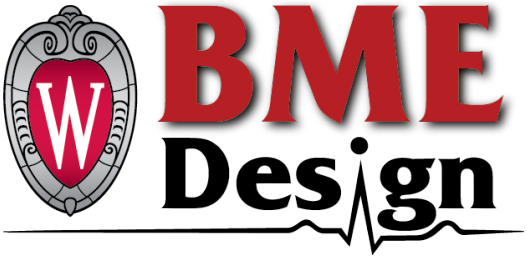

Wound Edge Approximation

Preliminary Report

Biomedical Engineering Design 400

Department of Biomedical Engineering

University of Wisconsin

October 9th, 2019

Team Members:

Jurnee Beilke (Team Leader)

Lizzy Schmida (Communicator)

Jack Fahy (BSAC/BPAG)

Kelly Starykowicz (BWIG)

Client:

Dr. Nicola Charlton, Aurora Health Center, Speciality in Family Medicine

Advisor:

Dr. Darilis Suarez-Gonzalez, Department of Biomedical Engineering, College of Engineering, University of Wisconsin-Madison

Abstract

Each year, 6 million laceration cases are treated in emergency departments. With lacerations larger than 1-2 cm, skin tensions tend to pull the wound edges apart, making repair difficult for clinicians in office settings, urgent care clinics, and emergency departments. Clinicians often need to involve a second individual to approximate wound edges while the wound is closed with sutures or tissue adhesive. Currently, no device exists on the market in the United States designed solely to approximate wound edges. There are wound closure systems that have two primary functions: approximate the wound edges, and seal the wound. A device will be designed to accurately and repeatedly approximate wound edges allowing the clinician use of both hands during wound repair. The proposed device is a small rectangular metal frame that consists of two long sides either covered in silicone or with an attached adhesive that will lay along the edges of the wound and create a stable contact point with the skin. The two short sides of the frame will have a gear system that will allow shortening of the device's edges to facilitate wound approximation. Fabrication will be done using the MakerSpace and TEAM Lab to create a functional prototype. Testing will include a stress concentration analysis using SolidWorks and wound edge approximation with a suture kit.

Introduction

Motivation

Over 6 million laceration cases are treated in emergency departments each year; 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 together or attempt to use forceps to hold the wound 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].

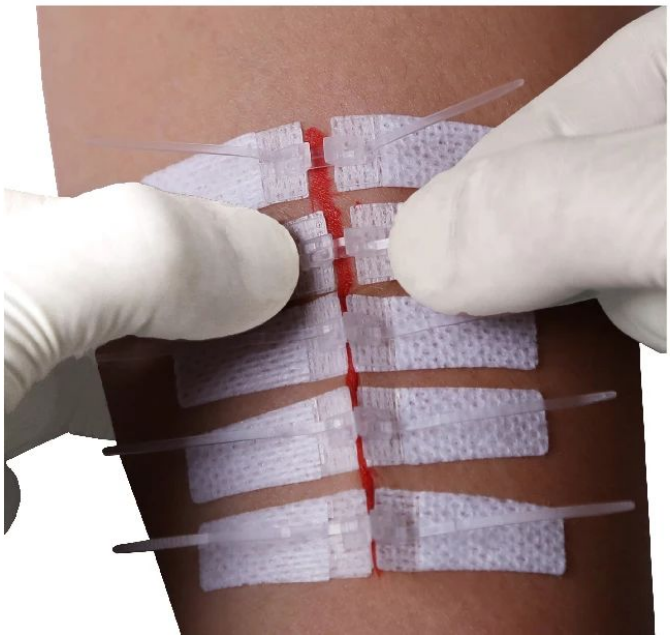

Figure 1. Image of multiple DermaClips being used to seal a wound [2].

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].

