Universal Surgical Drain for Suture-free Treatment of Cutaneous Abscesses

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Abstract

Background: In 2005, there were a reported 3.28 million emergency department (ED) cases for the treatment of cutaneous abscesses, accounting for 2% of all ED visits that year. The current treatment for cutaneous abscesses is incision and drainage followed by packing the abscess cavity with a Penrose drain (PD) or gauze. This treatment requires the PD to be sutured externally to the skin and is highly painful and expensive for the patient. A novel drain that eliminates the need for sutures would have immediate clinical and commercial impact.
Method of Approach: Mold cavities were designed using ProEngineer and were constructed using a Dimension FDM 3D printer. Four ladder drain variants distinguished by different anchoring post geometries were fabricated using 30A two-part polydimethylsiloxane (PDMS). The force required to remove the ladder drain variants from cadaver thigh and pig abdominal tissue *ex vivo* models was quantified using a tensile force gauge. The insertion force was also quantified using a pig abdominal tissue *ex vivo* model. Protein adsorption and contact angle measurements were taken to compare the biocompatibility of the PD and the four ladder drain variants.
Results: The ladder drain variants required forces between 0.62 and 1.28 lb to remove from the cadaver thigh (n=3). Similar trends were found using the pig tissue, with removal forces ranging from 1.29 to 2.67 lb (n=6) while insertion forces were lower, ranging from 0.71 to 1.35 lb (n=6). The contact angle of water was found to be 117^{o} and 92^{o} on the latex rubber PD and PDMS, respectively. Both the PD and four ladder drain variants adsorbed similar levels of reconstituted albumin at 12, 24 and 72 hour time points.
Conclusions: The 45^{o} in-plane post design exhibited optimal mechanical properties in the cadaver and pig tissue models. The higher contact angle of water on the latex rubber surface suggests the PD material is more susceptible to protein adsorption than the PDMS of the ladder drain, although a protein adsorption assay was inconclusive.

1. Background

Cutaneous abscesses are localized, pus-filled cavities under the skin caused by bacterial infections or prolonged exposure to foreign material. In 2005, there were a reported 3.28 million emergency department (ED) visits for the treatment of abscesses, accounting for 2% of all ED visits that year and making abscess treatment the seventh most common reason for ED admittance [1]. The current standard treatment for cutaneous abscess care is incision and drainage (I&D) followed by internal cavity debridement, cavity flushing with saline and subsequent packing with a Penrose drain (PD) or gauze [2]. I&D and packing allows for continuous drainage, preventing re-infection, allowing the abscess to heal without supplemental antibiotic use [2,3]. The PD is sutured externally to the skin adjacent to the incision and covered with a bandage.

Over the duration of healing, the abscess cavity contracts as it heals by secondary intention and the patient is required to make repeated visits to a primary care facility in order to have the abscess cleansed and repacked to accommodate the reduced cavity size. The process of cleansing and repacking is repeated until the abscess has completely healed, which can take from one week to greater than one month depending on numerous factors including, but not limited to, abscess size and location, pathogen responsible and individual healing rates [3,4]. Additional clinic visits may be required if the Penrose drain is dislodged due to patient movement. Subsequent clinic and primary care facility visits for abscess

treatment and management make the current treatment method inefficient and expensive. Besides the superfluous cost of specialty care required after the initial I&D, there is also significant of patient pain and discomfort while the tender abscess cavity is packed with a PD or gauze. The morbidity at the abscess site is increased as the PD needs to be sutured externally to the skin in order to remain anchored in the abscess cavity. Recent studies have gone as far as showing that routine packing of an abscess is both unnecessary and may reduce the efficacy of the treatment [5,6].

The PD, in particular, is outdated and no longer suitable for modern treatment protocols. First presented in 1890 by Penrose Charles Bingham, the PD is a natural latex rubber tube made in various widths. Alternatives treatment options are available including passive drains with unique interior lumens designed to prevent premature clogging and active drains such as KCI's vacuum assisted closure (VAC) system for chronic wounds; however, few devices are able to compete with the PD due to its low cost and simplicity.

Due to the inadequacy of current abscess treatment methods and the lack of feasible alternatives, we have developed a novel drain intended to replace the PD for the treatment of cutaneous abscesses. The goals in developing the new abscess drain were 1) eliminating the need for suturing, 2) reducing the patient pain and discomfort associated with using the PD, and 3) eliminating the need for follow-up hospital care, apart from the initial treatment, while remaining cost-effective. Particular emphasis was put on the simplicity of the drain, both in design and material composition, to enable a patient to manage their own treatment as well as minimize production costs. Four different drain variants were fabricated using polydimethylsiloxane (PDMS) and tested for mechanical function and biocompatibility. Two drain variants, the large angled 45° in-plane (LAIP) and small angled 45° in-plane (SAIP), were selected as the optimal designs due to mechanical functionality and stability within two model abscess cavities. The LAIP and SAIP provide a more effective alternative for cutaneous abscess treatment when compared to conventional options.

2. Method of Approach

2.1 Ladder drain fabrication

Four ladder drain variants intended for prototyping and testing purposes were produced using a novel small-scale production method (*Figure 1*). First, design variations and corresponding dimensions were theorized using engineering principles and knowledge. Flexural bending and beam bending equations were used to optimize design dimensions to fulfill product design specifications by using simplifying assumptions on drain geometry and material properties. Next, negative molds of the four hypothesized ladder drain variants were designed using computer-aided design (CAD) software. These CAD models were rendered into acrylonitrile butadiene styrene (ABS) 3D negative molds using a rapid prototyping 3D printer. Finally, two-part 30A PDMS was packed into the negative mold cavities, degassed in a vacuum and cured to produce the desired number of prototypes of the four ladder drain variants.

