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Design of Improved Surgical Scalpel Handles with Optimized Grips

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Abstract

The scalpel is one of the most commonly used tools in surgical applications. Current designs of scalpel handles are not ideal for hand ergonomics and can lead to difficulties for certain cutting motions or slipping of the instrument. A new design was created by a previous research team alongside Dr. Raymond Dunn at UMass Medical School, to improve the shape of the handle as well as incorporating a rubber material grip portion. The goal of this project is to address the need to limit slipping while taking into consideration comfort and mobility of the instrument. The addition of a texture pattern and choice of material was utilized to increase the friction between the surgical glove and the grip portion of the tool. Testing protocols were created to determine which surface textures provided the highest coefficient of friction, as well as determining which prototypes were comparable to the precision of the original scalpel design. Feedback based on Dr. Dunn's professional experience in the field and personal preference also aided in determining which grips were recommended for manufacturing.

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Chapter 1: Introduction

1.1 Background:

The Current State of the Art

Scalpels are essential instruments in surgery. Scalpels are manufactured to be reusable or disposable. Reusable scalpels come in two parts as a handle and blade that will be sterilized and configured before surgery, whereas disposable come in individual packaging already pre-assembled and pre-sterilized. The most common scalpel handle used in surgery is the number 3 handle [1]. Figure 1.1 shows a sample of varying handle sizes and designs.

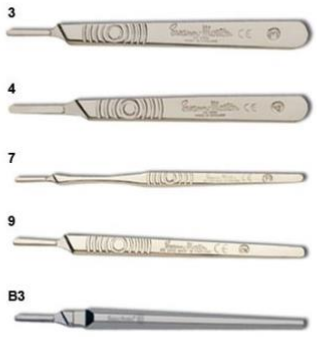

Figure 1.1: Scalpel Handle Types [2]

Reusable scalpel handles come in different sizes depending on the type of surgery and cutting techniques being performed. For example, handle number 3 is used for a wide range of cuts whereas number 7 is used more in plastic surgery because it is smaller and allows for a more precise and deeper cut [3]. These handles are made of stainless steel alloys, and can be steam sterilized for repeated use [4]. On the other hand, disposable scalpels are made of sterilizable plastics, and come in the shape of a No. 3 handle. These are typically inexpensive and are ordered in bulk for surgical use. Reusable scalpels generally cost between 10 to 17 dollars, while disposable versions typically cost between 1.50 to 3.20 dollars each.

Scalpels in particular can be hazardous in the operating room, with scalpel wounds occurring in up to 15% of operations, which expose members of the operating room to patients' blood in 6–50% of those cases [6]. Moreover on the topic of safety, scalpels do not exhibit satisfactory slip resistance depending on the bodily fluid that comes in contact with them, which can cause the surgeon to experience a negative effect on their haptic feedback with the instrument [7]. In other words, surgeons may lose their grasp on the instrument. This results in decreased precision, comfort, and efficiency [7]. Therefore, there is a need for a new scalpel design that permits the surgeon to increase efficiency in the operating room, and more confidence in their grasp of the instruments under circumstances that involve each type of bodily fluid.

The current scalpels used in surgeries become problematic when rotational wrist movements are required. Surgeries that require this type of motion for scalpels in particular are skin growths, where the surgeon has to make two symmetrical, hemispheric cuts around the

growth. Another includes surgeries to treat hand lesions, which requires the surgeon to make elliptical incisions on the patient's hand [7]. Both of these surgeries are done quite commonly, but can be difficult to administer with current scalpel designs.

Significance of the Project

While technology has increased significantly in the field of medicine, the design for scalpel handles has not had any significant changes since its patent in 1914. With the current designs, aspects of surgery like safety for both the surgeon and the patient, precision, and handling are impacted due to the limited range of motion and grip. This forces surgeons to continue working on delicate procedures even if the grip is uncomfortable.

It has been established that there is a need for design upgrades of these instruments. Dr. Raymond Dunn who is the Chief of Plastic Surgery at UMass Medical, has prototyped an upgraded scalpel in an attempt to correct instrument-hand ergonomics. However, even with his new design, there are still aspects of the design that can be improved upon. While the shape of the instrument is much improved for ergonomics, increasing the grip-ability on the instrument can limit safety or precision problems. In addition, considering material options for cost and manufacturability can improve the likelihood of surgeons making the switch to uncomfortable handled instruments, to more ergonomic tools.

The Goal of a New Design and The Scope

A new design of the scalpel handle should be able to comfortably be used in rotational motions made by the surgeon for all general surgery. It must incorporate the use of materials and dimensions that optimize the grip of the surgeon, decreasing the tendency for the instruments to slip when bodily fluid comes into contact with them. The design should feel natural to surgeons after sufficient practice and in no way impede their work.

This project concerns all types of surgeons with different competences, students in training, and patients who may benefit from minimal scarring if surgeries can be done more precisely. It also concerns manufacturers. It is necessary to convince manufacturers to create the designs and alter the way they have been producing scalpels for the last century, meaning a goal of the design is to have it be comparable to the current state of the art in terms of cost, but far exceed the current state of the art in terms of ergonomics, safety,

The goal is to design improved scalpel grips with materials for reusable and disposable applications that demonstrate increased slip resistance, efficient manufacturability, improved ergonomics, and optimal haptic feedback and tactile sensation during procedures that require rotational motion.

General Project Approach

The project strategy breaks down into a technical design requirements section created to form the solution to the problem presented by the client statement, engineering and industry standards that must be met, a revised client statement, and the team's management approach over the duration of the MQP. The general project approach is designed to achieve an ergonomic solution for a redesigned scalpel that has favorable haptic feedback due to its shape, mechanical, and material properties. The project will be completed by following milestones and objectives discussed in more depth in Chapter 3. The design process will explain the specific need for the redesign of the scalpel, display the conceptual design, the alternative design choices, and

feasibility testing. The objectives, constraints, functions, and specifications of the prototype designs are discussed and conceptualized in this section.

Technical background necessary to understand the approach:

To understand the approach of the project, there are certain technical elements of this project that should be addressed and understood. Knowledge of Solidworks, computer aided design, and different means of additive manufacturing are all necessary technical background in creating designs and prototypes. Properties of materials such as hydrophilicity, slip resistance, coefficients of friction, working temperature ranges, cost of materials, sterilizability, and manufacturability must be researched as well. These are addressed in Chapter 3.2.4 Design Specifications.

Chapter 2: Literature Review

2.1 Haptics and Tactile Sensation

Haptic feedback vs tactile sensation

Haptic feedback relates the sense of touch to the interactions with the world around us. Humans perceive haptics through two types of receptors: cutaneous and kinesthetic receptors [9]. Cutaneous receptors are found in the skin, and are responsible for tactile sensations such as touch, pain, temperature, vibrations and more [10]. Kinesthetic reception comes more specifically from muscle spindle receptors, which control limb position and movement during movements [11]. This is an important sensory channel because it combines touch to learning of motor skills and hand-eye coordination. In this project, altering the shape and surface of the surgical tool will affect the haptic feedback the surgeon is experiencing, and can affect the comfort and performance of the user.

Haptics in the operating room

Through research of haptic sensation in the operating room, correlations have been drawn between haptic feedback of using instruments and improved motor skills using those tools. This idea of haptics helping motor memory and trajectories is called “haptic guidance”[12]. Simulations using real world haptic setups allow training surgeons to gain a better understanding of how surgical procedures feel in relation with the patient, tool, and in their own hand, which can then be applied in the operating room. The tactile and force sensation from different tissues in the body can help guide the surgeon and also provide information on the orientation and location of the tools they are using.

2.2 Previous MQP Works

Reusable scalpels and disposable scalpels are types of scalpels that were requested to be redesigned by our sponsor. In both cases, it is important that these surgical instruments provide superior comfort and allow surgeons to make safe and calculated incisions with the blade. These types of scalpels will have common criteria that must be met, however, they also have criteria weighted by importance. Evaluated criteria includes durability, cost, comfort, and biocompatibility.

2010 MQP: Improving the Ergonomic Design of Scalpel Handles

At Worcester Polytechnic Institute, previous MQP teams have worked on the ergonomic redesign of scalpel handles in the past decade. In 2010, an MQP group began with Dr. Raymond Dunn about designing new scalpel handle designs that improve ergonomics for surgeons. This group found that the "Golden Section Ratio" has an evident relationship with forces distributed by the scalpel on the hand. Another conclusion the group had was that there would need to be multiple sizes of scalpel handles since many surgeons have different sized hands, and one handle does not fit all sizes. In the field of material selection, the team had decided that metals would be favorable as potential manufacturable materials for reusable instruments, while disposable instruments could be made using plastic materials [13].

2014 MQP: The Commercialization of an Ergonomic Scalpel

A group followed the progress made by the MQP in 2010 with a project centering around the commercialization of their ergonomic scalpel handles. The group determined that reusable instruments are more popular in surgeries as they decrease the overall cost and waste involved than disposable instrument options. Both types of devices are still used, having different strengths and weaknesses depending on the task. The team discovered that approximately 75% of handles used are reusable and 25% of handles used are disposable. Reusable tools are useful in most scenarios as the blade is interchangeable. The handles are sterilized after each use and are typically preferred in surgical settings over disposable handles. Disposable handles are preferable in scenarios where surgeons need to make precise incisions without the risk of having a dulling blade. Disposable handles are also useful when training students that have no need for their own scalpel handles. Because of the reusability of detachable handles and reasonable costs, reusable scalpel handles are more equitable in most hospitals. However, there are constraints based on repeated sterilization and safety that disposable scalpels are not a concern for one-time-use scalpel handles [14].

The students of this project considered a scalpel handle prototype that would be translated into both disposable and reusable models, however, reusable models were later not considered feasible due to the lack of market opportunity for the product. The team evaluated their model based on effectiveness, cost efficiency, and manufacturability. The team determined that Acrylonitrile Butadiene Styrene (ABS) molds for their model would cost approximately $35,000. Disposable materials would be approximately $3.00 per pound of Polycarbonate handle and an elastomer priced at approximately $6.00. Reusable scalpels were more difficult to consider because there was no market for the item since the market for reusable scalpels are fixed to the currently used scalpels [14].

2.3 Limitations/Opposing Viewpoints

Historic Use and Manufacturing

The earliest versions of scalpels could be dated back to ancient Greek times [15]. Scalpels continue to be essential tools used for cutting and slicing through layers of the body in surgery. For the past 100 years, the modern scalpel has been used in surgical and medical applications. Current reusable scalpels are made with stainless steel as a base material for handles. This design of the scalpel handle has been relatively the same, since the Bard-Parker

Company created the first version of a reusable model [16]. The most common design of the modern surgical scalpel handle is a thin rectangular slab of stainless steel with an attachment end that can connect to a number of different blade sizes. Blades could then be disposed of without having to dispose of the handle as a detachable piece. This design has remained popular because it is easily manufacturable, is effective, and has been effective for the past 100 years [16]. One of the largest challenges for a competitor to the common scalpel is that surgeons are used to using current scalpels to complete the surgeries. Since the design is relatively comfortable, it may be difficult for surgeons to consider a new design of a commonly used instrument at the operating room.

Muscle Memory

Any individual who frequently takes part in activities that involve certain motor skills, such as typing on a computer, playing an instrument, or riding a bicycle, develops the muscle memory to make that activity almost automatic in order to more skillfully and intrinsically perform that action. Surgeons also acquire muscle memory when completing surgical procedures, which leads to more efficient, natural, and reliable performance during surgical procedures.

With scalpels not having changed in the last century, surgeons have reliably developed the necessary muscle memory to complete their procedures using scalpels that currently exist. Just like one may have a period of adjusting their typing and where their fingers lay on the keyboard when they receive a new laptop, there is a period of adjustment when a surgeon is given a new instrument to perform their procedures with. In the latter case, however, others are affected by this adjustment period -- not just the user. Surgeons may not want to risk their ability to perform a medical procedure on a patient using a new scalpel especially when they are reliably able to trust their muscle memory with current, existing scalpels to do the procedure, even if the newer design is more ergonomic and efficient to use. Often, the evaluation as to whether newly innovated surgical methods or instruments should be introduced to the operating room is between the inclination to increase ergonomics, preciseness, and efficiency, and the apprehension to potentially risk the patient's experience by using these novel instruments or methods [17].

One way to try to address this concern is to "assess the amount of time needed for learning a new method, and if learning that method will be time-saving" [17]. This will allow the surgeon to logistically estimate how long it may take them to adjust to this new instrument and understand how the adjustment period will make their surgeries more efficient and precise in the future. By having select surgeons test the different instrument prototypes, they may be able to estimate how long it took them to completely adjust to the new device. Having a clear notion of how long it will take them to adjust to using the new device could help clients gain interest in purchasing a new instrument.

2.4 Material Options

2.4.1 Reusable Materials

Stainless Steel

Stainless steels are typically alloy composed of Iron, Nickel, Chromium, and other metals. These elements are melted together and homogenized. Manufacturing of the material is rather simple as this alloy could then be poured into a mold and cooled until solid [18]. More

recent manufacturing endeavors include additive manufacturing options as new 3D printing methods emerge for powdered metals including 316 and 316L stainless steels (Comparison of Hardness of Surface 316L Stainless Steel Made by Additive Technology and Cold Rolling).

Commonly used stainless steels for instruments used in the medical industry are typically either 316, 316L (low carbon), or other 300 series stainless steels. Medical grade stainless steels are stainless steels that have sterilization capabilities and are not subject to corrosion in most environments. As these stainless steels are already used to make reusable scalpel handles, it is a heavily considered material for a reusable handle base. Stainless steel can be priced as low as $1.00 per pound [19].

Stainless steel is also a material that can be overmolded onto. This would mean that a stainless-steel handle would be able to have a polymer-based grip molded on top of the surface of it. This process would be done by extruding a plastic solution around the handle base and letting the material cool and set. This method is compatible with thermoplastic elastomers and rubbers [20].

Thermoplastic Elastomers

Polymers are typically characterized by how they are processed. Thermoplastics are melt-processable materials that transition from a solid to a liquid state when the temperature reaches a specific point. Thermoplastics are able to be repetitively melted and cooled allowing them to be re-processed and recycled. Thermoplastics are commonly hard and crystalline, although softer surface options are available. Common thermoplastics include polyethylene, nylon, and PVC. Thermoset materials are chemically cured during manufacturing (vulcanization), causing permanent crosslinks to form between polymer chains. Thermoset materials cannot be re-melted once they are cured. Thermosets are typically soft and flexible materials. Common thermoset materials include rubbers, silicone, and epoxies [21].

Thermoplastic elastomers (TPEs) are a class of polymers that combine properties of thermoplastics and thermoset materials. TPEs can be made to be soft, flexible, and dimensionally stable like thermoset materials but have the ability to be melt-processed and re-processed continually.

TPEs flexible behavior is due to the physical structure of their composed molecules. Unlike thermoset materials, TPEs do not form chemical crosslinks between polymers, hence allowing them to be melted repeatedly. TPEs contain both crystalline and amorphous structures. This is achieved either through the composition of block copolymers containing both crystalline and amorphous domains, or through a composition of mechanically blended semi-crystalline and amorphous polymers [22].

Ease of manufacturing is the primary advantage of TPEs over thermoset materials. Both material classes are typically flexible and elastic and come in colorable and sterilizable grades. TPE however, has a shorter cycle time for injection molding manufacturing than most thermoset materials. Silicones and neoprene can take minutes to hours to manufacture since curing time must be allowed. The cycle time for TPEs takes seconds [23]. Another advantage of TPEs is the ease of modification. Copolymer blocks and polymer blends can be modified through the addition of sidechains Copolymer block domains can be altered in length and ratio [24]. Material weight can be fine-tuned through the use of fillers.

Silicone

In one study done on the effect of stainless steel and silicone on hand comfort and strength, it was found that silicone is less strenuous on the hand and reduces hand fatigue. The study also found that lighter instruments with a larger diameter that have a silicone grip have the ability to reduce force and load on the hand. Silicone also can withstand sterilization and it is easily manufacturable to have different textures since it can be manufactured as a liquid and molding resin. It does not absorb water, and it feels like natural rubber. It also has good colorability [25].

Pearson Dental, a dental tool company sells silicone grips that can be manually added to already existing dental tools to increase slip resistance. These can be made in a variety of colors as shown in Figure 2.1, and they are about $0.53 each.

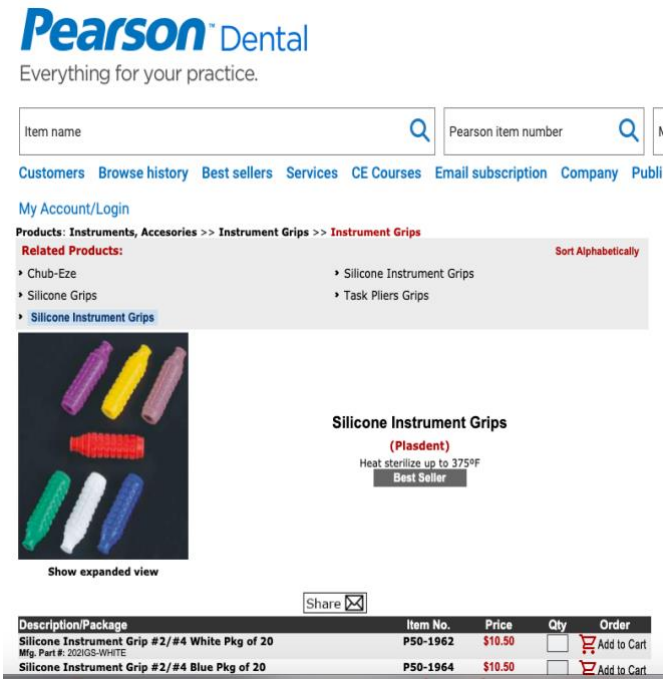

Figure 2.1: Silicone Grips for Dental Instruments [26]

Neoprene

Neoprene is a polychloroprene, which is a synthetic rubber. It has a range of properties, which can be modified via copolymerization with sulfur and blending the polychloroprene with other polymers [27]. Polychloroprenes have great chemical stability, resistance to water oils, gasoline, and UV light. Neoprene has outstanding chemical resistance, colorability, and it is able to operate in temperatures as high as 175 C [27]. Steam sterilization does not exceed 132 C, making this a material that can withstand the difficult environments that the operating room requires it to be resistant to [27]. Depending on the degree of hardness that the client or user wants, neoprene can be purchased with varying durometers, which measure the hardness of a material, shown in the figure below. When wet, rubbers have an admirably high coefficient of friction, demonstrating that they increase slip resistance when added to a product. Concerns of neoprene is that the durability of the material after repeated sterilization is unknown. It also is not as easily manufacturable as other materials like TPEs, and is requires an adhesive to bond to stainless steel.

