

Wound Edge Approximation

Final Report

Biomedical Engineering Design 400

Department of Biomedical Engineering

University of Wisconsin

December 11th, 2019

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Abstract

Each year, 6 million laceration cases are treated in emergency departments. With lacerations larger than 2 cm, skin tensions pull the wound edges apart, making repair difficult. Clinicians often require a second individual to approximate wound edges while the wound is closed. Currently, no device exists designed solely to approximate wounds. The team designed a device to accurately and repeatedly approximate wound edges, allowing the clinician use of both hands during repair. The prototype is a metal frame consisting of two identical stainless steel sides, which are connected via thumb screws and nuts through hollow slots. The device is assisted by four circular adhesive silicone bumpers, which are placed at the four corners of the wound. The opening of the device is placed around the bumpers, and the thumb screws can be adjusted until the long edges are brought together and the wound is approximated. The team utilized the Makerspace and TEAMLab for fabrication. Through MTS testing on a synthetic skin, tensile forces induced during approximation with the device were found to range between 27.68 and 38.95 N. Differences in device displacement averages during use on bare and SkinPrepped skin (0.7300 and 1.500 mm, respectively) were negligible. An average pain rating of 0.75 out of 5.0 was found with shallow indentations remaining in the skin upon removal. Further modifications and testing are required prior to device use in clinical settings.

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Introduction

Motivation

More than 10% of all emergency room visits involve the repair of a cut or laceration; during such repairs, skin tension pulls the wound apart while the clinician is attempting to approximate the wound edges [1]. Repair is therefore difficult, and imperfect approximation can lead to scarring and poor healing of the wound. This problem is often solved within operating rooms with wound closure systems for large wounds since multiple physicians can assist in wound approximation and closure. However, it poses a challenge for physicians in emergency rooms, urgent care clinics, and office settings when repairs on small wounds need to be completed quickly by one individual. Currently, there are a lack of devices on the market that function solely for wound edge approximation; many healthcare professionals rely on a second person to approximate the wound edges or attempt to use forceps to hold the wound together while it is sutured or glued. Surgical tools such as forceps are not designed to approximate wound edges, for they require at least one of the clinician's hands to function during the wound approximation, leaving only one free hand to partake in the wound closure. Forceps and other surgical tools may also pinch the skin and be uncomfortable to the patient. Therefore, there is a gap in the market for a device that allows accurate and quick wound approximation while functioning autonomously once placed on the skin to provide the clinician with both hands to participate in wound closure.

Existing Devices

Several products exist in the market known as wound closure systems that function to approximate wound edges and close the wound for healing. The apparatus the team designs will only possess one of these functions: approximating wound edges. The device will not need to include a wound closure function, for the wound will be closed primarily with tissue adhesives or sutures. The wound closure systems currently available include the following:

DermaClip: U.S. Pat. Nos. 8,157,839, 9,028,529, 9,301,760, and 9,603,596

The DermaClip is a skin closure device that allows for fast closure of skin surface wounds (Fig. 1). The closure system is non-invasive and single use only. The design consists of plastic sutures with a hinge between two layers of adhesive. To use, the area between the adhesives is aligned with the wound. The plastic tabs are then pulled tightly to lock them in place and pull the edges of the wound together; the device is left on the

skin during wound healing [2].

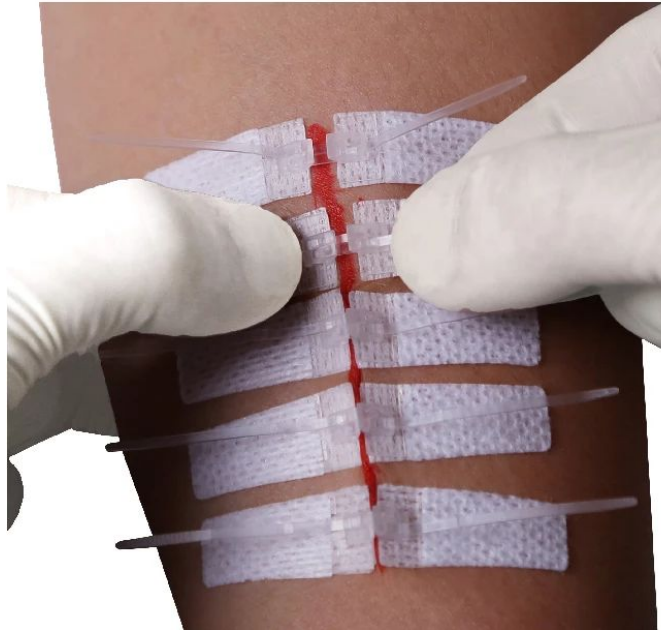


Figure 1. Image of multiple DermaClips being used to seal a wound [2].

microMend: US20170333039A1

The wound closure system known as microMend (Fig. 2) has a design similar to a bandage, but the adhesive backing contains two arrays of micro-staples. The device is placed across the wound one side at a time, so the staples can insert into the skin, approximate the wound edges and close the wound. The holding strength is similar to that of sutures, and the staples are said to inflict minimal to no pain [3].

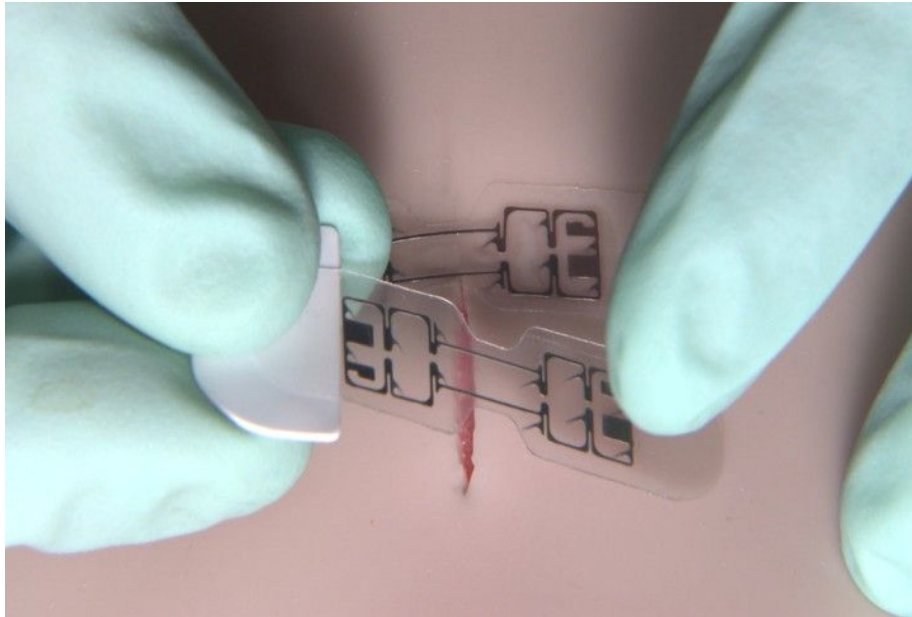


Figure 2. Image of the microMend device being applied to a wound [3].

Steri-Strip:

The adhesive skin closure system known as Steri-Strip (Fig. 3) is made of acrylate-based adhesive strips reinforced with polymer filaments for strong closure of skin lacerations. The strips offer a faster, non-invasive alternative to sutures and staples. The device is placed across the wound once the wound has been manually approximated, and stays in place during wound healing for around 7 days [4].



Figure 3. Image of Steri-Strips being used to seal a wound [4].

Problem Statement

A clinical tool will be developed to approximate the wound edges while the wound is either sutured or glued, acting as a “second pair of hands” for the physician. Wound edge approximation is difficult in office settings, urgent care clinics, or emergency departments because wound repairs need to be completed rapidly by one individual; however, approximating wound edges frequently requires more than one clinician per patient. Additionally, there are no products on the market that solely approximate wound edges. In addition to saving time for the clinician, the wound edge approximating device will also allow one clinician to easily and accurately approximate the wound edges before wound closure occurs. The device will consist of a rectangular-shaped metal frame that can be placed around the edges of a wound two to five centimeters in size. The long, slender sides of the rectangular frame can first be drawn together using a fastener system on the short sides to overcome the splaying tension from the skin until the wound is well-approximated. The device can then be locked into position in order for the clinician to repair the wound. The final design must be easy to use by healthcare professionals and should not impair the clinician’s access to the wound for closure purposes.

Background

Background Research

The skin is the largest organ of the human body weighing approximately 4 kg with a surface area close to two square meters [5]. Consisting of three different layers (epidermis, dermis, and hypodermis), the skin protects the body from the external environment and mechanical injuries. Within its physiological limits, the skin behaves almost like a rubber with an initially weak nonlinear response that becomes stiffer at high stretch levels [6]. When stretched above its physiological limit, the skin actually expands its surface area to reduce the mechanical loading. The skin is highly anisotropic, meaning that its measured biomechanical parameters vary with direction and location. Anisotropy is demonstrated in the skin's Langer lines - areas of maximum tension that generally correspond to the paths of collagen fibers located in the dermis (Fig. 4) [5].

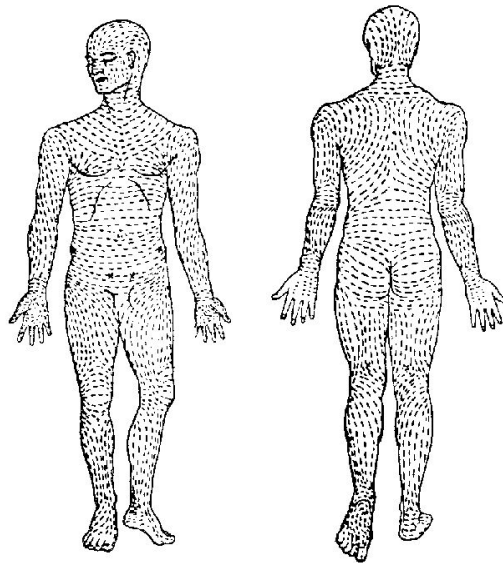


Figure 4. Langer lines, also known as cleavage lines, are paths of greatest tension that tend to follow the underlying collagen fibers within the dermis. Although they are present all over the body, these lines are only visible in certain areas such as the creases of the palm [7].

In response to applied forces, the skin deforms. The ability of the skin to deform and return to its original shape is known as elasticity. When the skin's elastic limit is exceeded, it will not return to its initial state once the applied forces are removed; the skin will have a permanent deformation which results in a change in stability and orientation of skin elements. The modulus of elasticity (Young's Modulus, E), defined in Eqn. 1, characterizes the skin's

resistance to elastic elongation and defines the relationship between the stress (σ) and strain (ϵ) that the skin experiences when forces are applied (Fig. 5). Typically, skin has a modulus of elasticity between 0.05 MPa to 0.15 MPa [6].

$$E = \sigma/\epsilon$$

Eqn. 1

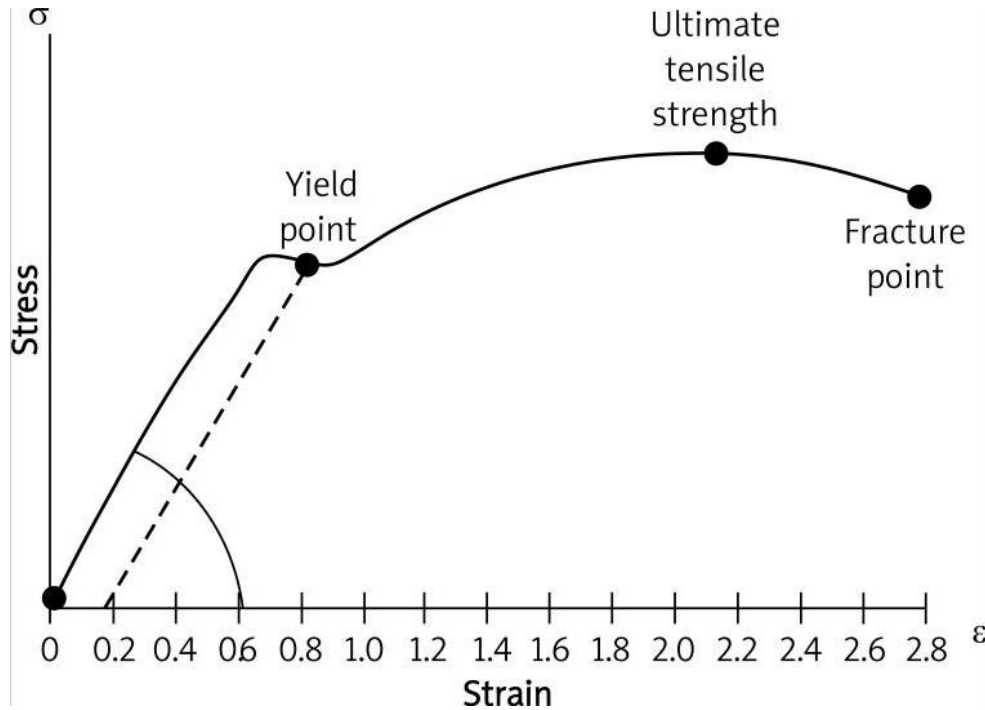


Figure 5. General stress-strain plot. The slope of the line before the yield point is known as the modulus of elasticity and can be calculated by dividing the stress by the strain. The modulus of elasticity characterizes the skin's resistance to elongation [6].