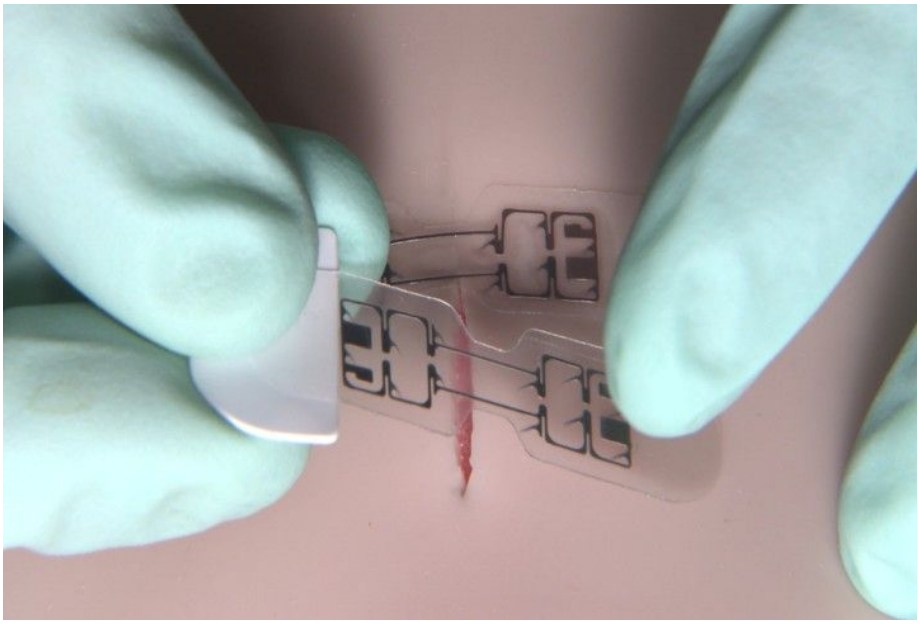

Figure 2. Image of the microMend device being applied to a wound [3].

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].

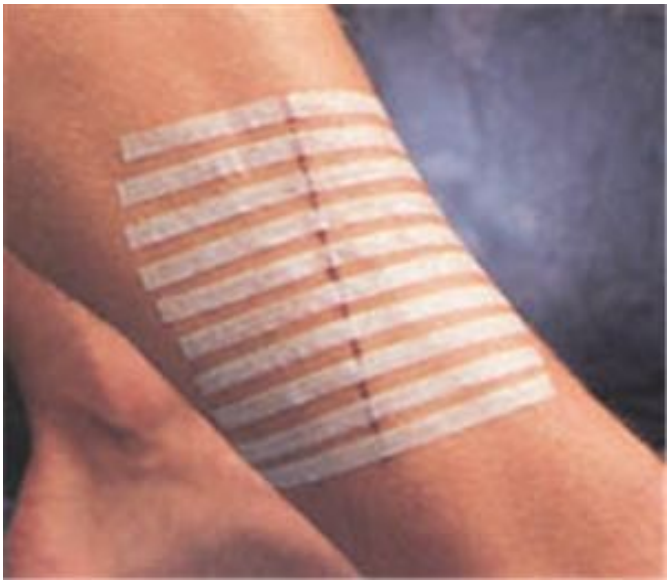

Figure 3. Image of Steri-Strips being used to seal a wound [4].

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 approximates wound edges. The wound approximating apparatus will not only save time for the clinician, but will 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 one to five centimeters in size. The long, slender sides of the rectangular frame can first be drawn together using a gear 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].

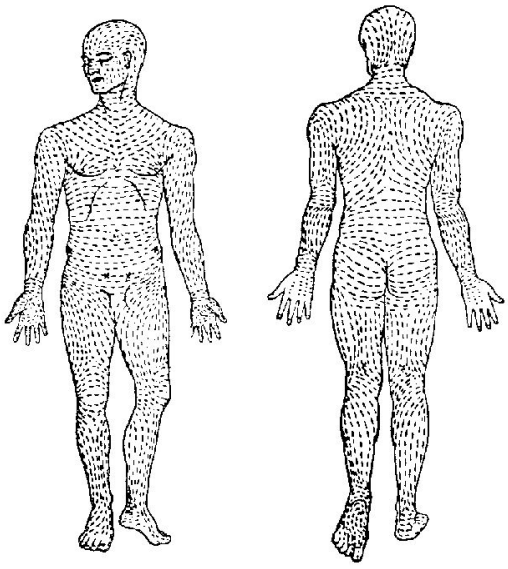

Figure 4. Langer lines, also known as cleavage lines, are paths of greatest tension that tend to follow the underlying collagen fibers within the dermis. Although they are present all over the body, these lines are only visible in certain areas such as the creases of the palm [7].

