Holes
- Length
- Pressure Rating

The outer diameter of a catheter is displayed and measured in standard units of French. This uniformity in unit measure allows for a universal acceptance across the medical community. The usefulness of a catheter is dependent on its size. This size influences how easily the catheter is handled and maneuvered through the body, the applicable maximal fluid pressure, and how large the puncture site in the artery must be. There are three parts to a catheter, a hub, a shaft, and a tip. When the catheter is inserted within the body, a hub is located outside of the patient. This component provides an entry port for injectors, syringes, and guidewires. The shaft provides the catheter length, and is determined by location of the target organ. Finally the tip is the most variant portion of the catheter, and is usually made out of a different material shaped according to the vessel of interest. Figure 2.3 shown below depicts different catheter tip angles.

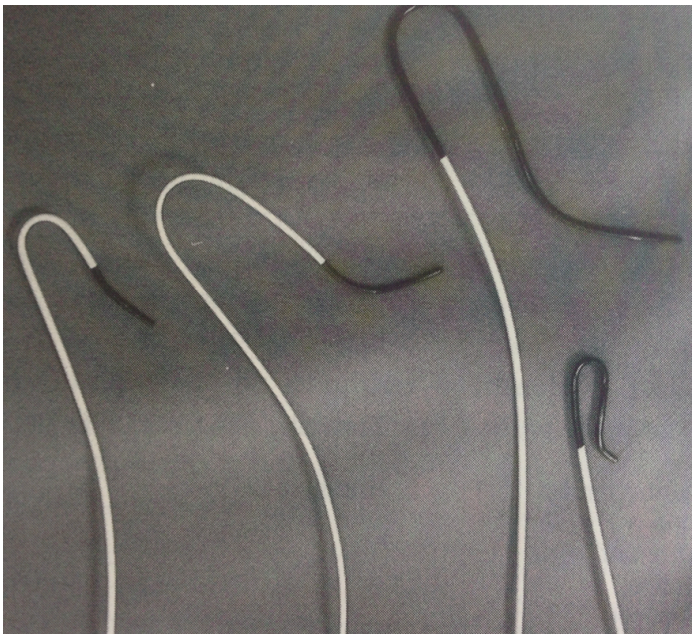

Figure 2.3: Curved Catheters [photograph]. (Bakal, 2002)

The part of the catheter where there is the greatest potential for design failure is in the fusion between the hub and the shaft. A large amount of pressure accumulates at this point sometimes resulting in a burst or tear in the joint.

The final component presented is the access needle. As discussed above, the access needle is the primary tool used in the Seldinger's Technique in order to puncture the arterial wall for access into the vascular system. Use of the one- or two-wall technique depends on the shape of the needle point. Further component specifications will be given next.

2.2.3 Access Needles

Once a target location is determined using fluoroscopic techniques as well anatomic landmarks, the access needle will then be used to puncture the vascular access site. There are two different types of puncture methods when using an access needle, the one- or two-wall technique. These methods of access are a great determinate of the size and shape of the access needle. Seldinger's one- and two-wall techniques require needle designs of sharp, hollow or beveled

with no inner stylet, and a blunt hollow cannula with a sharp inner stylet, respectively (Bakal, 2002). Figure 2.4 below depicts a one-wall needle. As can be noted in this figure, there is a sharp, small hollow opening on the distal end of the device with no visible stylet. Determination of which method to use is dependent on the operator and as with most processes there are advantages and disadvantages to each.

The needle used for a two-wall technique is advantageous because when it punctures the arterial wall it spreads out the fibers instead of slicing them, as does the single wall needle (Bakal, 2002). This manner of opening the arterial wall allows it to seal itself after removal of the needle. However, if the patient is unable to coagulate appropriately there can sometimes be a great amount of uncontrolled bleeding.

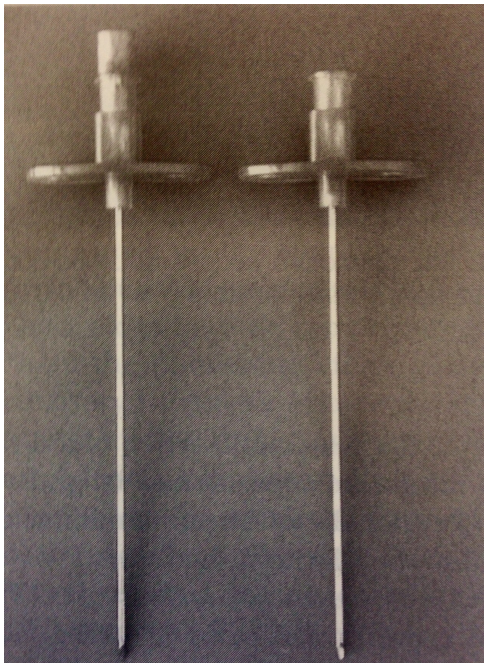

Figure 2.4: Single-Wall Sharp Hollow Needle [photograph]. (Bakal, 2002)

The needle used for the one-wall technique has advantages that when operating on an arterial wall that has been previously operated on and has remnants of scar tissue. There are

disadvantages and advantages to each technique and as stated above careful consideration of each method must be thoroughly reviewed prior to a surgical procedure.

CHAPTER 3

CURRENT PRODUCT ANAYLSIS

This chapter focuses on the guidewire torque devices presently on the market their physical characteristics, and limitations. After describing current products, a detailed description of the advantages of the newly designed torque device when compared to products already in use by the medical industry is provided. Finally, a list of tests still needing to be completed is given in order to proceed towards FDA approval.

3.1 Guidewire Torque Device Comparison

As previously described, guidewires are vital for the placement of larger instruments. Without them, it would be quite difficult to direct the larger device to the correct location in the patient's body, especially without causing unnecessary damage. Due to the importance of guidewires, torque devices have been developed to manipulate guidewires effectively.

Torque devices come in a range of different sizes to meet many special needs. Companies such as Terumo Interventional Systems, Elcam Medical Inc., Cook Medical, B. Braun, and Merit Medical have developed some of the devices currently used by medical professionals. However, many of these devices look and perform similarly. For instance, the following pictures were taken from the websites of various medical devices companies in order to demonstrate the similarities between each one of the designs:

Figure 3.1: Terumo's Guidewire Torque Device [photograph]. Retrieved February 3, 2014 from: http://www.terumois.com/products/guidewires/torque.aspx

Figure 3.1 is taken from Terumo's website. It is able to accommodate guidewires with diameters of 0.01 to 0.038 inches. The guidewire is inserted into the proximal end of the device. Once this is accomplished, the green cap is twisted clockwise to hold the wire snuggly in place. If loosening is needed to move the wire up or down, the cap is twisted counter-clockwise, thus allowing the guidewire freedom to move.

Figure 3.2: Cook Medical's Olcott Guidewire Torque Device [photograph]. Retrieved February 3, 2014 from: https://www.cookmedical.com/product/-/catalog/display?ds=uro_otd_webds

The torque device shown in Figure 3.2, referred to as the Olcott Torque Device, is offered by Cook Medical and works similarly to Terumo's product. However, this torque device uses a thumb-slide instead of a twisting cap. It is typically easier to move the thumb-slide forward and backward rather than twist an entire cap. To insert the guidewire in the proximal end of the device, the thumb-slide must be moved to the forward position as seen below in Figure 3.3, allowing for a clear path in which the wire is inserted. Once the wire is in place, the thumb-slide is moved backward to tighten the wire and keep it from moving, as seen in Figure 3.4. The Olcott Torque Device is able to accept guidewires ranging from 0.015 to 0.045 inches. This is a slightly different range than the device offered by Terumo.