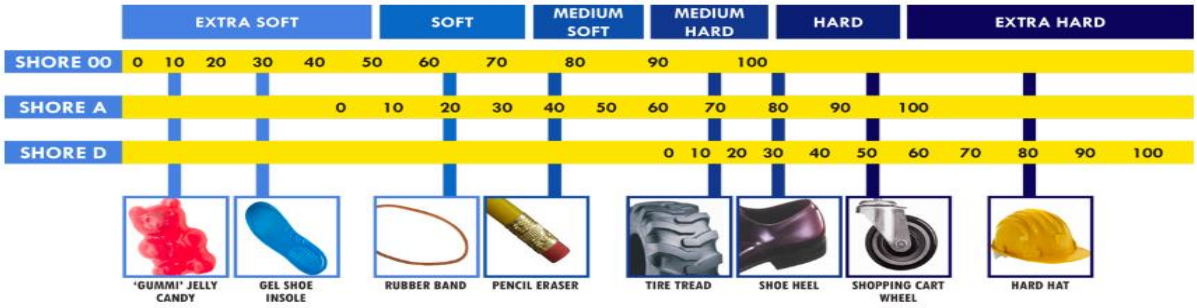

Figure 2.2: Hardness Scale in Shore 00, A, and D [28]

Acetal (Delrin)

Acetal or polyoxymethylene, which is more commonly known as Delrin, is a hard plastic that is known for its high strength, low friction, and incredible wear properties when it is in wet and dry conditions. It is very easily manufacturable, and it often is used as a metal replacement in dental applications [29, 30]. There are several different types. Homopolymer acetal has better temperature resistance, stiffness, and toughness, while copolymer acetal works well in high heat and hot water conditions, as well as having less porosity than homopolymer acetal. Acetal is FDA compliant, easily colorable, and resistant to many fuels. It has a higher coefficient of friction than stainless steel, but not much higher than that of stainless steel. The coefficient of friction of acetal, however, could be increased by texturizing its surface [30]. It is more expensive than hard plastics such as polypropylene.

2.4.2 Disposable Materials

Polypropylene

Polypropylene (PP) is a low-cost plastic that is commonly used in the medical field. PP comes in three material options such as a homopolymer, copolymer and carbon reinforced PP [31]. These different variations lead to different properties ranging from a rigid plastic to softer, more malleable materials. PP is often chosen for its cost, performance characteristics, and manufacturability. It is also used in many medical devices due to its good chemical resistance, high toughness, and ability to be sterilized [31]. Some examples of medical grade PP products are disposable syringes, vials, non absorbable sutures, and medical pouches. PP copolymers have a high degree of toughness, with an Izod impact toughness of 12.5 ft-lbs/in, making them very durable.

Like all medical devices it is very important to ensure all equipment is safe to use in surgery and will not cause harm to the patient. Testing performed from ISO 10993-1 standards, such as cytotoxicity, hemocompatibility, cancerogenity, etc. shows that PP can be used in short term to medium term contact with the body without causing harm to the patient [32]. In addition, this material can also be sterilized to ensure safety for patients, and minimize risk of infections or foreign contamination. While PP has a decent temperature resistance, meaning it can be autoclaved, however multiple autoclave cycles can degrade the plastic, which highlights the draw to use this as a single use plastic [32]. EtO has been used previously for sterilization of PP, however testing has shown that may cause a buildup of toxic residue, and this method of sterilization is no longer used [33]. This has led to gamma radiation sterilization being the most common method for PP [33].

Another draw towards PP as a disposable plastic for medical devices is that it is easily manufactured for low costs. The manufacturing options for PP include injection molding, extrusion, compression molding, with many more options available [32]. PP can be made to be clear plastic or dyed varying colors.

2.5 Manufacturing

2.5.1 Types of Manufacturing

Stainless Steel Manufacturing

Stainless steels are made with varying properties depending on the content of iron, chromium, silicon, nickel, carbon, nitrogen, and manganese. The process of manufacturing stainless steel products involves a number of steps [34].

The first step in steel manufacturing is melting the raw materials together in a large furnace. High heat is applied for 8-12 hours. Once melted, the molten steel is cast into simple molds. The molded steel is then shaped into more finalized forms. The steel may be heat rolled or shaped into rods and bars. The steel is then heat treated where it undergoes an annealing process. The steel is heated and cooled repeatedly under controlled conditions. This process alters the physical and chemical properties of the stainless steel to improve the desired material properties. During annealing a buildup from surface oxidation forms, requiring the stainless steel to be descaled. Pickling and electrocleaning are common methods of descaling annealed stainless steel. Finally, the steel is cut into its final shape using specific blades. A surface finish is added to give the steel an aesthetic surface appearance and to help fine-tune the surface properties of the material [35].

Injection Molding

Injection molding is a very simple technique that is one of the most common methods for manufacturing plastic. The basis of injection molding is broken down into three parts: filling, packing and cooling [36]. First the material is heated until it is liquid, and injected into a mold of the part required. Packing the mold is initiated when the pressure is increased, and more material is pushed through the developing part to ensure that the mold is filled completely [36]. Then once all the molten plastic is pushed through the mold, the mold cavity is cooled to ensure the material is properly solidified, and the part is ejected. The figure below shows the machine process of injection molding.

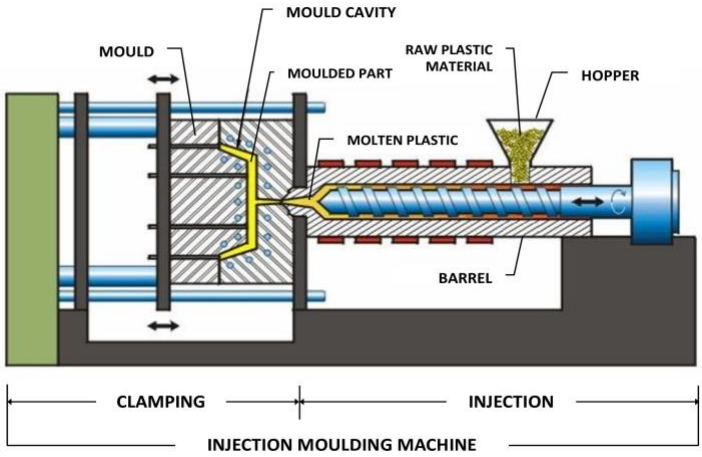

Figure 2.3: Injection Molding Process [37]

Rubber Manufacturing

There are multiple ways to manufacture rubber, the most common being extrusion, latex dipping, and different forms of molding [38]. Extrusion molding is similar to injection molding. The process begins with unvulcanized rubber being pushed through an extruder into a dye. Once the dye is filled, the extruded product needs to be vulcanized before being usable. It is critical that the rubber be vulcanized because the chemical process of vulcanizing is what allows rubber to return to its original shape after stress is applied [39].

Latex dipping is advantageous for products that require thinner walls of rubber, and have more complex shapes compared to those made by extrusion molding [38]. In this process a thin walled mold is dipped into the unvulcanized latex and slowly removed. Then, the product is cooled in the mold, vulcanized and removed to start the cycle again. Depending on the manufacturer's needs, latex dipping can be repeated to increase wall thickness before vulcanization.

Another way to shape and produce rubber is through various means of molding. Compression molding begins with a chunk of rubber, also known as a blank. Once placed in the mold cavity, it is compressed to take the shape of the mold, and is heated to ensure that blank fills the mold completely. While this method is the cheapest of the molding methods, the heating process of the blanks can be very slow, making curing time last longer than other processes, and slows down production [38]. To address the limitations of compression molding, transfer molding loads blanks into a chamber, preheats them, and then compresses them into several mold cavities. This preheating step speeds up the process, and allows the product to be made at a faster pace. The limitation to this step however is that the molds are more expensive than compression molds because of the multi cavity addition [38].

The third most common way to manufacture rubber is through injection molding. This process is similar to the section described above. Injection molding is advantageous because there is no need to produce blanks, easily automated for quick production, and is able to fill the molds more accurately [38].

2.5.2 Material Adhesion

Over Molding

Over molding is a process of adding a different material over a pre-made part of an object. For example, molding a rubber grip over a metal handle. The molds for this type of manufacturing are specifically made to hold the first material. Once the mold is locked around the object, in this example a metal handle, injection molding can be done. These special molds ensure the molten plastic or rubber surrounds the first material, and is shaped to the specific size, pattern, or texture that is required. Figure 2.4 shows this process with a two-step polymer injection overmolding.

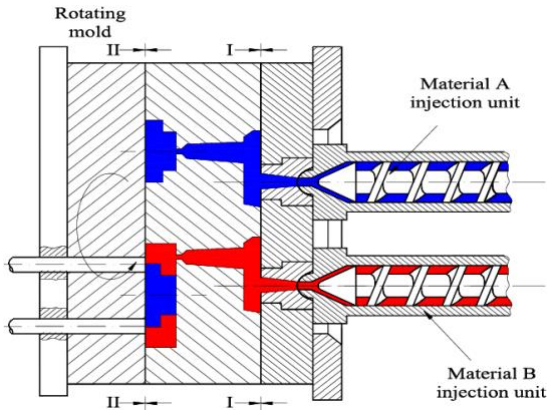

Figure 2.4: Injection Overmolding Between Two Polymers [40]

Injection over molding is advantageous for manufacturers who want to create a good bond between two different materials. While the second material is fitted specifically over the first, there are ways to ensure a stronger, more long-lasting bond between materials such as primers or physical attachment.

Primers

One option to strengthen an injection overmold interaction is to introduce a chemical primer to the base material. This is used to enhance adhesion of dissimilar materials like metals and polymers. During manufacturing, once the base material (metal) is produced, it is coated with a primer before entering the mold for injection over molding. Once the second material (polymer) comes in contact with the metal, it begins interacting with the primer to create a bond between the metal and polymer. Primers are used because they are created with specific amino groups and vinyl functional groups that allow inorganic and organic materials to bond together [41].

Other primers allow for polymer brushes to be added to the primers. Polymer brushes are small chains of polymer molecules that adhere to these designed primers. The chains are washed over the primer treated areas of a material. These brushes create a more secure bond between the polymer being added to the metal and the primers bonded to the metal because they act like molecular Velcro [42]. This primer/polymer brush adhesion is advantageous to include in overmolding because with some metals it can increase adhesion strength up to 50% [42]. Some of these products, such as RadiSurf™, can withstand high temperatures ranging up to 200°C [42].

Mechanical/ Physical Blending Bonding

Certain materials possess compatible properties that allow them to be physically blended together. This occurs for the most part between polymers with good flow melt compatibility. Flow melt compatibility is dependent on the polarity of the materials. A blend between a polar and a nonpolar material will have good flow melt compatibility. To blend polymers, materials with good flow compatibility are melted together at a desired connection point. The polymer chains at the contact point of each material will become entangled and a blend bond will be achieved upon solidification of the materials [43]. This process is illustrated in Figure 2.5.

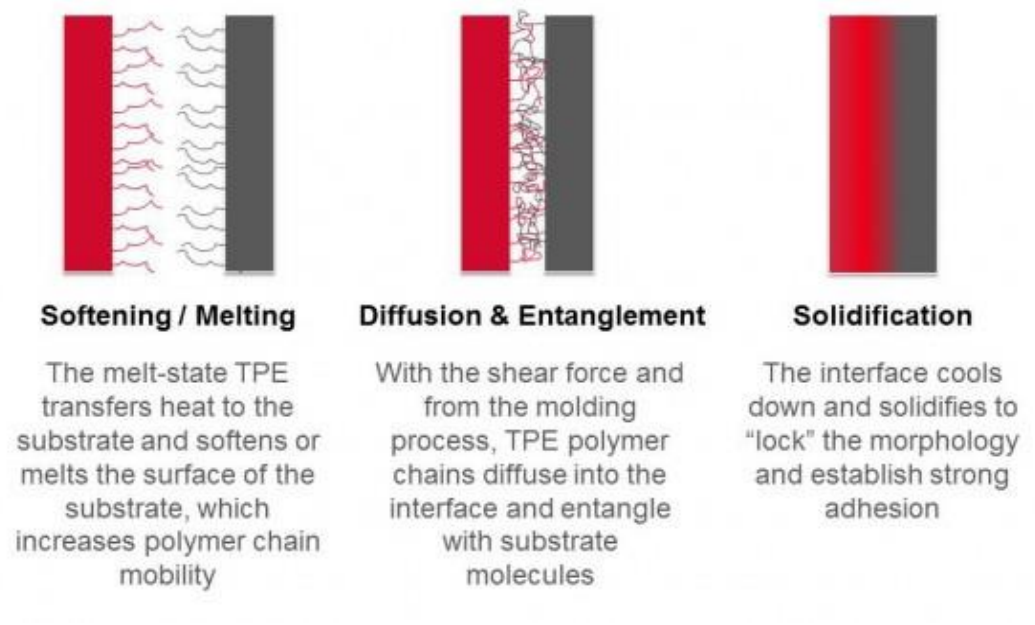

Figure 2.5: Physical Blending of Polymer Chains [43]

Not all materials are capable of this type of physical blending of polymer chains. For example, achieving a bond between a stainless-steel base and a polymer grip might require a mechanical bond. In this scenario the shape of both the base and grip aspects of the instrument must be considered. Adding a slot through the center of the base for the grip to connect through could add a mechanical interlock method of adhering the grip to the base. Adding texture or ridges to the surface of the base would also aid in mechanical adhesion between the polymer grip and the base component substrate. Figure 2.6 illustrates the concept of mechanical interlock using a TPE.

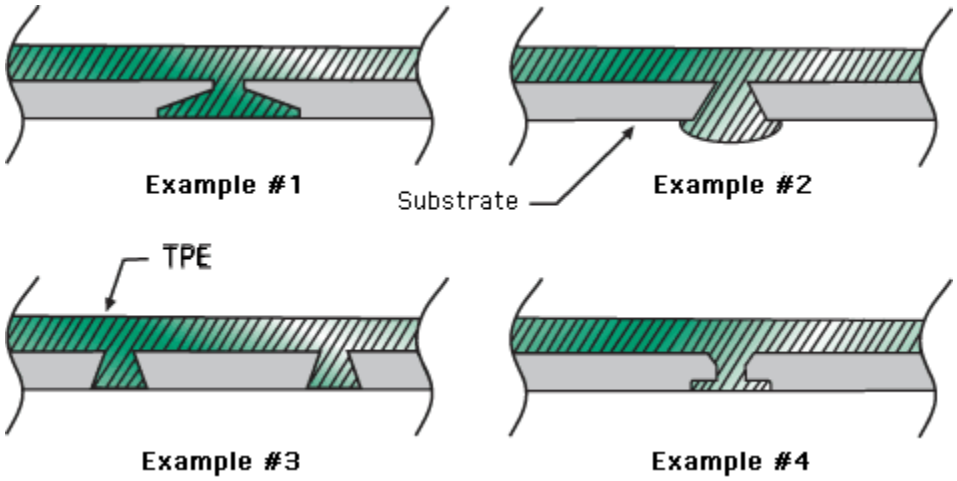

Figure 2.6: Mechanical Interlock [44]

2.6 Prototyping

2.6.1 Subtractive Manufacturing - Milling

Computer numerical control milling is a process that utilizes computerized controls and cutting tools to remove or cut material from an object of choice to produce a custom product. This works for metals, hard plastics, glass, and wood [45]. This process starts with designing a CAD model. Benefits of CNC machining is that the process is extremely precise, it can produce repeatable results, they work relatively quickly, and they demonstrate fast prototyping due to its integration with CAD [46]. Disadvantages of CNC and subtractive manufacturing is that they do not work as precisely on materials that are not hard, like rubbers. Subtractive manufacturing is also challenging to use on products that are not uniformly flat or uniformly round, such as concave materials [46]. For this project, hard plastics like polypropylene or acetal sheets and metals like stainless steel can become custom designed easily with subtractive manufacturing, while materials such as neoprene or TPEs can be more challenging to texturize using CNC or subtractive manufacturing; however, the hard plastics and stainless steel can only be texturized on uniformly flat samples of the materials. While this could be helpful for obtaining samples for testing coefficient of friction, this is not helpful for prototyping the scalpel, which has areas that need to be texturized that are concave.

2.6.2 Additive Manufacturing Plastics

Fused deposition modelling (FDM)

(FDM) is one of the most utilized form of 3D printing involving polymer filaments. This method involves using a thermoplastic polymer filament to print layers of the material of choice. First, the filament is heated to a liquid state and squeezed out of the nozzle onto a platform or other layers that had already been extruded [47]. The thermoplastic behavior of the filament is crucial for encouraging a fusion of each subsequent layer that is printed, and then solidifying after remaining in room temperature after printing has stopped. The main advantages of FDM is its low cost due to the simple nature of the process, and the high speed of the device. The disadvantages of this method is that the layers of the polymer are visible in the final product, and it does not have great surface quality. In addition, there are not many thermoplastic materials, meaning that the materials that can be used for FDM are limited [47].

