Designing of Ergonomic Scalpel Handles with Optimized Weight and Balance

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Abstract

Ergonomics can help improve the design of scalpel handles. An improved handle design will increase user comfort and efficiency. This project aimed to create an ergonomic scalpel optimized for weight and balance. This was done through user experience testing with various prototypes to gather data on design preferences. Prototypes were designed in SolidWorks, and manufactured with PLA plastic, tungsten and wooden rods, and disposable scalpel blades. Each prototype had different weights. Surgeons were informally interviewed and asked to give opinions on different aspects of each prototype. The feedback received from the user experience testing was used to create the final design. The final scalpel has a screw mechanism in the middle of the model to allow for interchangeable grips. It is hollowed out from the back of the model towards the middle to create a balance point at the front end. The model weighs 50 grams and is made of stainless steel.

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Chapter 1: Introduction

Today, scalpels and forceps are difficult for doctors and surgeons to use [1]. These tools have stainless steel handles that provide no comfort to the user. Some surgeries performed by surgeons today can last for hours on end. With such lengthy procedures, it is crucial to have tools that are comfortable for the user the entire duration of the surgery. There are no regulations in the US for how long surgeries can last, but surgeries have lasted up to 96 hours according to Newsweek [2]. OSHA has some regulations in place regarding what tools are used in the operating room, but the regulations are not overly specific. These regulations state that as long as the tool is proven safe, is useful to the surgery, and is sterilized it can be used in the operating room [3]. With such broad regulations, our team had the opportunity to develop an appropriate handle with few regulatory constraints.

Our project evaluates the needs of surgeons and develops an ergonomic scalpel handle that best suits those needs. The first area to understand is the surgical scalpel.

1.1 Surgical Scalpels

Scalpels are used around the world for surgical procedures. Scalpels are used to make incisions in the skin during surgery. This is one of the main first steps in surgical procedures. Scalpels are made in a short and long variety, and are commonly made out of metal for reusability. There are, however, disposable scalpels made from plastic that are discarded after their use. Some scalpels have an engraving of a ruler on the side, which helps surgeons measure while or before they make incisions. Scalpels are relatively light in weight and flat in form. The form could be more curved or straight, but is often flat or thin. There is a blade attachment at the end of each scalpel. Scalpel blades come in different shapes and sizes depending on the procedure. The blades are relatively small for precise incisions. After surgery, the blades are discarded, but the scalpel handle is reused and sterilized [4].

1.2 Ergonomics

According to the Oxford Dictionary, ergonomic means: relating to or designed for efficiency and comfort in the working environment [5]. Ergonomics can be seen in the design of everyday objects. For example, pens and computer mice have been constantly redesigned to have shapes that better fit the hand and cause less strain. Ergonomic design means creating products that fall under this description of ergonomics. It requires an understanding of the variability in human bodies as well as human preferences and incorporates that into the design process [6]. Ergonomic design can help reduce physiological and biomechanical stresses that the body undertakes while using a tool or machine, while also improving function and productivity. Incorporating ergonomic design when creating a product intended for commercial use is imperative to its success. An improperly designed pen or computer mouse could cause extra stresses on the hand, and possibly cause injury. Scalpel handles should also be designed with ergonomic considerations, but currently there are no widely distributed ergonomic designs beyond the original No. 3 scalpel handle. This project concerns designing an ergonomic scalpel, so it is important to understand the relationship between ergonomics and scalpels, which is described in the next section.

1.2.1 Ergonomics and Scalpels

Ergonomics can greatly improve the medical field, particularly a surgical environment. In operating rooms, surgeons and other medical professionals work directly with their hands to perform various procedures on patients. Ergonomic designs for surgical tools can improve the experience for the surgeons themselves, who can spend hours on end standing and performing surgery. Long, tedious surgeries lead to fatigue and discomfort, so having tools specifically designed to fix these problems is crucial. Not only does this improve the surgeon's experience, but it increases safety of patients as well. In hospitals, there are roughly 1.3 million unintentional patient injuries per year [7]. It is believed that improper design of surgical instruments is responsible for about half of those 1.3 million injuries [7]. With better instrument design, the number of unintentional patient injuries can decrease.

Improvements to surgical instruments can start with the most basic of surgical tools; the scalpel. Scalpels are used across varieties of surgical fields and specialties and are incredibly important for surgeons. The shape of current scalpels does not provide adequate comfort for surgeons who use them. Since these tools are so universally used, it is imperative that they have optimal design. There are several changes that can be made to scalpels to make them more ergonomic.

The shape of the handle itself can be changed to make use more comfortable. Shaping the handle to adjust the way surgeons grasp the scalpel can lower hand fatigue and help surgeons with precise incisions. The grip on the scalpel itself can also be improved. Surgeons work with bodily fluids such as blood when they are in an operating room. These fluids can make instruments slippery and hard to hold, thus more prone to accidents. Creating a grip for scalpels that will prevent slipping will increase comfort for the surgeons and decrease risk to the patients. Lastly, the weight of the scalpel and the balance of that weight can be improved. The standard scalpel weighs 22 grams. This is a fairly light weight instrument, and surgeons may prefer a tool with more substance to it to make it easier to hold. The goal of this project was to incorporate the concept of ergonomics into the redesign of surgical scalpel handles. The approaches that we took to address this issue are described in the following section.

1.3 Designing an Ergonomic Scalpel

In order to ensure that we were able to design an ergonomic scalpel, the team held an in person user experience interview. There were a number of steps required before we started our test. We started by compiling all the designs we could think of in the form of sketches, drawings, and CAD models. Once we had this list of ideas, we discussed amongst ourselves and our advisors to determine the designs we wanted to see through to a prototype. Our advisors are Professor Raymond Page of WPI, and Dr. Raymond Dunn, the Chief of Plastic Surgery at UMass Memorial Medical Center. We had a specific shape to work with given by Dr. Dunn, so the main goal during our test was to determine an optimal weight and balance. We tested this idea by having a selection of scalpel prototypes of different weights. Our prototyping was done using a 3D printer and WPI's machine shops. Once we had prototypes available to test with, the team created a guide on the questions we wanted from each participant. All of our testing was done at UMass Memorial Medical Center with surgeons from a variety of specialties and experience levels. This was able to give us information on the ergonomic preferences of a variety of different people. Based on the data we gathered from that test, we were able to create a final design to meet the needs of our users.

Chapter 2: Literature Review

2.1 Current Methods and Technologies for Surgical Incisions

The current most widely used technology for creating incisions during surgeries is the scalpel. Scalpels have a wide range of sizes: handles and blades could be long or short, thick or thin (Fig. 1). They are the most commonly used incision tool [4]. The scalpel has many advantages. It is widely produced and straightforward to use, but the scalpel has not seen a drastic change in design since 1936 when Morgan Parker and Charles Brad created the 2-piece scalpel design as seen in Figure 2 [8]. Another problem with scalpels is that they are hard to grip using gloves when fluids such as blood come into contact with them. There are also reported injuries associated with scalpels in the operating room. This could lead to mixing of the patient's, surgeon's, and/or staff's blood which could cause health hazards [9].

Figure 1. Various types of scalpel blades [10]

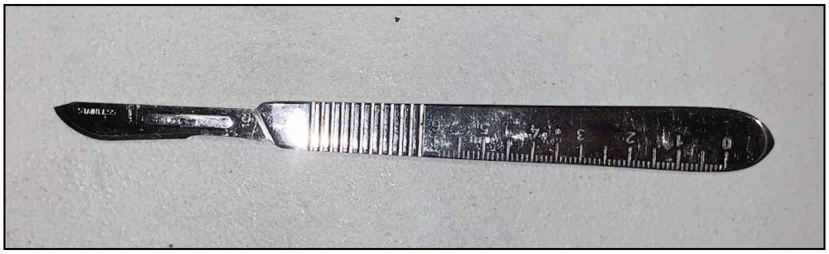

Figure 2. Original scalpel handle with blade

Another incision tool used in surgery are the surgical scissors. They are made out of steel and are used to cut sutures and tubing [11]. These scissors come in various sizes depending on the operator's preferences. The blade can be curved or straight, and long or short.

Electrosurgery is another tool for incision. It uses electric current to cut tissue selectively, and can control tissue coagulation. The disadvantage, however, is that it can ignite any alcohol treated skin. This device should also not be used on patients with pacemakers because the electric current from the electro scalpel could shock the pacemaker into irregular heartbeats [12].

Harmonic scalpels are another tool to make incisions for surgical operation. It uses ultrasound to activate its blade to cut and cauterize tissue. Its usage is less than the other tools listed above, but it has many advantages. The harmonic scalpel is very precise, stops bleeding immediately, the patient is not connected to an electrical current, and this type of scalpel often results in faster recovery and less pain for the patient. The disadvantage is that the device is rather large for various surgeries/incisions and is mostly used for laparoscopic surgeries [13]. It is also quite expensive.

With this general knowledge of common incision tools, it is important to understand common surgeries and incision techniques. The surgical scalpel is so commonly used and yet its design has not been changed since its creation. The other tools used for incision are niche, hence, choosing the surgical scalpel for a new ergonomic design would be beneficial.

2.2 General Surgeries and Incision Techniques

Scalpels are used across all surgical fields for a variety of types of surgeries. There are several specialties that surgeons can choose from when working in a hospital; general surgery, cardiothoracic, pediatric, orthopedic, neurosurgery, plastics, and more. Some of the most common surgical procedures are appendectomies, breast biopsies, cesarean sections, cataract surgery, and coronary artery bypass [14]. Each of these specialties and surgeries comes with its own unique challenges and sets of surgical tools. Amongst the differences in surgeries, scalpels play a common factor in it all.

2.2.1 Incision Technique

When surgeons use scalpels to make incisions, they must be incredibly precise. There are certain techniques used to ensure maximum precision. First, the scalpel must be held properly. The surgeon should hold the scalpel between the thumb and the third and fourth fingers. To maximize control over the scalpel, the index finger is placed on top of it as shown below in figure 3 [15].

Figure 3: The best way to hold a scalpel [15]

Next, the surgeon holds the scalpel at a 90-degree angle to the incision site. From there, they are able to puncture through the skin until no resistance to the scalpel is felt [15]. This particular step often takes lots of practice to ensure that surgeons plunge the scalpel in at the correct depth [15].

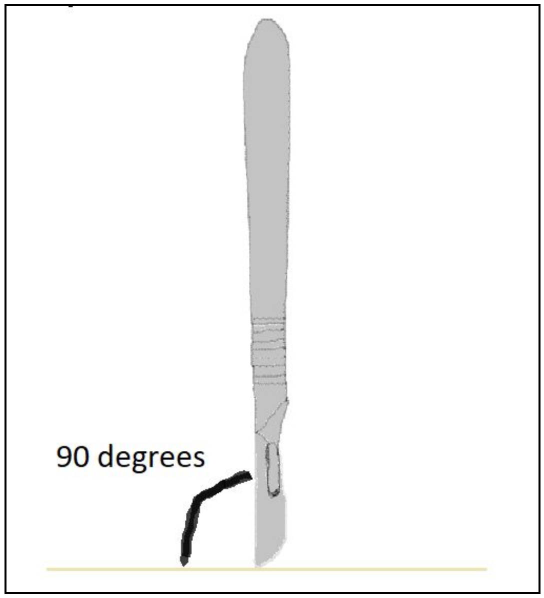

Figure 4. The proper 90-degree angle to start an incision

When the correct depth is reached, the scalpel is shifted to a 45-degree angle to make the incision with the curved edge [15].

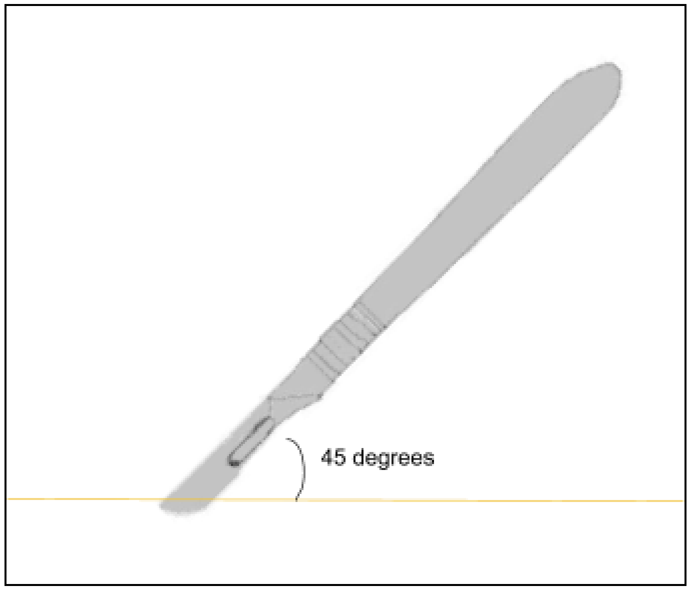

Figure 5. The proper 45-degree angle positioning for incision making

The surgeon holds this 45-degree angle positioning until the incision is complete. At the end of making the incision, the scalpel is rotated back to the 90-degree position and pulled out [15]. Without the use of these proper incision techniques, surgeons put their patients at risk. Improper techniques could cause excess scarring, unintentional damage to tissues, or even death depending on the surgery.

2.2.2 Risks of Surgeries and Incisions

All surgeries come with different types and levels of risks. The top three riskiest surgeries for a surgeon to perform are: 1) Craniectomy, 2) Surgical ventricular restoration, 3) Spinal Osteomyelitis surgery [16]. With complicated surgeries, surgeons need to be very careful when making incisions. With craniectomies, incisions around the head take lots of time and can be complicated [17]. It is crucial that surgeons do not hit critical blood vessels in the head while cutting with their scalpels, since the brain is the center of all bodily functions. With heart surgery, there are many risks that stem from complications unrelated to actual surgical technique. The surgeon, however, always has to be careful not to puncture the heart or any surrounding tissues/vessels when making incisions. This can cause further complications or even damage the heart permanently.

There are lots of risks when it comes to these general surgeries, but there are different risks when it comes to plastic surgery. For plastic surgeons, it is incredibly important that they have complete control over their scalpels for incision making. Complete control over the scalpel allows for precise incisions, leaving less noticeable scars on patients. Unfortunately, current scalpels do not always allow for such precision when it comes to plastic surgery procedures. For example, the previous surgical scalpel project through WPI mentioned a common plastic surgical procedure being removal of skin lesions [1]. This procedure ideally leaves little to no scar, but current scalpel designs do not always allow for the precision required [1].

There are ways to lower the risks and ease the difficulty of incision making for surgeons. One way to do this is by ensuring that the surgeons are happy and comfortable with the scalpels they are using in the operating room. This could mean designing an entirely new scalpel to maximize control and comfort for the surgeons using them. In order to understand what is best for the surgeons, it is imperative to incorporate user experience testing when designing a new scalpel. This user experience testing will bring prominent design issues to light and allow for more progress on the design front.

2.3 User Experience Research Techniques Relevant to Scalpel Design

User experience became a popular part of the design process in the 1990's with the advent of Apple devices. Donald Normal coined the term "UX Design" with Apple in 1995 which is becoming an entirely new area of study and product design [18]. Since user experience is so new, there are many different opinions about when and how user experience should be utilized in the design process. The decision to implement usability testing is subjective based on the product. For this application, since the user is so ingrained in the design of the project, usability testing will be done at the prototyping phase. Usability testing for comfort of the product is crucial to effectively meet our goals.

In order to successfully complete usability testing the team needed to identify the most effective way to collect user data from target users. By creating articulate usability tests, the team identified key criteria for creating a comfortable and easy to use product. The tests utilized existing user experience techniques to effectively collect qualitative data from users.

When completing multiple rounds of usability testing, it is in the researcher's best interest to use the participant's time wisely so that the participant does not get frustrated. In order for our group to do this, we conducted one usability test with both of our criteria playing a role. Consolidating our research into one concise study allowed us to run the study without experiencing participant fatigue.

This usability test was performed after test prototypes were built. Inserting usability studies in the prototyping phase ensured that the final product reflected the preferences of our users. Since this project is centered around improving the user experience, gathering data on what that user experience is throughout the process allowed us to produce the best possible handle.

2.4 Weight and Balance of the Scalpel

Usability and weight and balance are important to users to ensure a product feels comfortable in their hands. Different users have different weight preferences. If the product is too heavy for the user, fatigue would occur and handling the product could become more difficult. On the other hand, if the product were too light for the user, the product would be difficult to use precisely. For example, if a very light scalpel were being used to make an incision in the patient, the surgeon could accidentally cut too deep, or too far along a guideline because of the lack of balance between the scalpel's weight and the surgeon's force. Whether the surgeons have larger or smaller hands, their grasp on the scalpel would be different, thus the balance would shift [19].

Counterweights are a way to personalize and adjust the weight of a product to better fit the user. The center of gravity is also important. If the center of gravity is at the edge of the scalpel, the scalpel would tip on that side causing the incision to go awry. It is ideal for the center of gravity to be positioned towards the middle of the scalpel because that is where it is normally grasped [19].

2.5 Current Scalpel Patents

As stated previously, few to no advancements have occurred in the design of the scalpel since its inception. However, several inventors have attempted to redesign the scalpel handle in order to alleviate some of its most common issues. The following is a summary of current scalpel patents available in the world at the time of our project.

Inventors Eliot Gitman and David Hirsch attempted to create an ergonomic handle for scalpels. It was designed to facilitate the positioning of the user's hand grip and consisted of a longitudinally extended body that was substantially oval in cross-section. It contained four substantially concave indentations towards the proximal end of the handle intended to be used for grip [20]. Figure 6 depicts their design.

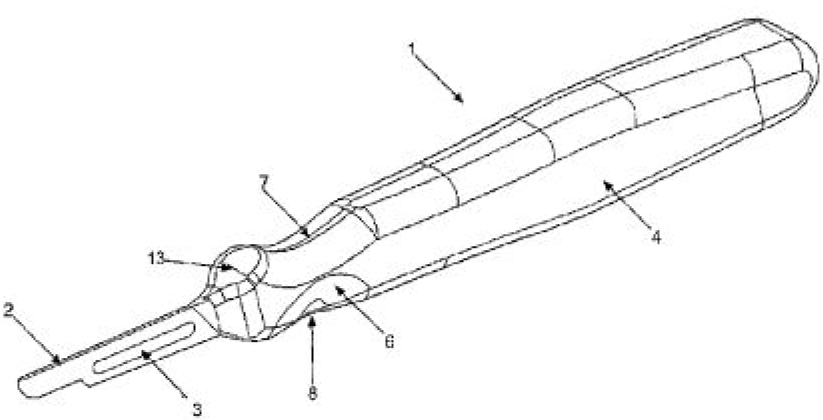

Figure 6. Ergonomic Scalpel Handle [20]

Modular Scalpel with Retractable Blade was invented by Michael Celota and patented in 2010 (Figure 7). This is a pen-like model with the blade being able to retract in its casing. In the casing, there is a spring mechanism where the inner rod retracts, and the blade follows. The casing can twist apart from each other for assembly or disassembly. The intent is to design a more ergonomic scalpel [21].

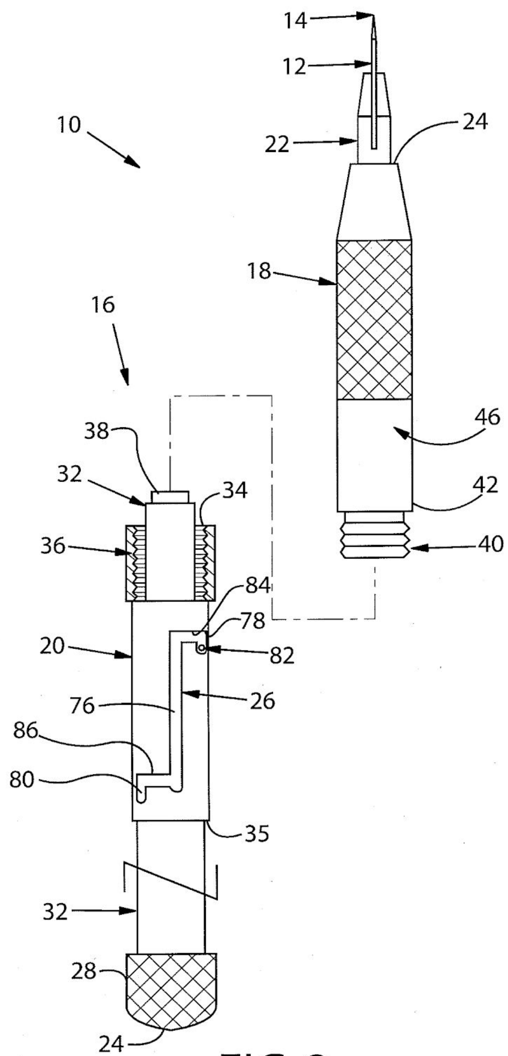

Figure 7. Modular Scalpel with Retractable Scalpel Blade [21]

The third and final scalpel design this background will review is from a previous MQP completed ten years ago also in collaboration with Dr. Dunn at UMass Memorial Medical Center titled "Ergonomic Scalpel Handle for Accurate Incision." They attempted to create an ergonomic scalpel handle using the Golden Section Ratio and utilized user testing to narrow down possibilities for their design [1]. Their final design followed closely to the Golden Section Ratio, was cylindrical, featured a divot in the middle of the handle as a resting position for the hand,

and tapered down by the blade with several concave divots meant to improve grip. Figure 8 is a model of their final design. While designing our prototypes, our team used some of these designs (especially the third and final design shown here) as inspiration and starting points. While all three designs attempted to fix common problems with scalpels and most likely tried to become popular among surgeons, none of them have become widely used. Clearly some improvements could be made, and our team planned to make those. We focused on the “Ergonomic Scalpel Handle Final Design Variation” as a starting point because our sponsor at UMass Memorial Medical Center, Dr. Dunn, strongly encouraged this. Dr. Dunn had helped create this design, but still saw several issues with it that he wanted our team to fix.