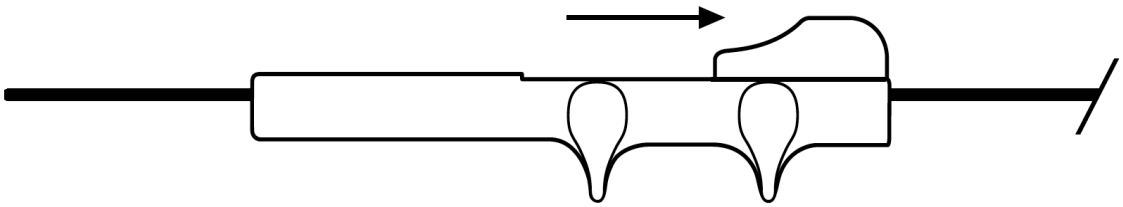

Figure 3.3: Olcott Device with Thumb-Slide in Forward Position [drawing]. Retrieved February 3, 2014 from: https://www.cookmedical.com/data/IFU_PDF/T_OCD_REV0.PDF

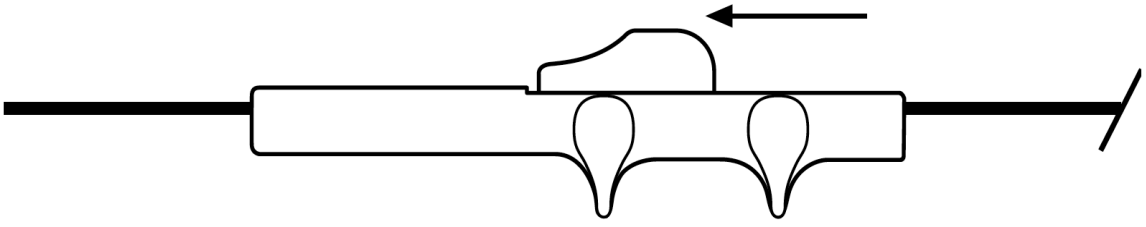

Figure 3.4: Olcott Device with Thumb-Slide in Locking Position [drawing]. Retrieved February 3, 2014 from: https://www.cookmedical.com/data/IFU_PDF/T_OCD_REV0.PDF

Merit Medical has developed three diverse torque devices to meet the special needs of its clients as well as to increase its share of the market. The first of these devices is on par with

Terumo's product and can be seen in Figure 3.5. This is referred to as the Merit® Torque Device and is compatible with wires 0.009 to 0.018 inches in diameter. Other than being useful for very small wires, this device is unique because it is fluorescently colored for use in low light conditions.

Merit Medical's second device is known as the SeaDragon™ Guidewire Torque Device as seen in Figure 3.6. This was developed to eliminate the tightening and untightening needed for repositioning the device. The SeaDragon™ Guidewire Torque device is used by squeezing the white cap on top and inserting the proximal end of the guidewire tip through the device. Once this is done, the white cap is released, which activates the locking mechanism. The ridges on the side of the device are used for an improved grip. This device is able to handle guidewires with diameters of 0.018 to 0.038 inches.

In addition to these two different torque devices, Merit Medical has yet a third device named the H_2O Torq™ as seen Figure 3.7. This device has a similar concept to the SeaDragon™ in that it is not meant to rotate to reposition the guidewire. Instead, the guidewire is inserted into the device, which is then closed by pushing the two finger pads firmly together. This locks the wire in place and allows the surgeon to manipulate accordingly. Repositioning the wire can be done by squeezing the finger pads together and moving the device up or down the wire. In order to unlock completely, the finger pads must be squeezed firmly to disengage the locking mechanism and the device may then be removed from the wire. The H_2O Torq™ also contains ridges on its side to improve the grip when manipulating the guidewire. The orange device is meant for guidewires with diameters of 0.025 to 0.04 inches, whereas the yellow device is meant for those with diameters of 0.01 to 0.02 inches.

Figure 3.5: Merit® Torque Device [photograph]. Retrieved February 6, 2014 from: http://www.merit.com/products/default.aspx?code=torq

Figure 3.6: SeaDragon™ Guidewire Torque Device [photograph]. Retrieved February 6, 2014 from: http://www.merit.com/products/default.aspx?code=seadragon

Figure 3.7: H_2O Torq™ [photograph]. Retrieved February 6, 2014 from: http://www.merit.com/products/media.aspx?type=brochure&id=150555

Figure 3.8: Braun Torque Device [photograph]. Retrieved February 6, 2014 from: http://us.bbraunoem.com/cps/rde/xchg/oem-bbraunoem-en-us/hs.xsl/products.html?id=00020742510000000045&prid=S1333120N

Figure 3.8 displays a torque device developed by B. Braun and operates by twisting the cap. The guidewire is inserted into the proximal end and the cap is twisted clockwise to tighten and counter-clockwise to loosen. The diameters of guidewires accepted by this device range from 0.014 to 0.022 inches.

Figure 3.9: Elcam Medical's Haskal™ Guide Wire Torque Device [photograph]. Retrieved February 6, 2014 from: http://www.elcam-medical.com/pdf/pdf_brochure/haskal_torque.pdf

This last design can be considered the most unique or, perhaps, innovative out of all. This device is Elcam Medical's Haskal™ Guide Wire Torque Device as shown in Figure 3.9. The most innovative part of this design is the fact that it is a side-loading torque device. This means

that the device does not need to be loaded or removed from over top of the wire, which is what typically creates the issues surgeons experience when using torque devices. The Haskal™ is designed to handle guidewires with diameters of 0.01 to 0.038 inches.

In sum, there are numerous guidewire torque devices currently on the market. Each device has a certain range of diameters it is able to handle effectively. In addition, each device has a unique way of holding the guidewires in place. Many torque devices use a screw cap to tighten or loosen the grip on the wire. However, it was also seen that push caps and thumb-slides are also the market, exemplifying that there is not one single way out there to hold a guidewire and be able to torque it. These various designs also indicate that surgeons do not all prefer the same style of device and are open to improved designs such as the new guidewire torque device of the present report.

3.2 FDA Approval Recommendations

To obtain FDA approval, there will be multiple tests left to perform on the new torque device. Following the example left by Elcam Medical's Haskal™ torque device when it filed under the 510(k), there are tests that still need to be completed. These tests are as follows:

- Packaging Environmental Endurance
- Dimensions Verification
- Device and Guidewire Axial Force
- Torque Force
- Device Operational Force
- Performance During Exposure to Fluids
- Usability

- Sterility Integrity and Shelf Life

In addition to the above tests, there are multiple biocompatibility tests that should be performed as well. These include:

- Cytotoxicity
- Systemic toxicity
- Sensitization
- Irritation
- Subchronic toxicity
- Genotoxicity
- Haemocompatibility – Hemolysis

The final biocompatibility test, Hemolysis, is not a necessary test to be performed on the torque device considering the product remains outside of the patient's body during the medical procedure and there is also no contact with blood. However, performing this test would only provide additional results that can be used in support of the torque device.

Aside from the tests previously discussed, it is also possible to have the torque device tested using what is known as Interventional Device Testing Equipment or IDTE, as shown in Figure 3.10.

The standard testing protocols for the IDTE consist of track force, push efficiency, flexibility, torquability, retractability, and crossability. Machine Solutions defines each of these standard testing protocols as follows.

- Track force measures the required force necessary to advance an interventional device through a tortuous path

- Push efficiency uses both the proximal and distal load cells to measure the amount of force on the distal top of the product when a known force is being applied to the proximal end of the product
- Flexibility is simply a measure of the product tip's ability to track over a guidewire, such as where the guidewire is bent
- Torquability measures the rotational response at the distal end of a device while imparting a rotation at the proximal end
- Retractability is a measure of the force needed to withdraw the device from a tortuous path
- Crossability is the measure of the force needed to advance an endovascular system through a simulated stenosis/lesion within a tracking model

Figure 3.10: Interventional Device Testing Equipment (IDTE) [photograph]. Retrieved February 6, 2014 from: http://www.machinesolutions.com/Medical-Device-Performance-Testing/Testing-Equipment/Catheter-Guidewire-Testing-Equipment-IDTE2000.htm

Upon completion of the tests previously described, sufficient data will be available to submit a complete 510(k) to the FDA. The entire purpose of a 510(k) is to provide a Premarket Notification. This ultimately tells the FDA that a company is ready to release a new product into the market. The 510(k) must be submitted at least 90 days in advance to the FDA in order to allow ample time for the FDA to review the document and decide whether the medical device falls into one of three existing categories of classifications.