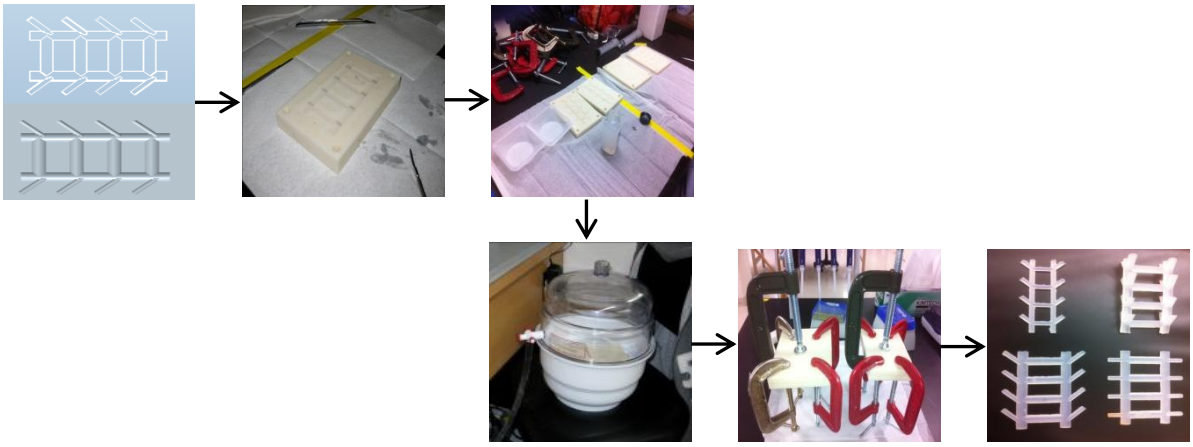
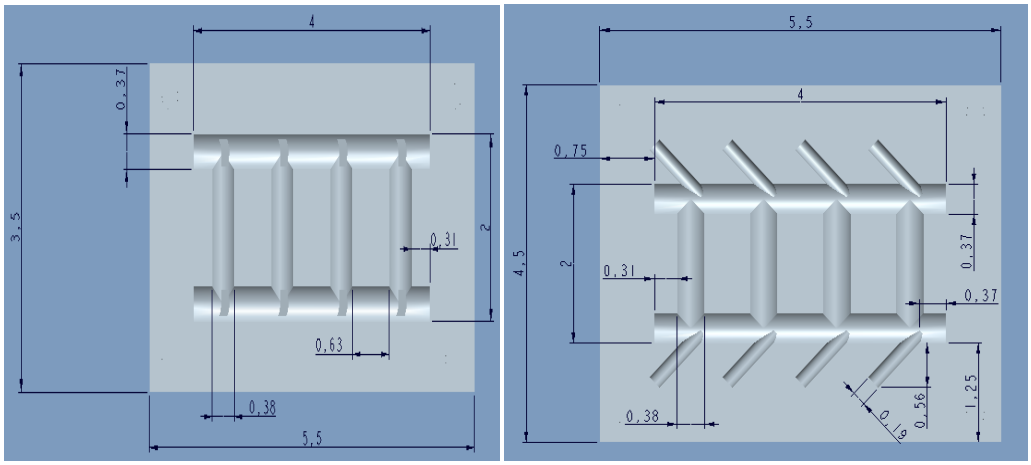


Figure 1: Design process for efficient small-scale production of prototype ladder drain variants. CAD models were developed in ProEngineering for production of ABS rapid prototyping negative molds. Two-part 30A PDMS was packed into the negative mold cavities, degassed and clamped using 3" c-clamps. After curing at 185 °F for 90 mins, PDMS prototypes were removed from the ABS negative molds.

2.1.1 3D CAD negative molds

Fabrication began with the creation of 3D computer-aided design (CAD) negative molds using ProEngineer graphic modeling software. Graphic models were produced for four ladder drain variants which differed from each other in either size or posting geometry. Post geometries consisted of angled 45° in-plane (small (SAIP) and large (LAIP) sizes), angled 45° out-of-plane (LAOP) and straight in-plane (LSIP) (*Figure 2*). All drains were prototyped with uniform length and thickness of 4" and 3/16", respectively. For the three large drain variants rungs were positioned with a center to center distance of 1" and a rung width of 3/8". Designed for use in a 2" surgical incision, the large drain design had a total width, not including posts, of 2". All large drains were designed with posts that protruded a horizontal distance of 1/2" from the two parallel 3/8" wide legs. The SAIP drain, designed for use in a 1" surgical incision, had 1" spacing center to center between rungs while dimensions of total width, rung width, leg width and horizontal post protrusion distance were scaled down by a factor of two when compared to the large drain.



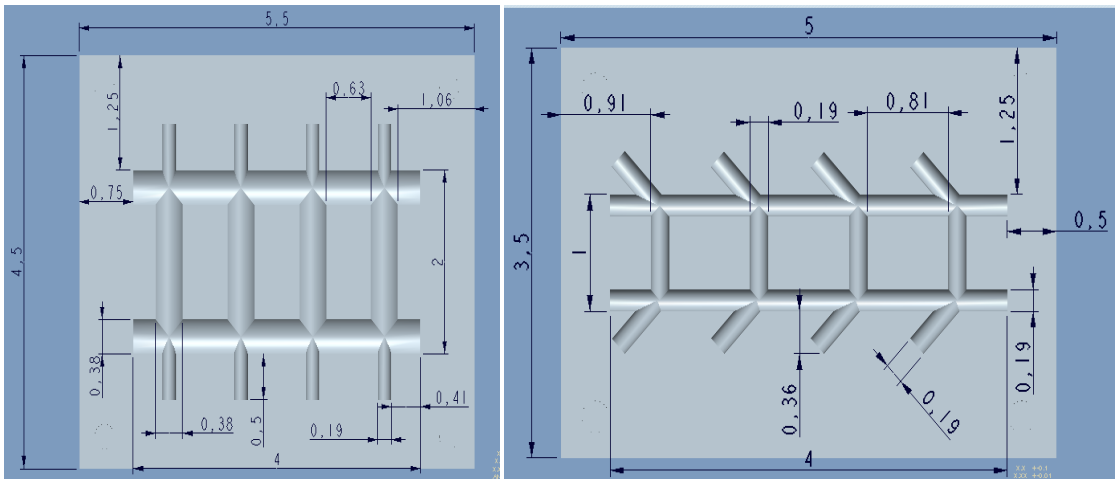


Figure 2: CAD model of four ladder drain variants with dimensions. From left to right: (TOP) LAOP, LAIP (bottom) LSIP, SAIP. Not standard dimensions between all large variants for rung, leg and total width as well as rung spacing and horizontal extension of posts.

