Universal Surgical Drain

Final Report

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Abstract

Abscesses are localized infections under the skin that result in the accumulation of pus. If left untreated, the infection can spread to nearby tissue. Abscesses are caused by exposure to foreign materials or by the presence of bacteria such as *S. aureus*. The two most common methods of treatment are surgical incision and drainage and/or antibiotic treatment. However, antibiotics alone have limited effect, and surgical drainage of the abscess is typically required to remove the pus from the body and promote natural healing. A surgical drain that eliminates the need for suturing, packing and specialized nursing care would allow for the drainage of boils and abscesses while minimizing the cost, time and pain associated with current practices. This semester, three design alternatives were proposed and evaluated using a design matrix. Two of the designs were fabricated into preliminary prototypes using two different fabrication methods: lost wax casting and 3D printer negative molds. After a functional analysis of the two preliminary prototypes one design, the A-drain was pursued further and several variations of it were tested using CAD simulation software. One of the A-drain variations, the curved single bar 50A durometer silicone rubber design, was chosen as the best option based on client feedback, CAD simulations and preliminary prototype functionality and aesthetics. Future work includes cadaver testing for proof of concept, continued mechanical property testing and design of an insertion tool applicator.

Background

Abscesses and chronic wounds

Abscesses and boils are localized infections under the skin that result in the accumulation of pus in subcutaneous cavities. This occurs when the body's immune response is activated in response to an infection, usually a result of bacteria (commonly *S. aureus*), parasites, or foreign substances (*e.g.*, excessive intravenous drug use, gunshot wound). This is used as a defensive mechanism by the body in an attempt to localize the infection and to prevent possible systemic infection. Activation of the immune response leads to the recruitment of white blood cells and increased blood flow to the region subsequently causing inflammation of the surrounding tissue which is accompanied by pain and discomfort for the patient.[1] The continued buildup of pus in the cavity increases the pressure in the wound and inhibits proper perfusion to the tissue surrounding the infection, thereby leaving the site more vulnerable to the spread of infection. If left untended, the infection can become systemic and spread to other parts of the body eventually leading to organ failure or, in extreme cases, death.

Current procedure

The most common method of treating abscesses is to surgically incise them and allow the pus to drain from the wound as the abscess cavity closes naturally. Generally, treatment methods are passive, with drains being inserted primarily to prevent the surgical incision from closing. This is a relatively simple procedure that begins with the surgical incision of the abscess or boil. Following the incision, the abscess cavity is debrided to remove necrotic tissue, widened using a curette and irrigated cavity with saline to cleanse the cavity. A drain is then placed in the incision (see *Figure 1*) for the remainder of the healing duration, or until the abscess exhibits cavity contracture. The drain keeps the incision opened to allow passive draining of any pus that may accumulate over time, which is typically collected by a bandage placed over the drain.

Figure 1: A Penrose drain inserted into a cutaneous abscess for treatment

The healing process can last anywhere from 2 weeks to as long as 3 months depending on the size and severity of the abscess. Antibiotics can be paired with surgical drainage, but they are generally not necessary for proper healing and even have potential adverse effects.[2]

In North America, the standard drain used for abscess treatment is the Penrose drain, which is essentially a short piece of natural latex rubber tubing that is sutured to one side of the incision to maintain its position in the wound. It is also very common to pack the abscess with strips of sterile gauze in conjunction with the insertion of a Penrose drain to help soak up pus. As the wound heals, the abscess will expel more pus which requires the packing of new gauze. Additionally, as the abscess drains and the cavity begins to shrink it eventually collapses upon itself. This necessitates the drain be periodically detached, shortened, and re-sutured as it is incrementally removed from the shrinking wound.

This method for abscess treatment requires frequent visits to the hospital as the replacement of the gauze and the drain can only be performed under the direction of specialized nursing care. The tissue surrounding the abscess is quite tender, and packing the wound with gauze is very painful for the patient. Furthermore, there is a fair amount of evidence that indicates that treating the wound by packing it with gauze is both painful and unnecessary.[3] Packing the wound can even delay healing by inhibiting perfusion to the surrounding tissue by increasing the pressure in the cavity and disallowing the proper drainage of any pus that might accumulate.[2] Suturing the drain to the tissue is also an unnecessary step as the drain does not function as a conventional drain would, to direct the flow of the fluid efflux. Rather, the drain is only present to prevent premature healing of the incision, which can lead to reformation of the abscess. As such, sutures only increase pain and morbidity of the tissue, and increase the amount of specialized care required.

Silicone

Silicone rubber is an inorganic synthetic elastomer made from a cross-linked silicone-based polymer reinforced with filler. It offers a unique combination of chemical and mechanical properties organic elastomers cannot match.[4] Medical grade silicone exhibits a wide array of properties including superb chemical resistance, high temperature performance, good thermal and electrical resistance, long-term resiliency, and easy fabrication. It also possesses excellent UV and ozone resistance, is non-volatile, and peroxide free. Medical grade silicone is platinum

cured and does not discolor over time. It is odorless, tasteless, chemically inert and non-toxic. Since being identified as a biocompatible material in 1954, it has been used extensively in implants and other medical devices placed in the body for extended periods of time.

Medical grade silicones are classified as either restricted or unrestricted based on their biocompatibility properties. Restricted silicones have limited biocompatibility and can only be placed in the body for a maximum of 29 days, whereas unrestricted silicones can be implanted in the body indefinitely.[5] Since the time required for an abscess to fully drain is typically longer than 29 days, an unrestricted medical grade silicone is an appropriate material for any drain used for this purpose.

