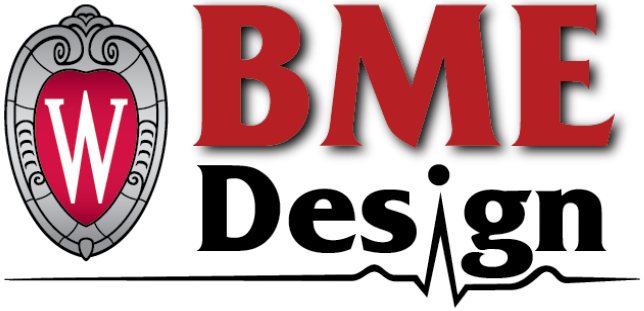


Ergonomic Surgical Stapler

Preliminary Report
BME Design 301
February 22, 2017

Team Leader: Andrew Fugate
Communicator: Albert Anderson
BSAC: Therese Besser
BPAG & BWIG: Ellen Restyanszki

Client:
Dr. Amy Liepert - UW Health

Advisor:
Dr. Beth Meyerand

Abstract

Laparoscopic surgeries have increased in popularity in recent years because of the reduced amount of blood loss, scarring, and recovery time when compared to traditional surgeries. This opens the door to the invention of a wide variety of surgical tools meant to be used in these laparoscopic procedures. These tools, however have largely been designed for the hands of young male surgeons. In recent years, the female and aging portions of the surgical population have been growing, and there has been an increasing demand for tools that are more accommodating to various hand sizes and strengths. The cutting stapler device, in particular, has been brought to this team by Dr. Liepert, a surgeon at UW Health in Madison, WI.

The problems being addressed deal largely with the ergonomics of the handle of the presented with the intention of making it smaller, easier to grip and clamp, and more versatile in the operating room. This paper presents three design alternatives as prospective ways of redesigning this stapling device in the hopes of reducing wrist and elbow strain, and movement during readjustment of the device in surgery. These designs were evaluated based on a range of criteria to determine which would be the most effective and one was tentatively chosen, pending a conference with the client shortly hereafter. This paper also addresses future considerations and plans for the fabrication of a deliverable prototype by the end of the semester.

Table of Contents

I. Introduction

1.0 Motivation

The laparoscopic surgical stapler is used for many different procedures in the operating room, and has become a standard method to separate and seal tissues. These staplers are essential when the surgery is performed in a body cavity that cannot be reached by the surgeon's hands for sutures. The surgical staplers used by UW Hospital today do not accommodate the variety of hand sizes and grip strengths found in their diverse surgeon population. For these populations, the ergonomics of the surgical stapler must be redesigned to accommodate a smaller grip size.[2]

1.1 Competing Designs

There are several comparable surgical staplers available on the market. Surgical staplers implement both manual and automatic firing mechanisms, and can be disposable or reusable. The average automatic, disposable stapler can cost up to $800 per unit.[5]

The competing design that best fulfills the project problem statement and design criteria is the iDrive Ultra Powered Stapling System by Medtronic. As seen in Figure 1, the stapler is powered by a battery pack and is controlled by three buttons by the surgeon's right hand. Not pictured is the stapler extension. The iDrive Stapler claims to have a 61% reduction in reload tip travel when compared to the Ethicon Echelon Flex stapler.[6] However, the grip size and required grip force of the stapler is not publicly available. The sizable battery pack at the base of the stapler adds weight to the device, which increases stress on the operator's wrist and elbow. In addition, UW-Hospital's contract with Ethicon limits the surgeon's options for surgical stapler selections.

Figure 1. iDrive Ultra Powered Stapler by Medtronic [5]

1.2 Problem Statement

Surgical staplers have undergone many design modifications over the years of their implementation, including the recent addition of powered devices. Stapling devices are used both for intestinal resections and anastomoses as well as for vascular control. The surgeons who use these devices have also changed overtime; female and aging surgeons are becoming an increasingly large number of the surgeon population. According to the American Medical Association, females make up 40% of the surgeon population.[7] In addition, one-third of the surgeon population are over the age of 55.[4] However, surgical staplers are typically designed for the average male grip size and strength and do not accommodate female or older surgeons.