When a skin wound forms, there are three main pathways of healing that can occur (Fig. 6). Which category a specific wound falls under depends on tissue type and the method of closure [8].

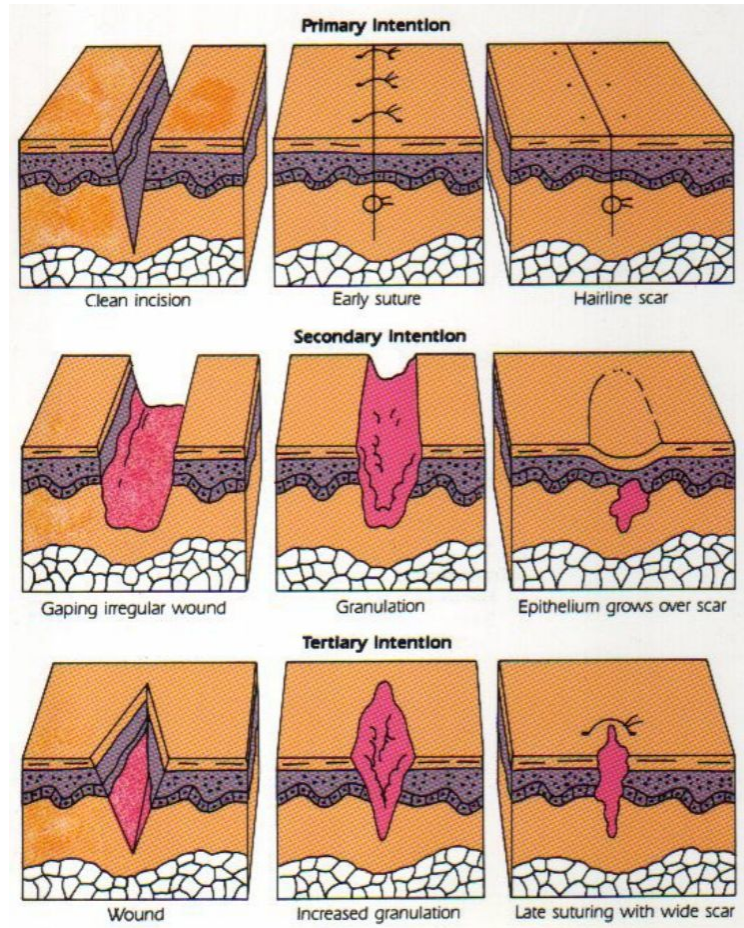


Figure 6. Graphic displaying the three main forms of wound healing, with primary being the most desired and tertiary being the least desired [9].

The first and most desired form of wound healing is primary intention. In this pathway, the wound heals in the minimum amount of time with minimal scar tissue formation and no wound edge separation. Primary intention occurs in three phases: Inflammatory, Proliferative, and Remodeling. The Inflammatory stage occurs in the first few days of wound formation. There is an increase in fibroblasts, cells, and blood supply to tissue at the site of the wound [8]. This effect lasts three to seven days. In the beginning of this phase, tensile strength of the skin does not increase significantly, so it is important that the wound closure method is strongly holding the wound edges together. In the Proliferative phase, granulation tissue forms due to fibroblasts forming a collagen matrix. This takes place from day three to the end of the healing process. After a variable amount of time, enough collagen has formed where the tissue can withstand normal stress conditions. Natural wound contraction pulls the wound edges tighter together. This can be beneficial, but is very harmful if the wound is on the hands, neck, or face, as it can cause disfigurement and excessive scarring. A major reason that primary intention is preferred is that it leads to minimal contraction response, thus decreasing the risk of scarring. The Remodeling

phase consists of paling of the scar tissue as blood supply to the wound area is decreased. The initial volume of granulation tissue determines the final amount of collagen formed, resulting in the final scar formation.

The second healing pathway is secondary intention, a much longer process than primary intention. It is caused by infection, excessive trauma, tissue loss, or imprecise wound edge approximation. If this occurs, the wound is sometimes left open to heal naturally from the inner to outer surface. Granulation tissue with myofibroblasts closes the wound by contraction, greatly increasing the chance of large scar formation [8]. Excessive granulation tissue can protrude above the wound surface and prevent epithelialization, worsening the appearance of the scar. The third pathway of healing is delayed primary closure, or tertiary intention. This is a surgical method for managing contaminated, dirty, or infected traumatic wounds, or if the wound has sustained a great deal of tissue loss with a high risk of infection. Delayed primary closure is common in military medical practices, or for dealing with traumatic shooting or knife wounds. The first step is debridement of nonviable tissue by a surgeon. The wound is then left open and packed with gauze. The gauze is changed twice per day. Within three to five days, wound edge approximation can be performed using adhesive strips, previously placed but untied sutures, or staples as long as there is no evidence of infection nor red granulation tissue. Otherwise, the wound is allowed to heal by secondary intention [8].

In terms of techniques for wound closure, tissue adhesives are becoming popular in comparison to traditional sutures or staples; tissue adhesives examined in clinical studies were faster to use by clinicians and were rated less painful by patients, without requiring the use of a local anesthetic. Tissue adhesives are often a type of cyanoacrylate, which polymerize on skin in an exothermic reaction to form a strong, flexible bond [10]. Specifically, the device will mainly be used with a product known as DermaBond Mini, which is a 2-octyl cyanoacrylate (Fig. 7). The product consists of a glass ampule that can be crushed inside a plastic vial connected to the applicator tip. Once the ampule is crushed, the adhesive will freely flow out of the tip for several minutes. During such time, the adhesive can be applied to the well-approximated wound. Each layer of adhesive will polymerize in 30 seconds, and most wounds required at least two layers of adhesive for effective wound closure [11]. In addition, tissue adhesives can provide better cosmetic outcomes since there is no need for additional punctures to the skin as with sutures and staples.



Figure 7. Image of the DermaBond vial [11].

Approximation devices may also be used with SkinPrep, which is a thin film coating that is applied to the skin to assist with adhesion. It comes as a wipe or a spray and is easily washed off with soap and water after use. SkinPrep forms a barrier and reduces friction between the skin and any adhesives while they are removed. It therefore makes the removal process less painful [12]. SkinPrep may be used in conjunction with the designed prototype to help the device stay on the skin while it approximates the wound edges.

Codes and Standards

Section 201(h) of the Federal Food, Drug, and Cosmetic Act defines a medical device as “any instrument, machine, contrivance, implant, in vitro reagent that's intended to treat, cure, prevent, mitigate, diagnose disease in man” [13]. As the designed device will classify as a medical device, FDA approval is required. The device is expected to classify as either Class I, 510(k) exempt similar to the classification of forceps, indicating the device will not require pre-market approval, or Class II similar to the classification of a removable skin clip [13]. Class I medical devices are the least regulated and risky of the three device classes whereas Class III devices are highly regulated as they often involve implantation. Medical devices must all follow the guidelines put forth in the 800 series of Title 21, which is a portion of the federal code that governs medical device quality in the United States.

Within the 800 series of Title 21, the designed device must meet various regulations such as parts 803, 820, and 878. Part 803 covers medical device reporting including general provisions, applicable requirements, and manufacturer reporting. Part 820 covers quality system regulation and includes design controls, documenting controls, identification and traceability, corrective and preventive action, labeling and packing, handling, storage and distribution. Part 878 details manual surgical instruments for use including non-powered, handheld devices that

are reusable or disposable. Regulations 878.4010 and 880.5240 cited for topical tissue adhesives used in skin approximation will also apply to the designed device [14].

Client Information

The client, Dr. Nicola Charlton, MD MPH DBIM, is a certified family practitioner. She is primarily based in Milwaukee, WI at Advocate-Aurora, but also works as an associate faculty member at the UW-Madison School of Medicine and Public Health. The client has personally experienced the struggle of approximating wound edges while suturing and gluing and is passionate about assisting the team in finding a solution to the problem.

Design Specifications

The overall goal of the design is to hold the wound edges together while a clinician is suturing or gluing. While doing this, the device must stay in place and not harm the skin or inflict pain on the patient. It needs to function for wounds between 2-5 centimeters for at least 350 uses—the estimated number of uses for one device in one year. Additionally, it must be reusable and therefore sterilizable. Thus, it should withstand standard autoclave sterilization: at least 30 minutes at 121°C. The final device must not weigh more than 0.23 kilograms (0.5 pounds) and should be fabricated within the \$300 budget. Since the device will be used in a variety of settings with many populations, it should have a simple, clean, and non-threatening appearance. The design should also be easy to use by a variety of clinicians with varying backgrounds. Further design specifications can be found in Appendix A.

Preliminary Designs

Bow-Shaped Design

The bow-shaped design includes two curved arms connected at the apex by a locking-hinge system (Fig. 8). This will allow the arms of the apparatus to be opened beyond the wound width, adjusted to approximate the wound edges, and locked into position. The ends of the arms will be fitted with a slender piece of rubber or silicone (a material with a high coefficient of friction against the skin). These edges will be placed on either side of the wound, and will provide enough frictional force to pull the wound edges together once the arms of the device are brought together.

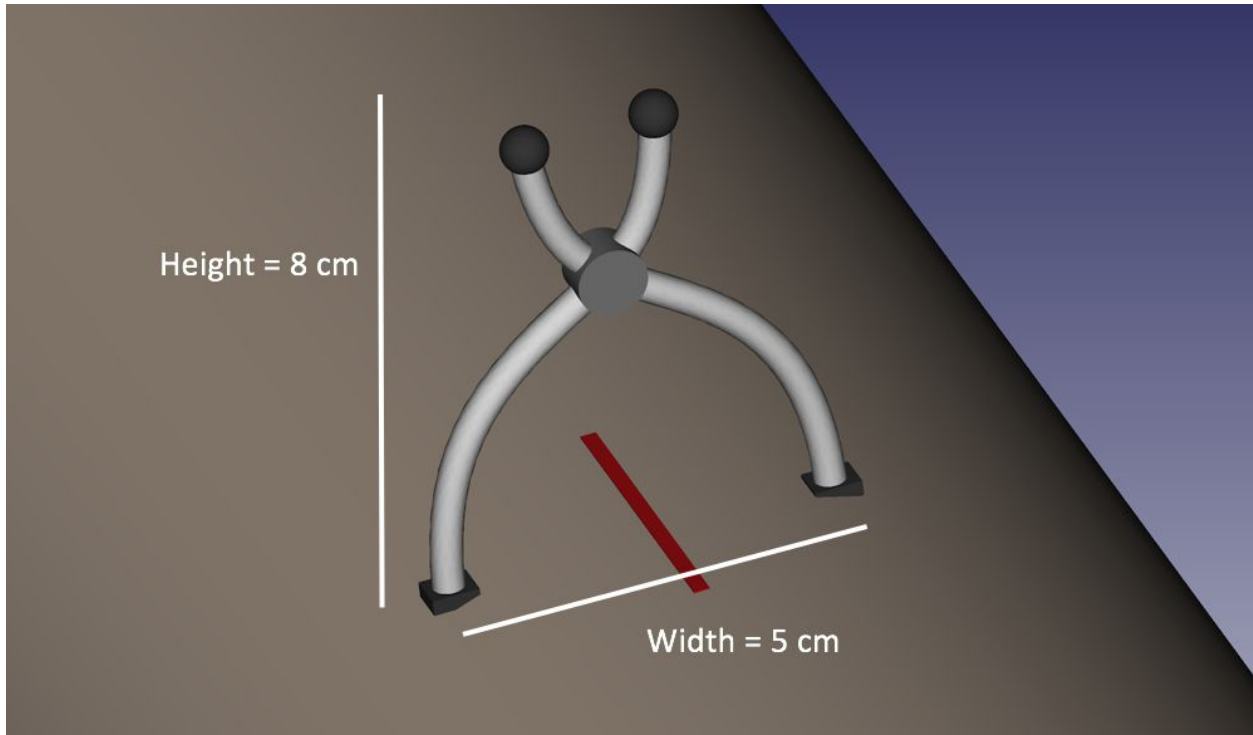


Figure 8. The bow-shaped design consists of two curved arms fitted with rubber end pieces to assist in wound edge approximation.