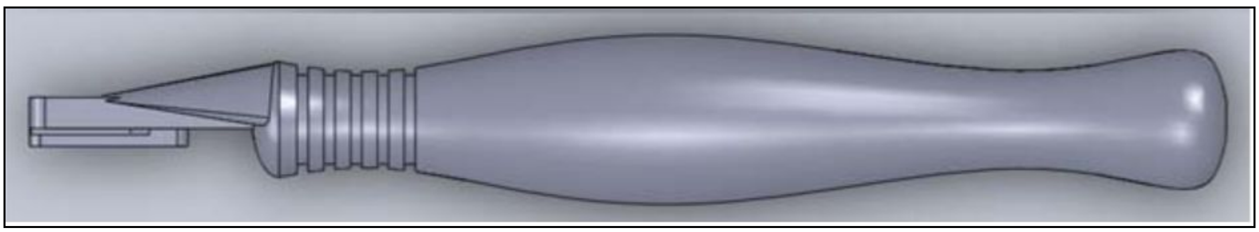

Figure 8. Ergonomic Scalpel Handle Final Design Variation [1]

Chapter 3: Project Strategy

3.1 Initial Client Statement

There are issues regarding the ergonomics of the surgical scalpel, leading to problems for surgeons during surgeries. Our goal was to investigate, develop, and test ergonomic and haptic considerations for the scalpel design. We prioritized material options with favorable manufacturability, sterilization, and durability in a surgical scalpel design, the most common instrument used in surgery.

3.2 Technical Design Requirements

The main purpose of this project was to redesign the scalpel for optimal weight, balance, and shape. During the redesign of the scalpel, there were many mechanical and technical issues that had to be considered. These design requirements fell into four categories: Objectives, Constraints, Functions, and Specifications. The following sections delve deeper into each of these categories and describe several of the considerations our team made during our design process.

3.2.1 Objectives

Objectives include our client's needs and/or wants, so they are contained within the initial client statement. From conversations with our sponsor at UMass Memorial Medical Center, Dr. Raymond Dunn, and through information gained from our initial client statement, our team was able to create the following objectives. First, our design needed to be ergonomic and contain haptic considerations to ensure that users have a positive experience with our new design. Second, the redesign needed to have an optimal balance and weight, meaning it could not be too heavy and must feel properly balanced in the hand. Third, the redesign needed to have a proper shape, made to fit comfortably in the hand and encourage more ergonomic hand positions while using the tool.

3.2.2 Constraints

Constraints are the considerations that must be met related to the confines of design parameters (upper and lower bounds). Constraints include manufacturing cost, time, budget, and the difficulty of getting surgeons/hospitals to adopt new technologies. Our team needed to ensure that the redesign did not cost too much to manufacture to ensure that it could stay competitive compared to current surgical tool options on the market.

Our team had to finish this project within the limited amount of time given to us. WPI has 4 terms: A, B, C and D. The project had to be completed within these four terms. A and D terms were mostly utilized for background research and writing, while B and C terms were utilized for designing, prototyping, and testing. Throughout the process, the team needed to consider our budget. The budget given to us was $1,000. The project had to be completed without going over this budget. This led to several limitations and considerations, such as material cost and amount of prototypes able to be made.

Another constraint with our project was testing availability. A major focus of our project was user experience, and we wanted to be able to get the best data possible from our tests. Therefore, our team interviewed surgeons in residencies, not just average people. Residents usually have very busy schedules, so finding times that work for both our team and these residents to perform tests was a challenge.

The final constraint given in this section is the idea that surgeons will be reluctant to adopt a new technology. Although this constraint is not quite quantifiable, our team needed to do our best to ensure that our product was considerably better than other current products on the market to ensure its adoption.

3.2.3 Functions

The design requirements related to function include those that are necessary for the design to operate properly. The redesign must be sturdy enough to endure the forces and environment commonly experienced by scalpels during surgeries. It must also, in the case of a scalpel handle, be able to have a scalpel blade attached and removed from it. Preferably, the redesign would make common incisions easier to perform in addition to having appropriate functionality.

3.2.4 Specifications

Specifications are those design requirements that are related to operational ranges, limits, tolerances, degree of precision and/or accuracy, and specific material requirements. Since our redesign will be used as a surgery tool in healthcare, several specifications must be met.

Healthcare equipment such as scalpels should be disinfected and sterilized according to the Guideline for Disinfection and Sterilization in Healthcare Facilities [22]. Sterilizing and disinfecting healthcare equipment is imperative, because it can reduce the risk for infection associated with the use of invasive and noninvasive medical and surgical devices. Many sterilization techniques, however, are rigorous and could result in destruction of equipment if the equipment is not designed to withstand the intensity of the sterilization techniques.

The most common sterilization technique is steam sterilization. The process is nontoxic, inexpensive, rapidly microbicidal, sporicidal, and rapidly heats and penetrates fabrics [22]. Tools are either sterilized for at least 30 minutes at 121 degrees Celsius in a gravity displacement sterilizer, or for 4 minutes at 132 degrees Celsius in a prevacuum sterilizer [22]. This technique can cause some negative effects on some materials, including corrosion and combustion of lubricants, reduction in ability to transmit light, and increased hardening time with plaster cast. Based on this, our redesign needed to be heat and moisture resistant, and be able to withstand temperatures of up to 132 degrees Celsius.

Beyond these technical requirements, many standards have been created that must be addressed. The following section outlines the standards that our design will consider.

3.3 Design Standards

The team utilized SolidWorks to sketch different renderings of prototypes, adding materials and creating drawings with a list of part(s) along with a materials list. SolidWorks has features to meet ISO standards. This way the design has the potential to be created through the help of Dr. Dunn at a manufacturing company.

Our scalpel handle design is able to fit the standard scalpel blades used currently. The standard measurements for the scalpel blade No. 10 is 30 mm cutting edge, 0.4 mm thickness, and the material is carbon steel [23]. We purchased ISO 7740:1985, which had the guidelines and measurements for surgical instruments (scalpels) with removal blades. We also took into consideration ISO 13486:2016, which is a quality management standard, and ISO 17664:2017 which outlines the standards for sterilization of reusable medical devices.

3.3.1 Usability Standards

In this project, the team utilized user experience techniques to improve the design of our handle. We used moderated usability interviews as opposed to unmoderated tests. We had a few reasons for choosing this method, the first being budget. Unmoderated testing through apps and websites are very expensive and require physical products to be shipped to users. We wanted a quick turnaround, so we performed moderated usability interviews. This allowed us to converse with the users directly and gather the data we needed immediately. Choosing to do a moderated interview instead of an unmoderated one allowed us to further explore the preferences of our users when necessary. This benefited us because it gave us more data. It also benefited the surgeons because interviews decrease the team's need for future studies. Doing the tests in person meant we were able to test multiple prototypes at once, saving our team time in the future when creating designs. Another benefit of moderated interviews is that we were able to take feedback and answer questions about the designs for the user. Since our prototypes were not in their final form during testing, it was crucial to communicate our place in the process to the user. All of these thoughts led the team to choose moderated interviews for our usability testing.

These usability tests were used to collect qualitative data using dialogue between the users and the moderator, with a note taker writing all comments on a sheet. Gathering this data gave us specific elements of the project to change and improve on in order to elevate the user experience. Because we performed testing involving people, it was important to consider the ethical implications of our in-person studies. In order to do that, we analyzed the ethical portion of our testing.

3.3.2 Ethics

In order to ensure that we ran our tests ethically, we informed each of our users of the entire study before they began. This ensured that the whole study was clear and well known by the user. Because we only used adults, we did not have to worry about working with minors.

In order to maintain the integrity and ethics of our research, we submitted our study to the Institutional Review Board. The Institutional Review Board (IRB) exists to be a check on the structure and intentions of academic research. The team submitted an IRB exemption because our study was done only on consenting adults and there was no risk greater than the everyday occupational risk of a surgeon.

3.4 Revised Client Statement

After completing our background research and evaluating what considerations we must undertake during the design of this project, we created the following revised client statement: Utilize established user experience research techniques and current surgical residents to determine the optimal design for an ergonomic scalpel. Using this research, appropriate design changes will be made to ensure the best possible product. This product must have a proper weight balance distribution while ensuring that the scalpel is not too heavy. The shape of the scalpel should allow for the surgeons to comfortably grip it. Along with the shape to enforce the grip, the material of the scalpel itself needs to prevent slipping from the surgeon's hand during surgery. The material needs to be able to be sterilized in the same way as those of current surgical instruments for the operating room. In the end, their goal is to have a cost-effective, ergonomic scalpel that the surgeons at UMass Memorial Medical Center would use in preference to the scalpels used currently.

Various objectives regarding this project were taken on by two different MQP teams. Both teams were working with UMass Memorial Medical Center and Dr. Raymond Dunn. One team focused on the material and grip aspect of the scalpel, now referred to as "materials and grip group," while our team focused on the weight and balance distribution of the scalpel. In order for this project to be a success, there was collaboration between the two teams. This collaboration allowed progress to be made on both fronts of the project and maximized the success of the scalpel design.

3.5 Project Management Approach

The following timelines display the original projected timeline of this project, and the actual timeline that the project followed. The actual timeline differs from the projected timeline due to a variety of project constraints. These constraints included surgeon availability for user experience testing, the time it took to learn prototyping techniques, design time for creating many different prototypes, and physically prototyping various scalpels.

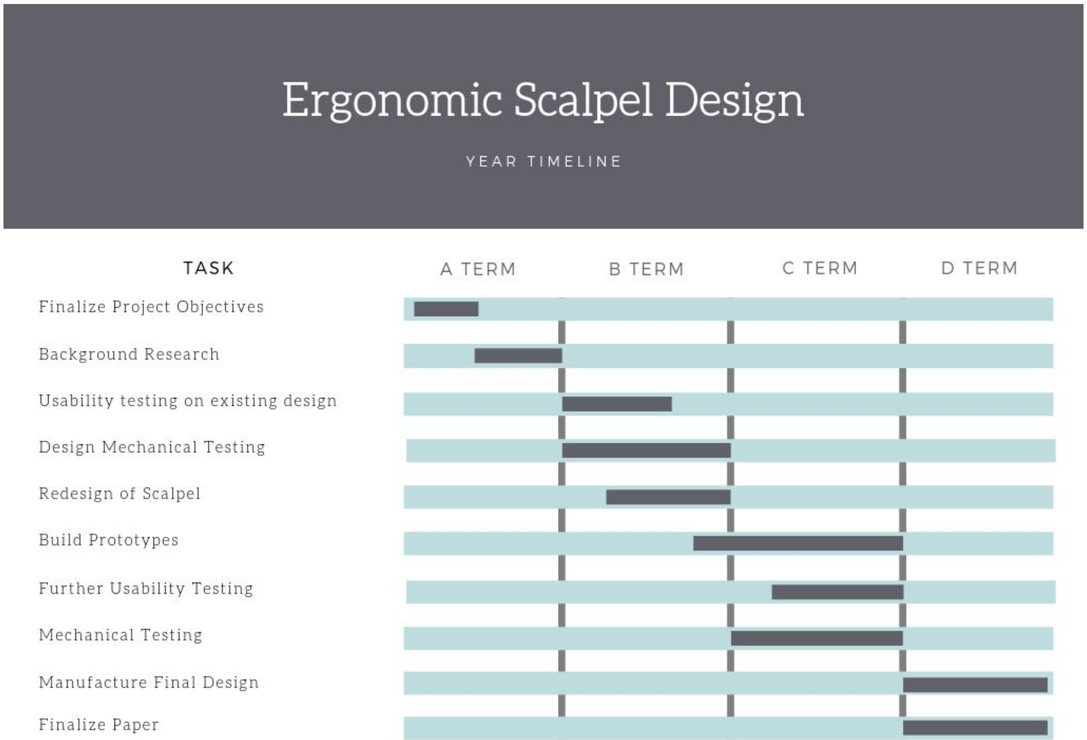

Figure 9. The projected project timeline for the whole school year

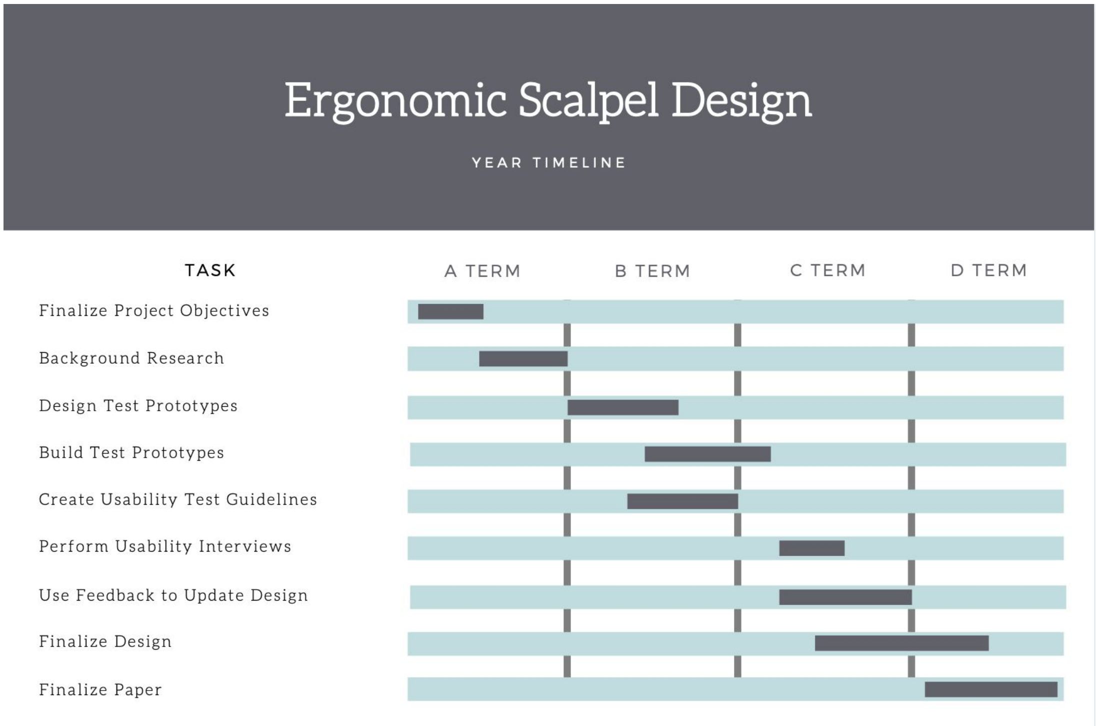

Figure 10. Actual project timeline for the year

Based on our progress and obstacles encountered throughout the design process, the team made an updated timeline to reflect the tasks completed. The main changes included shifting timeframes, longer design process, and unexpectedly being unable to return to school for our second test. This timeline accurately reflects those changes.

Chapter 4: Design Process

In order to begin our design process, we had to have a solid understanding of the needs of our stakeholders. This entailed creating a need statement and analyzing it. Our need statement is as follows: A device used by surgeons to improve the accuracy and ease of creating surgical incisions.

4.1 Needs Analysis

When designing a new product, it is essential to understand the actual requirements for the design as accurately as possible. This can be done through analyzing various stakeholders and their needs and wants for the design. The following section contains our process for determining our projects needs and each need's individual weight.

There were multiple stakeholders that had various needs and roles in the design process of this device. While each stakeholder is unique, they were all incredibly important and valuable to the design process. It was crucial to take their wants and needs into consideration. The first stakeholders were the surgeons who would be using the device. The design process was catered mostly to them and their needs, because they will interact with the device on a daily basis. Along with the surgeons, the hospitals were another essential stakeholder. The hospitals will be the biggest investors in the device, since they are the ones purchasing the device for surgeons to use. It is important to ensure that the device is affordable enough for hospitals to purchase. Without investment from the hospitals, the device will not be a success. The FDA was another stakeholder in the design process. The FDA will be the group to approve or not approve of the device, so complying with their needs is necessary. The project advisor, Dr. Raymond Dunn of UMass Memorial Medical Center, is an important component to the design process. The advisor leads the whole initiative and gives direction to the project, so the team needed to satisfy Dr. Dunn's needs in order to create a successful device. Insurance companies play an additional role in the device design, because the insurance companies control whether or not the device will be covered by their policies. Without insurance coverage, devices can be incredibly expensive or unattainable for buyers. Lastly, general medical professionals hold stakes in the design of the device. While general medical professionals may not interact with the device on a daily basis, it is likely they will learn on the device or come in contact with it from time to time.

The following table illustrates each of these stakeholders' titles, description, role, and priority (or importance). For priority, stakeholders with the most priority were given 1s, while those with the least priority were given 3s. Stakeholders in between were given 2s.

ID	***Title***	***Description***	***Role***	***Priority***
SH.01	Surgeons	Surgeons need to use the tool and interact with the tool on a daily basis. Their needs will dictate the design requirements of the device.	User	1
SH.02	Teaching Hospitals	Hospitals will be the main purchaser of equipment for the surgeons so they will have the final say in terms of buying. If it is too expensive for hospitals to purchase the product will not succeed.	Buyer	1
SH.03	FDA	The FDA will decide whether or not the tool is legal to use in medicine or not. This will make or break the project.	Regulator	1
SH.04	Advisor	Our advisor will lead and provide feedback about the project so he will have the final say about the direction of the project.	Designer	1
SH.05	Other Medical Professionals	Their day to day work may not involve this new tool but they may be able to learn on it and use it in the classroom.	User	3
SH.06	Insurance	Insurance companies can influence how popular the device is by providing incentives for or discouraging a product.	Buyer	2

Table 1. Stakeholder Analysis

With all of the stakeholders in mind, it was time to consider the needs for the device itself. There were multiple needs that were vital to the device; materials, comfort for surgeons, performance, cost, and ease of testing. The material that the device is made out of needed to be able to be sterilized. If the material cannot be sterilized, then it cannot be used by the surgeons in operating rooms. Along with the materials, the design of the device needed to allow for comfort for the surgeons. Surgeons need to be comfortable while using the device if it is going to improve the accuracy of incisions, so the device had to take physical comfort into consideration. This increase in physical comfort would reduce hand fatigue for the surgeons, which will allow for better long-term performance for the surgeons. The cost of the device could not be too high, otherwise hospitals and other buyers will not purchase the device. Lastly, the design of the device needed to allow for an easy testing process. If the device design is too complicated, then it would be more difficult for surgeons to give meaningful feedback on the design. The easier the testing process, the more efficiently the design can be improved. The following table illustrates each of these needs' titles, description, traceability, and priority (or importance). For priority, needs with the highest priority were given a score of 1, while those with the lowest priority were given a score of 3. Needs in between were given a score of 2.

The needs analysis was done to assess a number of project needs. For each need there is a title, description, and priority demarking how important each need is to the project. In addition, there is a traceability column denoting which stakeholder is responsible for that need. This chart was used to better understand the big picture of the project and the interconnection of our needs and stakeholders.