Powder Bed Fusion

Another form of additive manufacturing is powder bed fusion, which is the process of printing layers of fine powders, and these are closely packed on the platform [47]. In each layer, the powders are fused together using a laser beam. This continues until the product is printed. Excess powder is taken out using a vacuum, and often the application of a coating is done to improve surface qualities. The density of the product is reliant on the powder size. Only powders with a low melting temperature can be used with the laser to fuse the layers, otherwise a different binder -- most often a liquid binder-- must be used to fuse the powder layers together. Laser sintering can be used for many polymers, metals and alloy powders, while laser melting can be used for only certain metals [47].

Stereolithography

Stereolithography (SLA) is one of the first methods of additive manufacturing. It uses UV lights or electron beams to catalyze a chain reaction on a layer of resin or monomer solution [47]. These monomers are typically acrylic or epoxies, and are UV activated. When activated, they transform into polymer chains, also known as the process of polymerization [47]. After

polymerization, solidification occurs between the layers of the resin to hold the layers together, and the resin that is left unreacted is removed. SLA produces highly precise products, but it is slow, expensive, and the materials that can be used for this method are limited [47].

Laminated Object Manufacturing

Laminated object manufacturing (LOM) is another early method of additive manufacturing, which consists of a layer-by-layer cutting and lamination of rolls or sheets of materials [47]. Layers are cut using a mechanical cutting device or a laser, and then the layers are bonded together. LOM can be utilized for polymer composites, papers, ceramics, and metals [47].

Type of Additive Manufacturing	**Materials that can be Used**	**Benefits**	**Drawbacks**	**Resolution Range (um)**
FDM	Thermoplastic polymer filament and fiber reinforced polymers	Inexpensive, fast, simple	Weaker mechanical properties, and limited compliant materials (thermoplastics)	50-200
Powder Bed Fusion	Compacted powders, metals, alloys, and limited polymers	High quality	Slow, expensive, and high porosity	80-250
SLA	Resin with photoactive monomers	High quality	Very limited in the amount of materials, slow, expensive	10
LOM	Polymer composites, ceramics, paper, metals	Fast, large range of materials, inexpensive	Surface quality is not always sufficient, not reliable for complex shapes	Varies depending on the thickness of the laminates

Table 2.1: Additive Manufacturing [47]

2.7 Sterilizability

According to the Centers for Disease Control and Prevention, there are certain sterilization practices that must be maintained to guarantee disinfection and sterilization in healthcare facilities. The two most common forms of sterilization in healthcare facilities are steam sterilization and ethylene oxide sterilization.

Steam sterilization

The most commonly used form of sterilization in medical facilities is steam sterilization. Steam sterilization is inexpensive, fast, and nontoxic. It can, however, corrode some materials. Steam sterilization works by exposing medical instruments to direct steam. Ideal steam sterilization temperatures are 121 C and 132 C. Typically, instruments must be exposed to 30 minutes of steam sterilization at 121 C in a gravity displacement sterilizer or 4 minutes at 132 C in a prevacuum sterilizer. Polypropylene, acetal, silicones, and stainless steel can be steam sterilized [47] Flash sterilization is a variation of steam sterilization, where the object is placed in a covered container to contain the steam, and allow for faster penetration of the steam into the instrument for 3 minutes at 132 C. This method is acceptable for items that cannot be "packaged, sterilized and stored before use" [48].

Ethylene Oxide Sterilization

Ethylene oxide (ETO) has used as a low temperature sterilization method. ETO is a gas that is flammable. Gas concentrations of 450 to 1200 mg/l with a temperature from 37-63 C, humidity of 40-80% and exposure times of 1-6 hours affect the ability of ETO to successful sterilize a material [48]. Increasing gas concentration and temperature often shorten the time that is needed for sterilization. The disadvantages of ETO are the time it takes to sterilize, the cost, and its toxicity. Exposure to ETO could cause skin, eye, gastrointestinal and respiratory irritation, and it is considered to be a human carcinogen [48]. ETO, however, is excellent in killing all microorganisms. ETO is more commonly used on materials that should not be exposed to high heat due to morphological issues, such as TPEs or plastics with a low melting point [48].

2.8 Texturizing

Textures are added to the surfaces of many products to improve the friction and grip. Ridge height, spacing, and shape all contribute to the degree of friction of the grip. High, narrow, and widely spaced ridge textures contribute to a high degree of friction; however, the level of friction is not consistent as the material slides. Consistent friction (consider a finger sliding down the grip material) is better achieved under the opposite conditions [49]. A balance between high and consistent friction will need to be achieved. The shape and pattern of surface texture also contributes to the degree of friction between two different materials.

There have been many studies testing various methods of increasing coefficient of friction on the surface of materials. One study that is particularly applicable to increasing grip of the ergonomic scalpel tested common medical glove materials against varying textures in wet conditions. Figure 2.7 shows the various patterns that were tested.

Figure 2.7: Surface Textures for COF Testing on Gloves in Wet Conditions [30]

The results showed that patterns made using medium diamond 21 TPI blade (texture 5) and coarse diamond 14 TPI blade (texture 6) offered the best grip compared to finer diamond patterns and angular ridge patterns [30]. While the previous study found that the diamond textured tools performed better in friction testing, further research in enhancing coefficient of friction on surfaces showed that texture patterns of lines and ridges is commonly used. One study that was found compared how the orientation of line textures affect friction.

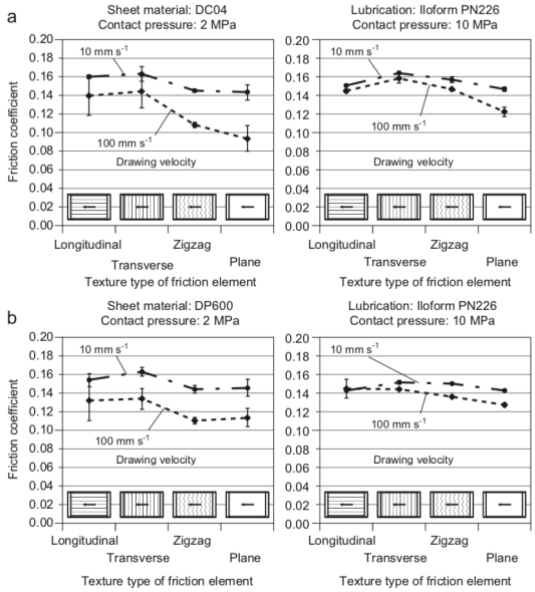

Figure 2.8: COF Testing on Multi-Oriented Line Textures [50]

Line textures that were oriented perpendicular to the pulling force outperformed longitudinal and zigzag lines when compared to the plane control. Other studies compared ridges to dot and Hilbert Curve patterns. Testing was done with patterns in three different orientations: parallel to force, a 45° rotation, and perpendicular to force. The dot indentations into the surface showed a large reduction in surface friction, followed by the Hilbert Curve pattern [51]. The ridges showed higher coefficient of friction, with the best results in the perpendicular orientation [51].

To further explore aspects of texture patterns on grip, a study was found showing how varying texture sizes affect the grip between tool surfaces and a bare finger pad. This study focused on ridge patterns with varying ridge height, width and spacing, to compare coefficient of friction between samples and the comfort for the user. Volunteers were asked to slide their fingers across the textured surface while the normal force of the finger and tangential forces were taken. Figure 2.9 demonstrates how varying ridge dimensions and forces affect the coefficient of friction between the finger and the brass material being tested.

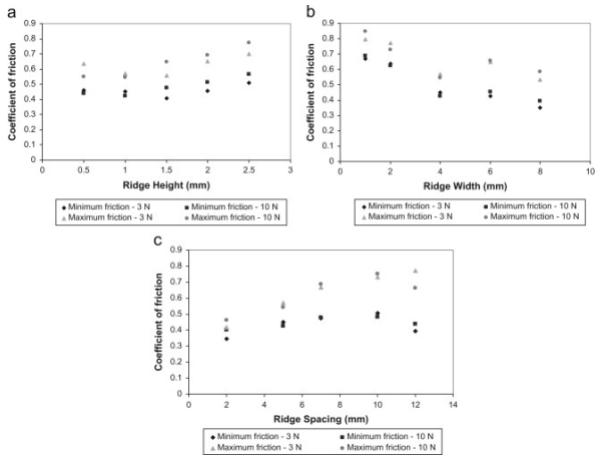

Figure 2.9: COF Tests Based on Ridge Height, Width, and Spacing [49]

It was concluded that greater distance between ridges, 10 mm or more, created higher friction on the finger [49]. This is due to the deformation of the finger pad over the pattern which in turn calls for more force to move over the ridge. However, this study suggests the use of smaller ridge spacing, higher height, and smaller width for tools requiring a more consistent pattern [49].

Chapter 3: Project Strategy

3.1 Initial Client Statement

The initial project statement as stated by our sponsor is as follows:

"Investigate, develop and test ergonomic and haptic considerations with material options compatible with favorable manufacturability, sterilization and durability in a surgical scalpel and/or various forceps designs, two of the most common instruments used in surgery."

3.2 Design Requirements

To achieve the goal set by the client statement, the team has categorized the needs of the clients into design requirements which can be seen in Table 3.1. While all of these aspects of design are important, they have been assigned to a ranking system to better choose what aspects need to be prioritized. For example, biocompatibility is top priority because the new iteration of the design should never cause harm to a patient. On the other hand, adding color to the instrument was ranked last because it's not vital to the completion of the project that color be incorporated.

Priority	Design Requirement	Attribute
2	Ergonomic	Design must demonstrate good haptic feedback and be comfortable for the surgeon to use in elliptical, circular, or rotational motions.

5	Manufacturability	Design must be able to be actualized into a working instrument, that is affordable to produce, and easy to repeatedly create perfectly
4	Reusable: Durability	The reusable designs must be able to be steam sterilized repetitively, which is the standard and compatible in surgical settings.
3	Wet-slip resistance	Both reusable and multi-use designs must maintain grip when working with all bodily fluids
6	Disposable: Affordable	The cost for disposable designs must be low to account for repeated purchases.
1	Biocompatibility	Raw materials must be sourced from sterile manufacturers and all materials considered cannot induce inflammatory or toxic responses in patients
7	Easily distinguishable	Design must be easily distinguishable (by color) for nurses to find in the operating room amongst all other stainless-steel colored instruments

Table 3.1: Design Requirements Ranked

Ethical concerns regarding the design requirements is that all surgeons would need to be able to practice using the instruments sufficiently prior to bringing them in the operating room. In general, no new surgical instruments should be used by the surgeon without the surgeon feeling exceptionally
confident in their ability to use them for their intended purpose. Meaning, that another element of the design implementation would have to consider practice time of the surgeon before utilization of the device in the operating room [52].

3.2.1 Design Objectives

In order to improve upon the current scalpel design, the project has been split up into four main objectives in relation to the design requirements.

1. Research and choose materials that fulfills design requirements set forward by research and client interviews.
2. Create a design with improved ergonomic grip and tactile feedback.
3. Explore manufacturability options, and product production considerations.
4. Create multiple product prototypes for surgical testing.

These objectives lay out the different needs and considerations going forward in this project. First, material selection is a huge consideration when designing any medical device. There are many criteria and requirements that the material needs to fulfill in order to be used in

this application. Some examples include having good mechanical properties, able to be sterilized, and most importantly, must be biocompatible. Materials used in this application must also conform to any FDA or ISO regulations in order to be considered.

Objective 2 addresses the need for a new design. Since the old designs are uncomfortable due to the fact that they are not efficiently contoured to the anatomy of the hand and can become very slippery when exposed to bodily fluids, Objective 2 will include testing of grip positions and possible applications of grip enhancers. One important consideration for designing an ergonomic handle, is that it needs to be both comfortable and allow for full range of motion when making cuts. After design considerations have been made, Objective 3 addresses the needs for manufacturing. Scalpels have been manufactured for decades and creating new designs will affect the manufacturing process and molds already being used. In this objective it's important to regulate prospective costs and ease of manufacturing to be more appealing to stakeholders in the manufacturing business.

The last objective allows for testing of the work done in Objective 2. In order to ensure the design is comfortable and usable, prototypes can be made in SolidWorks and 3D printed. These prototypes can allow stakeholders to try and test the product themselves. In addition, scalpel prototypes can be compared to old designs by side by side comparisons of precision cuts on human skin analogs. 3D printing the designs will also give insight on how the design fits in the hand during use and if there needs to be any alterations.

3.2.2 Design Constraints

During the design process, many factors can affect the design and production of a product. For this product, the dimensions and ability to interface with current scalpel blades could be a major design constraint and needed to be taken into consideration. The new shape of the scalpel could also affect the blade fixture methodology. Another design constraint for this project is the design budget. 3D printing and materials to make prototypes need to be cost effective in order to do multiple iterations of prototypes needed for objective 4. In addition, money is a design constraint in objectives 1 and 3. Choosing a material that is cost friendly for buyers will increase the likelihood of the stakeholders considering a new design. Manufacturing costs can also be a huge constraint when introducing a new product on the market. If something is too expensive to produce, the price of the product will increase and deter buyers.

In addition to costs and budget constraints, time is also an important factor. Objective 4 is a time sensitive requirement. The ergonomic design needs to be completed in a reasonable amount of time to allow for redesign if need be. In addition, testing of each design is required to demonstrate the effectiveness of the design. Testing will provide evidence that the new design is improved ergonomically and in the accuracy of its use. Once these prototypes have been tested, there needs to be enough time allocated to possibly produce a working product for Dr. Dunn.

3.2.3 Design Functions

Surgical precision is often dependent on the angle that the scalpel is oriented. Scalpels must be able to function and operate in all orientations they are used in. They must be able to functionally cut tissue with precision in all orientations. With the current design of the scalpel handle being flat and lacking a design contours to a user's hand, orienting this instrument in different positions can be inconvenient and strenuous. This difficulty increases the chance of the user's hands trembling during rotational and angular orientations of the design, resulting in less precise procedures. For example, for the surgical removal of skin growths, a surgeon has to

utilize the scalpel to perform two symmetrical incisions around the growth. In a simple procedure such as this one that is done often, creating the symmetrical incisions can be difficult since the current "flat handle requires the surgeon's wrist to roll more for one incision versus the other", which can result in the surgeon experiencing tremors, and resultantly causes the surgeon to make asymmetrical incisions [53]. Figure 3.1 demonstrates the incisions that need to be made.

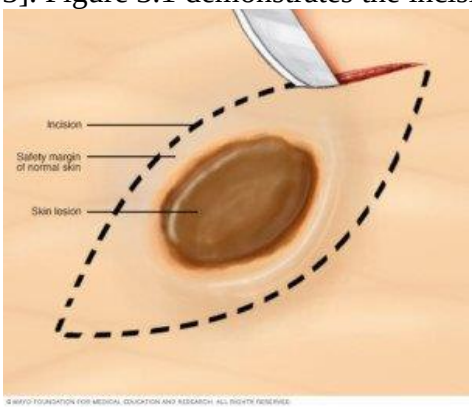

Figure 3.1: Symmetrical Incisions for Removal of Skin Growths [54]

Many procedures involve instrument contact with bodily fluids, meaning that the scalpel must be able to operate and function properly in wet and slippery conditions. As a result, the scalpel handle should be contoured, so that they can comfortably be held and can function in the hand of the surgeon, allowing for more control, confidence in the surgeon's grip, and precision in all types of surgeries [53].

3.2.4 Design Specifications

A brief overview of the desired design specifications can be seen below, and are further explained in the following paragraphs:

- Be the correct dimensions to contour the hand & allow for 0-180-degree angular rotation of the hand
- Be able to undergo steam sterilization up to 132℃
    - Be as durable as stainless steel in terms of withstanding repeated sterilization
- Be equal in cost or lower than current models for reusable designs and significantly less in cost for disposable designs
- Have a colored element on it making it easily distinguishable
- Use FDA compliant materials
- Have high dynamic coefficient of friction for the materials used (closer or greater than 1)
- For rubbery materials, have a durometer (hardness) that is ideal for grip materials -- most likely between 40A-60A

The scalpel design should have a circular cross section along the handle(s), allowing the surgeon to be able to rotate the instruments anywhere between 0-180 degrees [53]. This avoids requiring the surgeon to hold the scalpels or forceps differently for incisions or procedures that demand rotational or angular motions. The scalpel must follow the contouring of the hand and

have the correct dimensions that allow it to easily sit in the hand's architecture while allowing 0-180-degree motion.

The design should be able to also be manufactured via injection molding and should be composed of materials that can be sterilized for reuse, such as stainless-steel composites that are used today, and autoclavable plastics. According to the Center of Disease Control and Prevention, steam sterilization, used by most medical facilities such as UMass Medical, require medical supplies to be able to withstand sterilization maximum temperatures of 121 °C – 132 °C for at least 45 minutes, which are two of the most commonly used temperatures in steam sterilization [55]. As a result, the materials used in the reusable forceps and scalpels that are in the new designs must be able to withstand these temperatures like the current all-stainless-steel designs that exist, and not dull or corrode easily over time.

The manufacturing of the design also must be able to be modified for the creation of the disposable version with the same dimensions and function as the reusable one. The disposable version must be made of a cost-efficient molded plastic that is feasible for medical facilities to purchase in bulk for single use. The reusable versions should be either the same or less costly than current designs in order to encourage manufacturers to create them and medical facilities to purchase them. Below is Table 3.2 showing the costs of current designs that exist. Creating designs with cost specifications lower than these values is desirable.