Hook and Loop Design

The hook and loop design consists of two adhesive patches- one with a hook and one with an elastic loop (Fig. 9). These patches are adhered to the skin on opposing sides of a laceration. To close the wound, the loop is pulled across the laceration and is secured around the hook, pulling the wound edges together.

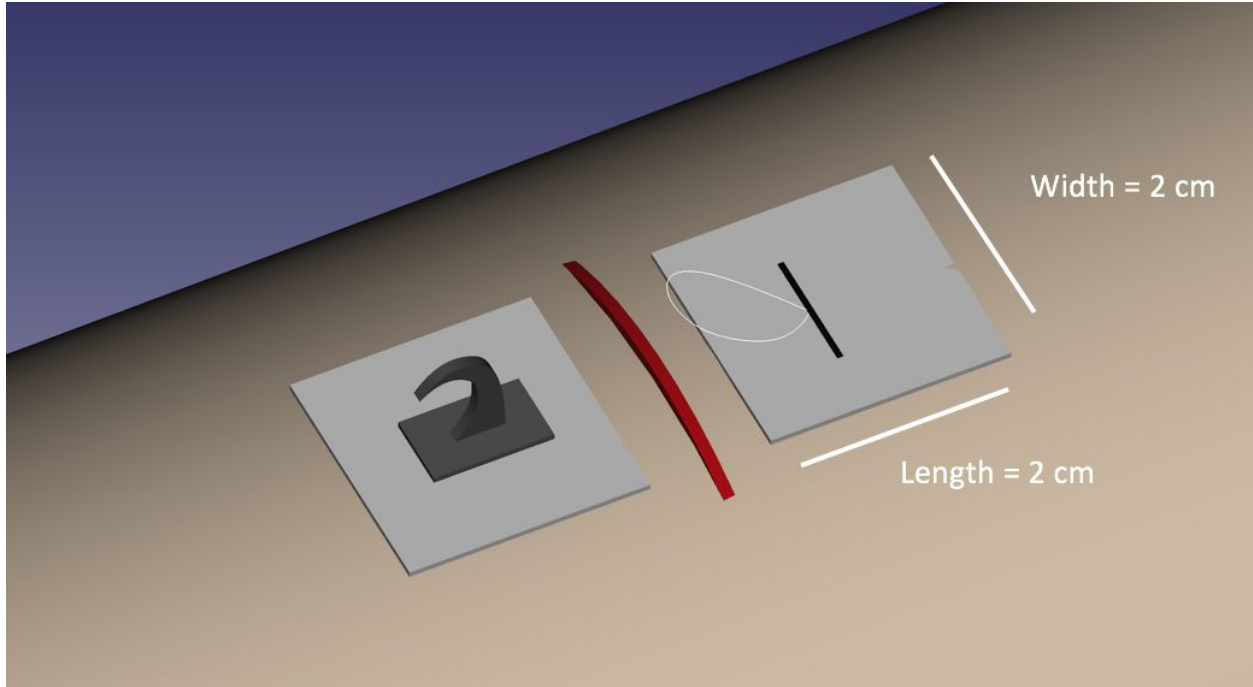


Figure 9. The hook and loop design consists of two separate adhesive patches placed on either side of the laceration. The elastic loop is connected to the hook to pull and hold the wound edges together during gluing.

Barrette Design

The barrette design consists of two long, curved arms that lay flush against the skin while in use. The arms open and close via the spring loaded hinge located at one end of the device (Fig. 10). During operation, the clinician pinches the end of the device to spread the arms to a width greater than that of the laceration. The device is then placed directly against the skin and slowly closed such that the wound edges are everted and the entire laceration is encompassed by the arms. Sutures or glue can then be applied. Removal of the barrette design simply involves the clinician pinching the end of apparatus to reopen the arms and lifting it away from the skin.

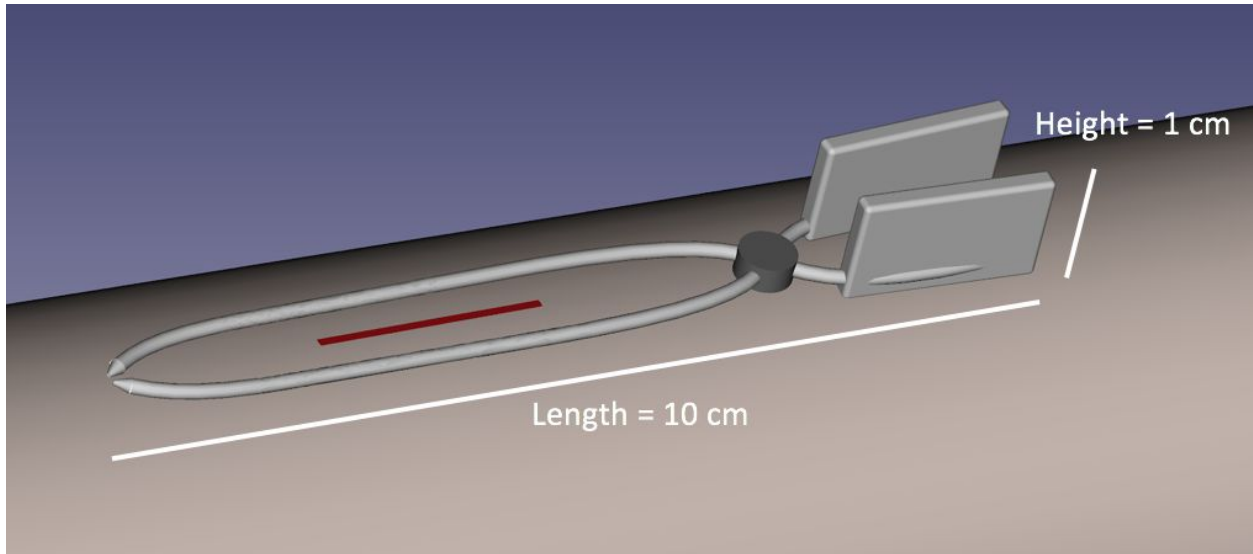


Figure 10. The barrette design utilizes a spring loaded hinge and two long arms that lay flush to the skin to pinch the wound edges together for suturing or gluing.

Rectangle Design

The rectangle design consists of two metal components connected by gears on both of the short sides of the device (Fig. 11). The long edge of the device would be made of a flexible yet sturdy material that possesses a high coefficient of friction against the patient's skin (silicone or rubber). The rectangle design would lay flat on the patient's skin with the flexible sides laying against either side of the wound to be closed. The clinician could then use the gears on both sides to draw the two sides of the rectangle together until the wound edges were approximated. The device is estimated to weigh 100 g.

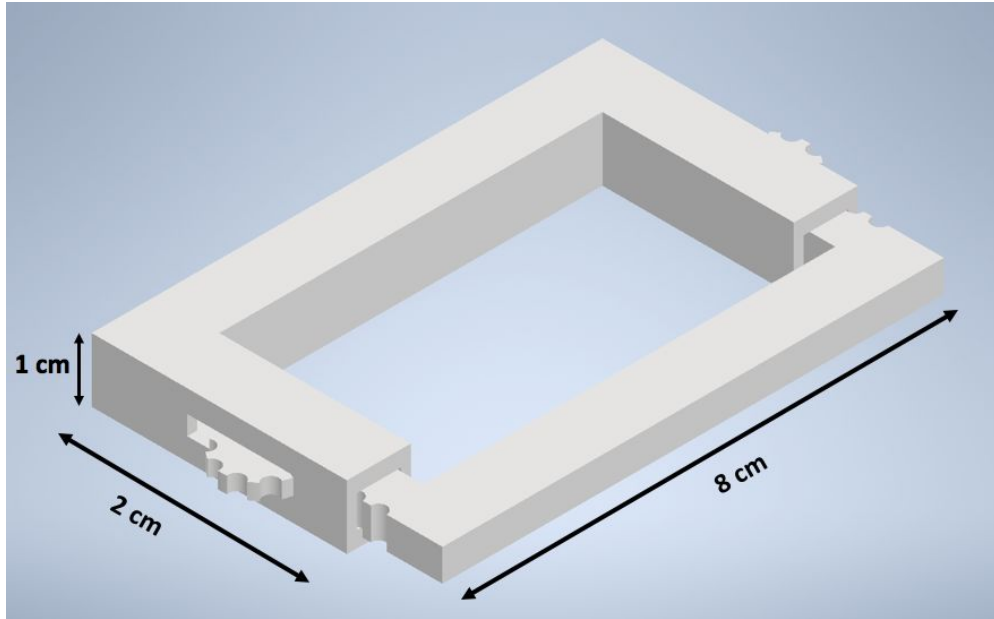


Figure 11. The rectangle design pushes the wound edges together by decreasing its width across the wound using the two gears located on its sides.

Preliminary Design Evaluation

After developing several different designs, a design matrix was created (Table 1). Seven different criteria were utilized to compare and rank the four preliminary designs.

Table 1. Design matrix evaluating the four different wound approximation designs.

Design Criteria	Bow-shaped Design	Hook & Loop Design	Barrette Design	Rectangle Design
Effectiveness (25)	(4/5) 20	(4/5) 20	(3/5) 15	(5/5) 25
Patient Comfort (20)	(4/5) 16	(5/5) 20	(3/5) 12	(4/5) 16
Safety (20)	(3/5) 12	(3/5) 12	(3/5) 12	(4/5) 16
Practicality (15)	(4/5) 12	(3/5) 9	(4/5) 12	(5/5) 15
Novelty (10)	(5/5) 10	(3/5) 6	(5/5) 10	(5/5) 10
Cost (5)	(4/5) 4	(3/5) 3	(4/5) 4	(4/5) 4
Ease of Fabrication (5)	(3/5) 3	(3/5) 3	(4/5) 4	(3/5) 3
Total (100)	77	73	69	89

Criteria

Effectiveness is a top priority for the design, which is why this category received the highest weighting of 25 points. This criterion is a measurement of how well the device can accurately and consistently approximate the wound edges in order for the wound to be glued or sutured. The design should bring the edges of the wound into contact and not interfere with

suture or glue application. The device must also maintain its grip and position on the skin during approximation.

Patient comfort and safety were both given weights of 20 points, as they are of the utmost importance while the device is in use. In terms of patient comfort, clinicians must be able to utilize the device without the use of local anesthetic on the tissue surrounding the laceration, and the wound approximation system must not be painful while placed on the patient. With respect to safety, the device must not cause any further damage to the patient's skin from excessive force or leave deep indentations in the skin upon removal. The product must not harm or pinch the user during application.

At a weighted value of 15 points, the criterion practicality refers to the ease with which the clinician can operate the device. The clinician should be able to hold the wound closed with the device in one hand, while simultaneously gluing the wound with the other hand. The design should therefore be lightweight and ergonomic.

There are currently many designs for wound closure available to clinicians. Therefore, this product should be unique in some way. The majority of these devices are used to both approximate and close a wound, while the client has asked for a product to approximate wound edges only. The product should hold the skin together while a clinician closes the wound using Dermabond or sutures. The mechanism of wound approximation should be different from devices currently on the market. Because there are few devices that solely approximate wounds, the team does not expect novelty to be a major challenge. For this reason, this criterion of novelty was awarded a weight of 10 points.

Both the criteria cost and ease of production were given weights of 5 points. Cost is a factor that the team must consider because low product cost is conducive to mass production, which is desired if the product makes it to the market. Additionally, as this product has excellent market potential, it must not be too difficult to fabricate. If the product makes it to the market, a design that can be mass produced is highly desirable.