2.1.2 ABS negative mold production

A Dimension Fused Deposition Modeling (FDM) 3D printer was used to create functional negative molds from ProEngineering CAD models. The FDM rapid prototyping machine converted .stl ProEngineering files to ABS parts through a solid-based additive process in which the models were extruded layer by layer. The ABS thermoplastic was melted, extruded and deposited to form successive 0.01” thick 2D cross-sectional layers. After solidification of the previously formed layer, a successive layer was added as the building platform descended, allowing for the creation of complex 3D shapes and parts. The FDM printer was ideal for the ladder drain mold creation as it provided both a fast fabrication rate (~4 hours per completed mold) and had strict dimensional tolerances (x, y planes: ±0.005” for the first inch and ±0.002” for each inch thereafter; z plane: ±0.01" for the first inch and ±0.002” for each inch thereafter), which were smaller than the minimal dimension of the mold (0.09375”) [7]. In addition, ABS provided a suitable material for the negative molds as it offered adequate rigidity for clamping during drain fabrication and had a high enough melting point (221 ^{o}F) to be used for PDMS curing (185 ^{o}F).

2.1.3 PDMS ladder drain prototyping

PDMS drains were produced using 30 shore A durometer PDMS. Two-part (1:1 ratio), titanium catalyst NuSil PDMS (MED-4930) was measured out using a 30 mL syringe. Large and small drains required 18 mL and 12 mL each of part A and B, respectively. Mixing time varied with the total amount of PDMS being stirred, roughly 3 min per 12 mL PDMS. Mixed PDMS was degassed by pulling a 27 inHg vacuum with 3x15 min cycling and slight agitation between cycles to further eliminate trapped air bubbles. The degassed PDMS was transferred back into a 30 mL syringe and dispensed into a larger 60 mL syringe taking care not to introduce new air bubbles. The 60 mL syringe was used to inject the PDMS into the ABS negative mold halves. The narrow syringe Luer port helped to eliminate any residual air pockets trapped within the PDMS after degassing. After filling both mold halves with excess PDMS, the two halves were clamped together using five 3” c-clamps. The five 3” c-clamps were positioned with one squarely in the middle of the mold and the other four approximately 0.75” in from each corner. This arrangement ensured an even pressure distribution and optimal PDMS flow within the mold cavity.

Clamped molds were cured at 185 ^{o}F for 90 min. After the molds cooled to room temperature, they were opened and the PDMS flash removed.

2.2 Mechanical testing

In order for an abscess drain to function properly, it must remain stable within an incision to prevent the skin from closing and blocking the drainage of pus. Mechanical testing was used to evaluate the stability of the ladder drain variants *ex vivo* while also quantifying the force required to insert and remove the four ladder drain variants from an incision. Two different models were chosen for testing: a cadaver thigh model and pig abdominal tissue model. A surgical scalpel was used to make incisions in both the cadaver and pig models, and a Shimpo FGE-50X digital tensile force gauge was used to measure the force required to insert and remove the drain variants from the incisions at increments of 0.01 lb.

2.2.1 Cadaver thigh model

A cadaver was obtained from the University of Wisconsin-Madison School of Public Health. It was preserved in formalin and stored in 60% ethanol solution. A 1" wide incision was made in the proximal medial thigh to the depth of the underlying muscle using a surgical scalpel. One rung of the SAIP ladder drain variant (1" width) was manually inserted into the incision so the first set of posts was fixated beneath the tissue. A clamp was secured to the exposed end of the SAIP drain to allow for uniform force distribution during removal. The Shimpo FGE-50X digital tensile force gauge was set to 'Peak' mode, zeroed and attached to the clamp. Tension was applied at a constant rate until the drain was pulled free from the incision, and the peak force was captured by the tensile force gauge and recorded (*Figure 3*). This process was repeated three times (n = 3) and the average peak removal force was calculated. The incision was widened to 2" and the previous steps were repeated using the LAIP, LAOP, and LSIP ladder drain variants.

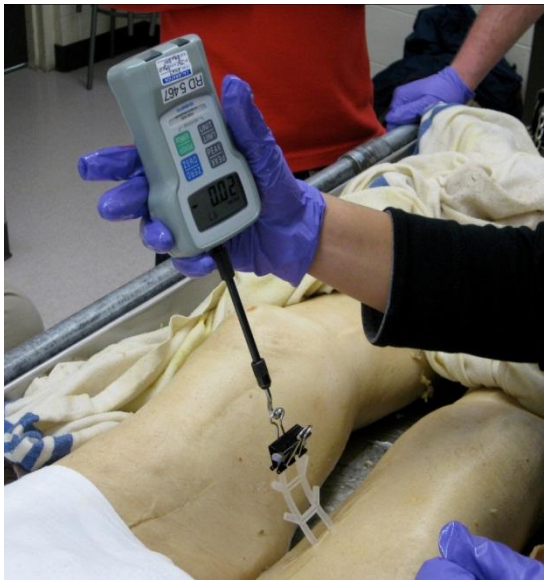


Figure 3: Cadaver thigh model testing for quantification of removal ladder drain variant removal force. A Shimpo FGE-50X digital tensile force gauge was used to record peak force for all ladder drain variants (n = 3).

