8-31-2010

Design of a New Suturing and Knot Tying Device for Laparoscopic Surgery

Sinan Onal
University of South Florida

Design of a New Suturing and Knot Tying Device for Laparoscopic Surgery

by

Sinan Onal

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science in Engineering Management
Department of Industrial and Management Systems Engineering
College of Engineering
University of South Florida

Major Professor: Susana Lai-Yuen, Ph.D.
Stuart Hart, M.D.
Patricia Zarate, Ph.D.

Date of Approval:
June 30, 2010

Keywords: suturing device, laparoscopy, hysterectomy, medical device design, prototype

Acknowledgments

I would like to express my heartfelt gratitude to my advisor, Dr. Susana Lai-Yuen for her supervision, and guidance from the very early stages of this research. She has always provided me constant encouragement and support in various ways in my journey of growing into the researcher and scientist that I want to be. I am indebted to her more than she knows. My sincere thanks also go to Dr. Stuart Hart for his advice and crucial contribution to this study, which made him a backbone of this research. His involvement with his expertise in this area has triggered and nourished mine. Above all, this thesis would have not been possible, had he not given me the opportunity to observe his operations. Likewise, Dr. Patricia Zarate deserves special thanks as another member of my committee. Her being accessible and approachable as well as her instant support when I am in need have helped me experience a smoother and more fruitful process throughout this study. I would also acknowledge my friends Issa Ramirez, Gokmen Demirkaya, Ricardo Vasquez Padilla and Humberto Gomez for their willingness to share their ideas with me. Last but not least, words fail me to express my appreciation to my wife Derya whose unconditional love and support, and persistent confidence in me, has taken the load off my shoulder, and to my one-and-only daughter, Pera, the reason of my life, for simply cheering it up and making it more meaningful with her presence every passing day. I would not be here today without them and their love.

Table of Contents

List of Tables

List of Figures

Design of a New Suturing and Knot Tying Device for Laparoscopic Surgery

Sinan Onal

Abstract

Minimally invasive or laparoscopic surgery has completely changed the focus of surgery becoming an alternative to various types of open surgery. Minimally invasive surgery avoids invasive open surgery as the operation is performed through one or more small incisions in the abdomen and using a small camera called laparoscope. Through these incisions, surgeons insert specialized surgical instruments to perform the operation resulting in less postoperative pain, shorter hospital stay, and faster recovery. However, the main problems during minimally-invasive surgery are the limited space for operating instruments and the reduced visibility and range of motion inside the patient's body. During minimally-invasive surgery, one of the most difficult and time consuming surgical procedures is suturing and knot tying. This procedure significantly increases the operation time as it requires advanced techniques and extensive experience by surgeons. The main goal of this research is to investigate, design, and develop a new suturing instrument to facilitate suturing procedures during minimally invasive surgery. Qualitative research data was collected through interviews with a surgeon and six in-depth observations of minimally invasive surgeries at Tampa General Hospital. Different design concepts and mechanisms were created using SolidWorks CAD software, and tested using SimulationXpress in order to identify dimensions, materials and expected

performance of the design and its components. The prototypes of the device were made using a Dimension SST 768 FDM machine and tested by the surgeon to ensure that the final design meets the specified needs and criteria. This new device will eliminate the use of many different devices during the operation and allow the use of any type of suture. The proposed suturing device aims to benefit both patients and surgeons. For surgeons, the new device aims to decrease the number of steps for laparoscopic suturing through an intuitive and ergonomic design. For patients, the proposed device will reduce time during surgery and under general anesthesia leading towards improved health care.

Chapter 1

Introduction

This chapter introduces the motivation underneath this research work and the current challenges in minimally-invasive surgical procedures. The research objectives are presented followed by the thesis outline.

1.1 Motivation

Minimally invasive surgery (MIS) or laparoscopic surgery has changed the focus of surgery becoming an alternative to various types of open surgery. Minimally invasive surgery is a new surgery technique that avoids invasive open surgery by operating through small incisions in the abdomen and using a small camera called laparoscope as shown in Figure 1.1. The small incisions measure about 6.5 – 12.7 mm in size compared to the minimum incision size of 20 cm required for traditional open surgery techniques ("Minimally invasive", 2010). Through these incisions, surgeons insert specialized surgical instruments to perform the operation while observing the working space through a video monitor as shown in Figure 1.2. For this reason, minimally invasive surgery results in less tissue trauma, less scarring, and faster post-operative recovery time.

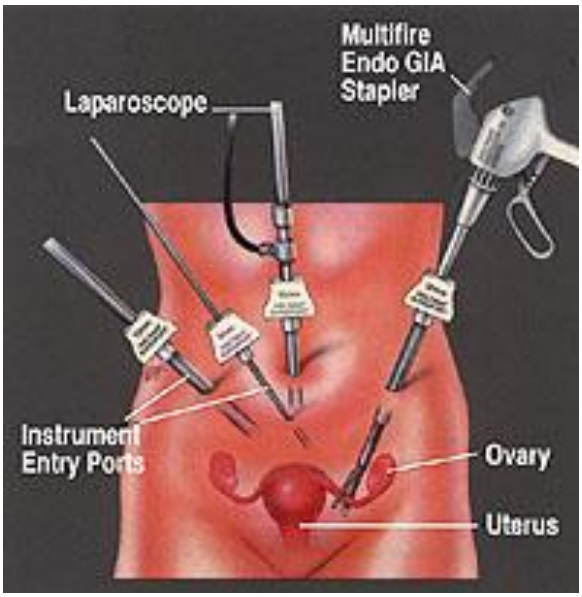


Figure 1.1: Minimally invasive surgery [drawing]. Retrieved January 10, 2010 from www.rfay.com.au/laparoscopic

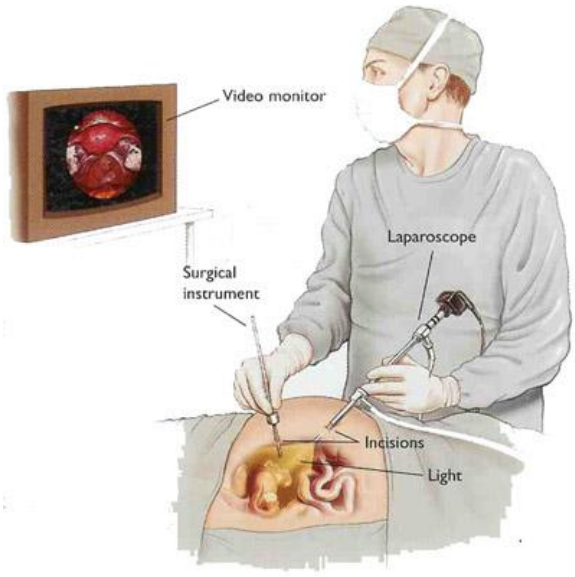


Figure 1.2: 2D monitoring during minimally invasive surgery [drawing]. Retrieved January 10 from www.rfay.com.au/laparoscopic

According to the U.S. Department of Health and Human Services, it is estimated that in 2008 there were around 220,000 gastric bypass procedures and more than 250,000

appendectomies performed in the United States. Also, about 50,000 patients in the United States are diagnosed each year with liver metastases that require a liver resection procedure. Furthermore, hysterectomies are the second most common surgery performed among women in the United States, with over 600,000 operations carried out each year and while up to 75% of hysterectomies are performed through open surgeries (Dunitz, Sheth, & Studd, 2002). The percentage of laparoscopic hysterectomies is increasing and will greatly benefit from new improved instruments that facilitate this type of surgery

There are several benefits of minimally invasive surgery over traditional methods. The most important benefit is that post-operative scars are much smaller than those that occur as a result of conventional "open" surgery thus resulting in less pain for the patient. Single-incision minimally invasive surgery leaves minimal scar because the surgery is performed through a single incision in the belly button. Patients require less pain medication and recover faster, normally returning home within 24 hours after their surgery. This is a major advantage when compared with hospital stays of 2 to 5 days from open surgery patients.

In recent years, minimally invasive surgery has developed in a way that it is now being used to perform a variety of procedures such as gastric bypass, appendectomy, liver resection, hysterectomy, and more. Although minimally invasive surgery has become increasingly popular, the problems pertaining to it, such as limited visibility, constrained working space, and the use of high-end technological tools, still complicate the surgery. Surgeons need to obtain extensive training to be qualified to perform minimally-invasive surgeries and not all hospitals have the special equipment necessary to perform such surgeries. In addition, the design of medical tools for minimally-invasive surgery is

constrained by the size of the ports used to insert the surgical instruments. These ports normally have an opening of 5-12 mm in diameter where the surgical instruments are inserted to perform a laparoscopic surgery. Therefore, surgical tools need to be small enough to fit through these ports making the design of these tools a challenge.

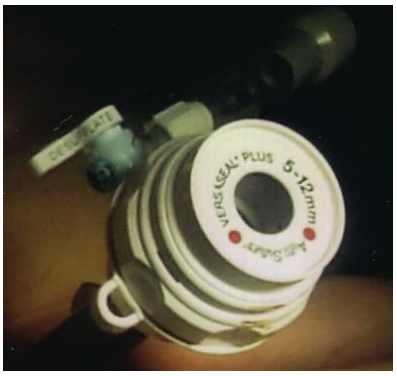


Figure 1.3*:* 12-mm laparoscopic port [photograph]. Retrieved February 6, 2010 from: http://www.laparoscopytoday.com/pediatricsurgery/page/3/

During a laparoscopic surgery, suturing and knot tying are among the most difficult and most time consuming procedures. These procedures significantly increase the operation time as they require advanced techniques and extensive experience by surgeons due to the limited operating space and motion range (Pattaras, Smith, Landman, & Moore, 2001). The most common suturing approach is the conventional technique, which consists of using a curved needle and two needle drivers to perform the task. According to Adams et al., the time for each suturing placement through the conventional method averages 151±24 seconds and each knot tying time of conventional technique is on average 197±70 seconds (Adams, Schulam, Moore, Partin, & Kavoussi, 1995). If we consider that a surgeon has to knot six times on average, the duration of the operation increases considerably due to suturing. Although suturing devices for minimally-invasive

surgery are commercially available and currently being used, surgeons still indicate the need for better devices that can facilitate the suturing and knot tying procedures during minimally-invasive surgeries. The main limitations for designing devices for this type of surgery are the limited space and motion range, which greatly constraint the dimensions and mechanisms of the device.

1.2 Thesis Objectives and Contributions

The proposed research aims to address the main laparoscopic suturing challenges and current literature limitations in the market. The main goal of this research is to investigate, design, and develop a new medical device system for facilitating suturing and knot tying procedures during minimally-invasive surgery. The device will also enable the use of any type of suture on the needle.

The major objectives of this thesis are:

1. To investigate and design a new suturing device to minimize the suturing risks and difficulties during minimally invasive surgery. This device aims to decrease the suturing operating time while being intuitive for surgeons to use.
2. To implement a physical prototype of the design to analyze and test the effectiveness of the device.

This research focuses on the suturing and knot tying procedures during hysterectomies, which is the second most common surgery among women in the U.S. according to the U.S. Department of Health & Human Services. However, the proposed research can be applied to any minimally-invasive surgical procedure that requires suturing and knot tying. The hysterectomy procedure consists of removing the women's

uterus and sometimes the ovaries and fallopian tubes. Suturing and knot tying is required after the uterus is removed from the patient.

This new instrument aims to benefit both patients and surgeons. For surgeons, the new device aims to minimize the suturing difficulties encountered during minimally-invasive surgery. This is expected to help surgeons in performing suturing faster and safer. For patients, the proposed device will reduce the surgery time thus reducing the time under general anesthesia. At the same time, the proposed suturing device contributes to patient's safety that can lead to improved health care.

1.3 Thesis Outline

Chapter 2 discusses current research work and available devices for suturing and knot tying during minimally-invasive surgery. Chapter 3 examines the conventional suturing device and knot tying technique commonly used in minimally-invasive surgery through a human factors approach. This examination provides recommendations for the device design. Chapter 4 describes a new surgical suturing device and its design stages. Each design stage is introduced to understand the logic behind the new instrument. Chapter 5 provides a summary of the research methodologies presented and future research work.

Chapter 2

Literature Review

This chapter provides the background of current research work in the area and introduces suturing devices currently used in minimally-invasive surgery. Current designs are analyzed and their limitations identified.

2.1 Conventional Laparoscopic Suturing and Knot Tying Process

The conventional suturing technique has been performed for many years and it is still the most common suturing technique used by surgeons even though it has many difficulties. It is performed by using a curved needle and two elongated needle drivers. The curved needle and needle drivers are inserted through the laparoscopic ports and suturing placement is performed manually inside body. Many types of needles exist that are specifically designed for conventional laparoscopic suturing. In previous years, straight needles were used for laparoscopic suturing as they were easier to introduce into the abdominal cavity; however, it was difficult to control them while suturing (Sanfilippo & Solnik). Curved needles are currently used for suturing in minimally-invasive surgery, as shown in Figure 2.1. They have become very popular but need to be handled using elongated laparoscopic needle drivers and Maryland Graspers as shown in Figures 2.2 and 2.3, respectively. For this reason, the first problem with curved needles is that hands-on experiences using these instruments are needed. The second problem is that curved

needles can be difficult to insert in the correct location as the abdominal wall prevents free movement of the needle driver (Sanfilippo & Solnik).

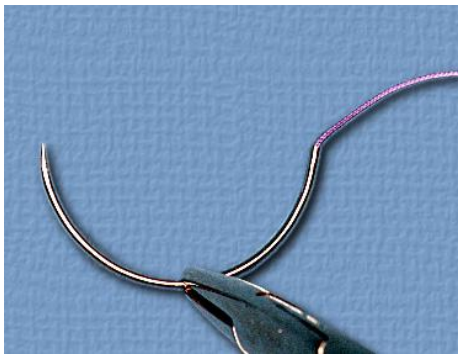


Figure 2.1: Curved needle with surgical suture [photograph]. Retrieved February 10, 2010 from www.wikisurgery.com

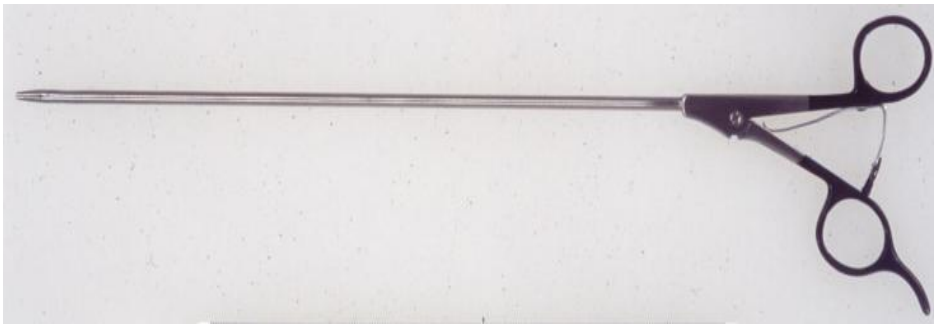


Figure 2.2: Laparoscopic needle driver [photograph]. Retrieved February 10, 2010 from www.kenzmedico.co.jp

Figure 2.3: Maryland grasper [photograph]. Retrieved February 10, 2010 from www.stryker.com

To facilitate the conventional suturing and knot tying technique, various types of suturing and knot tying approaches have been introduced in previous years. The oldest technique is intra-corporeal suturing and extra-corporeal knot tying technique as shown in Figure 2.4 (Liu, 1993). Extra-corporeal knot tying is a method to avoid the difficult and time-consuming skill of intra-corporeal knot tying. Two elongated laparoscopic needle drivers and a curved needle are used to suture. On the other hand, knot is tied outside the body and then the loop is pushed into the operating area by a knot pusher as shown in Figure 2.5. This technique also requires high level skills.