The device is compared to existing products on the market. Once a match has been made then the new device will fall into the same category as the preexisting product. Once the 510(k) has been submitted for a product, it does not have to be re-submitted later unless the device has been significantly changed. The modification must be substantial enough that the product's safety or effectiveness has been altered from the original. This modification may arise in the design, material, chemical composition, energy source, manufacturing process, or even intended use of the product (FDA).

3.2.1 Sample 510(k)

In order to better describe what a 510(k) consists of as well as to provide a demonstration of what the future 510(k) will look like, a sample 510(k) has been generated to reflect the information pertaining to the torque device in question. The sample 510(k) was modeled after an actual 510(k) submitted by Elcam Medical for its Haskal™ Torque Device. This can be seen in Appendix B at the conclusion of Chapter 6.

CHAPTER 4

DESIGN PROCESS OF THE PROPOSED GUIDEWIRE TORQUE DEVICE

In this chapter, the stages in the design process of a new medical device will be further analyzed. A detailed description and categorization of the following sections: conception, development, and evaluation, will be presented with a further examination provided for each one. Current medical devices that provide the same function are also presented and analyzed, which provides the basis for the design of the current innovative guide wire torque device.

4.1 Medical Device Definition and FDA Classification

It is imperative to recognize the key factors that define a medical device. The Food and Drug Administration labels a medical device as " an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent

upon being metabolized for the achievement of any of its primary intended purposes." (Food and Drug Administration, 2012)

Depending on the class in which each medical device is assigned to determines, among many other things, the type of premarketing submission/application required for FDA clearance to market (Food and Drug Administration, 2012). There are three regulatory classes in which each device is classified under: Class I, Class II and Class III. Each regulatory class is based on the level of control necessary to assure the safety and effectiveness of the device (Food and Drug Administration, 2012). In other words, classification is based on the risk involved with using that device on a patient. Any medical apparatus that is deemed to be a low risk, harmless to a patient, will be classified under a Class I device. All other devices that either have direct contact or are inserted into the patient will require Class II and Class III classification respectively. In accordance to FDA regulations, "Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control." (Food and Drug Administration, 2012).

For purposes of this design, the guide wire torque device will be classified under a Class I device. The Class I classification of the guide wire torque device signifies that due to its low risk in producing adverse effects to a patient it will not require an extraneous level of testing or product validation.

4.2 Problem Statement

The design flaws to the guidewire torque devices that are currently used led to the design of a torque device that fulfilled user specifications as shown in Table 4.1 in Section 4.2.1, Design

Requirements. Certain approaches were taken to further analyze this problem, which aided in the development and production of the current design.

In order to fully understand current industry limitations and to better define design specifications, an in-depth literature review was conducted. Through the use of journal articles, medical textbooks, and online databases much information about current practices and other basic complimentary devices was attained. A more proficient understanding for the use of the guidewire torque device was developed because compositional aspects of the guidewire prevent it from being able to be manipulated without the aid of a gripping tool.

A second method used to understand the design failures of torque devices was attained through an observational analysis at Tampa General Hospital, including weekly observations spanning five days a week in some cases, for the duration of six months. Random selections of surgical procedures were witnessed during these weekly visits to provide a basis of understanding of surgical techniques and systematic approaches in the handling of medical devices. Questions, comments, or concerns that accumulated at anytime during this observational period were quickly discussed and evaluated with the assistance of surgical and medical professionals alike.

The final observational method was accomplished by regular attendance at weekly vascular surgery grand rounds and meetings providing personal contact with medical personal that consisted of: physicians, residents, medical students, surgical assistants, registered nurses and others. Personal interaction with medical personal provided a first-hand determination and visualization to the advantages and disadvantages of current medical devices. A comparison analysis was also done in order to create a basis for design characteristics that must be met and

design failures that must be corrected. Such design requirements are discussed below following an explanation of methods followed to develop the new guidewire torque device.

4.2.1 Design Requirements

There were key elements stipulated by physicians during the observational period that became the principle design specifications. It was apparent that if the new design was going to succeed it must not only satisfy but also surpass user specifications. Table 4.1 displays user specifications that were determined with attending physicians and residents alike. These medical professionals were prompted to generate a criteria list that must be satisfied by the new torque device. The criteria as specified by proficient torque device handlers is listed below.

Table 4.1: User Specifications

Function	**Requirements**
Utilization	Device shall be compatible for varying guidewire diameter sizes
Operation	Must only require the use of one hand to operate the device
Efficiency	New Device shall not cause any delay to surgical procedure and must maintain a secure grip on guidewire despite the environment

Such parameters were extrapolated from the disadvantages and advantages of highly rated torque devices. The thought perspective was to create a baseline for the design elements of the new guidewire torque device.

Table 4.2: Design Parameters

Function	**Requirements**
Ergonomic	Device will be easily maneuverable
Education	Mastery of the device must be achieved in a short period
Utilization	Device shall not be loaded through the proximal end of the wire or removed by sliding off

Table 4.2: Continued

Safety	Must not cause harm to the patient or surrounding personal
Accuracy/Reliability	Will provide the same result regardless of the times used.
Performance	Does not interfere with surgical procedures and processes
Feasibility	The Device will provide a Low Manufacturing Cost

Once general consensus was attained regarding user specifications and design parameters further advancement of potential design ideas commenced.

4.2.2 Preliminary Designs

After researching relevant patents and analyzing their strengths and weakness, it became apparent that what almost all guidewire torque devices lacked was the ability to latch on to the wire at any desired location. Pursing this design modification by eliminating the hassle of having to load the torque device through the proximal end of the wire and incorporating a side-mounting characteristic was the first step in the preliminary design of the new device. Further analysis of current marketed devices lead to a second essential design modification. The new guidewire torque device was no longer going to take the same form as all previous designs. Instead, this new design will still provide the same function while being secured from the index finger and thumb of the physician's hand. Realization that the new torque device should not be limited to being a hand held gadget but instead be an extension of an already natural process was a concept that had never been attempted. This novel design satisfied the idea of being able to relocate to any desired point along the length of the guidewire with great simplicity and without wasting surgical time. The challenge was now redirected to developing a mechanism in which the torque device could be secured, by the surgeon's fingers.

The initial design was suggested to be an adjustable ring with a patterned interlocking network on the surface as displayed in Figure 4.1. The benefits to such a design are that it is easily adjustable and removable, disposable, and can be manufactured with a very low material cost or labor to the provider. However, the biggest setback to such a design is that secure placement on physician's finger cannot be guaranteed. This design *lacks* the ability to effectively grip the guidewire. This design was in effect discarded and efforts were redirected to another design.

Figure 4.1: First Design: Adjustable Ring with Ridges [photograph]. Retrieved March 28, 2014 from: http://www.riogrande.com/Product/687743

The second design took into account the first design's *inability* to provide a secure placement Figure 4.2 portrays a veterinary toothbrush that could be modified into a torque device. The torque device would slide over the index finger and thumb and the portion of the veterinary toothbrush that has the bristles would consist of a patterned anti-slip surface. The downfall to such a design was that this device was size dependent. Many different sized devices

would need to be manufactured in order to accommodate multiple finger sizes and guidewire diameters so, such a design was not a feasible avenue to pursue.

Figure 4.2: Second Design: Finger Glove [photograph]. Retrieved March 28, 2014 from: http://mypeted.com/pet-health/articles/teeth-cleaning-for-dogs-and-cats/

Efforts were redirected to developing a device that not only satisfied design parameters but also was strategically capable of surpassing current torque devices. A new device was designed to be a patch that fits over the glove on a surgeon's thumb and forefinger. This means that in no way are the two pieces connected except for the fact that they are both attached to the same glove. Being that the device consists of simply two patches, this allows for multiple advantages not previously seen in other torque devices. For instance, the doctor is able to experience increased control, minimal effort in gripping the wire, no guidewire diameter limitations, and even a faster time in learning to use the patch. In other words, there is little to no learning curve in being able to understand how to use the patch to manipulate the guidewire.

4.3 Development

The simplicity of the adhesive patch's innovation was the driving factor in compiling potential material specifications. The section that follows discusses and analyzes the first material of choice, which focuses on the material characteristics.

