Improved Method of Securing Surgical Drains

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BME Design

Overview of Presentation

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2. Client
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Problem Statement

- Design a device that secures the surgical drain in place and reduces the tension on the suture site
  - Clip opening modification to prevent drain tubing impingement
  - Ensure that design works in various conditions mimicking daily activities
- Safety and sterility for clinical use
  - Attachment of clip using different adhesive methods
  - Sterilization of fabricated product
  - Packaging for long term storage and extended shelf life

Client

- Dr. Katie Kalscheur
- Instructor in UW-Madison Engineering Department
- Presented the project concept with hope to aid others experiencing drain-related pain

Design Constraints

- Compatible with any type of surgical drain
- Accessible drainage site
- Operate effectively at body temperature 98.3 +/- 4.0 °F [1]
- Water and sweat resistant
- Materials used cannot interfere with natural wound healing
- Can be utilized without need for replacement for up to a week

Design Impact

- Estimated **47.8 million** drains sold in 2020, projected to reach **59.7 million** by 2030 [2]
- In a study **7 out of 104** (6.6%) of sutured drains fell out unintentionally 3 days after insertion [3]
    - Reinsertion leads to more discomfort and higher risk of infection
- Risk of infection increases by **76.2%** with each additional week past 21 days [4]

Competing Designs

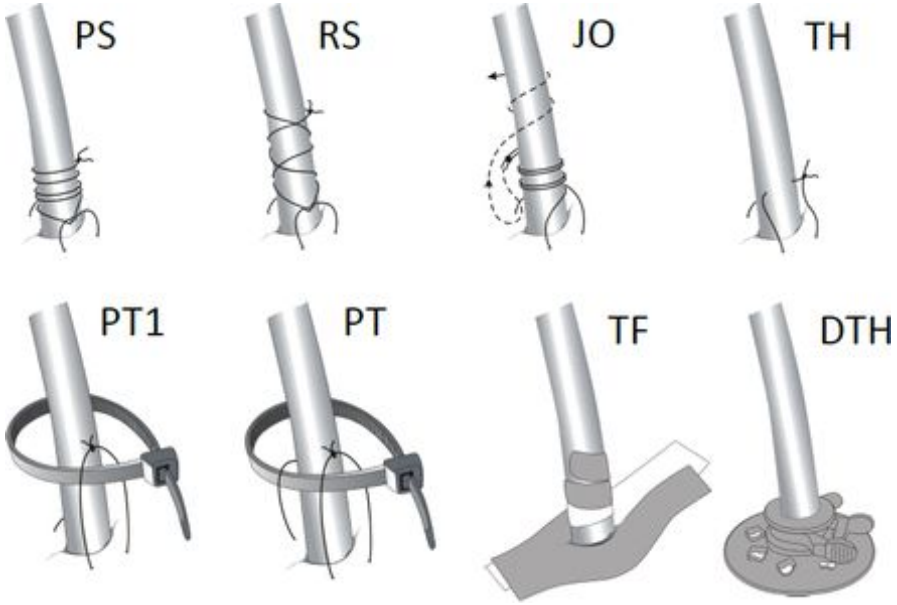

Figure 1: Surgical drain fixation techniques [5]

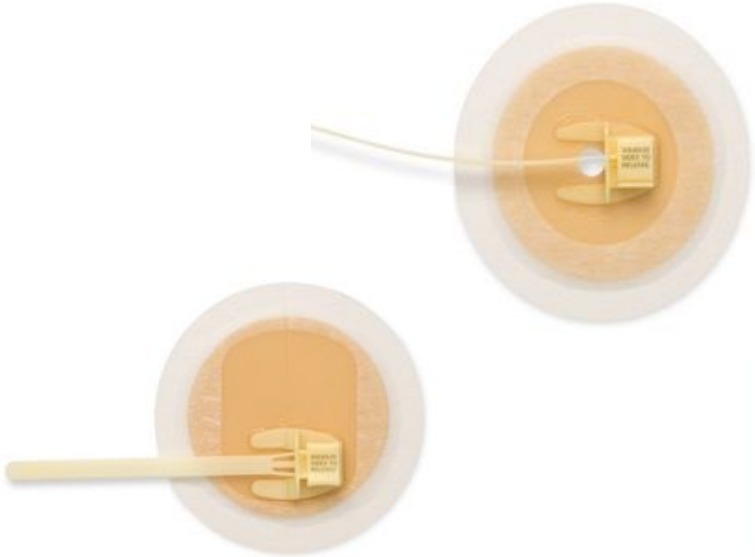

Figure 2: Drain tube attachment devices from Hollister Incorporated [6]

