Wound Edge Approximation

Product Design Specification

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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 hold the wound edges together while the wound is either sutured or glued, acting as a “second pair of hands” for the physician. The device may consist of a bow-shaped design to pinch the skin together or a bandage-like adhesive tool that functions by pulling the wound edges together for physicians to repair. 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. Currently, the team has two potential designs for the device. The first of which is a reusable bow shaped tool with wide and flat tips. The tips could be placed on either side of the wound, so the physician could then squeeze the sides of the bow tool until the wound edges were approximated, and the device could be locked into position during wound closure. Alternatively, the device could consist of an adhesive bandage-like tool including a velcro/clip component in a railroad track design, where adhesive tapes would be placed on both sides of the wound with a clip or tie reaching across the wound to pull and hold the edges together. The physician could then disperse the glue or suture in the intermittent spaces between the clips to stabilize the wound. After device removal, the physician could then go back in and place glue or sutures onto the sections of the wound previously covered by the device to close the entirety of the wound.

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 if the team chooses the reusable design. 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. Both of the potential designs 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 bow-shaped design must have a minimum lifetime of one year with repeated uses and sterilizations, while the bandage/adhesive design must remain sticky and pliable for a least several hours once removed from the sterile packaging.

e. *Shelf Life*: When in storage, both designs must maintain their functionality when stored at room temperature of 20-25 °C. More specifically, the bow-shaped device should not weaken or corrode over time, while the adhesive design should not lose its adhesion ability. Theoretically, the bow-shaped design could be stored for at least a year, while the bandage design should last at least 3-6 months within its sterile packaging.

f. *Operating Environment*: If the bow-shaped design is used, it should be able to withstand basic sterilization procedures in an autoclave. Additionally, any glue on the device should be able to be cleaned off in a timely manner. For the adhesive design, it should adhere to dry skin for approximately 20 minutes without slipping in a typical clinic environment, 20-25 °C.

g. *Ergonomics*: Both devices should be easily and comfortably used by the administering physician or healthcare professional. For the bow-shaped design, this means that the grips used to position the tips should be 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 shape of the bow-shaped device. The adhesive design should also be easy to use and administered without losing the effectiveness of the adhesion.

h. *Size*: The final design should function for a target wound size of 1-5 cm. Therefore, the tips of the bow-shaped design should be able to extend from 1-5 cm. The adhesive design should include thin strips of adhesive that would cover a small portion of the wound, while still allowing the physician access to at least half of the wound. However, these thin adhesive strips still need to maintain the end goal of approximating the wound edges.

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) for the bow-shaped design. The weight of the adhesive bandages should be minimal enough to be considered negligible to the patient or healthcare professional.

j. *Materials*: If the team decides to go with the bandage-like design, materials will include a bandage material made of plastic (PVC, polyethylene, or polyurethane) with an alkylate- or acrylate-based adhesive. The design will also include plastic or velcro

clips to pull the wound edges together and stabilize the wound for gluing [5]. If the team instead chooses the bow-shaped 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. With the bow shaped design, there should be a softer component that contacts the skin and is attached to the ends of the metal body. 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 [6]. 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 [7].

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. If a bow-shaped device is constructed, it should not have a texture that is too smooth and slippery, so that user error can be avoided. A bandage-like device should be thin and translucent to allow for easier approximation of the wound edge.

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 [8].

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 if it is reusable, using simple sterilization in an autoclave. If the device is single-use only, it should be sterile and packaged appropriately to protect the device from microbes before use. 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 [9].

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 [10].

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 [11].

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