Existing Technology

Penrose drain

As mentioned above, the most common method of treating abscesses is the insertion of a latex rubber Penrose drain (*Figure 2*). The Penrose drain allows for the passive draining of pus from the abscess by gravity and capillary action. The pus exits the wound both within the lumen of the drain and around its exterior. The drain's sole purpose is to keep the surgical incision open and maintain a channel for pus to exit the body. It was invented by the American gynecologist Charles Bingham Penrose nearly a century ago and is still widely used today. However, it has several notable drawbacks. First, it must be sutured to the skin to maintain its position in the abscess, which is costly, time-intensive, painful and undoubtedly uncomfortable for the patient. Additionally, should the drain unintentionally fall off or become detached, it is impossible for the patient to replace it in the wound without professional medical care. Second, the Penrose drain must be periodically shortened in conjunction with the shrinking and collapsing of the abscess cavity. This requires the patient to visit a surgeon several times throughout the healing process to remove, modify and replace the drain, incurring additional cost and time. Finally, the drain requires the surgical incision to be

Figure 2: Penrose drain

packed with gauze to absorb excess pus. This packing is very painful for the patient and also requires costly nursing care.

KCI VAC therapy

Another method for treating abscesses is VAC therapy (*Figure 3*). VAC therapy creates negative pressure on the wound and actively drains pus from the incision. A foam dressing is placed over the incision site, which is connected to a VAC Therapy Unit™; a self-contained computer which provides the pressure necessary for pumping and also allows for real-time analysis of the wound volume and any potential leak sites in the foam dressing.

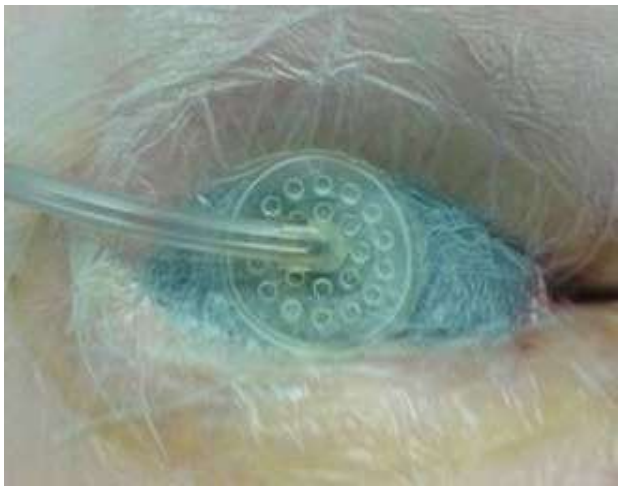


Figure 3: VAC system in abscess wound

It works through the combination of two processes termed macrostrain and microstrain. Macrostrain is the visible stretch caused by the negative pressure of the foam dressing. It draws the wound edges together promoting healing and removes any infectious material, including pus. Microstrain is the micro-deformation on the cellular level which leads to cell stretch. Microstrain reduces edema, promotes perfusion, and promotes granulation tissue formation by facilitating cell migration and proliferation. Thus, the combination of these two processes simultaneously drain the wound while promoting healing and regeneration. While there are many advantages to VAC, its main disadvantage is its immense cost. Whereas a Penrose drain costs under $2, a portable VAC therapy unit costs a patient several hundred dollars a day. Coupled with the complexity and steep learning curve associated with this therapy, it is generally only used for severe cases.[6]

Various patents

- US Patent 3753439 (General Purpose Surgical Drain – Surgical drain for operative and post-operative usage with padding layer of absorbent material)
- US Patent 3860008 (Flat Drain – Elastomeric Drain with series of channels spaced evenly from one another)

- US Patent 3957054 (Surgical Drainage Tube – Flexible, pliable ribbed drain for draining surgical procedures)
- US Patent 5053021 (Surgical Drain – Surgical Drain fabric and device for providing channel of exit or discharge from wound or wound cavity)
- US Patent 5232440 (Method and Device for Draining Abscess – Cutting device with expandable bulb to hold within abscess)

Client Specifications

Overall design goal

The goal of this project is to develop a novel surgical drain that will minimize the cost, time and patient discomfort associated with current abscess treatment methods. The drain should be available in several sizes to accommodate for the variation in the width and depth of different abscesses, and should be fabricated from an unrestricted medical grade silicone.

Design parameters

Dr. Ramzi Shehadi has several requirements he would like us to meet:

- The drain must be able to physically prevent the incision from healing and closing without having to be sutured to the skin
- The drain must be able to maintain its position within the abscess cavity without falling out/being easily removed and without putting excessive pressure on the wound
- The patient should be able to easily remove and reinsert the drain into the wound at home without the aid of a nurse or physician
- The drain must be made of a cheap, flexible, medical grade non-latex material, preferably unrestricted silicone rubber
- The drain must be made in different sizes to accommodate all size of abscess incisions, which generally range from 1.5 - 4 cm in length
- The drain should be made as cheaply and simply as possible to allow for easy mass production and to maximize patentability

Design Alternatives

As dictated by the client, all prototypes will be made of medical grade silicone, as it is already an FDA approved material for use in implantable medical devices. This would maximize patient comfort as well as provide a safe material for use in a cutaneous cavity. To determine the appropriate durometer of silicone to use, samples of silicone with differing durometers were obtained and examined. The silicone needed to have enough stiffness to be able to retain its shape and maintain a certain level of elasticity while still being soft and pliable enough to avoid discomfort when inserted in an incision. The final hardness was chosen to between 40A-50A as described below.

Incorporating different materials into the design of the prototypes was considered to enhance mechanical properties at key points. This included the insertion of springs or other elastic materials to maintain enhance the structure. This notion was dismissed on the basis of minimizing production costs and the client's previous experience with attempts at patenting devices. He was concerned that heterogeneous composition would compromise the approval of such a device. It was determined that making slight changes to the structure of the prototype would provide the necessary mechanical properties to have a functional device while keeping a homogeneous frame.

A general criterion for the design of a drain is universality, either by having a design that can be cut down to fit an abscess or by making different sizes of the same model. For this reason, dimensions of the prototype are not clearly defined and it is assumed that if the models are made to be on the larger size they can then be scaled down at a later time.