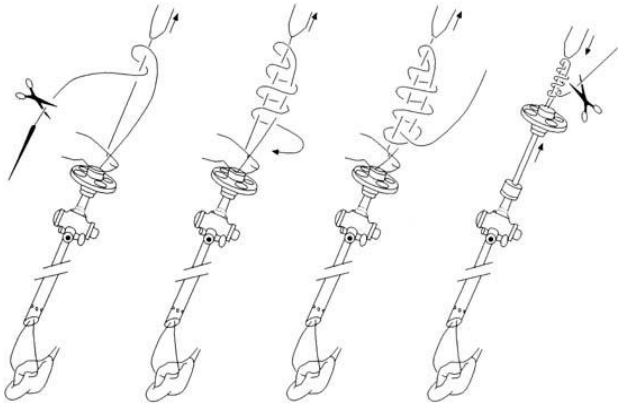


Figure 2.4: Extra-corporeal knot tying technique. (Liu, 1993)

Figure 2.5: Knot pusher [photograph]. Retrieved February 15, 2010 from www.calicutsurgicals.com

There are two categories of knot tying techniques that are used in extra-corporeal tying: half-hitches and compound sliding knots. As shown Figure 2.6, the half-hitches knot is the simplest of all sliding knots formed and the basis for a multitude of other knots used. The half-hitches technique is described in the medical dictionary as consisting of "… one straight strand with the other thrown over, back over itself, under the original strand and back through the loop created by the earlier steps. It is the basis for square, granny and surgeon's knots, depending on how the hitches are thrown ("Half-hitches technique", 2010)

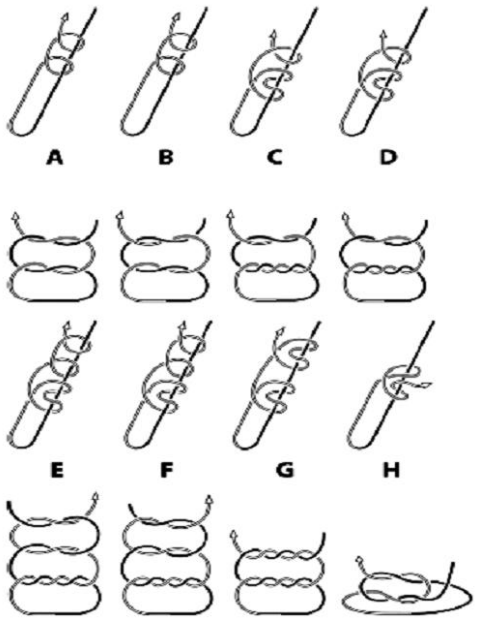


Figure 2.6: Half- hitches knot techniques. (Khattab, 2008)

The compound sliding knots technique is shown in Figure 2.7. This knot technique has more than one turn of the wrapping limb around the post (i.e., any sliding knot other than a half hitch). It can be applied in situations where the suture slides smoothly and freely through the tissue and anchoring device. The advantage of the

compound sliding knots is that the knots can be made to slide down the post limb without unraveling or jamming prematurely. Theoretical disadvantages include abrasion of suture against the anchor eyelet and suture cutting through tissue as it slides (Lo, 2008), (Gunderson, 1987), (De Beer, van Rooyen, & Boezaart, 1998), (Delimar, 1996), (Fleega & Sokkar, 1999), (Holmlund, 1974), (Hughes, Hagan, Fisher, Hold, & Frostick, 2001), (Ilahi, Younas, Alexander, & Noble, 2004).

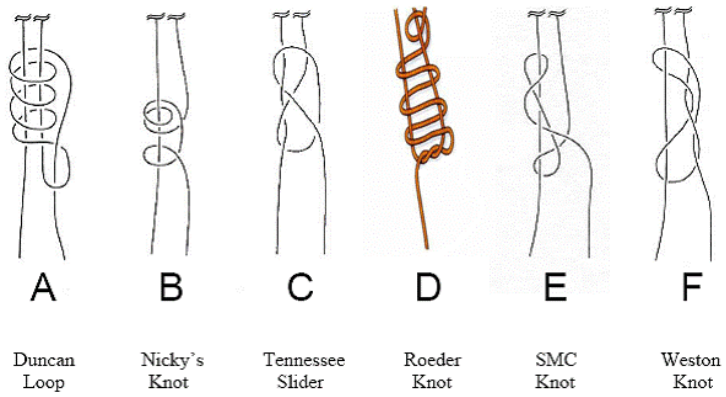


Figure 2.7: Compound sliding knots. (Khattab, 2008)

Due to the difficulties to operate the intra-corporeal suturing and extra-corporeal knot tying technique, another technique called intra-corporeal suturing and intra-corporeal knot tying technique was introduced as shown in Figure 2.8 (Topel, 1996). In this technique, a curved needle with suture and two elongated laparoscopic needle drivers are used for suturing and knot tying. As the operation is performed inside the body, this technique requires high level skills to manipulate the curved needle and to pass the needle from the first needle driver to the next. Another difficulty of this technique is the limited working space available to use the knot tying instruments inside the body

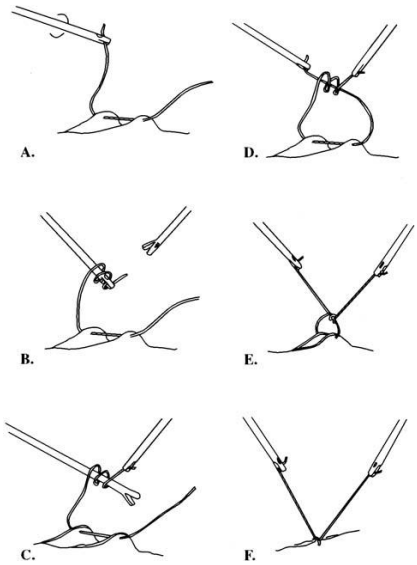


Figure 2.8: Intra-corporeal suturing and intra-corporeal knot-tying technique. (Topel, 1996)

2.2 Commercially Available Suturing Devices

Many laparoscopic suturing systems have been developed in recent years (Kennedy, 1992), (Grace, P, & D., 1992.). However, most of them are not always successful and sometimes cause new and different problems such as loss of pneumoperitoneum, excess tension on the tissue that is being re-approximated, and suture breakage during placement (Adams, et al., 1995). The most commonly used suturing devices are Endo Stitch™ by Covidien and Capio® by Boston Scientific, which are described in the following sections.

2.2.1 Endo Stitch™ 10 mm Suturing Device

As shown in Figure 2.9, Endo Stitch™ 10-mm ("Endostitch 10 mm suturing", 2008) serviced by Covidien is one of the devices currently used for laparoscopic suturing. Endo Stitch™ single-use suturing device has two jaws and consists of four main parts: a

handle, a toggle lever, a needle holder secured inside the jaws and a needle. The device can be operated through the handle and the toggle lever. Also, the suture is secured in the middle of the needle so that the suture can pass through the tissue. After the needle holder is loaded with the needle and suture, the needle is passed from one jaw to the other by closing the handles and flipping the toggle lever. Rotating the toggle lever and releasing the handle enables the needle to stay on the opposite jaw. When this is complete, the needle is ready for the next maneuver. This device can also be used to tie knots as shown in Figure 2.10.

Figure 2.9: Endo Stitch™ 10 mm suturing device [photograph]. Retrieved February 13, 2010 from www.autosuture.com

Adams et al. compared the automated suturing using the Endo Stitch™ with conventional techniques in 1995. Results showed that the Endo Stitch™ allowed placing individual sutures faster, reducing the required time by two thirds. The data demonstrated that the Endo Stitch™ significantly decreased times for suturing placement and knot tying compared to the conventional approach. For suturing placement time, the Endo Stitch™ averaged 43±27 seconds whereas the conventional method averaged 151±24 seconds. Moreover, while Endo Stitch™ knot tying was performed on an average of 74±50 seconds, conventional technique averaged 197±70 seconds. The Endo Stitch™ also automatically reloads the needle for each maneuver.

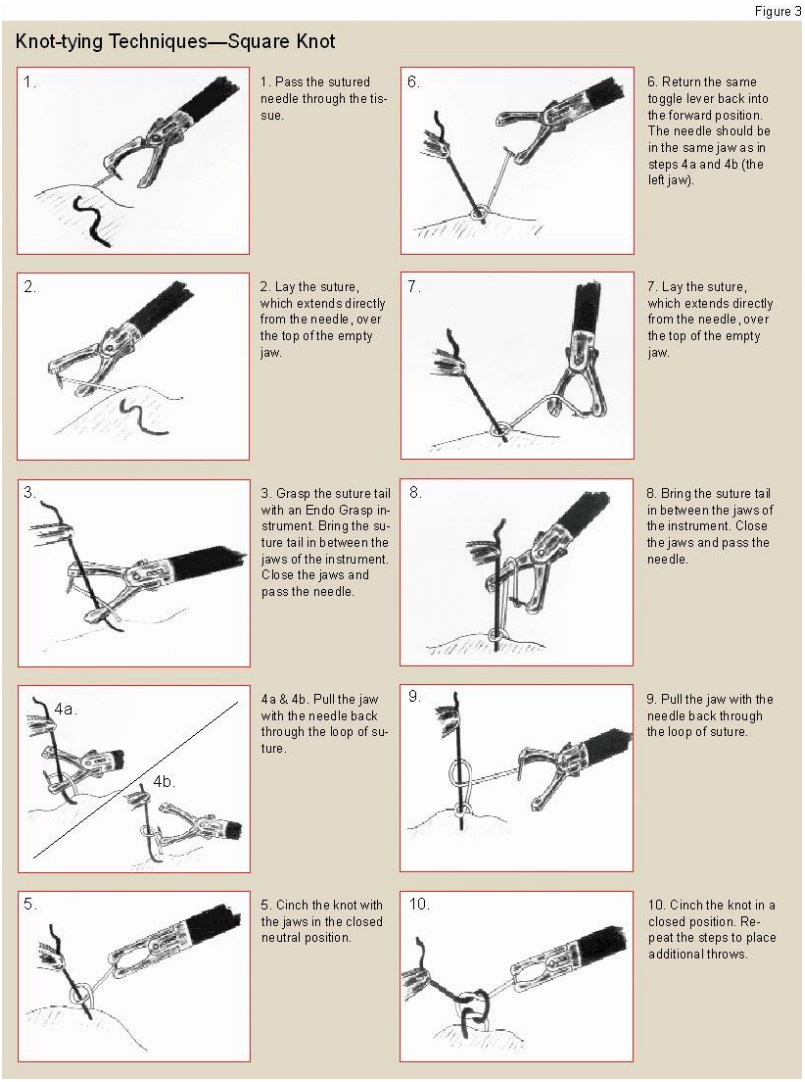


Figure 2.10: Knot tying technique with Endo Stitch™. (Huhn, 2004)

2.2.2 Capio® Open Access and Standard Suture Capturing Device

Another instrument used for suture placing is Capio®. The device is designed for general suturing applications during open and endoscopic surgery to assist in the placement of suture at the operative site ("Capio open access", 2010).

As shown in Figure 2.11, the device has six main parts, (1) needle carrier, (2) head, (3) suture, (4) elongate body, (5) needle driver button, (6) alignment indicator ("Capio open access", 2010).

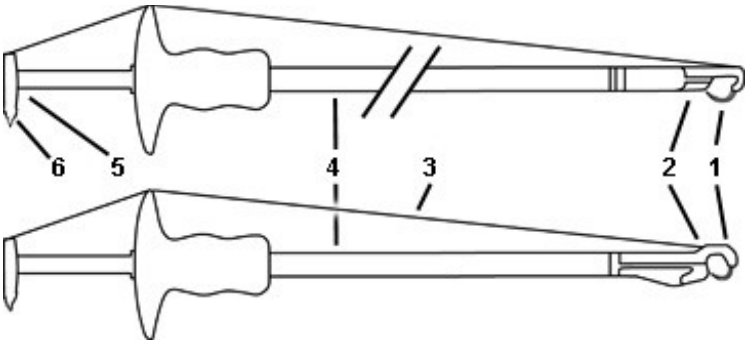


Figure 2.11: Capio® suture capturing device [drawing]. Retrieved February 13, 2010 from www.bostonscientific.com

The principle of operation is suture placing with a needle and thread. As shown in Figure 2.12, the needle is placed at the tip of the device. With the push of the button, the needle is transported through the tissue carrying a thread and is caught by the needle catcher. The user removes the needle from the needle catcher and reloads the needle at the tip of the device.

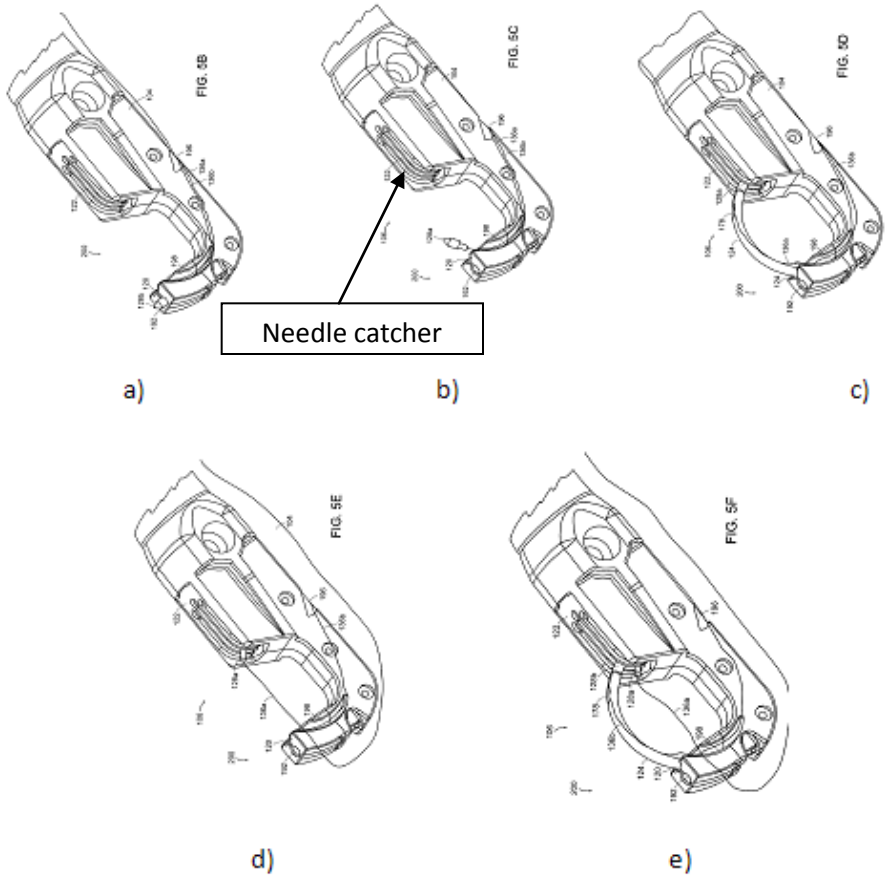


Figure 2.12: Partial schematic perspective views of distal portion of Capio® [drawing]. Retrieved February 13, 2010 from www.bostonscientific.com

Using this device is more effective and less painful for surgeons than a method where the surgeon has to remove the device from the surgical site and reload. This is particularly useful when the surgical site is located very deep inside the body and is difficult to reach. For instance, Capio® is used for trans-vaginal repair of para-vaginal defect operation as the surgical site is located deep inside the body and is not easily accessible as shown in Figure 2.13 (Nguyen & Bhatia, 1999).