4.3.1 PDMS as a Material of Choice

Polydimethylsiloxane (PDMS) is a silicon-based organic polymer that has many applications in various fields. However, over the years PDMS has grown to be a key ingredient for many biomedical products due the nature of its bonding and chemical characteristics. PDMS applications in the medical field range from implants through catheters to soft contact lenses (PDMS & Suitability). As shown in Figure 4.3, the Si-O backbone of this polymer is the source from which most of its unique characteristics originate.

It is very rare to use pure siloxane polymers in production because of limited applications and restricted us of manufacturing capabilities. An addition of additives, such as a curing agent, must be incorporated in order to make it useful (Mark, 2005). Such malleable properties allow the PDMS substance to be easily manipulated to adjust to user needs. As a result, this silicone-based polymer is a highly sought out substance for the use of rapid prototyping.

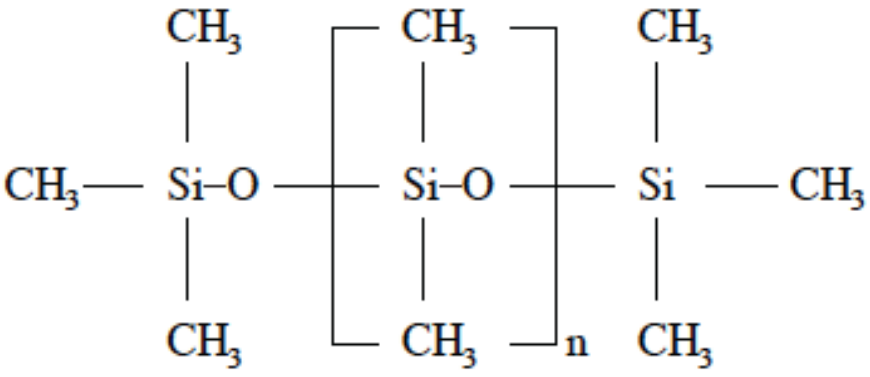

Figure 4.3 Polydimethylsiloxane (PDMS) Molecular Structure [drawing]. Retrieved April 5, 2014 from: https://www.xiameter.com/en/ExploreSilicones/Documents/95-725-01%20Overview%20of%20Polydimethylsiloxane%20Fluids.pdf

Among its unique and intriguing properties, PDMS as a material is inexpensive, flexible, and optically transparent down to 230 nm (Microfluidic Devices Fabricated). Therefore, using this polymer as the benchmark to the fabrication of the guidewire torque device seemed to be an ideal option. Initial trials were begun with the assistance of SolidWorks CAD software for the concept design of the device.

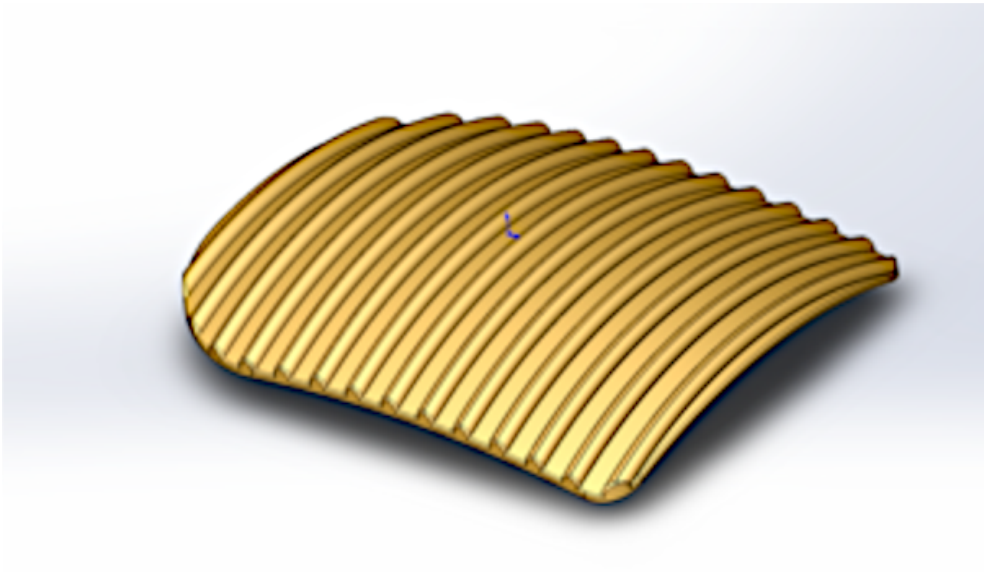

Figure 4.4 Concept Design for Patch Torque Device, Angle View [drawing]

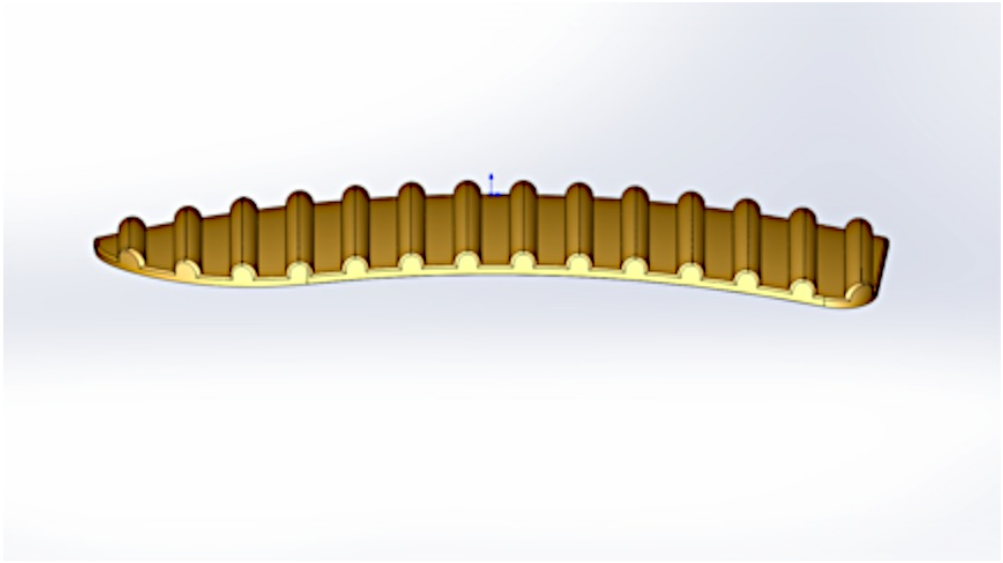

Figure 4.5 Concept Design for Patch Torque Device, Side View [drawing]

In Figures 4.4 and 4.5, the concept design for the patch guidewire torque device is presented. As noted in Table 4.1 above, the overall purpose of this design was to produce a patch that adhered to a standard surgical glove, was slender enough not to interfere with surgical capabilities, and was able to advance the guidewire with ease. The patterned surface as displayed in Figures 4.4 and 4.5 represent a conceptual design strategized to grip the hydrophilic coating of the directional guidewire. Different options were made to the patterned surface of the patch. It was determined that horizontal ridges which laid parallel to one another will not properly prevent the guide wire from slipping. A new design was then developed and is shown in Figure 4.6. As noted in this figure, the microfluidic pillars are staggered among each row for the purpose of creating a more uniform grip of the guidewire. However, initial trials using the patterned surface proved otherwise.

Figure 4.6: PDMS Surface Patch Design [photograph]

In order to comply with design parameters, the PDMS patch was manufactured with an extremely small thickness value. It was imperative that the patch be as thin as possible in order to be adhered to the surgical glove without much trouble. Also, design parameters called for a

device that would not distract or delay the overall surgical procedure. Therefore it was highly desirable to manufacture a patch that would in essence be an extension of the surgical glove. Such thickness was achieved and adhered with a durable double-sided adhesive tape to the surgical glove. A series of initial evaluations was then conducted with the Vascular Surgery Division at the University of South Florida to evaluate the effectiveness of the PDMS patch.

Evaluations in turn resulted in less than desirable data. The nature of the PDMS patch was so thin that its elemental material properties were sacrificed. In other words, the PDMS patch lacked so much of the required thickness, that essential material properties were not adequate. For example, this design faltered by the material tearing when index and thumb finger were rubbed together while gripping the guidewire in-between them. Also, further material evaluations indicated an inability to grip the directional guidewire in a wet environment. The PDMS was resistant to water absorption which was a desired feature; however its inability to absorb water resulted in creating a slippery surface instead. As a result, efforts were now redirected to the selection of another material with the hopes of prototyping the new guidewire torque device.