Scissor frame

This concept was designed to reduce cross sectional area of the device during insertion to increase ease of use and reduce pain. The frame consists of a bridge and two crossing, but separate legs. The conformation of the frame would provide a wide base and top to maintain secure placement then inserted into an incision (*Figure 4*). The bridge of the device would

Figure 4: A wax model of the scissor frame

have a slight bend or notch to ensure the proper folding of the frame during insertion. To insert, the corners of the device are squeezed together, narrowing the base considerably, and then the device is placed inside the abscess. Once in, the corners are released and the material properties of the frame would return it to the original conformation.

The scissor frame would provide a basis to secure placement with reduced emphasis on structural integrity due to the conformation of the design. When inserted in an incision, the top and bottom would be wider than the incision. This would permit a smaller incision length and therefore less morbidity at the site of the abscess, however the single point of opening may inhibit the efflux of pus from the cavity. Additionally, the incision has the potential to close up and further narrow the incision size. The frame would exert a slight compressive force on the edges of the incision and would inflict undue pain to the patient as inflamed and infected tissue is particularly tender.

A-drain

The A-drain is a design that is driven by its ability to maintain the size of the incision during the healing process while still maintaining its placement within the abscess. This drain is roughly the shape of a rounded 'A', thereby inspiring its name (see *Figure 5*). Retention of the drain inside the abscess is facilitated by the shape of the legs which will be wider than the incision. The cross bar of the 'A' will provide enhancement of the elasticity of the structure during use. The frame is pinched near the base to narrow it for insertion, and once in, the arch and cross bar will force the drain back to its original conformation. Originally, the cross bar was designed to be a circular shape as depicted in *Figure 6*. However, after initial prototype fabrication and discussion with the client, the circular shape was dismissed and a bar that simply connected the two legs was adopted, possibly incorporating a bend in it to direct the folding during insertion.

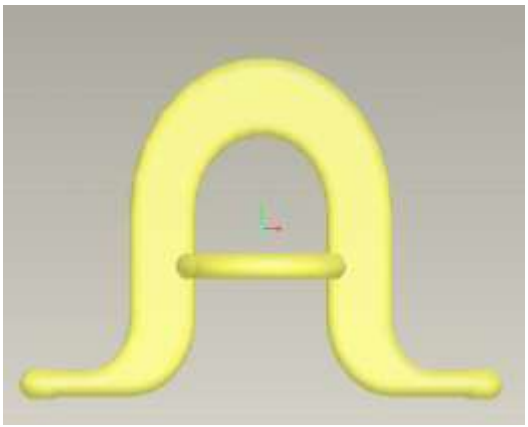


Figure 5: CAD model of the A-drain

The advantage of this design manifests itself in its ability to maintain its placement in the abscess cavity without exerting any force on the surrounding tissue, thereby mitigating any pain that might be inflicted on the patient by the device. Also, as it sits in the incision, the gap

between the legs maintains the length of the incision and prevents its closure, thus allowing any pus to freely flow out of the cavity. The high profile of the frame presents potential problem with its use. The device would be inserted and a large portion of it would remain outside of the abscess. This would be a problem to put a bandage over; also, the high profile could snag on something throughout the course of a patient's day and either wrench it out of the incision or simply jar the drain around, inflicting pain to the patient in either case.

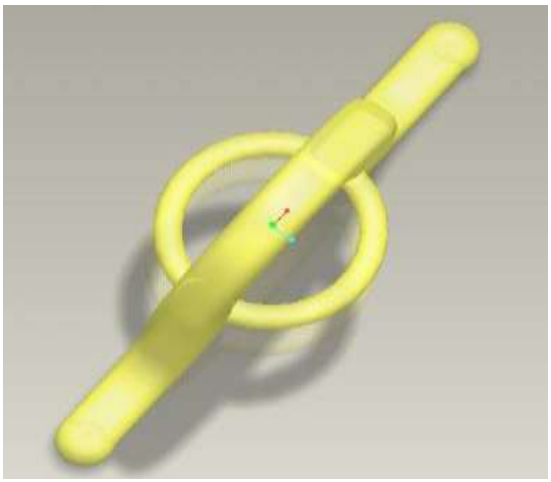


Figure 6: A CAD model of the preliminary design of the A-drain depicting circular cross-bar

Spool

The shape of the spool design resembles a spool of yarn (*Figure 7*). It is a hollow tube with a large central hole for draining pus and several flanges on both ends to hold it within the wound. The design would be very effective at draining pus through the large central opening, and would fit snugly in the abscess incision with very little chance of becoming dislodged. However, there are several disadvantages with this design.

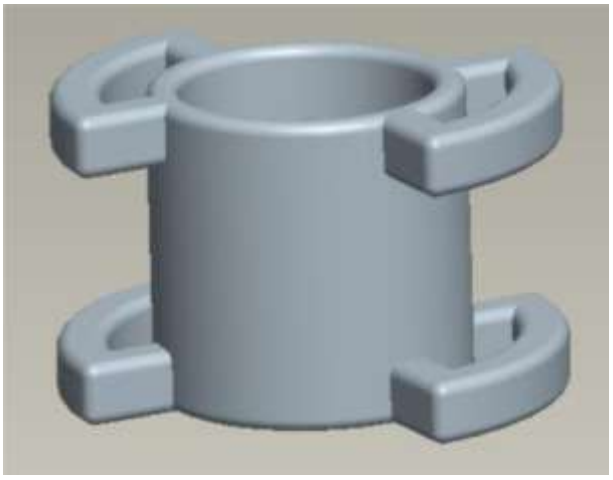


Figure 7: CAD model of the spool design

First, it would be hard to compress the drain and insert it into the wound. This would lead to increased patient pain and discomfort. Second, the height of the spool would have to exactly match the depth of the abscess incision. This would necessitate many different sizes of the drain rather than only two or three to accommodate for different sized incision lengths. Third, the design is more complex than both the scissor and A-drain and would be more difficult and costly to fabricate.

Design Matrix

The following criteria were used in assessing the possible designs: fabrication, ease of use/patient comfort, efficacy, and universality (*Table 1* below). Patient comfort and efficacy were given the most weight in evaluating the models as these would be the deciding factors in the success of the project. Fabrication and universality were not as stressed as it was assumed that all designs will eventually be made via injection molding and universality is achieved in all designs by having different sizes of models.