Product	Brand	Price/Quantity	Size
No. 10 disposable scalpel.	Thermo scientific	$34.25/ 10 individually wrapped [56]	14.6cm
No. 10 disposable scalpel	Exel International	$15.07/ 10 individually wrapped [57]	N/a
No. 3 reusable scalpel handle	World Precision Instruments	$10.00/ 1 handle [58]	13-14cm
No. 3 reusable	Fine Science Tools	$17.00/ 1 handle [59]	12cm

Table 3.2: Sample Brands and Costs of Scalpels

Additionally, the scalpel (reusable or disposable) should have an element of color other than stainless steel on the handle for medical professionals to quickly locate it in the operating room among all the other stainless-steel instruments on the Mayo table. Colors such as blues and greens are ideal to use in medical equipment, since they are contrast red, allowing blood to visually stick out in the operating room [63]. The scalpel must also be FDA compliant and demonstrate excellent slip resistance to bodily fluids to ensure that the surgeon has a sufficient grip on it and prevent any unsafe or inefficient procedures from taking place. This includes using materials with a high dynamic coefficient of friction, meaning it has a coefficient of friction closer to or greater than 1 than 0, and perforated grips to increase the surgeons grasp [64].

Finally, for rubbery materials, a durometer of 40-60 Shore A are ideal, as they are similar hardnesses used in toothbrushes and tire treading, which still exhibit a high coefficient of friction in wet conditions [65]

3.3 Industry Standards

Engineering standards specify guidelines and specifications that should be met by the product in question. Standards help ensure that minimum performance characteristics and safety standards are met. Standards also aid in ensuring a product's consistency and that it is compatible with other standard compliant parts. Standards are especially important in the medical field as they're typically higher risk compared to consumer products. Once standards are incorporated into regulations, they become requirements. Products must adhere to regulations in order to be approved for market and use.

The International Organization for Standardization (ISO) is an independent organization that develops international standards. Individual countries have national organizations that correspond with and represent their country to ISO. In the United States, the standards organization that corresponds with ISO is the American National Standards Institute (ANSI.) ANSI is composed of other more specific US organizations such as the Advancement of Medical Instrumentation (AAMI.)

ISO has many standards pertaining to medical devices such as ISO 11737 which specifies requirements on the sterilization of medical products, components, raw materials, and packaging [66]. It will be necessary to keep this standard in mind while developing our product. The raw materials and final product must have the capability to abide by this regulation. Another relevant standard is ISO 10993-5 which describes standard tests for testing the in vitro cytotoxicity of medical devices [67]. It was determined that the most prioritized design requirement of the project is ensuring the final product is completely biocompatible. It is vital that surgical instruments do not induce a cytotoxic response in internal environments. ISO 10993 in general will be relevant during the design and fabrication of our product. ISO 10993 lays out guidelines for evaluation and testing of medical devices with respect to biocompatibility.

The United States Pharmacopeia Convention (USP) is another independent organization but is specific to the United States. USP develops standards primarily for medicines and foods but also raw materials. USP Class Testing I-VI lay out standardized methods and specifications for pharmaceutical grade raw materials. These tests provide standardized testing for in-vitro and in-vivo biological reactivity [68]. Ideally, the raw materials used in the final product will have passed these tests.

Many standards specify what additives are allowed in materials used in medical devices. In general, the final product will not use materials containing Phthalates, PVC, BPA and latex. Some people have adverse reactions to these materials and additives. BPA and latex may induce allergic reactions in some individuals [69].

As the project will focus heavily on biomaterials, raw materials standards will be very important to be aware of. It will also be important that the final design will be compatible with preexisting and standardized blades. ISO 7740 defines the dimensions of fitting features for detachable scalpel blades and the handles. It ensures minimal performance and interchangeability of scalpel parts from different manufacturers [70]. This will be important when designing the final product as an instrument that is not compatible with necessary parts cannot be effectively used.

3.4 Revised Client Statement .

Upon review of the initial client statement it was decided that the project would focus primarily on biomaterials pertaining to scalpel grips; more broadly, the project concerns the materials for the reusable and disposable scalpel designs that are slip resistant, affordable, and autoclavable.

Investigate, develop and test ergonomic and haptic considerations with material options compatible with favorable manufacturability, sterilization and durability in a surgical scalpel design. The project will focus specifically on the material properties of disposable and reusable surgical scalpel grasps, their costs, and their viability for universal surgical applications. The goal of our project is to improve upon a current prototype of a scalpel design that increases the comfort, precision, and ease of use for the surgeon by selecting ideal materials for both disposable and reusable versions.

3.5 Management Approach

The management approach to the project includes various milestones the team will achieve to reach the final goal. The team ultimately produced prototypes for a specially designed reusable scalpel grip, a disposable scalpel handle, and a forceps handle. We finalized the ideal material options for these prototypes by identifying characteristics and properties necessary and favorable for these handles: manufacturability, shape, sterilizability, cost, biocompatibility, durability, safety, and comfort.

For reusable scalpel handles, low cost was not prioritized because the instrument would have the ability to be reused many times. Instead, durability became a higher priority. On the other hand, the team prioritized manufacturability and low cost over comfort and durability for disposable scalpel handles. For material properties, it is essential to have biocompatibility and to accomplish the objectives discussed in the needs statement. Determining materials was concluded before November 2019.

After determining the most ideal materials, the team developed prototypes using computer aided design. Here the prototypes are tested by mechanical properties and the structural design can be developed. Once the prototypes can be manufactured or 3D printed, these may be tested for haptic feedback and ergonomic comfort for the surgeons. For initial prototyping, these devices are tested on objects that are comparable to cutting through and grasping tissue or skin (e.g. orange peels). Mechanical and haptics testing was concluded in December 2019.

After receiving mechanical feedback from the other MQP team working on the ergonomics of surgical instruments and haptic feedback from surgeons who had tested the ergonomics of the instruments, final prototypes were created by February 2020 with acceptance from our sponsor and advisor. Patenting paperwork was finalized by the end of February 2020. The final handle designs were completed and verified by March 2020 so the final goals and final paper could be completed for this project by April 2020.

Project completion was tracked by following the completion of objectives in the Objectives Tree that the team created seen in Figure 3.2 below. This diagram is a way to visualize the general paths we took in order to complete our overall objectives. Major objectives were achieved by completing minor objectives and testing shown in each of the paths. The overall goal of redesigning the scalpel and forceps handles were completed using various levels of research, testing, and prototyping. For milestone completion, progress was tracked by

following the Gantt Chart seen in Figure 3.3. This Gantt Chart was created to outline the time frame of our major milestones.

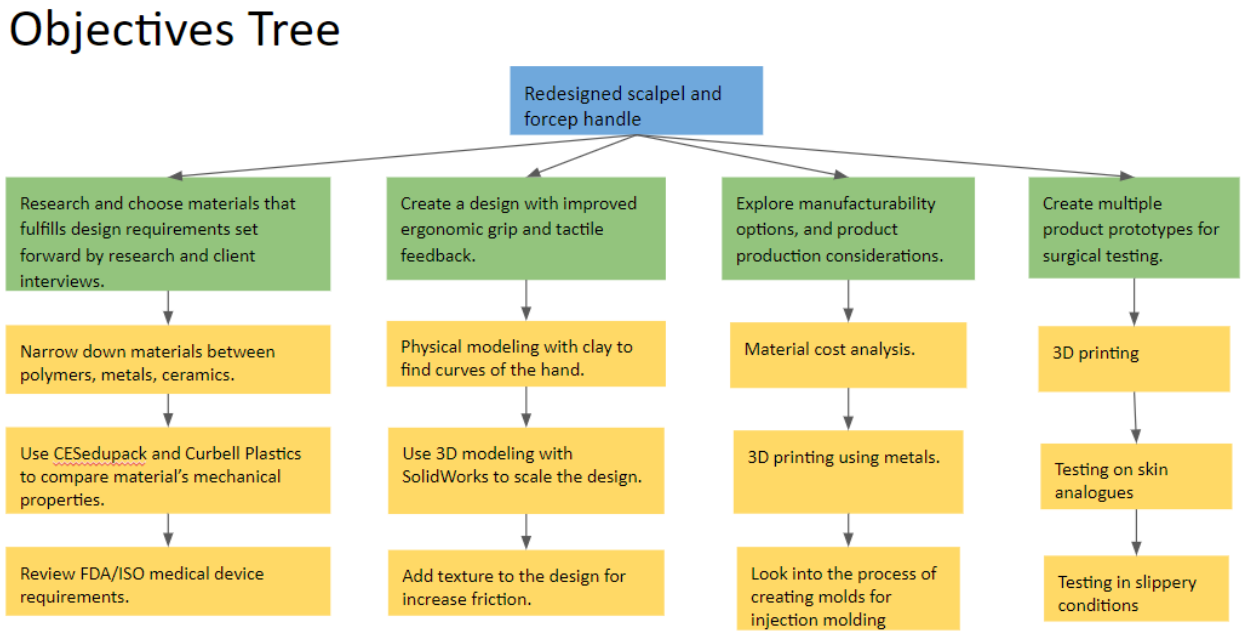

Figure 3.2 Major Objectives for Project Completion and Progress

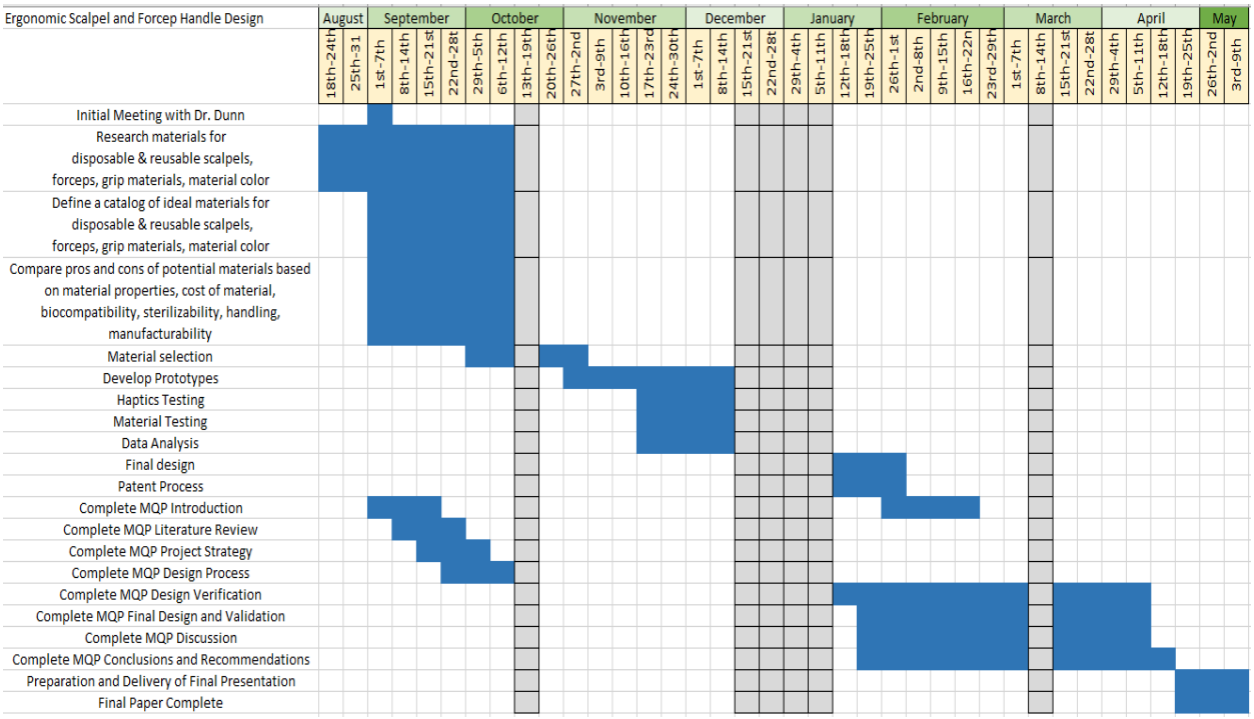

Figure 3.3: Gantt Chart Tracking of Project Completion and Progress

Through the Worcester Polytechnic Institute, there is a $250 budget per registered student. Therefore, the project team has a $1000 budget total. This budget is split into smaller

categories to organize where money is allocated. The team allows $50 for prototyping grip shape, physical properties, and material properties. $550 of the budget however will be allocated for developing and purchasing the materials chosen for the grips. The remaining $400 will be allotted for the manufacturing options chosen for the material. If the material is capable of being used in 3D printing or additive manufacturing, development can be much more affordable than manufacturing counterparts. As certain materials and manufacturing methods are more expensive, it is important to research the ability and feasibility of their options.

Additive manufacturing and 3D printing have been on the rise in the recent past. This is partially because additive methods use less material, which in turn makes the manufacturing less expensive compared to other manufacturing methods. Additive manufacturing methods include fused deposition modeling, extrusion, jetting, Inkjet binding, powder bed fusion, and resin-bath lithography. Depending on the materials at hand, cost, and the availability to manufacture, the additive manufacturing can be chosen.

Financial Statement	
Total Budget	**$1000**
Prototyping	$50
Materials	$550
Additive Manufacturing/3D Printing Services	$400

Table 3.3: Financial Statement.

Chapter 4: Project Design Process

4.1 Needs Analysis

Current scalpels do not demonstrate sufficient tactile sensation, ergonomics, leading to decreased safety, ease of use for many procedures, and slip resistance. This problem directly affects surgeons as they are the ones directly experiencing the performance feedback of the surgical instruments. In a more derivative fashion patients are also affected by the shortcomings of current instruments. If the surgeon's job is difficult there is greater opportunity for error in the surgery. To a lesser extent, medical device manufacturers would be affected by a design change as the production of medical devices is strictly regulated and production will need to adjust to the changes. The ultimate outcome of device improvement would be increased ease of use and subsequently reduced chance of error in surgeries.

Broadly speaking, we aim for our finalized product to be ergonomic, manufacturable, durable, have good wet slip resistance, be affordable, biocompatible, and easily distinguishable on the Mayo table. However, it is important to distinguish the priority of these objectives as an objective with a higher weighted score should take precedence over an objective with a lower weighted score. A design matrix was constructed by scoring these objectives based on design criteria as shown in table 4.1. Additionally, each criteria statement is weighted based on importance with safety and effectiveness being top priority and cost being less of a priority. Each objective is then scored out of 5 based on how well it satisfied the criteria. To come up with

weighted scores for each objective based on how well they satisfied the most important weighted criteria, the following equation is used:

Weighted Score = Weight(Score/5)*

It was determined through this matrix that in order of priority our project objectives are as follows; ergonomics, wet slip resistance, biocompatibility, durability, manufacturability, affordability, and distinguishability.

A central point made in our client statement is the need for this project to develop an ergonomic surgical instrument. Our final product should rotate easily and sit securely in the surgeon's hand while providing a good tactile sensation. It makes sense that achieving an ergonomic design would be a top priority. On a similar note, a product with good wet-slip resistance addresses important criteria such as safety, effectiveness, ease of rotation, and stability of grip. Finally, it is necessary for the final product to be biocompatible in order to adhere to industry regulations and be approved for market. It is determined that these three objectives, an ergonomic, wet-slip resistant, and biocompatible design, will be the primary objectives moving forward. Durability, manufacturability, affordability, and distinguishability are less crucial objectives. They would benefit the product's design but should not be prioritized over ergonomics, wet-slip resistance, and biocompatibility.

Objective: **Criteria (Weight):**	Ergonomic	Manufacturability	Reusable: Durability	Wet-slip resistance	Disposable: Affordable	Biocompatibility	Easily distinguishable
Safety (25)	5/5 25	0/5 0	2/5 10	4/5 20	0/5 0	5/5 25	0/5 0
Effectiveness (25)	5/5 25	2/5 10	4/5 20	5/5 25	1/5 5	5/5 25	3/5 15
Ease of Rotation (20)	5/5 20	0/5 0	0/5 0	4/5 16	0/5 0	0/5 0	0/5 0
Stability of Grip (20)	5/5 20	0/5 0	1/5 4	5/5 20	0/5 0	0/5 0	0/5 0
Interchangeability of Parts (15)	4/5 12	5/5 15	3/5 9	0/5 0	3/5 9	1/5 3	2/5 6
Cost (10)	0/5 0	5/5 10	2/5 4	0/5 0	5/5 10	0/5 0	0/5 0
Rank Score	**102**	**35**	**47**	**81**	**24**	**53**	**21**

Table 4.1: Design Matrix: Priority of Design Criteria and Objectives

In order to achieve each objective, physical limitations and technical constraints will need to be adhered to. To design an ergonomic instrument, the instrument must fit comfortably in the surgeon's hand, rotate easily, sit securely, and provide good tactical sensation. Hand

measurements for males in females in 5th, 50th, and 95th percentile groupings have been quantified as shown in tables 4.2 – 4.5 [71].

Percentile	5th	50th	95th
Male	7.9	8.6	9.7
Female	6.9	7.6	8.6

Table 4.2: Hand Breadth at Metacarpal (cm)

Percentile	5th	50th	95th
Male	2.8	3.0	3.3
Female	2.0	2.5	2.8

Table 4.3: Hand Thickness at Metacarpal (cm)

Percentile	5th	50th	95th
Male	9.4	10.4	11.2
Female	8.1	9.1	10.2

Table 4.4: Hand Breadth at Thumb (cm)

Percentile	5th	50th	95th
Male	17.8	19.3	20.8
Female	16.3	17.5	18.8

Table 4.5: Hand Length (cm)

Based on this information, the size of our handle should suit these measurements and perhaps multiple sizes will be required to suit each percentile and sex.