Design Evaluations

The Bow-Shaped Design

The bow-shaped design scored high in effectiveness because the design will offer control over the wound edges and be able to repeatedly approximate wound edges. However, the design lost points because the arms of the apparatus may interfere with the suturing or gluing of the wound as they are directly above the wound. In terms of patient comfort, the design lost points because the design may pinch or hold the patient's skin in a way that is uncomfortable. This pinching is not expected to harm the patient but may provide a sense of discomfort. For safety, the ends of arms are protected with a soft material that will contact that skin to not harm the

patient. However, the device lost points because the locking hinge may provide a pinch hazard for the user or could potentially provide excessive force and pinch the patient if used incorrectly. In the category of practicality, the bow-shaped design scored high since it will likely be easy and simple to use by the healthcare professional; but the arms of the design may be awkward to work around. The design scored the highest in novelty, for there are currently no devices on the market with this structure and function. As for cost, this design scored the highest because the equipment is reusable and made of simple parts. The device lost points because it consists of multiple components that will be made from various materials that need to be purchased. For the last category, ease of fabrication, the bow-shaped design requires a simple assembly, but the process may require machining and the hinge may be hard to fabricate.

The Hook & Loop Design

In the category of effectiveness, this design would likely be effective at closing the wound, but once the adhesive patches are placed on the skin, they cannot be adjusted and the hook will cover portions of the wound that cannot be glued/sutured. While the other designs could pinch the skin and cause discomfort, the hook and loop simply adheres to the skin and would cause minimal discomfort to the patient. Therefore, the design scored highest in patient comfort. The hook and loop is also relatively safe, with the only danger being the adhesive patches pulling at the patient's skin/wound or hair (similar to removing a bandage), so it lost some points in the safety category. The hook and loop design lost points for practicality, as it would be more complicated to use than the other designs and more time consuming to apply as there are multiple working components. While there are no products exactly like it, there are other products on the market that use a similar method of wound closure, causing this design to lose points in novelty. In terms of cost and ease of fabrication, the hook and loop design would likely be more expensive and more difficult to produce than the other designs due to its various materials and adhesive quality. The device is also not reusable.

The Barrette Design

The barrette design scored low in the effectiveness category because it would not be very precise when approximating wound edges, as it only has one setting of closure. It also scored low in the categories of patient and safety comfort because it might pinch the skin in the hinge corner of the device and therefore be uncomfortable for the patient. Additionally, the skin nearest the barrette hinge could be damaged more severely and bruising could result. The barrette design lost points in the practicality category because it would require a significant amount of effort to orientate the device so that the wound edges are properly aligned. This apparatus was awarded full points in the category of novelty because it is unlike the other devices that are currently on the market. The barrette design also scored the highest in the cost and ease of fabrication categories because it would require few materials and the assembly would be rather

straightforward (simple hinge design). This device would also be reusable, so the cost of repeated use would be minimal.

The Rectangle Design

The rectangle design would score the highest in effectiveness because the design could repeatedly approximate wound edges without impeding the clinician's access to the wound. In the category of patient comfort, the design scored high because the silicone edges would be comfortable against the patient's skin, but the device may provide some level of discomfort when drawing the edges of the wound together. For safety, the design lost points because the regions where the fasteners are located provides potential pinch points if not used carefully. However, for the most part, the design presents minimal risk to the patient and user, scoring the highest for safety. In the category of practicality, the design scored the highest, for it will be easy and straightforward to use by the clinician. The design also scored the highest in the category of novelty since there are no designs currently on the market with the same function and structural design. For cost, the rectangle design scored highly because there are minimal parts to create the design and it is reusable if sterilized. Finally, in the category of ease of fabrication, the design lost points because there are several components of the design that require machining.

Proposed Final Design

Due to the fact that the rectangle design ranked highest, the team decided to move forward with this design (See Appendix B for engineering drawing). After further fabrication brainstorming, the team revised the rectangle design to consist of two angled slotted pieces on either end of the device to allow the long edges to slide together without the need for a gear system (Fig. 12). Additionally, the sides in contact with the skin were covered in a layer of silicone to protect against slip on the skin [15].

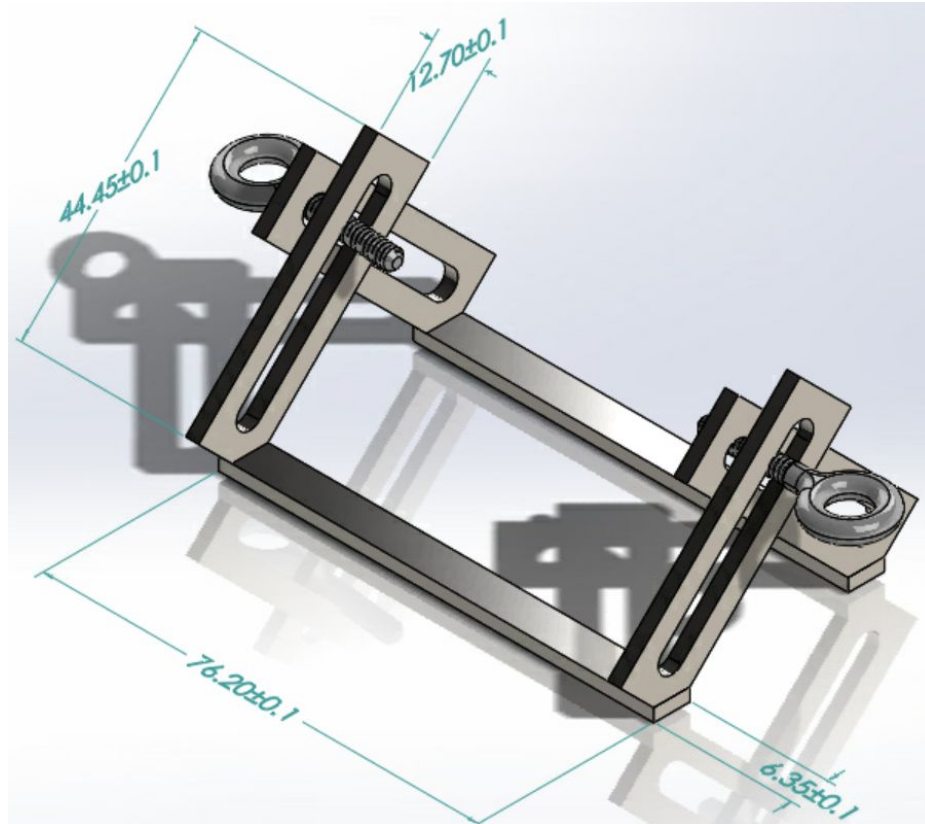


Figure 12. SolidWorks model of the final prototype. Dimensions in mm.

Fabrication

Materials

Stainless Steel 304 (SS 304) is the most popular grade of stainless steel and is used in a variety of applications beyond just the medical world [16]. High corrosion resistance and low carbon content are the two key factors that make Stainless Steel 304 highly suitable for medical devices. Corrosion resistance means SS 304 will not rust, reducing infection risk for the patient. SS 304 is also inert and will not react with bodily tissue, making it safe to use around open wounds and within the body. SS 304 can also be autoclaved; this is an important aspect of the device, as autoclaving is the main method of tool sterilization in clinics. SS 304 is a very workable metal, meaning it can easily be drawn into shape with no need for annealing, making the fabrication process much more simple. The raw material cost of SS 304 is relatively inexpensive at around \$3.42/kg [17]. All of these factors combined make SS 304 an excellent choice for the body of the device.

The sides of the device that contact the skin and push the wound edges together must be coated with a material that is soft, to minimize patient discomfort, and able to firmly grip the skin. For this application, silicone is an excellent choice. Silicone is a flexible rubber that is commonly used in products designed for human usage. Due to its soft texture and pliability, it would cause minimal discomfort to the patient when pushed onto their skin. It is often used in certain clothing products, often strapless ones, to provide a strong grip between the fabric and the wearer's skin so that the item of clothing does not fall off. This is because silicone can have a relatively high coefficient of friction with skin, usually between 0.25-0.75, but sometimes reaching 1.0 [18][19]. This is important, as the two long sides of the device must be able to grip the patient's skin without slipping when pushing the wound edges together. Silicone is also used for o-rings and gaskets due to its excellent temperature resistance. It can operate normally under temperatures as high as 315.6 °C (600 °F) and as low as -101.1 °C (-150 °F) without degradation of its mechanical properties [19]. This means silicone can be easily sterilized, without degradation of mechanical properties, in an emergency room or clinic through steam autoclaving, a process that reaches temperatures of 121 °C (250°F) [20].

Methods

A 25.4 mm x 914.4 mm x 2.29 mm (Width x Length x Thickness) strip of SS 304 was purchased from McMaster-Carr. Using the band saw in the TEAM Lab, a 76.2 mm (3 in.) long piece and two 44.45 mm (1.75 in.) long pieces were cut from the strip. A belt sander was used to smooth out rough edges on the cut pieces. The 44.45 mm pieces were taken to an Eisen Mill in the TEAM Lab and two slots were cut on each piece using a 4.7625 mm endmill (6/32 in.). Then, utilizing the waterjet cutter in the UW Makerspace, the 76.2 mm piece was cut down its length to make two 76.2 mm x 6.35 mm pieces. These pieces would act as the long sides of the device that contact the skin. The slotted pieces were cut down the middle lengthwise with the waterjet cutter to create four 44.45 mm x 12.7 mm pieces (Fig. 13). Using a belt sander, one corner of each slotted piece was sanded down to a flat edge so that they rested at a 45 degree angle on the long pieces. One slotted piece was then welded to each end of the long pieces. To enhance the grip of the device on skin, a thin layer of liquid silicone was applied to the bottom of the long pieces and allowed to cure for 24 hours. To fully assemble the prototype, a 6-32 x ½ thumb screw was screwed through a 6-32 hex nut on the outer side and a 6-32 zinc-plated wing nut on the inner side of the device.



Figure 13. Separated pieces after waterjet cutting.

Final Prototype

The final assembled prototype is depicted in Fig. 14, 15, and 16. Dimensions are consistent with those shown in Fig. 12. The prototype is a metal frame consisting of two identical stainless steel sides with three pieces: one long, thin segment with a thin layer of silicone along the bottom and two rectangular slotted segments welded to opposite ends of the long segment at 45 degree angles. The segments of each half are connected via thumb screws and nuts through the slots. To increase the effectiveness of the device, hard silicone bumpers were included in the device operation procedure. One bumper is placed at each corner of the designated wound area, and the long sides of the device are fit around the bumpers. Those sides are then pushed together to approximate the wound edges. The thumb screws can then be tightened to secure the device in place on the skin.

The final cost of the device was \$43.07. A table of the cost breakdown can be found in Appendix C. The device weighed 50.81 g.

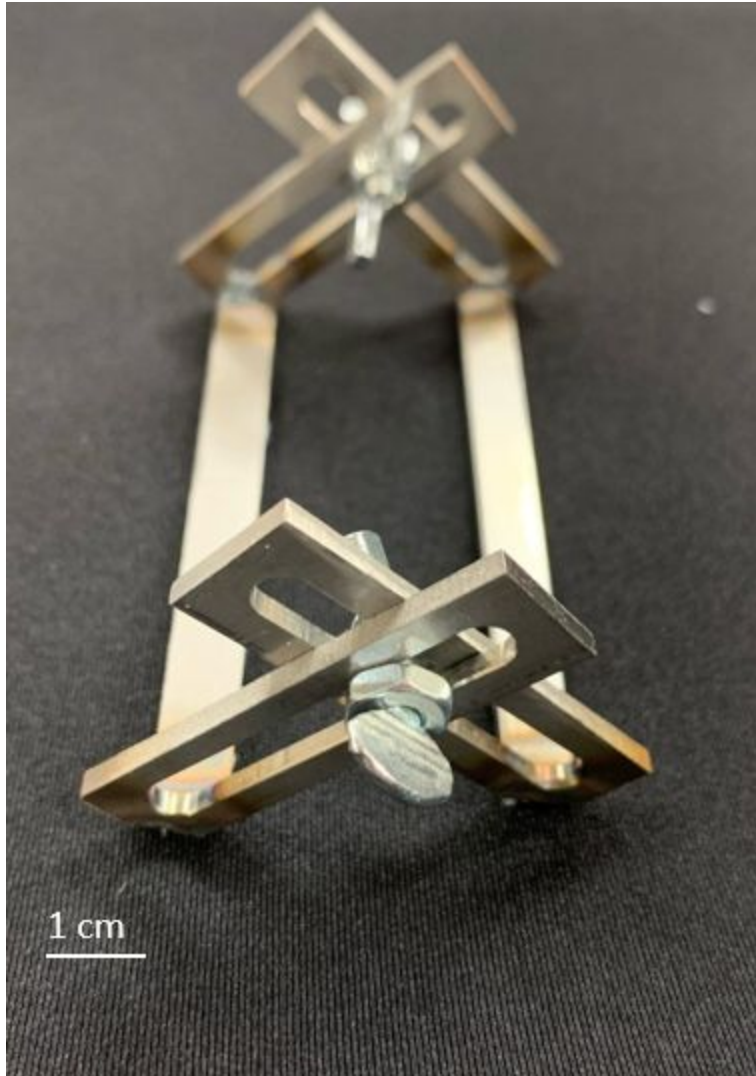


Figure 14. Side view of assembled prototype.



