Wound Edge Approximation

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ABSTRACT

Each year, 6 million laceration cases are treated in emergency departments. With lacerations larger than 1-2 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. Testing a suture kit in MTS tension resulted in a model to predict skin tensile forces during wound approximation. Use of the device by a team member showed minimal displacement after three minutes with minor, painless skin markings remaining after device removal.

BACKGROUND

- Wound edge approximation: pulling the edges of a laceration together without gaps [1]
  - Wounds over 1-2 cm in size begin to splay
  - Improper approximation of wound edges leads to scarring
- Dermabond: liquid tissue adhesive used to glue wound edges together [2]
  - Polymerizes within 30 seconds of application
  - Preferred over suturing because it is faster and does not require local anesthesia
- SkinPrep: thin film coating applied to skin that assists with adhesion [3]
  - Applied with a wipe or spray
  - Reduces friction between adhesive devices and skin during removal

EXISTING DEVICES

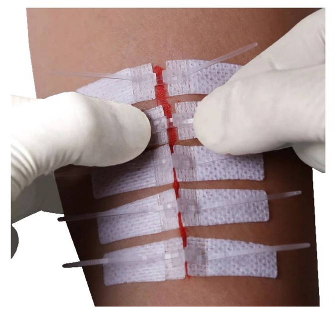

Figure 1: DermaClip device made up of plastic sutures to hold wound edges together [4].

Figure 2: Steri-strip device consisting of adhesion strips with polymer filaments [5].

MOTIVATION

- Six million laceration cases are treated in emergency departments each year [1]
- Skin tension pulls wound edges apart
- Repair is difficult and usually requires two individuals
  - One to hold wound edges together
  - One to suture or glue the wound

DESIGN CRITERIA

- Approximate wound edges for wounds on limbs and torso
- Should withstand autoclave sterilization: 30 minutes at 121°C [6]
- Produce skin tension forces between 6.5 and 7.8 N [7]
- Maintain position during approximation
- Must not harm skin, inflict pain, or have a threatening appearance
- Function for a minimum of 350 uses on wounds 2-5 cm in length
- Weigh less than 230 g
- Fabrication should be within a budget of $300

FINAL DESIGN

Materials & Fabrication:

- Strip of stainless steel 304 cut into a 76.2 mm and 44.45 mm piece
- Slots milled out with 4.7625 mm end mill
- Pieces cut down the middle using waterjet cutter in the Makerspace
- Edges of slotted pieces sanded down and welded to long pieces at 45° angle
- Thin layer of liquid silicone rubber applied to bottom of long sides
- Design utilizes silicone bumpers for skin adhesion

Final Prototype & Operation:

- Adhesive silicone bumpers applied on corners of wound
- Long edges of device placed around bumpers, pushed together to approximate wound edges
- Thumb screws tightened to secure device in place
- Device remains on the skin, allowing the clinician to use two hands while gluing or suturing

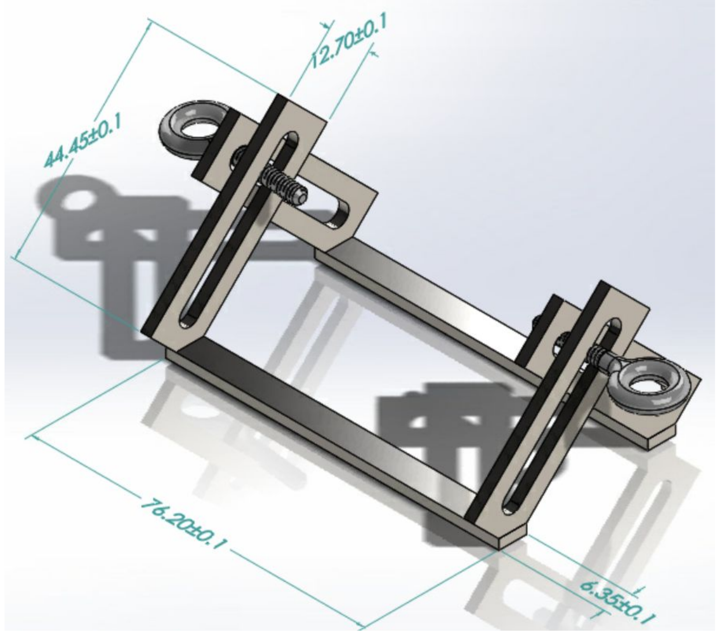

Figure 3: Solidworks model of final device with dimensions.