To design an instrument with ideal wet-slip resistance the coefficient of friction between the grip material and wet and dry standard medical grade latex gloves. A thermoplastic elastomer developed specifically for grip in wet conditions has a coefficient of friction against a smooth stainless-steel surface from 1.5 to 2.5 under dry conditions and 1.3 to 2.4 under wet conditions [72]. The final design will be tested under slightly different conditions, however, a COF between 1.5-2.5 gives a baseline range to aim for. Disposable versions may be able to include plastics that have a coefficient of friction this high, but reusable, autoclavable versions may have a more limited variety of COFs.

Biocompatibility of the device can be quantified using the testing parameters set in ISO 10993-5 [67] for measuring in vitro cytotoxicity will be adhered to. In this test, standard mammalian cells exposed to the material being tested should maintain approximately 80% confluency by the end of their growth period.

4.2 Concepts and Feasibility

4.2.1 Existing Conceptual Design and Relevant Design Calculations

Dr. Raymond Dunn created a more ergonomic handle for the surgical scalpel and has patented the design detailing measurements of the device. He drafted dimensions that he tested to be sufficient for more precision and control of the instrument. The blade can be detached, and different sized blades can be attached to it. The scalpel in particular has a distal section, proximal section, and center section. Between the distal section and the center section is a concave area with a circular cross section diameter minimum of 1.0-1.5 cm [53]. The distal section itself has an increasing diameter toward the blade, to prevent hand slippage toward the blade. The larger area of the distal portion has a diameter in the range of 1.2-1.8 cm [53]. The central portion has a diameter in the range of 1.6-2.4 cm [53]. There is another concave between the central section and the proximal section, with a diameter from 1.0-1.5 cm [53]. The proximal portion is flared, with a radius ranging from 1.5-2.0 cm [53]. The distance between the two concaves is in the range of 6.4-7.2 cm, and the distance between the distal end to the proximal end is in the range of 12-14 cm [53]. The length of the device in total should be in the range of 14-15 cm. The image below has these areas labeled. The new design of the scalpel should have a conceptual design containing measurements similar to these shown in Figure 4.1 [53].

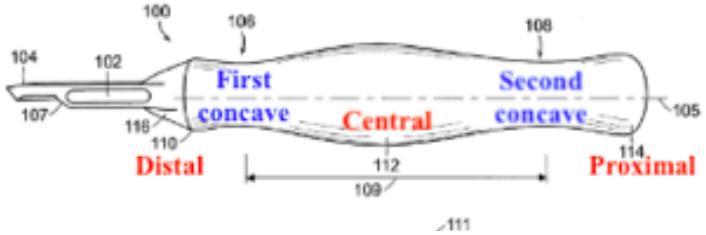

Figure 4.1: Sponsor's Previous Scalpel Design

The design should also be able to be manufactured using materials that can be reused for the reusable options, as well as more cost-efficient disposable options. This means that the materials used for the conceptual designs are extremely critical to its success and adoption in the medical field.

4.2.2 Material Options for Conceptual Design

Although the aim for the conceptual design is to find ideal materials with a coefficient of friction greater than 1.5, some autoclavable via steam sterilization materials that could be used that have a coefficient of friction greater than that of greasy-conditioned stainless steel include Neoprene, Delrin, Polypropylene, Silicone, and TPEs. Although the coefficient is extremely critical for ensuring slip resistance, reusable options have the priority of being autoclavable. If they are being conceptually designed using autoclavable materials, they are simply not reusable as surgical instruments. Characteristics of each of these autoclavable materials are listed below in Table 4.6. The table demonstrates that the materials and currently used stainless steel options are comparable, but under greasy conditions, the plastics may have a slightly higher coefficient of friction. For autoclavable plastics, the coefficient of friction may not be extremely different than

that of stainless steel when being used in the operating room, but the combination of a slightly better coefficient of friction and a more contoured, hand-fitting design, will ensure slip resistance. As stated previously in section 4.1, the coefficient of friction for disposable conceptual design versions may be able to be as high as 1.5, but designs drafted with autoclavable plastics may have a more limited variety of coefficients of friction.

Material	**Stainless Steel**	**Neoprene**	**Delrin**	**Silicone Elastomer**	**TPE**	**Polypropylene**
Coefficient of Dynamic Friction	Can be as low as 0.11 [73]	High	0.21-0.35	High	High	0.28
Machining/Manufacturing of textured pattern	Easy to machine	Not easy to texturize	Easy to texturize	Easy to texturize	Easy to texturize	Easy to texturize
Ability to bond to/be incorporated onto stainless steel	n/a	n/a	Used as metal replacement, not as grip itself	Great	Great	Used as metal replacement, not as grip itself
Chemical Resistance to oil/most alcohols	Outstanding	Outstanding	Outstanding	Outstanding	Outstanding	Outstanding
Radiation/Heat Sterilization Resistant	x	yes	yes	yes	yes	yes
FDA Compliant	x	yes	yes	yes	yes	yes
Color	Stainless Steel	Black	Any color	Any color	Black/Natural	Natural/White

Table 4.6: Material Comparison [74]

4.2.3 Addressing Overall Need

The design that Dr. Dunn created includes dimensions of a scalpel handle that contour the hand, which provides "increased contact area with the user's hand using a larger diameter central portion and a smaller diameter trough", or concave, that "allows rotation of the angle of the blade relative to the tissue without the need to change the grip on the handle" [53]. Dr. Dunn's design is also a handle that can be utilized as an "adapter sleeve", where the handle of already existing scalpels can be inserted. Using an adapter sleeve meets the need of making the design universally accepted; perhaps since it can fit over already existing scalpel blades that are currently used in every hospital, medical professionals will be much more willing to purchase them rather than needing to purchase newly designed scalpels altogether. The dimensions of the scalpel meet the need of making the scalpel more ergonomic during rotation of the angle of the blade: it contours the hand so it can sit comfortably in the hand, and it is easy to use during rotational incisions or motions. It also addresses the need for a safer design. With the distal section having an increasing diameter toward the blade, and the dramatic concave troughs, the hand is much less

likely to slip out of the surgeon's hand due to the design's stability. The polymer grip would also have a coefficient of friction closer to one, or greater than one, than that of stainless steel, making it more slip resistant. As a result, the new designs would be able to address the needs and requirements that Dr. Dunn desires to achieve.

4.2.4 Design Feedback

After handling the first manufactured prototype, and receiving opinions from colleagues, he provided feedback on the current design on his own ergonomic scalpel. His current design of the reusable ergonomic scalpel, according to him, does not have the proper weight to it, which is a requirement that would have to be altered. Currently, the proximal portion of the new scalpel is heavier than the distal or central sections, making the design slightly unbalanced during use. Other feedback received on ideas include also adding perforated or textured grips to the handle to increase slip resistance. By using these instruments, surgeons will experience a more comfortable tactile sensation when compared against standard instruments. This feedback was incorporated into the designs that are updated and drafted, while working alongside Dr. Dunn and the other MQP team.

4.2.5 Initial Design Alterations

The first design iteration attempts to maintain aspects of the original patent, as well as incorporating feedback. The materials chosen for the scalpel are stainless steel for handle and medical grade TPE was chosen to be the grip material. During material consideration, contacts from Teknor Apex provided samples of TPE with varying hardness ranging from 30 Shore A to 80 Shore A to determine which hardness would be optimal for this application. After the material was chosen, the length of the grip piece was increased to ensure more optimal contact with the user's hand, taking into consideration variations of hand size.

The next step in the design was to improve the friction between user and tool. The variety of texture patterns was chosen based on previously conducted research and personal preference from Dr. Dunn. The initial designs included a variety of ridges, diamond textures, knurled textures, and raised bumps to test. Out of these texture patterns, the most optimal grip was chosen to be manufactured onto the stainless-steel core of the body.

4.2.6 CAD Modeling and Prototyping

Computer aided modeling was completed using the Solidworks 2019-2020 software. Dr. Dunn's previous prototype of the improved ergonomic scalpel handle was recreated using precise measuring tools to determine its dimensions. Both the reusable and disposable models used the same dimensions. The major difference between the disposable and reusable models was that the reusable models were created using two material components.

The initial 3D model we received was given to us by the other team working on the improvement of the scalpel handle to remain consistent with dimensions (Designing of Ergonomic Scalpel Handles with Optimized Weight and Balance). Their model is shown below in Figure 4.2. The model is shown to have a 7mm diameter hole through 118.675mm of the length of the scalpel starting at the base and 2 rectangular indents of 1.452mm on the grip segment. The base was given a fillet with a radius of 7.7mm. The scalpel handle part was segmented into 3 portions to make further alterations more approachable. Dimensions are shown in Table 4.7. Each iteration mentioned onwards has the same dimensions unless a change is stated in this section.

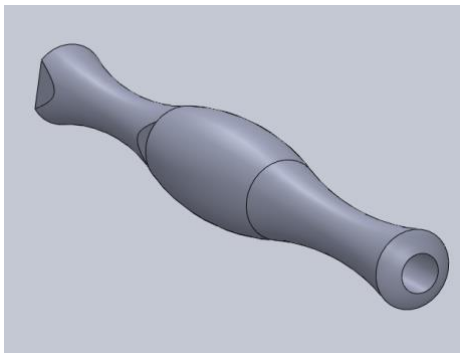

Figure 4.2: Weight and Balance MQP Group's Model

Next, our team recreated our own model that would be more useful for the purposes of the group. This model consisted of a solid core and slightly altered concavities at the grip and back segments of the handle. Dimensions are shown in Table 4.7.

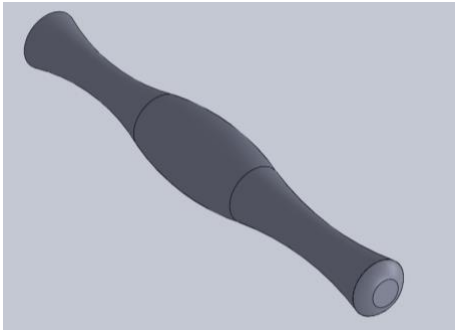

Figure 4.3: Optimized Grip MQP Group's Model

	Handle Length (mm)	**Grip Segment Length (mm)**	**Grip Segment Concave Radius (mm)**	**Middle Handle Segment Length (mm)**	**Middle Handle Convex Radius (mm)**	**Back Handle Segment Length (mm)**	**Back Handle Segment Concave Radius (mm)**
Weight and Balance Group's Model	122	40	68	35	72	45	101
Optimized Grip Group's Model	122	40	94	35	72	45	104

Table 4.7: Model Dimension Comparison

Each of the following pictures will be displayed with the scalpel head side to the bottom right to help better visualize the grip portion of the handle consistently.

Using the model in Figure 4.3 above, grip textures could then be added onto the surface of the grip segment. Grip textures were chosen based on research articles about high friction

textures in medical and dental applications. These textures were then tested for frictional properties. Each testing slab was created with 3 standard variations in texture size in PLA. The base of each slab was 76.2mm in width, 152.4mm in length, and 6.35mm in height. Textures were printed on the top face of each slab. This can be seen in Figures 4.4 through 4.9. Each type of texture had slabs printed with 1mm offsets from the slab and shape sizes of 3mm, 6mm, and 9mm.

Figure 4.4 shows slabs with the "Checkered Knurl" texture in 3mm, 6mm, and 9mm shape sizes (left to right).

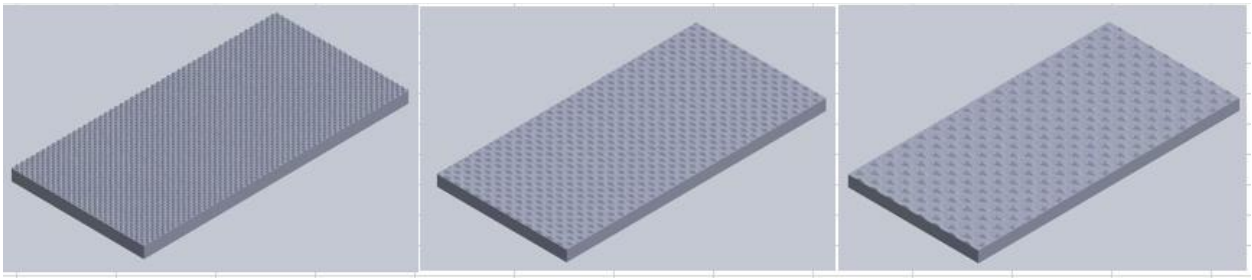

Figure 4.4: Checkered Knurl Texture Slabs

Figure 4.5 shows slabs with the "Gear Teeth" texture in 3mm, 6mm, and 9mm shape sizes (left to right).

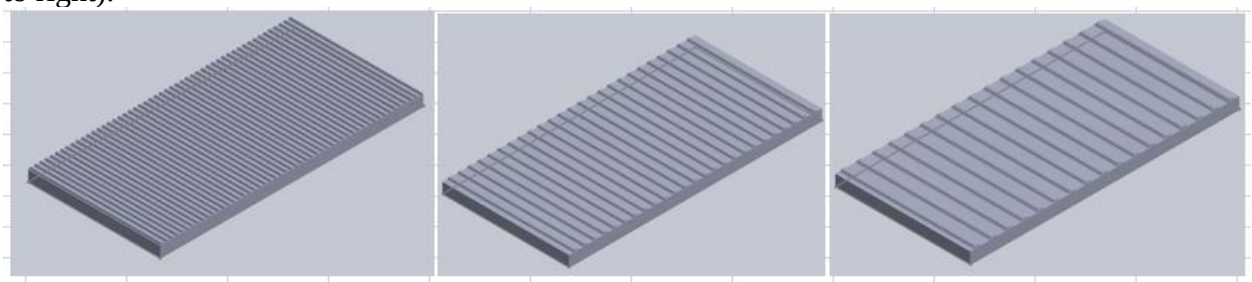

Figure 4.5: Gear Teeth Texture Slabs

Figure 4.6 shows slabs with the "Knurl Bump 4" texture in 3mm, 6mm, and 9mm shape sizes (left to right).

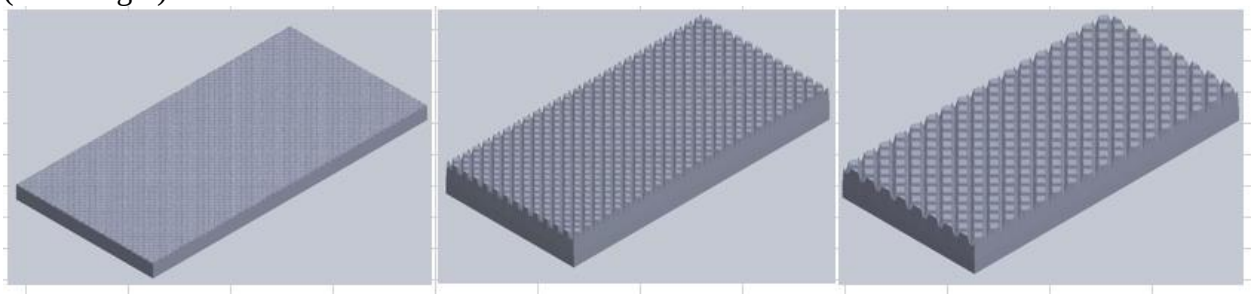

Figure 4.6: Knurl Bump 4 Texture Slabs

Figure 4.7 shows slabs with the "Knurl Bump" texture in 3mm, 6mm, and 9mm shape sizes (left to right).

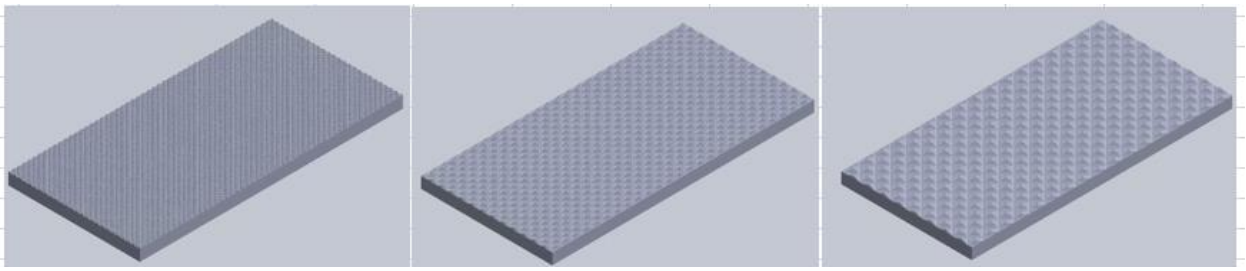

Figure 4.7: Knurl Bump Texture Slabs

Figure 4.8 shows slabs with the “Straight Knurl” texture in 3mm, 6mm, and 9mm shape sizes (left to right).

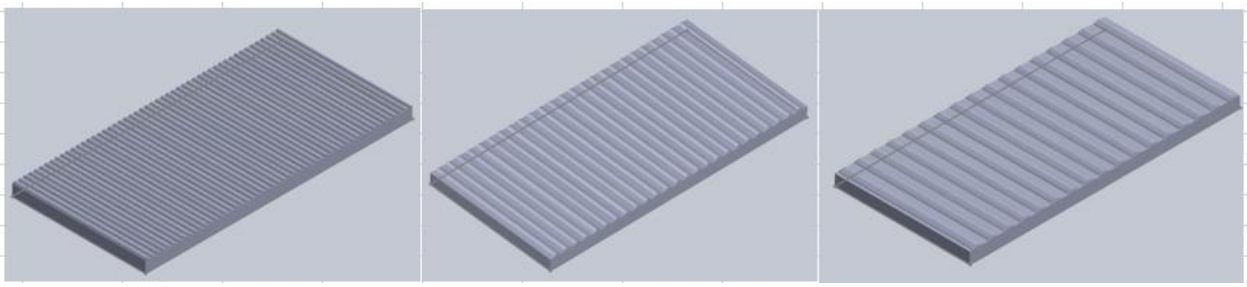

Figure 4.8: Straight Knurl Texture Slabs

Figure 4.9 shows slabs without texture to be used as a control for testing.