Current Design

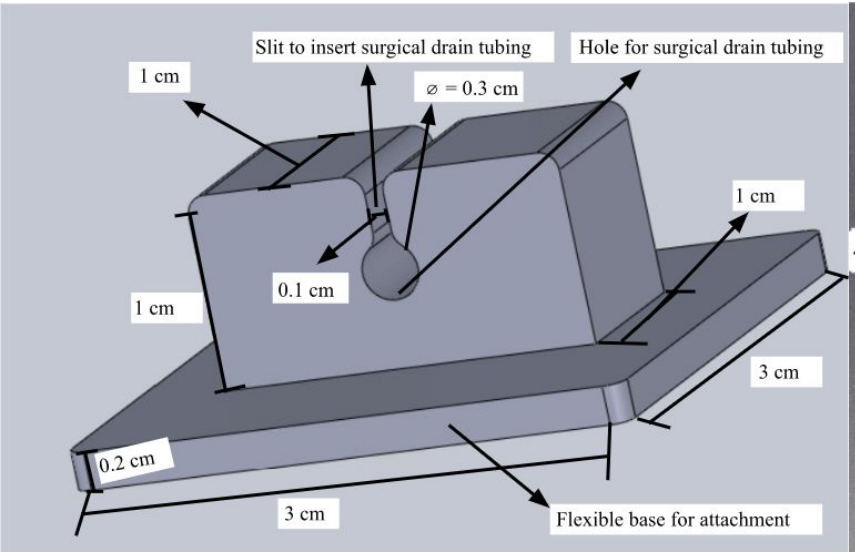

Figure 3: Clip design with dimensions.

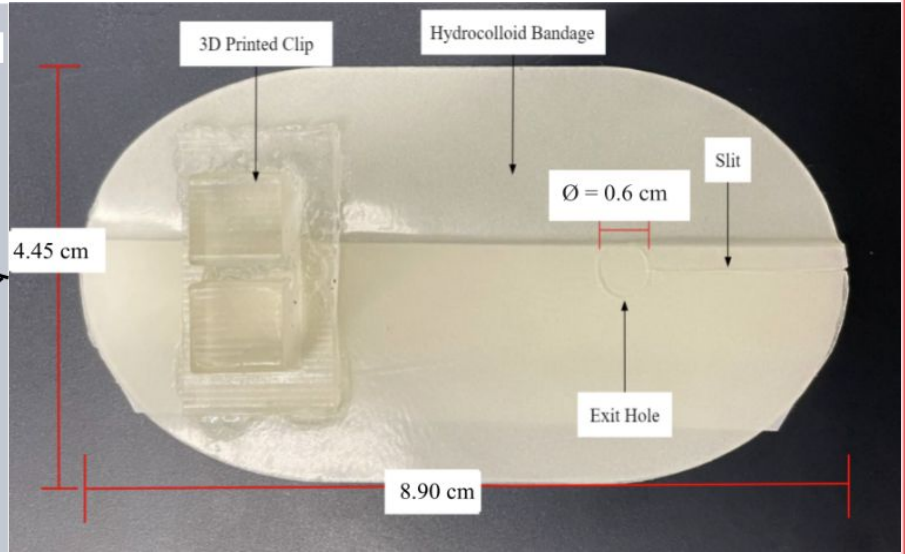

Figure 4: Top view of final prototype highlighting the important features.