There are numerous opportunities for improvements in device design for the increasingly diversified group of surgeons who use surgical staplers. This project provides the opportunity for a lab-based and field study investigation of the ergonomic improvements for the users of surgical staplers as well as the potential for novel design modifications and/or solutions.

II. Background

2.0 Client Information

Figure 2: Dr. Amy Liepert [1]

Dr. Amy Liepert, a surgeon at UW Health. Dr. Liepert specializes in acute care and emergency general surgery.[1] The focus of her research involves patient safety and health quality. The most common operations performed by Dr. Leipert are appendectomies, typically requiring only 5-10 staples for the completion of the operation. Dr. Liepert reported that her hand does not fit around around the surgical grip of the stapler that she currently uses, and the stapler itself is too heavy to comfortably hold and support for sustained periods of time.

2.1 Previous Design Project

This design project was initiated by a BME 200/300 design group (Madelyn Goedland, Justin DeShaw, Gregory Wolf, Alexander Babinski, Jacob Andreae) in Fall 2016 with Dr. Amy Liepert as the client. Their goal for the semester was to design a more ergonomic grip for the Ethicon stapler. After a series of redesigns, they 3D printed a final prototype, which can be seen in Figure 3. The team presented the in-line handle design to the client, who reported that the model is viable. The primary issues with the model are: the hand hole is too small for a comfortable grip, and the triggers should be repositioned for easier access. They concluded that the comfort and success of an ergonomic redesign cannot be evaluated until the prototype is fabricated.

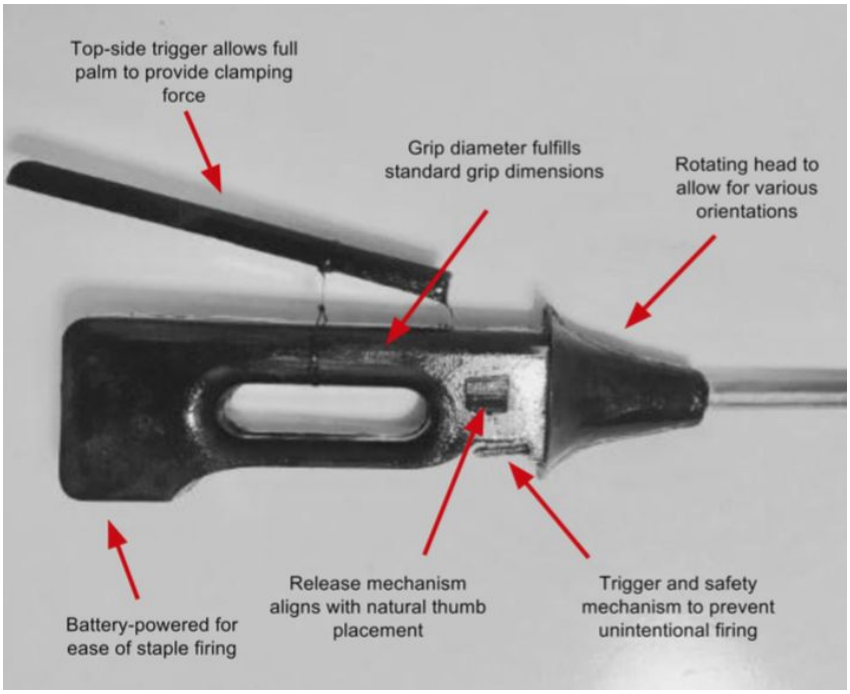


Figure 3. Previous Design group final prototype

2.2 Surgical Stapler Background

There are various approaches to the construction of a surgical stapler, but the general purpose is to cut, separate, and seal two halves of tissue that need to be removed or resected. The detail that sets these particular staplers apart is that they are designed for laparoscopic surgeries only. This means that the entire procedure is performed through a small incision of only ½ to 1 ½ inches in length.[3] That is why there is a long shaft on the end and all of the handling of the device happens outside of the body cavity. When fired, a blade runs down the shaft while three rows of staples are deployed at the same time in order to close off both halves of tissue. As a result of the different surgeries that can all be performed using the same tool, some of them require the shaft to be at such an angle that the surgeon has to strain their wrist and elbow in order to complete it. This is one of the things being addressed in this project. The other main problems being addressed are grip size and force applied to the handle lever.