4.4 Current Design

Prior to initiating the search for a new material, specific properties were determined and used as the criteria for material selection. It was apparent that the new guidewire torque device required certain non-negotiable material properties that ultimately would dictate the success or failure of this design. A desirable attribute for a chosen material was the ability to function well in a wet environment, hold its design specifications despite an aqueous environment.

Additionally the material thickness needed to be small enough to coincide with its addition to the surgical glove.

So, efforts were redirected to analyzing anti-slip adhesives and repurposing their intended use to become applicable to the current design. The anti-slip adhesives that were easily accessible for public acquisition were utilized in a manner different from there intended uses in areas with a combination of high foot traffic and sharp edges. Figure 4.7, 4.8, 4.9 and 4.10 display each anti-slip adhesive sample acquired and analyzed for the purpose of this study. Through an examination of one of the anti-slip samples it was found that such a tape was composed of a highly course material that expelled a gritty powder when rubbed against itself, the adhesive is displayed in Figure 4.7.

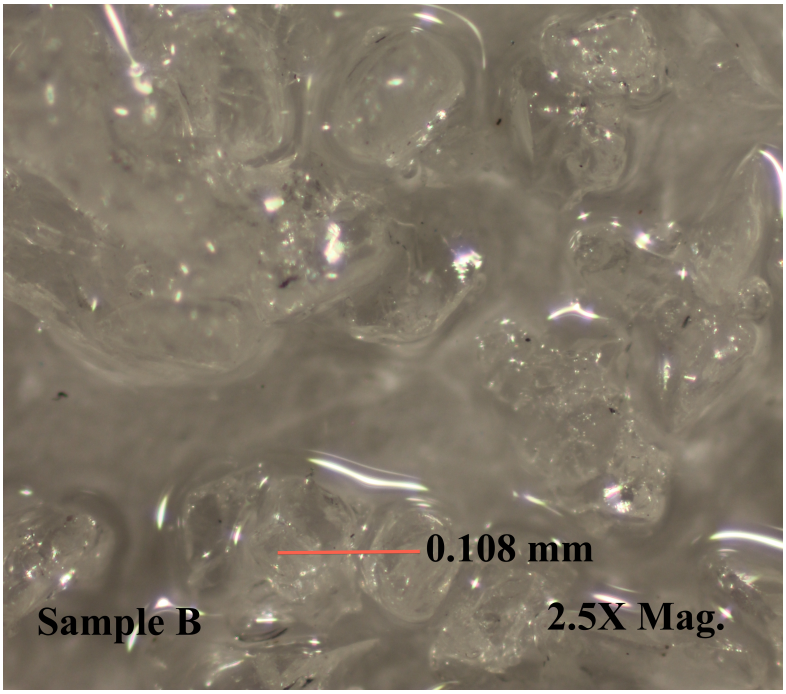

Figure 4.7: Anti-Slip Adhesive, Sample B

Material specifications were then reclassified to reject course materials that disintegrate when rubbed together. Instead, efforts where directed to find an anti-slip adhesive that

incorporated all the same elemental features of a course anti-slip tape, but was relatively inert and compatible with exposure to sensitive elements such as the skin.

The final design incorporates of use of an anti-slip bathroom adhesive and is repurposed for the use as a guidewire torque device. This adhesive was evaluated and tested with basic experiments to determine if it met design specifications. Figure 4.9 displays a magnified image of the chosen anti-slip shower adhesive.

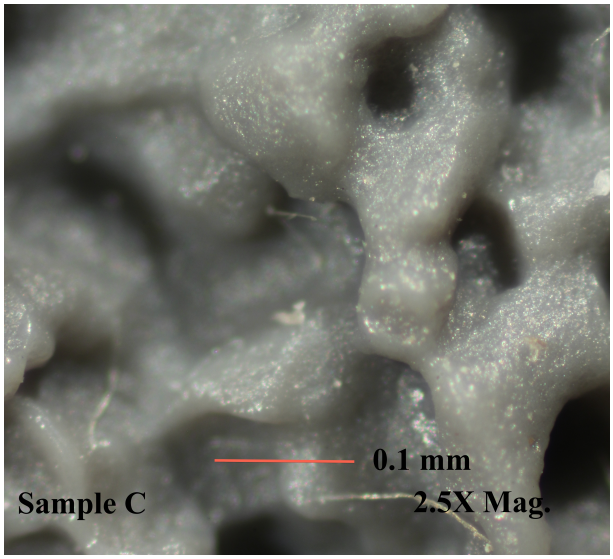

Figure 4.8: Anti-Slip Adhesive, Sample C

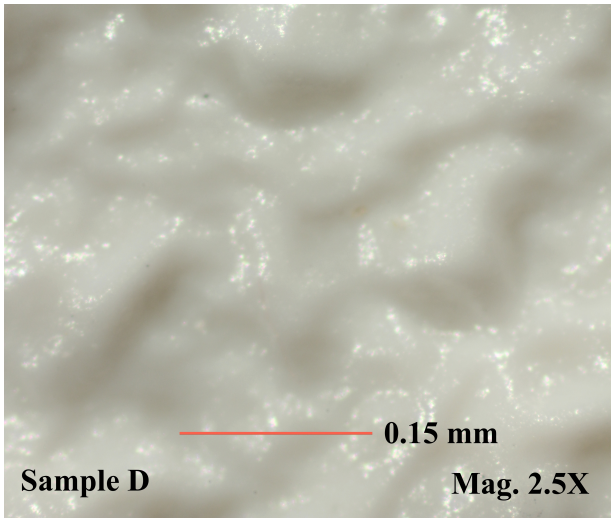

Figure 4.9: Anti-Slip Adhesive, Sample D

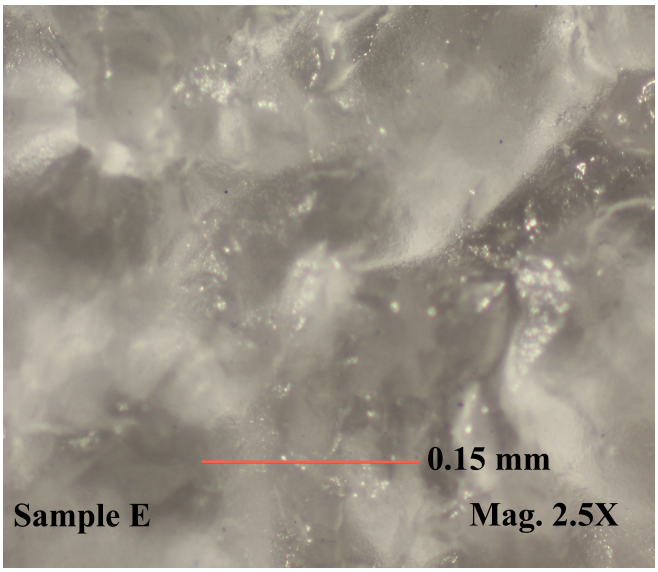

Figure 4.10: Anti-Slip Adhesive, Sample E

A further analysis of the material characterization was done on the chosen anti-slip adhesive to attain a better understanding of its properties. Table 4.3 contains a summary of such characterization. The table lists optimum dimensions for the anti-slip adhesive as well as data acquired by measuring the distance of each textured point from a central location. The average of this distance was recorded and listed in Table 4.3.

Table 4.3: Sample D Material Specifications

Thickness	<1.5 mm
Textured Surface Distance (mean)	170.242 μm
Forefinger Dimensions	30 mm X 15 mm
Thumb Dimensions	35 mm X 20 mm
Shape	Elongated Oval

As noted in all the figures displaying the anti-slip adhesives, the surface pattern of each adhesive is composed of a randomized pattern. It can be inferred that this randomized pattern is the reason to why each adhesive is so optimal in its resistance to slipping.