Figure 4: Silicone bumpers used for device placement.

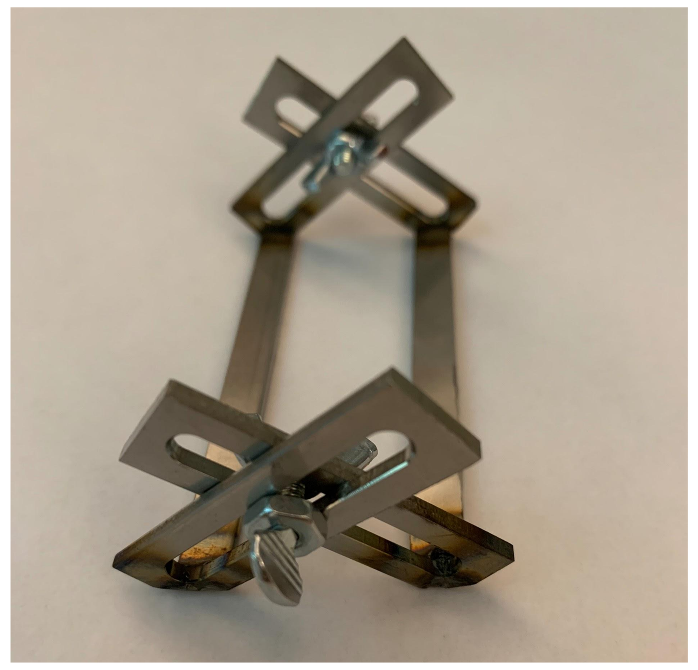

Figure 5: Side view of the final device.

TESTING PROCEDURES

- Force required to maintain wound approximation (n=3)
  - MTS tensile testing of silicone skin for stress-strain data
  - Skin creates tension - wound edges are pulled apart
  - Approximation: pulling the skin edges in tension until wound closure
  - Measure skin deformation to compute the force applied by the device to approximate the wound

Figure 6: Silicone strip being tested in tension in the MTS machine.

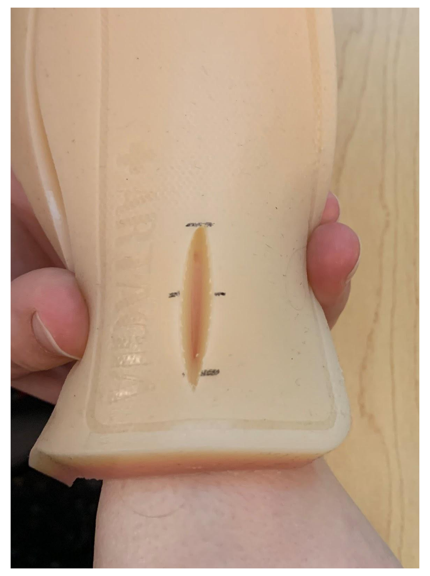

Figure 7: Silicone skin with 3 cm incision used to practice approximating and measuring the deformation.

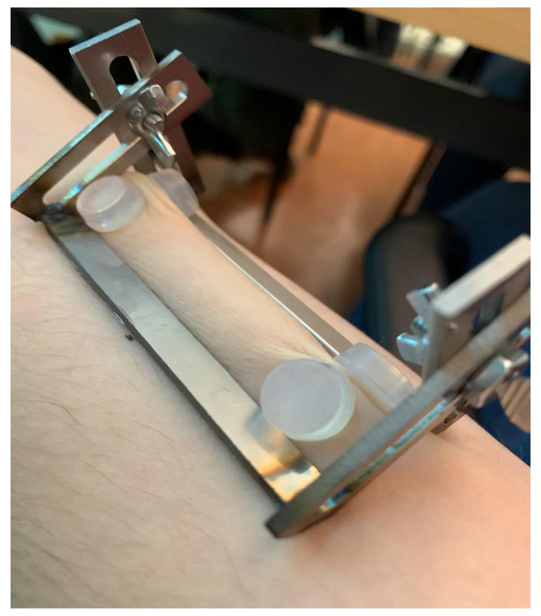

Figure 8: Final design in service on human skin.