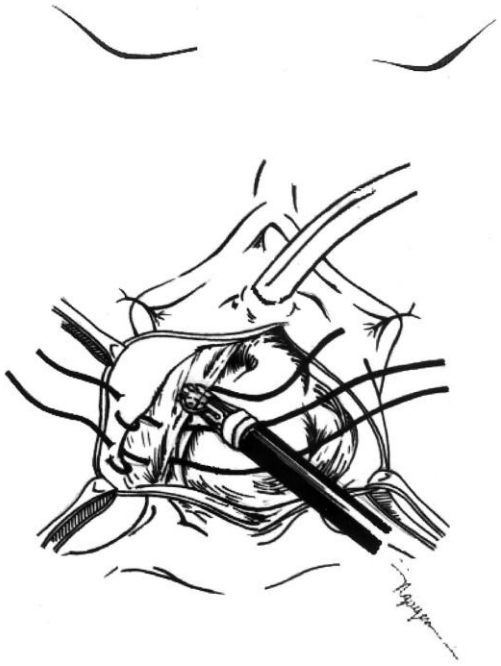


Figure 2.13: Transvaginal and paravaginal defect repair using the Capio®. (Nguyen & Bhatia, 1999)

Chapter 3

Case Study on Conventional Suturing Process

The conventional suturing process, which is commonly used by surgeons during minimally-invasive surgery, is analyzed in this chapter. Based on a case study on human factors analysis, the limitations of the conventional suturing process are identified and recommendations are proposed for a new device design.

3.1 Human Factors Engineering

Human Factors Engineering (HFE) is the science of designing or improving products, processes, and work environments by considering human capabilities and limitations. HFE can be applied to any process that involves a human interface ranging from the improvement of a system design, performance and reliability to user satisfaction. It can also be applied to procedures to reduce operational errors, operator's stress, user's fatigue and product liability. HFE helps improve human capabilities while decreasing possible risks that can occur during the use of the device. It also enables a better understanding of the operating process of a medical device to reduce device training and to increase the safe use of the device.

3.2 Introduction to Case Study

The conventional suturing and knot tying process was selected for the case study because it is still the most common suturing technique used by surgeons. Task Analysis and Failure Mode and Effect Analysis (FMEA) are used to identify the difficulties faced by surgeons. In this study, data for the user needs came from observations and interviews.

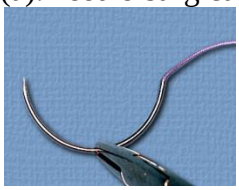
Information about the features of the user environment and the device functions were collected through on-site observation of the users, the surgeon and nurses were observed informally in operating rooms at the time of surgery for several days. Field notes were taken during these operations to identify the features of the user environment and the requirements for the suturing device. With this approach, the tasks carried out by the device were analyzed. It was observed that the device is to be used under direct visualization only during open or endoscopic surgeries. The device is to be of single use only and disposable so that it does not require any maintenance. The device is to be made of biocompatible materials and its main function is to assist in the placement of suture material in tissues. In addition, the length of the device should be larger than 280 mm and its diameter should be less than 12 mm due to the size of the maximum laparoscopic port.

3.3 Laparoscopic Instruments Used for Suturing and Knot Tying

The extra-corporeal knot tying approach uses many devices for the suturing and knot tying process, as shown in Figure 3.1. Curved needles of different sizes are used for the suturing operation and are manipulated with a laparoscopic needle driver and a Maryland needle grasper inside the patient's body. Surgical scissors are used by nurses to cut the surgical suture out of the body after the suturing operation is finished. Small

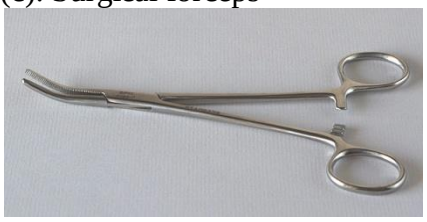
surgical forceps are used to retain the suture outside of the body. After knot tying is performed by using extra-corporeal knot tying approach, the loop is pushed into the body using a knot pusher. Finally, laparoscopic scissors are used to cut the suture after the knot is tied inside the body. These seven devices are used only for one loop.

(a).Needle-surgical suture



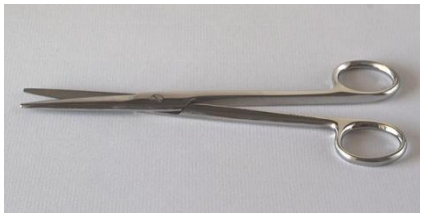
(b). Needle Driver

(c). Surgical forceps



(d). Maryland needle driver

(e). Surgical scissors



(f). Knot pusher

(g). Endo Shears- Laparoscopic scissor

Figure 3.1: Instruments used for conventional laparoscopic suturing and knot tying

3.4 Task Analysis

Task analysis is the analysis of how a task is accomplished. A task could be a process or the use of a device. Task analysis is used for several different purposes including personnel training, process understanding and device or process design. Jonassen describes task analysis as "a process of analyzing and articulating the kind of learning that you expect the learners to know how to perform" (Jonassen, Tessmer, & Hannum, 1999).

Table 3.1 shows the task analysis to understand the steps of the suturing and knot tying procedure using the extra-corporeal knot tying approach. These steps are performed for one loop and must be repeated for each additional loop, which shows the complexity of the suturing and knot-tying process. Each step in the table represents actions performed in the suturing and knot-tying process and how the device responded after those actions. Task analysis was also used to observe if there was any problem with the current processes and devices. For instance, although there was no observed problem for step 1 in the table, there was an observed problem for step 5. Once the user inserts the needle driver with needle-suture into the body through the biggest incision, the needle sometimes gets trapped by the port. This observation helped to see the current issues with the conventional suturing process. Therefore, performing the task analysis was very important in this research to anticipate potential problems when designing the proposed device.

Table 3.1: Task analysis for conventional suturing process

Step	User Action	Device Response	Observed Problem
1	Pick up the needle-suture	None	None
2	Unpack the needle-suture	None	None
3	Hold the suture from 2 cm with the needle driver	The needle driver grasps the suture	None
4	Hold the suture's other side with a small surgical forceps. It stays outside the body.	The surgical forceps grasp the suture	None
5	Insert the needle driver with needle-suture into the body through the biggest incision	The needle driver goes into the body with the needle and suture	The needle sometimes gets trapped by the port.
6	Insert the Maryland needle grasper into the body through one of the small incisions	It goes into the body	None
7	Hold the needle with the Maryland needle grasper	Maryland needle grasper seizes the needle	The needle is not caught in the correct position on the first time
8	Pass the needle to the needle driver	The needle driver grabs the needle	The needle cannot be caught by the needle driver on the first time. The needle is in the wrong position so it has to be corrected to the right position. Sometimes it takes time.
9	Hold the tissue with the Maryland needle grasper	Maryland needle grasper catches the tissue	None

Table 3.1: (Continued)

10	Place the needle on the tissue with the needle driver	The needle goes through the tissue	The needle cannot stay on the head of needle driver in the correct position. It has to be caught with the Maryland needle grasper first and then it is grasped by the needle driver. This is repeated until the needle is grasped in the correct position.
11	Release the tissue and Maryland needle grasper is free now	None	None
12	Hold the needle with the Maryland needle grasper	Maryland needle grasper seizes the needle	The needle is not caught in the correct position on the first time
13	Pull the needle away from the tissue	The needle goes out	Hands-on experiences are needed
14	Hold the needle with the needle driver	Needle driver grasps the needle	The needle cannot be caught by the needle driver on the first time. The needle stays in the wrong position so it has to be corrected to the right position. Sometimes it takes time.
15	Hold the other tissue with the Maryland needle grasper	Maryland needle grasper catches the tissue	None

Table 3.1: (Continued)

16	Place the needle on the tissue with the needle driver	The needle goes through the tissue	The needle cannot stay on the head of needle driver in the correct position. It has to be caught with the Maryland needle grasper first and then it is grasped with the needle driver. This is repeated until the needle is grasped in the correct position.
17	Release the tissue and Maryland needle grasper is free now	None	None
18	Hold the needle with Maryland needle grasper	Maryland needle grasper grasps the needle	The needle is not caught the correct position at the first time
19	Hold the suture from 2 cm with the needle driver	The needle driver grasps the suture	None
20	Take out the Maryland needle grasper from inside the body	None	None
21	Take out the needle driver and needle from inside the body	The needle driver and needle go out of the body	The needle sometimes gets trapped by the port.
22	Cut the suture with a scissor	The needle and suture are separated	None
23	Put the needle and the needle driver on the table	None	None
24	Take the knot pusher	None	None
25	Hold the suture with one hand	None	None
26	Replace the suture into the knot pusher	None	None
27	Take the small surgical forceps from end of suture	None	None
28	Hold the suture with the small surgical forceps on the same side with knot pusher	None	None

Table 3.1: (Continued)

29	While an assistant is holding the small surgical forceps, hold the suture with the left hand and hold the knot pusher with the right hand at the same time	None	A second person is needed to do it.
30	Tie a knot outside of the body	None	Hands-on experience is needed.
31	Push the loop inside the body by using the knot pusher	Knots go inside the body	It should go inside the body smoothly. Otherwise it breaks
32	Make sure the loop is placed in the correct direction	None	None
33	Take out the knot pusher from inside the body	None	None
34	Cut the suture inside the body with Endo Shears- Laparoscopic scissors	Knots stay inside	None
35	Repeat steps 1-33 about seven times	None	None

3.5 Failure Mode and Effect Analysis (FMEA)

Failure mode and effect analysis is a procedure used in the product development and product design stages for avoiding any possible failure before the process or device design are completed. It helps people to define the potential failure modes. FMEA is used to identify potential failure modes, determine their effect on the operation of the product, and identify actions to mitigate the failures. Ramasamy defines FMEA as "a methodology for analyzing potential reliability problems early in the development cycle where it is easier to take actions to overcome these issues" (Ramasamy, 2005).

Table 3.2 shows the Failure Mode and Effect Analysis to identify the current and potential failures during the conventional suturing process. The main objective of performing such analysis was to find the Risk Priority Number (RPN) score, which is used to prioritize potential failures that require additional quality planning or action. The

RPN is the mathematical product of the severity ranking of each effect of failure and the probability ranking of each potential cause of failure to the user and patient. As a common industry standard scale, the range of values for severity and probability ranking are from 1 to 10 as shown in Tables 3.3 and 3.4, respectively. Based on these values, the RPN scores for each function were obtained using Eq. 3.1 as follows (Crow, 2020):

$$\text{RPN} = (\text{Severity ranking}) \times (\text{Probability ranking}) \tag{3.1}$$

The Failure Mode and Effect Analysis enables the designers to focus more on eliminating the high-scored failures. For instance, one of the potential failures with high score in Table 3.2 is "the tissue cannot be caught by using the needle drivers" with a RPN score of 72. This happens because of the difficulty to maneuver the two needle drivers and results in a long time to catch the tissue by the surgeons. This failure was considered in the design process of the proposed device.

Table 3.2: Failure mode and effect analysis for conventional suturing process

Item/Part/ Function	Potential Failure Mode(s) (what might happen)	Potential Cause(s) of Failure (why it happens)	Effects	Sev.	Prob.	RPN
Holding the curved needle with needle drivers	The needle cannot be held with the needle driver	Difficult to hold the needle because of the needle's shape	Long operation time	8	4	32
		The user does not have experience	Same as above	8	3	24
		A wrong needle driver is used	Same as above	8	2	16
	The needle falls down	Difficult to hold the needle because of the needle's shape	The needle has to be changed	5	4	20
		The user does not have experience	Long/expen sive oper.	9	3	27

Table 3.2: (Continued)

		A wrong needle driver is used	Same as above	8	2	16
Inserting the curved needle into the body	The needle cannot be inserted into the body	The port is too small	The operation cannot be performed	10	3	30
		The needle is held in the wrong position	Dangerous maneuver	10	7	70
		The needle is too big	The operation cannot be performed	10	6	60
Passing the needle from a needle driver to another needle driver	The needle falls loose inside the body	Difficult to hold the needle because of the needle's shape	The user can damage the organs	10	4	40
		The user does not have experience	Same as above	10	3	30
		The working area is not visible	Same as above	10	9	90
Catching the tissue with the curved needle by using needle drives	The tissue cannot be caught by using the needle drivers	The working area is not visible	The user can damage the organs	10	9	90
		There is too much blood in the working area	Same as above	10	8	80
		Difficult to maneuver the two needle drivers	Long operation time	8	9	72
		The user does not have experience	The user can damage the organs	10	3	30
Performing the knot-tying out of the body.	Loops are too loose	The user does not have experience	Long and expensive operation	9	3	27

Table 3.3: Severity ranking criteria. (Villacourt, 1992)

Rank	Description
1-2	Failure is of such minor nature that the customer (internal or external) will probably not detect the failure.
3-5	Failure will result in slight customer annoyance and/or slight deterioration of part or system performance.
6-7	Failure will result in customer dissatisfaction and annoyance and/or deterioration of part or system performance.
8-9	Failure will result in high degree of customer dissatisfaction and cause non-functionality of system.
10	Failure will result in major customer dissatisfaction and cause non-system operation or non-compliance with government regulations

Table 3.4: Probability ranking criteria. (Villacourt, 1992)

Rank	Description
1	An unlikely probability of occurrence
2-3	A remote probability of occurrence
4-6	An occasional probability of occurrence
7-9	A moderate probability of occurrence
10	A high probability of occurrence

Chapter 4

Design Process of the Proposed Laparoscopic Suturing Device

In this chapter, the design process for a new medical device for laparoscopic suturing is described through the stages of analysis, synthesis, and evaluation. Various design concepts are presented and discussed followed by concept selection and testing.

4.1 Definition of Medical Device and Design Process

A brief description of the medical device can be useful to understand the design process of a medical device. According to the Food and Drug Administration (FDA), a medical device is "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 2010).

Also, the Food and Drug Administration has categorized medical devices into three classifications, Class 1, Class 2 and Class 3. Classification is risk based so the lowest risk devices fall into Class 1 while Class 3 includes high-risk medical devices such as artificial hearts. The proposed device can be considered a Class II device because it needs special controls such as endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing.

The medical device design process includes the steps that are helpful in the design of a new product. The Analysis-Synthesis-Evaluation model has mostly been used in design activities. A design process involves a considerable amount of analysis, investigation of basic physical processes, experimental verification and difficult decisions. The design process is a cyclical process as each step in the process follows and leads to one another as shown in Figure 4.1.

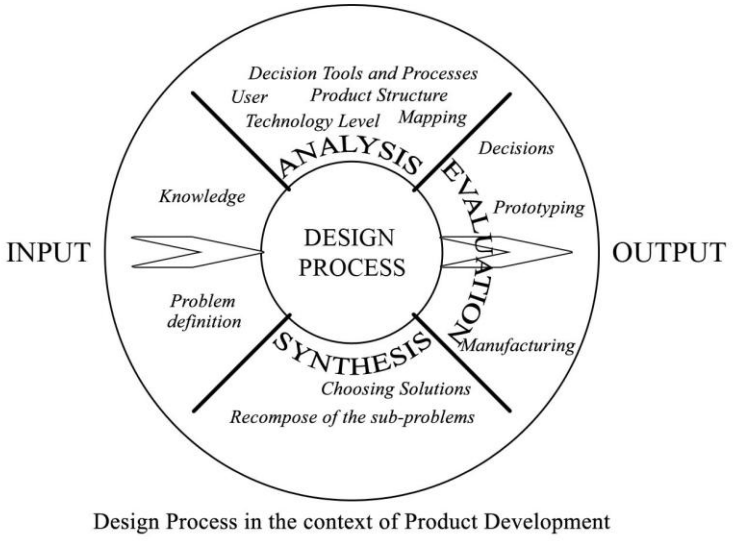


Figure 4.1: Product development process. (Cetin, 2004)

The following sections describe the analysis-synthesis-evaluation model used for developing the proposed laparoscopic suturing device, as shown in Figure 4.2. Results are also presented and discussed.