This procedure can be used for a range of surgeries and the devices can come in different configurations. As mentioned earlier, there are several companies that have developed their own designs, but the one being redesigned for this project, pictured in Figure 4 below, is the Echelon Flex powered cutter stapler made by Ethicon. It is partially powered by a removable battery, meaning it needs to be clamped manually using a lever, but it is fired by an electric motor using a one-finger trigger mechanism.

Figure 4: This is an image of the Ethicon Echelon Flex 45 cutter stapler, the same model that the client, Dr. Liepert uses in her surgeries.

This project will focus on the handle section of this device. The mechanisms that are operated inside the body cavity will be beyond the scope of this semester's design.

2.3 Physiological Background

The relevant physiology regarding the surgical procedures, while not addressed in the scope of this project, is very important when understanding the purpose and use of these devices. Surgical staplers can be used for a variety of surgeries, including appendectomies, lung lobectomies, and gastrointestinal operations. It is assumed that the tissue stapling mechanisms are sufficient and will not be altered. Therefore, the focus of this project is on the ergonomics for the surgeon, not physiological impact on the patient.

2.4 Ergonomics Background

Understanding ergonomics and how to design using key facts found by ergonomic analysis is crucial to this project. Modifying the surgical stapler requires two main features, hand size and strength.

2.41 Anthropometry Considerations

The rule of thumb in ergonomics is to design to fit the 5% female to the 95% male. Because this project is concerned about how the hand is fitted and wrapped around an object, the focus will be to fit the 5% female. After taking measurement data from the client, it is clear a design that fits this criteria will be sufficient for her, as she falls into the 56% female palm length. This is shown as length number 61 on Figure 5.

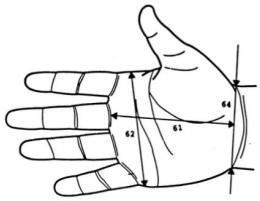


Figure 5: Anthropometric hand measurements. Palm length #61.

2.42 Grip Strength Considerations

The rule of thumb in ergonomics for strength is to design at 15% of the maximum force. To measure this, the JAMAR Hand Dynamometer, shown in Figure 6, was used. The dynamometer grips simulates the stapler handle and measures both grip strength and size. The grip strength for the average female, as reported in literature, is 329N.[4] We tested this value on a mixed group of male and female students and found the average max grip strength to be 388N. Therefore, the maximum force to be used in the design of the clamp should be around 50N.

Figure 6: Demonstration of the JAMAR Hand Dynamometer

2.5 Design Specifications

The core goal of the design is to ensure that it effectively accommodates surgeon hand sizes ranging from 95% of the male population to 5% of the female population. The required grip force should also be significantly reduced. The design should be smaller than the current Ethicon stapler in use by Dr. Liepert and should be disposable. The device should be lighter than the current Ethicon stapler and should have a better distribution of weight, minimizing the strain on the wrist and hand. Finally, the design must meet the safety standards of the UW Health System.

III. Preliminary Designs

3.0 Design 1: Multi Handle

The multi handle design was created with versatility in mind. It has one in-line grip similar to the one from last semester and one oriented like an electric drill. It would be partially powered and have various aspects of the traditional handle revised with ergonomic considerations in mind. The main drawbacks of this design are the same as those of the existing product; it would still require a large amount of clamping force, as well as the fact that movement and regripping of the hand would be required if the surgeon wanted to reorient the device.