ID	Title	Description	Traceability	Priority
N.01	Material	Medical grade material should be used so that the tool can be sterilized for surgeries. Without this feature, it may not be acceptable to use in an operating room.	SH.03, SH.02	1
N.02	Comfort	The tool should be designed in such a way that it's use would improve the comfort to the surgeon (SH.01).	SH.01	2
N.03	Performance	The tool should reduce overall hand fatigue to the surgeon (SH.01) resulting in better long-term control and performance for the surgeon (SH.01). This could result in reduced costs for hospitals (SH.02) and insurance companies (SH.06)	SH.01, SH.06, SH.02	1
N.04	Cost	The tool must not be too expensive for hospitals (SH.02) to buy it. If the tool is too expensive it will not get adopted and will not succeed	SH.02	2
N. 05	Ease of Testing	The tool should be simple to use and easy to test on the surgeons (SH.01). Ease of testing allows surgeons to give meaningful design feedback, which in turn lets the team create a more successful device.	SH.01	1

Table 2. Needs Analysis

Once all of the needs and stakeholders are taken into consideration, design concepts can be brought to life. Several different ideas for design approaches were drafted and put into a concept map for evaluation. These different approaches were improvements to electrosurgical devices, laser incisions, automated incisions, and improved scalpel design.

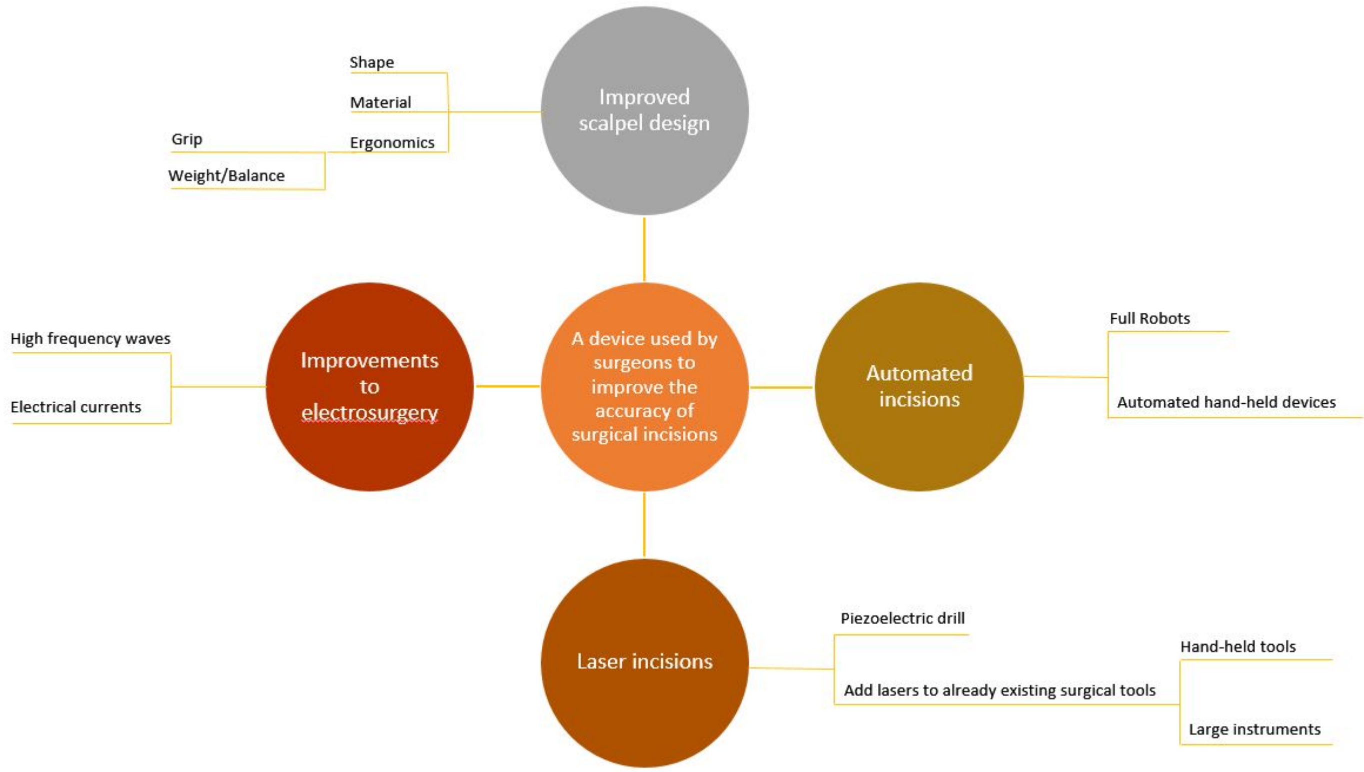

Figure 11. Concept Map

We looked into the various approaches to determine which one would be best for this project. In order to fully analyze the needs and approaches, a decision matrix was constructed. The decision matrix would allow us to see which approach would be most effective for the project. Approaches that were below the standard of a traditional scalpel were given a ranking of -1. Approaches that were at the basic standard were given a ranking of “0.” Approaches that were above the basic standard were given a ranking of “1.”

	Improvements to Electrosurgery Devices	Laser Incisions	Automated Incisions	Improved Scalpel Design
Comfort	-1	-1	-1	1
Cost	-1	-1	-1	1
Material	0	0	0	0
Ease of Testing	-1	-1	0	1
Performance	0	0	0	1
Total	-3	-3	-2	4

Table 3. Decision Matrix

The final score for “Improvements to Electrosurgery Devices” was -3, “Laser Incisions” was -3, “Automated Incisions” was -2, and “Improved Scalpel Design” was 4. It was determined that improvements to electrosurgery, laser incisions, and automated incision devices were far too expensive and technically advanced for this project’s budget and time frame. Scalpels, however, are the most widely used surgical tool in existence and will always be incredibly prominent in the medical industry. Redesign of scalpels fit into the team budget and allowed for ease of testing of the designs. Based on these observations and the decision matrix above, we decided to move forward with the redesign of surgical scalpels.

4.2 Design Concept and Prototyping for the Test Prototypes

Once the decision to move forward with the redesign of surgical scalpels was made, the team needed to consider different designs for prototypes. There was a baseline concept for the design from an MQP ten years ago. This design was prototyped by our current advisor Dr. Dunn. The concept of our design was based on the prototype, referred to as the “Dunn Plastic,” that Dr.

Dunn had provided the team. He also provided us with a manufactured metal scalpel with a composite grip, which we will refer to as "Dunn Metal."

Figure 12. Dunn Plastic

Figure 13. Dunn Metal

Our team set out to find the optimal balance and weight for a scalpel handle while maintaining the same shape as "Dunn Plastic" and "Dunn Metal." Therefore, it was necessary for us to create a system or device that allowed for testing of these parameters. To be able to test the weight and balance of the prototype, the team made several 3D models in the CAD software SolidWorks. Our goal was to determine the best weight and balance for the scalpel model. For balance, there would be a set amount of weight distributed optimally throughout the model. There was a possibility of having more weight in the middle, back, or front end of the model depending on user preferences. The team made different models with varied weights in the middle, back, and front to test. The weight of the "Dunn Plastic" scalpel is 20.2 grams and the weight of the "Dunn Metal" scalpel is 109.6 grams. Since the "Dunn Plastic" scalpel was thought to be too light while the "Dunn Metal" scalpel was thought to be too heavy by our advisor, we decided that our model's weight should fall somewhere in between.

We decided to use additive manufacturing, in our case 3D printing with PLA plastic, to create prototypes intended for testing different weights and balances of scalpels. Our team utilized the Foisie Makerspace to 3D print prototypes using Ultimaker 3 printers with PLA filament. Ultimaker 3 Printers were readily available and more accurate than other printers for smaller prints, and PLA was cheap and easy to print with. The team created several prototypes until we found one that was optimal for testing. The images in the following section are of several of our prototypes, from the first to the last.

4.3 Alternative Designs for the Test Prototype

This section outlines several of our alternative designs created for testing, each with a brief description on the specific needs they are meant to address and how they address those needs.

The team first conceptualized a prototype with similar dimensions as the original design. The difference is, however, that this first design named “Slots 1” had slots in the middle of the prototype. The weight of “Slots 1” without weights added is 13.1 grams. For testing, we decided to add in 5-gram weights. The team decided on 5-gram weights initially because they added the right enough weight to not make “Slots” 1 heavier than “Dunn Metal,” or lighter than “Dunn Plastic.” The initial intent for this design was just to test different balances.

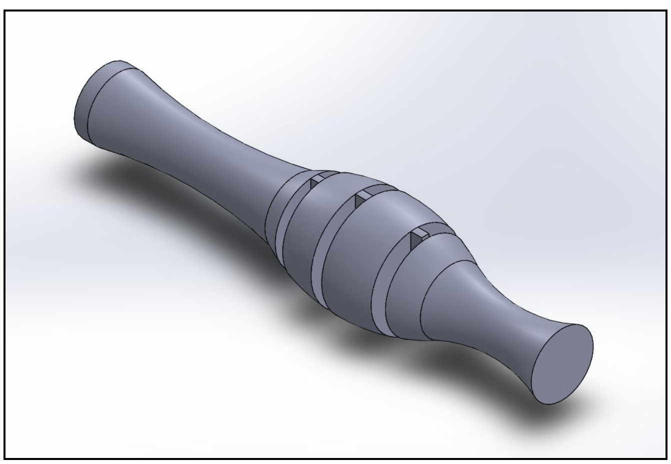

Figure 14. Slots 1 prototype

After reviewing Slots 1 with Dr. Dunn, the team decided to create another version; "Slots 2." This was because of Dr. Dunn's desire to test more balances, as well as test different weights. We created "Slots 2" and added more slots in the middle, some of which could hold 5-gram weights, and some that could hold 10-gram weights. "Slots 2" also had two slots in the back to hold additional 5-gram weights. "Slots 2" had slits in the middle with the following pattern; 5 grams, 10 grams, 10 grams, and 5 grams. The team decided on this pattern because when holding "Dunn Metal," there was considerably more weight towards the center of the middle section before it tapers off. This design was able to accommodate weights between 15 - 55 grams and allowed for more balance considerations testing for extra weight in the back.

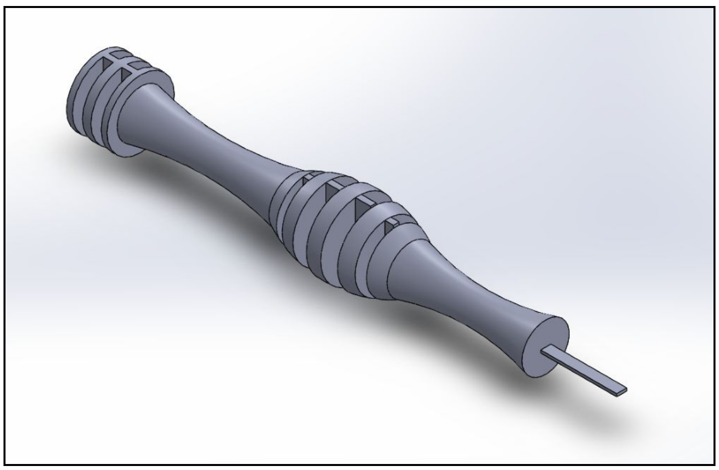

Figure 15. Slots 2 prototype

"Slots 2," however, had several issues and another design was made. The size and shape of slotted weights compromised the shape of the scalpel, weights could easily fall out, and the design did not allow for many variations of weight/balance. Taking feedback from our advisors Professor Page and Dr. Dunn, our team designed the "Hollow" prototype. This prototype was the same shape as the original but had a hole through the center length of the design, allowing for different lengths of tungsten-carbide and wooden dowels to be inserted. The tungsten was intended to add weight and change balance, while the wood was intended to be used as a filler to allow different spacing of the tungsten. This was the prototype used for user experience testing and is illustrated in the following section.

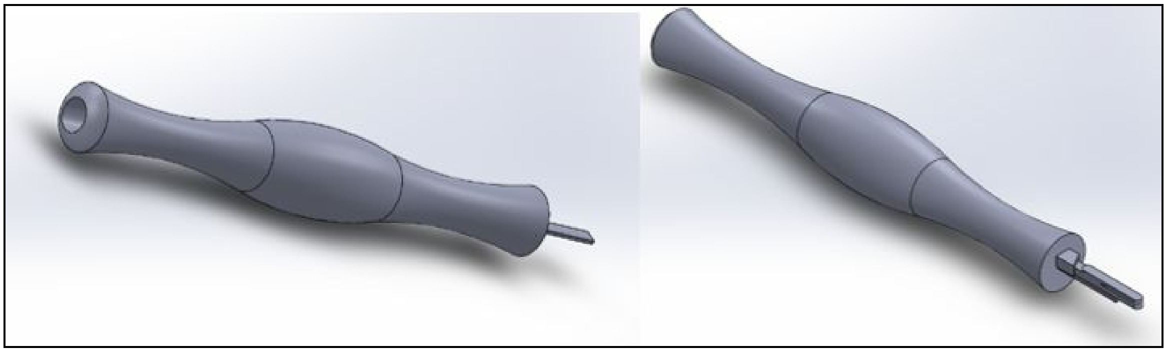

Figure 16. Hollow prototype

“Cleaved” was a similar design to “Hollow” but rather than having a hole through the center of a solid prototype, two halves would be printed that could be combined together with varying amounts of tungsten distributed within. There were potential problems with this prototype because it would be difficult to close and reopen the model to replace weights for testing.

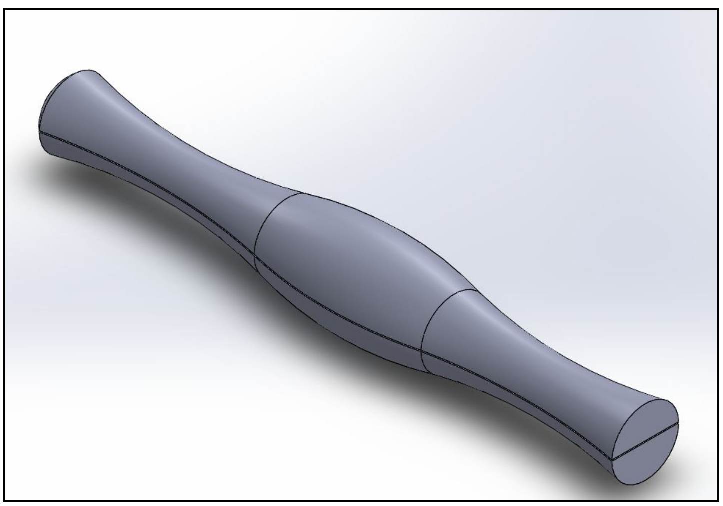

Figure 17. Cleaved prototype

4.4 Final Design Selection of the Test Prototype

The team completed preliminary testing amongst ourselves and with our advisors. The “Slots” variation of the prototype was found to be tedious to hold because of the wider middle section of the handle. Weights could also only be added to certain sections of the prototypes in order to not compromise its shape. This did not allow the team enough freedom when testing balances. Therefore, testing certain weights and balances resulted in an imbalance on one side or too much weight overall. The weights often fell out of the "Slots" models if the user held it a certain way or rotated it. This was due to the weights not interlocking with the scalpel handle and only sliding inside. This design was insufficient and did not allow for testing both weight and balance at the same time. These issues would lead to bad test results and our team decided to redesign our prototypes to our final testing design: "Hollow." The "Hollow" design allowed for testing of several different weights and balance distributions simultaneously, and it was able to do this all without compromising the desired shape from "Dunn Plastic." The following paragraph describes in more detail how our team decided on "Hollow" for the final testing prototype.

First, we had to determine what traits were important for our testing prototype. The six categories our team felt were important for the prototype design were as follows; Comfort, Cost, Initial Weight, Ease of Testing, Aesthetic, and Ease of Replication. Comfort was overall how comfortable the prototype felt to the user, as well as how similar the shape was to the original. Cost was how much building the prototype cost, with a higher score meaning a cheaper design. Initial weight was the initial weight of the design, with a higher score meaning that the initial weight was low enough to test for different weights starting at or below the weight of a normal metal scalpel. Ease of testing indicates how easy it is to test different metrics, as well as how many different metrics can be tested (Ex. Able to test weights varying from 20 g - 110 g). A high aesthetic score indicates a good overall aesthetic for the design. Finally, a high ease of replication means that the design would be easily replicated by a manufacturer. The following chart is a decision matrix outlining the benefits and shortcomings of each design. Prototype models that received a "1" had the least favorable use for that trait. Prototype models that received a "5" had the most favorable use for that trait. Scores "2," "3," and "4" are in between the least and most favorable scores.

Design	Comfort	Cost	Initial Weight	Ease of Testing	Aesthetic	Ease of Replication
Slots 1	2	5	2	1	1	1
Slots 2	3	5	2	2	2	1
Cleaved	4	4	4	4	4	4
Hollow	5	4	4	5	5	5

Table 4. Decision Matrix 2

The “Hollow” design scored the best in all categories of the decision matrix and was decided upon to be used for testing. “Hollow” was most comfortable, easy to test, had the best aesthetic, and was easy to recreate. Figure 17 below depicts our “Hollow” model.

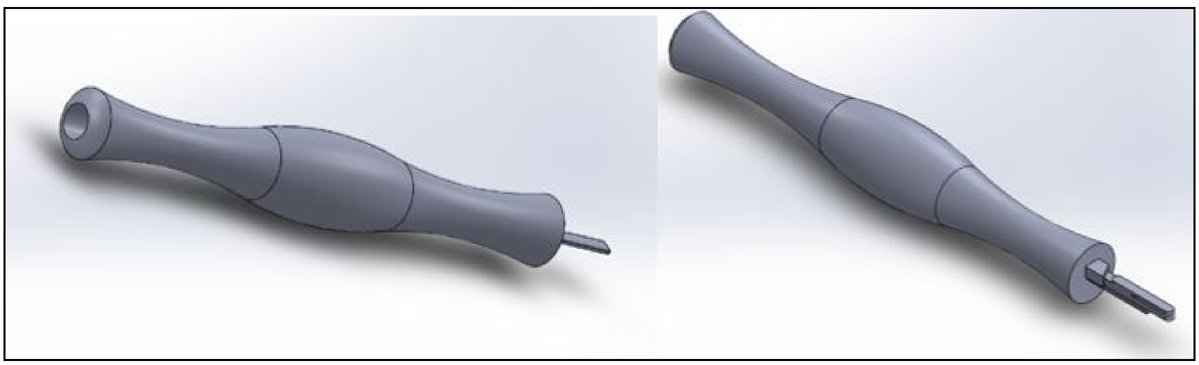

Figure 18. “Hollow” prototype

4.5 Prototype Manufacturing and Manufacturing Constraints

Our team had several constraints we had to address during prototyping. First off, we only had certain prototyping tools available to us. Our team was able to utilize the Foisie Makerspace, the Washburn machine shop, and the Goddard Labs during our prototyping. The Foisie Makerspace on WPI’s campus had several resources available for us to use, most importantly the 3D printers. The makerspace had both Luzbot 6 and Ultimaker 3 printers. Our team decided to use the Ultimaker 3 printers because they were more accurate for smaller prints. The only printing filament available to us was PLA, so we used that material during prototyping. Using more advanced materials and techniques required higher authority than we were able to obtain and wasn't necessary. Unfortunately, during the first round of prototypes we were unable to create the portion of the handle that blades could attach to. This is because that section of the handle needed to have more precise and accurate printing than the 3D printers at the Foisie Makerspace could accomplish. Our team worked around this by utilizing the available machine shop to cut off the top portion of disposable scalpel blades and then using epoxy to glue the blade and our prototype together. To ensure the glue held we sanded each surface to have material for the epoxy to grip to. When the team needed to add or subtract weight from the test scalpels, we used a diamond blade saw to cut tungsten carbide rods to make weights. We chose this metal because it was heavy and affordable. Because of its high density, each cut took a long time and had to be done manually.

For future designs, our group decided to create prototypes out of aluminum, and then stainless steel. This allowed us to ensure our manufacturing techniques worked for metal and stainless steel before creating the final product. These prototypes were to be made in the Washburn machine shops using the CAM software ESPRIT, and the machines known as lathes. The aluminum prototype we created was also sandblasted in Washburn. This added texture and allowed us to add a grip using Plasti-Dip® the front third of the prototype. At the time that we created our first aluminum prototype, and throughout our project, we were still unable to create the section of the handle that allowed blades to attach. However, outsourcing manufacturing to an existing scalpel manufacturer would be sufficient in addressing this issue.

4.6 User Experience Testing

4.6.1 Testing Protocol

In order to properly execute a user experience test, we needed a moderator guide and a consent form. These resources were necessary in order to maintain the validity of the test. These measures were consistent with existing protocols for user experience testing.

Consent forms are used as a preliminary tool to ensure the participant is aware of and agrees to the testing procedure and activities. Without informing the participant of the activities being performed, the test is unethical. Our consent forms also included some basic information about each participant that we used as an analysis tool for our data.