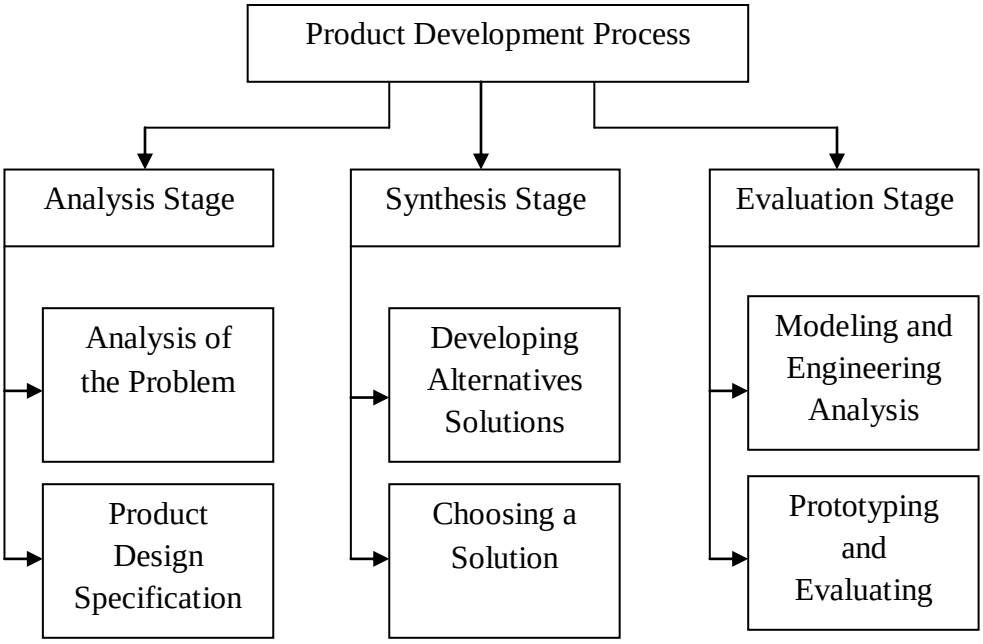


Figure 4.2: Product development process for the proposed device

4.2 Analysis Stage

In the analysis stage, the problem is defined and also client and design requirements are created. As shown in Figure 4.3, the analysis stage consists of two sub-steps: analysis of the problem and product design specification.

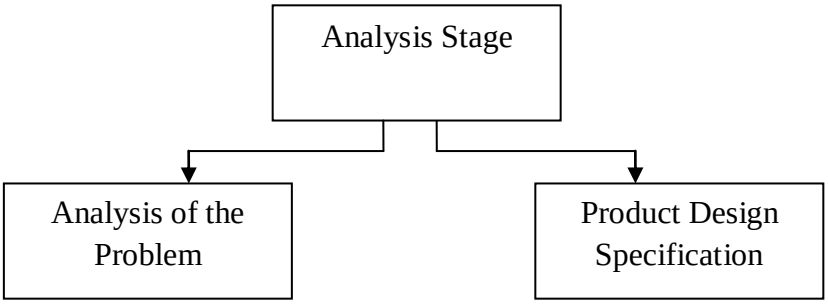


Figure 4.3: Sub-steps of the analysis stage

4.2.1 Analysis of the Problem

In order to solve a problem, it has to be clearly analyzed and defined. There are methods to help understand the problem and they are usually used in the analysis stage of the medical device design. As the first method, a literature search was conducted. Important and useful information about the field was obtained through this method by analyzing and evaluating the published reports, patent records and published books.

The second method for understanding the problem was observational analysis. On-site observations of the surgical procedure were performed at a local hospital to identify the needs and difficulties of the users. Through these observations, the surgeon's use of current devices and conventional techniques were observed. Observations were performed at Tampa General Hospital every other month during one year. Six cases were randomly selected and observed. Informal field notes were taken throughout these observations.

User interviewing was the third method to be used to understand the problem. In this research, there was a constant collaboration with a surgeon operating minimally invasive surgery. This collaboration provided important and useful information on the problem and served as reference for design planning. Interviews were done during and after each operation observed. During the interviews, the researcher took informal notes.

Another method used in this stage was benchmarking. This method helps to understand the capabilities of the devices currently available in the market. Three suturing approaches were analyzed to identify advantages and drawbacks: Endo Stitch™, Capio®, and conventional suturing process. The patent documents were used to get

information about other devices that are in the patent process but not currently commercialized.

Finally, task analysis was performed to capture the structure of tasks underlying the activity. This stage was used after the interview and observation methods. Through this analysis, the operating sequence was understood, and problems were defined.

4.2.2 Product Design Specifications

Once the problem is defined, the functions, purpose and characteristics of the new instrument are defined. The product design specification "specifies what the product will do, how it will do it and how reliable it will be. To be effective, it must be as precise as possible" (Fries, 2001). Requirements that are most important for the solution of the problem were defined and separated into two main categories: client requirements and design requirements. Client requirements were determined as:

- The new tool should be easy to use, ergonomic and be able to be operated by one hand.
- The new tool should be able to perform suture and knot tying inside the patient's body.
- The new tool should be able to be used on all types of surgeries that require suturing and knot tying.

On the other hand, the design requirements were determined as follow:

- Performance requirements: Must be portable and require minimal hands-on experience by the surgeons.
- Safety: Must not harm patient in any way.

- Accuracy and Reliability: Must be able to perform suturing and knot tying accurately and reliably.
- Life in Service: Must be disposable with no need for maintenance.
- Operating Environment: This device will be used in a surgery room environment and will be in contact with tissue, organs, blood and other liquids.
- Ergonomics: Device should be comfortable and not interfere with the surgeons' natural holding.
- Size: The device must fit into a 12-mm endoscopic port and its length must be at least 280 mm to reach the operating area.
- Weight: The entire device should not weigh more than 1 pound.
- Shelf Life: The shelf life will be five years stored at room temperature in a dry location.
- Materials: There are no restrictions on materials.

Detailed product design specifications are shown in Table 4.1 below.

Table 4.1: Product design specifications

Client requirements

Function	Requirements
Utilization	The new device should be used on all types of laparoscopic surgery
Operating	It should be operated by one hand
Ergonomic	It should be easy to hold and maneuver
Suturing/Knot tying	Knot tying should be made inside the patients' body

Design requirements

	Value
Needle and thread	Should be able to operate in two directions, left and right
Length of the shaft	>280 mm
Outer diameter	<12 mm
Weight	<1 pound
Life in service	Disposable/ no need for maintenance
Safety	Must not harm the patient in any way
Accuracy/ Reliability	Must be accurate and reliable

4.3 Synthesis Stage

In the synthesis stage, all possible solutions are developed and the best ones are combined. Then, the best solution is selected based on the customer and design requirements. Figure 4.4 shows the sub-steps of the synthesis stage.

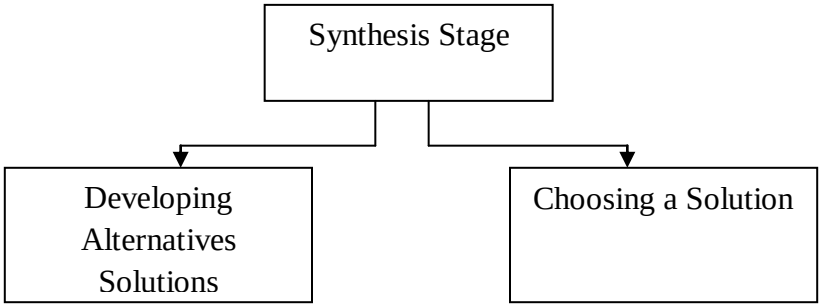


Figure 4.4: Sub- steps of the synthesis stage

4.3.1 Developing Alternative Solutions

Design concepts were generated based on the client and design requirements for the new device. Current devices and mechanisms used for suturing were investigated to create alternative solutions that address existing drawbacks. The similar and possible devices were brainstormed and analyzed. The design concepts were discussed and compared to create alternatives. Some questions, such as ‘How the current devices can be improved?’ or ‘What can be done to solve the current problems?’ were the starting point to guide the brainstorming process.

Critical functions of the new device were determined and evaluated. Two functions were determined to be critical such as suturing placement and needle movement in both directions during suturing. The most important part for the new device was the suturing mechanism followed by the ergonomic handle. According to the research results,

hand sketches for possible mechanisms were prepared and discussed. Solidworks was used as 3D CAD software to simulate possible alternatives as shown in Figures 4.5-4.9. In this stage, it was very important to cover every possible solution since the following phases require discussions with the surgeon.

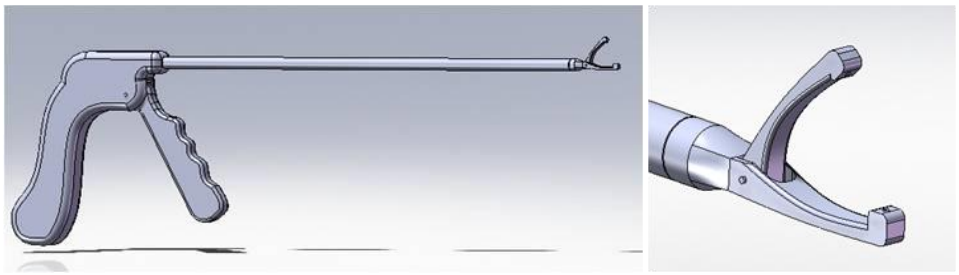


Figure 4.5: Alternative design 1

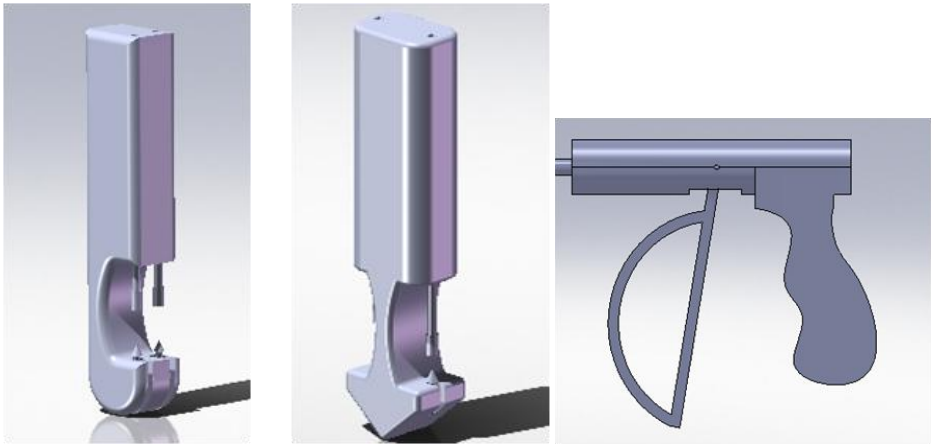


Figure 4.6: Alternative design 2

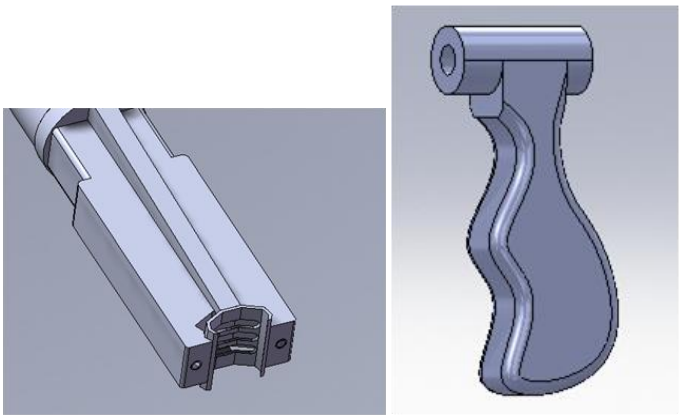


Figure 4.7: Alternative design 3

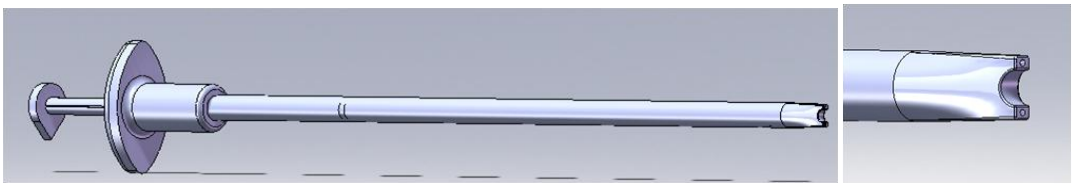


Figure 4.8: Alternative design 4

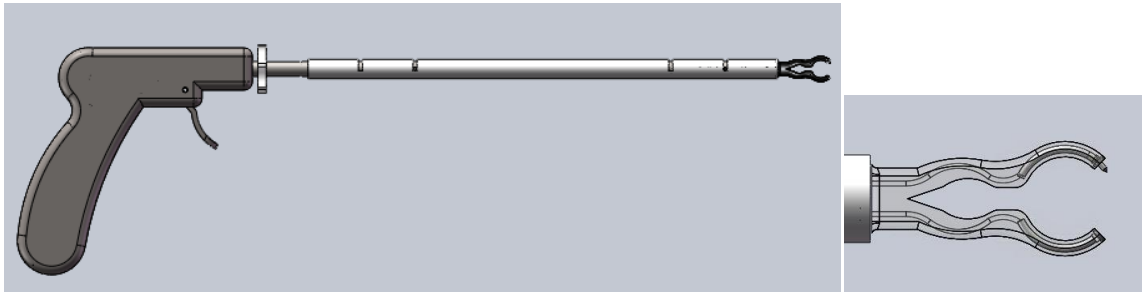


Figure 4.9: Alternative design 5

4.3.2 Choosing a Solution

In this stage, the data obtained in the analysis stage was transformed into the synthesis stage in order to select new device concepts. The first method was synectics. According to Jones, the aim of synectics is "to direct the spontaneous activity of the brain and the nervous system towards the exploration and transformation of design problems"

(Jones, 1992). Also, synectics is considered as “a group activity in which criticism is ruled out, and the group members attempt to built, combine and develop ideas towards a creative solution to set the problem” (Cross, 2000).

Critical functions of the new instrument were identified and evaluated according to the client requirements and design specifications. Five main factors were identified including utilization, operating, ergonomic, operating direction and suturing- knot tying. For each of these functions, several different alternatives were brainstormed. Then, these alternatives were evaluated and selected based on external criteria, internal criteria and social factors as shown Figure 4.10

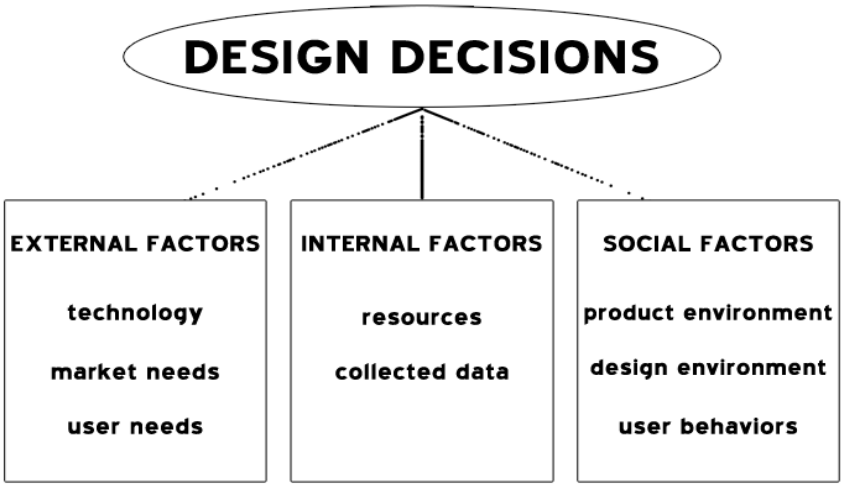


Figure 4.10: Design decision factors. (Ulrich & Krishnan, January 2001)

The best alternative for each function was determined using Pugh charts as shown in Table 4.2. To produce complete tool concepts, the highest ranking and most compatible forms were chosen for each of the five functions and integrated together. From these complete concepts, a system Pugh chart was used to select the best design. As shown in Table 4.2, a weight was assigned to each function indicating the importance of

each criterion. Then, for each alternative, a value of 1 or -1 was assigned based on whether the alternative meets or does not meet the user needs, respectively. After each alternative was rated, the alternative that has highest score was selected as the best alternative. It can be observed that alternative 5 has the highest rating compared to the other alternatives and consequently, it was selected as the best design.

