Wound Edge Approximation

Jurnee Beilke, Isabel Erickson, Jack Fahy, Kelly Starykowicz, & Kavya Vasan

Client: Dr. Nicola Charlton, *Department of Medicine and Public Health*

Advisor: Dr. Darilis Suarez-Gonzalez, *Department of Biomedical Engineering*

April 24, 2020

ABSTRACT

More than 10% of emergency room visits involve the repair of a cut or laceration. With lacerations larger than two centimeters, skin tension pulls the wound apart, making repair difficult without assistance. Clinicians often require a second individual to pull the edges of the wound together, also known as wound approximation, while repairing the wound. Precise wound approximation is imperative to ensure proper healing with minimal scarring. Currently, there are no devices on the market designed solely to approximate wounds. Therefore, a prototype was designed for use in clinics where a physician can accurately and repeatedly approximate wounds with the device freeing both hands for wound repair. The proposed solution is a metal frame consisting of two identical stainless steel sides, which are connected via tension springs and thumb screws secured by hex nuts. The device works by having the user pull the sides of the device apart, place them around the wound, and the springs then pull the long sides together to approximate the edges of the wound. The device attaches to the skin via double-sided adhesives in order to prevent dislocation during use. Ideal locations for use of the device include the arms, legs, and torso. Preliminary testing demonstrated that the device was able to maintain approximation during a five minute interval, caused minimal discomfort to patients, and was easy to use as rated by multiple individuals. Further modifications and testing are required prior to device use in clinical settings.

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 and poor healing
- 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

EXISTING DEVICES

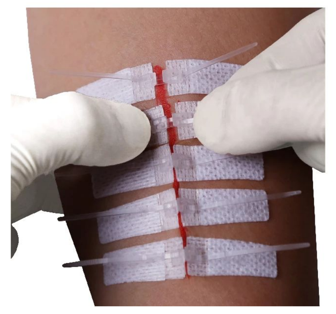

Figure 1: DermaClip device made up of plastic sutures to hold wound edges together [3].

Figure 2: Steri-strip device consisting of adhesion strips with polymer filaments [4].

PROBLEM & MOTIVATION

- Solution designed to accurately approximate wounds while freeing both hands during repair
- 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 [5]
- Produce skin tension forces between 6.5 and 7.8 N [6]
- 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 grams
- Fabrication should be within a budget of $300

FINAL DESIGN

Materials & Fabrication:

- Strip of stainless steel 304
- Slots milled out with end mill
- Pieces cut down the middle using waterjet cutter in the Makerspace
- Edges of slotted pieces sanded down and welded to long pieces
- Slot fillers added to hold thumb screws in place

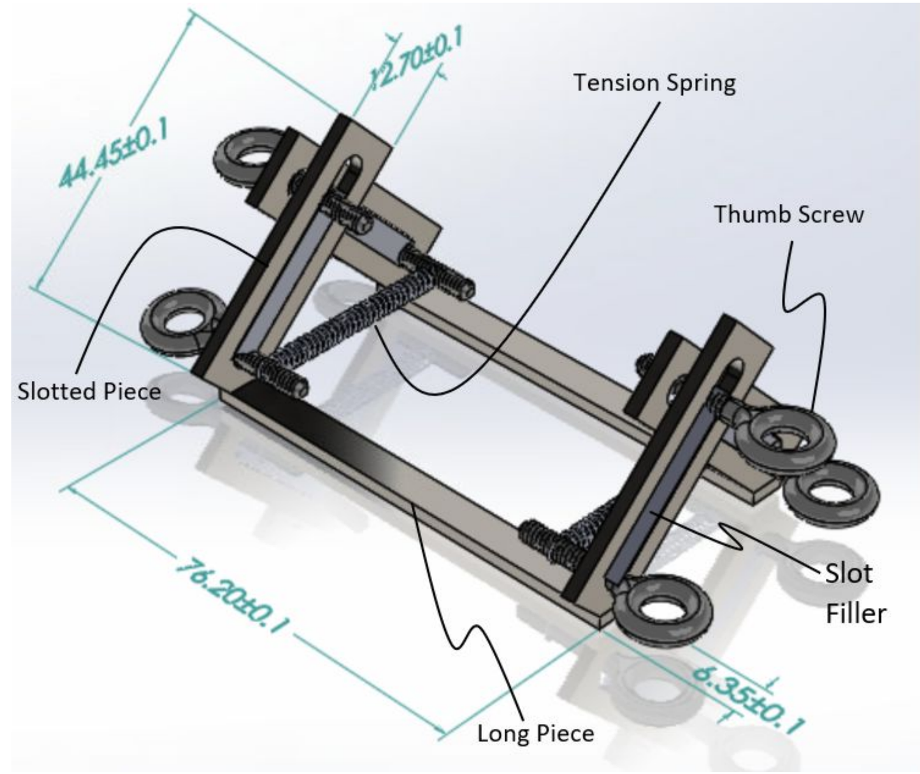

Figure 3: Solidworks model of final device with dimensions (mm). Thumb screws secured by 6-32 inch hex nuts on both sides. Slot fillers are 3D-printed PLA.