The moderator guide is intended to inform the moderator of the flow of the study and maintain consistency between participants/tests. By asking the same questions in the same order as listed in the moderator guide, each participant was able to receive the same experience. Consistency between participants is crucial to maintaining the validity of the study. In addition to maintaining validity, it allows the team to more easily break up the areas of improvement for the prototypes. The moderator guide does this by breaking up the interview into sections and collecting feedback within each section, which made it easier for the team to evaluate. The moderator guide for our user experience test can be found in Appendix 5.

The tests required a minimum of two team members to conduct. One team member acted as the moderator and guided the test participants through the study. Another team member was responsible for setting up a camera to record the discussion between the moderator and the participant, as well as the participants' hand motions. Once the test began, we assigned a third team member to be responsible for taking notes.

4.6.2 The First Test

To determine the efficacy of our scalpel handle design, we planned to conduct a series of user experience studies. To decide what to ask in our studies and how to conduct them, we considered a number of factors. These factors included variables we could control, as well as external factors such as time and resources. For our first test, we decided to conduct informal guided interviews.

The number of participants in a user experience study depends largely on the scale of the end goal. The participants in the studies for this project were surgical residents from UMass Memorial Medical Center. The surgeons came from a variety of backgrounds; orthopedic surgery, plastic surgery, and general surgery. For this particular application, the team had to be realistic about the availability of the surgeons that would be surveyed. The team wanted to ensure that most problems with the prototypes in the testing would be identified through the first round. By identifying most of the problems in the first round of testing, the final design could be created faster and more efficiently. The number of surgeons to participate in the study was decided on using previous experience with user experience testing, as well as the table below.

No. Users	Minimum % Found	Mean % Found
5	55	85.6
10	82	94.7
15	90	97.1
20	95	98.4
30	97	99.0
40	98	99.6
50	98	100

Figure 19. User experience testing statistics for the number of participants involved in a study to issues identified with design [24].

Since the team wanted to identify the majority of the prototype problems without taking up too much of the surgeons' time, the number of 8 surgeons was decided on for the user experience test. This would allow for around 90% of the issues with the prototypes to be identified.

The first study of the scalpel handles was intended to be exploratory. We came up with a series of questions to ask each participant to influence the topic of discussion. The questions asked the surgeons about the feel of the prototypes, how the weight of each prototype felt, and which two models were their favorites. All of these questions were compiled into the moderator guide that was mentioned in section 4.6.1. For the full list of questions asked and the moderator guide, please refer to Appendix 5.

There were five prototypes used for this testing. One was the original scalpel that all surgeons use; very light in weight. Two were prototypes that Dr. Dunn of UMass Memorial

Medical Center had manufactured in the past; one was made of plastic (“Dunn Plastic”) and rather light in weight, and one was very heavy and made of stainless steel (“Dunn Metal”). The last two were PLA plastic prototypes that the team had made; both had different amounts of tungsten rod in the middle to create different weights. One of the team’s prototypes had a No. 11 blade while the other had a No. 10. The different blades helped us differentiate between the two without checking the weights inside.

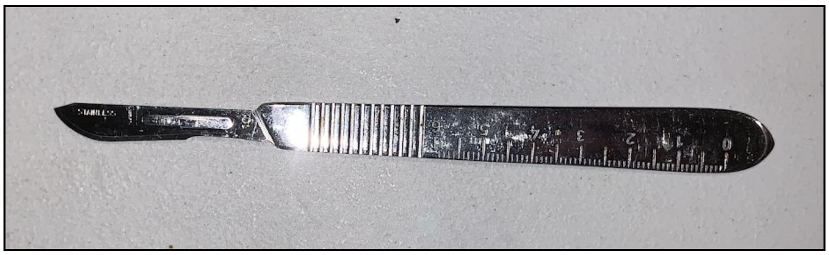

Figure 20. Original scalpel (22 grams)

Figure 21. Dunn Plastic (20 grams)

Figure 22. Dunn Metal (109 grams)

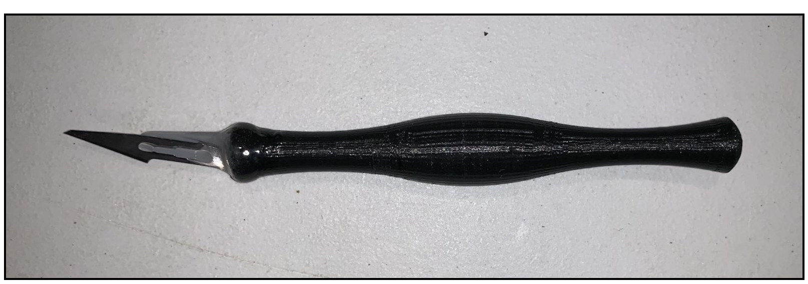

Figure 23. The team’s 11-blade PLA plastic scalpel prototype (43 grams)

Figure 24. The team's 10-blade PLA plastic scalpel prototype (66 grams)

The various prototypes had different weights from the original 22-gram scalpel that every surgeon sees on a regular basis. The team wanted to discover what weight or range of weights was ideal for the scalpel design. The following tables describe the dimensions and weight distributions of the prototypes that were used for testing.

Total Length (mm)	Front Length (mm)	Middle Bulge Length (mm)	Long Back Length (mm)
125 mm	45 mm	35 mm	45 mm

Table 5. The dimensions for all of the scalpel prototypes used in the first user experience test, except for the original scalpel

Model	Total Weight (g)	Tungsten Insert Weight (g)	Wood Insert Weight (g)	PLA Plastic Weight (g)	Balance Point (mm from the front)
No. 11 Blade	43 g	28 g	2 g	13 g	40 mm
No. 10 Blade	66 g	50 g	2 g	14 g	63 mm

Table 6. The information about the team's PLA plastic scalpel prototype designs

Model	Total Weight (g)	Balance Point (mm from the front)
Dunn Plastic	20 g	50 mm
Dunn Metal	109 g	48 mm

Table 7. The information about Dr. Dunn's scalpel prototypes

The surgeons handled all five of the scalpel models throughout the test. For each of these tests the team filmed the participant and recorded the responses to the questions. Based on trends we noticed in the preferences of participants, we made appropriate changes to our prototypes and came up with more specific numerical questions for more clear data. This is the system we planned to use in our second trial.

Chapter 5: Design Verification

5.1 Results of the First User Experience Test

The data gathered from the first user experience test was collected in a document with the questions listed in it. Each of the surgeon's responses were recorded in their own section. Once the test was over and all data was collected, the data was organized in a spreadsheet. The spreadsheet of data was organized into two categories; design and usage. The design category was for any data that was related to the physical design of the prototypes, and the usage category was for any data that was related to the use of the prototypes. The number of surgeons that commented about each data point was totaled next to the data point itself. For the full table, see Appendix 6.

After the data was divided into the two categories, each individual data point was given a severity rating. Severity ratings determine the severity of usability issues on a scale determined by the data analyzer [25]. The scale for this data set was based off of resources found online.

1. I don't agree that this is a usability problem at all
2. Cosmetic problem only: does not need to be fixed unless extra time is available for the project
3. Minor usability problem: fixing this should be given low priority
4. Major usability problem: important to fix, should be given high priority
5. Usability catastrophe: imperative to fix this before product can be released

Figure 25. The scale for severity scores of user experience data [25]

These severity ratings of each data point were based off of the number of surgeons that commented on each data point. Based on the categorization of feedback and severity ratings for each data point, the biggest issues in the scalpel prototypes were identified. See Appendix 6 for the full table of user experience data and severity ratings. In the design and usage categories, the biggest issues were as follows:

Category	Comments made	1	2	3	4	5	6	7	8	Total	Severity Score
Design	Dunn's plastic scalpel is too light, but a good shape and grip	1		1				1	1	4	5
Design	The metal prototype is too heavy	1		1			1			3	5
Design	It is easier to guide the scalpel when the weight is heavier on the front or evenly distributed	1	1				1			3	5
Design	The plastic scalpel was best because it was a big size and easy to control, but is also light	1			1		1			3	5
Design	The rounded shape is easier to rotate at any angle - good plus!	1		1		1				3	4
Design	Our scalpels look thick and hefty - negative				1	1				2	4
Design	The entire body of the scalpel should be thinner					1			1	2	4

Figure 26. The top identified problems for the design category

Usage	Rolling handles is a big concern						1			1	5
Usage	Need a flat back so you can clear an airway							1		1	4

Figure 27. The top identified problems for the usage category

The most important design take-aways from the testing (as shown above) gave our team great insight into what improvements should be made to the prototypes. It was clear that the surgeons most preferred the shape and grip of the "Dunn Plastic" prototype; it was light enough to maneuver easily. The "Dunn Metal" prototype was too heavy, which made it hard for surgeons to hold it comfortably. There was also some good feedback directly concerning the weight/balance distribution, showing that surgeons preferred the weight to be distributed on the front end of the scalpel. One surgeon had concerns about the round shape of the scalpel causing the scalpel to roll, and another expressed wanting a flat back for clearing patient's airways. Based on the questions asked during the surgeons' tests, the team was able to identify the top choice prototypes for six out of the eight surgeons.

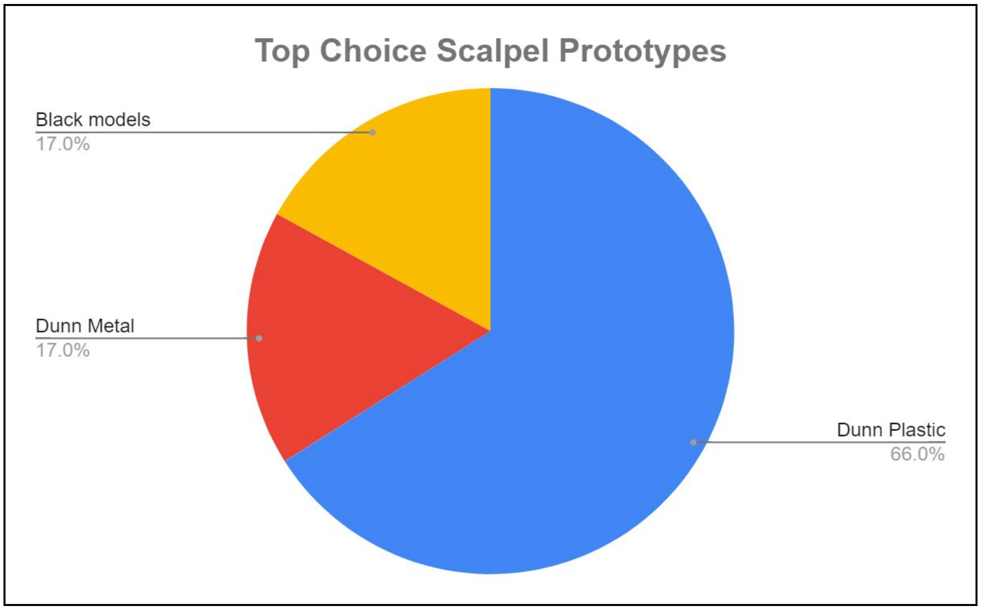

Figure 28. The top scalpel choices for the six out of the eight surgeons who had a favorite

Four out of the six surgeons who had a favorite preferred “Dunn Plastic,” one preferred “Dunn Metal,” and one preferred the black models that the team created. After receiving the feedback from the first test, the team decided what needed to be done for the second test. Since the lack of grip skewed the data so much in the first round, the team decided that there needed to be a grip on the models in the second round of testing. This would create less of a bias towards other scalpel designs. Since the first test was more informal and exploratory, the team decided to generate questions that would provide more hard, numerical data and feedback for the second round of testing. This hard data and numbers would allow the team to perform more statistics on the results of the second test. The team also decided to create the next round of prototypes out of aluminum. This made them look more official and similar to Dunn’s original models.

5.2 Manufacturing Outcomes

Throughout the course of our project, our team was able to create several rounds of prototypes. First, we created several “slots” designs which have been described earlier in this paper. These were created using the Ultimaker 3 printers. Next, we created the “hollow” design. We were able to create two of these using the Ultimaker 3 printers, and cut wooden dowels and tungsten rods to insert into them to change the weight and balance. Our team used a diamond blade to cut the tungsten rods. Finally, we were able to create an aluminum prototype. This was created using CAM software and a lathe on 6061 Aluminum. Our aluminum prototype is shown in Figure 29 below.

Figure 29. Final Aluminum Prototype

Unfortunately, no further prototypes were created due to the extenuating circumstances of a remote D term, which was beyond our team's ability to overcome.

Chapter 6: Final Design and Validation

This chapter will summarize the experimental methods and data analysis of the project from earlier in this paper. We will also describe the final design, and discuss the broad scope of the project and how it can have an influence on various parts of society.

6.1 Summary of Experimental Methods

6.1.1 User Experience Methods

The team used user experience (UX) testing as our primary avenue for making non-essential design choices, meaning design choices that only changed the user experience and not the actual function of the scalpel. Most of our usage decisions were predetermined by existing constraints. The remaining design choices were made based on UX tests. In order to successfully run a UX test, the team had to research existing practices.

Because UX is such a new field, there are fewer hard rules and more general guidelines. This meant that the team had a lot of choices when it came to creating the test. The team decided on a moderator-led personal interview. We chose this study design because it would give the team leeway to explore the concerns and opinions of our participants without having to stick to an exact script. Not only does this method save time for the interviewer and the participant, it also can make the participant feel more at ease and willing to share their opinion. We had 8 participants who each provided valuable feedback that was distilled to categories and key pieces of information, which can be found in Appendix 6. We used this information to narrow down our final designs. Our guided questions for the participants gave us specific information on preferred weights and balance of the scalpel. This allowed us to narrow down exactly how much the model should weigh. Our conversational portion of the interview pointed out some concerns we had not yet considered. One participant commented on how a round scalpel would not be useful to create an airway, which is a use we had never thought of. Based on the information we gathered from the interviews, we made our final design decisions.

6.1.2 Manufacturing Methods

All designs and models were first created using the CAD software, SolidWorks. The models were modeled based on the “Dunn Plastic” model. A revolve tool was used to create the main body. A rectangular divot was cut into the front of the model, and a hole was cut into the model at ¼ inches. We had chosen a ¼ inch hole for the test prototype because ¼ inches was slightly smaller than the thinnest part of the model, and ¼ inch tungsten rods were readily available for purchase. The hole was designed for the metal weight to be inserted at different lengths for different balances. The base model was 13 grams. Our target weights were 43 grams and 66 grams. These numbers were chosen based on the “Dunn Plastic” scalpel (20 grams) and “Dunn Metal” scalpel (109 grams). 66 grams is the average of 109 grams and 20 grams. 43 grams is the average between 66 grams and 20 grams. We had planned to create a model of 87 grams, which is the average between 66 grams and 109 grams. Given the lightness of the PLA plastic and the limited dimensions of the “Hollow” prototype, however, the team could not reach 87 grams. These weights were achieved using solid tungsten rods and wooden dowels for different weight distributions.

Once the test models were printed assembly began. Tungsten and wood rods were cut and loaded into the models at different intervals. The team ordered disposable scalpels to be able to attach blades onto the test model. The blades of the disposable scalpels were cut off. Epoxy was the adhesive of choice to adhere the disposable scalpel blades onto the test model. This method of blade attachment was used because the blade attachment piece of the scalpel was too small to be manufactured with WPI’s prototyping facilities.

As stated previously in the paper, after the first round of testing the team decided to redesign our models and make them out of metal. This decision was made to ensure that our prototypes were more similar to what our final product would be. Our team decided to use multipurpose 6061 Aluminum with a one-inch diameter, which was the perfect weight to test prototypes balanced towards the front, back, and center given our previous results. Only one prototype was able to be made. It was made using the CAM software ESPRIT and a Lathe in the machine shop at Washburn on WPI's campus. After machining, it was sandblasted to give it some texture, and the front third was dipped in plasti-dip to model a grip. Our team was unable to make more prototypes, but they would have been made in a very similar way, and the final design would have been made similarly but with stainless steel.

6.2 Summary of Data Analysis

After the user experience studies were conducted, all of the data was categorized into two groups; design and usage. The design category was for feedback based on the design of the scalpel, and the usage category was for feedback based on the use of the scalpel. The top design based feedback showed the team that the surgeons liked the shape of the prototype "Dunn Plastic," but it was far too light. On the other end of the spectrum, the prototype "Dunn Metal" was too heavy. The surgeons also said that the scalpel was easiest to guide when the scalpel was front-heavy. The top usage based feedback was that the rolling handles were a concern with a round design, and that the scalpel should have a flat back so that it can be used to clear airways. The top choice scalpel prototypes were "Dunn Plastic" (66% preference), "Dunn Metal" (17% preference), and both of the team's black PLA plastic models (17%).

It was important for the team to note the reasons that the surgeons preferred certain prototypes over others. There was a bias towards the "Dunn Plastic" and "Dunn Metal" prototypes because those prototypes had grips on them. The black 11-blade and 10-blade PLA plastic models that the team produced did not have grips on them. The surgeons overall preferred the weights of our team's models, which in the end helped us to decide on the weight of the final design. It was clear that having a grip on the scalpel was important, so that was taken into consideration as well.

6.3 Final Design

The team has designed the Screw model as our final design. It encompasses the Dunn Plastic/Metal shape which was widely accepted by the surgeons in our first round of UX testing. After receiving and analyzing the results from our first round of testing, our team decided to meet with the "Materials and Grip" team mentioned in section 3.4 to create a final design that combined our findings. “Materials and Grip” and our team had decided on stainless steel (316L) for the main component of the handle, with a grip that could be slipped on and off made out of TPE. Their team’s work is titled “Design of Improved Surgical Scalpel Handle with Optimized Grips” and can be found on WPI’s MQP database at the time of this paper’s publication. The “materials and grip” team proposed a design referred to as “Rod” illustrated below.

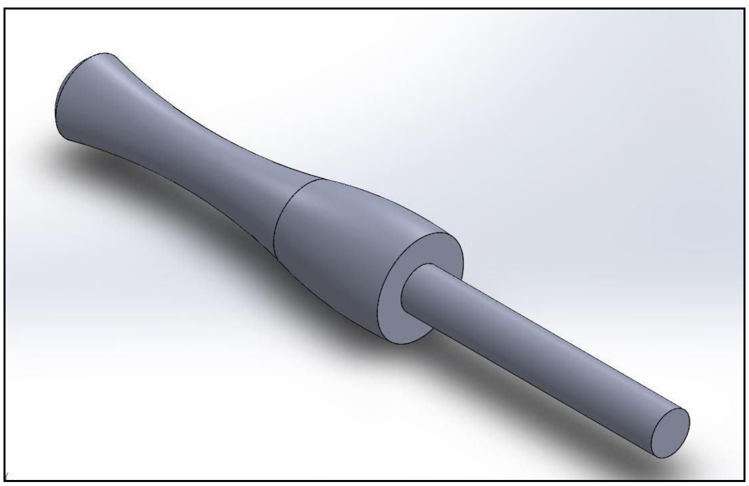

Figure 30. Rod scalpel model.

In this design, the back half of the scalpel was the same as previous designs, but the grip area was just a rod with an 8 mm diameter. This design component was meant for a grip to slip on and off. Our team then faced the challenge of creating this design in a way that allowed for the grip to slip on while still being within the parameters for weight and balance that we discovered during our testing.

After considering the results from the first round of testing, collaboration with the "Materials and Grip" team to attach a grip, and the ability to easily interchange grip shape and size, the team has come to the final design; the “Screw.” The “Screw” design has the “Dunn Plastic” shape original scalpel shape Dr. Dunn had presented to the team. However, it would be made out of stainless steel instead of the material from “Dunn Plastic.” “Dunn Metal” was 109 grams, which the surgeons had agreed was too heavy. From the first round of testing, the data has shown that the ideal weight is between 43 and 66 grams as mentioned earlier. The surgeons could not tell the difference in weight between the two testing prototypes. Thus, the “Screw” has a weight of 504 grams. This was due to the hollowing of the end and midsection of the scalpel to bring down the weight from 94 grams, if the model was solid. The balance point after hollowing the model is 76 mm from the back. The “Screw” design also has a screw design mechanism for easy interchanging of grips for personal preference or for situational circumstances. It will also ease sterilizing the model. The photo below displays the “Screw” design.

