UNIVERSAL ABSCESS DRAIN

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Abstract

Cutaneous abscesses are localized, pus-filled cavities under the skin caused by bacterial infections or prolonged exposure to foreign material. In 2005 there were 3.28 million emergency department visits (2% total ED visits) for cutaneous abscesses, ranking them the seventh most common cause for ED admittance. In addition to being painful, they can lead to local tissue ischemia, tissue death, and systemic infection if left untreated. The most common method of treatment is surgical incision and drainage of pus from the abscess cavity using a Penrose drain. We have developed a novel surgical drain that minimizes the cost, time, and patient pain associated with abscess treatment. Using an array of silicone posts, our drain eliminates the need for suturing and can be replaced in the abscess without the help of a nurse or physician, substantially reducing treatment costs. Made from resilient medical-grade polydimethylsiloxane (PDMS), the drain is flexible enough for easy insertion into the abscess, yet stiff enough to remain affixed during normal patient activity. The drain was prototyped in large and small sizes (L and S, respectively) and three different variants based on posting geometry: 45˚ angled in-plane (LA and SA), straight in-plane (LS) and 45˚ in/out-of-plane posting (LIO). The drain variants were evaluated using a cadaver model, a pig model, a contact angle measurement, and a Bradford protein adsorption assay. The LA and SA variants were found to be optimal. Average removal forces of 0.99 lbs and 1.40 lbs were required to remove the LA drain from incisions made in the cadaver and pig models, respectively. The water contact angle was found to be lower on the PDMS surface compared to the latex surface, suggesting a design material less susceptible to protein adsorption. Bradford assay results showed moderate levels of protein adsorption on all four drain variants over 72 hrs, with the Penrose drain having similar levels. Overall, this product effectively meets all of our client's requirements and should greatly improve the treatment of cutaneous abscesses.

Background

What is an Abscess?

- Pus-filled cavity under the skin caused by bacterial infection or presence of a foreign object
- If left untreated, may lead to tissue death, tissue ischemia, and systemic infections

Project Motivation

- Current treatment method is costly, time consuming, and painful for the patient
- If dislodged, Penrose drain requires specialized medical care to be replaced and re-sutured

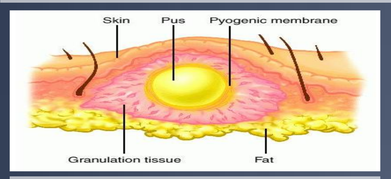


Figure 1: Subcutaneous abscess

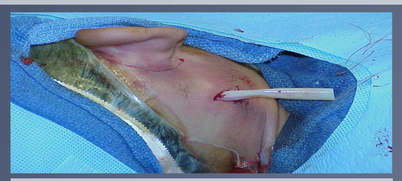


Figure 2: Penrose drain inserted in an abscess

Design Requirements

1. Eliminate necessity for sutures
2. Minimize wound pressure & associated pain
3. Reduce need for specialized medical attention
4. Construct drain from medical-grade silicone rubber
5. Design *simplicity* is paramount for market competitiveness

Fabrication

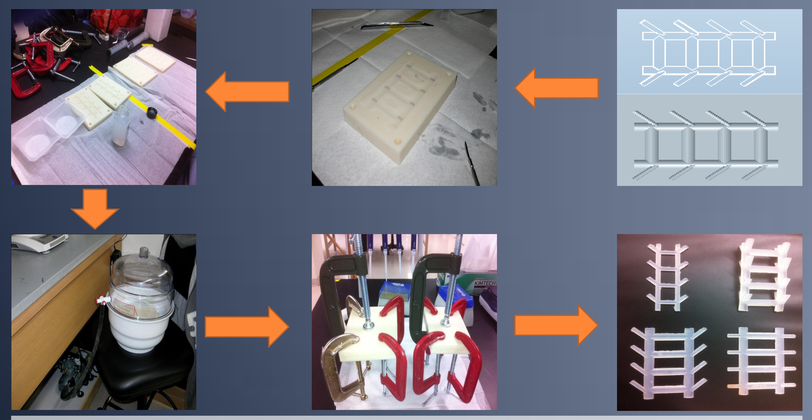


Figure 3: Fabrication process - from CAD model to final prototypes

Testing

Mechanical Testing

Cadaver Protocol

- Inserted into 2" incision, medial anterior thigh
- Shimpo FGE-50X tensile force gauge to measure removal force from incision (n=3)

Results

- Angled variants displayed increased stability in the wound; however, LIO required excessive force to remove
- Posting geometry, not size, was the determining factor in drain stability