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 Equation 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 0.42 MPa to 0.85 MPa [6].

$$E = /\mathfrak{E} \qquad \text{Eqn. 1}$$

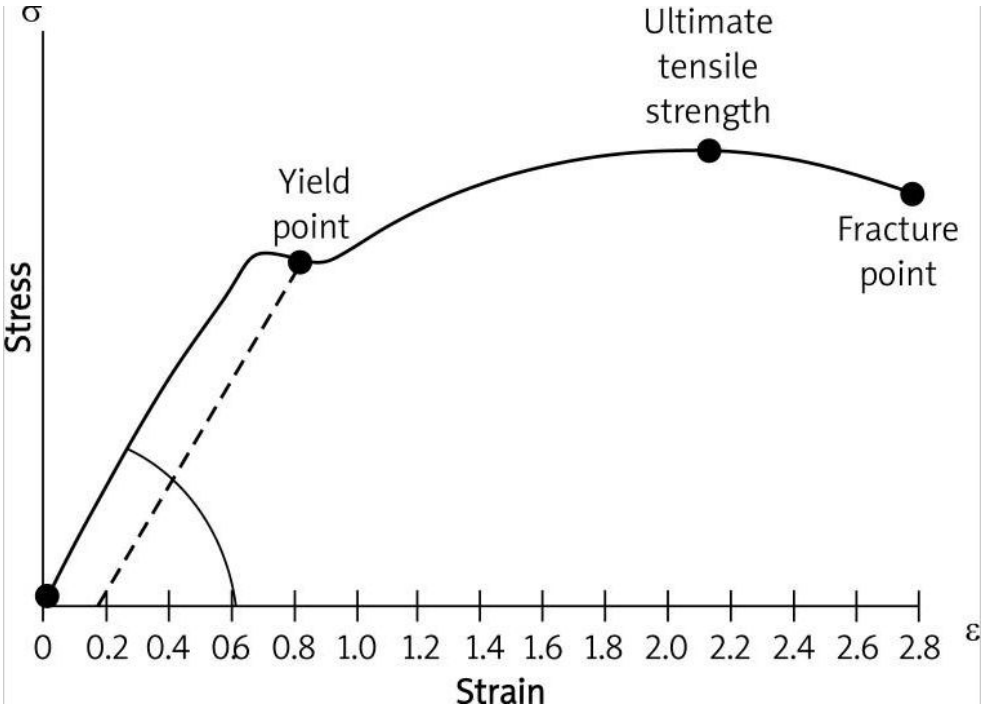

Figure 5. General stress-strain plot. The slope of the line before the yield point is known as the modulus of elasticity and can be calculated by dividing the stress by the strain. The modulus of elasticity characterizes the skin's resistance to elongation [6].

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].