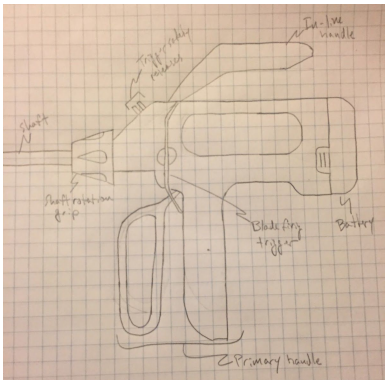


Figure 7. Sketch of the Multi Handle Design

3.1 Design 2: The Pencil

The Pencil is a complete reimagination of the Laparoscopic stapler. It redefines how the stapler is held by implementing a double

push lock and fire mechanism similar to that of a micropipet. All of the stapling actions can be comfortably accessed by the surgeon's thumb. Unlike the other designs, this design eliminates the battery pack, which will reduce the weight and torque on the operator's elbow and wrist. However, the current hardware will have to be redesigned to fit within the pencil, which will significantly increase the cost of the device.

Figure 8. Sketch of the Pencil design

3.2 Design 3: Button Grip

The Button Grip is similar in outward appearance to the Ethicon stapler in use by Dr. Liepert, but with several key differences. The grip system of firing is replaced with two buttons (a safety switch on the side of the handle, and a firing button beneath the body of the device), which alleviates the need to generate significant force in order to fire the device. Additionally, the handle (and the battery/motor within) will be placed toward the center of the body of the device, balancing the distribution of weight when the battery is placed in the back of the body. The distal piece will be maneuverable, allowing for easy adjustment of surgeon hand and stapler position.

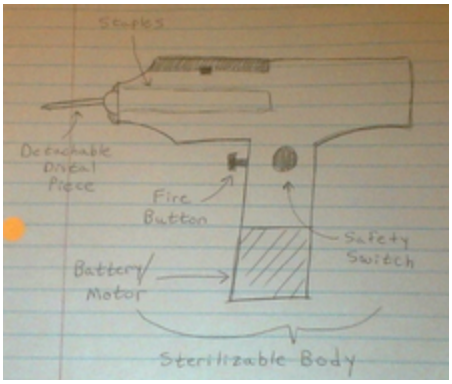


Figure 9. Sketch of the Button Design

IV. Preliminary Design Evaluations

4.1 Design Criteria

The preliminary designs will be judged on six main criteria: the percent of population accommodated, the required grip strength, wrist strain, safety, cost, and ease of fabrication. The percent of population accommodated, the design specification with the highest weight, refers the hand size required to comfortably operate the stapler. Without prototyping and testing each design, the percent of population accommodated can only be predicted. We made the assumption that a smaller grip will accommodate more surgeons. The required grip strength refers to the strength required to trigger the device. The wrist strain is determined by the weight of the device and the orientation of the grip. It is important for the weight of the device to be minimized to decrease the torque and strain that the stapler inflicts on the surgeon's wrist and elbow. The percent population accommodated, the required grip strength, and wrist strain are the three highest prioritized design criteria because they encapsulate the ergonomic concerns for the surgical stapler, the primary focus of the project. Safety, cost, and ease of fabrication are design criteria that must be accounted for in any medical device. However, they receive smaller weights for this project because it is not within the specifications of the project to manufacture a complete working prototype of the stapler.

4.2 Design Matrix

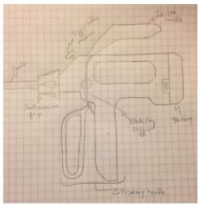
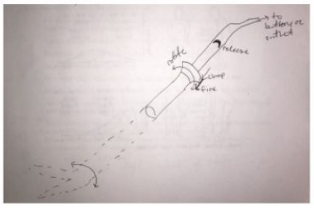
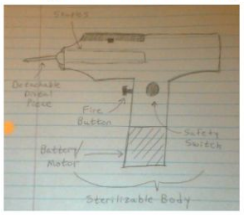
	Design #1: Multi Handle 		Design #2: The Pencil 		Design #3: Button Grip 	
Percent Population Accommodated (35)	2/5	14	5/5	35	4/5	28
Required Grip Strength (20)	2/5	8	5/5	20	5/5	20
Wrist Strain (15)	5/5	15	4/5	12	5/5	15
Safety (15)	5/5	15	5/5	15	5/5	15
Cost (10)	4/5	8	0/5	0	2/5	4
Ease of Fabrication (5)	2/5	2	2/5	4	3/5	3
Total (100)	62		86		85	