Current Design

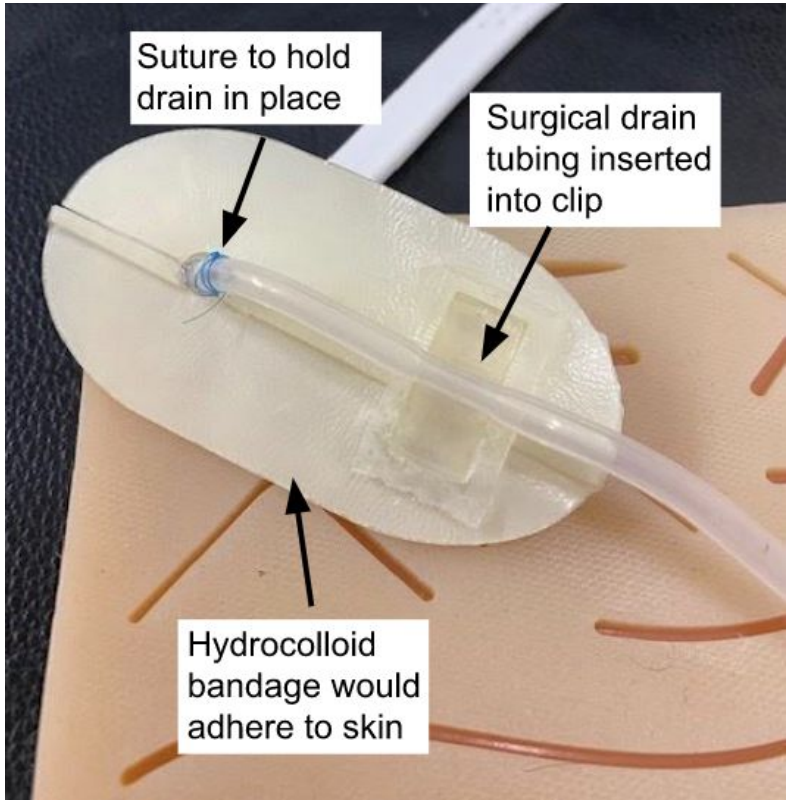

Figure 5: Design system placed on drain site mimicked using a suture kit.

Previous Testing Results

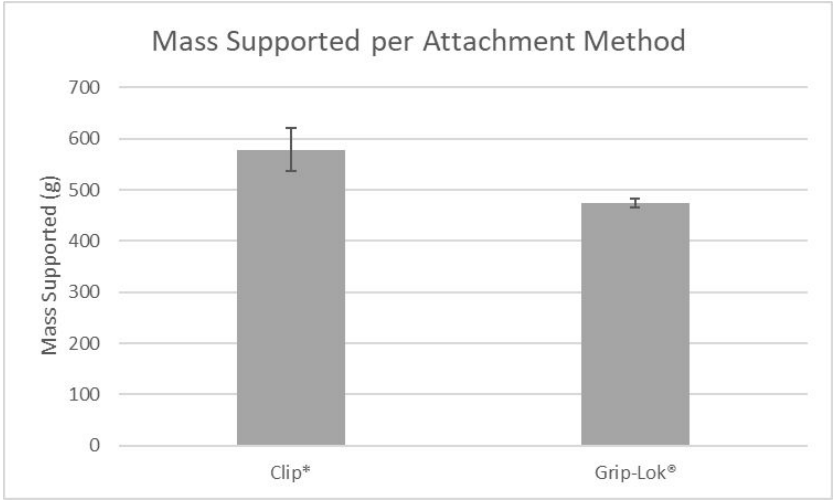

Figure 6: The mass supported (in g) of a 3D-printed clip and Grip-Lok® when attached to a Jackson Pratt surgical drain. The clip supported more mass than the Grip-Lok® (p=0.0261).