2.2.2 Pig abdominal tissue model

A ½" thick epidermis and subcutaneous fat layer of pig abdominal tissue was acquired from the Lodi Sausage Company slaughterhouse in Lodi, WI. A 4"x6" rectangular cut of the tissue was warmed to 96 ^{o}F to mimic *in vivo* temperature. The tissue was placed in a solid 4"x6" container to prevent movement and tissue expansion during testing. A 1"x3" section was removed from the bottom of the container to allow for drain insertion and removal. The container was then suspended between two tables, allowing for the ladder drain variants to be both pulled down through the tissue (measuring insertion force) and pulled up through of the tissue (measuring removal force). Once the container was in place a 1" wide incision was made in the center of the tissue. One rung of the SAIP ladder drain variant (1" width) was manually inserted into the incision so that the first set of posts was fixated beneath the tissue (*Figure 4*). A clamp was secured onto the bottom of the SAIP drain to allow for uniform force distribution during insertion into the incision. The Shimpo FGE-50X digital tensile force gauge was set to 'Peak' mode, zeroed and attached to the clamp. Tension was applied at a constant rate until the second rung of the drain was pulled through the tissue. The peak force was recorded, the tensile force gauge was re-zeroed and peak force required to pull the third rung of the drain through the tissue was recorded. This process was repeated three times (n = 6) and the average peak insertion force was calculated. The clamp was then moved from the bottom to the top of the drain and the peak force required to pull both the second and third rungs up through the tissue was recorded. This process was repeated three times (n = 6) and the average peak removal force was calculated. The incision was widened to 2" and the previous steps were repeated using the LAIP, LAOP, and LSIP ladder drain variants.

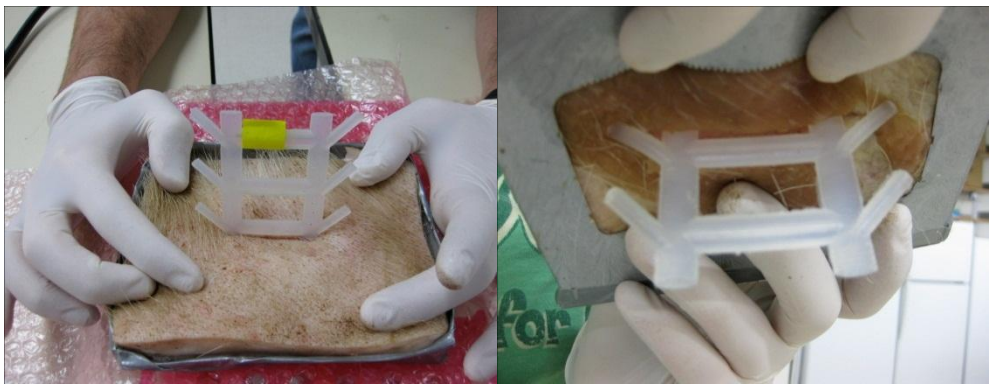


Figure 4: Pig abdominal tissue testing showing LAIP inserted into a 2" surgical incision. Note manner in which the angled posts anchor once inserted through the pig tissue. Both insertion and removal forces were quantified using this mock abscess model.

2.3 Biocompatibility testing

Medical-grade PDMS is an approved material for use *in vivo*; therefore it was assumed that there would be minimal host response to a drain made from PDMS. Two tests that would help elucidate the biocompatibility of the PDMS drains were performed: a water contact angle test and a protein adsorption test using egg white albumin. The tests provided a quantitative comparison between the PDMS ladder drain and PD.

2.3.1 Water contact angle

Water contact angle measurements were recorded in order to compare the relative hydrophobicity of the natural latex rubber PD and the PDMS of the ladder drains. The measurements were conducted using dyed red DI water and flat strips of the PD natural latex rubber and the ladder drain PDMS. A small amount of two-part PDMS was mixed and allowed to cure in the bottom of a glass beaker and subsequently removed to obtain a smooth, flat surface for testing. Small strips of both the PDMS and natural latex rubber were washed for 10 min in 70% ethanol, cut to size and taped the flat, hard surface of a laboratory bench. Next, four 25 µL drops of dyed water were placed on the surface of each material (*Figure 5*). A canon digital camera was used to obtain pictures of all eight water droplets. The contact angle for each water droplet was measured using ImageJ software and the relative hydrophobicity of each material was reported as the average angle of all four droplets on its surface.

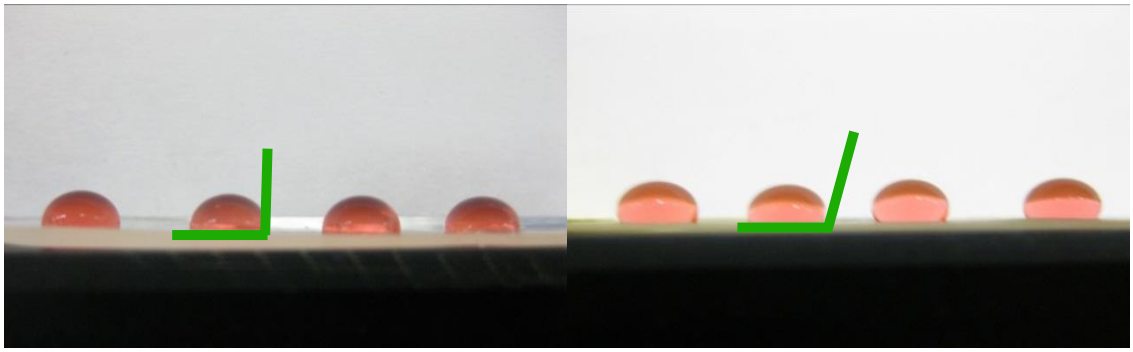


Figure 5: Water contact angle measurements were taken on the PDMS used to fabricate ladder drains (left) and the natural latex rubber surface of the PD (right). Angles were measured in ImageJ and used as a measure of material hydrophobicity (*n* = 4).

2.3.2 Protein adsorption

Protein adsorption analysis was conducted on the PD and all four ladder drain variants using 1" drain segments. Drain segments were sterilized in 70% ethanol solution for 1 hr and air dried in a laminar flow hood. Sterile drain segments were placed in a Falcon 6-well plate and incubated in 8 mL of 3 g/dL egg white albumin protein in DMEM for 12, 24 and 72 hrs. The plates were kept at 37 °C on a shaker plate at 100 RPM in order to mimic the protein concentration of exudate and *in vivo* abscess cavity conditions [8]. Each time point tested 10 drain segments (2 segments for each of the five drains). At each time point the egg white albumin protein solution was aspirated from the plates and the drain segments were rinsed with 5 mL 1x PBS. The PBS was aspirated and replaced with 8 mL of 0.1% SDS in 1x PBS. The drain segments were incubated in the detergent solution for 24-48 hrs to ensure denaturation and desorption of all proteins adhered to the drain surface.