Table 1: Design matrix to judge three design ideas

Model	Fabrication .2	Ease of Use / Patient Comfort .3	Efficacy .35	Universality .15	Total 1.0
The 'A' Drain	7	8	7	9	7.6
Scissor Frame	8	9	8	6	8.0
Spool	5	6	8	7	6.65

Through the use of the above matrix, the spool design was determined clearly inferior to the rest overall, and only slightly better in efficacy due to its ability to keep the wound open. The scissor frame and A-drain were largely similar based on initial evaluation. The scissor frame was estimated to be slightly superior in every category except universality due to its awkward shape. After conferring with the client, he expressed an interest in fabricating both the scissor frame and A-drain to provide examples of the structural properties of both.

Fabrication Methods

Lost wax casting

In the lost wax casting method, a replica mold is first made from dental baseplate wax. The wax is melted to facilitate the process of forming the desired shape of the mold. Once the shape is produced, the wax mold is left to harden. The dental stone is then created by mixing Vel-mix dental stone with water. The resultant putty is then poured into a shelled case and allowed to harden. While the stone hardens the wax mold is impressed approximately halfway into it. Once the mold is in place the dental stone is allowed to finish hardening, as shown in *Figure 8*. After the bottom half stone mold is formed, a separator (*e.g.*, vasoline) is applied to the surface of the already set dental stone to ensure the two halves of the mold do not fuse. Additional dental stone mix is poured over the bottom half of the mold, which at this point is set, to make the top half of the mold. Once the top half sets, the mold is separated to remove the wax. The wax leaves a cavity in the dental stone, as shown in *Figure 9*, where the two-part silicone can be applied to make the silicone mold.

Figure 8: Wax mold in dental stone

Figure 9: Dental stone mold cavity

The silicone, which is two parts, is applied equally on a PVC tile in a 1:1 ratio through the use of syringes. The silicone parts are then thoroughly mixed and are spread out and stretched on the surface of the tile to minimize tiny air bubbles that are caught in the silicone during the turbulent mixing process. The silicone is then applied inside the mold cavity in excess of what is required to ensure the cavity is completely filled. Any residual silicone that leaks out after closing the mold halves is removed and the halves are clamped tightly and set to bake in an oven for 350 °F for 1 hr. The clamped mold is then taken out of the oven and allowed to cool to

room temperature. The clamps are taken off and the mold halves are gently pried open with the aid of a screwdriver.

3D printing

Negatives of the A-drain and the scissor frame design were created in PRO/E and then produced with a STRATASYS uPrint 3D printer (*Figure 10*). 3D printing technology involves laying down successive layers of material to produce a three dimensional product. A 3D computer file in PRO/E is used to design several cross-sectional slices, where each slice is then printed on top of one another to create the designed 3D image (See *Appendix* for all 3D printer CAD models). The printer deposits layers of molten plastic or powder and fuses them together. The material used to create the A-drain and scissor frame molds is polyvinyl chloride (PVC).

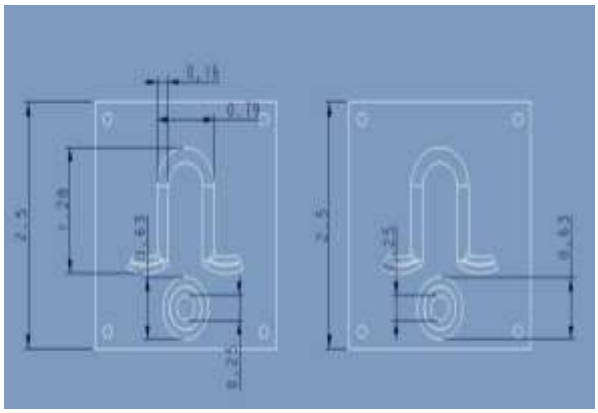


Figure 10: PRO/E model of the A-drain (with ring) made for 3D printing

The process of 3D printer silicone prototype fabrication originally followed the same specifications used during fabrication with the dental stone mold: 350 °F for 1 hr. However the melting temperature of the PVC 3D mold was below 350 °F which caused the mold to soften and melt. In order to compensate for this the oven temperature was lowered to 230 °F while the curing time was kept constant. Due to these complications, only the A-drain was pursued to be manufactured through the 3D printing fabrication method.

Final Designs

A-drain

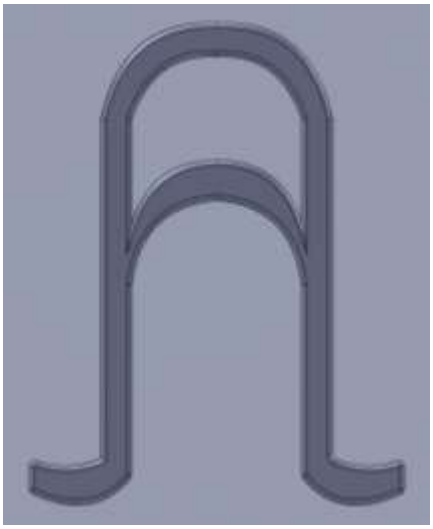


Figure 11: CAD model of final design for the A-drain

After initial prototypes of the A-drain were made, the circular bar was determined to be insufficient in its function and added additional complications to a device that is intended to be as simplistic as possible. As such, it was replaced by a curved bar in the plane of the device. This bar will curve up in the same manner as the top of the drain to ensure that the device will remain as narrow as possible during insertion (see *Figure 11*). Additionally, the flanges going away from the legs of the device are made with a slight bend but are straighter than the original design. Dimensions for the large model are approximately 9 cm tall with a width of 4 cm (leg to leg) and 8 cm (flange to flange). The width (as viewed in *Figure 11*) of the silicone throughout the device is approximately 0.6 cm with a thickness of 0.4 cm. For comprehensive progression of molds and silicone prototypes see *Appendix*.