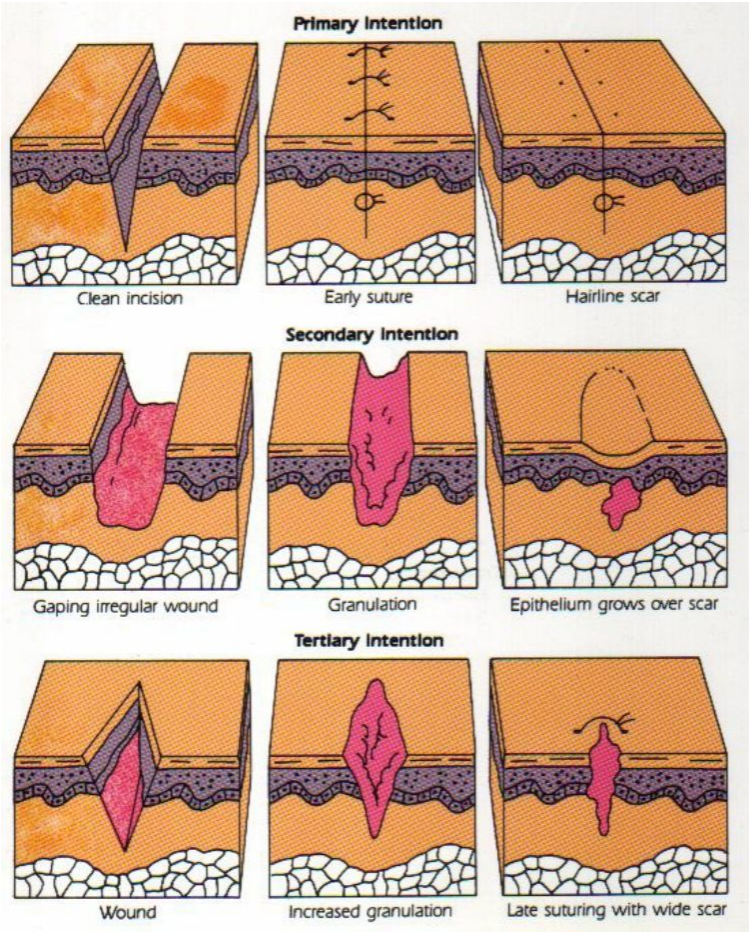

Figure 6. Graphic displaying the three main forms of wound healing, with primary being the most desired and tertiary being the least desired [9].

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. 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.

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 not harm the skin or inflict pain on the patient. It needs to function for wounds between 1-5 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. 7). 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.

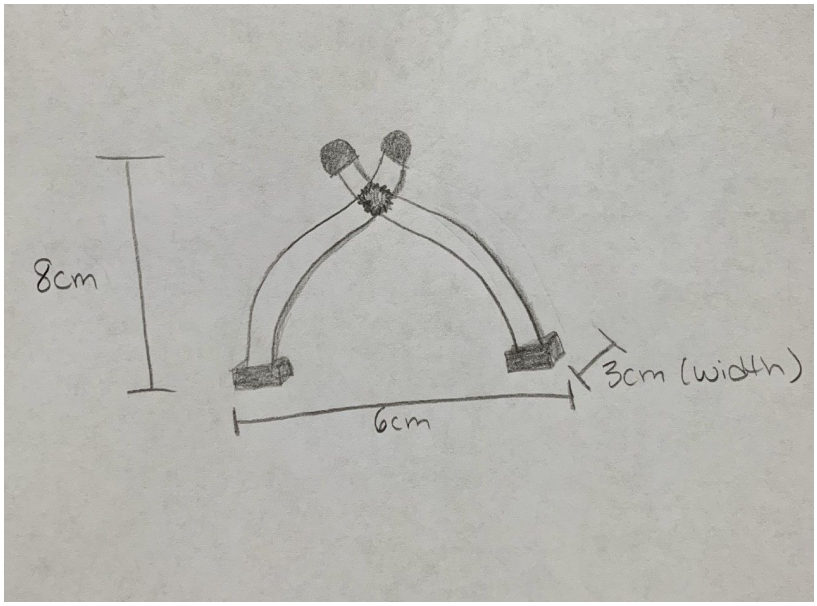

Figure 7. The bow-shaped design consists of two curved arms fitted with rubber end pieces to assist in wound edge approximation.

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. 8). 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.