Total protein amount was quantified using a Bradford assay. A plate reader, reading at 595 nm, was used to measure absorbance. A standard curve was generated and was used to determine total protein concentration in the detergent solution of each drain segment at each time point. The standard curve was produced through eight serial dilutions (DF = 2) of 20.5 mg egg white albumin in 1 mL DI water (*Figure 6*). Each well of the plate consisted of 5 µL of detergent solution of unknown concentration or standard protein solution with the appropriate background, either 5 µL 0.1% SDS in 1x PBS or 5 µL DI water, respectively. To each well 250 µl Coomassie Brillian blue dye was added and the plate was placed on a shaker plate at 37 °C and 100 RPM for 10 min prior to reading.

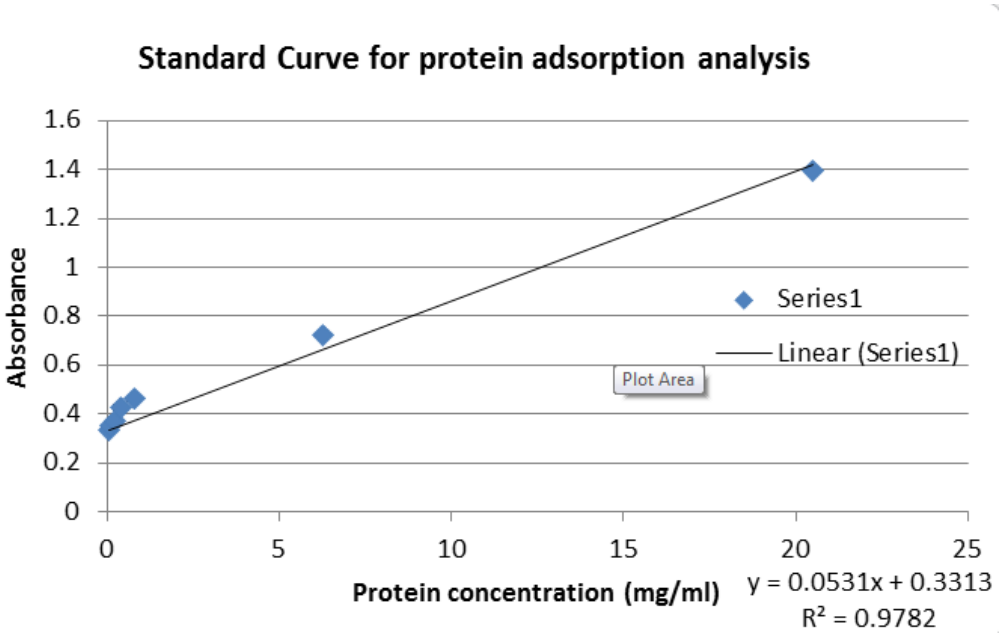


Figure 6: Standard curve generated for protein adsorption study. Using Beer-Lambert law, A = Cεl where A is absorbance, C is the concentration of the absorbing species, ε is the extinction coefficient and *l* is the path length of light

2.4 Statistical analysis

All experimental results are reported as mean ± standard deviation where applicable. Experimental trials were carried out in duplicate, triplicate or higher replication as noted where applicable (*n* = 2-6). Statistical analyses of the three mechanical tests were performed in Excel 2010. Single factor ANOVA was used to compare all three large ladder drain variants while the SAIP and LAIP designs were compared using paired two sample t-test. Water contact angle measurements were also compared using paired two sample t-test. A cut-off value of α=0.05 was used in determining significance.

3. Results

3.1 Mechanical testing

3.1.1 Cadaver thigh model results

The removal force required for the SAIP, LAIP, LSIP and LAOP was 0.83 ± 0.26, 0.99 ± 0.136, 0.63 ± 0.144 and 1.27 ± 0.107 lb, respectively (*n* = 3, *Figure 7*). The order from lowest to highest removal force was LSIP<SAIP<LAIP<LAOP. The three large drain variants, LAIP, LSIP and LAOP, required significantly different removal forces (P = 0.00256), while the required removal force between the SAIP and LAIP drains was not significantly different (P = 0.509).

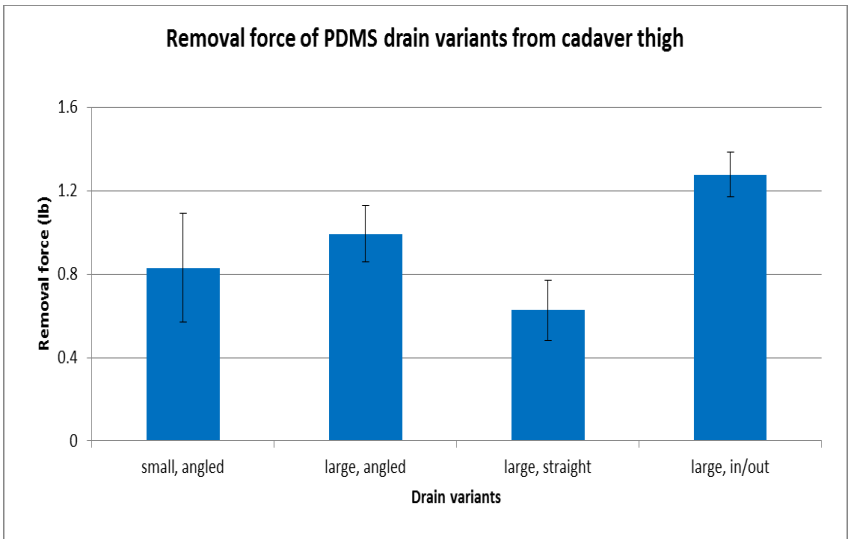


Figure 7: Quantified removal force of PDMS drain variants from cadaver thigh model. The three large drains required significantly different removal forces (P = 0.00256) while the removal force between the SAIP and LAIP drains was not significantly different (P = 0.509, *n* = 3)