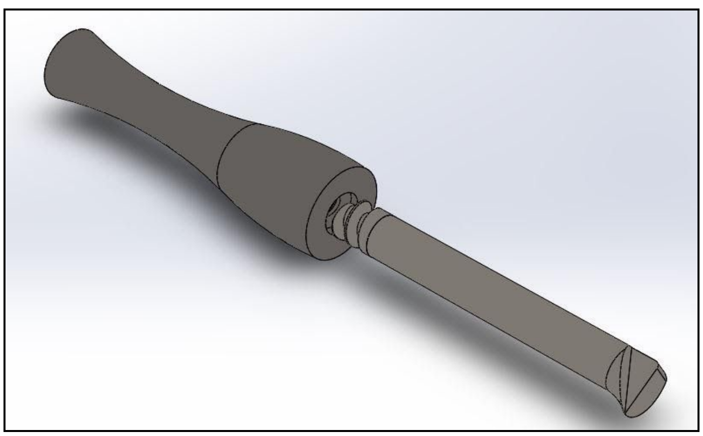

Figure 31. Screw scalpel model

It is designed to have an interchangeable grip to add personalization and wider utility than Dunn Plastic/Metal. The screw mechanism is also designed for better stability when the surgeons are using the model during surgery. The model is made to be front weighted. To accomplish this, the model is hollowed from the center to the back. The rod has a flare at the end for ease of attaching the blade as a visual aid.

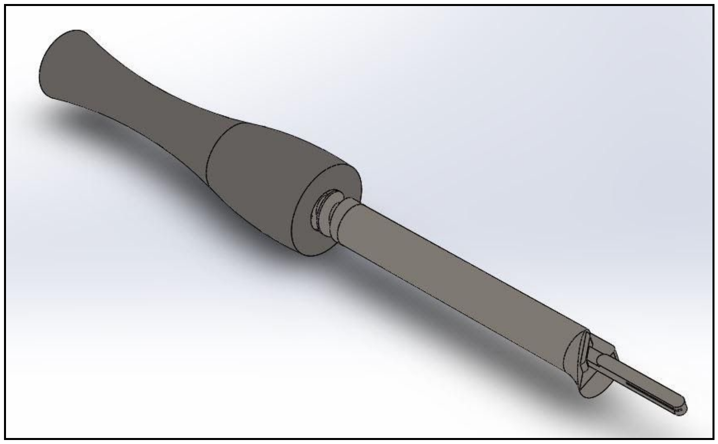

Figure 32. Screw model with blade holder attachment sketch in SolidWorks.

6.4 Industry Standards

Multiple standards were incorporated in our design. One of the features of the scalpel is the blade attachment. The blade attachment is standard throughout the industry. The blade holder follows the ISO 7740 standard [26]. This standard is a drawing of the blade holder. The dimensions and tables were shown in the standard for the two main scalpel blades: the small and large. The models made were based off of the smaller dimensions because smaller blades are more commonly used than the larger blades. An example is shown in Figure 32 below.

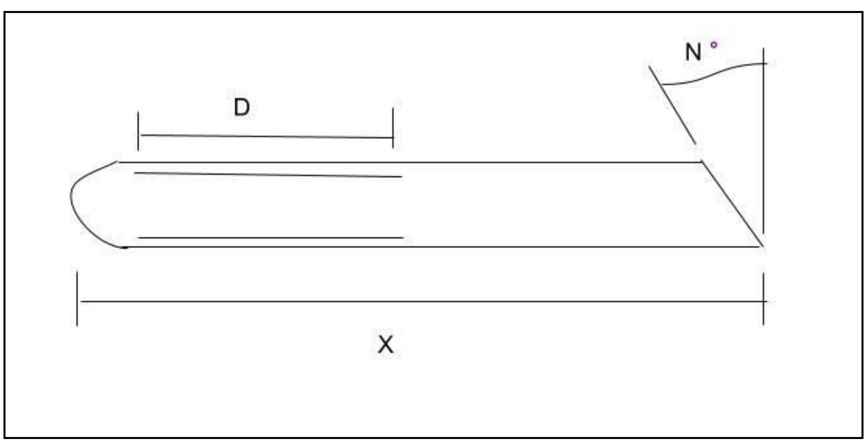

Figure 33. This is an example of the schematic given in the ISO 7740 standard [26].

Another standard utilized was the sterilabilty of the scalpel. Commonly used in implants and tools, stainless steel 316 was chosen. Stainless steel 316 can be sterilized using steam [27]. We believe our final product addresses all of the standards discussed in section 3.3 of this paper.

6.5 Influence of the Project

Surgery impacts many aspects of our society. Surgery could be lifesaving or life changing. Surgeons have been using the same scalpel for many decades and there have not been many changes to help the ergonomics of the handle. The following sections describe the influence of this project on a larger scale.

6.5.1 Economics

As stated earlier in this paper, scalpels are the most widely used surgical tool. Since these instruments are so crucial to hospitals and the medical field, hospitals need to invest a fair amount of money in scalpels. If the scalpel design from this project were to be adopted by hospitals, it would affect the way that the hospitals spend money on their scalpels. This scalpel design would be more expensive than a standard scalpel, so hospitals would be spending more money on these instruments. This would affect the economics of the hospital overall. Although the cost of this scalpel is greater, it can also add several benefits including the possibility of fewer injuries, reduced surgery time, and reduced surgeon fatigue.

6.5.2 Environmental Impact and Sustainability

Our final product, if widely manufactured, could have a negative environmental impact. New machines or tools may need to be bought/made in order to manufacture our product, and due to the nature of its manufacturing methods (subtractive manufacturing), some materials may be wasted. Our scalpels will need more stainless steel to make, and this factor could cause strain on the environment. It's reusability and ease of sterilization, however, alleviates some of these concerns, as the product could last for a long time.

6.5.3 Societal Influence

The societal influence of our project comes from two primary goals; increasing product usability and improving hand comfort for surgeons. The first way the product could have a societal impact is through the increase of user-centered design in surgical instrumentation. The hope is that as more ergonomic scalpels enter operating rooms, the demand for ergonomically designed tools and equipment will increase. Should that happen, it could increase the productivity and experience of surgeons and medical staff. The second way this product could produce a societal impact is by increasing comfort for surgeons. The sheer act of increasing the usability and comfort of scalpels could allow surgeons to more easily make small and precise cuts. This could benefit society because it could improve the quality of surgery being done.

6.5.4 Political Ramifications

Our product could potentially have severe influence on the global market. If it is adopted by surgeons and accepted as a better product than the “original scalpel,” the original scalpel and its manufacturers could be put in a difficult situation. Potentially, our design could replace the original scalpel. However, we doubt that that will happen due to how widely used the current design is. The original design’s advantages in making emergent airways and inclusion of a ruler may still be preferred by some surgeons. Another possible political ramification would be a gap in surgical tool availability between countries. Some countries may not be able to afford to create or buy this new design, which could cause issues between those who have the tool and those who do not. Our team still believes that the positives for the countries that can manage to acquire our design outweigh these negatives.

6.5.5 Health, Safety, and Ethics

The design of our scalpel directly affects health and safety. Since the scalpel is linked mainly to the healthcare industry, its design affects people all across the field; surgeons, patients, family of the patients, etc. The updated scalpel design is meant to improve the day-to-day activities of the surgeons. The ergonomic design allows surgeons' hands to perform longer surgeries with less fatigue. Less fatigue improves surgeon performance overall, thus saving lives and reducing surgery risk for patients. With reduced patient risk, there should not be any ethical concerns with the scalpel design.

6.5.6 Manufacturability

Manufacturability is a concern we had when creating our products; whatever we have designed should be able to be created relatively easily. The 3D printed prototypes we created can be very easily reproduced with the Ultimaker 3 printers at WPI, some epoxy, and disposable scalpels. The aluminum prototypes were slightly more difficult to create, but anyone experienced with CAM can easily replicate our prototype. Although we have not created the final design ourselves, we believe it can be manufactured by common scalpel handle manufacturers without too much difficulty. We believe that the components of our final design can be lathed from stainless steel rods using CAM. The back portion can be hollowed out during this process, and then they can thread the two components to allow for the "screw" mechanism.

Chapter 7: Discussion

7.1 Interpretation of the User Experience Test Results

The results of the user experience test were crucial in designing the final scalpel product. As stated earlier in this paper, the results were divided into two categories; “design” and “usage.” The first we will discuss are the top design-based results.

Based on the feedback, the surgeons preferred the shape and grip of the “Dunn Plastic” model but said that it was too light weight. From this, our team gathered that the 20-gram weight of “Dunn Plastic” was too light and we needed something heavier. Another piece of feedback about this prototype was that it felt easy to control due to the shape and size. We decided that this shape was ideal for the prototype since so many surgeons liked it, and Dr. Dunn liked it as well. On the other end of the spectrum, the surgeons all thought that the 109 gram “Dunn Metal” model was way too heavy. This led the team to decide that the ideal scalpel weight needed to be somewhere between 20 grams and 109 grams.

The surgeons had reported that the scalpels are easiest to use when the scalpel is front heavy or when the weight is evenly distributed. The surgeons felt that front weighting the scalpel made it easier to maneuver and control. Because this data supported the goals of the team, we shifted the scalpel’s center of balance as far forward as possible.

The last of the design-based results were that some surgeons thought that all of the scalpel prototypes were too thick and hefty, and that the entire body should be thinner. This was something that the team took into consideration when designing the following round of prototypes but did not incorporate into the final design. This was not incorporated into the final design because our sponsor preferred the original, more thick shape.

The top two usage-based results relate to the round shape of the scalpel handles. One surgeon thought that the round shape would cause the scalpels to roll around on surgical trays. The round shape was otherwise praised by the surgeons and was necessary to allow for more advanced incisions, so we decided to solve the issue without compromising the round shape.

Once the scalpels were manufactured, the team wanted to create holders for the scalpels to keep them from rolling. The reason we decided on holders, rather than flattening the handle, was because of our advisor Dr. Dunn's advice. The handle should be round in shape to allow for easy control during circular incisions. Another surgeon thought that the back of the scalpel should be flat because surgeons can use the flat back to clear patient airways. This piece of feedback was discussed with our sponsor, and we decided to keep the back of the scalpel round. This was decided because the practice of clearing airways with a scalpel is not common, and therefore not necessary to the design.

In the end, the top three scalpel designs that surgeons preferred were "Dunn Plastic" (66%), "Dunn Metal" (17%), and the black 11-blade and 10-blade models that the team produced (17%). From this data, it is important to note that there are a lot of factors that went into the users choosing their favorite prototypes. The surgeons who chose the prototypes that were not made by the team only preferred the heavy "Dunn Metal" and lighter "Dunn Plastic" because of the grips on the scalpels. The scalpels that the team created were the overall favorite for the weight and balance of the design, which was the goal of this test. The team's prototypes, however, did not have grips on them since they were 3D printed on WPI's campus. The team only wanted the surgeons to focus on the weight and balance distribution, but the lack of grips caused a bias in overall favorites towards the manufactured scalpels. This allowed the team to see the importance of incorporating a good grip. Since a proper grip was clearly highly desired by the surgeons, the final design for this scalpel incorporates the final grip design of the "materials and grip" group. For professionalism of the final scalpel, the team designed the final product in stainless steel (316L). This stainless-steel design allows for the scalpel to be sterilized.

7.2 Ergonomic Design vs. the Original Scalpel

When evaluating how our proposed design compares with existing scalpels, it is important to keep in mind that we were never able to produce our final model. Because of this, the team is taking feedback from our advisors, sponsor, and study participants to summarize the differences based on the information we have. Gathering unbiased information about a comparison between our prototype and a standard scalpel was difficult for surgeons who only had experience working with standard scalpels. This is because the prototype felt unfamiliar in comparison. Thankfully we were able to get some feedback from plastic surgeons who have some experience using a similar scalpel to our prototype, "Dunn Metal." We also gathered data from general surgeons and an orthopedic surgeon, who provided good feedback despite their unfamiliarity with the product.

The majority of the feedback we got comparing the traditional scalpel and our prototype was favorable towards our prototype due to its ergonomic design. Many surgeons compared it to a molded pen grip which they felt was favorable and easy to maneuver. Two of our eight participants spoke about how the round design allows them to more easily make precise and curved cuts than with a traditional scalpel. Despite this positive feedback, we did receive some comments mentioning that the traditional scalpel had a ruler on it and could be used to open up an airway, which are both useful aspects our product lacks. On average our design was preferred due to its ease of use and comfort.

7.3 Limitations of this Data

There were several issues and limitations that our team ran into during the course of this project, some of which we were unable to overcome which will be discussed here. The end of our project occurred during the COVID-19 pandemic. This severely limited our ability to continue progressing. The testing and manufacturing we had planned on finishing were no longer options. Therefore, we were unable to do a second round of testing and were unable to manufacture a final design. Our team also could no longer perform the mechanical testing we had planned to use to validate our final design. The extra tests that we planned to do but were not able to complete are described in more detail in the next chapter. In spite of this, our team still completed a successful project. The data we received from our first round of testing was strong and expected to give us above 90% of the problems with our design. Even though our team was not able to manufacture and test our final design, we still created one that we believe will be successful.

Chapter 8: Conclusions and Recommendations

8.1 Accomplishments and Interpretations

The results of our project indicate that a redesign of the flat metal scalpel would be helpful to many surgeons. Since the original flat scalpel has not been redesigned, there is a clear market for an ergonomic scalpel handle that can accommodate different surgeons. The surgeons enjoyed the dexterity of the team's prototypes.

During this project's duration, the team has accomplished the first round of testing with surgeons, made plans for the second test, manufactured iterations of our prototypes in various materials, and made numerous CAD drawings. The team had to first create CAD drawings based on "Dunn Plastic" and figure out how to best manipulate the shape for weight and balance testing. The team went through several designs and manufactured some of those models through 3D printing. After gathering data from the first user experience test, surgeons seemed to enjoy the prototypes between 43-66 grams, wanted grips, and a front weighted feel. The team then began making CAD drawings and started collaborating with the "Materials and Grip" team to create the "Screw" model. This model has an interchangeable grip, weighs 50 grams, and the center of mass location is towards the front. The "Screw" prototype will also be hollowed towards the center and back to create a lighter scalpel due to the heavy prototyping material. Since the back of the prototype is hollowed, the center of mass will be more towards the front. The team was able to create this successful final design that incorporated all of the criteria established at the beginning of the project.

8.2 Recommendations

8.2.1 User Experience Recommendations

The first recommendation the team would make for further development of the product is to perform a second user experience test. This test would differ from the first test in a couple of ways. For this test, the team would recommend using a 1-5 rating scale for each product, professional metal prototypes with grips, and organic tissue to cut into. This would give the participants a better idea of the actual product, as well as create a simulation more similar to an actual surgical environment. This sort of test would greatly add to our existing results from the first test. In addition to another test for product development, the team recommends a post-production test one year after the product is put on the market. This test would be designed to determine how users felt about the product after using it for an extended period. It would also serve as a measure to project future success of the product based on the experience and feelings of users.

8.2.2 Manufacturing Recommendations

Future prototypes could continue to be made using resources available on WPI's campus, however our team would not recommend doing this. It is not the most efficient approach to prototyping, and WPI may not have every tool necessary to make exactly what we would like to design. Discussions with our advisors led to us believing that reaching out and outsourcing manufacturing to an existing scalpel manufacturer would be the best course of action to create more prototypes and final models. Possible existing manufacturers we briefly looked into included Bard-Parker and Swann Morton.

8.3 Unfinished Tasks

This section describes the tasks that the team had planned to do, but were not able to complete due to D Term being remote away from campus. The unfinished tasks include a second user experience test, a proper in-depth selection and creation of the final design, and mechanical testing of the final design.

8.3.1 The Second Test

The goal of the second test would be to study our team's next round of scalpel prototypes. These prototypes would be designed based on the first test's results. This test would identify the optimal balance of the scalpel with our chosen weight. To do this, we would use our existing data on weight preferences and change only the balance of each scalpel. These new prototypes would be made of aluminum to improve the appearance of each design while ensuring the prototypes were light enough to be modified to our desired weight/balance. In the first study, many participants found the plastic prototypes to be distracting and difficult to visualize in their daily lives. To combat this, the team would create metal prototypes to the specific weights identified and use those for testing.

Based on our previous tests, the team determined that the best weight for the prototypes was between 43 and 66 grams. This was determined by investigating participant preferences and evaluating data from the first study. A useful finding from the first test was that most participants had difficulty distinguishing between 43 and 66 grams. This led the team to decide to design all of the prototypes for the second test to weigh between 43 and 66 grams. Since the participants had trouble distinguishing between the 43 and 66 gram weights, the team decided anywhere in that range would satisfy our user experience goals.

With all of this useful information and insight, the team designed the final test prototypes. The following photos display each prototype that would be made and tested by the surgeons.

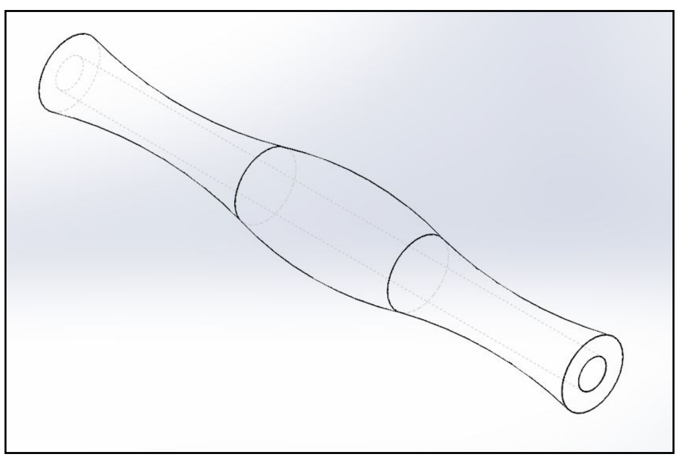

Figure 34. Aluminum model with ¼" hole through the entire body.

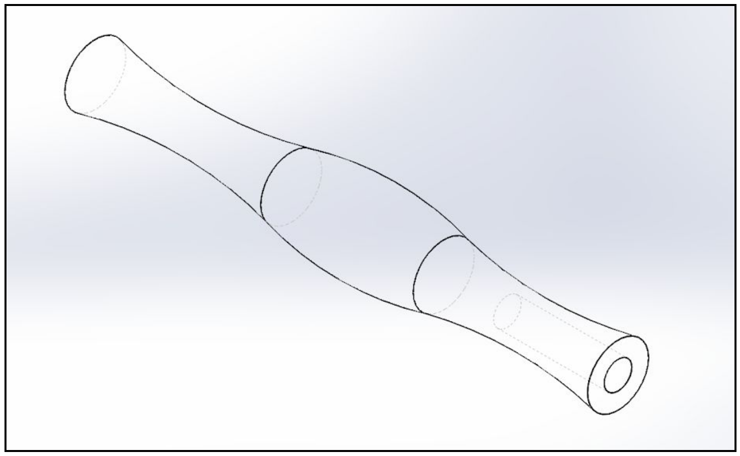

Figure 35. Aluminum model with ¼ inch hole through the front of the body at 1 inch deep.

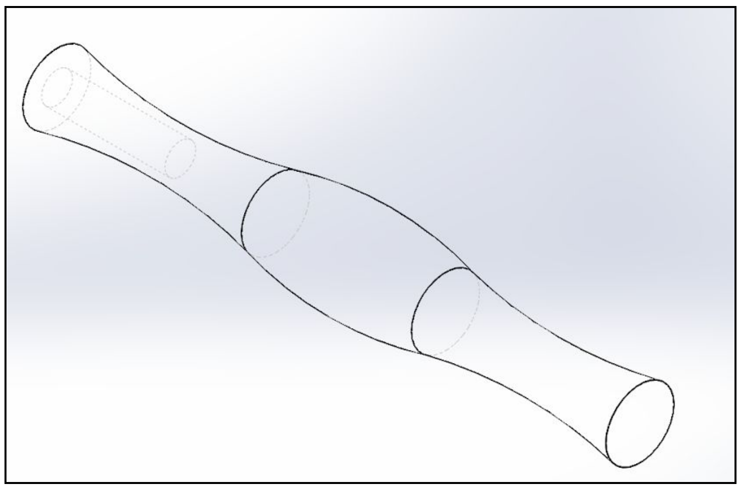

Figure 36. Aluminum model with ¼ inch hole through the back end of the body at 1 inch deep.

This test would be different from the first test in a couple of ways. The previous test had the surgeons test each prototype by cutting into neoprene. While we felt the neoprene was sufficient for the first test, the team and our advisors felt that a more real world scenario would help give us more specific and situation based feedback from our participants. This second test would be done to more closely resemble actual surgery conditions. These surgery conditions would be mimicked by placing a thin layer of pig skin over a foam board for the surgeons to cut into. The pig skin and foam board setup would resemble human skin and tissues beneath it.

This test was also aimed to provide the team with numerical data for statistical analysis. To collect that data, the team would use a SUS score analysis and a sheet of questions that asked the surgeons to rank aspects of these metal prototypes on scales from 1 to 5 [28]. For the question sheets, please see Appendix 7 and Appendix 8.