4.5 Testing/Characterization

The material was adhered to a surgical glove and evaluated "blindly" by a group of vascular surgeons and surgical residents, and rated quantitatively according to their level of satisfaction with different versions of the new design. Anti-slip bathroom adhesive has elemental components that prevent the material from sliding when put in contact with a wet environment. The surface of this material has a pattern that causes friction and grips whatever element is put in contact with it. Such attributes are highly desired and were the reason for the selection of this adhesive. A survey was conducted to further analyze this material and accurately determine compliance with user specifications. Appendix A provides a copy of the survey given to the medical professionals (N=13). The survey presents a compilation of multiple anti-slip adhesive options. For this quantitative survey, Design A, was the guidewire torque device that is currently used by the medical staff and designs B through E were different anti-slip adhesives. All adhesives were shaped in the form of a patch and were adhered to the forefinger and thumb of the surgical glove.

The surgical gloves were presented to each medical professional individually and they were asked to rate each glove on a scale of 1-5, for each of the following criteria: material, ease of use, grip force, torquability, and device quality. Of the thirteen individuals that took the survey about 6 of them were administered the survey after testing the adhesives against a vascular simulator. This simulator allows residents and medical personal alike to practice inserting a directional guidewire through a computerized image of a tortuous lumen. Such testing allowed for a more realistic approach to the adhesive patch. Interestingly, years of experience as a vascular surgeon was correlated to the acceptance of the proposed design. Among the five different designs presented to the surgeons, the proposed patch was rated the highest, with the

current medical torque device following in a second place. These results to the survey were highly favorable and verified that in fact the new design has the potential to be accepted among medical industry professionals.

4.6 Evaluation Stage

As previously stated, the surgeon has amplified control over the wire when using the patch rather than when using a separate torque device. This is because the patch is attached to the glove in which the surgeon's hand is located. The patch immediately responds to any way the doctor moves his/her hands. This means there is no lag time or extra movement the doctor must compensate for to manipulate the guidewire precisely. Plus, the surgeon is able to feel the guidewire much more realistically since the only surface separating the surgeon's hand from the wire is a thin patch on the surgical glove.

The close proximity of the hand to the wire is what allows gripping the wire to be effortless. The surgeon simply closes his/her thumb and forefinger around the wire to begin manipulation. Whenever the surgeon needs to reposition or is done using the wire, he/she may simply release the grip between the thumb and forefinger. Also, the patch is designed to contain a textured surface to enhance the grip.

One of the more unique advantages is the lack of limitation the patch has in regards to guidewire diameters it can use. In other words, the patch can handle the smallest diameter of guidewire available up to the largest diameter. This is because it is only the thumb and forefinger clasping together that holds and torques the wire. There is no specified hole the wire must fit through to be held tight, which is a constraint of current devices. Due to this advantage the new patch can be used in any type of surgery with any type of hydrophilic directional guidewire, with

no needs for different models. This increases its value and allows for more widespread adoption in the medical community.

Finally, there is little necessity for large amounts of training with this device. The patch is fairly intuitive and easy to navigate the wires, virtually eliminating the learning curve. No longer will surgeons have to practice for many hours using various torque devices in order to become familiar and be able to perform surgeries accurately. They can now slip on the glove containing the patch and manipulate the guidewires intuitively.

Given all of these distinct benefits over the current torque devices, it is no wonder this design was accepted so positively by surgeons when given the chance to test it. Anecdotally, the surgeons exposed to this patch could not be happier that a design with these abilities was in development. It fit the criteria required by those that regularly perform surgeries in need of torque devices.

CHAPTER 5

FEASIBILITY ANAYLSIS AND PRODUCT BUSINESS PLAN

It is in this chapter that a thorough analysis is performed regarding the feasibility of starting a new business focused on the manufacturing and sale of the new torque device. Two avenues will be analyzed and thoroughly reviewed for purposes of product development. A recommendation will be provided with the aid of computational data to support its claim. This chapter provides the necessary data and insight to determine the attractiveness of such a venture.

5.1 The Business Idea

5.1.1 Business Description

One of the most fascinating elements of the medical field is the never-ending development of more advanced equipment that improves not only efficiency and effectiveness of a surgical procedure but also the safety of the patient outcomes and safety. These devices can cost anywhere from thousands of dollars to less than a dollar. However, the importance of the device is not determined by its cost. For instance, torque devices used in the manipulation of guidewires for surgery are vital in order to ensure proper placement of the next device, such as the catheter. This is exactly why MedAmerika Inc. will provide high-quality torque devices aimed at catering to physician's needs, thus enabling them to perform their procedures while minimizing the difficulties experienced with products currently on the market.

5.2 The Product

5.2.1 Unique Features: Benefits

One of the rewards of the medical device industry is knowing that the products being used are changing the lives of numerous individuals; anywhere from saving the person's life to reducing pain and suffering. For this reason, MedAmerika Inc. will offer products focused on improving medical care and surgical outcomes. The very first product being an adhesive patch that will allow doctors to torque, grip, and advance guide wires and other products more adeptly, thus eliminating a great deal of frustration and wasted time in the procedure center or operating room. Due to the patch being located on the thumb and index finger of the glove, doctors have increased control over the guidewires, as well as feeling a stronger sense of connection. This connection is due to the close proximity of the glove to the physician's touch. In a sense, the glove becomes part of the hand, allowing the doctors to feel as if their own fingers are gripping and twisting the wires so effortlessly.

5.2.2 Unique Features: Limitations

The positive side of basing a new company on the new patch is that the product is easily manufactured and due to its very small size and weight, easily packaged and shipped as inexpensively. Along with this, it should not run into any legal restrictions nor be heavily regulated. However, in terms of limitations, this is an entirely new method of implementing torque devices. Thus, doctors and others interested in using this product will have no previous experience with it. It may prove difficult to change the methods already employed in the medical field with respect to torque devices. Doctors may decide that even though this product is highly useful they prefer to stick with what they know and have trained with previously. In addition to altering habits, the current torque devices sold are already packaged in combination with

guidewires or other devices. As a result, MedAmerika Inc. would need to develop or acquire these other products in order to provide the medical community what is currently expected. Otherwise, it will be necessary to develop a plan to penetrate the market using other means. Aside from this, there is very little to hinder a much larger competitor from developing a similar product. Even with a patent, a competitor could manage to work around or simply overpower the legal rights due to their resource depth. In the end, it may prove more beneficial to either partner or license to one of these larger companies and avoid many of these issues.

5.2.3 Stage of Development

MedAmerika Inc. is currently in its initial stages of development. This report initiates the idea development and market research for the potential of MedAmerika Inc. If deemed to be feasible, MedAmerika Inc.'s time frame for opening is approximately two years. This is due to the necessity for creating its own unique lineup of products with the help of other engineers and health care professionals. Along with this, it is necessary to acquire a patent as well as place other restrictions on the use of its products, which can be a slow process.

5.2.4 Legal Restrictions, Rights, and Insurance

MedAmerika Inc. will operate as a Sub-Chapter S Corporation. This will grant its sole owner limited personal liability in case of a financial downfall. A board of directors will also be elected by the owner to ensure proper business practices as well as the pursuit of sound strategies for progressing the business.

Protection and development of products will be the largest categories of expenditure. It will be necessary to acquire patents for most products deemed profitable by the company. Along with this, it will be costly to hire the appropriate lawyers and follow the processes laid out by the U.S. Patent and Trademark Office.

5.3 The Industry and Market

5.3.1 Current Market

MedAmerika Inc. will be categorized as Medical Instrument & Supply Manufacturing in the U.S. or NAICS code 33911a. This industry is defined as researching, developing, and producing nonelectronic medical, surgical, dental, and veterinary instruments and apparatus (Phillips, 2014). The entire industry makes combined total revenue of $96.4 billion annually with profits reaching slightly over 10% of that at $10.1 billion (Phillips, 2014). The industry's four largest players account for less than 20% of market share meaning the market is highly fragmented, so somewhat competitive and penetrable. According to Net Resources International, 56% of new industry products are developed by small businesses, and 85% of these contain fewer than 20 employees (Phillips, 2014). These small companies tend to be much better at adapting and shifting to meet changing market demands.

Regardless of the industry being seen as mature, revenue growth is anticipated to rise over 3.5% during the next five years (Phillips, 2014). In addition, the elderly are one of the key economic drivers of the industry given their increased need for medical attention and care. Their numbers are expected to rise as well as those holding private health insurance. These are all key indicators for the expected growth in the field of medical devices.