Figure 10. Surgical Stapler Preliminary Designs Evaluation Matrix

4.2 Design Matrix Discussion

From the decision matrix in Figure 10, you can see that the pencil and button grip designs both scored very well. The multi handle design fell short as a result of the weight that was placed on the percent of the population accommodated and required grip strength, both categories taken by the pencil. The pencil design scored very low on the cost category, and this is a result of the long term discussions regarding more advanced technologies once they have to be reintegrated into the structure that is built this semester. None of the designs scored highly on the ease of fabrication criterion, a consideration that will be crucial in the coming months. From these criteria, we have decided to progress with the pencil design.

V. Proposed Final Design

After reviewing the designs in relation to the decision matrix, the team decided to pursue the pencil design. It is a seemingly original design, which gives us the opportunity to design freely without worrying about patent infringement, it will cover nearly the full spectrum of hand sizes in surgeons of all ages, and the fabrication of a prototype within the scope of this semester looks to be very possible in the time that we have available to us. Surely this will not look exactly like the final design at the end of the year, but this design makes the team very excited to move forward into the rest of the design process with

this idea as the starting point. The team will meet with Dr. Liepert in the near future to discuss the preliminary designs and to hear her opinion as we begin to focus on creating our final design.

VI. Conclusions

6.0 Discussion

This project has the opportunity to have a positive impact on the lives of both surgery patients and surgeons throughout the world. Ideally, the design would allow for surgeons with smaller hands to more reliably and comfortably conduct their surgeries, resulting in more consistent, safe results for the patients and less pressure and stress on the wrists and hands of the surgeons. Regarding the pencil design, the team will have to carefully consider what features can be feasibly implemented within the time frame provided and with the resources available to us.

6.1 Future Work

The team will meet with Dr. Liepert in the near future to discuss her opinions on the progress of the project and on the preliminary designs that have been presented. Once she provides her input, the team will fully decide on a final design and begin the fabrication process. Various modeling materials and tools will need to be acquired. Ultimately, the goal is not to create a fully-functional stapler; instead, the goal is to fabricate the external components without worrying about the underlying mechanisms that allow it to function.

6.2 Fabrication Plans

Currently, the team has finalized the fabrication plan for our prototype; various ideas have been suggested, including modeling clay, styrofoam, and 3D printing. The meeting with Dr. Liepert should clarify which design procedure we wish to begin. Once it is decided upon, the team will begin acquiring the necessary materials and discovering locations that we can use to create our designs.

VII. References

[1] "Amy E. Liepert, MD," in ***UW Health Find a Doctor***, UW Health, 2016. [Online]. Available: http://www.uwhealth.org/findadoctor/profile/amy-e-liepert-md/9451. Accessed: Feb. 15, 2017.

[2] Liepert, Amy: personal correspondence, 1/30/2017

[3] C. Vidal, "Procedure for use of laparoscopic surgical instruments," United States, 1998.

[4] E. Walker and S. Poley, “The Aging Surgeon Population Replacement rates vary by specialty and rural-urban status,” ***American College of Surgeons Health Policy Research Institute***, no. 5, May 2012.

[5] "Ethicon echelon Endopath Stapler, 60mm," in ***Medex Supply***, 2017. [Online]. Available: https://www.medexsupply.com/surgical-supplies-surgical-instruments-skin-staplers-removers-ethicon-echelon-endopath-stapler-60mm-x_pid-63191.html?pid=63191&gclid=CPaYuMrZmNICFVq1wAodjKEOHw. Accessed: Feb. 18, 2017.

[6] "IDrive™ ultra powered stapling system," in ***Medtronic Covidien Products***, 2017. [Online]. Available:http://www.medtronic.com/covidien/products/surgical-stapling/idrive-ultra-powered-stapling-system. Accessed: Feb. 16, 2017.