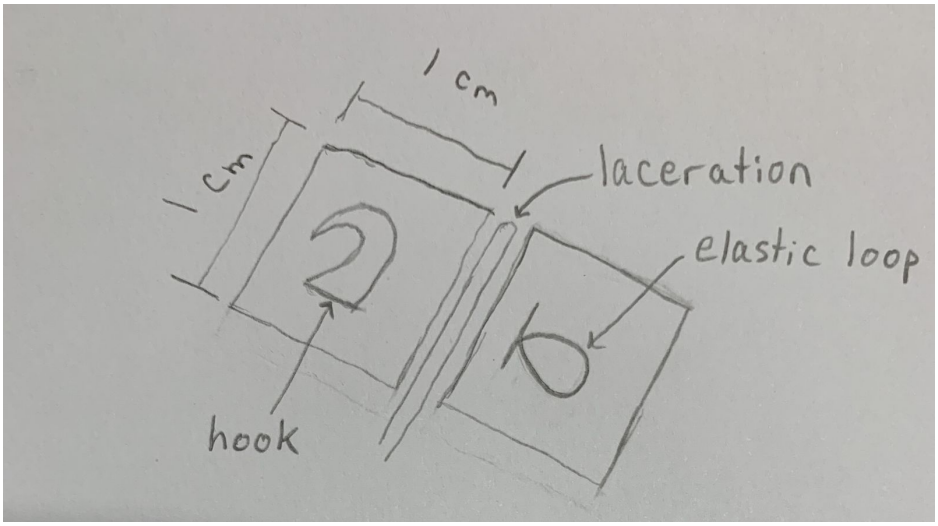

Figure 8. The hook and loop design consists of two separate adhesive patches placed on either side of the laceration. The elastic loop is connected to the hook to pull and hold the wound edges together during gluing.

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. 9). 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.

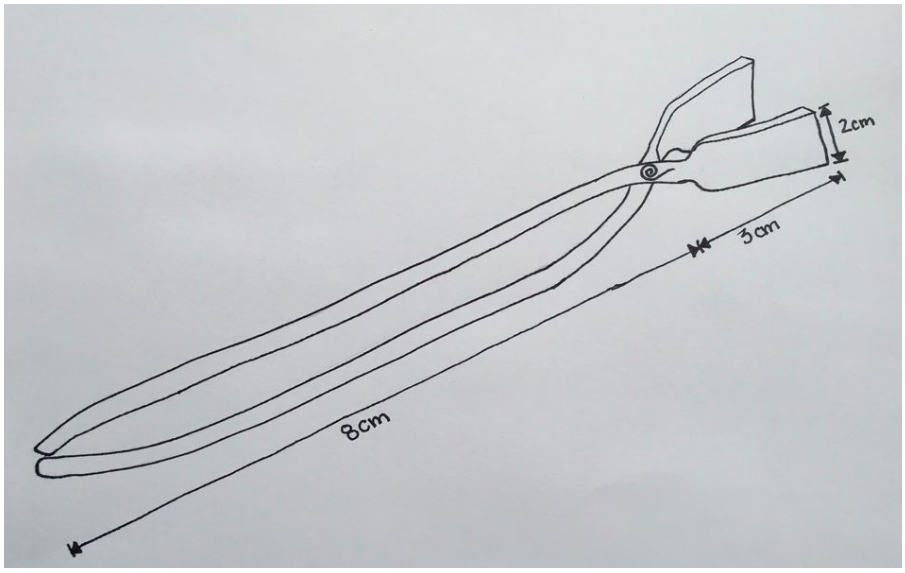

Figure 9. The barrette design utilizes a spring loaded hinge and two long arms that lay flush to the skin to pinch the wound edges together for suturing or gluing.

Rectangle Design

The rectangle design consists of two metal components connected by gears on both of the short sides of the device (Fig. 10). 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.