5.3.2 Market Potential for the Industry

As previously stated, the market is expected to grow over 3.5% during the next five years (Phillips, 2014). Even that past five years have seen growth of 2.5% annually, and this was during the recent economic downturn in the U.S (Phillips, 2014). Aside from this, the industry is far from concentrated, especially given that there are over 15,000 businesses currently classified. The competition is seen as a medium barrier, which leaves room for new businesses to soak up

profits while also deterring those less ambitious. Barriers to entry and capital intensity are also seen as being medium making it also an attractive industry to enter (Phillips, 2014). Revenue volatility is very low, thus allowing for more stable business practices and the development of stronger relationships with both suppliers and customers. Overall, the industry can be seen as an attractive option for investment.

5.3.3 The Competition

Primary competitors include the larger firms such as Johnson & Johnson, Stryker, Boston Scientific, Baxter, Covidien, etc. (Phillips, 2014). These firms clearly have a greater pool of resources as well as an established customer base and processes in place for the development and marketing of new products. Along with this, these companies are able to buy in bulk for their products supplies, which typically provides them with discounts and other perks not recognized or achievable by smaller companies. Another distinct advantage these companies exert is there established brand names. Customers are extremely familiar with these companies and what they have to offer, since these companies have been around, sometimes for several decades. These are the largest advantages that will be difficult to overcome by a startup.

5.3.4 Customers

MedAmerika Inc. will primarily target hospitals, clinics, and physicians. These groups make up close to 55% of total industry revenue (Phillips, 2014). There are approximately 5,700 hospitals in the U.S (American Hospital Association, 2014). Of course, not every hospital will be interested or in need of the products to be offered by MedAmerika Inc. In terms of surgeries, there were over 51.4 million procedures performed during 2010 (Centers for Disease Control and Prevention, 2014). Torque devices are not needed in every type of surgery, but they are used frequently. It can be seen that even if a small fraction of procedures use hydrophilic directional

guidewires or similar devices then success is likely. The most important aspect of MedAmerica's marketing process is to promote the advantages of the new design by attending multiple medical devices tradeshows that are presented around the world.

As presented above and given in detail in Appendix, a survey was conducted to determine how well doctors received the new torque device as well as their preferences for certain characteristics of various torque devices currently in use or potentially in development. Upon analyzing the results, it became apparent that doctors with more years of experience in the field were inclined to accept this new device than those just entering the field indicating that medical professionals can accept new products upon being exposed to their capabilities and advantages.

5.3.5 Market Penetration

MedAmerika Inc. will initially operate from a single facility with the intention of expanding as necessary depending on market and demand conditions. Apart from designing the building to be visually appealing, it will be placed in an area easily accessed by large trucks shipping supplies to and from. Having the location be easily accessible will be key in the sending and receiving of materials, which will ultimately allow for a more efficient process.

There will be no need to spend heavily, if at all, on direct consumer advertising. Instead, MedAmerika Inc. must invest more in sales personnel, who would travel to hospitals to demonstrate to doctors the use and advantages of the new products. Also, MedAmerika believes that through intense marketing strategies such as attending various trade shows around the country, the introduction of such a novel device will warrant physicians and medical professional alike will be more inclined to accept the it.

5.4 Financial Analysis

5.4.1 Pricing

In order to begin the break-even analysis, the average selling price per product, variable cost per product, and fixed costs were calculated based on analyzing the 2013 annual report of Merit Medical. The assumption was made that MedAmerika Inc. will be able to acquire and sell comparable products around the same price as Merit Medical. Taking Merit Medical's cost structure, it was determined that cost of goods sold would be equivalent to 57% of total revenue. Fixed costs such as selling, marketing, and administrative expenses are estimated to be around 29%. Research and Development (R&D) costs will be approximately 7.5% of total revenue.

The break-even analysis, seen in Table 5.1, was calculated using these percentages. Upon researching prices for Merit Medical's, Covidien's, and Abiomed's medical guidewires, it was discovered that the average unit-selling price would be set around $160. This is because each unit will consist of a guidewire, which is priced at $145 and a torque device priced at $15. This brings the total unit price to $160, on average.

Table 5.1: Break-Even Calculation

Selling Price (X) = Variable Costs (X) + Fixed Costs
$160X = $103.20X + $725,000
$56.80X = $725,000
X = 12,760 units

Analyzing Merit Medical's 2013 Annual Report, it was discovered that the company generated close to $125.5 million with its stand-alone devices. Guidewires and torque devices as well as hemostasis valves are what help to compose this category. If MedAmerika can even reach 2% of these sales then this will be equivalent to total revenue of $2.5 million. With the assumption of selling $2.5 million worth of products in the first year, the appropriate percentages were applied. Taking the selling price and subtracting the variable cost provided the profit

margin for each unit ($56.80). Dividing the fixed costs by the profit margin determined how many units must be sold in order to break even. In other words, 12,760 units must be sold in order to break-even or for expenses to equal revenue. This means that every unit over 12,760 will be $56.80 in profit.

5.4.2 Variable Costs

In order to find the average variable cost of the products sold at MedAmerika Inc., the annual reports of Merit Medical were first consulted. The profit margin was attained by taking the percentage of cost of goods sold and applying it to the total revenue. It showed that this percentage of cost of goods sold would be equivalent to 57% of the total revenue.

A consultation was then initiated with sales representatives at Tampa General Hospital in order to find the selling price of products similar to the guide wire torque device. This associated cost was estimated to be around $15. This cost was added to the previously determined cost of a guidewire ($145). This makes the total selling price at $160, while the total cost to make these goods would be around $91.20. However, expenses will be structured in a way that will include R&D funding as a variable cost. This way the amount of products sold will be directly correlated with the funding for R&D giving MedAmerika Inc. increased R&D funding during higher levels of profitability. R&D will be set around 7.5% as it is with Merit Medical leaving the total variable costs at $103.20 or 64.5% of total revenue.

5.4.3 Fixed Costs

Fixed costs are defined as the selling, general, and administrative expenses incurred from operating a facility. As taken from the annual reports of Merit Medical, the selling, general and administrative expenses were found to be 29% of total revenue for the year 2013. With this said, the anticipated total revenue, assuming the capture of 2% of Merit Medical's total stand-alone

device market, will be $2.5 million for the first year. This would mean fixed costs would be set at $725,000.

This number may seem low, however this is due to the fact that management will offset the costs by taking a minimal salary during the initial stages of the business. In addition, production will carry out in an already established facility, eliminating the costs associated with erecting a new building.

5.4.4 Payback Period

The payback period can be seen in below in Table 5.2. First, it was assumed that an average of just over 15,600 products would be sold annually at an average price of $160 in order to generate $2.5 million in revenue for the first year. These products cost the company $103.20 per unit. This means that the company should generate a gross margin of roughly $887,500 annually. Since the fixed costs are $7250,000 annually, the company will only make slightly over $160,000 each year before taxes and other expenses are taken out. It will cost upwards of $750,000 to open up the new facility and begin production. This is due to the rental of the facility, a 50,000 sq. ft. warehouse at $375,000 annually, as well as the purchase of all equipment necessary to begin production. This signifies that the payback period would be slightly over 4.5 years.

Table 5.2 Payback Period Calculations

Units Sold Annually	15,600
Average Selling Price per Unit	$160
Average Variable Cost per Unit	$103.20
Annual Fixed Costs	$725,000
Total Annual Profit (disregarding taxes and other expenses)	$162,500
Startup Costs	$750,000
Approximate Annual Revenue	$162,500
Payback Period in Years	<5

With this calculation, it would appear that the payback period is relatively reasonable and that MedAmerika Inc. can reach profitability at an early stage. However, these calculations do not take into account many other expenses that will be placed upon the company and the numbers in question are only reasonable estimates.

Given that expensive equipment must be purchased, a building must be leased, personnel must be hired, and many other aspects of running a business will cost additional money, this would *suggest licensing the product to be a safer and more cost-effective approach*. This would allow for much of the risk in starting a brand-new company to be eliminated and would also allow for profits to be received at a much earlier stage.