[7] L. Vassar, "How medical specialties vary by gender," in ***American Medical Association***, AMA Wire, 2016. [Online]. Available: https://wire.ama-assn.org/education/how-medical-specialties-vary-gender. Accessed: Feb. 15, 2017.

X. Appendix

A. Product Design Specifications

Product Design Specifications:
Ergonomic Redesign of a Surgical Stapling Device
February 3, 2017

Client: Dr. Amy Liepert, liepert@surgery.wisc.edu
Advisor: Beth Meyerand, memeyerand@wisc.edu
Team:

Andrew Fugate - afugate@wisc.edu, Team Leader
Albert Anderson - afanderson2@wisc.edu, Communicator
Therese Besser - tmbesser@wisc.edu, BSAC
Ellen Restyanszki, restyanszki@wisc.edu, BWIG & BPAG

Function:
Surgical staplers have undergone many design modifications including the recent addition of powered devices. Stapling devices are used both for intestinal resections and anastomoses as well as for vascular control. The users of these devices have changed overtime with both the increase in female surgeons as well as an aging surgeon population. Opportunities for improvements in device design for the increasingly diversified surgeon users are multiple. This project provides the opportunity for lab based and field study investigation of the ergonomic implications for the device users as well as potential for novel design modifications and/or solutions.

Dr. Liepert performs laparoscopic surgeries and utilizes a surgical stapler to separate and seal tissues. Her procedures require her to fire the stapler approximately five times. The existing stapler, the Ethicon Echelon Flex, is too large for her hand and the force required to fire causes excess stress and strain on her hand and elbow. The goal of this project is to either design a new stapler, or update an existing device, to be compatible for Dr. Liepert.

Client Requirements:

- Fabricate a prototype for a disposable laparoscopic surgical stapler
- Reduce stress and strain on arm and elbow upon firing
- Compatible with client's hand size

Design requirements:
1. Physical and Operational Characteristics
a. Performance requirements:

The stapler will be designed to be disposable after one surgery, approximately 5-10 staples. It is not feasible to design a device that can be sterilized and reused. It will be preloaded with staples.

b. Safety:

Patient:

The stapler will puncture the desired tissue without harming any surrounding tissue of the patient. The ISO standards focus on the physical implant, the staplers, which will not be augmented by the team.

Surgeon:

The device aims to minimize the strain on the clinician's wrist and elbow, minimizing injury such as Musculoskeletal Disorders from repeated use.

c. Accuracy and Reliability:

The stapler will reliably supply a minimum of 5 staples into the desired tissue location. The ergonomic redesign will not affect the accuracy or reliability of the existing device, the Ethicon Echelon Flex.

d. Life in Service:

The stapler will only be employed once before disposal. The single use will supply a maximum of 10 staples. It is not within the specifications of the project to design a device that can be autoclaved for multiple surgical uses.

e. Shelf Life:

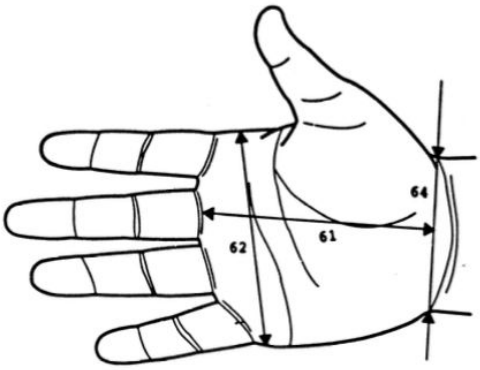
The shelf life of the prototype will be 5 years. The electronics within the device will remain viable for the entirety of the shelf life. The device will be sterilized during the manufacturing process and cannot be contaminated before it is used in the operating room.

f. Operating Environment:

The device will remain in the original packaging until use. Therefore, the device should be stored at room temperature, away from any liquids, and handled with care until the packaging is opened in the operating room. For this reason set-up and opening of the package must be fast and simple so as to not hold up the surgery. The stapler can be reused multiple times on the same patient during a single operation, but must be disposed of as hazardous material following the operation.

g. Ergonomics:

The goal of the project is to improve the ergonomics of the Ethicon Echelon Flex 45 Endopath Stapler. Currently, the grip of the device is too large for our client's hand. The prototype will be compatiable with Dr. Liepert's grip. The device will also be designed to be held in a comfortable position by the clinician during operations, minimizing strain on the user's wrist and elbow. The force required to fire a staple will be minimized for ease of use in the female and elderly population.