The results from the second test would give the team the last information necessary for producing the final prototype. The surgeons would identify which balance distribution they preferred the most out of the presented prototypes. This particular test was going to provide the team with more numerical data than the first test. Based on the numerical data from the questions in Appendix 7 and Appendix 8, the team would perform statistical analysis for the prototypes. Based on the highest ranked prototype, statistical analysis, and any last feedback from the surgeons, the team would be able to produce a final design. This design would first be produced in SolidWorks, and then manufactured out of stainless steel.

8.3.2 Mechanical Testing of Final Design

After deciding on a final design, it is necessary to ensure that it is not only qualitatively better than previous iterations, but also that it is better quantitatively. Our team planned to do this through mechanical testing of our final design, the original scalpel, and the "Dunn Plastic" model using force plate data. This type of testing was decided upon due to it having a precedent. The "Dunn Plastic" model was designed and created in a previous MQP titled "Ergonomic Scalpel Handle for Accurate Incision." Our test would attempt to replicate the testing they conducted on their models.

The testing protocol as described in "Ergonomic Scalpel Handle for Accurate Incision" would be as follows: Using a black marker, draw 8 centimeter lines on a "self-healing" cutting surface. One line will be linear, the other elliptical, and the final circular. These lines will be traced by study participants to model common incisions made during surgery. The cutting surface will be placed on an AccuSway force plate. The study participant will then stand next to the plate and trace the lines with a scalpel. The participant must stand so that their chest is 15 inches from the center of the incision being created, and must lean against the force plate as if during an actual procedure. Data will be collected and analyzed using BioAnalysis software and Microsoft Excel. The most important result to gather from this experiment is the moment in the x, y, and z directions. Each time a moment switched from positive to negative or vice versa was an indicator that the hands were compensating for poor scalpel design. If our design had similar or less moment "switches" than the original scalpel and "Dunn Plastic," then our team could be confident in our design.

8.3.3 Proper Final Design Selection

With the second round of testing, and manufacturing ability being cancelled, there was not a proper final design selection. The team made a prototype that was believed to be the best choice considering the collaboration with the "Materials and Grip" team and making the handle more personal. The second round of tests on pig skin would have given immense feedback on the prototypes. The surgeons would have been able to tell if the prototypes were feasible in design to perform their surgeries. The tests were designed to use the aluminum models with 1 inch hollows which are similar in weight as the final "Screw" design. There could have been other factors to change the "Screw" model significantly. Such factors include colors for personal touch, sizing, and a flat side to prevent the prototype from rolling. Using the UX and mechanical data, new CAD drawings could have been made if there were any issues in making incisions or errors in varying forces on the force plate. If the scalpel does not allow the surgeons to create an incision at the correct layer of the skin, it leaves room for human surgical error. The final design should assist surgeons rather than sabotage their work. The data from the second test would help prove the significance of the team's design as well.

8.4 Final Remarks

This project was a worthwhile pursuit for this team throughout the year. We created multiple design options, with many iterations for prototypes that could be used in testing. Using all of the feedback that we got from our advisors and the surgeons who participated in the user experience test, a final design was created that met our objectives outlined in the beginning of the design process. Our team hopes that in the future, the final product can be physically manufactured so that the project can fully come to fruition. The final product that came out of this project provides an ergonomic scalpel that can improve the user experience for surgeons everywhere.

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Glossary

Dr. Raymond Dunn: An advisor for this project and the Chief of Plastic Surgery at UMass Memorial Medical Center.

Dunn Plastic: The scalpel model created by Dr. Dunn and the MQP team that worked on this project before us. It had the ergonomic shape used as a model throughout our project, and an ergonomic grip.

Dunn Metal: The composite manufactured scalpel that Dr. Dunn had made prior to the beginning of this project, with a design similar to Dunn Plastic.

Ergonomic(s): Designing products to maximize comfort and efficiency for the user.

Hollow: Name of prototype used in the first round of testing. This prototype has the shape of Dunn Plastic, but has a quarter inch hole cut out to be filled with various weights.

"Materials and Grip:" The team that worked alongside ours to improve the grip aspect of scalpels while we worked on the weight/balance distribution.

Scalpel: A tool used to create incisions in surfaces (typically biological tissue in surgical environments).

Screw: The final design the team made in collaboration with the "Materials and Grip" team. Includes a rod with a flare piece and a base. Both have a screw mechanism.

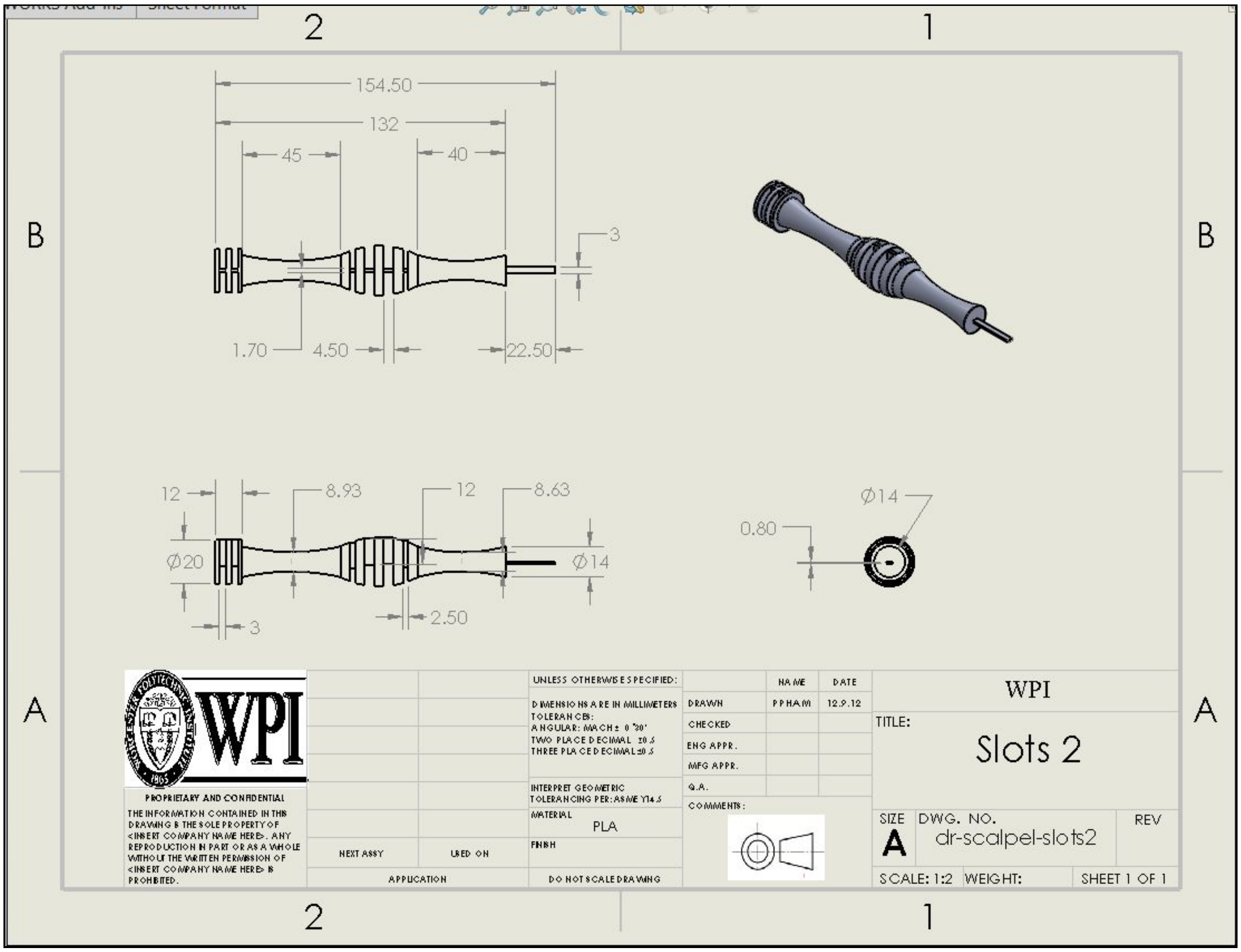
Slots: The first prototype our team made, which was plastic and had slots that weights could fit into.

User Experience (UX): All aspects of a product that a person using it would see or interact with.

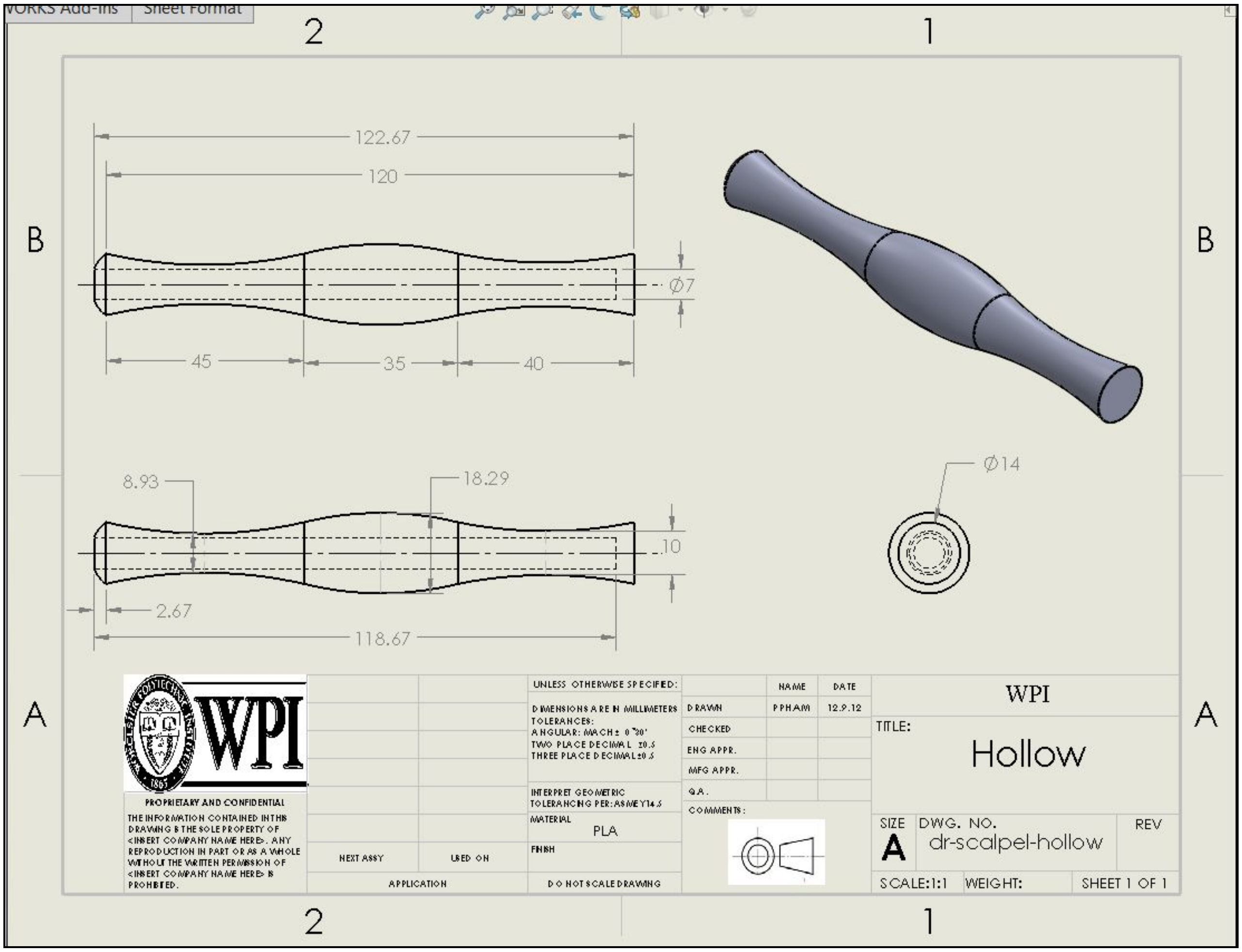
User Experience Design: Designing a product with the end goal of improving the overall experience of a person using it.

Weight/Balance: A reference to the distribution of the weight of the scalpel, and the balance of that weight while the scalpel is being used.

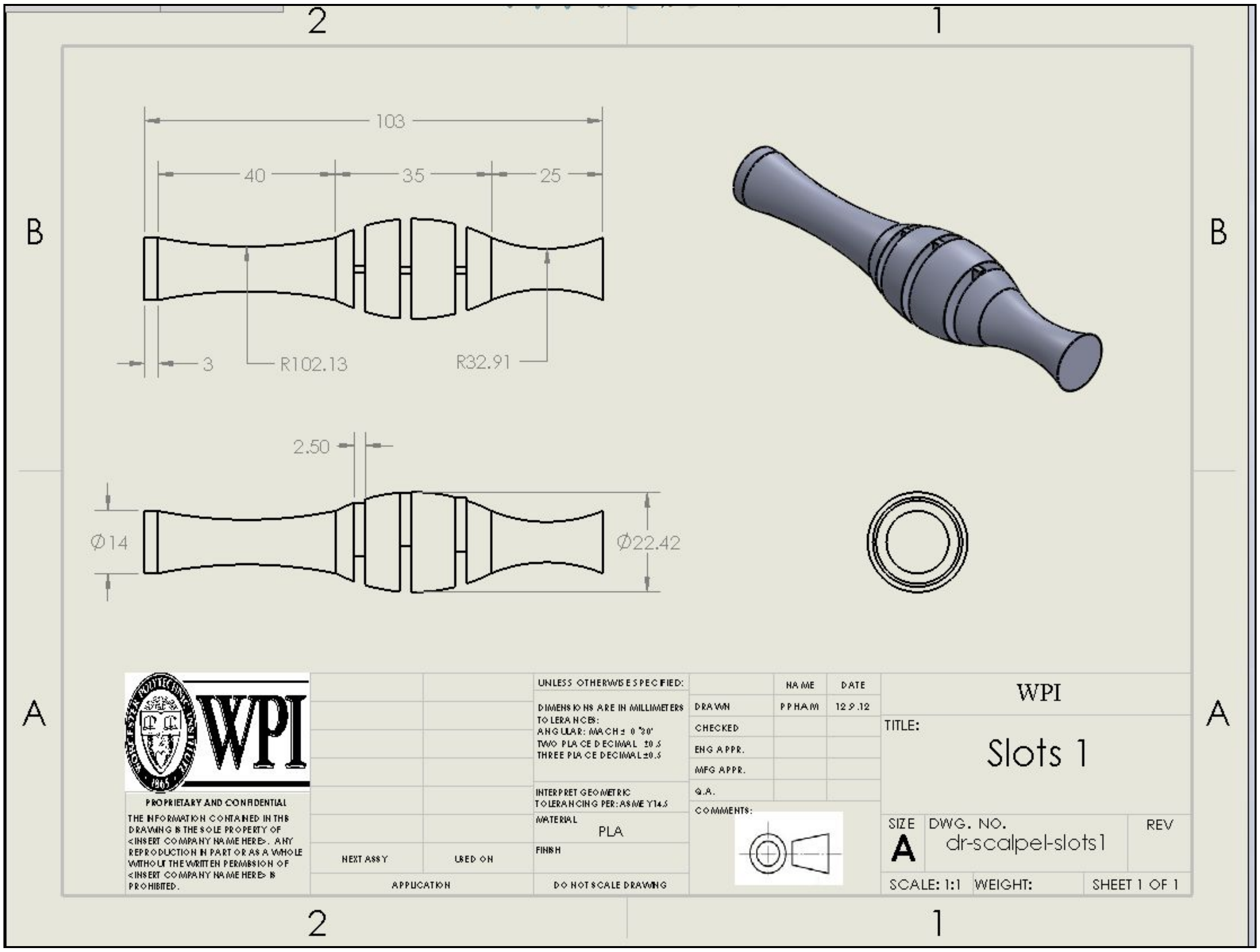
Appendix 1: CAD Drawings



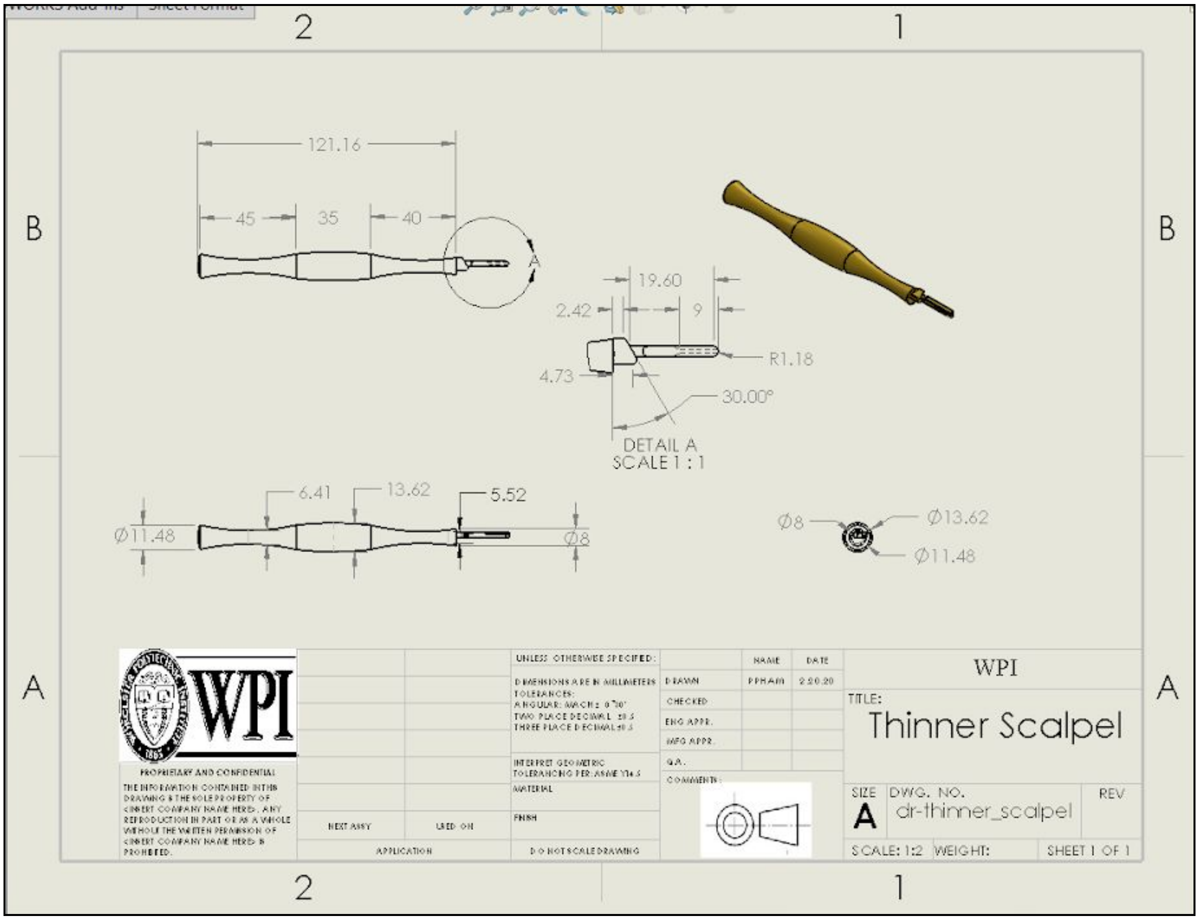
CAD drawing of the Slots 2 design iteration