With this said, licensing royalties are typically set anywhere from 5-10% depending on the industry and the quality of the negotiator (Licensing Royalty Rates, 2014). The royalty fee can also be applied to sales of the product or what it costs to manufacture the product. If a royalty fee of 7% of sales is assumed then the amount to be made through licensing can be estimated. In addition, an upfront fee is often included in order to indicate good faith. This can be assumed to be $100,000 based on the fees others typically receive. If the torque device were to be licensed to Merit Medical in order to enhance its product offering and Merit Medical was only able to do $2.5 million in sales, this would imply $175,000 in royalty fees to be paid. This is on top of the initial $100,000 upfront fee. This means in the first year a total of $275,000 would be paid without having to incur any other liability or manufacturing or distribution expense.

This is exactly why licensing the product is much more appealing than going the creation of a new company route. It can also be assumed that Merit Medical or any other large medical device company could achieve economies of scale much easier which would lower the manufacturing cost of the device. Along with this, a large and already established company

already possesses the proper distribution network and can substantially increase the sale of that product. In other words, a company of this nature could sell well beyond the $2.5 million mark, thus leading to even more royalty fees to be collected.

5.5 Summary

As can be seen through this analysis, the market potential for this industry is highly attractive. This is not only because the market is growing at a steady pace, but the key economic indicators are also favorable. MedAmerika Inc. would be able to penetrate the market relatively easily given the type of product it will offer as well as given the physician's initial positive evaluation.

After the calculations, it was seen that profitability should be able to be reached within the first five years of production. However, it may be more profitable as well as extremely less risky to license the product to companies such as Cook Medical, Medtronic, Merit Medical, Abiomed, Covidien, Boston Scientific, or a host of other large and successful companies instead of pursuing the creation of the business. With this said, MedAmerika Inc. will remain optimistic and keep the idea of opening in the future, but, for now, will pursue opportunities related to licensing its products.

CHAPTER 6

CONCLUSION

This chapter provides a final summary of the analysis of the proposed design of the new guidewire torque device. The challenges and limitations along with future work and design recommendations will be discussed below.

6.1 Research Summary

This research presented the design and analysis of a new guidewire torque device for the use of vascular surgery and cardiology applications. Evaluation data were collected through the use of surveys, surgical observations, and personal interactions with physicians. An array of design concepts were analyzed to decide on a final design for the manufacturing for the new medical device. Proceeding an in-depth examination of current guidewire torque devices through direct observation and examination of the literature and relevant patents design elements were developed. Such design elements, along with the support and suggestions of physicians who use guidewires, allowed for the new guidewire torque device to be developed with characteristics unseen in current medical devices. With the use of SolidWorks CAD software, initials designs were developed with minor adjustments made. It was recognized at this point that parallel, horizontal ridges or bumps were not a desired pattern to effectively grip the guidewire. As a result, efforts were refocused in attaining another material that would comply with design

specifications. The anti-slip shower adhesive fulfilled the required parameters, which allowed for the further development of the torque device.

The proposed medical device complies with user specifications as well as design requirements listed in the tables above. The ease in which the device is mounted and secured both on the guidewire and surgical glove respectively sets this design apart from other devices currently in the marketplace and currently used in many operating rooms across the nation. Additionally, the anti-slip adhesive used for this device was manufactured at a very small thickness value, which minimizes and possibilities for surgical interference. This device is cost effective to manufacture, allowing physicians to discard the device once its purpose is served.

6.2 Future Work

It is advised to proceed with more testing procedures to further characterize the anti-slip adhesive. Also, the FDA requires a set of general examinations that must be met in order for the new guidewire torque device to gain approval. Such examinations require an additional level of monetary funding to carry out the tests to its fullest potential. With an extensive understanding of material properties, further opportunities such as patent rights and licensure agreements can be attained.

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APPENDICES

Appendix A: Medical Device Survey

Today's Date: _____ **Time:** _____

Gender: ☐ Male ☐ Female

Please choose one of the following: ☐ Resident ☐ Attending Physician

If you are a resident, please indicate the amount of years you have been one: _____

Please choose one of the following: ☐ Right-Handed ☐ Left-Handed

Please rate each of the following numbers in accordance to each of the stated categories.
Circle a number that best agrees with your opinion according to the following criteria:
1 = Very Unsatisfied 3 = Neutral 5 = Very Satisfied

	Design A	Design B	Design C	Design D	Design E
Material -Does the patch adhere securely to glove? Is it conducive to user needs?	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Ease of Use -How easy is the device to use? Is it simple to apply to surgical glove? Does it interfere with other surgical handling?	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Grip Force -Does the device resist the guide wire from sliding back and forth in a wet environment?	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Torquability - How is the rotational response at the distal end of the device while imparting a rotation at the proximal end?	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Device Quality -Please rate the overall quality of the device, taking all other categories into consideration?	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Do you have any suggestions for improving our product?

_____

_____

_____

_____

Figure A.1: Medical Torque Device Survey

Appendix B: 510(k) Sample Summary Report

510(k) Summary

Patch Torque Device

510(k) Number K123456

1. Applicant's Name:

MedAmerika Inc.

1234 Undiscovered St.

Tampa, FL 33620

Tel: (123) 456-7890

Fax: (123) 456-7890

2. Contact Person:

Name: Erika Rigaud

Title: President

Tel: (123) 456-7890

Fax: (123) 456-7890

E-mail: erigaud@mail.usf.edu

3. Trade Name:

Patch Torque Device

Figure B.1: 510(k) Example Report

4. Classification:

Name:	Guidewire Torque Device
Product Code:	DQX
Regulation No:	870.1330
Class:	I
Classification Panel:	Cardiovascular

5. Predicate Devices:

- Guide Wire Torque Device (Merit Medical), catheter guidewire, product code DQX, cleared for marketing under K072552
- WireClip™ Torquer (Boston Scientific Corporation), guidewire torquer, product code DQX, cleared for marketing under K003398

6. Intended Use:

The Patch Torque Device is intended to facilitate steering of guidewires during interventional procedures.

7. Device Description:

The Patch Torque Device consists of two similar yet distinct pieces of rubberized polymer. These pieces are attached to the thumb and forefinger areas of a surgical glove. The thumb and forefinger may then simply line up where desired on the guidewire and squeeze firmly together in order to begin manipulation. The Patch Torque Device is able to accommodate guidewires of all diameters given that there is nothing requiring the guidewire to fit into.

Figure B.1: Continued

The Patch Torque Device is designed to grip any and all size guidewires as well as in hydrophobic and hydrophilic conditions. Being positioned on the surgical glove allows for easy placement and removal from the guidewire. The need to insert the guidewire through a tube or into a groove has been eliminated.

The Patch Torque Device is a sterile, non-pyrogenic single use device. It is manufactured in several sizes to accommodate the variation from hand to hand.

8. Technological Characteristics:

The Patch Torque Device's technological characteristics are the same as those of its predicate devices. It is an accessory torque device for manipulating guidewires, Is compatible for use with all types of guidewire diameters and lengths, and can be positioned and repositioned on the guidewire. In comparison to the predicates, rotating the device results in steering the guidewire.

Identical to the predicates, Patch Torque Device is a sterile, non-pyrogenic single use device manufactured from biocompatible materials and sterilized by ETO.

9. Summary of Supporting Data:

The Patch Torque Device performance characteristics were evaluated in the following in-vitro/bench studies:

- Packaging Environmental Endurance
- Dimensions Verification

Figure B.1: Continued

- Device and Guidewire Axial Force
- Torque Force
- Device Operational Force
- Performance During Exposure to Fluids
- Usability
- Sterility Integrity and Shelf Life
- Biocompatibility:
    - Cytotoxicity
    - Systemic toxicity
    - Sensitization
    - Irritation
    - Subchronic toxicity
    - Genotoxicity
    - Haemocompatibility – Hemolysis

Results of nonclinical testing demonstrated that the device is as safe, as effective, and performs as well as the legally marketed devices identified in paragraph 5 of this section.

10. Conclusion:

MedAmerika Inc. believes that, based on the information provided in this submission, the Patch Torque Device, is substantially equivalent to its predicate devices without raising any new safety or effectiveness issues.

Figure B.1: Continued