3.1.2 Pig abdominal tissue model results

The insertion force required for the SAIP, LAIP, LSIP and LAOP drains was 0.71 ± 0.223, 0.71 ± 0.187, 1.12 ± 0.201 and 1.35 ± 0.210 lb, respectively (*n* = 6). The order from lowest to highest insertion force was SAIP=LAIP<LSIP<LAOP. The removal force required for the SAIP, LAIP, LSIP and LAOP drains was 1.38 ± 0.104, 1.40 ± 0.244, 1.29 ± 0.110 and 2.67 ± 0.452 lb, respectively (n = 6, Figure *8*). The order from lowest to highest removal force was LSIP<SAIP<LAIP<LAOP. The difference between removal and insertion force was highest in the LAOP and lowest in the LSIP. Both the SAIP and LAIP had similar differences between removal and insertion force. The three large drain variants, LAIP, LSIP and LAOP, required significantly different removal forces (P = 0.00000124) and insertion forces (P = 0.00021), while the required removal force between the SAIP and LAIP drains was not significantly different (P = 0.828), nor was the required insertion force (P = 1).

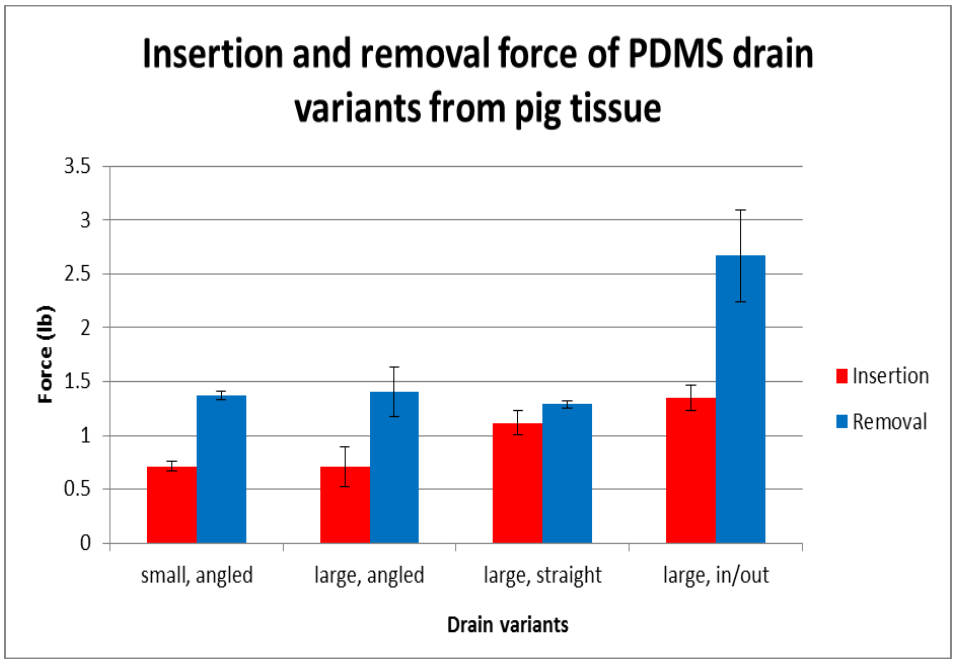


Figure 8: Quantified insertion and removal force of PDMS drain variants from pig abdominal tissue model. The three large drains required significantly different insertion (P = 0.00021) and removal forces (P = 0.00000124) while the insertion force between the SAIP and LAIP drains was not significantly different (P = 1), nor was the removal foce (P = 0.828, *n* = 6).

3.2 Biocompatibility testing

3.2.1 Water contact angle

The water contact angle for the PDMS was 91.72° ± 0.95°, while the natural latex rubber PD had a water contact angle of 117.34° ± 16.32° (*n* = 4, *Table 1*). The difference between these two measurements was found to be significant (P = 0.0448).

Table 1: Water contact angles of PDMS and natural latex rubber were found to be significantly different (P = 0.0448, *n* = 4)

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

3.2.2 Protein adsorption

The protein adsorption test showed no discernable trends in the adsorption of egg white albumin to the five drains tested. However, the total protein adsorption was of the same order of magnitude when comparing the PDMS drains to the natural latex rubber PD. The SAIP had minimum and maximum total adsorbed protein levels of 18.14 ± 1.49 and 48.42 ± 5.11 mg at 12 hr and 72 hr, respectively. The LAIP had minimum and maximum total adsorbed protein levels of 17.54 ± 2.77 and 42.24 ± 15.05 mg at 72 hr and 24 hr, respectively. The LSIP had minimum and maximum total adsorbed protein levels of 17.54 ± 7.39 and 31.25 ± 8.95 mg at 24 hr and 12 hr, respectively. The LAOP had

minimum and maximum total adsorbed protein levels of 27.03 ± 7.48 and 49.33 ± 8.10 mg at 24 hr and 72 hr, respectively. The PD had minimum and maximum total adsorbed protein levels of 19.54 ± 1.07 and 35.13 ± 11.19 mg at 24 hr and 72 hr, respectively (*Figure 9*).