Final Prototype & Operation:

- Double-sided adhesives applied to long edges of device
- Adhesive edges of device pulled apart and placed on skin around wound
- Edges brought together by tension springs to approximate wound edges

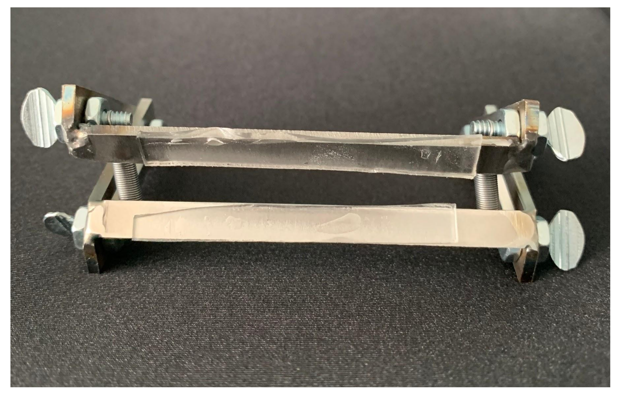

Figure 4: Device with double-sided adhesives used for device placement.

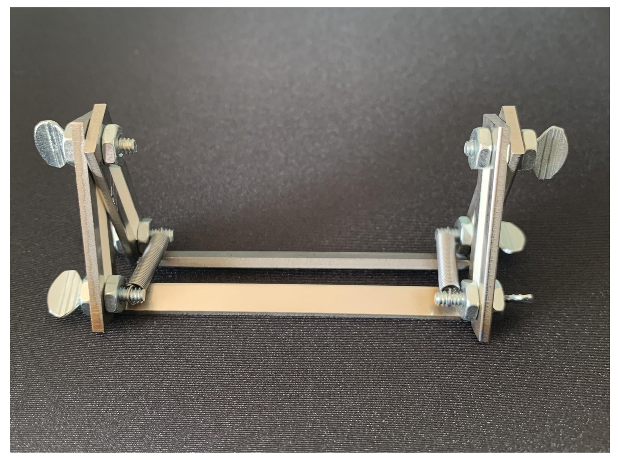

Figure 5: Front view of the final device including tension springs.

TESTING PROCEDURES

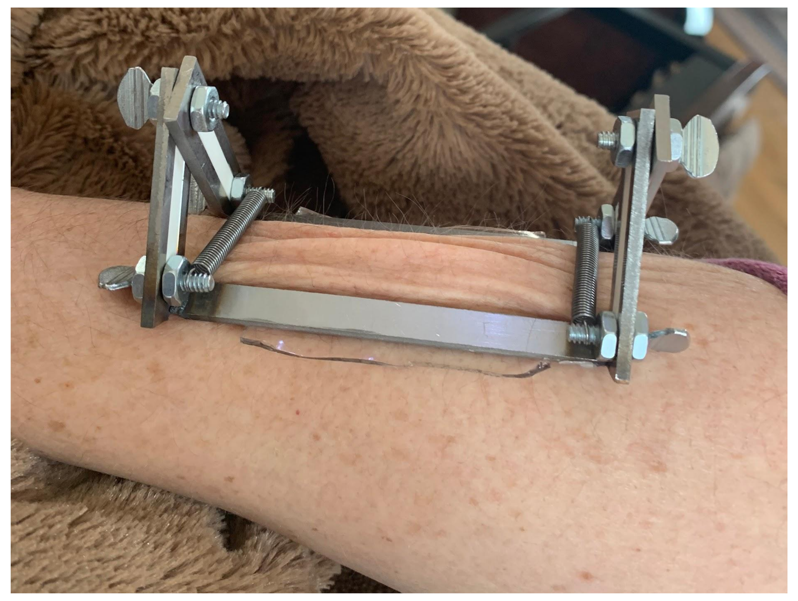

Figure 6: Final design in service on human skin.

- Device displacement during use
  - Measure displacement of the device over the service life of 5 minutes (n=2)
  - Lateral forearm, upper arm, thigh, calf, torso
- Discomfort scale
  - Individuals rank discomfort from 0-5 (n=2)
  - 0 being no pain, 5 being extreme pain
- Ease of use scale
  - Individuals rank ease of use from 1-10 (n=2)
  - 1 being easy to use, 10 being impossible to use
- 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
  - Measure skin deformation to compute the force applied by the device to approximate the wound

Figure 7: Silicone strip being tested in tension in the MTS machine.