Figure 15. Bottom view of prototype displaying the thin silicone layer.

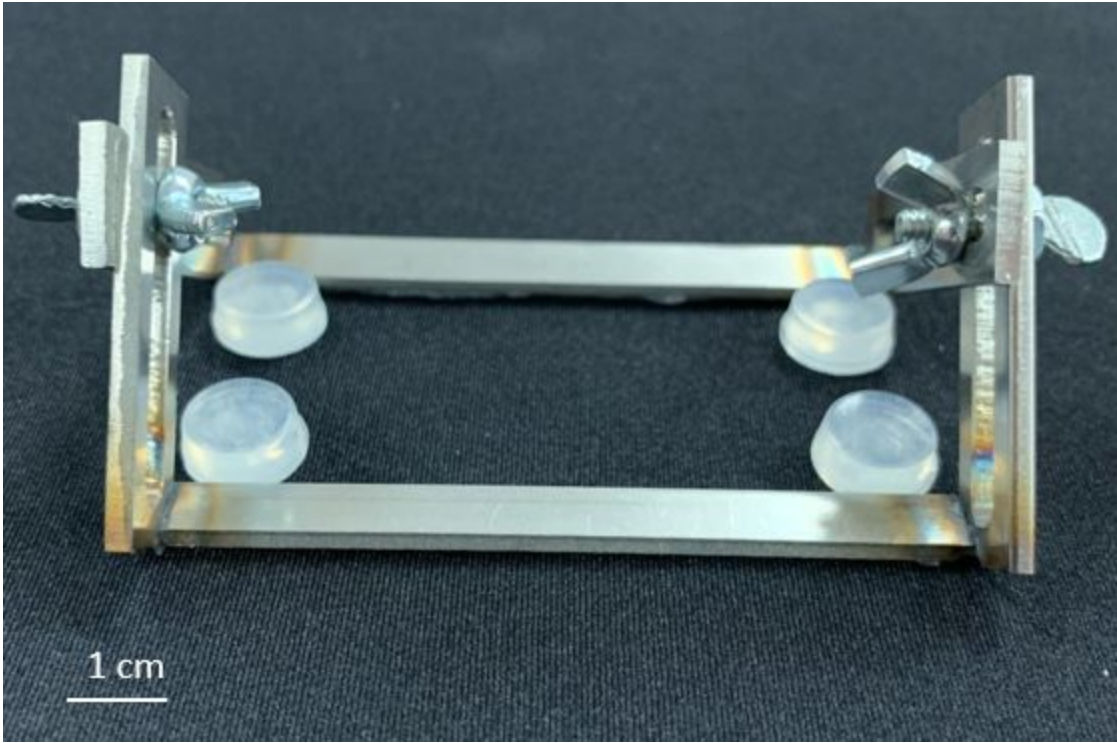


Figure 16. Front view of prototype with four silicone bumpers used during wound edge approximation.

Testing

Testing of the final device consisted of three quantifiable measurements and one qualitative method. The first quantitative method was used to determine the force applied by the user and the device to the patient's skin in order to approximate the wound edges. Since the team did not have access to real skin lacerations, a silicone model suture kit was acquired (Fig. 17). To determine the stress-strain relationship of this skin, the silicone was cut into roughly 3 cm and 5 cm long strips that averaged about 1 cm wide and 1 cm thick. The sample size was three for each length tested. Refer to Appendix D for exact sample measurements. Once the strips were cut, they were tested in tension using an MTS machine (Fig. 18). The silicone strips were secured in the machine using grips, and were all tested at the extension rate of 100 mm/min until the silicone began to slide out of the grips under the load. This typically occurred around 15 mm of extension. The silicone never reached failure before slipping from the grips. It should be noted that the silicone was fully secured in the grips before testing, yet managed to slip out during every trial of testing. The portion of the data during slipping will not be examined in the results section.



Figure 17. Suture pad (fake skin) included in the suture practice kit that was provided by the client to test the device.

Once the tensile testing was complete, the data was analyzed using MATLAB to create stress-strain curves from the output data consisting of load and deformation values. To convert from load to stress (σ), the force (F) can be divided by the cross-sectional area (A) (Eqn. 2). To obtain strain (ϵ), the change in length of the specimen (ΔL) is divided by the original length (L) (Eqn 3). Using Hooke's Law (Eqn. 1), equations 2 and 3 can be combined and the force solved for (Eqn. 4).

$$\sigma = \frac{F}{A} \quad \text{Eqn. 2}$$

$$\epsilon = \frac{\Delta L}{L} \quad \text{Eqn. 3}$$

$$F = \epsilon EA = \frac{\Delta L}{L} EA \quad \text{Eqn. 4}$$



Figure 18. Image of the silicone skin strips in the MTS grips during tensile testing. The specimen was exposed to axial tension until the silicone began to slip from the grips.

After all suture pad specimens were tested in the MTS machine, the team tested the final design as follows. An incision was made in the silicone skin that was 3 cm in length. The silicone was then draped over a team member's forearm until the wound edges splayed to mimic a real wound (Fig. 19). Two markings were made on opposite sides of the wound, and the original distance between the two markings was measured using calipers. The final device was then used to approximate the laceration edges of the silicone skin. Once the skin edges were approximated, the final distance between the markings was measured. The change in length of the silicone could then be computed. With the change in length and the original length measured, the strain of the silicone could be calculated using the strain equation (Eqn. 3). With the strain value, the team used the graphs generated from MATLAB to find the stress applied to the silicone skin to approximate the wound edges. The force applied was also determined by multiplying the stress value by the area normal to the force (Eqn. 2). The values of force required for wound approximation on the silicone skin were then compared to the values reported for human skin in the PDS (found in Appendix A). This test method was able to provide information of the forces applied by the device to the skin as well as how well the silicone suture kit models and compares to real human skin.



Figure 19. The laceration made on the silicone skin for testing. The skin was then draped over a forearm to cause the wound edges to splay.

A second quantifiable method used was device displacement during life in service. Two conditions were compared during testing. One condition used SkinPrep, which was applied to the skin before the device was applied, and the second condition involved using the device without any form of skin treatment. The device was then placed on a team member's forearm until the skin was raised to simulate wound approximation (Fig. 20). Markings were placed on the skin on either side of the device to denote the starting position. A timer was then set for 3 minutes. The team chose a 3 minute interval since the device will likely be used for this length of time when used in conjunction with DermaBond. The glue takes less than a minute to mix and apply and polymerizes in 30 seconds. Additionally, the glue only requires 2 layers to close a wound, so theoretically, the maximum service life is three minutes per use. After the three minute interval was completed, new markings were made to denote final position of the device. The distance between the original and final markings was recorded to determine how much the device moved and slipped while in use (See Appendix D for measurements). This procedure was completed three times for each condition. This method determined how much the device moved while in service, and if the device remained on the skin while in use. Additionally, the conditions of SkinPrep or control determined if the use of SkinPrep along with the final device minimized device displacement and maximized the chances of the device remaining on the skin during wound closure.

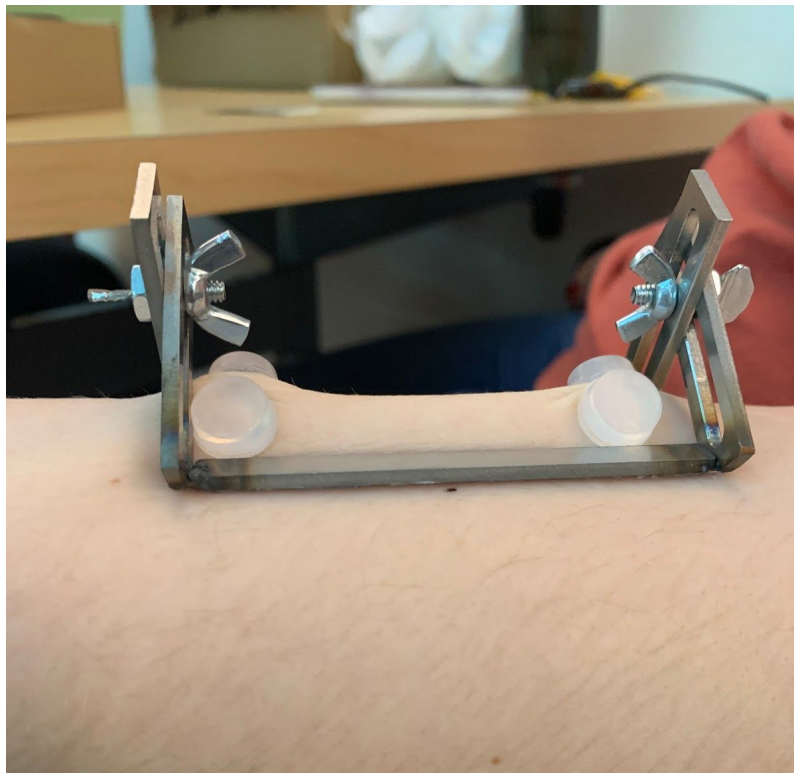


Figure 20. Final design in service on human skin. The skin was pinched until raised to simulate approximation of wound edges.

The third quantitative testing method involved subjects ranking their pain level during skin approximation. The team developed a zero to five point scale to quantify the comfort of the device (Table 2). The device was tested on the lateral forearm of each team member. While in place, the individual was asked to rank their pain level. These scores were recorded and averaged to determine the overall comfort of the device during use.

Table 2. Definitions of the pain ratings for the pain level assessment.

Pain Rating	Description
0	Aware of the device, but no pain experienced
1	Uncomfortable
2	Slight pain
3	Mild pain or pinching
4	Moderate pain
5	Severe pain

The final method of testing included a qualitative examination of device functionality. One design requirement was that the device should not harm the patient or leave dark skin markings after use. The team conducted this test simultaneously with device displacement. The device was applied to the skin as described above and left in place for a three minute duration. After which, pictures were taken of the skin to determine what marks were left on the skin by the device.