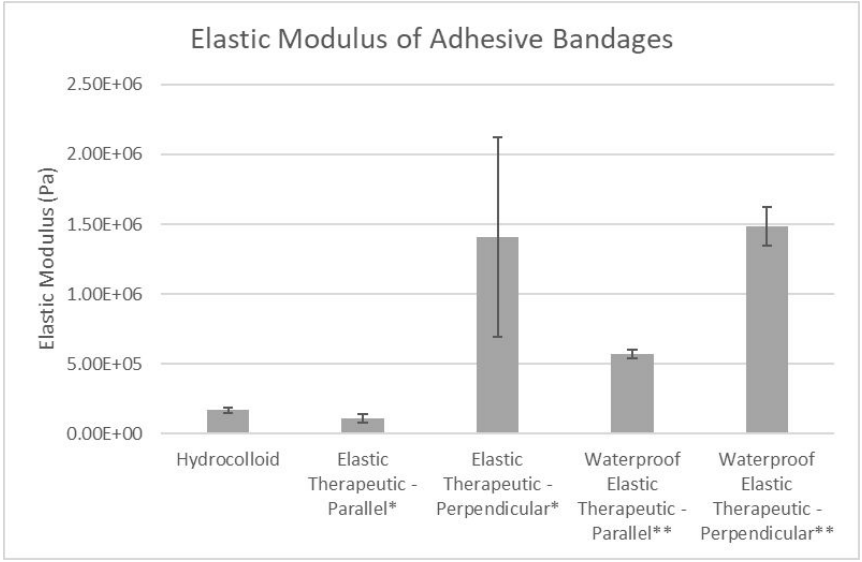

Figure 7: The elastic modulus of adhesive bandages as determined by an MTS machine. The parallel and perpendicular directions of the elastic therapeutic tape and waterproof elastic therapeutic tape were significantly different (p=0.0348 and p=0.000398, respectively).

Previous Testing Results

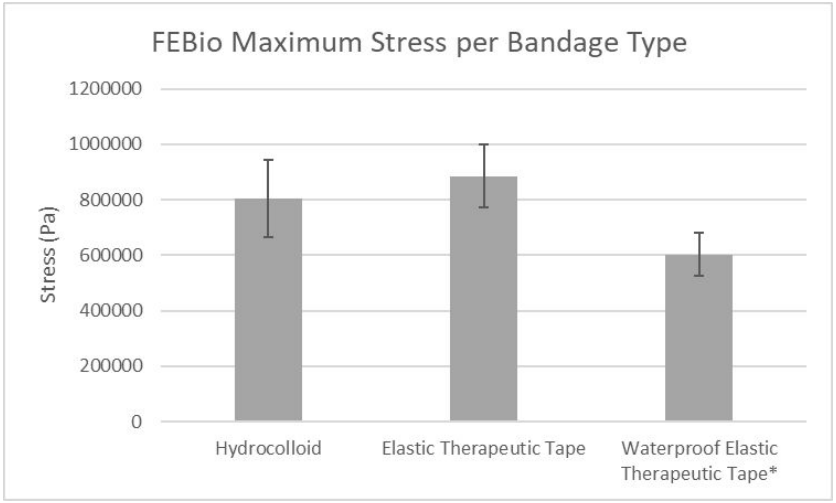

Figure 8: The maximum stress in each adhesive bandage as calculated by FEBio. Maximum stress was significantly different, determined by ANOVA (p=0.0246).

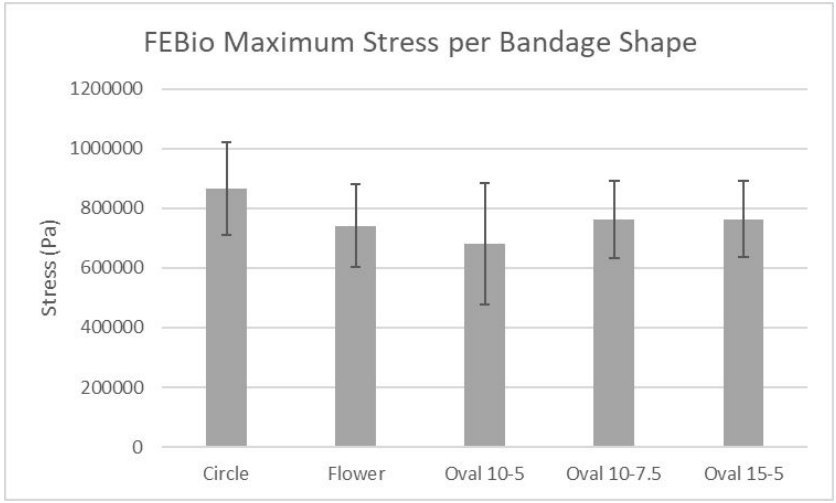

Figure 9: The maximum stress of various adhesive bandage shapes as calculated by FEBio. Maximum stress was not significantly different, determined by ANOVA (p=0.583).