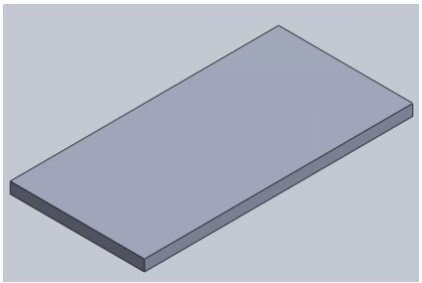

Figure 4.9: Blank Texture Slab

Figure 4.10 shows the same scalpel handle as in Figure 4.3, however the grip segment of the handle is replaced with an 8mm diameter core of the same material. This was done so that it could supplement removable grip prototypes with different surface textures.

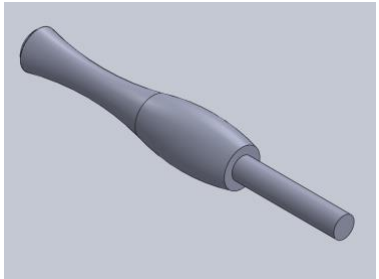

Figure 4.10: Main Body Scalpel Handle with 40mm Grip Core

Next, textured grip surfaces were made of each texture in Figure 4.11. Figure 4.11 shows an example of an isolated grip textured with “Knurl Bump” texture. The shape size of this example was set at 3mm and the offset of the shapes outwards from the material was set at 1mm.

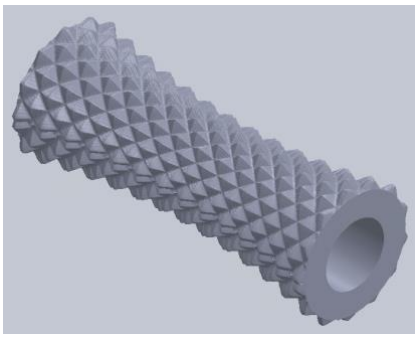

Figure 4.11: Knurl Bump 3mm Grip

Furthermore, another handle design was created with an extended grip segment towards the middle segment. This would allow for longer grips to be made and is shown in Figure 4.12. The new grip segment length was 51.67mm instead of the previous length of 40mm.

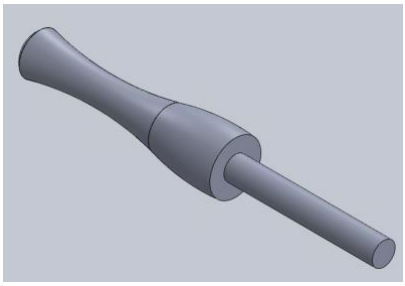

Figure 4.12: Main Body Scalpel Handle with 51.67mm Grip Core

Naturally, longer grips were also created at the same 51.67mm length with the same design as shown in Figure 4.3. An example of the longer grips can be seen below in Figure 4.13. This example shows the texture “Straight Knurl” with a 6mm shape size and 1mm offset outward from its center.

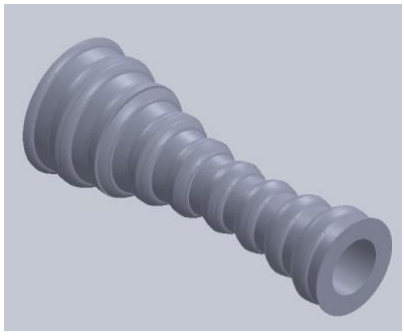

Figure 4.13: Straight Knurl 6mm Grip

4.2.7 Final Design

The length of the cylindrical handle, from base (back end) to head (blade attachment site), was measured to be 122.675mm. At the base, the diameter was measured to be 14mm, at its widest point ... mm, and 14mm at the head of the handle. The back-end concavity was measured to have a radius of 104.628mm, the convexity of the handle was measured to have a radius of 72.459mm, and the anterior concavity was measured to have a radius of 94.149mm. The base of the recreated model was given a fillet with a radius of 7.7mm. Based on testing results, three separate surface textures were chosen as final designs: Knurl Bump 6mm shape size by 1.5mm offset, Straight Knurl 6mm shape size by 1mm offset, and Knurl Bump 3mm shape size by 1.5mm offset pivoted by 45 degrees. The reusable handle was altered by separating the grip portion from the remainder of the handle. This was done by replacing the dimensions of the model with an 8mm diameter core of material that extended 51.67mm into the handle from the head. Figures 4.14, 4.15, and 4.16 show the 3D modeling of the final design of the reusable and disposable scalpel handles.

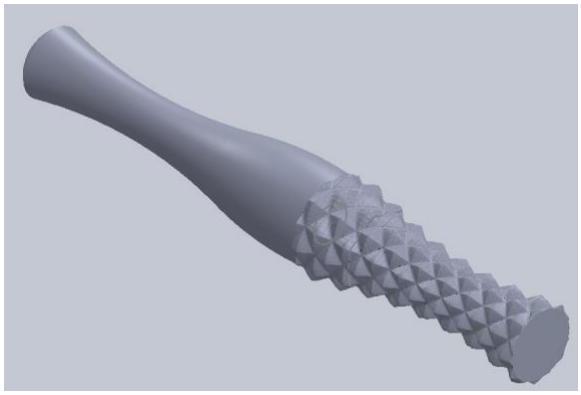

Figure 4.14: Knurl Bump 6mm x 1.5mm Grip Scalpel

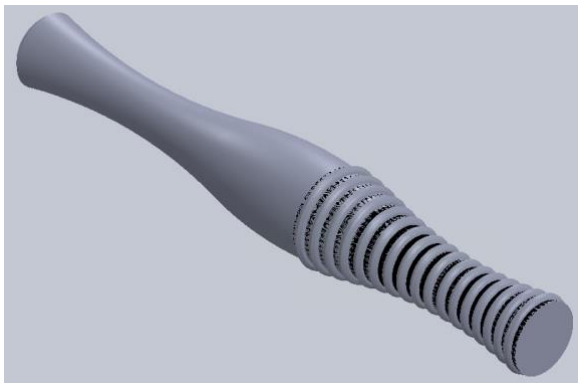

Figure 4.15: Straight Knurl 6mm x 1mm Grip Scalpel

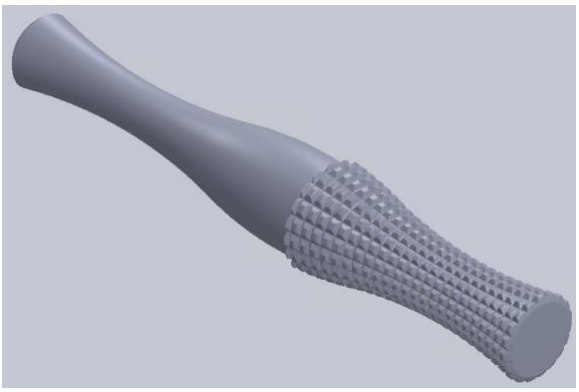

Figure 4.16: Knurled 6 Pivoted 45° 3mm D x 1.5mm Grip Scalpel

4.2.8 Feasibility Studies

In order to determine if aspects of the design are applicable to the design requirements set forth earlier in the paper, feasibility studies were conducted. These studies were designed to allow both quantitative and qualitative data to be taken on the designs. Two aspects of the design that are being prioritized is functionality of a more ergonomic handle, and the safety of using these instruments. Safety is highly concerned with the slip resistance that the scalpel handle is able to perform. The feasibility studies here will determine if prototyped designs meet the requirements needed to be manufactured into usable instruments from a safety standpoint.

To narrow down texture patterns that were discussed earlier in the chapter, coefficient of friction testing was done to provide quantitative data that would determine which textures were better for this application. This was done to be able to see which textures had the largest coefficient of friction on metal and on a rubbered surface (emulating a rubber glove). As mentioned previously, a larger coefficient of friction indicates better slip resistance, which was one of the major goals of this project.

The textures and their variations were 3D printed on PLA flat blocks for the coefficient of friction testing. Using these set up in the schematic below, the test was set up. The texture pattern side was placed face down on the metal runway with a known weight (M_a) attached to the top of it. Attached to the block was also a string that ran over a pulley which was attached to another weight (M_b). The pulley was securely fastened to the table, and M_a was securely fastened to the textured block. A velocity and displacement sensor made by Vernier® was placed on one side of the runway and connected to the Logger Pro® software. When M_b was released to fall due to gravity, the velocity, acceleration, displacement, and time were recorded into a comma separated file for data analysis. The experiment was repeated with a rubber of 20A shore hardness sheet on the runway to emulate the coefficient of friction each texture would have against rubber gloves.

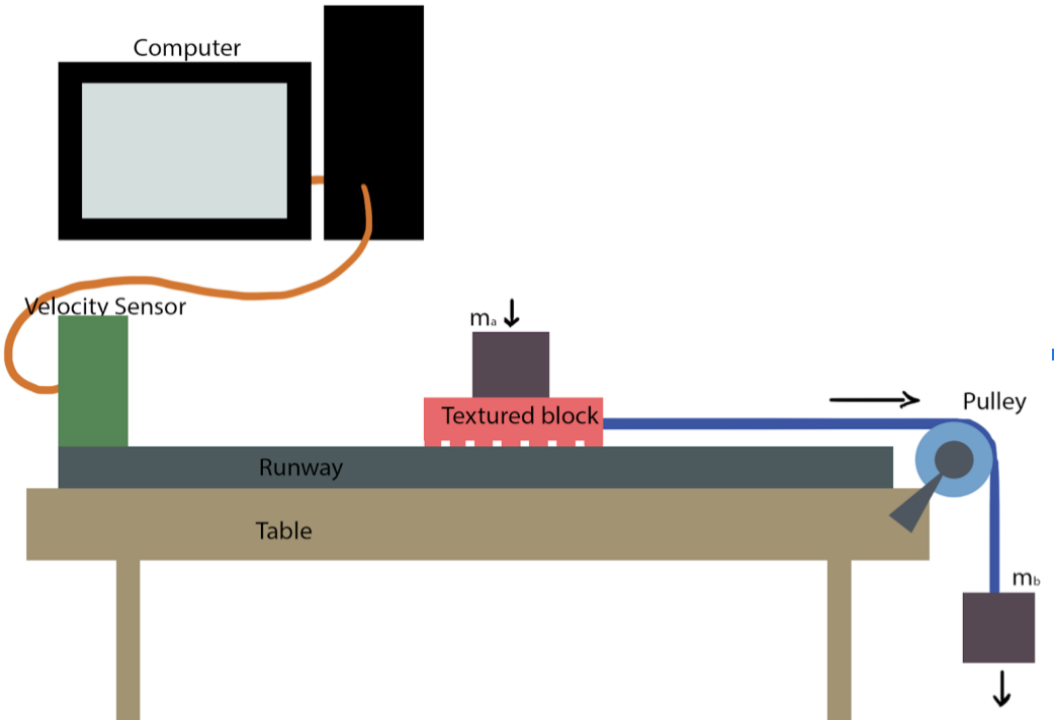

Figure 4.17: Coefficient of Friction Set Up

The coefficient of dynamic friction was calculated since this describes the coefficient of friction a material has when one object is moving against another, or if both objects are moving. This helped us estimate the coefficient of friction that a surgeon may have with these textures while their hand is moving on the scalpel handle. The acceleration that was used in the data was the average of the acceleration during the time that the black weight was moving. The equation that was used can be seen below.

Equation 1: $u_d = (a(M_b+M_a) - M_bg)/-M_ag$

Where u_d is the coefficient of dynamic friction, a is the average acceleration while the block is moving, M_a and M_b are the weights defined in the schematic, and g is gravity (9.81 m/s2). After completing these calculations for all of the textures, the following results were found. Checkered Knurl 3mm and Knurl Bump 3 mm were not able to be printed with the student printers at WPI, so those results are missing.

Pattern	**Coefficient of Friction**
Checkered Knurl 3 mm	N/A
Checkered Knurl 6 mm	0.19239217
Checkered Knurl 9 mm	0.19524076
Knurl 4 3 mm	0.20027623
Knurl 4 6 mm	0.17942971

Knurl 4 9 mm	0.17879563
Knurl Bump 3 mm	N/A
Knurl Bump 6 mm	0.19550908
Knurl Bump 9 mm	0.1955473
Gear Teeth 3 mm	0.21569011
Gear Teeth 6 mm	0.21571578
Gear Teeth 9 mm	0.20152888
Straight Knurl 3 mm	0.20182785
Straight Knurl 6 mm	0.20121172
Straight Knurl 9 mm	0.20138151
Control	0.17698614

Table 4.8: COF Results for Test 1

Here, we can see that the Gear Teeth, the Straight Knurls, and Knurl 4 3mm did the best during this testing by demonstrating higher coefficients of friction, closely followed by Knurl Bump and Checkered Knurl, which was consistent with the literature that we found. Since Gear Teeth 6mm, Straight Knurl 3mm, Knurl Bump, and Knurl 4 3 mm did well in the testing, the patterns we decided to move forward and do more testing with were these ones and their counterparts of different sizes.

Using the more successful patterns, the same coefficient of friction test was repeated with a rubber sheet on the runway. Here, we expected the coefficients of friction to be much higher since the rubber would inhibit the block from moving more than the bare metal runway. The results can be seen below.

Pattern	**Coefficient of Friction**
Checkered Knurl 6 mm	3.02296459
Knurl 4 3 mm	2.12732807
Knurl 4 6 mm	1.53073337
Knurl 4 9 mm	1.53857683
Knurl Bump 6 mm	2.0127038
Knurl Bump 9 mm	2.01987031
Gear Teeth 3 mm	1.8404908
Gear Teeth 6 mm	1.84048234
Gear Teeth 9 mm	2.25538919
Straight Knurl 3 mm	2.22027957

Straight Knurl 6 mm	2.22776619
Straight Knurl 9 mm	2.23123067
Control	1.3069645

Table 4.9: COF Results for Test 2

The patterns that did the best during this testing included the Checkered Knurl 6 mm pattern by far, which had the highest coefficient of friction, followed by Gear Teeth 9 mm, the Straight Knurl patterns, Knurl 4 3 mm, and the Knurl Bumps. Although Gear Teeth 9mm performed well in a block form during this testing, it was eliminated for this project due to the fact that the spaces between each ridge would be too large to fit on the scalpel grip and would not be feasible. Dr. Dunn was interested in us creating a Knurl Bump pattern that included more of a square pattern than a diamond pattern, which can be seen below. He was also interested in creating a Knurl Bump 6 mm texture with a greater depth.

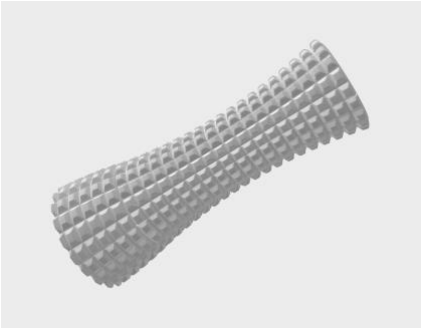

Figure 4.18: Knurl Bump Pivoted to be Squares

Because of these results, the textures that remained the most relevant and interesting for our project to pursue were the following:

1. Checkered Knurl 6 mm
2. Straight Knurl 3 mm
3. Knurl 4 3 mm
4. Knurl Bump 6mm with a greater depth
5. Knurl Bump Pivoted to be squares

4.3 Alternative Design Options:

Mechanical Interlock design.

In order to maintain a smooth transition from stainless steel to TPE, the diameter of the stainless-steel grip portion was decreased to an 8 mm core, enabling the TPE grip to replace the dimensions where the stainless-steel material would have been. This allows for the addition of a material grip portion without altering the diameter dimensions of the original patent. Once the decision was made to add a non-removable TPE grip around a stainless-steel core, aspects of manufacturing a plastic to metal interface had to be taken into account. To ensure that the TPE remains securely attached to the scalpel, small ridges were designed onto the stainless-steel core to ensure mechanical interlocking during compression molding manufacturing.

Two-part design:

With it being crucial that the design have a slip resistant material component to it, manufacturing of these materials onto the scalpel handle as discussed with more detail in Chapters 2.4 and 2.5, is critical for characterizing how the material can be sterilized, it's durability, it's cost, and it's ease of bulk production. Dr. Dunn's patented design involves the stainless-steel material being blended or incorporated with the slip resistant material (black) to be one full body, as seen below.

Figure 4.19: Dr. Dunn's Scalpel

In addition to the first design, other design options were considered that would also fulfill the design criteria set for this product. One alternative iteration includes similar dimensions and parameters as the previous design, however the product is a two-part assembly which we call the "Pencil Grip" design, since many pencil grips can slip on and off. The stainless-steel body is designed to have a core section for the attachment of the TPE grip. This core is smooth, compared to the ridged core of the previous design, because the body and grip are manufactured as separate components that the user assembles when needed. This allows the user to slide on and off TPE grips before and after use. Adjustments are able to be made to the user's texture preferences, instead of being limited to one universal grip. This can be seen below in Figure 4.20.

Figure 4.20: Pencil Grip Design

There are several reasons for why this design was created, which can be summarized below. This summary also includes possible ideas for this alternative design.

1. Sterilizability
    a. The grip will degrade faster than the stainless steel, so making the grip disposable after however many cycles will make this design more practical, so one doesn't have to buy the whole device each time the grip degrades.
    b. Being able to take each part of the scalpel apart decreases the chance of crevice contamination, where microbes can enter crevices and remain alive even after steam sterilization.
2. Grip Choice
    a. The surgeon could be able to choose the grip pattern that they find to be the most comfortable for them.
3. Ease of manufacturing
    a. Manufacturing just one material is easier than manufacturing a stainless-steel body and an overmolding of a grip with a different material on it.