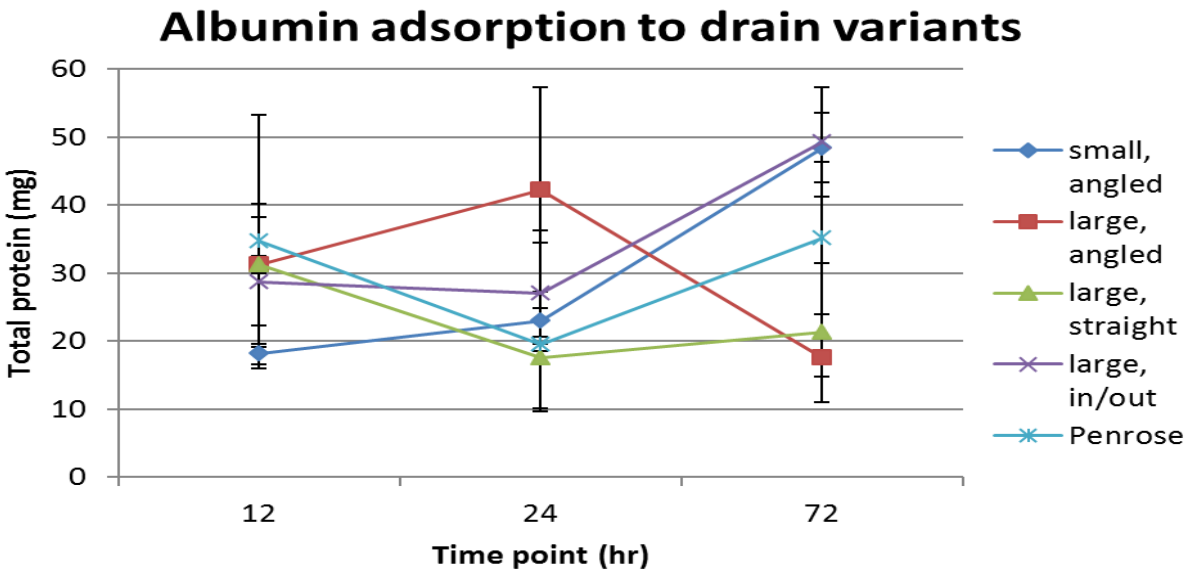


Figure 9: Albumin protein adsorption on PD, SAIP, LAIP, LSIP, and LAOP drain variants. Data shows ladder drain variants are similar to the PD in the total amount of protein adsorption at 12, 24, & 72 hrs.

4. Conclusions

4.1 Design process

The final ladder drain design was the result of following a well-established engineering design process. Preliminary designs were evaluated based on a number of weighted criteria, including expected drain effectiveness, cost and ease of fabrication, patient discomfort and biocompatibility in a design matrix. The ladder drain received the highest cumulative score across all the criteria evaluated, and thus it was chosen as the final design to pursue. This process proved to be highly effective at determining the best possible drain design. For the purposes of small-scale prototyping, the fabrication method using 3D ABS negative molds proved to be highly efficacious and cost-effective as a method to rapidly progress from engineering ideas to functional, testable prototypes for evaluation. The 3D printer allowed for the creation of accurately dimensioned and precise professional quality negative molds while eliminating the steep cost and time requirements of creating an injection mold cavity.

4.2 Mechanical testing

Using the cadaver thigh model for drain removal force, the LAOP was found to have the highest removal force, while the LSIP had the smallest removal force. A study aimed at quantifying pain during catheter sheath removal in a transradial procedure found that traction forces of 0.584 ± 0.368 lb had self-reported pain values of 0.6 ± 1.2 while traction forces of 1.903 ± 0.701 lb had self-reported pain values of 4.8 ± 2.9 [9]. Using this study as a benchmark, the LAOP required excessive force to remove from the cadaver thigh and was higher than the 1 lb limit set in the product design specification. Surprisingly, the cadaver results indicate that post geometry contributed significantly to the stability of

the drain variants while the size of the drain did not have a significant influence on wound stability. All three angled drain variants (SAIP, LAIP and LAOP) displayed increased stability in the wound compared to the straight drain variant (LSIP). The LSIP showed low stability due to a lower angle of rotation needed by the straight post in order to be removed from the incision. Conversely, the angled drains (SAIP, LAIP and LAOP) showed higher degrees of stability due to larger angle of rotation needed by the posts, which allowed for a greater degree of fixation within the incision. The LAOP displayed the greatest stability in the wound but required an excessively high removal force.

The trends observed in the pig abdominal tissue model were very similar to those observed in the cadaver thigh model. The angled drain variants required greater removal force than the straight variant and displayed greater stability in the wound. However, the angled drain variants also required a lower insertion force than the straight variant due to the small degree of bend the posts needed to undergo to pass beneath the tissue. The LAOP required nearly double the removal force of the other angled drain variants and would be much more likely to cause significant patient pain when removed from an abscess cavity. The LAIP and SAIP displayed the optimal mechanical properties, requiring a small insertion force and a larger removal force below the threshold of patient pain, thus increasing the stability of the drains in the wound while minimizing undue pain for the patient during drain insertion.

While the observed trends between the two *ex vivo* abscess models were similar, the magnitude of the force required to remove all drain variants from the pig abdominal tissue was nearly double that required to remove them from the cadaver thigh. This was due to the different degrees of post fixation achieved between the two models. Several important differences should be noted when comparing the cadaver thigh model and pig abdominal tissue model. First, the cadaver tissue has been fixed in formalin, altering the tissue mechanical properties and ultrastructure and leading to less stiff tissue [10,11]. Second, a more shallow incision depth was used in the cadaver thigh model making it more difficult for the ladder drain posts to become fully deployed beneath the tissue. Lastly, the pig tissue was more physically characteristic of human flesh, warmed to body temperature and moister than the cadaver tissue. The pig abdominal tissue was only 1/2” thick and thus it was possible to fully insert the drain into the wound and ensure that the ladder drain posts were fully engaged, resulting in the higher observed removal forces.

4.3 Biocompatibility testing

The higher water contact angle of the PD indicates it is a more hydrophobic material than the PDMS. A higher degree of hydrophobicity often results in increased levels of protein adsorption [12,13]. While our experimental data provided no basis to support a differential level of adsorption between the PD and our PDMS drain variants, it can be concluded that the PDMS drain material at most equaled the protein adsorption of the PD, since all drains tested showed protein adsorption on the same order of magnitude. In addition, this test does not account for the difference between how much drain would be packed into an abscess. While equal lengths of drain were compared in this study (1” segments), much more PD would be packed into an abscess cavity, greatly increasing the surface area of the drain exposed to the protein rich exudate, when compared to the ladder drain.