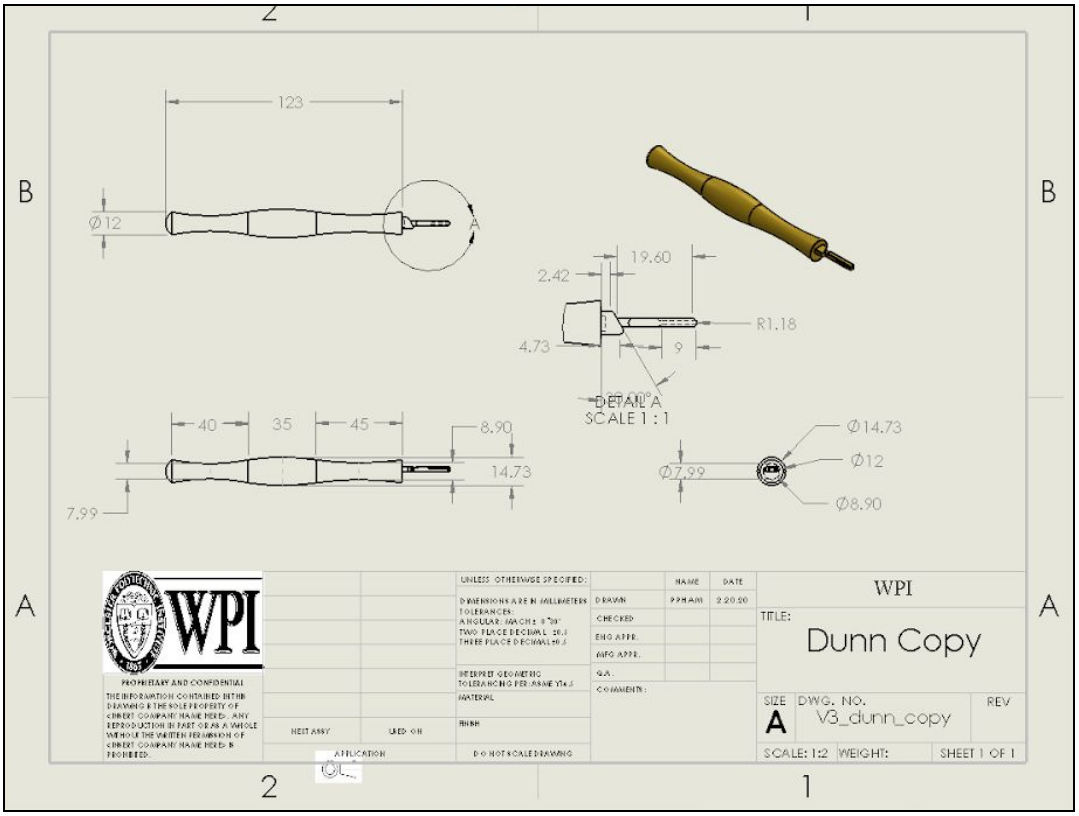
CAD drawing of the Hollow design iteration approved for first round of testing



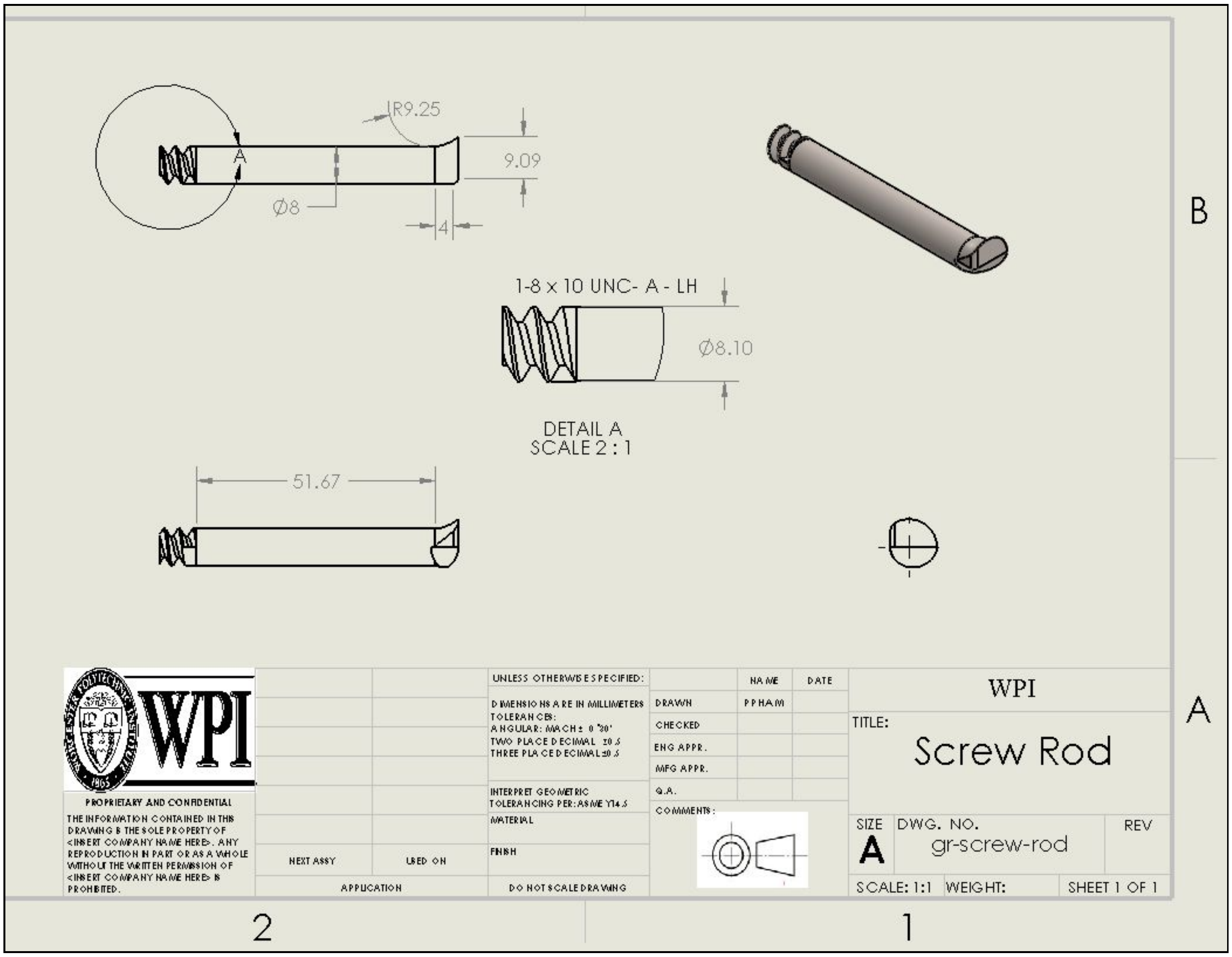
CAD drawing of the Slots 1 design iteration



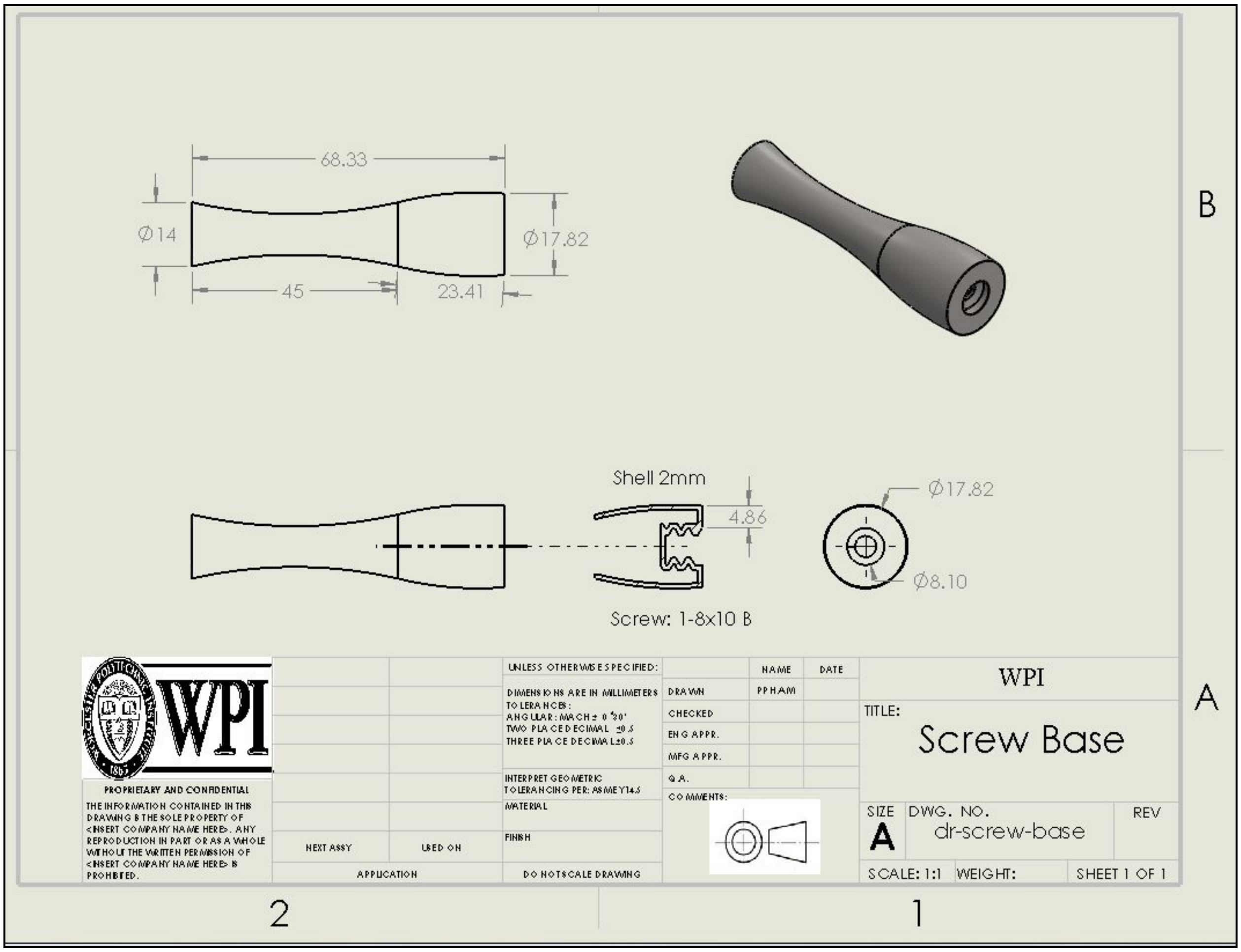
CAD drawing of the Thinner Scalpel design iteration for second round of testing



CAD drawing of the Dunn Copy design iteration for second round of testing

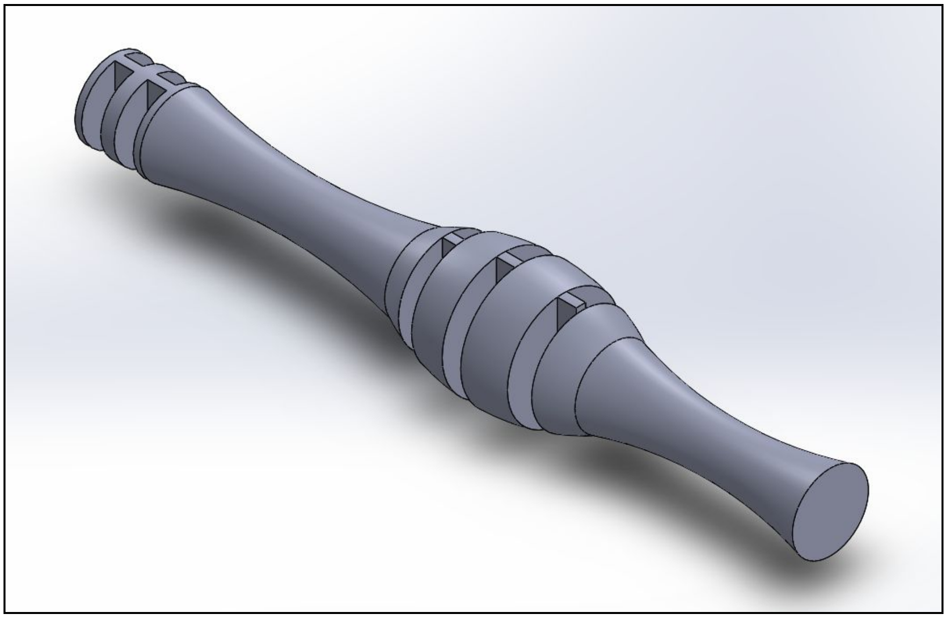


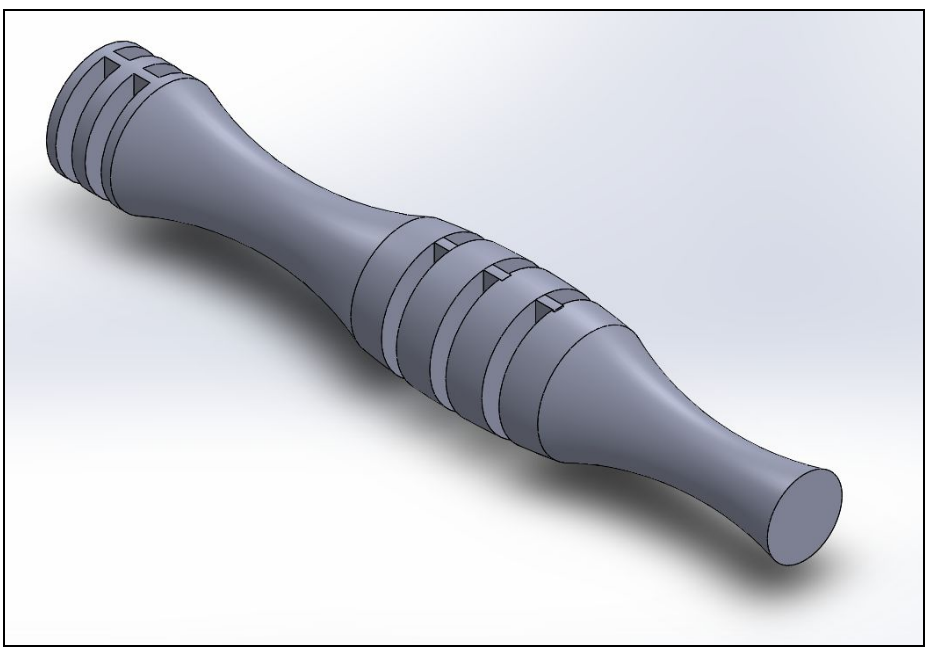
Drawing of Rod part of Screw model.

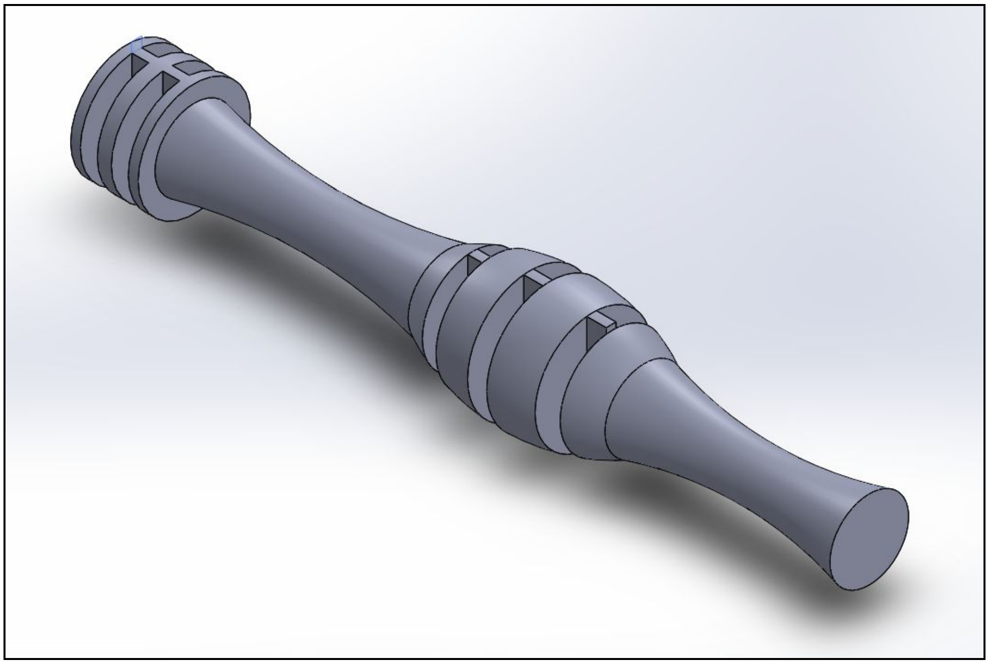


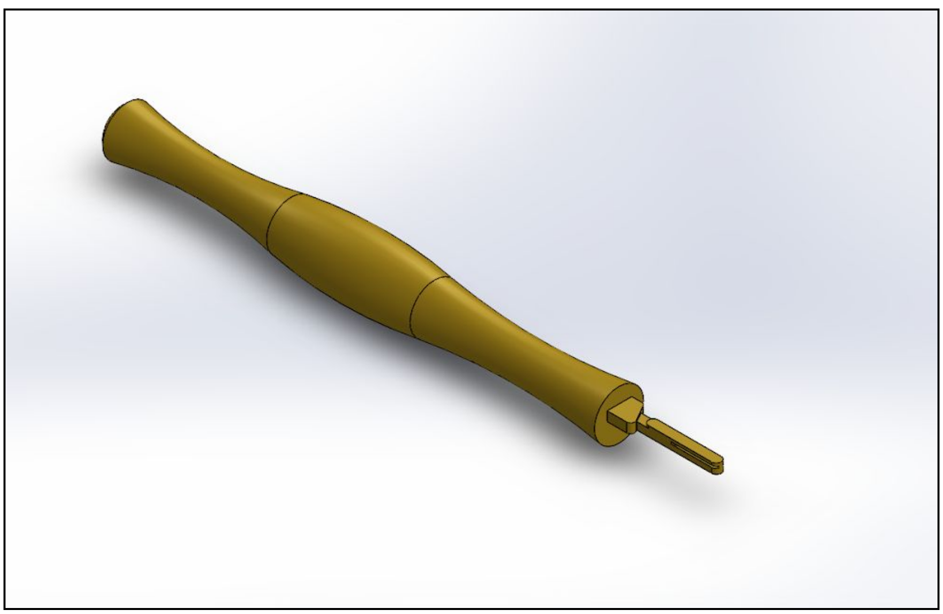
Drawing of Base part of the Screw model.

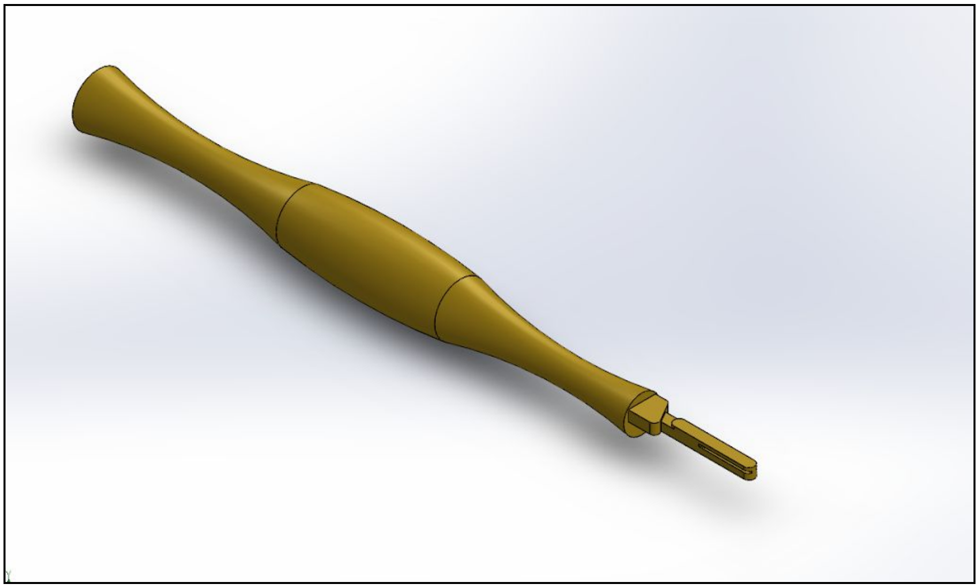
Appendix 2: CAD Sketches of Design Alternatives