- Device displacement during use
  - Measure displacement of the device over the service life of 3 minutes (n=3)
  - Two conditions: with the addition of SkinPrep and bare skin
- Skin markings from device service
  - Qualitatively examine the marks left on patient skin after use
- Pain scale from 0-5 (n=4)
  - 0: no pain
  - 5: severe pain

RESULTS

- Model developed to predict skin tensile forces during wound edge approximation

$$F = E*A*\varepsilon$$

F = Force
E = Elastic Modulus
A = Cross-Sectional Area
ε = Strain

E_{sample} = 0.436 MPa

E_{skin} = 0.05 - 0.15 MPa [8]

$E_{silicone}$ = 0.2 MPa [9]

- Sample tensile forces ranged between 27-40 N
  - **Conclusion:** suture pad with durable mesh layer is not an accurate model of human skin mechanics

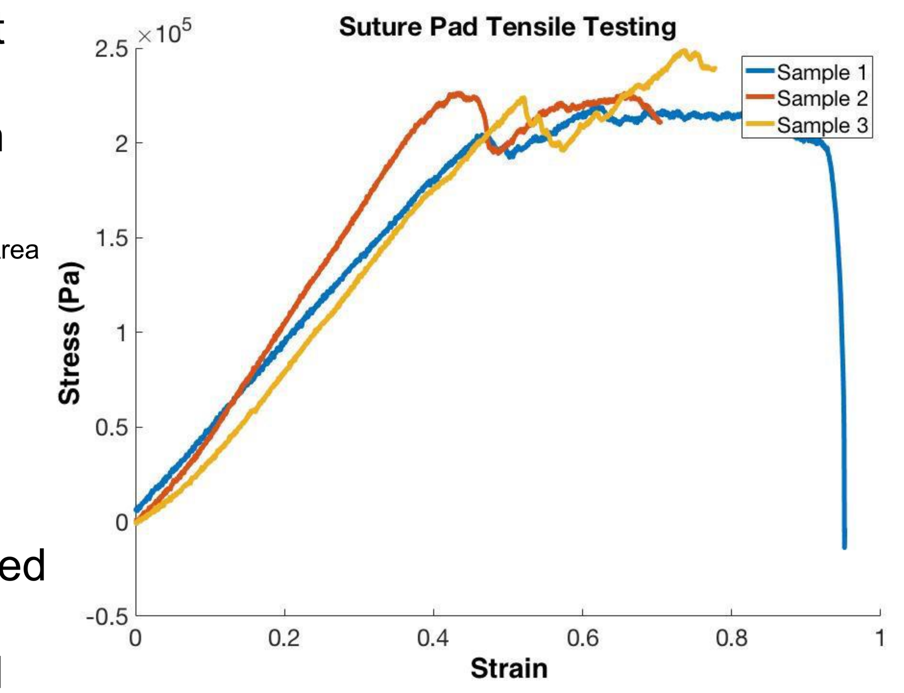

Figure 9: Stress-strain curves generated through MTS tensile testing suture pad samples.

- Average displacement over 3 minutes: 1.12 mm
  - **Conclusion**: Insignificant device displacement between bare skin and Skin-Prepped skin (p = 0.222)
- Light red markings remained briefly on skin after device removal
- Average pain score: 0.75 out of 5.0
- Final Weight: 50.81 g, ~79% lighter
- Cost: $43.07

Figure 10: Image of the markings remaining on human skin after use of the final prototype.

FUTURE WORK

- Purchase smaller, sterile adhesive bumpers
- Improve fastener mechanism
- Improve silicone application method
- Testing:
  - Real skin wounds, potentially animal skin, or more adequate synthetic model for mechanical testing
  - Ease of use among a variety of users
  - Stress Concentration Analysis in Solidworks
  - Additional parts of the body: torso, legs, upper arms

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