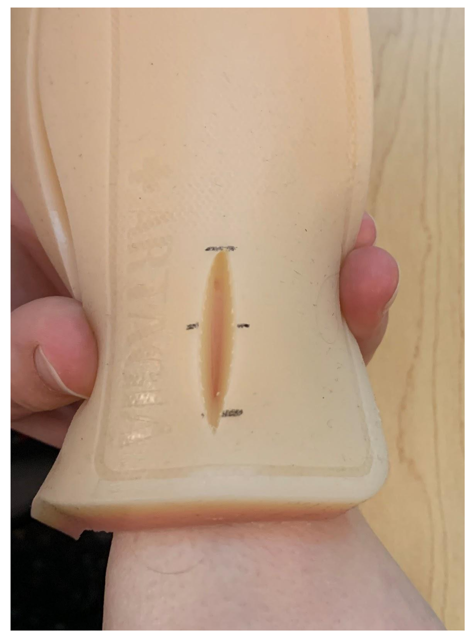

Figure 8: Silicone skin with 3 cm incision used to practice approximating and measuring the deformation.

RESULTS

- Average displacement over 5 minutes: 0.48 mm
  - Forearm = 0.4 mm, Upper arm = 1.05 mm, Thigh = 0.2 mm, Calf = 0.5 mm, and Torso = 0.25 mm
- Light red markings remained briefly (2 minutes) on skin after device removal
- Average pain score: 1.0 out of 5.0
- Ease of use score: 1.5 out of 10.0
- Final Weight: 70.0 g
- Cost: $87.49
- Model developed to predict skin tensile forces during wound edge approximation

  $$F = E*A*\mathcal{E}$$

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

  E_{sample} = 0.436 MPa

  E_{skin} = 0.05 - 0.15 MPa [7]

  $E_{silicone}$ = 0.2 MPa [8]
- Sample tensile forces ranged between 27-40 N
  - **Conclusion:** suture pad with durable mesh layer is not an accurate model

Figure 9: Image of the markings remaining on human skin after use of the final prototype.

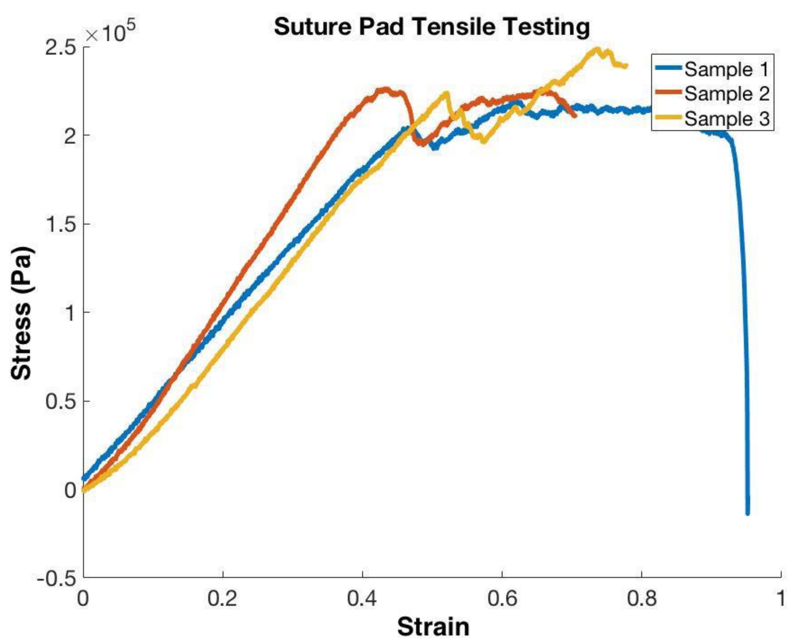

Figure 10: Stress-strain curves generated through MTS tensile testing suture pad samples.

FUTURE WORK

- Replace the double-sided adhesive with a surgical grade adhesive
- Refabricate the device with holes rather than long slots
- Acquire human testing clearance from the Institutional Review Board
- Testing:
  - Repeat ease of use and displacement testing with a larger sample size
  - Redo tensile testing with a more accurate skin model
  - Real skin wounds, potentially animal skin, or more adequate synthetic model for mechanical testing

ACKNOWLEDGEMENTS

The team extends their gratitude to their former group member Lizzy Schmida, their advisor Dr. Suarez-Gonzalez and their client Dr. Nicola Charlton. Additionally, the team would like to recognize Dr. Christa Wille for her assistance with the MTS tensile testing, the workers in the TEAM Lab for their guidance throughout the fabrication stage, and Brad Beilke for his input during the design process.

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] 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].

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

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

[7] 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 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3858658/

[8] J. Dargahi and A. Atieh, "Design, Fabrication and Testing of a Piezoresistive-Based Tactile Sensor for Minimally Invasive Surgery," *International Journal of Advanced Research in Engineering*, vol. 1, no. 2, p. 17, 2015.