Table 4.2: Pugh chart

Alternatives **Criteria**	**Weight**	**Altern.1**	**Altern.2**	**Altern.3**	**Altern.4**	**Altern.5**
Utilization	5	-1	-1	1	1	-1
Operating	7	-1	-1	1	-1	1
Ergonomic	9	1	-1	-1	-1	1
Knot Tying	7	1	-1	-1	1	1
Oper. Direction	10	1	-1	-1	1	1
Score		**14**	**-38**	**4**	**6**	**28**

4.4 Evaluation Stage

In the evaluation stage, the chosen solution is modeled, analyzed, and further improved prior to the fabrication of the physical prototype for testing. As shown in Figure 4.11, this stage has two sub-steps to evaluate the prototype: modeling and engineering analysis and prototyping and evaluating.

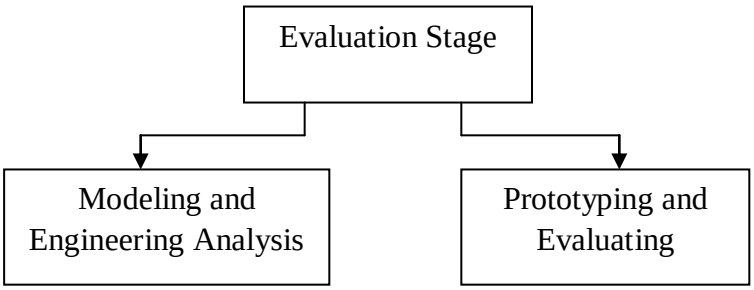


Figure 4.11: Sub-steps of the evaluation stage

4.4.1 Modeling and Engineering Analysis

In this research, SolidWorks 2009 CAD software was used to make detailed 3D solid models of the device. Prior to prototyping, the design was tested using finite element analysis (FEA) with SolidWorks SimulationXpress. This identifies potential design problems in advance to make the corresponding design modifications.

Figure 4.12 shows the selected detailed design concept from Section 4.3.2. It consists of eight main parts: handle, trigger, arm, needle carrier, needle holder, needle, sheath and flexible wire. The sheath of the proposed device is 11.5 mm in diameter and can be used on a 12-mm port. At the tip of the device, the two arms can be closed by sliding the sheath from back to front. Once the sheath is retracted, the suturing arms return to their original positions. The suture is secured at the center of the needle, which is sharp on both ends to allow passage through the tissue in both directions. An advantage of the design is that the needle can use any type of suture while current devices require the use of a proprietary suture. The trigger activates the needle carrier from one side of the arm to the other while the toggle lever changes the direction of the needle between the arms, as shown in Figure 4.13. A needle holder secures the needle inside the arms while also allowing the needle to be transferred to the opposite arm. After the needle has been

transferred, the stitch is then pulled through the tissue. At this point, the needle is ready for the next maneuver.

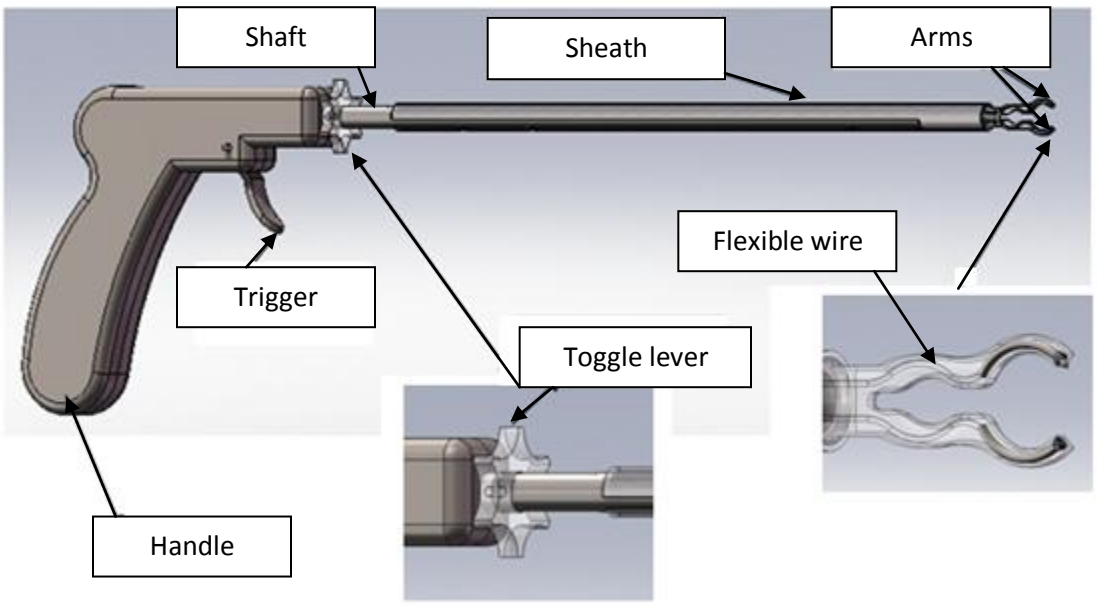


Figure 4.12: 3D CAD model of the proposed device

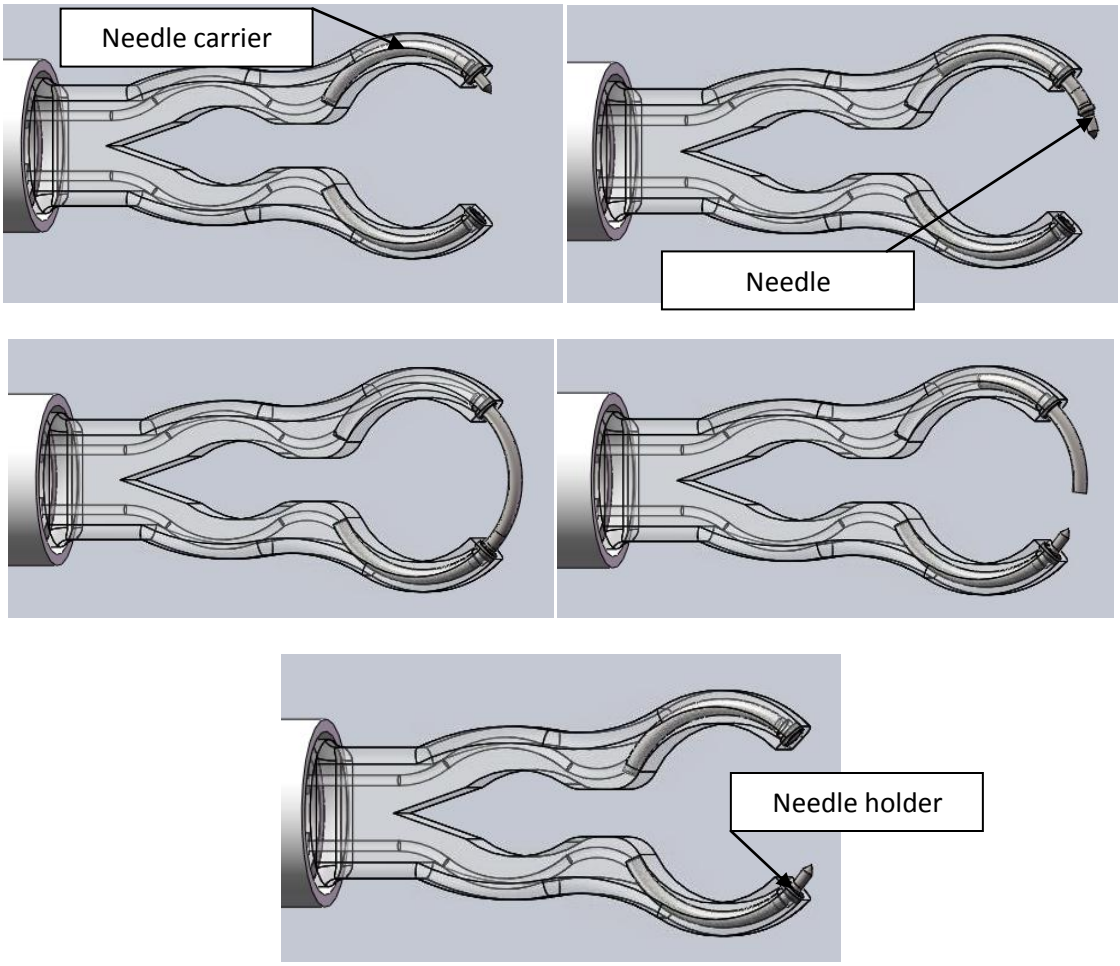


Figure 4.13: Mechanism for needle transporting of the proposed device

Suturing and knot tying operation procedures for the proposed device is outlined as below. The procedure is meant to be quick and simple for the surgeons, as well as being safe for the patients.

1. Load the needle and suture to the needle holder.
2. Rotate the sheath and push it to the front.
3. Insert the tool inside the body.
4. Retract the sheath to open the device's arms.
5. Rotate the toggle lever to the same side with needle.

6. Push the trigger.
7. The needle with the suture goes through the tissue and stays on the opposite arm.
8. The device is ready for next maneuver.

The proposed device can also be used to tie square knots, a surgeon's knot, and a variety of knot tying. The design concept aims to enable surgeons to perform suturing and knot tying procedures through extra- corporeal or intra- corporeal knot tying approaches.

In order to analyze the new device, materials have to be defined. Table 4.3 shows the different components for the proposed device with their corresponding selected material and important dimensions.

Table 4.3: Types of material

Part	**Material Type**	**Important Dimensions**
Handle	Thermoplastic	Width: 140 mm Depth: 50 mm Height: 140 mm
Trigger	Thermoplastic	Width: 10 mm Depth: 3 mm Height: 55 mm
Outside shaft	Thermoplastic	Diameter: 11.5 mm Length: 280 mm
Sheath	Thermoplastic	Diameter: 9 mm Length: 320 mm
Main plunger	Titanium	Diameter: 5.5 mm Length: 285 mm

Table 4.3: (continued)

Toggle	Thermoplastic	Diameter: 30 mm Thickness: 5 mm
Small plunger	Titanium	Width: 1.5 mm Depth: 1.5 mm Height: 30 mm
Arms	Polycarbonate	Width: 15 mm Depth: 4 mm Height: 50 mm
Flexible wire	Titanium	Diameter: 0.60 mm Length: 40 mm
Needle	Stainless steel	Diameter: 0.70-1.2 mm Length: 4 mm
Needle carrier	Stainless steel	Diameter: 1.2 mm Length: 10 mm
Needle holder	Silicon rubber	Diameter: 1.55 mm Thickness: 1.2 mm

Three parts were the most important parts for the proposed device. The first part is the tip of the device where the arms are located as shown in Figure 4.14. The arms stay inside the sheath and then move to the open position once the sheath is retracted. This requires a flexible and strong material such as polycarbonate (PC). Polycarbonate is a highly hard plastic and it is traded by Lexan ®. This plastic is very useful in designing medical devices as it provides high impact strength, crystal clear transparency, abrasion resistance, and dimensional stability. It can be found in the market in different colors such as black, gray, and optical clear and in different shapes such as rod, plate and sheet. Yield strength of polycarbonate is 69.7 MPa and Poisson's ratio is 0.37. Polycarbonate is

a thermoplastic and can be injection molded for mass production, which is the ideal method for potential manufacturing of this part.

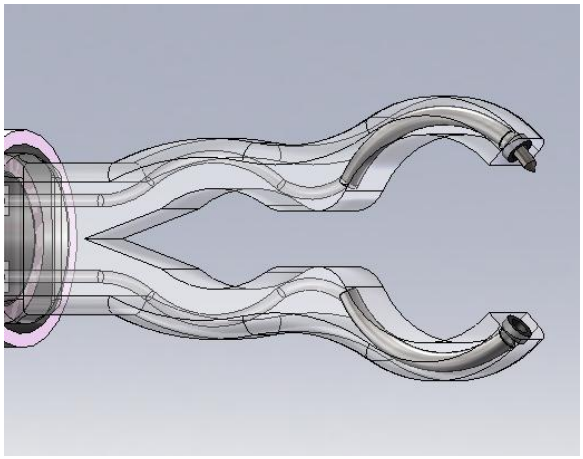


Figure 4.14: Arms at the tip of the proposed device

To perform the finite element analysis for the arms, 1 lb force was applied to the arms. Figure 4.15 shows the stress distribution on the arms. As shown in the figure, yield strength of the selected material is 69.7 MPa. On the other hand, maximum stress for the critical part is 26.47 Mpa according to the applied force. The blue area in the picture is the area with the least stress of the part. Red areas indicate the most critical regions for the parts and show the maximum stress at 26.47 MPa. According to the result of the stress distribution test, the arms can be stored inside the sheath, which is 11.5 mm in diameter, without any permanent deformation because the maximum stress for the part is smaller than the yield strength of the selected material.

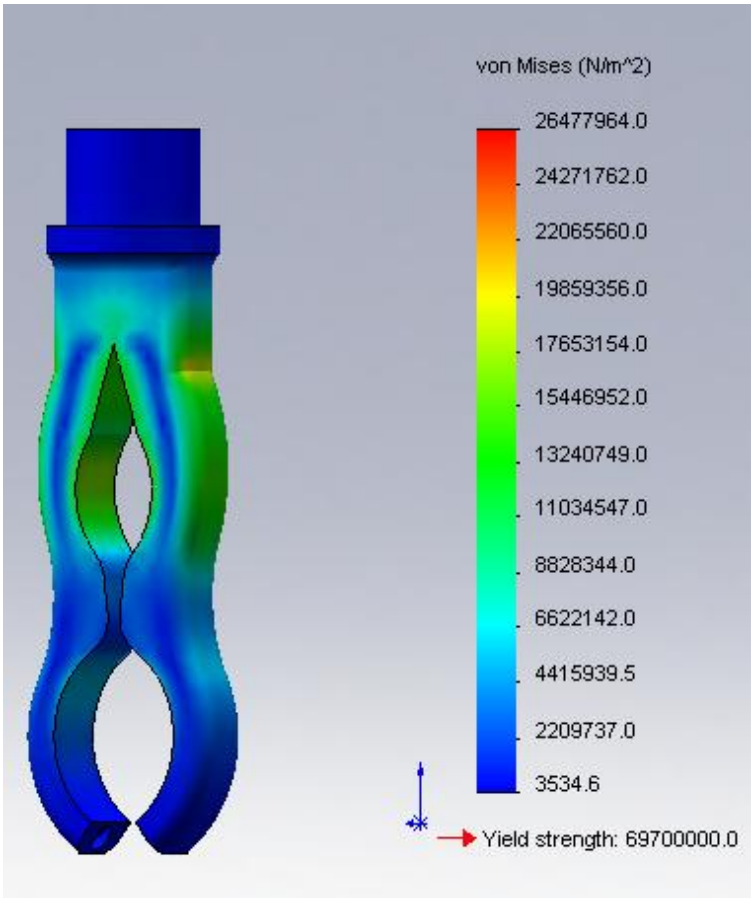


Figure 4.15: FEA results of stress distribution in the arms of the device

Factor of safety [FOS] for this part is: 2.63238. Parts with [FOS] higher than 1 are considered to be safe. This value can be increased or decreased by choosing different types of materials. Figure 4.16 shows displacement distribution in the arms and deformed shape of the arms. As shown in the figure, maximum displacement distribution is 1.636 mm.