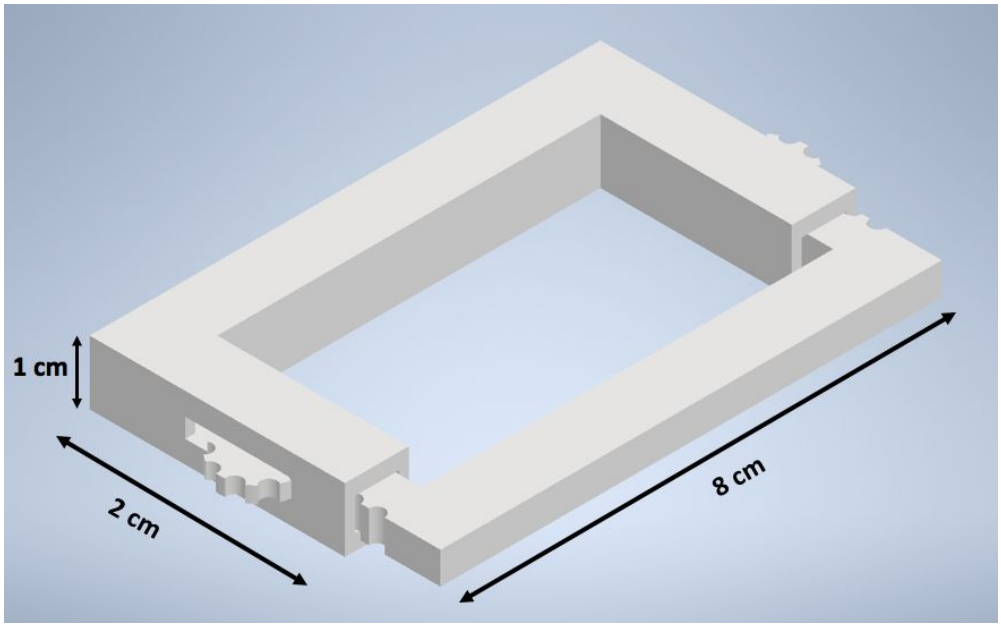

Figure 10. The rectangle design pushes the wound edges together by decreasing its width across the wound using the two gears located on its sides.

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.

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 uncomfortable 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). The team will revise the proposed final design to potentially include a slight curvature in the two shorter sides of the rectangle to better grip the skin. Additionally, the portion of the rectangle in contact with the skin will be textured to guard against slip. Another option the team will further explore is the use of adhesive tape to secure the device to the skin if texturing the metal and the silicone edges do not prove sufficient [12]. The design will be revised based on testing results and client feedback.

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 [13]. 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 our 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 $1.55/lb [14]. 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 made of 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 [15][16]. 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 [16]. 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) [17].

Methods

Fabrication of this device will first involve purchasing several stainless steel hollow rectangular rods with 1 cm by 1 cm cross-sections, as well as several solid rectangular rods with 0.70 cm by 0.70 cm cross-sections. The rods will need to be cut to the correct lengths before welding. The TEAM Lab can be utilized for this step. A mill can be used to cut the rods down to the correct dimensions. A slot can be milled out of each short side for placement of the simple spur gears. Three hollow rods can be welded together at the corners in the shape of an open-sided rectangle. Three solid rods will also be welded in this fashion to yield an open-sided rectangle. The solid rod ends will be able to fit inside the hollow ends of the partner piece of the device. The team will also need to purchase two gears for the sides of the device that function to draw the two long sides of the frame together. The solid rods will need to be machined with notches that fit into the gear notches. For the retractable sides, CNC milling may be required so that the teeth of this piece are correctly dimensioned to fit the gear teeth. Silicone rubber can be purchased in liquid form and fabricated into a solid form that molds around the long sides of the rectangle.

Testing

Initially, there will be two primary means of testing the device: SolidWorks testing and evaluation using a suture practice kit that contains a suture pad (fake skin) (Fig. 11). In SolidWorks, the rectangle design can be subjected to stress testing and analysis, and then the design can be modified accordingly. Using the suture pad, the team will test the approximation

capabilities of the rectangle design for accuracy of wound edge approximation, its consistency, as well as to determine if performance variation is present between operators. Furthermore, approximation testing will occur with the suture pad in various orientations and curvatures to better mimic the topography of the human body. Through the use of a tensiometer or a scale, the tension forces induced on the laceration edges of the suture pad will also be measured to ensure a tension between 6.5-7.8 N is experienced during closure [18]. The team will compile all testing results as well as feedback from multiple practitioners and modify the device as needed.