Scissor frame

The essence of this project has put a large emphasis on the simplicity of the design. Throughout the design and fabrication of the scissor frame, it was determined that there were too many complications added in the fabrication process without providing proper mechanical properties to accomplish its operation. The frames that were fabricated consistently showed less than optimal rigidity to provide easy insertion of the drain. Adjusting the durometer to provide the optimal stiffness in the legs of the drain and the reduction in pliability of the material would significantly increase patient discomfort. Due to the aforementioned reasons, the scissor frame was dismissed as a fruitless endeavor and emphasis was put on the A-drain.

Testing

Preliminary testing was carried out on both the curved bar and straight bar forms of the A-drain to determine which conformation would be ideal for our final design. In addition to this, preliminary deformation testing, conducted using Solidworks SimulationXpress, was employed to compare and contrast the mechanical properties associated with 30, 50, and 70 durometer silicones.

Durometer testing

Durometer testing was carried out by comparing the deformation data associated with each version of the A-drain (flat or curved bar, one or two bars) at each durometer. In all 12 trials were conducted, 3 (30, 50, and 70 durometer) per A-drain model (1 straight bar/curved bar & 2 straight bars/curved bars). All trials applied a constant 5 N force to a universal location on each leg of the drain. Solidworks was then able to generate deformation data by correlating the location and magnitude of the applied force with the material properties of the silicone (see *Appendix* for the material properties associated with each durometer of silicone). As would be expected the data showed a universal correlation between the durometer of the silicone used and the maximal leg displacement (see *figs 12,13*).

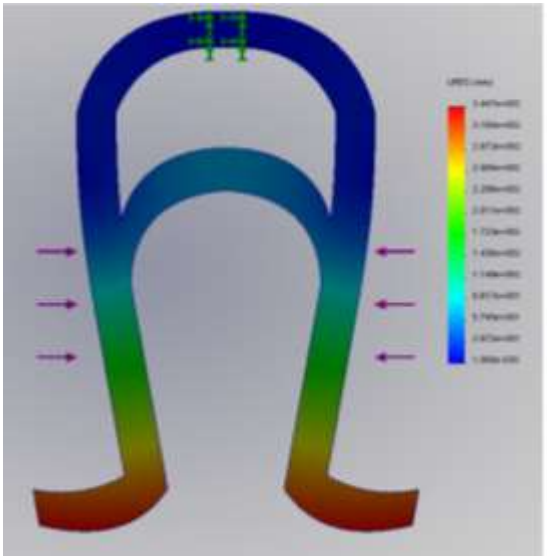


Figure 12:30 Durometer Single Curved Bar A-drain exposed to 5 N force in Solidworks SimulationXpress

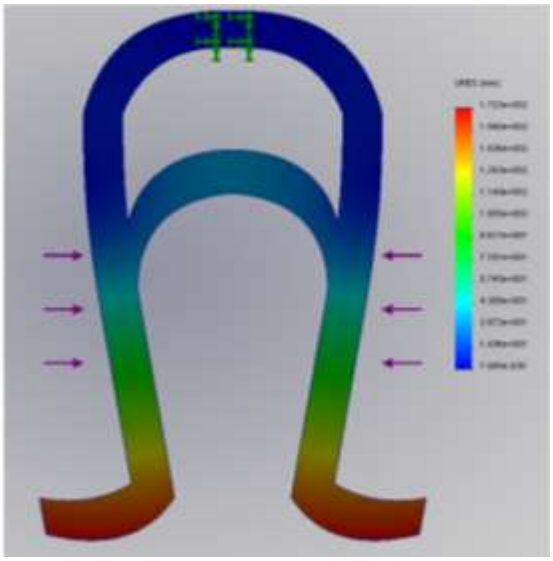


Figure 13:70 Durometer Single Curved Bar A-drain exposed to 5 N force in Solidworks SimulationXpress

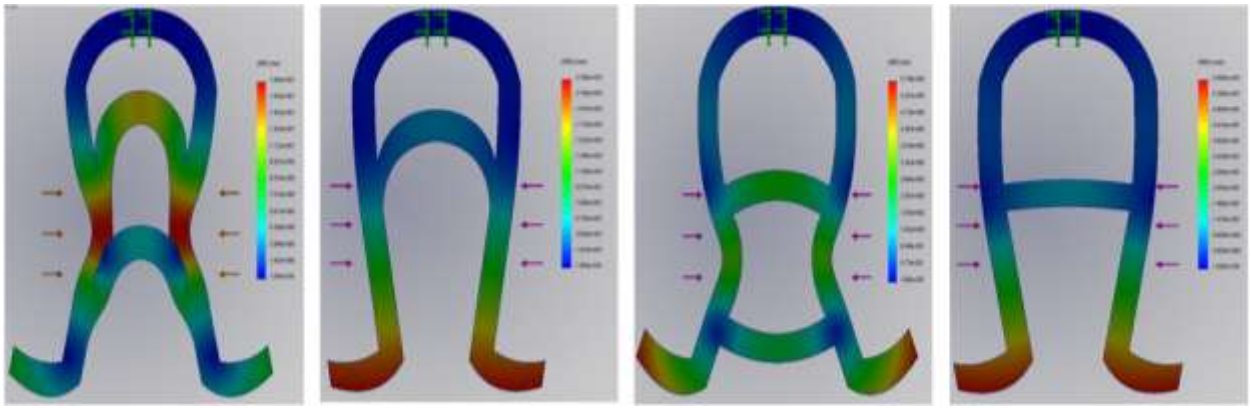
The maximal leg displacement of the single curved bar A-drain was shown to be 34.47 cm when a 30 durometer silicone was used. This is substantially more than the maximal deformation shown with the same drain made out of either the 50 or the 70 durometer silicones, 22.98 and 17.23 cm respectively. While the actual dimensions of the drain would prohibit even a 17.23 cm leg displacement the data generated by Solidworks allowed for a semi-quantitative comparison of the mechanical properties associated with the various silicone durometers. This comparison confirmed that increasing the durometer of the silicone has significant effects on the stiffness and rigidity of the drain.