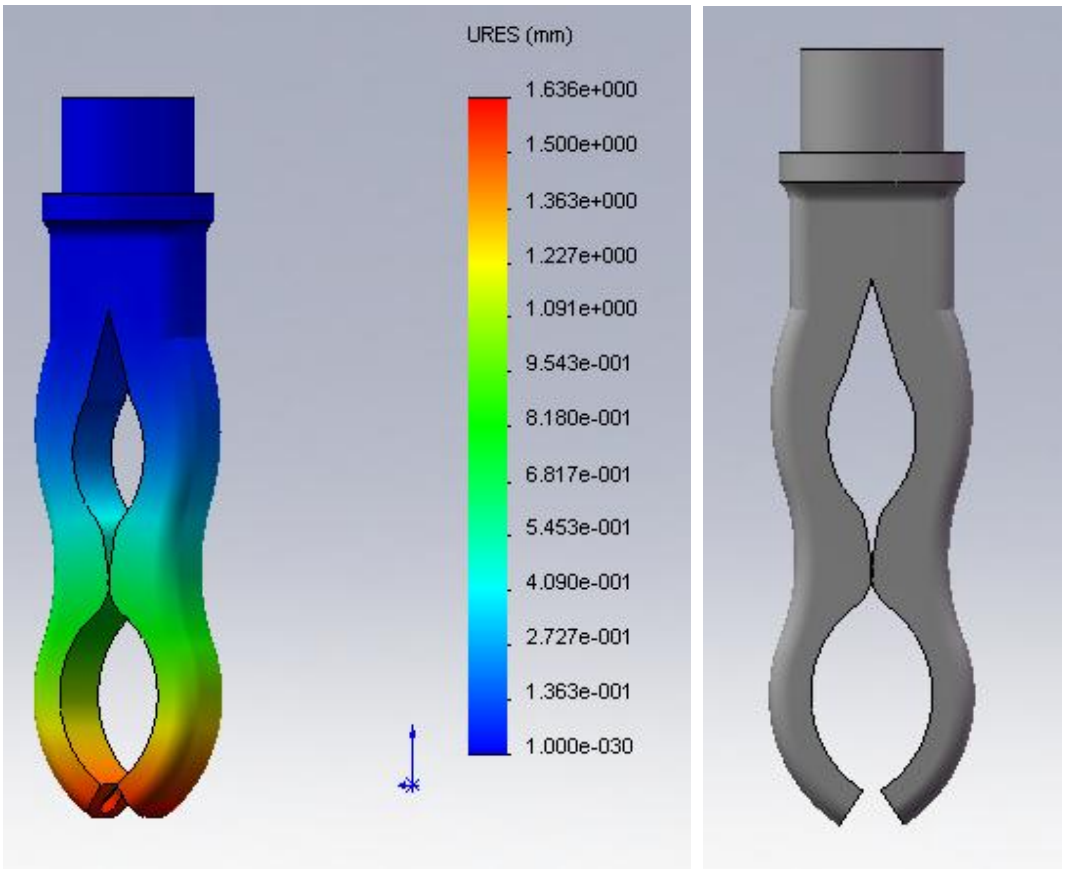


Figure 4.16: Displacement distribution in the arms and deformed shape of the arms

Other critical parts of the proposed device are the flexible wire, small plunger and main plunger as shown in Figures 4.17-4.19, respectively. The flexible wire is located inside the arms and shaft and is used to push the needle carriers. It must be flexible because it moves through two curves inside the jaws to apply more force to push the needle carriers.

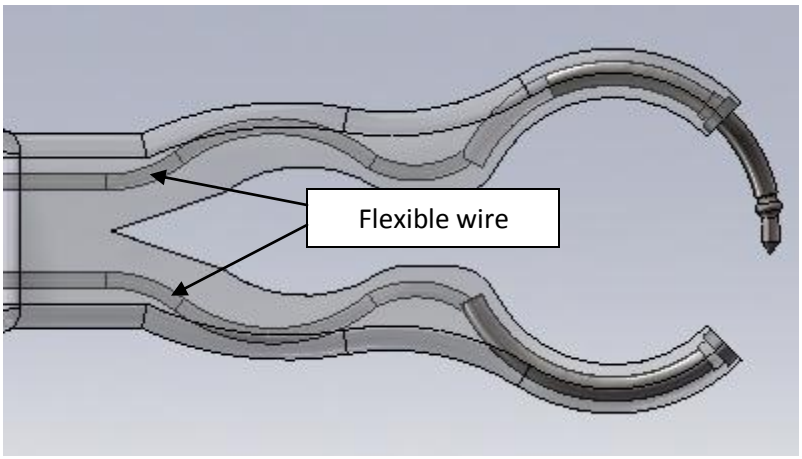


Figure 4.17: The flexible wire to control the needle carriers

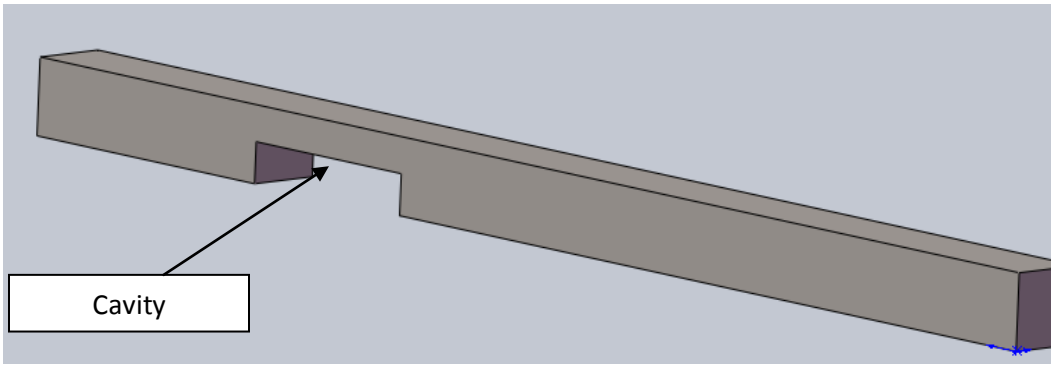


Figure 4.18: Small plunger

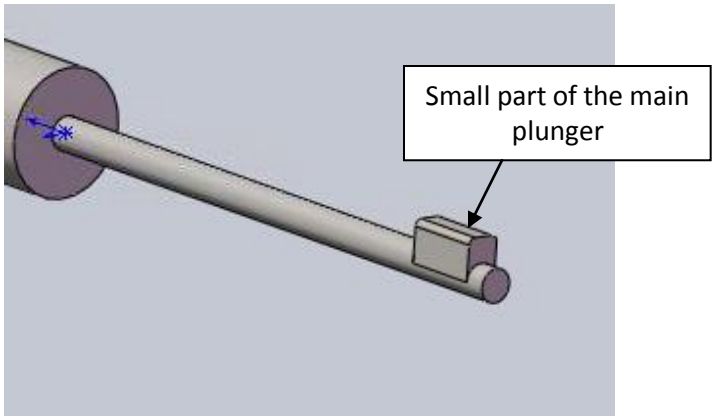


Figure 4.19: Main plunger

The small plungers and main plunger are also located inside the shaft and the flexible wire is connected to a small plunger as shown in Figure 4.20. There are two small plungers to control the arms at the tip of the device. As the user rotates the toggle lever, the small part of the main plunger goes into the cavity of one of the small plungers as shown in Figure 4.21. This engages the main plunger with the small plunger and consequently enables the control of the corresponding arm's needle carrier. When the user rotates the toggle lever in the opposite direction, the main plunger engages with the other arm to move the corresponding needle carrier. Therefore, the toggle lever is used to alternate control between the two arms and thus provide the motion of the needle in both directions.

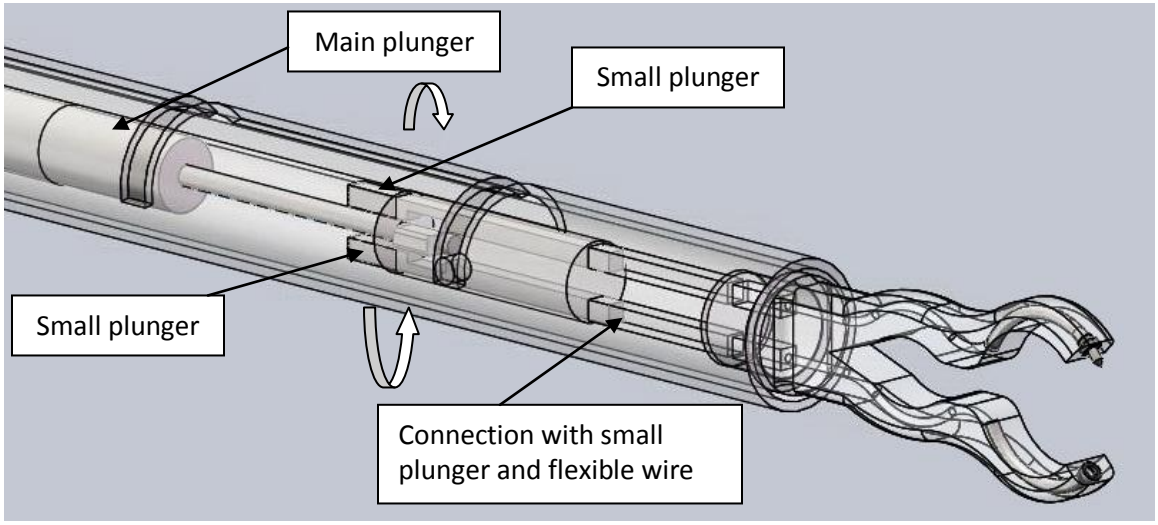


Figure 4.20: Relationship between the main plunger and small plunger

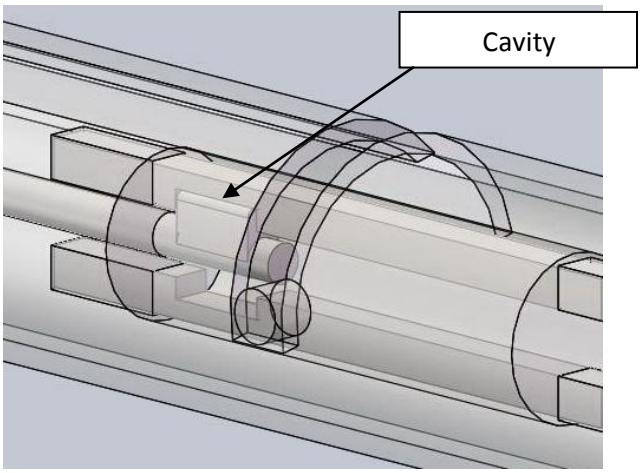


Figure 4.21: Detailed view of the mechanism for changing the needle direction

The main plunger and small plungers must be strong because forces will be applied here to make the needle go through the tissue. For this reason, titanium was selected as a proposed material. Titanium has significant benefits as it is flexible, light-weight, easily worked, biocompatible and strong. Titanium is not as dense as stainless steel but yields double the strength as stainless steel. Also, the ultimate tensile strength of titanium is approximately 25% higher. In addition to these features, titanium has outstanding corrosion resistance. All these features allow a wide range of successful applications of titanium that result in high levels of reliable performance in a broad range of major industries from medicine and surgery to aerospace and automotive. For example, in the field of medicine, titanium is perfect for implantation in the human body, such as joint replacements.

To perform the finite element analysis for the small plunger and main plunger, the force that would be applied had to be defined. From previous research, it was determined that a minimum puncture force of 4.61 N is required to puncture the toughest tissue of the stomach with a laparoscopic suturing needle (Cronin, Frecker, & Mathew, 2007). There

is no study that defines puncture force for the uterus, so 4.61 N (F_1) was established as the minimum puncture force for the finite element analysis. The force at the tip of the device needed to generate at least 4.61 N was investigated. To define that force, Eq. 4.1 was used as follows:

$$\ln (F_2/F_1) = \mu\beta \tag{4.1}$$

Where F2 is the force needed to get minimum puncture force and F1 is minimum puncture force. After applying the force to the small plunger, Figure 4.22 shows the stress distribution on the small plunger and deformed shape of the part. As shown in the figure, the yield strength of the selected material, which is titanium, is 1,034.21 MPa and Poisson's ratio is 0.33. The maximum stress for the critical portion is 11.21 Mpa according to the applied force. The lowest factor of safety [FOS] for this part is 92.2098, which is good for safety design. Also, Figure 4.23 demonstrates that there is only 0.00005129 mm displacement distribution for the most critical part of the small plunger according to the applied force of 6N.

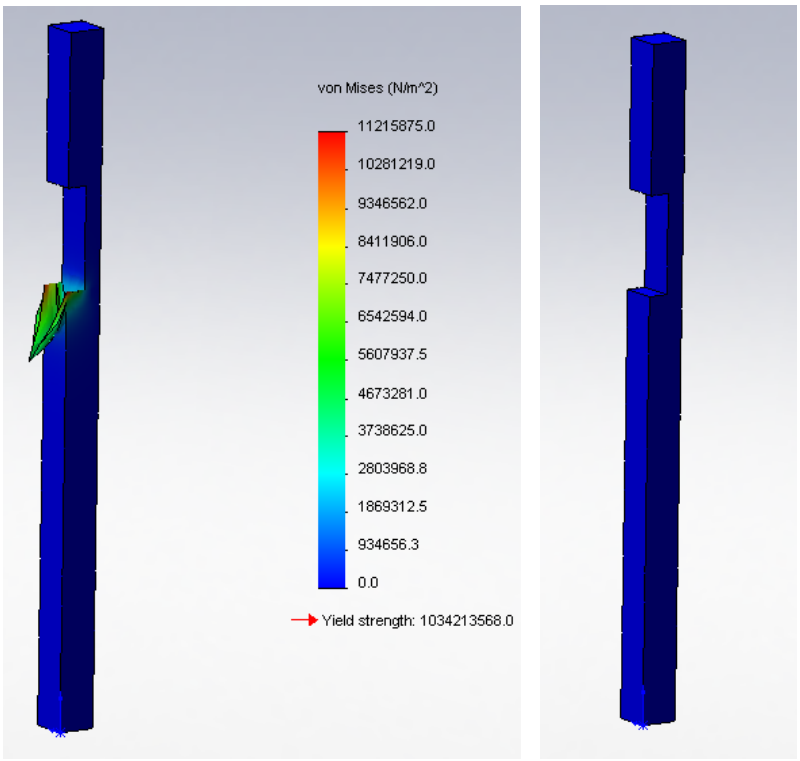


Figure 4.22: Stress distribution on the small plunger and deformed shape of the part

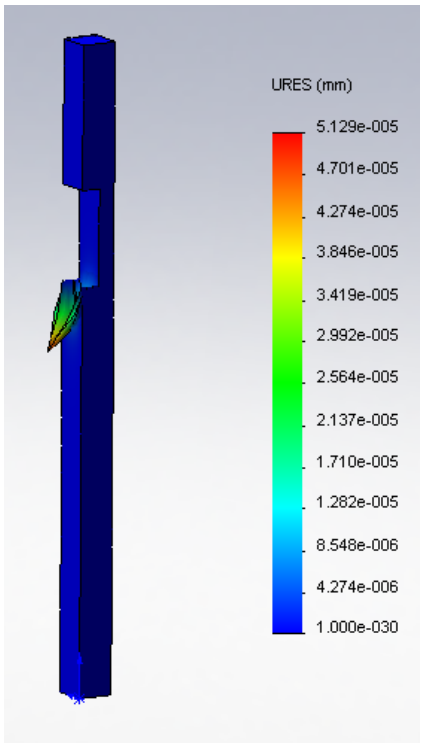


Figure 4.23: Displacement distribution on the arms of the small plunger

Similarly, finite element analysis was performed on the main plunger and the results are shown in Figure 4.24. A force of 6N was applied to test the part and results show that the lowest factor of safety for the main plunger [FOS] is 68.2331, which is a high value indicating that the part can be used safely for this operation. Likewise, Figure 4.25 shows there is only a 0.00007146 mm displacement distribution for the most critical part of the main plunger according to the applied force of 6N.