Figure 11. Suture pad (fake skin) included in the suture practice kit that was provided by the client to test the device.

References

[1] Quinn, J., Polevoi, S. and Kohn, M. (2013). Traumatic lacerations: what are the risks for infection and has the ‘golden period’ of laceration care disappeared?. *Emergency Medicine Journal*, 31(2), pp.96-100.

[2] DermaClip US, LLC. (2019). *DermaClip Non-Invasive Skin Closure Device, Revolutionizing Wound Care*. [online] Available at: https://www.dermaclipus.com/ [Accessed 18 Sep. 2019].

[3] Kitotechmedical.com. (2019). *microMend | Time-saving skin closure alternative*. [online] Available at: http://www.kitotechmedical.com/ [Accessed 18 Sep. 2019].

[4] 3m.com. (2019). *3M™ Steri-Strip™ Reinforced Adhesive Skin Closures | 3M United States*. [online] Available at: https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Steri-Strip-Reinforced-Adhesive-Skin-Closures/?N=5002385+3293321968&rt=rud [Accessed 21 Sep. 2019].

[5] Tepole, Adrián Buganza et al. “Stretching skin: The physiological limit and beyond.” *International journal of non-linear mechanics* vol. 47,8 (2012): 938-949. doi:10.1016/j.ijnonlinmec.2011.07.006

[6] Pawlaczyk, Mariola et al. “Age-dependent biomechanical properties of the skin.” *Postepy dermatologii i alergologii* vol. 30,5 (2013): 302-6. doi:10.5114/pdia.2013.38359

[7] Kvistedal, Yme. (2003). “Multiaxial in-vivo testing of human skin”.

[8] Ethicon Inc, D. Dunn, "Wound Closure Manual", *uphs.upenn.edu*, 2019. [Online]. Available: http://www.uphs.upenn.edu/surgery/Education/facilities/measey/Wound_Closure_Manual.pdf. [Accessed: 02- Oct- 2019].

[9] *Wound Dressings Healing*. Oasis Hospital, 2019. Available at: http://www.oasishospital.com/wp-content/uploads/2018/04/Wound-Dressings-Healing.pdf. [Accessed: 07- Oct- 2019].

[10] Quinn, J. (1997). A Randomized Trial Comparing Octylcyanoacrylate Tissue Adhesive and Sutures in the Management of Lacerations. *JAMA: The Journal of the American Medical Association*, 277(19), p.1527.

[11] Jnjmedicaldevices.com. (2019). *DERMABOND® Mini Topical Skin Adhesive | J&J Medical Devices*. [online] Available at: https://www.jnjmedicaldevices.com/en-US/product/dermabond-mini-topical-skin-adhesive [Accessed 18 Sep. 2019].

[12] Parafix. (2019). *Stick to Skin Wearable Device Tape | Die-Cut Tape | Parafix*. [online] Available at: https://parafix.com/industries/healthcare/device-attachment-to-skin/ [Accessed 8 Oct. 2019].

[13] "Medical Applications of Stainless Steel 304 (UNS S30400)", *AZoM.com*, 2019. [Online]. Available: https://www.azom.com/article.aspx?ArticleID=6641. [Accessed: 01- Oct- 2019].

[14] B. Fuller, F. Egbaria and I. Canorea, "MetalMiner Prices: Stainless Steel Prices", *Steel, Aluminum, Copper, Stainless, Rare Earth, Metal Prices, Forecasting | MetalMiner*, 2019. [Online]. Available: https://agmetalminer.com/metal-prices/stainless-steel/. [Accessed: 01- Oct- 2019].

[15] "The Coefficient of Friction of Silicone | Article | Jehbco Silicones", *Jehbco*, 2019. [Online]. Available: https://jehbco.com.au/coefficient-friction-changes/. [Accessed: 22- Sep- 2019].

[16] "Types and Properties of Moldable Silicone Rubber - Albright Technologies", *Albright Technologies | Silicone Molding, Medical Silicone Prototyping, Injection Molding & More*, 2019. [Online]. Available: https://albrightsilicone.com/types-and-properties/. [Accessed: 22- Sep- 2019].