Disposable design:

Since the disposable design had slightly different design criteria based on cost and ease of manufacturing, a different design was made. The grip length and diameter were held constant, but to limit cost expenditures, it was decided that the disposable scalpel be made of one material. Polypropylene was chosen as the disposable material due to its low cost and easy manufacturing. Since there was no need to account for multiple materials, the grip texture was added to the surface of the scalpel, eliminating the core rod design element in previous iterations. This allows the scalpel to be produced through injection molding in a singular mold, which reduces production and material costs.

4.4 Final Design Selection

After reading the literature, discussing Dr. Dunn's preferences, and completing our coefficient of friction testing and analysis, we finalized our design selection. The current literature and our coefficient of friction testing proved the success of patterns similar to the Checkered Knurl 6 mm, the Straight Knurl 3 mm, and the Knurl 4 3 mm textures. Dr. Dunn was interested in the Straight Knurl 3 mm texture, the Knurl Bump 6 mm texture with a greater depth, and the Knurl Bump Pivoted Square texture.

Because of the discrepancy between preferences, it is possible that different surgeons may have different preferences in terms of the grip texture. With the two part assembly "pencil grip" design, this discrepancy can be ameliorated. This will allow surgeons to pick their ideal grip pattern. The decision matrix below shows the comparison between the designs. The priority of each requirement and characteristic is ranked via a weight that is assigned to it, closely matching the priority of the design requirements listed in Table 4.10. The most important requirements or desirable characteristics are weighted as 5 in the decision matrix, and the lowest priority characteristics are labeled as 1. The current standard, which are the No.3 and No.7 scalpels used in most surgeries today, is assigned "0" for all characteristics. The Two Part Pencil Grip design, and the Mechanical Interlock design are assigned a 1 or a -1 if they are better or worse respectively, than the current standard with regards to each characteristic. The Two part

Pencil Grip and the Mechanical Interlock designs are assigned a 0 if the characteristics are not better or worse in the new designs versus the standard.

Characteristics	Weight	The Standard (Currently Used Scalpels)	Two Part Pencil Grip Design	Mechanical Interlock Design
Easy Manufacturability	4	0	-1	-1
Affordable Cost	4	0	0	-1
Biocompatibility/Medically compatibility	5	0	0	0
Colorability/ Easily Distinguishable in the OR	3	0	1	1
No Crevice Contamination	5	0	0	-1
Durability for repeated sterilization	5	0	1	-1
Labor to clean the instrument	3	0	-1	0
Slip Resistance/ Safety	5	0	1	1
Accuracy/Precision of Surgeon using instrument	5	0	1	1
Ergonomics	5	0	1	1
Easily addresses the problem of different surgeons having different texture preferences	3	0	1	0
Physical Appearance/Aesthetics	2	0	1	1
Profitable for the Seller	2	0	0	1
TOTAL		**0**	**21**	**4**

Table 4.10: Decision Matrix for Choosing Final Design

According to this table, the two part Pencil Grip design demonstrates more of the desired or positive characteristics than the one piece Mechanical Interlock design. Because of this, we are recommending that the final design that we chose is the Pencil Grip design. Since our testing and the literature we found support the Checkered Knurl 6 mm, the Straight Knurl 3 mm, and the Knurl 4 3 mm textures, our final design is focused on implementing these textures due to their scientific verification. We believe the surgeon or customer should be able to purchase their favorite grip out of these three patterns, since they were the most successful in the literature and our testing.

Because one of the goals of our project was to manufacture designs for Dr. Dunn specifically, the final design that we are manufacturing at Teknor Apex, a plastics company in Leominster, MA, is the Pencil Grip Design, with the Straight Knurl 3 mm texture, the Knurl

Bump 6 mm texture with a greater depth, and the Knurl Bump Pivoted Square textures, which were the textures that he preferred.

Although Dr. Dunn originally preferred a one-piece design, which is the Mechanical Interlock Design, this product was difficult to manufacture during the scope of this project for several reasons. The first is that manufacturability of the Mechanical Interlock design is a complex and costly process that would require our team to closely work with our consultant at Teknor Apex. It would require us to have access to the Manufacturing Labs at WPI, because we would have to manufacture the metal handle in the lab, bring it to Teknor Apex, and be onsite at the company to help with any troubleshooting. However, because the COVID-19 pandemic prevented us from being at WPI or Teknor Apex onsite, the Pencil Grip design is a better choice since its manufacturing does not require as complex as a process according to the consultant at Teknor Apex, and would not require an onsite presence, and it can be manufactured independently of the stainless steel handle. As a result, to be able to manufacture a product for this project, the Pencil Grip design became the final design.

Chapter 5: Testing and Results

The following testing protocols were drafted, however due to the COVID-19 pandemic, they could not be done during the scope of this project. Therefore, we recommend that this testing be done to verify the grip strength, the slip resistance, and the accuracy of the surgeon while using this device.

The first study that can be run is practicing scalpel cuts on skin analogues, which Dr. Dunn suggested should be a grapefruit. This study can be broken down into two parts: comfort using the instrument, and precision and accuracy when making circular (0°-180°) or curved motions. This testing would be done with the help of resident surgeons who would volunteer to do the incisions on the grapefruit. This would allow feedback on the shape of the design because they would be able to express their opinions on comfort or ease of use, and how the instrument fits into their hand. The full protocols can be found in the Appendix.

Testing would include tracing common cutting techniques on the grapefruit. This will be used in a side by side comparison between cuts from old scalpel handles, to determine the precision of the new design. Testing cuts such as circular or elliptical patterns will also give feedback if the design can increase ability to do 0°-180° motions, which is one of the priorities of a more ergonomic design. The grapefruits would be cut in half, with the flat, cut side being face down on a cutting board. Each surgeon would be given gloves, the new scalpel design, a No.3 scalpel, and five halves of a grapefruit. The first grapefruit would be used as a practice for the surgeons to become comfortable using the new scalpel. The remaining second grapefruit halves will have stencil tracings similar to what can be seen below in Figure 5.1. The surgeon would be asked to make incisions that follow the stencil tracings using the new scalpel on one grapefruit half, and again using the No.3 scalpel on another grapefruit half.

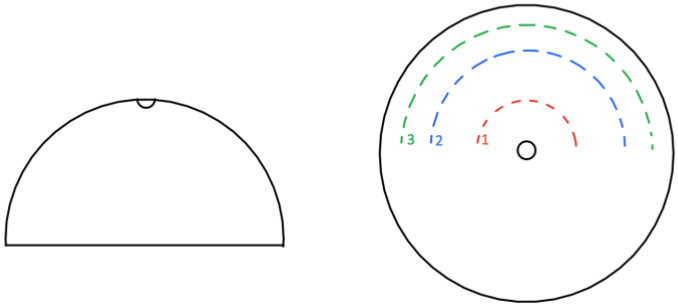

Figure 5.1: User Testing Semi-Circle Cut Setup

The second test would be done to compare how different materials and designs may interact with liquids similar to bodily fluids. This test will help determine the ability to grip the instrument, even when in contact with body fluids that make conventional instruments slippery to handle. To do this, the test subject, while wearing surgical gloves, would perform the same test above, with the No.3 scalpel and the new design having been introduced to a lubricant or oil. This will mimic the slippery conditions commonly endured in a surgery. The test subjects would then be asked to provide feedback on how comfortable they feel using these designs in comparison to current handles.

The third test would include a mole removal simulation. Section 3.2.3 mentions how mole removals are a common surgery that can be difficult to do with current scalpels. To simulate this and see if the new scalpel design makes this procedure easier, an irregular shape would be drawn on the grapefruit, and the surgeon would be asked to complete a standard mole removal surgery around the mole drawing on the other halves of the grapefruits that were not drawn on. This can be seen below in Figure 5.2.

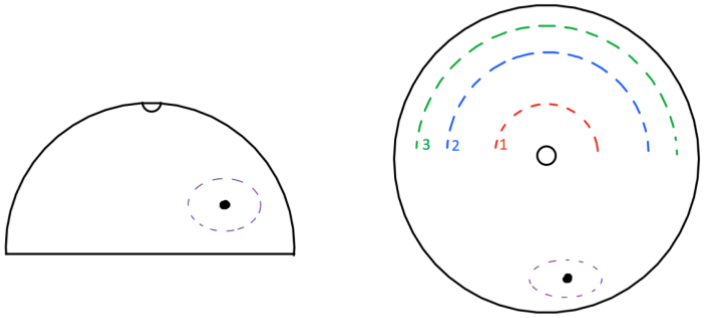

Figure 5.2: User Testing Semi-Circle and Ellipses Incision Cut Setup

The surgeons would be asked a series of questions to help us both quantify and qualify our results. These questions include asking the surgeon to rate the quality of comfort of the new instrument and the No.3 scalpel on a scale of 1 to 5, with 1 being low comfort and 5 being high comfort. The surgeon will be asked to rate the slip resistance they experienced on the new design and the No.3 scalpel on a scale of 1 to 5, with 1 being low slip resistance and 5 being high. We will also ask how accurate they felt like they were while tracing the stencil tracings with the new

design versus the No.3, and if they felt like any improvements could be made to improve their accuracy with the new design. Finally, we would ask if they had any other general comments.

Chapter 6: Final Design Validation

Final Appropriate Engineering Standards

There were final appropriate engineering standards that were taken into account for our final products. ISO 11737 is concerned with the sterilization of medical products, components, raw materials, and packaging [66]. Although packaging of our final design is something that was not a concern that was covered during the scope of this project, all of the materials used in the final designs are autoclave sterilizable and EtO sterilizable, complying with this standard [75]. The raw materials and final product have the capability to abide by this regulation. More testing and information has to be researched in terms of packaging the designs.

ISO 10993-5 which is concerned with biocompatibility and cytotoxicity was also considered when choosing our materials [67]. Teknor Apex's medical grade TPEs, which is what is to be used for our device, are ISO 10993-5 compliant, and the stainless steel on the handle, which is used in most scalpels today, is also of a medical grade, showing its compliance with this standard [76].

Another standard that was taken into account was ISO 13485, which details requirements of a quality management system that a company must show to prove its ability to create medical grade materials or medical devices that abide by regulatory requirements and customer needs. [77]. The medical grade stainless steel that is used in current scalpels abides by this standard for it to be used as a medical device, and the medical grade TPE sold by Teknor Apex also abides by this standard [75].

Finally, ISO 7740 defines the dimensions of fitting features for detachable scalpel blades and the handles. This ensures interchangeability of scalpel parts from different manufacturers [70]. The blade fittings were also considered for the final design.

6.1 Economics

The proposed design will have an effect on the economy, especially the disposable version. One study that investigated the economic advantages of single-use, sterile-packed instruments for total knee arthroplasty found that single use instruments like our disposable scalpel improve efficiency and safety in the operating room [78]. The event of surgical site infections is less likely to occur via single-use instruments according to several studies that illustrate the possibility of reusable instruments being contaminated even after sterilization [economy]. They also found that for total knee arthroplasties, there were significantly more infections at the surgical site when reusable instruments were used rather than single-use instruments [economy]. Additionally, the operating room staff members that must clean the instruments were found to save a significant amount of time not having to clean the instruments and sterilize them, improving efficiency. Overall, from the 500 total knee arthroplasty cases at each of the 200 sites the researchers tested the usage of disposable instruments at, the average cost savings that they found by using disposable instruments rather than reusable instruments saved about 994 dollars per total knee arthroplasty. This was largely due to the decreased need to sterilize trays, which is expensive. Hospitals with higher wages and sterilization costs had more apparent cost savings with single-use instruments, and they found that up to 51% of operating days could have been used to do additional procedures due to the time that was saved in the OR from having to perform less cleaning [78]. As a result, the reusable instrument may not have

much economic impact as current instruments, but the disposable version may have a significant impact. It may even entice hospitals to pursue other disposable instruments, improving their efficiency more.

6.2 Environmental Impacts.

As with most consumable products, these scalpel handles do not provide any major positive changes to the environment. The disposable scalpel handles are made out of Polypropylene, a hard plastic. These handles are used for a total of one operation, and are meant to be disposed afterwards. The negative impacts that the disposable handle will have on the environment is equal to the current standard of the competitors on the market. Within recent years, Polypropylene has been optimized to cause a lower negative impact on the environment. The chemical makeup of polypropylene does not have any toxic components. However, Polypropylene has a slow degradation rate [79].

The reusable scalpel handles are made of two primary materials, stainless steel and thermoplastic elastomer. The effects on the environment are lesser as these tools are meant to be reused. Due to the lower durability of the thermoplastic elastomer, the grip portion of the reusable handle would need to be replaced every so often due to wear on the material. Because of this, the grip portion may cause a similar negative effect on the environment to that of the Polypropylene. Both the Polypropylene and the thermoplastic elastomer would be disposed of by biotrash disposal.

6.3 Ethical Concerns

With new surgical instruments comes a learning curve for surgeons to undergo in order to achieve proper usage of the instruments. Although a procedure using current scalpels and our proposed design would be the same, the incisions that the surgeons make on the patients using the proposed design will inevitably feel different than incisions made using current scalpels. As mentioned in section 2.1, sufficient practice with a surgical instrument instils a learned sense of haptic feedback associated with each instrument, which is necessary for a surgeon to better understand how surgical procedures feel in relation with the patient, tool, and in their own hand. The tactile and force sensation from different tissues in the body can help guide the surgeon and also provide information on the orientation and location of the tools they are using, and how hard to press the scalpel on the bodily tissue that they are making an incision on. A new instrument, regardless of how similar the haptic feedback the new instrument demonstrates in relation to current instruments, would require a new understanding of the haptics of that new instrument.

According to an article written by the Society of American Gastrointestinal and Endoscopic Surgeons on ethical considerations involving new surgical instruments or techniques, when new instruments and techniques are created and shared experience with the new device is limited, there is a need for early users to document the outcomes of using these instruments. This helps to improve the number of shared experiences with the device in early clinical use of the instrument, as well as allow more surgeons to ask for improvements on the device to be made before mass production of it [80]. It’s also critical for surgeons to gain enough training on the device on skin or flesh analogs prior to using them in the operating room, to ensure that their patients are not being put at risk due to a surgeon’s lack of confidence associated with the proposed scalpel [80].

6.4 Health and Safety

Both the disposable and reusable design were made to address issues that are associated with the use of the current block scalpel design. The age-old design of the surgeon's scalpel has made very little change, in an ever expanding medical world. Tools become covered in bodily fluids and become slippery when handled with surgical gloves. Oftentimes tools need to be swapped out for clean, dry scalpels to minimize slip. In addition, the rectangular shape of the scalpel does not fit comfortably in the hand and can hinder movement or rotation of the tool [53]. These can lead to slipping and injury to patients or doctors, and directly impact the safety and health of those involved.

To combat these design limitations, the increased curvature and addition of a grip material and texture has been incorporated into the design for increased gripping ability of the surgeons during procedures. The ergonomic scalpel will allow for an increase in the safety of both the surgeon and the patient. Both the material and textures of the grips have been chosen because of their comfort and data showing increased coefficient of friction. Increasing the friction, and ensuring the comfort of the user, allows the doctors to have better haptic feedback with their instrument, and better control of the procedures they are performing. More importantly, the addition of the texture is intended to limit the hand slipping down the tool when applying pressure to perform a cut. The round shape of the tool will allow the surgeon to perform circular or elliptical cuts without having to adjust the instrument, leading to cleaner and more precise cuts, which can minimize scarring. With better control over the instrument, and less need to swap instruments during surgery, this can improve incidental poking injuries for all parties in the operating room. As stated previously, scalpel injuries are seen in up to 15% of surgeries, and pose a risk of blood contamination between user and patient [6]. Increasing the ergonomics of this tool and addition of a grip section can increase the safety of the patient and staff in the surgical room.

Other aspects of the design, such as the two-part assembly and the materials are chosen greatly impact the stakeholders in this project. The two-part assembly was specifically designed to minimize bodily fluids from building up between the TPE and metal interface, which allows for a more thorough sterilization between uses. Additionally, giving the surgeons multiple grip textures allows them to choose which grip they are most comfortable with, instead of having to adapt to a texture that might not be ideal for them. The materials were all chosen based on biocompatibility, sterilizability, and other medical standards to ensure the best quality tool for the job. All these aspects combined into one design ensures improved health and safety for the medical staff and the patients who are the most important stakeholders in the project.

6.5 Manufacturability Prospects

The next step in the project is large scale manufacturing. Prototype creation and large-scale manufacturing typically follow different processes. The goal of a prototype is to test that an idea can be actualized. The goal of large-scale manufacturing is to maximize the efficiency of production. Prototype production may be slow and expensive while large scale manufacturing should be efficient.

Manufacturing will be executed in two parts. The steel base component will be manufactured separately from the TPE grip component. The grip component will be manufactured via injection molding, a process in which pressurized melted material is injected into a die where the material fills a mold and solidifies into a part. Injection molding is ideal because it allows cost efficient manufacturing quickly of many precisely detailed parts since the process is automated. The texture design will not be lost using this method. To achieve this, an

initial mold will be designed in Solidworks to interface with an injection molder. The simplest injection mold design is that of an insert that fits into aluminum frames within the injection molder. The insert must be made out of a 3D printable material that has high temperature resistance and toughness. Specialty materials for this purpose exist including Formlabs High Temperature resin and Stratasys Digital ABS [81].

This manufacturing would be produced by an external company that has injection molding plants that adhere to the regulations of manufacturing medical devices in facilities such as ISO-13485.