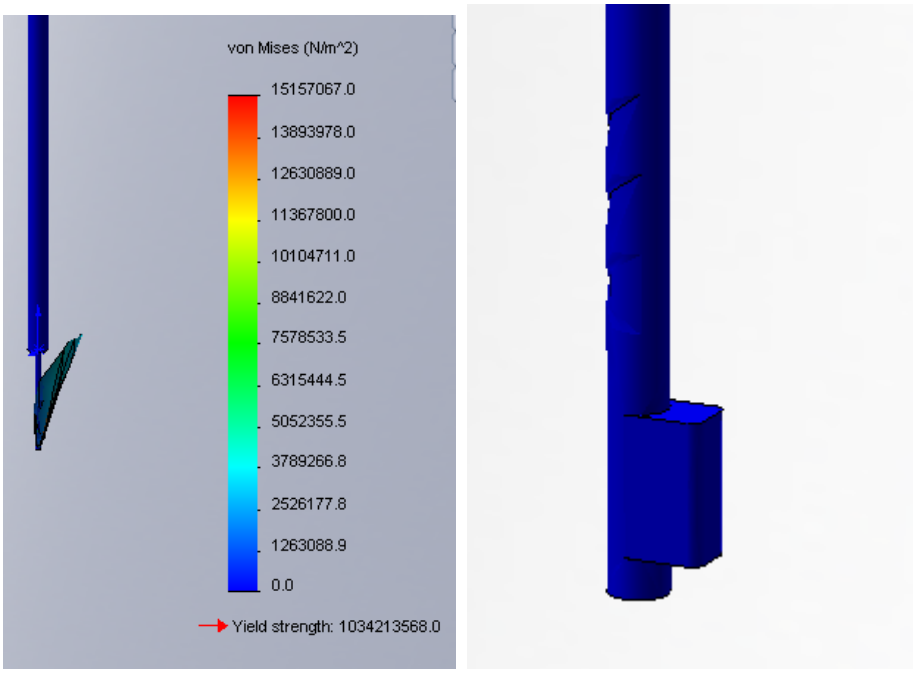


Figure 4.24: Stress distribution on the main plunger and deformed shape of the part

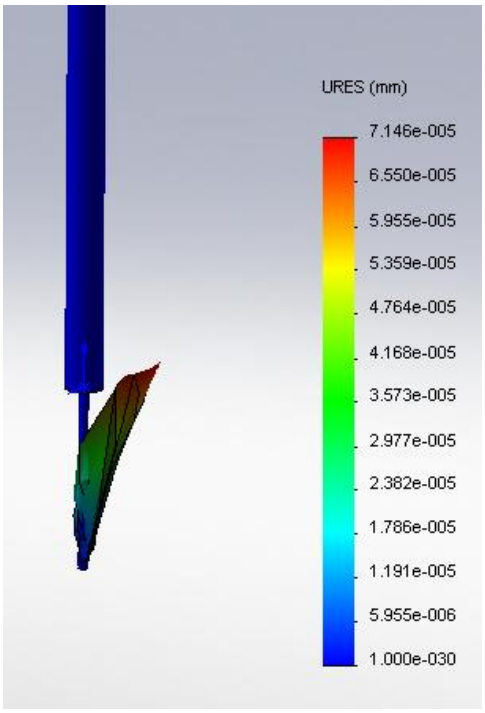


Figure 4.25: Displacement distribution on the arms of the small plunger

Stainless steel was used on the needle and needle carriers as shown in Figure 4.26. Stainless steel is a low carbon steel that contains at least 10% of chromium in its weigh. The chromium gives the steel stainless and corrosion resisting features. Although there are more than 60 different types of stainless steel in the market, the main group is divided into five classes: austenitic, ferritic, martensitic, precipitation-hardening martensitic, and duplex. Each is identified by the alloying elements, which affect their microstructure and for which each is named. There are several benefits of stainless steel such as corrosion resistance, fire and heat resistance and hygiene ("Stainless steel", 2010).

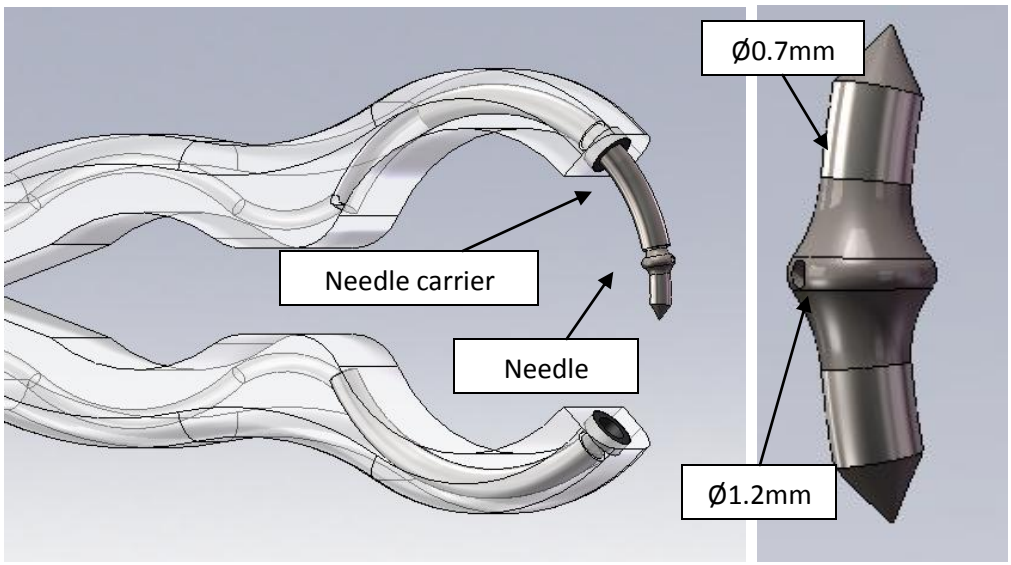


Figure 4.26: Needle and needle carrier

Silicon rubber was another material used in the new instrument. It was used for the needle holder as shown in Figure 4.27. The needle holder keeps the needle while also releasing it when transported by the needle carrier. A type of plastic with a thermoset feature is silicon. Silicon is highly stable and has a strong resistance to heat. It is also biocompatible. It is cured by two catalyst systems: peroxide and platinum cure.

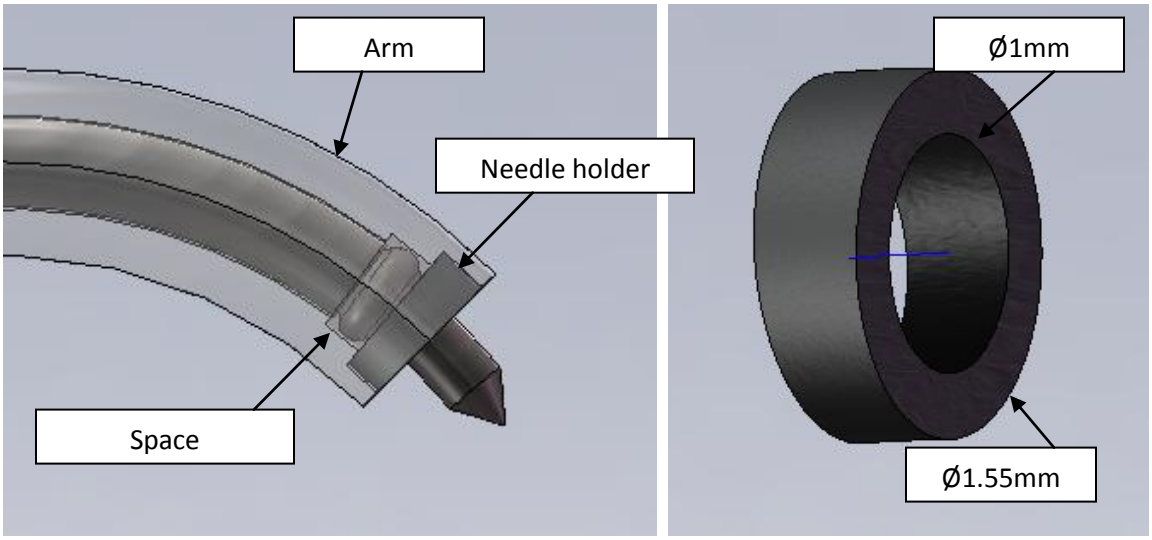
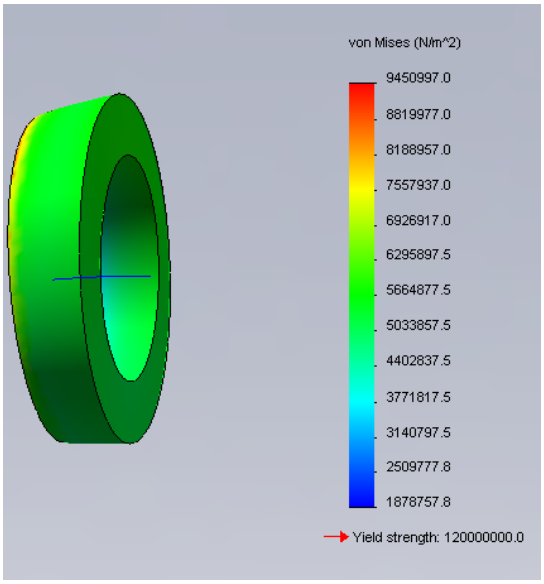


Figure 4.27: Needle holder

According to the test results shown in Figure 4.28, the yield strength of the selected material, which is silicon, is 120 MPa and the Poisson's ratio is 0.28. The maximum stress for the critical portion is 9.45 MPa according to the applied force. Lowest factor of safety for the needle holder is 12.6971.



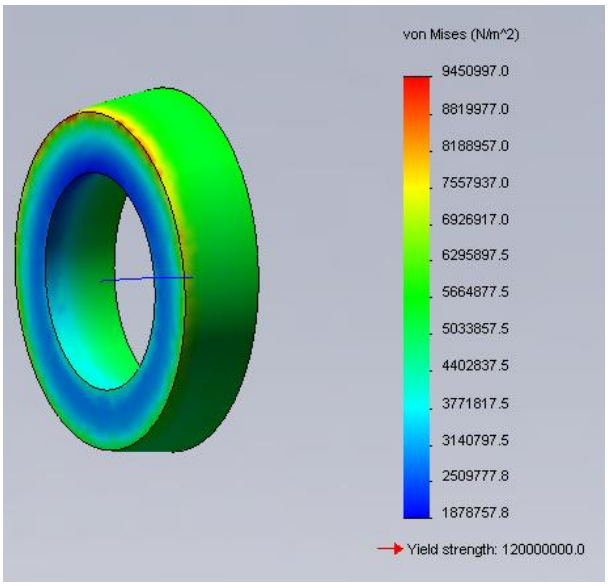


Figure 4.28: Stress distribution on the needle holder

4.4.2 Prototyping and Evaluating

After modeling and finite element analysis testing, the next step was to make a physical prototype for evaluation. Rapid Prototyping was used to construct the physical model from CAD data. As shown in Figure 4.29, a fused deposition modeling (FDM) system, Dimension SST 768, was used as a rapid prototyping machine to make the physical model. Fused Deposition Modeling (FDM) was developed by Stratasys and is a manufacturing process that creates a 3-D model using successive deposits of ABS material through a layer by layer approach.

Figure 4.29: Fused deposition modeling (FDM) machine, Dimension SST-768

The prototyping process enables designers to physically evaluate their designs and control their functions to make any necessary design changes. The prototyping process

enables making such changes in a shorter time and allows a better visualization of the design.

For this study, a prototype of the proposed device was created by using the FDM machine mentioned previously. There were three critical parts of this device to be prototyped: handle, toggle lever, and arms. The first prototypes of the handle, shown in Figures 4.30a and 4.30b, were tested for ergonomics and functionality. The handle had to be ergonomic enough to allow extended usage during the operation. In addition, it had to enable easy control and functionality over the other parts of the device such as the toggle lever and trigger. Based on the feedback from the surgeon, the design of the handle was gradually improved and led to the design and development of the current prototype, shown in Figure 4.31. The current handle allows easier access to the toggle and trigger with only one hand.

(a) Handle-1 (b) Handle-2

Figure 4.30: Prototypes of the first version of the handle

Figure 4.31: Prototype of the final version of the handle

Additionally, the arms of the device were also prototyped to check the functionality. Arms were tested in order to see if:

- The needle can move easily between the arms.
- Their size is appropriate to grasp the tissue in the patient's body.
- Their size is appropriate to enter through the 12 mm laparoscopic port.

After this first prototype shown in Figure 4.32 was created and tested, it was found to be not appropriate to meet these conditions. It was designed to have a maximum width of 10 mm, which was small enough to enter through the 12 mm laparoscopic port but it was not big enough to grasp the tissue inside the patient's body based on discussions with the surgeon. Therefore, the arms were redesigned as shown in Figures 4.33 and 4.34 in order to meet both of these conditions. In the current prototype, a sheath is used close the arms and allow them to go through the 12 mm laparoscopic port. Then, retracting the sheath allows the arms to open inside the patient's body to grasp the tissue.