Results

The average modulus of elasticity for the 3 and 5 cm length suture pad specimens were found to be 0.4358 ± 0.0738 and 0.6292 ± 0.0949 MPa respectfully. A paired t-test comparing the mean elastic moduli found a significant difference present between the two sample lengths tested ($p = 0.0494$). Based on the average modulus of elasticity for the 3 cm specimens, a linear model was developed for estimating the tensile forces the wound edges of the suture pad experience during approximation (Eqn. 5). Using the stress-strain plot generated in MATLAB, the developed linear model is applicable for measured strains between 0.00 and 0.35 (Fig. 21, see Appendix E for code).

$$F = 0.4358 * \epsilon * A \quad \text{Eqn. 5}$$

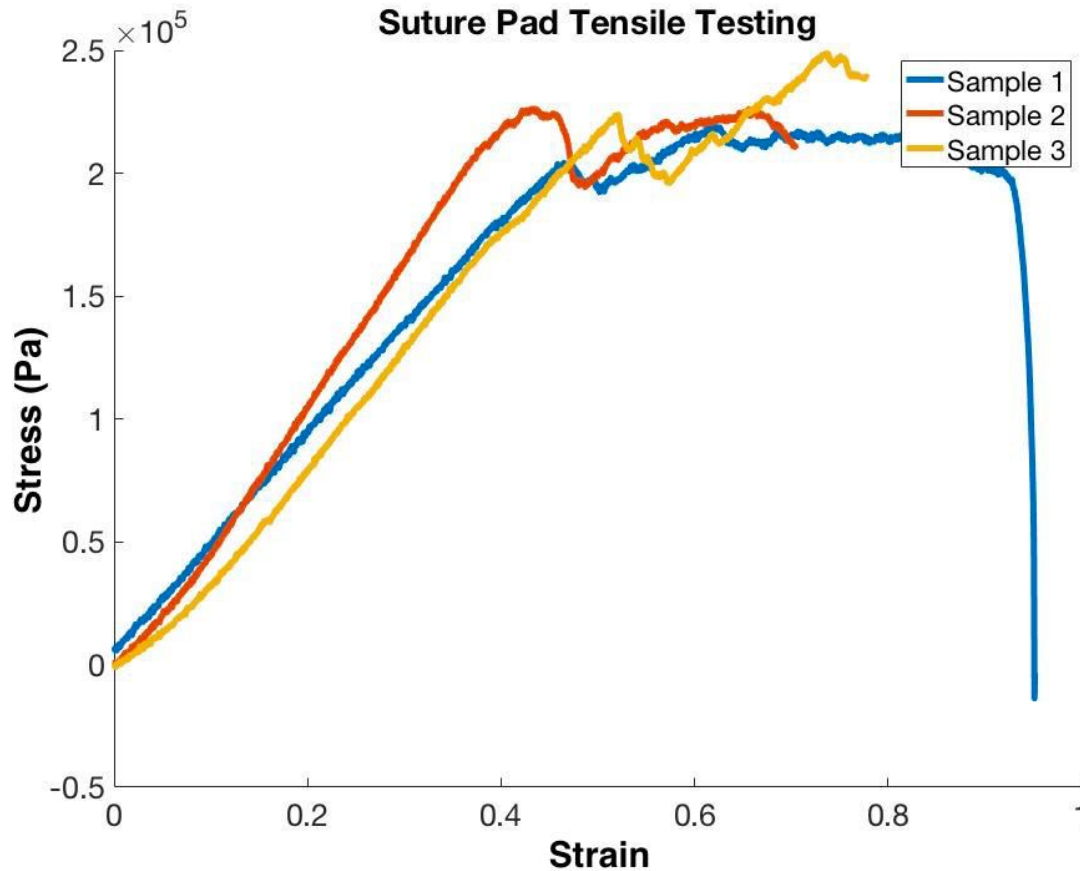


Figure 21. Stress-strain curves for the three 3 cm suture pad samples that underwent MTS testing.

Using the above model (Eqn. 5) and the measured displacements of the suture pad during approximation, induced tensile forces ranging from 27.68 to 38.95 N were observed (See Appendix D for raw data).

Upon analyzing the total displacement of the device on skin after a 3 minute period, average displacements of $0.7300 \pm .633$ mm and 1.500 ± 0.737 mm were measured for SkinPrep and no SkinPrep respectively (See Appendix D for raw data). A paired t-test found no significant difference between these mean displacement values ($p = 0.2222$).

An average pain score of 0.75 out of 5.0 during device use was found (See Appendix D for raw data). Upon removal, shallow indentations were observable in the individual's skin for up to 2 minutes after use (Fig. 22).



Figure 22. Example of the red markings left on the subject's skin after device use.

Discussion

Interestingly, a significant difference was found between the moduli of elasticity of the 3 cm and 5 cm suture pad samples tested in the MTS machine. Theoretically, there should be no difference in the elastic moduli due to sample length. As the p-value was found to be close to the significance level of 0.05, it is likely that further testing to increase the sample size would result in an increased p-value, thus, conveying a negligible difference in moduli.

Based on the MTS testing, an average modulus of 0.436 MPa was found. Using this value and the measured areas and strains of the suture pad during wound edge approximation, tensile forces ranging between 27.68 and 38.95 N were calculated. These tensile forces induced by the device in the suture pad were far greater than the target range of 6.5 to 7.8 N [21]. This drastic difference in tensile forces is due to the high modulus of elasticity found for the suture pad samples. The elastic modulus of skin typically ranges from 0.05 to 0.15 MPa and the average modulus of silicone is 0.20 MPa [6][22]. While the modulus of the silicone is slightly higher than that of skin, it is significantly lower than the calculated modulus of the suture pad samples. Upon further investigation, it was found that suture pads have an embedded mesh to enhance durability. While this mesh allows for an optimal lifespan of the device with respect to suturing practice, it ultimately makes its use as a skin model for mechanical testing invalid. Moving forward, the team will reconduct the MTS testing using a more accurate, synthetic model of skin in order to determine the tensile forces induced during wound edge approximation.

The final prototype was approximately 79% lighter than the maximum allowable weight; thus, its weight will not hinder its ability to stay in place. The total fabrication cost was \$43.07, which was well within the provided budget. Since the device will be used to approximate wounds 2 cm to 5 cm in length, the average displacement of 1.12 mm from initial position was a maximum of 5.6% of the wound length of 2 cm. This indicates the device displaced a small yet detectable amount during approximation, and this issue of displacement must be addressed in the future. A goal for improvement in function would be to achieve maximum displacement of less than 2.5% of the total wound length (<0.5 mm displacement). Ideally, the device would remain in the initial position to maintain approximation without any gaps. There was also negligible difference in displacement between the bare skin and SkinPrep conditions, indicating that the use of SkinPrep did not enhance device function. Additionally, the device only caused slight discomfort to the users and did not harm the skin, which was an important design criterion that the team had established. Ethically, the device should not cause additional harm to the patient or leave dark red markings on the skin. The primary concern in the use of the device is to maintain the safety of the patient and user. The final design is also sterilizable in an autoclave, as it consists of stainless steel and zinc products [17]. The silicone adhesive applied to the bottom of the device can withstand high temperatures as well. However, the silicone bumpers are the only part of the device that would not be reusable because they stick to the patient's skin and would lose their adhesion over time.

Potential sources of error include the assumptions made for mechanical testing and the pain testing. For MTS testing of the silicone, the material was assumed to be homogenous, isotropic, linear, and elastic (HILE). However, the silicone used with the embedded mesh was not uniform throughout the cross-section. The HILE assumption was necessary to utilize Hooke's Law and the derivation of the force model. Taking this information into account, the calculations for mechanical testing and model created to compute force are not extremely accurate. Additionally, during approximation, the wound on the silicone was perfectly linear. In reality, wounds are not linear and the edges are often rough. Therefore, the data generated only applies to linear wounds, jagged wounds may require varying amounts of force. Finally, the pain and displacement tested was completed on human skin that did not possess a wound. This lack of a real wound may have influenced the pain rating to be lower than in reality. Also, in the presence of a real wound, the device may displace a greater distance due to the presence of bodily fluids and antiseptic agents present on the skin. The tension provided by the skin, pulling the wound edges apart may cause the device to displace from its initial position.

As a result of evaluation, the device must be refined to adhere more strongly to the patient's skin to prevent displacement during use. However, the device must not cause harm or leave markings on the skin. In the future, the device should rely more on the adhesion to the skin to approximate the wound edges rather than forceful pinching of the skin. This will reduce patient discomfort and lighten the markings left on the skin. To accomplish this, the team could purchase and apply a medical grade silicone for enhanced adhesion and grip on skin. For ease of

use, the device fastening system will need to be made simpler through implementing a locking hinge mechanism instead of thumb screws, which are cumbersome to manipulate.

Conclusion

The team's goal for the semester was to design a device to approximate wound edges while suturing or gluing. This would reduce the number of clinicians needed to repair lacerations from two people to one. The resulting prototype from this semester's work is two identical metal structures that are connected via thumb screws and nuts through hollow slots. To aid in wound closure, four cylindrical adhesive silicone bumpers are placed in the corners of the wound area and the device is fit around them before approximating the wound edges.

As a result of testing and evaluation, the force required for approximation on the silicone suture pad was higher than reported the values of human skin. This was due to the durable mesh layer within the silicone; the elastic modulus of the suture pad was significantly higher than both the values for pure silicone and human skin. The silicone suture pad is therefore not an accurate model for skin. In terms of device functionality, the displacement of the device from its initial position was detectable and a significant percentage of the total wound length. However, the device caused the patient minimal discomfort, and only left light markings on the skin. The prototype also weighed less than the stated design requirements.

Overall, the device worked well to approximate wound edges initially, but it did not hold the edges together completely for the desired amount of time. With the addition of the silicone bumpers, the device stayed on the skin without falling off. It also provided enough space for a clinician to repair the wound while the device was on the skin. However, the fastening mechanism on the device was rather difficult to use because each thumb screw had to be fastened individually while the long edges of the device were held in place. Though the device left some marks and caused discomfort, the marks went away within several minutes and any pain caused was mild. The silicone on the bottom of the device also assisted the gripping of the skin, but it did not stay applied to the device well with repeated use and had to be reapplied.

The team would have liked to develop a better method of adhering and securing the device to the skin, so one point of future work is finding a new, sterile adhesive that is smaller than the bumpers currently being used. Additionally, in order to extend the service life of the device, a silicone alternative or a better method of applying the silicone must be used. With the current method, the silicone would peel off the prototype after a repetitive uses. The team would also like to find new fasteners that are easier to use or create a type of hinge system to lock the edges in place. Though the stainless steel worked well for the prototype, the team is considering re-fabricating with a thinner and lighter stainless steel.

In retrospect, the team would have conducted MTS testing on a more suitable synthetic skin model. For future testing methods, the team wants to test the prototype on either a more realistic synthetic model or real skin wounds - possibly a pig or other type of animal skin- and on

other parts of the human body, such as the torso, legs, and upper arm. It would also be worthwhile to test ease of use with various clinicians by having them use the device and rate it on a scale of one to ten. SolidWorks testing could also be performed using stress concentration testing and analysis. Additionally, the team will acquire human testing clearance from the Institutional Review Board (IRB) for the purpose of testing the device on and with people aside from the design team.

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Appendix A: Product Design Specifications

Wound Edge Approximation

Product Design Specification

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Date Updated: 12/05/19

Function:

Over 6 million laceration cases are treated in emergency departments each year; during such repairs, skin tension pulls the wound apart while the provider is attempting to approximate the wound edges [1]. Repair is therefore difficult, and imperfect approximation can lead to scarring and poor healing of the wound. This problem is often solved within operating rooms with wound closure systems for large wounds; however, it poses a challenge for physicians in emergency rooms, urgent care clinics, and office settings on small wounds ranging from 2 cm to 5 cm. A clinical tool will be developed to approximate the wound edges together while the wound is either sutured or glued, acting as a “second pair of hands” for the physician. The final design must be easy to use by healthcare professionals and must not impart any pain or markings onto the patient’s skin during use.

Client requirements:

- The device must remain in place and hold the edges of the wound together for suturing or gluing; however, the tool must not interfere with the wound repair.
- The device must not harm healthy skin by leaving marks or cause pain for the patient during use.
- The device needs to be sterilizable since the tool will be used near open wounds, with the possibility of infection.
- The device should be effective to use for linear wounds 2-5 cm in length located typically on patient limbs or torso, not facial or scalp tissue.

- The device must be easy and simple to use, not cumbersome or difficult to handle.

Design requirements: The device the team will design must approximate the wound edges during wound closure. The design that the team is currently considering is a metal frame consisting of two long edges that will be placed on the sides of the wound and can be adjusted using fasteners on the shorter sides. To use this device, the clinician centers the device opening on the wound and manually pulls the long sides and tightens the fasteners until the skin edges are approximated. The long edges of the device will consist of a material that remains on the skin until the clinician removes it. Therefore, the clinician would be able to use two hands to suture or glue while the wound edges are approximated.