While the displacement data was useful in determining the relative effects of increasing the silicone durometer on the mechanical properties of the drain, the most useful analysis was physically creating and working with prototypes. In order to fully understand the effects of different silicone durometers on the touch, feel, and aesthetics of the drain, 3 single curved bar A-drains were made using 30, 50, and 70 durometer silicones. These models were then compressed, pulled, and squeezed by our client to ensure they would meet his requirements. Through this analysis it was determined that a silicone durometer ranging from 40-50 would be ideal for clinical use (the variation in durometer is associated with size of the drain, i.e. smaller drains would require a lower durometer silicone where a larger drain would need added leg stability and consequently require a higher durometer).

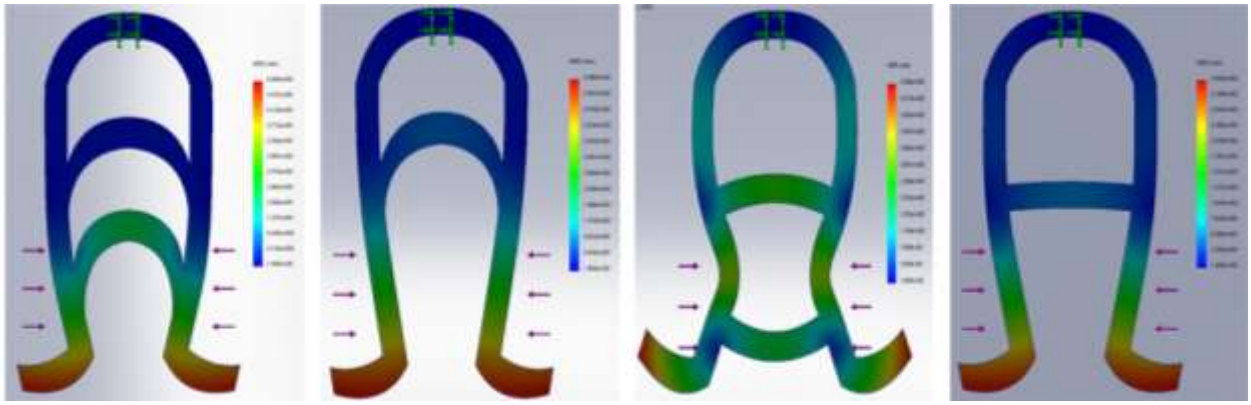
"High force" and "low force" testing

All four A-drain models, each in three different durometers, were tested by applying a 5 N force on both sides of the drain while keeping the top of the drain fixed in space. These tests were designated as "higher force" or "lower force" to indicate the spatial position of the force on the drain (not to be confused with the magnitude of the applied force). In the "higher force" test, the force was applied midway down the side of the two drain models directly opposite the single straight or curved bar (see *Figures 14-17* below), while in the "lower force" test the force was applied lower on the drain, near the lower bar on the two drain models with two straight or curved bars (*Figures 18-21* below). Both of these simulations were intended to mimic the force that would be exerted on the drain if it was pinched for insertion by a physician and the displacement of the legs was measured semi-quantitatively. The data is only semi-quantitative for two reasons: 1) the values are an estimate from a color scale in the simulation indicating

displacement and 2) the program does not constrain the simulation to only allow displacements to occur in the range of the model's dimensions.



Figures 14,15,16,17: A-drains exposed to 5N "high force" in Solidworks SimulationXpress



Figures 18,19,20,21: A-drains exposed to 5N "low force" in Solidworks SimulationXpress

The "higher force" simulation was used to illustrate what would happen if the A-drain was pinched higher than the optimal lower position. For example, if an abscess was deep below the surface of the skin the drain would need to be pinched higher up during insertion to avoid accidentally inserting the fingers into the abscess incision. *Table 2* below summarizes the effect of a 5 N force being applied midway down the four drain models for all three silicone durometers and is semi-quantitative with respect to how far the bottom of the legs are displaced.

*Table 2:*Effect of 5 N "high force" on all four A-drain models of 30, 50 and 70 durometers

Model	Silicone Durometer	Max Leg Displacement* (cm)
Two curved bars	30A	-1.26
	50A	-0.84
	70A	-0.63
One curved bar	30A	34.5
	50A	22.9
	70A	17.2
Two straight bars	30A	-0.86
	50A	-0.57
	70A	-0.43
One straight bar	30A	8.82
	50A	5.88
	70A	4.41
* Negative values indicate leg displacement outward		

From the table it becomes apparent that using two bars, either straight or curved, caused the A-drain legs to displace outward instead of the intended inward direction. This would be disadvantageous in the design as the legs need to be displaced inward to narrow the drain base so it can be inserted into an abscess incision. When comparing the one curved bar design to the one straight bar design it can be noted that the straight bar increases the design's rigidity much more than the curved bar. This would be a desired feature of the A-drain design in theory, however as described below the model does not entirely reflect happens when a straight bar is compressed in practice.

A second simulation with a "lower force" was used to show how the four A-drain models reacted to a force applied lower on the body of the drain near the base. This simulation is a better representation of how the A-drain would be squeezed prior to insertion into an abscess cavity and the data is presented below in *Table 3.*

*Table 3:*Effect of 5 N "high force" on all four A-drain models of 30, 50 and 70 durometers

Model	Silicone Durometer	Max Leg Displacement* (cm)
Two curved bars	30A	7.43
	50A	4.95
	70A	3.71
One curved bar	30A	88.5
	50A	58.9
	70A	44.2
Two straight bars	30A	-0.69
	50A	-0.46
	70A	-0.34
One straight bar	30A	45.8
	50A	30.5
	70A	22.9
* Negative values indicate leg displacement outward		

The data indicate that the two straight bar design would be the only design of the four that would not have the legs bend inward when compressed at a lower position. As was noted with the above "higher force" simulation, the straight bars again add rigidity to the design. An intriguing result is that the two curved bars design had the legs displaced inward even with the force being applied at a lower position. This is attributed to the curved shape of the bars which allows them to flex upward so the legs on the drain can swing inward in the same plane of the drain as a whole.