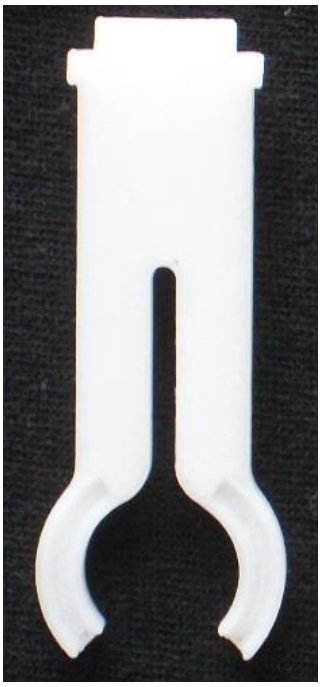


Figure 4.32: Prototype of the first version of the arms

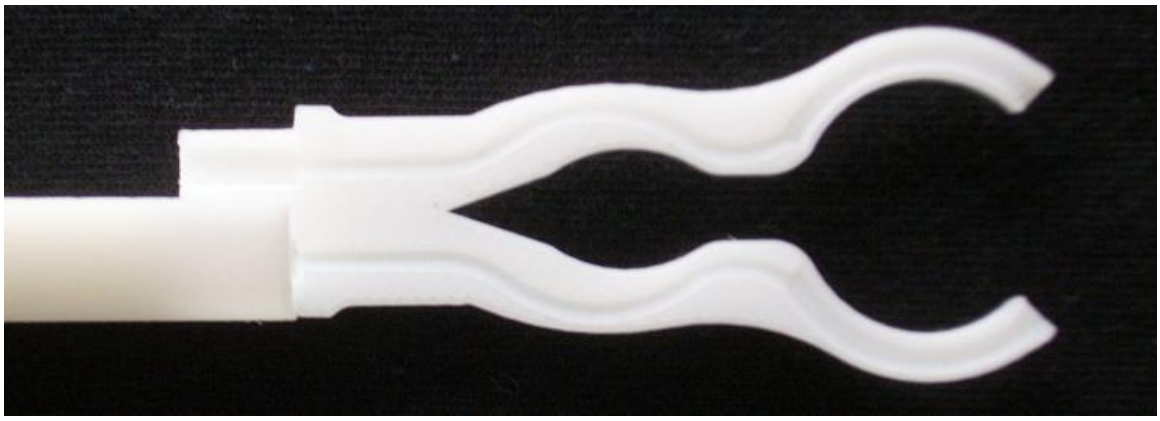


Figure 4.33: Prototype of the final version of the arms

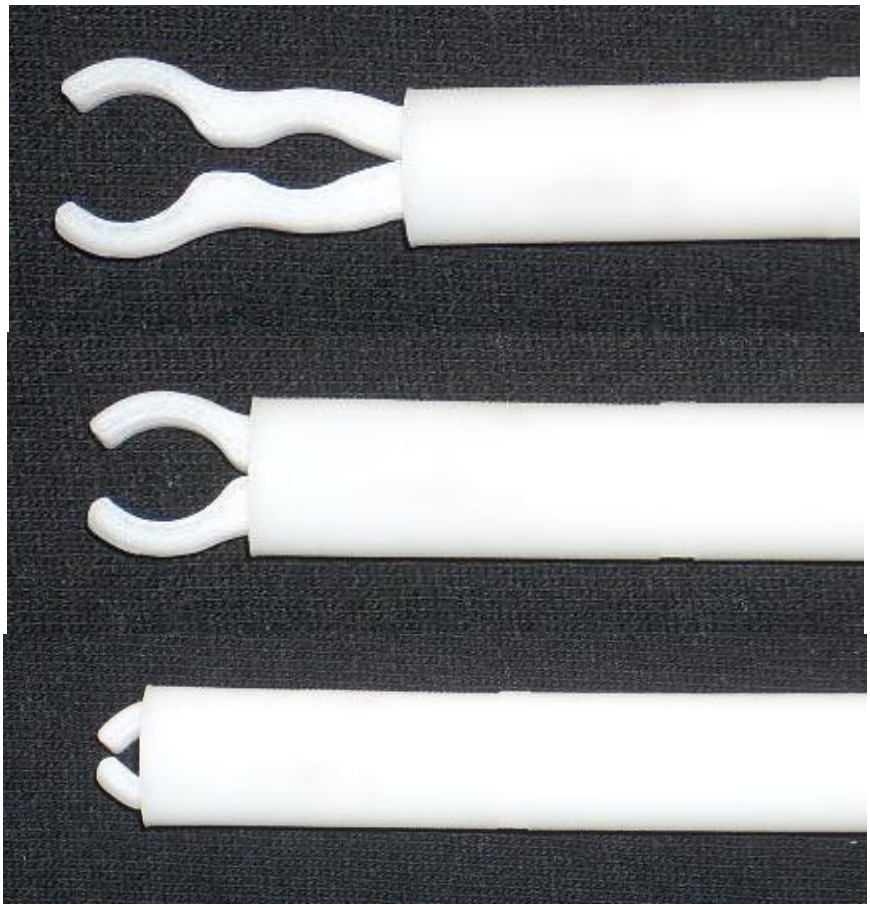


Figure 4.34: Prototype of the final version of the arms-assembled

Once the device could be inserted through the laparoscopic port without any problems, the easy movement of the needle between the arms needed to be ensured. In order to do this, a toggle lever, as shown in Figure 4.35, was developed and tested during the prototyping process. Its evaluation showed that the toggle lever can change the direction of the needle so that it can move between the arms. Also, Figures 4.36 and 4.37 show the prototype of the main plunger and small plunger that are used to push both the needle carrier and the needle.

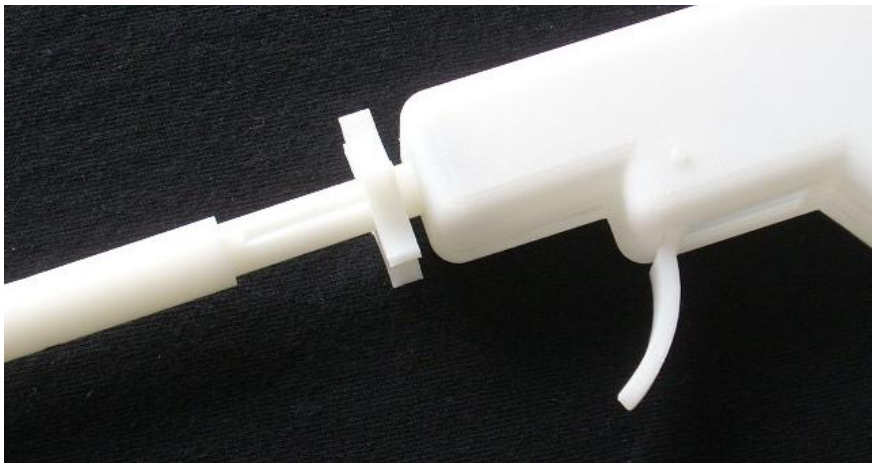


Figure 4.35: Prototype of the final version of the toggle lever

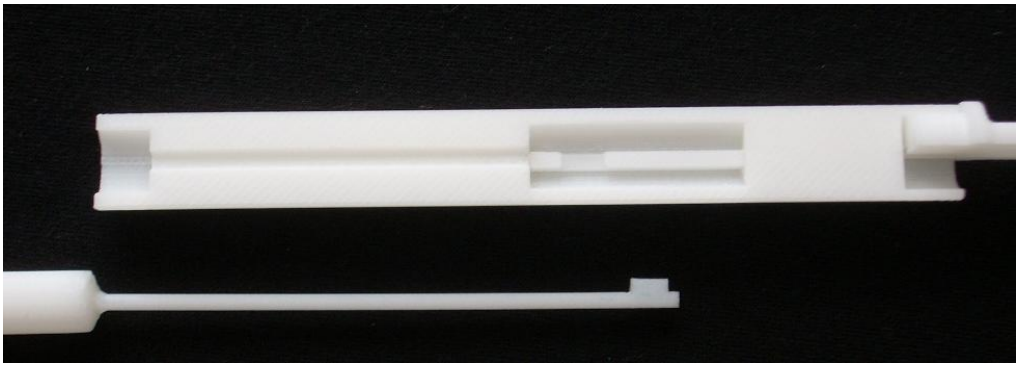


Figure 4.36: Prototype of the main plunger and small plunger

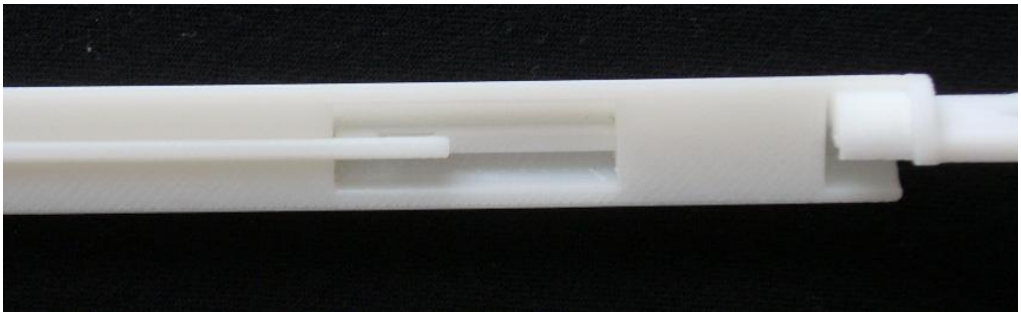


Figure 4.37: Prototype of the main plunger and small plunger- assembled

In addition, Figure 4.38 shows the relationship between the flexible wire and the needle carrier. The flexible wire was used to be able to move the needle carrier by pushing the trigger.

Figure 4.38: Prototype of the final flexible wire

After obtaining feedback from the surgeon and modifying the current design accordingly, the prototype of the final version of the device was made. Figure 4.39 shows the prototype of the new suturing and knot tying device for laparoscopic surgery.

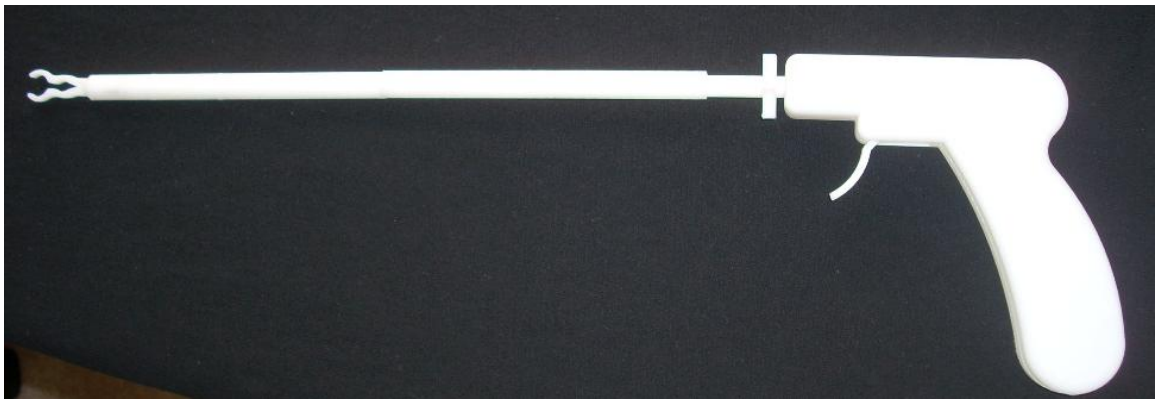


Figure 4.39: Prototype of the final version of the proposed device

Chapter 5

Research Summary and Future Work

This chapter provides a summary of the research methodologies presented to develop and analyze the new suturing and knot tying device for laparoscopic surgery. The conclusions, including encountered challenges and limitations, are also discussed here, followed by a description of future research work.

5.1 Research Summary

This research presented a new suturing and knot tying device for laparoscopic surgery. Qualitative data was collected through interviews with a surgeon and six in-depth observations of minimally invasive surgeries at Tampa General Hospital. Different design concepts and mechanisms were generated using SolidWorks CAD software, and tested using SimulationXpress in order to identify dimensions, materials and expected performance of the design and its components. Based on the finite element analysis, it was determined that the materials selected for the components are expected to enable the components to perform their functions accordingly.

The prototypes of the device were made using a Dimension SST 768 FDM machine. The functionality of these prototypes were tested by the surgeon to ensure that the final design meets the needs and criteria that were initially determined. The results of

the tests performed by the surgeon also confirmed that the working principle of the proposed device was feasible and ergonomic.

The proposed suturing device aims to address the difficulties encountered by surgeons during the suturing procedure and to reduce the risks to the patients. This new device will eliminate the use of many different devices during the operation and allow the surgeon to suture with only one device. This will help reduce the time spent and potential complications during the suturing procedure. Furthermore, the needle, which is sharp on both ends to allow passage through the tissue in both directions, can use any type of suture in contrast with current devices that require the use of proprietary suture.

5.2 Future Research Work

This research proposed a new medical device for laparoscopic suturing and provided the feasibility analysis on the device assembly and components. Additional facilities, resources, and time are necessary to develop a complete working prototype that can be tested on animal models, which is out of the scope of this research work. This will lead to a more complete evaluation of the device from the design and user perspectives.

References

Adams, B. J., Schulam, G. P., Moore, G. R., Partin, W. A., & Kavoussi, R. L. (1995). Laparoscopic suturing device: Initial clinical experience. *Urology, 46*(2), 242-245.

Capio open access and standard suture capturing devices. (2010). Retrieved November 10, 2009, from http://www.bostonscientific.com/Device.bsci?page=ResourceDetail&navRelId=1000.1003&method=DevDetailHCP&id=10004521&resource_type_category_id=1&resource_type_id=91&pageDisclaimer=Disclaimer.ProductPage

Cetin, A. (2004). *Applying product design methods to medical device design with a case study on home care devices.* Izmir Institute of Technology, Izmir.

Cronin, S., Frecker, M., & Mathew, A. (2007). Puncture force measurements on a porcine stomach. *Gastrointest. Endosc., 65*(5), AB294.

Cross, N. (2000). *Engineering design methods* (3th ed.). Milton Keynes, UK: John Wiley & Sons, Inc.

Crow, K. (2020). Failure modes and effects analysis (fmea) Retrieved June, 20, 2010, from http://www.npd-solutions.com/fmea.html

De Beer, J. F., van Rooyen, K., & Boezaart, A. P. (1998). Nicky's knot-a new slip knot for arthroscopic surgery. *Arthroscopy, 14*, 109-110.

Delimar, D. (1996). A secure arthroscopic knot. *Arthroscopy, 12*, 345-347.

Dunitz, M., Sheth, S., & Studd, J. (2002). The scope of vaginal hysterectomy. *European Journal of Obstetrics & Gynecology and Reproductive Biology, 115*(2).

Endostitch 10 mm suturing device. (2008). Retrieved November 5, 2009, from http://www.autosuture.com/AutoSuture/pagebuilder.aspx?topicID=7407&breadcrumbs=0:63659,30691:0,309:0

Fleega, B. A., & Sokkar, S. H. (1999). The giant knot: A new one-way self-locking secured arthroscopic slip knot giant knot: *Arthroscopy, 15*(4), 451-452.

Food and drug administration (2010). Retrieved May, 15, 2010, from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm

Fries, R. C. (2001). *Handbook of medical device design*. New York: Marcel Dekker Inc.

Grace, P. A., P, B., & D., B.-H. (1992.). Tying a laparoscopic knot. *The British Journal of Surgery, 79*, 512.

Gunderson, P. K. (1987). The half-hitch knot: A rational alternative to the square knot. *American Journal of Surgery, 154*, 538-540.

Half-hitches technique. (2010). Retrieved May, 10, 2010, from http://medical-dictionary.thefreedictionary.com/

Holmlund, D. E. (1974). Knot properties of surgical suture materials. *Acta Chir Scand, 140*, 355-362.

Hughes, P. J., Hagan, R. P., Fisher, A. C., Hold, E. M., & Frostick, S. P. (2001). The kinematics and kinetics of slipknots for arthroscopic bankart repair. *American Journal of Surgery, 29*, 738-745.

Huhn, J., C. . (2004). Intracorporeal suturing in minimally invasive surgery Retrieved February, 5, 2010, from http://veterinarynews.dvm360.com/dvm/Medicine/Intracorporeal-suturing-in-minimally-invasive-surg/ArticleStandard/Article/detail/152907

Ilahi, O. A., Younas, S. A., Alexander, J., & Noble, P. C. (2004). Cyclic testing of arthroscopic knot security. *Arthroscopy, 20*, 62-68.

Jonassen, D. H., Tessmer, M., & Hannum, W. H. (1999). *Task analysis methods for instructional design*. New Jersey: Lawrence Erlbaum Associates Inc. .

Jones, J. C. (1992). *Design methods* (2nd Edition ed.). New York: John Wiley & Johns, Inc.

Kennedy, J. S. (1992). A technique for extracorporeal suturing *J Laparoendosc Surg. , 2*, 269-272.

Khattab, O. S. (2008). Role of extracorporeal knots in laparoscopic surgery Retrieved December 15, 2010, from www.laparoscopyhospital.com/extracorporael_knot.html

Liu, C. Y. (1993). Laparoscopic hysterectomy. In N. Osborne & G. Padial (Eds.), *Operative laparoscopy for gynecologists* (pp. 156-163). Omoha: IDI Publications.

Lo, I. K. Y. (2008). Arthroscopic knot tying In J. S. Abrams & R. H. Bell (Eds.), *Arthroscopic rotator cuff surgery* (pp. 68-82). New York: Springer Link.

Minimally invasive surgery. (2010). Retrieved January 1, 2010, from http://www.mssm.edu/misc/defined.shtml

Nguyen, J. K., & Bhatia, N. N. (1999). Transvaginal repair of paravaginal defects using the capio suturing device: A preliminary experience. *J Gynecol Tech., 5*, 51–54.

Pattaras, J. G., Smith, G. S., Landman, J., & Moore, R. G. (2001). Comparison and analysis of laparoscopic intracorporeal suturing devices: Preliminary results. *J. Endourol. , 15*(2), 187-192.

Ramasamy, S. (2005). *Total quality management* Tata McGraw-Hill.

Sanfilippo, J. S., & Solnik, M. J. (2008). Operative laparoscopy Retrieved December 15, 2009, from http://glowm.com/?p=glowm.cml/section_view&articleid=88

Stainless steel world. (2010). Retrieved June, 1, 2010, from http://www.stainless-steel-world.net/

Topel, H. (1996). Laparoscopic suturing techniques. In J. S. Sanfilippo & R. Levine (Eds.), *Operative gynecologic endoscopy* (pp. 270–277). New York: Springer-Verlag.

Ulrich, T. K., & Krishnan, V. (January 2001). Product development decisions: A view of the literature. *Management Science, 47*(1).

Villacourt, M. (1992). Failure mode and effects analysis (fmea): A guide for continuous improvement for the semiconductor equipment industry: SEMATECH Inc.