It is well known that cells interact with materials *in vivo* via the proteins adsorbed to the substratum surface, thus we aimed to ensure that there would be no possible adherence of the tissue to the PDMS drain at the incision site when inserted. The PD has few, if any, reported problems with this and with constant agitation of the drain during regular body movement, and semi-frequent rinsing in lieu of the specialty care, adherence of tissue to the PDMS ladder drain is unlikely to occur. When the drain is inserted, the only points of contact with tissue are at the tissue around the incision; adherence as a whole is an extraneous concern at best. The vast majority of the ladder drain surface area would

not be touching any tissue and therefore high levels of adsorption are largely inconsequential in the operational efficacy of the drain.

4.4 Optimal drain design

The optimal drain design was determined to be the SAIP and LAIP. While two sizes of this drain were designed and fabricated, a third size would ideally be included with the set to provide effective treatment for the entire gamut of abscess shapes and sizes. The ladder rung spacing will be left constant at 1" for all drains to accommodate the thickness of skin and cutaneous fat, but leg widths would include 2", 1" and 0.5" with an accompanying horizontal post distance of one quarter that of the leg width at 0.5", 0.25" and 0.125", respectively.

4.5 Future direction and mass marketing

Small design changes will be implemented to the LAIP and SAIP drains to increase their market potential. Potential changes include the addition of an irrigation port and the incorporation of diffusible antimicrobial agents, such as silver nanoparticles. The irrigation port would be incorporated during the injection molding process where one of the legs would be either hollowed out to allow for fluid flow or have embedded PVC tubing with an external Luer lock for syringe attachment. Introducing an irrigation port would increase the marketability of the product by granting a patient the ability to periodically cleanse the wound with saline solution, helping to facilitate wound healing. The incorporation of antimicrobial nanoparticle agents to PDMS is a widely explored field in biomedical engineering [14-17]**.** The addition of an antimicrobial agent to the surface of the ladder drain could potentially decrease wound healing time by sterilizing the abscess cavity, giving further benefit over the PD.

Mass production of the ladder drain will be executed using standard injection molding practices. An injection molding cost estimate was provided by 3M injection molding specialists (*Table 2*). The estimated cost of a low volume single cavity aluminum mold (100,000 total parts) was approximately $25,000. This is significantly less expensive than the estimated cost of a high volume multiple cavity steel mold ($250,000) which would produce a total of 20,000,000 parts. It was anticipated that PDMS drains produced from these two molds would cost roughly $0.25 and $0.10 respectively [18]. A $5.00 selling point for the LAIP and SAIP variations puts our target market at approximately $15-25 million annually.

Table 2: Estimate for mass production of ladder drain variants. The data was provided by 3M Company injection molding specialists. Estimates were given for low volume (aluminum cavity) and high volume (steel cavity) injection molding.

	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**

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6. References

[1] Taira BR, Singer AJ, Thode HC and LEE CC. National epidemiology of cutaneous abscesses: 1996 to 2005. *Am J Emerg Med* 2009; 27(3): 289-292.

[2] Fitch MT, Manthey DE, McGinnis HD, Nicks BA and Pariyadath M. Abscess incision and drainage. *N Engl J Med* 2007; 357(20): 1-4.

[3] Hankin A and Everett WW. Are antibiotics necessary after incision and drainage of a cutaneous abscess? *Ann Emerg Med* 2007; 1-3.

[4] Benson EA and Goodman MA. Incision with primary suture in the treatment of acute puerperal breast abscess. *Brit J Surgery* 1970; 57(1): 55-58.

[5] OMalley GF, Dominici P, Giraldo P, Aguilera E, Verma M, Lares C, Burger P and Williams E. Routine packing of simple cutaneous abscesses is painful and probably unnecessary. *Academ Emerg Med* 2009; 16: 470-473.

[6] Randomized clinical trial of wound packing following incision and drainage of superficial skin abscesses in the pediatric emergency department. Phase IV clinical trial. New York University School of Medicine. NCT00746109, March 2010. <clinicaltrials.gov>

[7] http://www.quickparts.com/LowVolumePrototypes/FDM.aspx

[8] Heffner J, Brown L and Barbieri C. Diagnostic value of tests that discriminate between exudative and transudative pleural effusions. *Chest* 1997; 111(4): 970–80.

[9] Dery JP, Simard S and Barbeau GR. Reduction of discomfort at sheath removal during transradial coronary procedures with the use of a hydrophilic-coated sheath. *Catheterization and Cardiovascular Interventions* 2001; 54(3): 289-294.

[10] Tilley JMR, Carr AJ and Czemuszka JT. Atomic force microscopy of bulk tendon samples: Affect of location and fixation on tissue ultrastructure. *Micron* 2011; 42(5): 531-535.

[11] Park JB and Lakes RS. Biomaterials: An introduction 3rd Ed. *Springer* 2007: p 250.

[12] Malmsten M. Ellipsometry studies on the effects of surface hydrophobicity on protein adsorption. *Colloids and Surfaces B: Biointerfaces* 1995; 3(5): 297-308.

[13] Tangpasuthadol V, Pongchaisirkul N and Hoven VP. Surface modification of chitosan films: Effects of hydrophobicity on protein adsorption. *Carbohydrate Research* 2003; 338(9): 937-942.

[14] Goyal A, Kumar A, Patra PK, Mahendra S, Tabatabaei S, Alvarez PJJ, John G and Ajayan PM. In situ synthesis of metal nanoparticle embedded free standing multifunctional PDMS films. *Macromoledular rapid Comm* 2009; 30(13): 1116-1122.

[15] Wu WY, Bian ZP, Wang W, Wang W and Zhu JJ. PDMS gold nanoparticle composite film-bvased silver enhanced colorimetric detection of cardiac troponin I. *Sensors and Actuators B: Chemical* 2010; 147(1): 298-303.

[16] US Patent 2009/0098366 A1

[17] Huda S, Smoukov SR, Nakanishi H, Kowalczyk B, Bishop K and Grzybowski BA. Antibacterial nanoparticle monolayers prepared on chemically inert surfaces by cooperative electrostatic adsorption (CELA). *Appl Mat Interfaces* 2010; 2(4): 1206-1210.

[18] 3M Company estimate