Force testing for full compression

The final test we conducted was done to determine the force necessary to fully compress the legs of both the single curved bar and double curved bar A-drains. The idea behind this force analysis was to ensure that the force required to insert the drain into a wound would be feasible for the average person. Also the data was generated to give us an idea of the force a perforated insertion wrapper would need to apply to the legs of the drain in order to fully compress the legs prior to insertion. In order to obtain this data a force was applied uniformly over the entire side of each leg and the displacement data was generated based on a 50 silicone durometer drain. The force was then varied until the displacement of each leg at the region located just below the top curved bar was equal to half the total displacement of the prototypes previously made (1.66 cm). For the single bar curved drain the force required to fully compress the legs was between 1.8 and 2 N (see *Figure 22*). This was much lower than the force required to compress the double curved

bar drain (~20 N). Both of the predicted compression forces are well within the average pinching force for males and females (~60 N & 40 N respectively). This shows that most people should be able to fully compress the drain easily to allow for efficient insertion.[7]

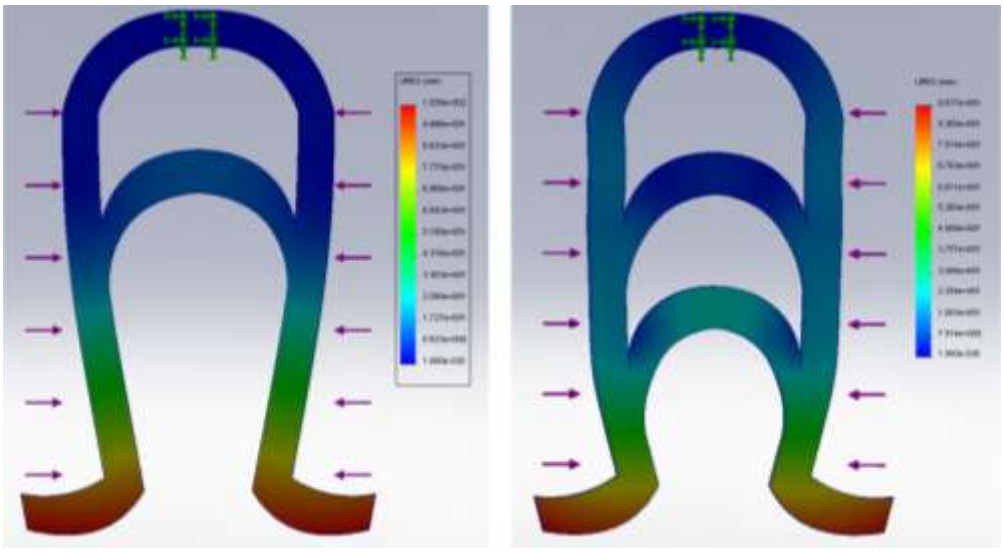


*Figure 22:*Full compression force analysis for one and two curved bar A-drains

Cost Analysis

Our client gave us a project budget of $500 for this semester. The 3D printing silicone prototypes were made at no cost through the Biomedical Engineering Department. All of the following materials were ordered to ensure fabrication of silicone prototypes with the lost wax casting method. These materials were suggested by Greg Gion, an expert of silicone molding. The 10A and 30A durometer silicone samples were obtained from NuSil at no cost. The separating film was purchased from FactorII for a price of $32.35. Two 33 lb. bags of Velmix stone were ordered from Pearson Dental and Patterson Dental for $65.70 and $67.26 respectively. The baseplate wax (medium/soft) was purchased from Patterson Dental for $56.17. The silicone adhesive kit was purchased from FactorII for $45.31. All these materials have shipping charges included within the purchasing price. Several mold construction materials were purchased from Menards. These materials include five O-rings for $0.67 per ring, clamps for $7.58, utility lighter for $3.98, tape for $0.97, six electrical boxes for $0.73 per box ($4.38), box cutter knife for $4.92 and putty knife for $1.98 for a total of $28.76. The total cost of all purchased materials is $295.55. All these costs are shown in *Table 4* below.

Table 4: Cost of materials used for creating prototypes

Item	Cost
Separator (Factor II)	$32.35
Velmix Dental Stone (Pearson and Patterson)	$132.96
Wax (Patterson)	$56.17
Silicone Adhesive Kit (Factor II)	$45.31
Mold Construction Materials (Menards)	$28.76
TOTAL	**$295.55**

Future Work

Testing

The next phase of this project is to conduct bench top tests on the prototypes and measure forces necessary for insertion and removal of the device. This will be to further optimize the design to ensure patient comfort and determine if any disadvantageous conformation changes occur while in compression or tension. After bench top testing is complete and the prototype has been adjusted appropriately, Dr. Shehadi will submit a request for cadaver testing. Upon approval of the request, we will need to coordinate with the UW Anatomy Department to determine when and how to conduct the tests. During testing, a simulated abscess will be made in the cadaver using knives and other simple tools and the drain will be inserted and removed while we visually monitor its conformation during these procedure. We will also be concerned with how the drain sits in the wound, for instance if the skin is separated in the area between the legs of the device.

Refinement of current designs

There will be a push to enhance the design to make it as universal as possible. A hypothetical design has been suggested that would modify the A-drain into somewhat of a ladder conformation and reducing the size of the flanges sticking out from the sides. This idea and others like it are, however, untouched as far as development and making possible prototypes. The emphasis in the next stage of the project will be mostly on testing, and modification of the structure of the drain will most likely be as needed.

New accessory designs

There has been a small concern about the method of insertion for the A-drain as it has to be squeezed from the bottom to ensure proper conformation. One way to address this may be in the design of an insertion sleeve that would hold the legs close together prior to insertion of the drain. After the abscess has been incised and cleaned, the sleeve-drain combination is place at the incision and the drain is inserted while tearing away the sleeve. This results in an easier insertion without difficulties in trying to keep the correct shape.