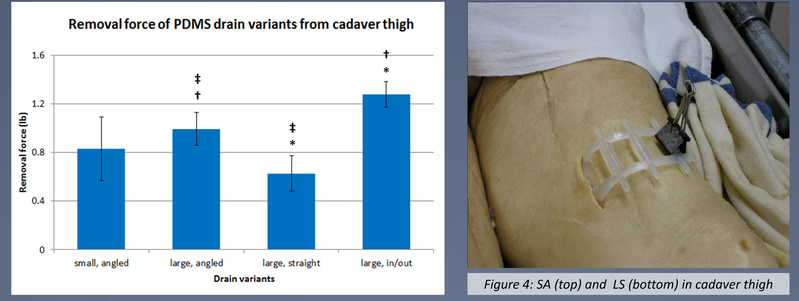


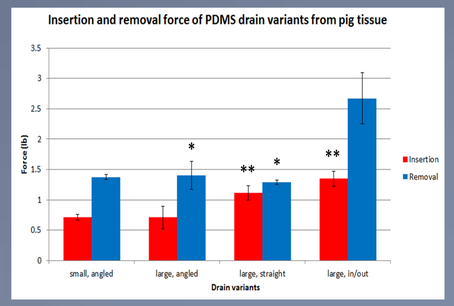
Figure 4: SA (top) and LS (bottom) in cadaver thigh

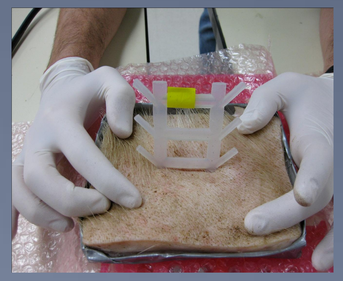
Pig Protocol

- 0.5" thick pig abdominal tissue incised
- Shimpo FGE-50X tensile force gauge to measure insertion and removal force (n=3)

Results

- LA and SA drains displayed optimal insertion and removal forces
- Ideal drain design is easy to insert yet difficult to remove
- Results correlate strongly to cadaver test





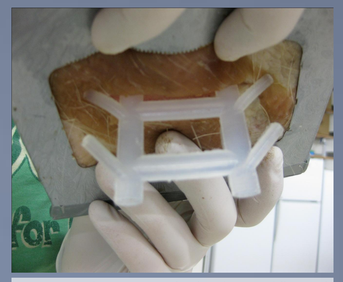


Figure 5: LA drain insertion (top) and removal (bottom)

Biocompatibility Testing

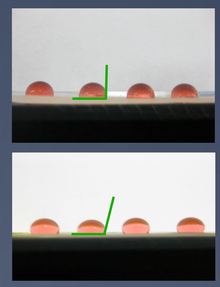


Figure 6: Water contact angle pictures: PDMS (top) and Penrose (bottom)

Table 2: Water contact angle comparison between PDMS & Penrose material

	Average contact angle
Polydimethylsiloxane	91.72˚ ± 0.95
Penrose drain	117.34˚ ± 16.32

Contact Angle Protocol

- Measured contact angle of 25 µL dyed water on substrate using ImageJ software (n=4)

Results

- Penrose drain found to have higher water contact angle, indicating it is more hydrophobic and likely to exhibit higher levels of protein adsorption *in vivo*

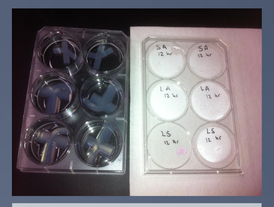
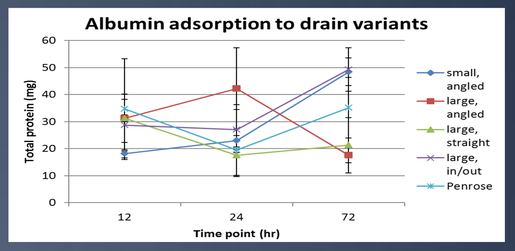


Figure 7: Drain segments were incubated in 3 g/dL egg white albumin for 12-72 hrs



Protein Adsorption Protocol

- Egg white albumin dissolved at 3 g/dL in DMEM, incubated drain variant segments for 12, 24, and 72 hr at 37 ˚C
- Proteins desorbed with 0.1% SDS in 1X PBS and absorbance read at 595 nm after addition of Coomassie Brilliant Blue dye

Results

- All drain variants exhibited similar levels of protein adsorption from 12 to 72 hr
- High level of protein concentration in media may have negated material hyrophobicity

Final Design

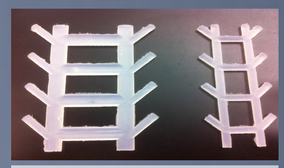


Figure 8: LA (left) and SA (right) PDMS drains

- Best mechanical properties; easy to insert, moderately difficult to remove
- Ergonomic and patient-friendly
- Easiest to manufacture, least intricate mold cavity
- Cut-to-fit once inserted into abscess to minimize profile above skin
- 30A PDMS flexible and resilient

Financial Analysis

Table 1: Estimated costs of production for a PDMS drain

	Aluminum, one cavity	Steel, four cavity
Cost of mold	$25,000	$250,000
Parts per month	10,000	100,000
Projected cycle life	100,000	5,000,000
Total parts produced	100,000	20,000,000
Cost per unit:	**$0.25**	**$0.10**

- Selling point of $10 per unit puts market potential for our device is $20-30 million annually

Future Work

- Submit IDR to WARF and executive summary for BMEStart competition
- Add irrigation channel to drain leg for periodic abscess care
- Conduct animal trials to observe abscess healing rate, verify cadaver and pig tests
- Submit manuscript to *Journal of Medical Devices*

Acknowledgements/References

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