1. Physical and Operational Characteristics

a. *Performance requirements:* The device designed will be used daily in emergency rooms and office settings with sterilization in an autoclave taking place between uses. The device must withstand the temperatures (at least 121°C for 30 minutes) of the autoclave without deterioration in mechanical properties [2]. While in use, the device must provide skin tension forces between 6.5 and 7.8 N to allow efficient repositioning and eversion of the wound edges during wound closure [3].

b. *Safety:* The device must not cause further tissue damage during use or leave visible markings on the surrounding skin upon removal. Materials used must be hypoallergenic, non-toxic, medical grade and approved by the FDA. Wound edge approximation using the device must be possible without anesthetizing the surrounding tissues.

c. *Accuracy and Reliability:* During each use, the device must pull the wound edges into direct contact with each other to permit wound eversion. It must securely hold the wound edges in place while suturing or gluing occurs.

d. *Life in Service:* The device will be used daily for approximately 20 minutes at a time. The design must have a minimum lifetime of one year with repeated uses and sterilizations. One year of use with sterilization in between is estimated to be about 350 uses that the device must withstand.

e. *Shelf Life:* When in storage, the design must maintain its functionality when stored at room temperature of 20-25 °C. More specifically, the final device should not weaken or corrode over time. Theoretically, it can be stored for at least a year.

f. *Operating Environment:* The design should be able to withstand basic sterilization

procedures in an autoclave. Additionally, any tissue adhesive on the device should be able to be cleaned off in a timely manner. The design should also remain on dry skin without slipping for approximately 20 minutes in a typical clinic environment, 20-25 °C.

g. *Ergonomics*: The device should be easily and comfortably used by the administering physician or healthcare professional. Therefore, the fasteners on the device should be positioned in a way that is appropriate for the shape of the average clinician's hand and easy to handle. The average hand length for males and females is 19.4 and 18.0 cm, respectively. The average hand breadth is 9.04 cm for males and 7.95 cm for females [4]. The team must consider this anthropometric data when designing the size and position of the fasteners.

h. *Size*: The final design should function for a target wound size of 2-5 cm. Therefore, the sides of the rectangle design should be able to extend enough for the device to cover wounds ranging from 2-5 cm.

i. *Weight*: The final product should be light enough to allow the user to easily manipulate it with one hand as well as to avoid inflicting lasting discomfort to the patient. An ideal weight would be <0.23 kg (<0.5 lb).

j. *Materials*: For the design, the body of the device can be made of surgical-grade metal, most likely stainless steel. A plastic body could be an option; however, the device must be sterilized and plastic is often not allowed in autoclaves due to high heat. The long sides of the design should consist of a softer component that contacts and grasps the skin. This could possibly be made of rubber. Rubber can be sterilized, but repeated cycles can accelerate the degradation of the rubber, so that aspect of the device may need to be replaced more frequently [5]. Silicone could also be used, as it would provide a firm frictional grip on the skin. The temperature and moisture resistant properties of silicone allow it to be sterilized through a variety of methods, including steam autoclaving and dry heat, without losing its physical properties [6]. The long sides of the device could also be texturized to provide better frictional forces against the skin or possibly covered in a material with adhesive properties to maintain stable contact with the patient's skin.

k. *Aesthetics, Appearance, and Finish*: The product would likely be used with patients of all ages, including young children, so a non-threatening appearance is ideal in order to minimize patient discomfort. A simple, clean look should be sufficient for the device. In order to avoid user error, the texture of the rectangle device should not be too smooth or slippery.

2. Production Characteristics

a. *Quantity*: The team plans on fabricating one prototype for the client by the end of the semester time frame.

b. *Target Product Cost*: The client has not yet specified a budget, but the team hopes to fabricate the prototype with a budget of \$300.

3. Miscellaneous

a. *Standards and Specifications*: The device will need to be registered with the FDA since it is a medical device, expected to classify as Class I, 510(k) exempt, indicating the device will not require pre-market approval [7].

b. *Customer*: The customers for this device are healthcare professionals that practice in urgent care clinics, emergency rooms, or office settings. From the commentary and opinions provided by the client, the device must be user-friendly for any healthcare provider with easy-to-understand instructions on device use. Additionally, the client made it clear that an overly complex or cumbersome device would be unfavorable to customers.

c. *Patient-related concerns*: Since the device will be used near open wounds with the possibility of infection, the device will need to be sterilized, using simple sterilization in an autoclave. The device also must not be uncomfortable to the patient or pinch the patient's skin to the point of harm.

d. *Competition*: Several products exist in the market that function to approximate wound edges and close the wound for healing. The device the team designs will only possess one of these functions: approximating wound edges. The device will not need to include a wound closure function. Currently, there is a lack of devices on the market that function solely for wound edge approximation; many healthcare professionals rely on a second person to push the wound edges together or attempt to use forceps to hold the wound while it is sutured or glued.

DermaClip: U.S. Pat. Nos. 8,157,839, 9,028,529, 9,301,760, and 9,603,596

The DermaClip is a skin closure device that allows for fast closure of skin surface wounds. The closure system is non-invasive and single use only. The design consists of plastic sutures with a hinge between two layers of adhesive. To use, the area between the

adhesives is aligned with the wound. The plastic tabs are then pulled tightly to lock them in place and pull the edges of the wound together; the device is left on the skin during wound healing [8].

microMend: US20170333039A1

The wound closure system known as microMend has a design similar to a bandage, but the adhesive backing contains two arrays of micro-staples. The device is placed across the wound one side at a time, so the staples can insert into the skin, approximate the wound edges and close the wound. The holding strength is similar to that of sutures, and the staples are said to inflict minimal to no pain [9].

Steri-Strip: The adhesive skin closure system known as Steri-Strip is made of acrylate-based adhesive strips reinforced with polymer filaments for strong closure of skin lacerations. The strips offer a faster and non-invasive alternative to sutures and staples. The device is placed across the wound once the wound has been manually approximated, and stays in place during wound healing for around 7 days [10].

References:

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- [9] Kitotechmedical.com. (2019). *microMend | Time-saving skin closure alternative*. [online] Available at: <http://www.kitotechmedical.com/> [Accessed 18 Sep. 2019].
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Appendix B: SolidWorks Models and Drawings

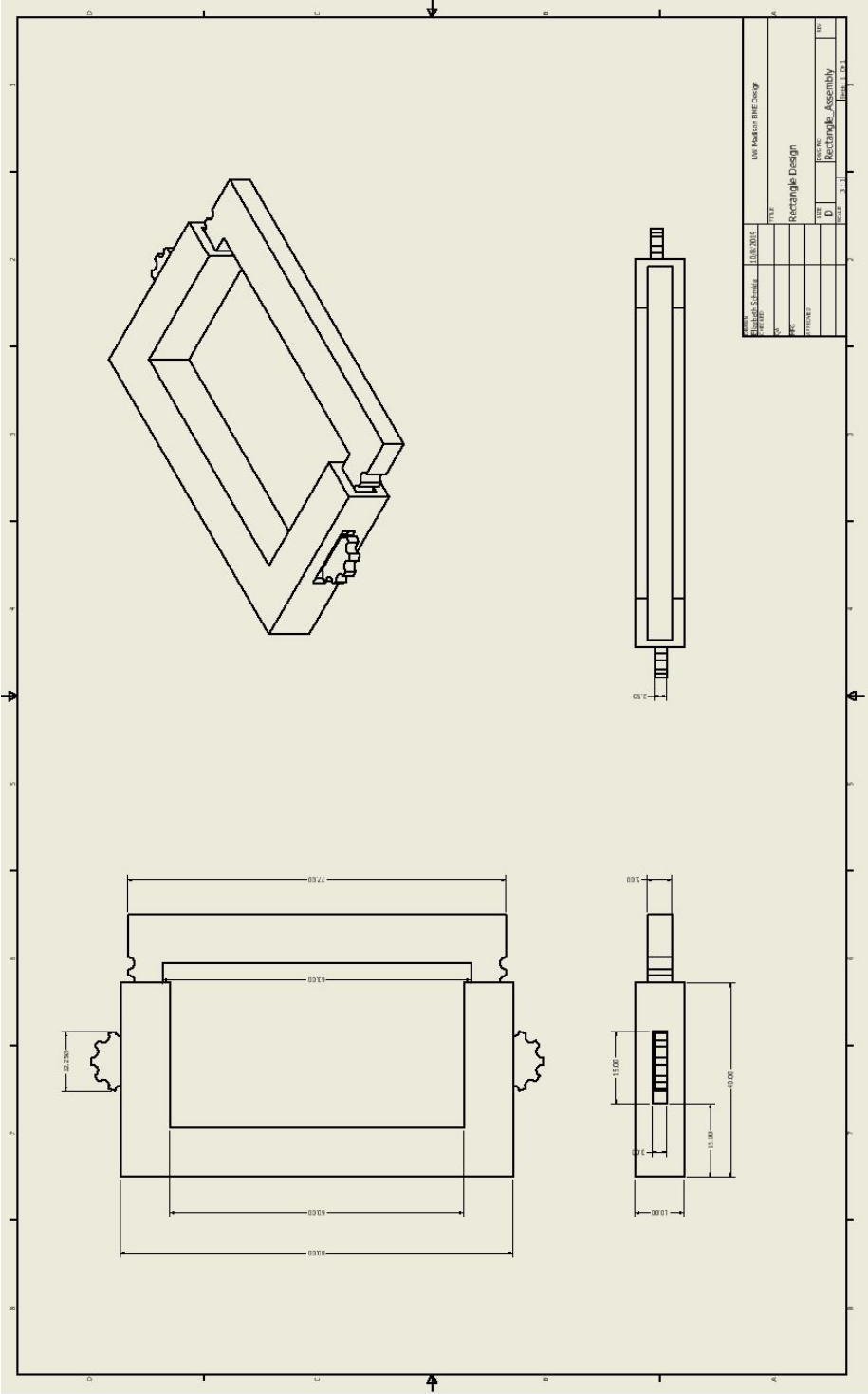


Figure 1. Preliminary rectangle design drawing.

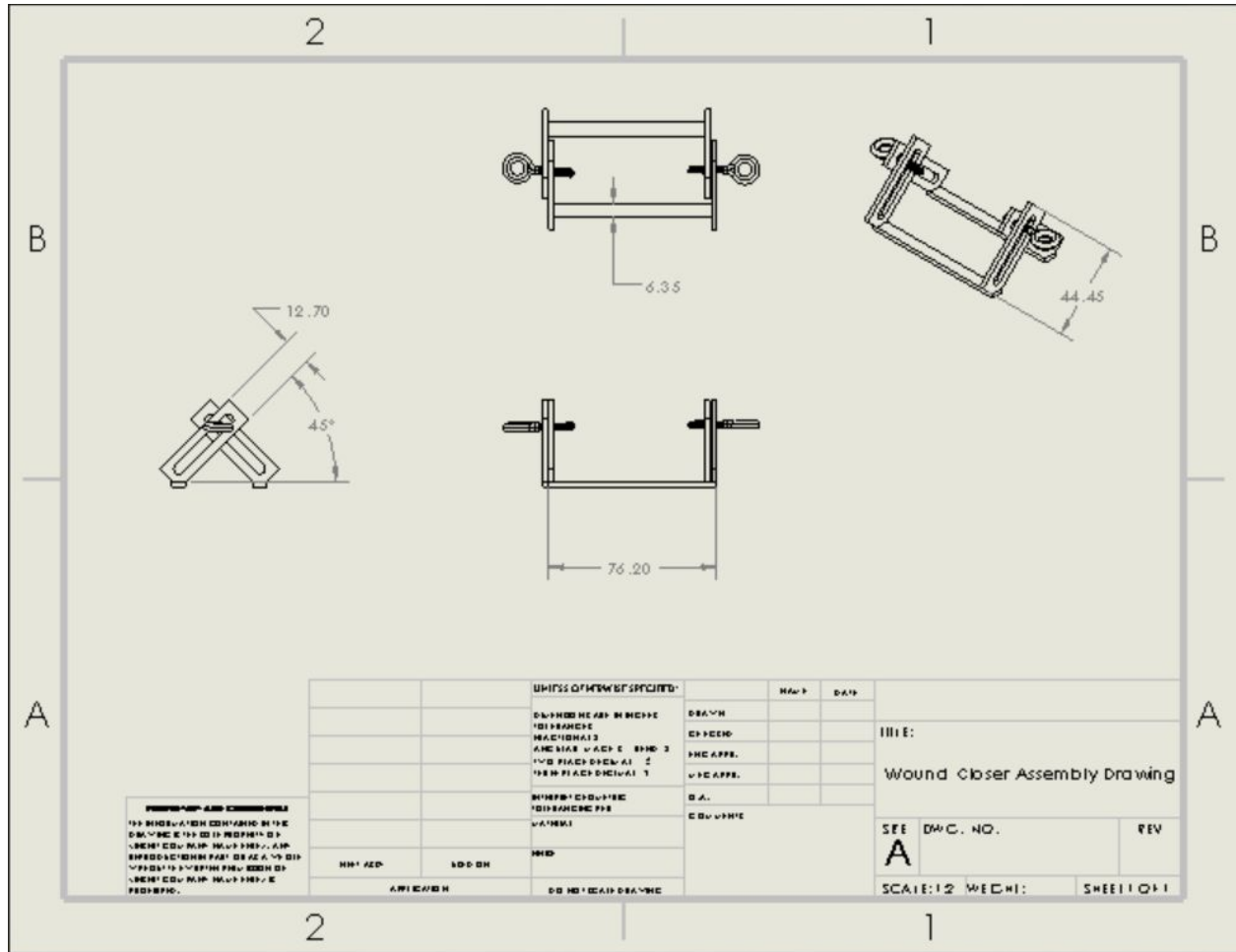


Figure 2. SolidWorks Drawing of Final Proposed Design. Dimensions in mm.