Chapter 7

The results of the testing detailed in Chapter 5 that was completed with one of our MQP teammates can be seen below. Ideally, the scalpels would be tested with several surgeons; however due to the COVID-19 pandemic, these had to be tested by the teammate who had the scalpels with her. It was not feasible to send the scalpels to Dr. Dunn for testing because the hospital was concerned with combatting the pandemic. To prove that the user testing protocol and the process of data analysis was sufficient, the testing was done by one of our teammates and her results can be seen below. ImageJ was used for this analysis.

In the table below, the "ratio" value in the table and in the bar graph depicts how close the user was able to make incisions that followed the elliptical symmetry for the skin growth removal simulation. The closer the number is to 1, the more symmetrical the cut was. It is evident that Straight Knurl 3mm did the best, closely followed by Knurl Bump Pivoted to be Squares, and the scalpel without a texture. The ones that did the most poorly were Knurl 4 3mm and Checkered Knurl 6mm.

Grapefruit	**Scalpel**	**Area Hemi-Ellipse A (cm)**	**Area Hemi-Ellipse B (cm)**	**Difference (cm)**	**Ratio**
1	Knurl Bump 6mm with greater depth	3.087	4.238	1.151	0.72
2	Knurl 4 3mm	2.545	1.690	0.855	0.66
3	No Pattern	5.735	6.759	1.024	0.85
4	Checkered Knurl 6mm	4.976	3.450	1.526	0.69
5	**Straight Knurl 3mm**	**6.913**	**6.121**	**0.792**	**0.89**
6	No.3 scalpel	5.251	3.929	1.322	0.75
7	**Knurl Bump**	**2.665**	**2.290**	**0.375**	**0.86**

	Square				

Table 7.1: Ellipses Cut Symmetry User Testing

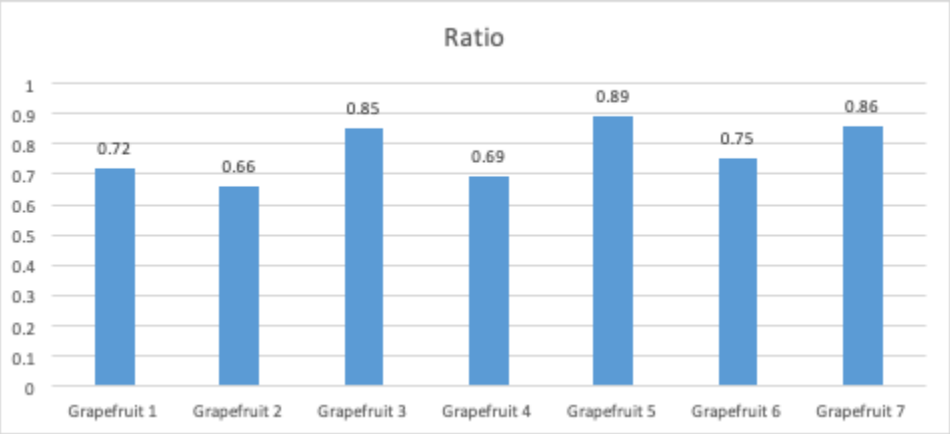

Figure 7.1: Ellipses Cut Symmetry User Testing Ratio

Qualitative

After the user completed the test, they were asked to rank the comfort they experienced with each scalpel grip and the slip resistance they experienced when the scalpel was dipped in oil. The results can be seen in the table below.

Scalpel Prototype	**Comfort (1 = low comfort, 5 = high comfort)**	**Slip (1 = worse slip resistance, 5= excellent slip resistance)**
Checkered Knurl 6 mm	**5**	**5**
Straight Knurl 3mm	4	3
Knurl 4 3mm	3	2
Knurl Bump 6mm 1.5mm offset	**4**	**5**
Knurl Bump Pivoted Squares	**4**	**5**
No texture at all	2	2
No.3 scalpel	1	1

Table 7.2: Textured Scalpels Comfort Rating

In terms of comfort, Checkered Knurl 6 mm was the most comfortable for the user, followed by Straight Knurl 3mm, Knurl Bump 6mm 1.5 offset, and Knurl Bump pivoted to be squares. The user felt that the worst for comfort was the No.3 scalpel and the scalpel that did not have any texture at all. The most slip resistant patterns scored equally. They were Checkered Knurl 6 mm, Knurl Bump 6mm 1.5 offset, and Knurl Bump pivoted to be squares. The reason why the user scored Checkered Knurl 6mm higher overall than the Knurl Bump designs was because the Checkered Knurl Pattern 6mm had enough space between each raised diamond where rotation of the scalpel was easier. However, even with this space, the user felt that when the device was covered in oil, the pattern was still able to inhibit her hand from falling toward the blade while cutting. While the Knurl Bumps did well in the slip resistance aspect, it was difficult for the user to move their fingers at all. This inhibition of any movement made the rotational cuts more challenging in comparison to the Checkered Knurl pattern.

Knurl 4 3mm was a pattern that did exceptionally well in the coefficient of friction testing and in the literature. However, according to the user, the pattern was not raised enough for it to have enough friction when the user had gloves on, which caused the user's to feel like their hand was slipping toward the blade when it was covered in oil. Straight Knurl 3 mm was also a design that was confirmed in the literature and in coefficient of friction testing. According to the user, this pattern was comfortable until rotational motion was being performed. Since the straight-line pattern goes across the circumference of the grip, the user felt like there was barely any friction when the user was performing elliptical incisions, which could cause slippage in dry or wet conditions. As a result, according to this user, Checkered Knurl 6mm performed the best in terms of comfort.

Although Checkered Knurl scored highly in the comfort area, it scored low in the precision area. This can be attributed to the user not being a surgeon who knows how to make the elliptical cuts, however, so the precision data is not reflective of a user who has experience with these procedures. However, this data is still useful because it provides validation that the protocol for this experiment is usable and would yield accurate information if a surgeon were to complete the protocol.

It is likely that if every teammate completed the test, that these opinions would be different. It is also likely that if we did this testing with surgeons who have different specialties, the grip choice between them would be varied, or different surgical procedures could have different grips that are the most beneficial to use for that specific surgery. One may need a grip that completely inhibits any rotational motion, for example. This only validates that the final design choice made would effectively please a wide variety of people. Allowing the surgeon to pick the grip of their choice out of several tested options that are proved to be effective in the operating room, would eradicate the need to choose the "best" grip design. The "best" grip design could vary between different surgeons and even different procedures.

Literature Comparison

The texture designs in this project were based on current literature, testing, and feedback from surgeons at University of Massachusetts Memorial Medical Center.

From our initial literature review it was anticipated that diamond patterned texture would provide the scalpel with the best grip under wet conditions compared with a straight knurl texture [30]. It was also anticipated based on past literature that textures oriented perpendicular to the direction of pulling force would provide the highest coefficient of friction [[51]. Additionally, it was also found in a study that ridge height, width, and spacing making up the texture affect the

coefficient of friction against a gloveless finger. This study recommended the use of 10 mm spacing between ridges, a ridge height of around 2.5 mm, and a short ridge width of around 1mm to create the optimal gripping texture. The study also noted that depending on the height and width of the ridges, the optimal ridge spacing is also likely to be less than 10 mm especially for hand gripped textures [50].

Our own results show that the straight knurl pattern with 3 mm ridge spacing and the pivoted (square) knurl bump pattern performed the best in the user test in which the subject performed an elliptical incision to remove a hypothetical mole from a grapefruit. The aim of the incision is to create a shape as symmetrical as possible. The incisions made with the Straight Knurl 3mm and the Knurl Bump Pivoted textured scalpels were found to possess the highest symmetry of all the cuts. Knurl 4 3mm and Checker Knurl 6mm texturized scalpels performed the most poorly during this test. These results deviated slightly from what was anticipated based on the literature. Straight Knurl 3mm for one does not offer any perpendicular texture in the direction of rotation which hypothetically should decrease the rotational grip. However, the Knurl Bump Pivoted (Square) texture did well on this test as well. This texture does offer texture in both planes. Based on the literature, we anticipated this texture to do well in user testing and it did. Both textures display ridge spacing less than 10 mm apart, however, so do the textures that did the most poorly on this test. The discrepancies between our results and those expected based on previously published literature could be to do with a number of factors. Most importantly, our test was novel. None of the literature we examined performed testing where textured instruments were being used as intended. Perhaps when actually using a scalpel, maximum grip force is not necessarily ideal, especially since the instrument is required to rotate in the surgeon's hand. Additionally, our sample size was quite small and not made up of trained surgeons. There is a good chance that the data we collected is not reflective of the population we are targeting.

Users rated the Checkered Knurl 6 mm, Straight Knurl 3 mm, Knurl Bump 6mm 1.5 offset, and Knurl Bump Pivoted (Square) textures the highest in terms of comfort. The textures that scored the highest during the elliptical incision user testing, Straight Knurl 3mm and the Knurl Bump Pivoted, scored high in terms of comfort as well. The studies looked at did not investigate user comfort but there could be a correlation between grip effectiveness and comfort. The untextured scalpel and the control No.3 scalpel scored the lowest in terms of comfort. Knurl 4 3mm was a pattern that performed well in the coefficient of friction testing and in the literature. However, according to the user, the pattern was not raised enough for it to have sufficient grip. Straight Knurl 3 mm was also a design that was confirmed in the literature and in coefficient of friction testing. According to the user, this texture did not provide sufficient grip for rotational motion.

Chapter 8

Recommendations:

After considering design criteria, manufacturing, testing, and feedback from our peers, we recommend the use of the two part "pencil grip" design. This design was ultimately chosen because it functions similarly to the one-part design in improving grip, but the interchangeable grips allow for additional benefits for the buyer and manufacturer. This product would allow for an easier manufacturing process and saves on production costs. From the testing and feedback that was received: the textures recommended for final production are as follows: Checkered Knurl 6 mm, Straight Knurl 3 mm, Knurl 4 3 mm, the Knurl Bump 6 mm texture with a greater depth, and the Knurl Bump but with slight alteration with the orientation. This allows buyers to

choose and swap grips according to their favorite grip with varying colors. We believe the ability to customize the tools would be a more marketable product than one universal grip. In terms of long-term use of the tool, since the rubber grip will degrade from repeat sterilization quicker than the metal handle, replacing only the grip portion is more cost effective than having to buy a new tool. Sterilization of the scalpel is recommended to be done as separate parts for ensuring the tool is fully clean and not storing hazardous material in crevices.

For future work on this project, it is recommended that further testing be done on the grip textures and user testing of the final prototypes. The final grip textures were chosen based on coefficient of friction testing done by the group, and personal preference feedback from the group and both advisors. It is suggested that the textures that performed well in coefficient of friction testing, as well as Dr. Dunn's preferred textures, be evaluated by user testing outlined in chapter 5. Further testing will provide a larger sample number, and more reliable data. One key aspect of testing is to see how the different textures and shape of the tool affect the accuracy and precision of surgeons. Additionally, feedback on comfort and aesthetics is important in determining what prototypes should move forward to final production.

Conclusion:

As mentioned, current designs of scalpel handles are not ideal for hand ergonomics and can lead to difficulties for certain cutting motions or slipping of the instrument. The goal of this project was to address the need to limit slipping while taking into consideration comfort and mobility of the instrument. The final Pencil grip design was created to enhance the shape of the Dr. Dunn's already existing handle as well as to incorporate a rubber material grip portion to Dr. Dunn's design. The addition of a texture pattern and choice of material was utilized to increase the friction between the surgical glove and the grip portion of the tool. Testing protocols were created to determine which surface textures provided the highest coefficient of friction, as well as determining which prototypes were comparable to the precision of the original scalpel design. Feedback based on Dr. Dunn's professional experience in the field and personal preference also aided in determining which grips were recommended for manufacturing.

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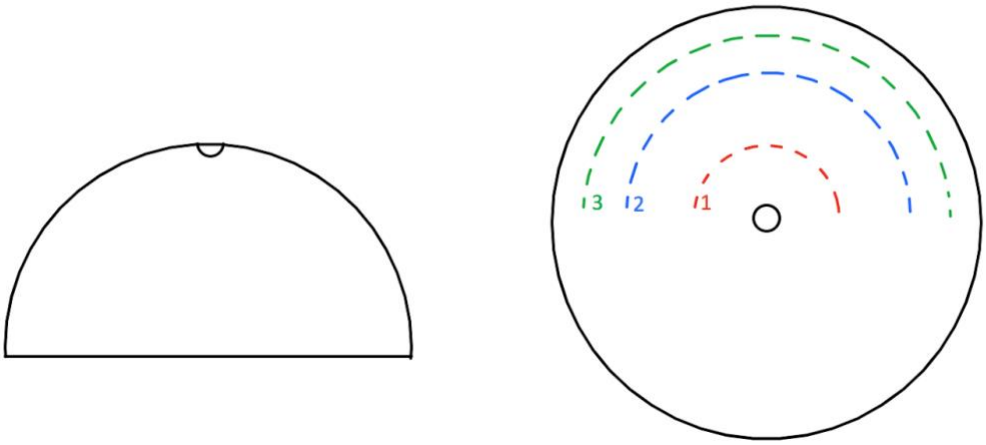
Appendix: Testing Protocols

****Tests must be done in the following order:**

I.DRY TEST

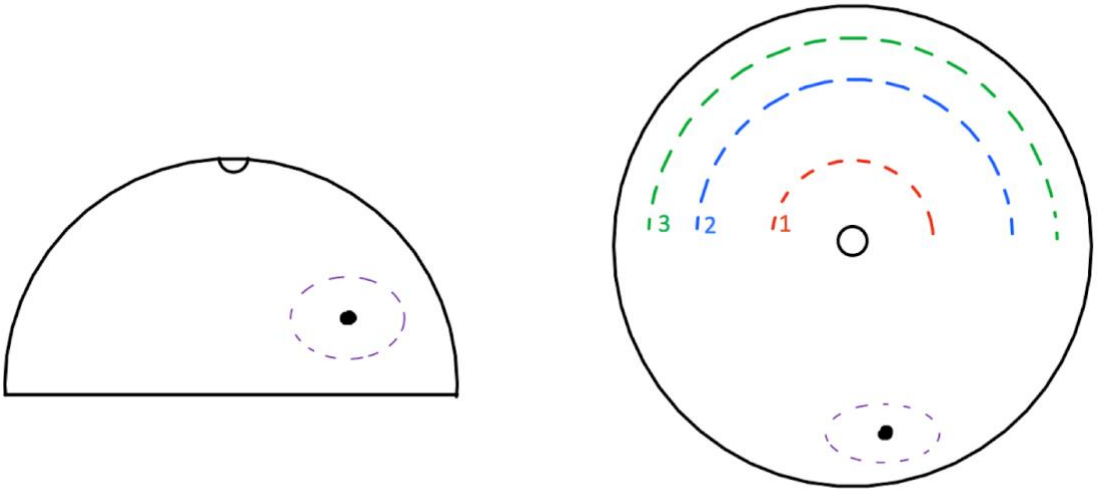
1. Setup: cut grapefruit into halves and place onto table. Layout scalpels of choice in order of testing, as well as No.3 scalpel.
    1. Layout surgical gloves
    2. Use a compass to draw concentric semi-circles on the grapefruit using a light pink or green color seen below



2. Begin warmup:
    1. Have the surgeon trace designs to allow for multiple tests/trials with the scalpel prior to the test
    2. Total warmup time: 1-2 minutes for each practice run, on the first half of warmup-grapefruit.
    3. Throw out practice run
3. Begin testing
    1. Give surgeon 30 seconds minute per cut: total of 1.5 minutes for the dry run
    2. Label each grapefruit: student number, grip texture,
    3. Take pictures to then collect accuracy trace data on ImageJ
    4. Repeat steps a-d with each scalpel

II. MOLE REMOVAL TEST:

1. On other side of the grapefruit used in the dry run, draw a small circle to emulate a mole seen below (mole removals require symmetrical elliptical cuts, which are deemed difficult to do with the current scalpel)
2. Surgeon is asked to cut what would be the dotted line in the figure below (but the dotted line will not be there; they are expected to make the symmetrical cuts without guidance



4. Begin testing
    1. Surgeon has 30 seconds minute side: total of 1 minute for the dry run
    2. Label each grapefruit: student number, grip texture,
    3. Take pictures to then collect accuracy trace data on ImageJ
    4. Repeat steps a-d with each scalpel

III. OIL TEST

1. Setup: cut grapefruit into halves and place onto table. Layout scalpels of choice in order of testing, as well as No.3 scalpel.
    1. Layout surgical gloves
    2. Use a compass to draw concentric semi-circles on the grapefruit using a light pink or green color seen below
2. Begin testing
    1. Surgeon has 30 seconds minute per cut: total of 1.5 minutes for the oil run
    2. Label each grapefruit: student number, grip texture
    3. Take pictures to then collect accuracy trace data on ImageJ
    4. Repeat steps a-d with each scalpel

SURVEY AFTER TESTING

- Ask surgeons on a scale of 1 to 5 to quantify comfort
    - 1= low, 5= high
- Ask surgeons on a scale of 1 to 5 to quantify slip
- How accurate do you think you were/Do you think there is anything about the design that could have improved your accuracy?
- Any other general comments?

Outcome: Determine best textures and create sterilizable models with TPE

IMAGEJ ANALYSIS

1. A photo taken from the ellipses incision test is opened in ImageJ
2. Using the Polygon Selection Tool, one half of the ellipse cut is selected (hemi-ellipse A).
3. Hemi-ellipse A's area is measured in pixels and then converted to cm using a known length in the analyzed image.
4. The other half of the ellipse cut is then selected using the Polygon Selection Tool (hemi-ellipse B)
5. Hemi-ellipse A's area is measured in pixels and then converted to cm.
6. The ratio between the areas of each symmetrical half should be as close to 1 as possible.