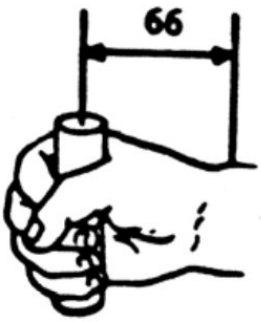


Figure 1 and 2: Hand dimensions from US Army Anthropometry tables

Dr. Liepert's hand measurements are as follows: palm length (61) is 4in, hand breadth from digitizer (62) is 3.25in, wrist-center of grip length (66) is 2.5in, and hand length from digitizer (58) is 7in.

h. Size:

Portability and storage space are not primary concerns of the design of the tool or of the tool itself. Ideally, the product will be smaller than the current surgical stapler used by Dr. Leipert and will be comfortably held in one hand.

i. Weight:

While no specific weight was set by Dr. Leipert, the weight of the stapler is one of the key aspects of the design that must be considered. The product must weigh less than the current surgical stapler used by Dr. Leipert and, ideally, have a more even distribution of weight for more comfortable and convenient operation and handling with one hand.

j. Materials:

The product will likely be made of a plastic alloy; this is in keeping with the designs of current disposable surgical staplers on the market. The material should comply with current FDA guidelines and other relevant requirements.

k. Aesthetics, Appearance, and Finish:

Dr. Liepert did not specify a preference of aesthetic, appearance, or finish. The example surgical stapler shown featured a standard white and blue plastic color scheme and finish; many surgical staplers seen on the market feature a similar appearance and style.

2. Production Characteristics

a. Quantity:

The goal of the semester is to create one working prototype.

b. Target Product Cost:

In the current market the going rate for a laparoscopic surgical stapler ranges from $600-800. For our purposes this semester, we will work with a budget of $100.

a. Standards and Specifications:

ISO standards regulate specifications for the implanted device (the staples), but not the stapler. [1] We will not be augmenting the staples, therefore this is not a concern for our project.

b. Customer:

Our customer would prefer a small and easy to pick up and handle machine. The design is for a customer with a smaller hand size or weaker grip strength. Eventually this product could be marketed not only to female surgeons but surgeons who are losing hand strength and dexterity to age-related problems.

c. Patient-related concerns:

The product will be used on a one per procedure basis. The product will be delivered to the Operating Room sterile, and be disposed of post procedure, therefore sterilization is not a concern. Stapler malfunction, however, is a concern for the patient. Every year, there are 8000-9000 adverse events reported to the FDA as a result of stapler malfunction, approximately 1% of which result in death. The primary patient problems as a result of a stapler malfunction are prolonged surgery, excess bleeding, and infection. [2]

d. Competition:

The market of surgical staplers is quite large and diverse, as evidenced by searches through online marketplaces. Available staplers vary wildly in price, design, quality, sophistication, and application; staplers of nearly all shapes, sizes, and colors are available with a wide variety of options and design considerations, including how the device is powered, if it is reusable, and several other key factors. These staplers range from $10 for a single, plastic, disposable device to several hundred dollars for metal alloy, reusable staplers. Additionally, each disposable Ethicon stapler used by Dr. Liepert and the UW Hospital costs between $500 and $600.

Sources:

[1] “Implants for surgery -- Staples with parallel legs for orthopaedic use -- General requirements ISO 8827:1988,” ***International Organization for Standardization***. [Online]. Available: http://www.iso.org/iso/catalogue_detail.htm?csnumber=16301. [Accessed: 02-Feb-2017].

[2] "Surgical Staplers," in ***US Food and Drug Administration***, Center for Devices and Radiological Health, 2015. [Online]. Available: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/ucm110739.htm. Accessed: Feb. 3, 2017.