Appendix C. Cost and Materials

Table 1. List of materials and expenses.

Item	Quantity	Unit Cost	Extended Cost
Multipurpose Stainless Steel 304	1 Strip, 1" x 36" x 0.09"	\$18.38	\$26.22
GE Silicone 2+ Sealant Caulk	1	\$3.77	\$3.77
Waterjet Cutting at Makerspace	N/A	\$2.53	\$2.53
Sontax 96pc. 1/2" Clear Bumpers	Pack of 96	N/A	\$8.79
Thumb Screws #6-32 x 1/2	2	\$0.39	\$0.78
Zinc Plated Wingnuts	Pack of 6	N/A	\$0.98
Total			\$43.07

Appendix D. Raw Data

Table 1. MTS Suture Pad Sample Measurements

Sample	Gage Length (mm)	Width (mm)	Thickness (mm)
1	27.39	13.19	8.97
2	37.10	15.19	8.84
3	35.46	16.00	8.91
4	68.08	12.04	9.07
5	51.39	14.51	9.04
6	59.37	11.51	9.11

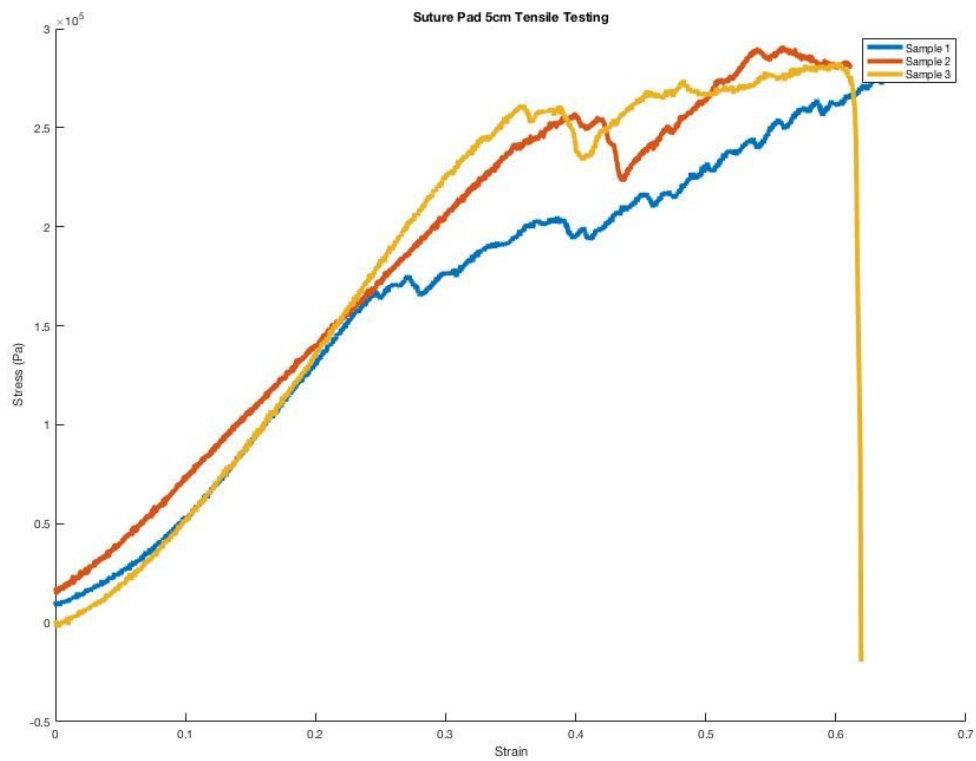


Figure 1. Stress-strain curves for the three 5 cm suture pad samples.

Table 2. Suture pad measurements and calculations during approximation

Test Number	Length (m)	Δ Length (m)	Strain	Area (m ²)	Elastic Modulus (Pa)	Tensile Force (N)
1	0.01288	0.00357	0.27717	0.000282	435770	34.0611
2	0.00937	0.00297	0.31697	0.000282	435770	38.9514
3	0.00666	0.0015	0.22523	0.000282	435770	27.6773

Table 3. Device displacement data for SkinPrep and bare skin

SkinPrep	Bare Skin
0 mm displacement	1.42 mm displacement
1.07 mm	2.33 mm
1.12 mm	0.87 mm

Table 4. Pain level scores during approximation

Subject	Pain Rating
1	0
2	0
3	2
4	1

Appendix E. MATLAB Code

```
%BME 400: Senior Design, Wound Edge Approximation
%Written by Elizabeth Schmida
%Last modified: 12/05/2019
%
%This code processes MTS data collected on suture pad samples and
%determines the average modulus of elasticity. Paired t-tests are also
%performed on device displacement data.

TR1 = load('/Volumes/Lexar/JDesign/Sample 1/Sample1.txt');
TR2 = load('/Volumes/Lexar/JDesign/Sample2/Sample2.txt');
TR3 = load('/Volumes/Lexar/JDesign/Sample3/Sample3.txt');
TR4 = load('/Volumes/Lexar/JDesign/Sample4/Sample4.txt');
TR5 = load('/Volumes/Lexar/JDesign/Sample5/Sample5.txt');
TR6 = load('/Volumes/Lexar/JDesign/Sample6/Sample6.txt');
sample_info = load('/Users/Lizzy/Desktop/BME400_sample_data.txt');

%Displacement Data (mm)
DTRmm1 = TR1(:,1);
DTRmm2 = TR2(:,1);
DTRmm3 = TR3(:,1);
DTRmm4 = TR4(:,1);
DTRmm5 = TR5(:,1);
DTRmm6 = TR6(:,1);

%Displacement Data conversion into meters (m)
DTR1 = DTRmm1/10^3;
DTR2 = DTRmm2/10^3;
DTR3 = DTRmm3/10^3;
DTR4 = DTRmm4/10^3;
DTR5 = DTRmm5/10^3;
DTR6 = DTRmm6/10^3;

%Force Data
LTR1 = TR1(:,2);
LTR2 = TR2(:,2);
LTR3 = TR3(:,2);
```

```
LTR4 = TR4(:,2);
LTR5 = TR5(:,2);
LTR6 = TR6(:,2);
```

```
%Calculate cross section area of samples
thickness = sample_info(:,4);
width = sample_info(:,3);
sample_length = sample_info(:,2);
```

```
for i = 1 : length(thickness)
    area(i,1) = thickness(i,1) * width(i,1);
end
```

```
%Strain Data for each trial both displacement and length are in m
str1 = (DTR1 / sample_length(1));
str2 = (DTR2 / sample_length(2));
str3 = (DTR3 / sample_length(3));
```

```
str4 = (DTR4 / sample_length(4));
str5 = (DTR5 / sample_length(5));
str6 = (DTR6 / sample_length(6));
```

```
% %Max Loading Force
```

```
% ML1 = max(LTR1);
% ML2 = max(LTR2);
% ML3 = max(LTR3);
% ML4 = max(LTR4);
% ML5 = max(LTR5);
% ML6 = max(LTR6);
```

```
%
```

```
% %Average of Max Load
```

```
% ave_max_load_3cm = (ML1 + ML2 + ML3)/3
% ave_max_load_5cm = (ML4 + ML5 + ML6)/3
```

```
%Stress--force/area(Pa)
```

```
s1 = (LTR1/area(1,1));
s2 = (LTR2/area(2,1));
s3 = (LTR3/area(3,1));
s4 = (LTR4/area(4,1));
```

```
s5 = (LTR5/area(5,1));  
s6 = (LTR6/area(6,1));
```

```
%Overall plots from MTS testing  
figure; %3cm samples  
hold on;  
set(gca,'FontSize',25)  
plot(str1,s1,'LineWidth',5);  
plot(str2,s2,'LineWidth',5);  
plot(str3,s3,'LineWidth',5);  
xlabel('Strain');  
ylabel("Stress (Pa)")  
legend("Sample 1", "Sample 2", "Sample 3");  
title("Suture Pad Tensile Testing");
```

```
hold off
```

```
figure; %5cm samples  
hold on;  
set(gca,'FontSize',25)  
plot(str4,s4,'LineWidth',5);  
plot(str5,s5,'LineWidth',5);  
plot(str6,s6,'LineWidth',5);  
xlabel('Strain');  
ylabel("Stress (Pa)")  
legend("Sample 1", "Sample 2", "Sample 3");  
title("Suture Pad 5cm Tensile Testing");
```

```
hold off
```

```
%Strain in linear region INDICES**** start at 1mm  
strain1_1 = str1(61:576);%strain of 0.35 just before out of linearity  
strain2_1 = str2(61:576);  
strain3_1 = str3(61:576);  
strain4_1 = str4(61:940); %strain of 0.25 just before 5cm samples out of linear region  
strain5_1 = str5(61:940);  
strain6_1 = str6(61:940);
```

```
%Stress in linear region (INDICES)****
```

```
stress1 = s1(61:576);
```

```
stress2 = s2(61:576);
```

```
stress3 = s3(61:576);
```

```
stress4 = s4(61:940);
```

```
stress5 = s5(61:940);
```

```
stress6 = s6(61:940);
```

```
%Elastic Modulus in Linear Region Only
```

```
E_1 = stress1./strain1_1;
```

```
E_2 = stress2./strain2_1;
```

```
E_3 = stress3./strain3_1;
```

```
E_4 = stress4./strain4_1;
```

```
E_5 = stress5./strain5_1;
```

```
E_6 = stress6./strain6_1;
```

```
% Modulus Analysis
```

```
ave_E1 = mean(E_1);
```

```
ave_E2 = mean(E_2);
```

```
ave_E3 = mean(E_3);
```

```
ave_E4 = mean(E_4);
```

```
ave_E5 = mean(E_5);
```

```
ave_E6 = mean(E_6);
```

```
E_3cm = [ave_E1, ave_E2, ave_E3];
```

```
E_5cm = [ave_E4, ave_E5, ave_E6];
```

```
ave_E_3cm = mean ([ave_E1, ave_E2, ave_E3])
```

```
ave_E_5cm = mean ([ave_E4, ave_E5, ave_E6])
```

```
E_sd_3cm = std([ave_E1, ave_E2, ave_E3])
```

```
E_sd_5cm = std([ave_E4, ave_E5, ave_E6])
```

```
%Ttest for differences in moduli of Elasticity for 3 and 5cm samples
```

```
[h_E_modulus,p_E_modulus] = ttest2(E_3cm, E_5cm)
```

```
%%%%%%%%%%%%%Skin Prep Analysis%%%%%%%%%%%%%
```

```
skin_prep_disp= [0.0,0.00107, 0.00112]; %meters
```

```
no_skin_prep_disp = [0.00142, 0.00233, 0.00087]; %meters
```

```
ave_skin_prep_disp = mean(skin_prep_disp)
```

```
ave_no_skin_prep_disp = mean(no_skin_prep_disp)
```

```
sd_skin_prep_disp = std(skin_prep_disp)
```

```
sd_no_skin_prep_disp = std(no_skin_prep_disp)
```

```
%Ttest for displacement differences between skin prep procedures
```

```
[h_skin_prep,p_skin_prep] = ttest2(skin_prep_disp, no_skin_prep_disp)
```