[17] "Sterilizing Silicone", *Electronic Component News*, 2008. [Online]. Available: https://www.ecnmag.com/article/2008/08/sterilizing-silicone. [Accessed: 22- Sep- 2019].

[18] Omar E Beidas, Jeffrey A Gusenoff, Deep and Superficial Closure, *Aesthetic Surgery Journal*, Volume 39, Issue Supplement_2, April 2019, Pages S85–S93.

Appendix A: Product Design Specification

Wound Edge Approximation

Product Design Specification

Client: Dr. Nicola Charlton

Advisor: Dr. Suarez-Gonzalez

Team:

Lizzy Schmida (Comm)	schmida@wisc.edu
Jurnee Beilke (Team Leader)	jbeilke2@wisc.edu
Kelly Starykowicz (BWIG)	kstarykowicz@wisc.edu
Jack Fahy (BSAC/BPAG)	jfahy@wisc.edu

Date Updated: 10/05/19

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 1 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 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 causing 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 1-5 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 rectangular frame made of metal, consisting of two long edges that will be placed on the sides of the wound and can be adjusted using gears and fasteners on the shorter sides. To use this device, the clinician centers the rectangular opening on the wound and manually retracts the adjustable long sides using the gears and fasteners until the skin edges are approximated. The long edges of the device will consist of a material that remains on, possibly adheres to 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 rectangle 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 rectangle 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 gears on the rectangle 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 gears.

h. *Size*: The final design should function for a target wound size of 1-5 cm. Therefore, the sides of the rectangle design should be able to extend enough for the device to cover wounds ranging from 1-5 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 rectangle 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 rectangle 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. Additionally, the device 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:

[1] Quinn, J., Polevoi, S. and Kohn, M. (2013). Traumatic lacerations: what are the risks for infection and has the 'golden period' of laceration care disappeared?. *Emergency Medicine Journal*, 31(2), pp.96-100.

[2] CDC.gov. (2008). *Steam Sterilization: Guideline for Disinfection and Sterilization in Healthcare Facilities*. [online] Available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/steam.html.

[3] Omar E Beidas, Jeffrey A Gusenoff, Deep and Superficial Closure, *Aesthetic Surgery Journal*, Volume 39, Issue Supplement_2, April 2019, Pages S85–S93.

[4] S. M. Donelson and C. C. Gordon, "Anthropometric Survey of U.S. Army Personnel: Pilot Summary Statistics, 1988," Jan. 1991.

[5]. Mainlinemedical.com. (2019). *Mainline Medical, Inc.*. [online] Available at: http://www.mainlinemedical.com/mm/Rubber-Products-Storage-Cleaning-and-Sterilization-Guidelines.html [Accessed 22 Sep. 2019].

[6] Electronic Component News. (2008). *Sterilizing Silicone*. [online] Available at: https://www.ecnmag.com/article/2008/08/sterilizing-silicone [Accessed 22 Sep. 2019].

[7] U.S. Food and Drug Administration. (2019). *Consumers (Medical Devices)*. [online] Available at: https://www.fda.gov/medical-devices/resources-you-medical-devices/consumers-medical-devices [Accessed 14 Sep. 2019].

[8] DermaClip US, LLC. (2019). *DermaClip Non-Invasive Skin Closure Device, Revolutionizing Wound Care*. [online] Available at: https://www.dermaclipus.com/ [Accessed 18 Sep. 2019].

[9] Kitotechmedical.com. (2019). *microMend | Time-saving skin closure alternative*. [online] Available at: http://www.kitotechmedical.com/ [Accessed 18 Sep. 2019].

[10] 3m.com. (2019). *3M™ Steri-Strip™ Reinforced Adhesive Skin Closures | 3M United States*. [online] Available at: https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Steri-Strip-Reinforced-Adhesive-Skin-Closures/?N=5002385+3293321968&rt=rud [Accessed 21 Sep. 2019].

Appendix B: Design Drawing