Timeline – February

Feb. 10th

Contact 3M and Mölnlycke

Beki and Oscar will reach out to their contacts that work at these companies.

Feb. 10th

Print Clip Iteration

Print new clip iteration.

Feb. 14th

Contact IRB About Testing

Create testing proposal for testing bandage design comfort.

Feb. 20th

Complete Testing of Clip Design

Conduct testing of new clip iteration utilizing the attachment support testing protocol and a flow test.

Feb. 27th

Write Test Protocol for Human Testing

Create detailed testing protocol for self-test of longevity. Dependent on the guidelines from the IRB.

Timeline – March

Mar. 1st

Preliminary Deliverables Due

Complete preliminary deliverables.

Mar. 10th

Begin Testing

Utilize testing protocols written based on the IRB guidelines.

Mar. 24th

Outreach

Complete outreach activity within local school district.

Mar. 31st

Complete Testing

Complete self-testing, sweat testing, and adhesive testing.

Mar. 31st

Validate Attachment Design

Verify the design meets requirements of PDS.

Timeline – April/May

April 7th

Finalize Fabrication and Sterilization Methods

Decide on fabrication and sterilization methods for final design. Finalize documentation and packaging.

April 14th

Complete Test Analysis

Analyze data to get statistical results for the final deliverables.

April 21st

Executive Summary Due

Complete executive summary for award consideration.

April 28th

Final Presentation

Present final design and results from testing.

May 3rd

Final Deliverables Due

Complete all final deliverables.

User Manual and Sterilization

- Explore sterile packaging outsourcing
- A user manual providing detailed instructions will be created
  - Attachment & Removal
  - Maintenance
  - Safety
  - Ingredients
  - Expiration date / Shelf life

Budget

	Items Purchased	Total
Bandages	Hydrocolloid dressing, silicon bandage, elastic therapeutic tape, waterproof bandages	$90.48
Attachment Methods	Griplok, velcro, cable clip, 3D printed clip prototypes	$150.24
Miscellaneous	Practice suture kit	$27.99
	Last Semester:	$268.71
Adhesives	3M/Mölnlycke Adhesive	TBD
Bandages	Hydrocolloid dressing	$30.00
Attachment Methods	3D printed clip	$100.00
	Total Estimated Cost:	$398.71

References

[1] “Fever: First aid,” Mayo Clinic, 11-Jun-2022. [Online]. Available: https://www.mayoclinic.org/first-aid/first-aid-fever/basics/art-20056685.

[2] “Surgical drains market statistics, Growth Drivers: Forecast- 2030,” *Allied Market Research*. [Online]. Available: https://www.alliedmarketresearch.com/wound-drainage-surgical-drains-market-A07517.

[3] R. Asciak *et al.*, “Chest drain fall-out rate according to suturing practices: A retrospective direct comparison,” *Respiration*, vol. 96, no. 1, pp. 48–51, 2018.

[4] Chen CF, Lin SF, Hung CF, Chou P. Risk of infection is associated more with drain duration than daily drainage volume in prosthesis-based breast reconstruction: A cohort study. Medicine (Baltimore). 2016 Dec;95(49):e5605. doi: 10.1097/MD.0000000000005605. PMID: 27930584; PMCID: PMC5266056.

[5] Y. Ringel, O. Haberfeld, R. Kremer, E. Kroll, R. Steinberg, and A. Lehavi, “Intercostal chest drain fixation strength: comparison of techniques and sutures,” BMJ Military Health, vol. 167, no. 4, p. bmjmilitary-2020-001555, Oct. 2020, doi: 10.1136/bmjmilitary-2020-001555.

[6] “Tube Attachment Devices | Critical Care Products | Hollister US,” www.hollister.com, 2022. https://www.hollister.com/en/products/Critical-Care-Products/Tube-Securement/Tube-Attachment-Devices#