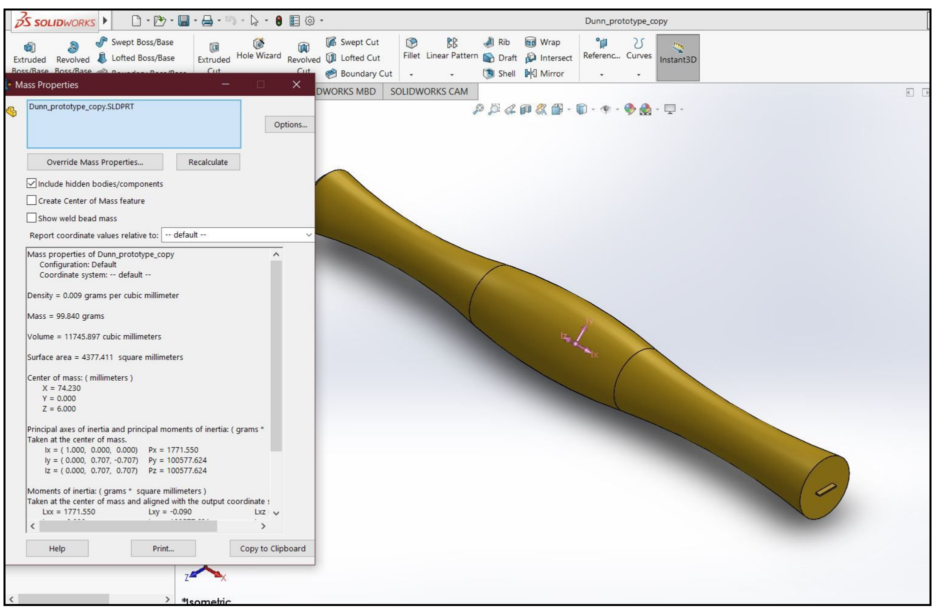


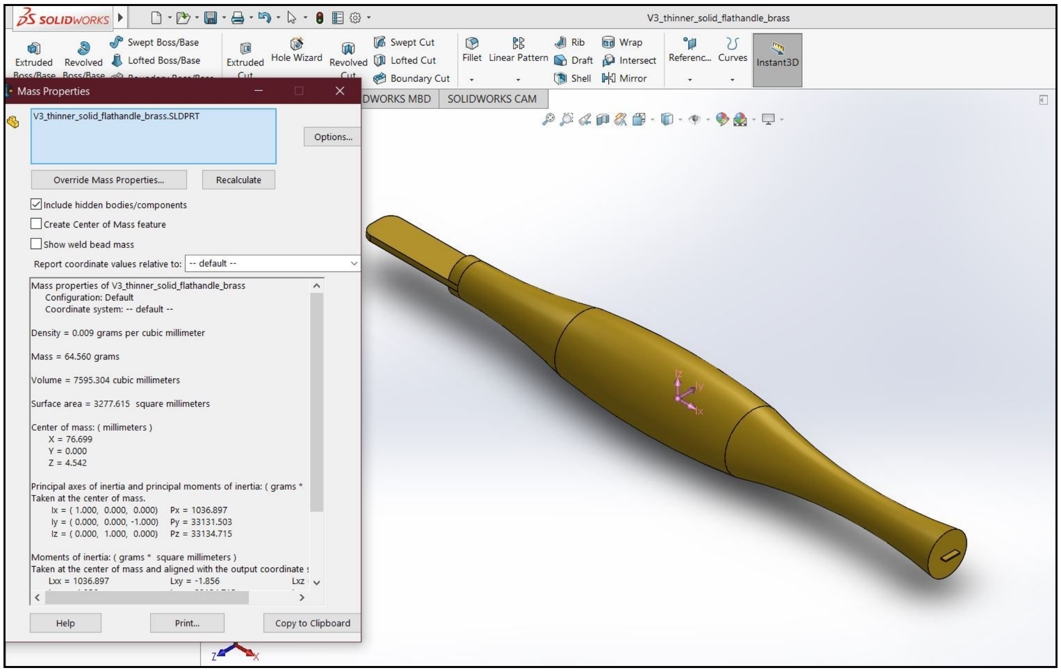


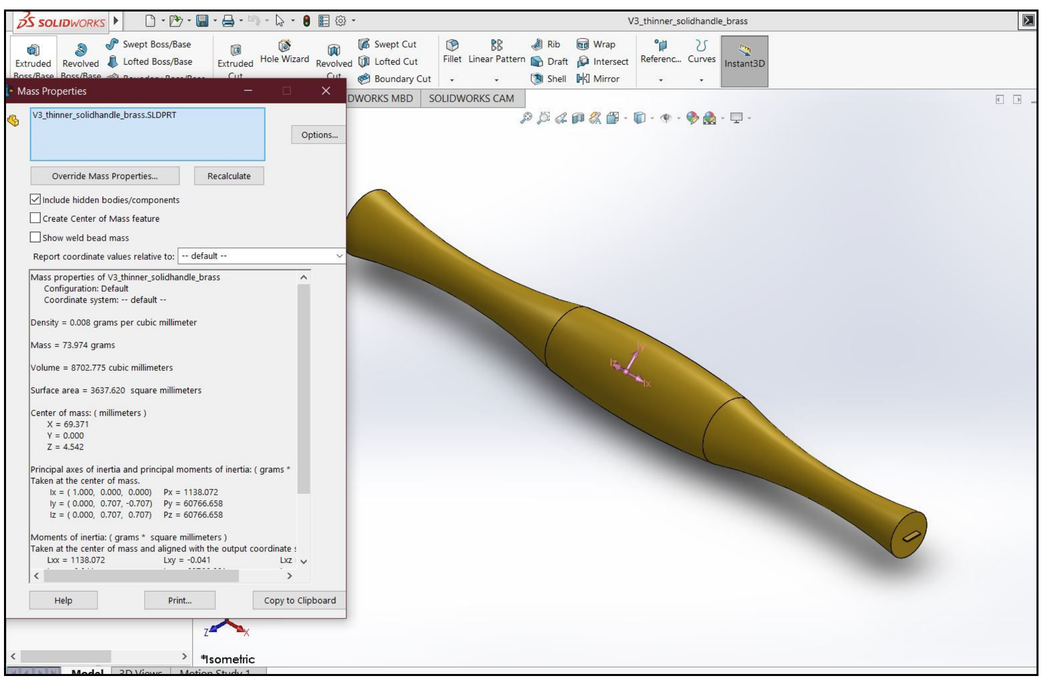




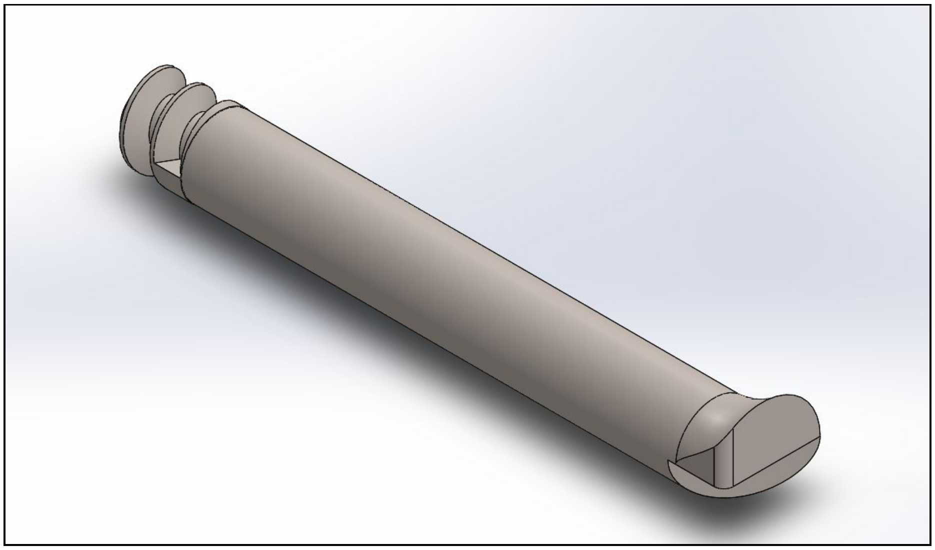



SOLIDWORKS
Dunn_prototype_copy
Extruded Boss/Base
Revolved Boss/Base
Swept Boss/Base
Lofted Boss/Base
Extruded Cut
Hole Wizard
Revolved Cut
Swept Cut
Lofted Cut
Boundary Cut
Fillet
Linear Pattern
Rib
Draft
Shell
Wrap
Intersect
Mirror
Referenc...
Curves
Instant3D
DWORKS MBD
SOLIDWORKS CAM
Mass Properties
Dunn_prototype_copy.SLDPRT
Options...
Override Mass Properties...
Recalculate
Include hidden bodies/components
Create Center of Mass feature
Show weld bead mass
Report coordinate values relative to:
-- default --
Mass properties of Dunn_prototype_copy
Configuration: Default
Coordinate system: -- default --
Density = 0.009 grams per cubic millimeter
Mass = 99.840 grams
Volume = 11745.897 cubic millimeters
Surface area = 4377.411 square millimeters
Center of mass: (millimeters)
X = 74.230
Y = 0.000
Z = 6.000
Principal axes of inertia and principal moments of inertia: (grams *
Taken at the center of mass.
Ix = (1.000, 0.000, 0.000) Px = 1771.550
Iy = (0.000, 0.707, -0.707) Py = 100577.624
Iz = (0.000, 0.707, 0.707) Pz = 100577.624
Moments of inertia: (grams * square millimeters)
Taken at the center of mass and aligned with the output coordinate
Lxx = 1771.550 Lxy = -0.090 Lxz
Help
Print...
Copy to Clipboard
*Isometric

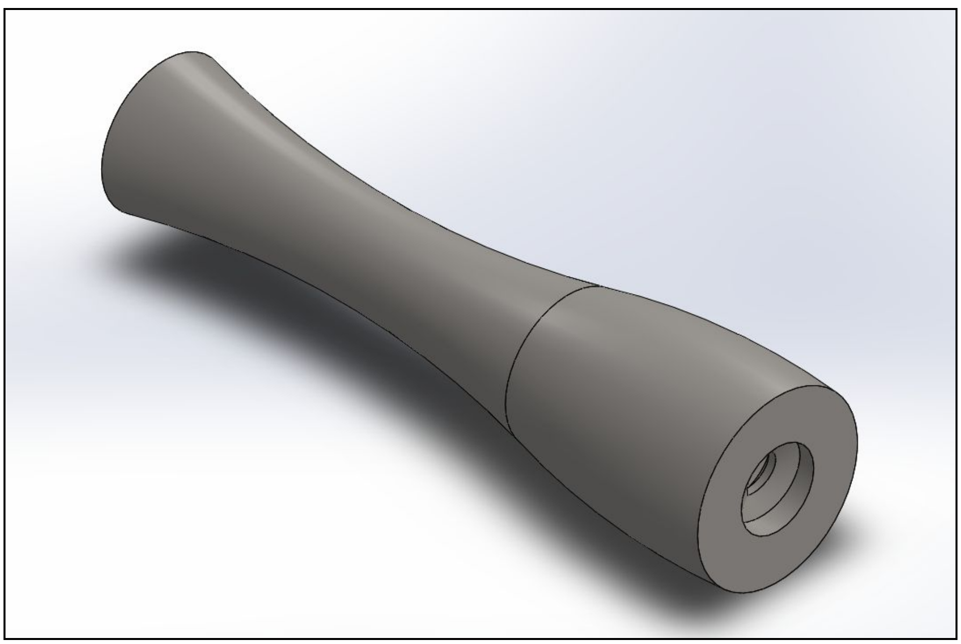

V3_thinner_solid_flathandle_brass
Mass Properties
V3_thinner_solid_flathandle_brass.SLDPRT
Options...
Override Mass Properties...
Recalculate
Include hidden bodies/components
Create Center of Mass feature
Show weld bead mass
Report coordinate values relative to: -- default --
Mass properties of V3_thinner_solid_flathandle_brass
Configuration: Default
Coordinate system: -- default --
Density = 0.009 grams per cubic millimeter
Mass = 64.560 grams
Volume = 7595.304 cubic millimeters
Surface area = 3277.615 square millimeters
Center of mass: (millimeters)
X = 76.699
Y = 0.000
Z = 4.542
Principal axes of inertia and principal moments of inertia: (grams *
Taken at the center of mass.
Ix = (1.000, 0.000, 0.000) Px = 1036.897
Iy = (0.000, 0.000, -1.000) Py = 33131.503
Iz = (0.000, 1.000, 0.000) Pz = 33134.715
Moments of inertia: (grams * square millimeters)
Taken at the center of mass and aligned with the output coordinate
Lxx = 1036.897 Lxy = -1.856
Help
Print...
Copy to Clipboard


V3_thinner_solidhandle_brass
Mass Properties
V3_thinner_solidhandle_brass.SLDPRT
Options...
Override Mass Properties...
Recalculate
Include hidden bodies/components
Create Center of Mass feature
Show weld bead mass
Report coordinate values relative to: -- default --
Mass properties of V3_thinner_solidhandle_brass
Configuration: Default
Coordinate system: -- default --
Density = 0.008 grams per cubic millimeter
Mass = 73.974 grams
Volume = 8702.775 cubic millimeters
Surface area = 3637.620 square millimeters
Center of mass: (millimeters)
X = 69.371
Y = 0.000
Z = 4.542
Principal axes of inertia and principal moments of inertia: (grams *
Taken at the center of mass.
Ix = (1.000, 0.000, 0.000) Px = 1138.072
Iy = (0.000, 0.707, -0.707) Py = 60766.658
Iz = (0.000, 0.707, 0.707) Pz = 60766.658
Moments of inertia: (grams * square millimeters)
Taken at the center of mass and aligned with the output coordinate
Lxx = 1138.072 Lxy = -0.041
Help
Print...
Copy to Clipboard
*Isometric

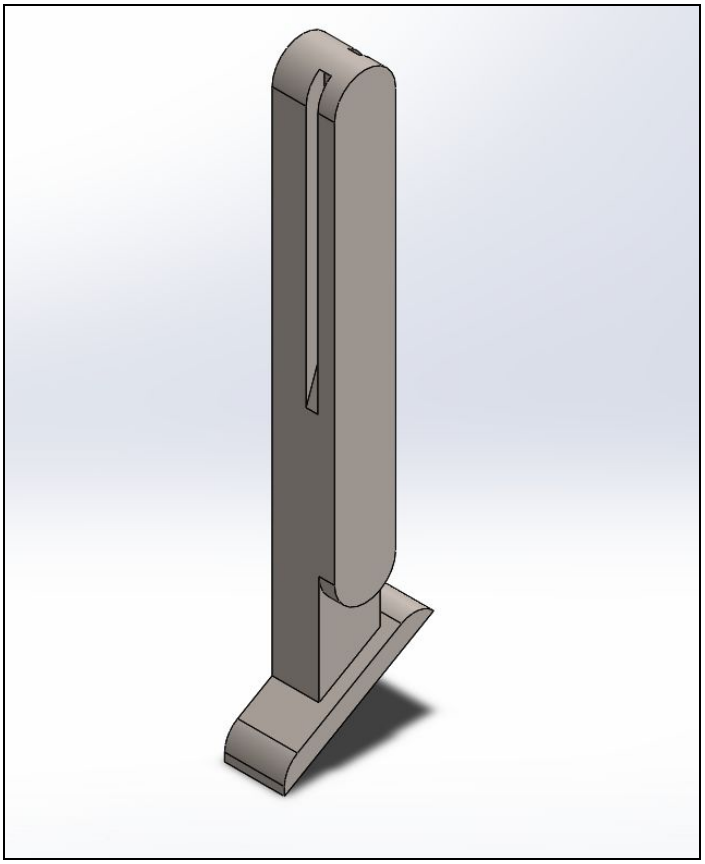
Appendix 3: CAD Sketches of Final Design Components



Rod part of the Screw model with a flare.



Base part of the Screw model.



Blade holder for Screw model.

Appendix 4: User Experience Test Consent Form

Scalpel Weight and Balance Consent Form
Worcester Polytechnic Institute
Biomedical Engineering Major Qualifying Project

<u>Description of Study</u>: This usability study will be done using 3D printed prototypes of potential scalpel handle designs. The prototypes have empty spaces to add in weight increments of 5 grams in various locations of the handle to help determine proper weight/balance distribution.

During this study you will not be identified in any way. The team will, however, take measurements of your hands and note your surgical specialty to be associated with your scalpel weight and size preferences. The session will be videotaped for internal use only.

<u>The study will include:</u>

- Measuring hand size of those who participate in the study
- Recording the surgical specialty of the participating surgeons
- Associating hand size and surgical specialty with scalpel weight and size preference

Please check here if you consent to the following:

Videos:

- o I consent to being videotaped during this study.
- o I consent to having the video clips viewed internally by the team members and sponsors to maximize study success.
- o I consent to my video clips being used publically for presentations of the user experience study.

Research Paper:

- o I consent to allowing the team to anonymously quote me in their research paper

By signing below, I confirm that I have read and understand the information listed above. I understand that my participation in this study is completely voluntary and I can decide not to continue at any time. I understand that the team will not use any videos or quotes from me unless I specified so by checking the boxes above.

Printed Name ______________________________

Signature _________________________________

Date _____________________________________

Appendix 5: User Experience Test 1 Moderator Guide

Moderator Guide for Weight-Balance Study #1

1. This study will be done to determine weight balance preferences for surgical scalpel handle designs. Feel free to take a break at any time. Your participation in the study is completely voluntary and should you become uncomfortable you are free to leave at any time. At this time could you look over the consent form and sign if you agree?
2. While we are completing the study we would like you to be as vocal as you can be with any thoughts of feelings you may have with the handle. As a neutral moderator I have no personal stake in the outcome of the study so please express both positive and negative impressions on the device.
3. Collect information:
    a. Size of hand - length from wrist to tip of middle finger - length of finger and palm - width of middle of the palm to thumb
    b. Surgical Specialty
    c. Male/Female
    d. How useful to you is the measurements on typical scalpel handles?
4. Before picking up the handle do you have any first impressions on the appearance of the handle?
5. Now pick it up, is there anything you immediately notice about the shape and how it fits in your hand?
6. What would you change and keep the same with the size and shape of the device?
7. Now that you have gotten a feel for the physical shape we would like you to experiment with weights in the device. We are looking to gain insight into what sort of weight distribution would be the most comfortable and easy to use in a scalpel. We have a number of weights and spacers for you to experiment with. I will show you some examples to demonstrate what I am talking about:
8. While you experiment with the testing platform on your own make sure to talk through your experience with both the tool and the testing method.

Ruler instead of measurement
Templates to cut
Change measurement on consent form
What sort of incision
Change to patterns instead of different options
Neoprene

Appendix 6: User Experience Data with Severity Ratings

Category	Comments made	1	2	3	4	5	6	7	8	Total	Severity Score
Design	Dunn's plastic scalpel is too light, but a good shape and grip	1		1				1	1	4	5
Design	The metal prototype is too heavy	1		1			1			3	5
Design	It is easier to guide the scalpel when the weight is heavier on the front or evenly distributed	1	1				1			3	5
Design	The plastic scalpel was best because it was a big size and easy to control, but is also light	1			1		1			3	5
Design	The rounded shape is easier to rotate at any angle - good plus!	1		1		1				3	4
Design	Our scalpels look thick and hefty - negative				1	1				2	4
Design	The entire body of the scalpel should be thinner					1			1	2	4
Design	The weight makes the scalpel easier to guide, and is good for larger incisions	1			1	1				3	3
Design	The grip on the blue plastic one was great		1		1					2	2
Design	The scalpels look ergonimic and aesthetically pleasing		1	1						2	2
Design	The metal scalpel had a good grip		1	1						2	2
Design	The black scalpels are a good middle ground for weight	1								1	1
Design	The regular blade black scalpel seems to have a better cutting angle than the plastic one		1							1	1
Design	The metal ergonomic scalpel was the best		1							1	1
Design	The grip should be extended farther up the scalpel		1							1	1
Design	The black scalpels had the best weights			1						1	1
Design	The flat surface of the metal scalpel grip was best			1						1	1
Design	Does not like the grey plastic scalpel					1				1	1
Design	No. 10 black scalpel feels heavy								1	1	1
Design	No. 11 black scalpel has a good weight								1	1	1
Usage	Rolling handles is a big concern						1			1	5
Usage	Need a flat back so you can clear an airway							1		1	4
Usage	I am the most familiar and comfortable with the original flat scalpel	1	1	1	1	1	1	1	1	8	2
Usage	Does not use the ruler on the scalpel handles	1							1	2	2
Usage	Uses the measuring tool on the scalpel							1		1	2
Usage	The black pointed blade scalpel felt unstable		1							1	1

Appendix 7: User Experience Test 2 Feedback Part 1

Test 2 Scalpel Prototype Feedback Part 1

You only need to fill this sheet out once.

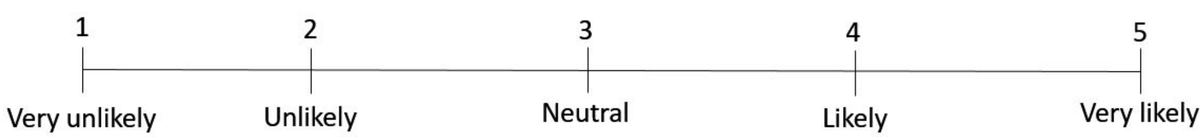
1. Please rank all of the scalpel prototypes here, with 1 being your favorite and 3 being your least favorite:

    1. _______________

    2. _______________

    3. _______________

2. How likely are you to recommend your two favorite designs to a coworker?



Appendix 8: User Experience Test 2 Feedback Part 2

Test 2 Scalpel Prototype Feedback Part 2

Please fill this sheet out for each of the prototypes you used today.

1. Please rank the overall balance of this scalpe design.

1	2	3	4	5
Very bad	Bad	Neutral	Good	Very good

2. Please rank the ease of use of this scalpel design.

1	2	3	4	5
Very difficult	Difficult	Neutral	Easy	Very easy