Conclusion

In conclusion, this universal surgical drain has several distinct advantages over existing technologies. The design is simple and cheap to fabricate. It is able to passively maintain its position in the abscess while preventing the incision from closing, allowing pus to drain from the wound for the duration of the healing process. It is easy and relatively painless for the patient to reinsert the drain into the wound should it become dislodged. This eliminates the need for suturing and packing, substantially reducing the pain experienced by the patient while also eliminating the need for costly and inconvenient nursing care. The A-drain is made from unrestricted medical grade silicone and is completely biocompatible, inert and able to be implanted in the body indefinitely. Initial 3D modeling has indicated that 50 durometer silicone is the optimal material stiffness, and that the A-drain designed with curved central bars provides superior stiffness and elasticity compared to the drain designed with straight central bars. Future testing will be conducted to determine the forces necessary for insertion and removal of the A-drain, and ultimately the drain will be tested on human cadavers to assess its efficacy. The final design will be made in several different sizes to ensure a universal product that is compatible with all sizes of abscesses.

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Appendix

PDS

Function: The universal surgical drain will be used to drain pus from boils and abscesses that form underneath the skin. When inserted into a surgical incision made upon an abscess, the drain will keep the cavity of the abscess open by physically preventing the healing and closing of the skin, allowing the pus to drain. This device will be an improvement upon the existing Penrose drain. It will eliminate the need to suture the drain to the wound, and it will be simple to reinsert into the abscess cavity. This will eliminate the need for costly outpatient nursing visits. Additionally, it should be simple, cheap, and easy to produce so that it remains a viable competing product. The drain will be made in several different sizes to accommodate all size of abscess incisions.

Design requirements: Dr. Ramzi Shehadi has several requirements he would like us to meet. First, the drain must be able to physically prevent the incision from healing and closing without having to be sutured to the skin. Second, the drain must be able to passively maintain its position within the abscess cavity without falling out/being easily removed and without putting excessive pressure on the wound. Third, the patient should be able to easily remove and reinsert the drain into the wound at home without the aid of a nurse or physician. Fourth, the drain must be made of a cheap, flexible and medical grade non-latex material, preferably the material of the non-latex rubber finger tourniquet given to us by Dr. Shehadi. The drain must be made in different sizes to accommodate all size of abscess incisions, which generally range from 1.5 - 4 cm in length. Our client would like the drain to be made as cheaply and simply as possible to allow for easy mass production. \

1. Physical and Operational Characteristics

a. *Performance requirements*: The drain will be used to hold open a surgical incision leading to a subcutaneous abscess for the duration of the healing process (2 weeks to 2 months). The drain should not impede the drainage of fluid from the abscess cavity nor should it place excessive pressure on the inside or outside of the abscess. The drain is intended to be passive with no active components, other than an irrigation port for saline washes, and should be resilient enough to flex and bend without causing structural damage.

b. *Safety*: The drain should be non-toxic and should be made from a medical grade polymer that will not leach toxic products. The drain should not cause an adverse foreign body reaction or lead to a heightened inflammatory response. The drain should be comfortable for extended patient wear and should not cause irritation. The drain should be easy to put in place by a patient if necessary, given instructions are provided. Lastly, the drain will likely need sterile packaging and will be intended as a one-time use product.

c. *Accuracy and Reliability*: The drain should reliably allow an infected abscess cavity to drain. See *Safety* section above.

d. *Life in Service*: The drain will be in place for the duration of the abscess closure process which can range from 2 weeks to 2 months depending on a number of factors (age, original insult, severity, diseases, etc.), but is ultimately disposable and one-time use. The drain should have a shelf-life of at least 2 years.

e. *Operating Environment*: The drain will be inserted into an abscess cavity through a surgical incision and covered by gauze. It will be used by a patient during normal day-to-day activities. As such it should be resistant to external stress and movements by the patient. Additionally it should have a low profile at

the incision site to minimize snagging, accidental dislodgement, and further wounding. The device will be originally put in place by a trained physician but will be maintained, and replaced as needed, by the patient.

f. *Ergonomics*: The drain should require minimum force to insert and should remain securely in place for the duration of the wound healing process. It should be comfortable for extended patient wear and should not cause any additional irritation. A cognizant patient should be able to use the drain in an instructed manner.

g. *Size*: The drain will be designed in 3 stock sizes that will cover a range of incision sizes from 1.5 – 4 cm. The drain will need to span 0.5 cm across the dermis and epidermis layers from the external environment into the abscess cavity. The drain should not extend more than 2 cm from the surface of the incision to minimize and prevent accidental snags.

h. *Materials*: The drain should be made of a medical grade polymer such as PDMS, PTFE, or PVC that does not contain toxic, leachable byproducts or additives. If metal is needed for structural reinforcement, stainless steel will be used.

i. *Aesthetics, Appearance, and Finish*: The drain should have a smooth finish to promote patient comfort. The drain should exude safety and efficacy.

2. Production Characteristics

a. *Quantity*: One prototype is needed for proof of concept; however, the design should be engineered to be injection moldable.

b. *Target Product Cost*: The drain cost should be kept to a minimum and be kept as simple as possible to manufacture. Per unit cost should be comparable to the Bard Penrose Drain, which retails at ~$1.50.

3. Miscellaneous

a.*Standards and Specifications:* FDA approval would be required for this device before clinical use. The device would at a minimum have to be proven substantially similar to current drainage devices (i.e. Penrose Drain) and could possibly fall under a class three device.

b. *Customer:* This surgical drain is made to be used by patients under the direction and supervision of a licensed physician. The customers (both the physicians and patients) prefer that the product be latex free, flexible, and easy to manipulate into place. Products that are low in cost and easy to manufacture have been shown to do well in this market.

c. *Patient-Related Concerns:* The device should be stored in its original package at room temperature away from direct exposure to light. The device is designed to be used on a single use basis and sterilization is not required unless directed to do so by a physician. Patients are suggested to consult their doctors prior to removing or changing the drain.

d. *Competition:* There are currently many surgical drains on the market. Specifically we are looking to compete with surgical drains that require no suction and have no added wound healing characteristics. Examples include:

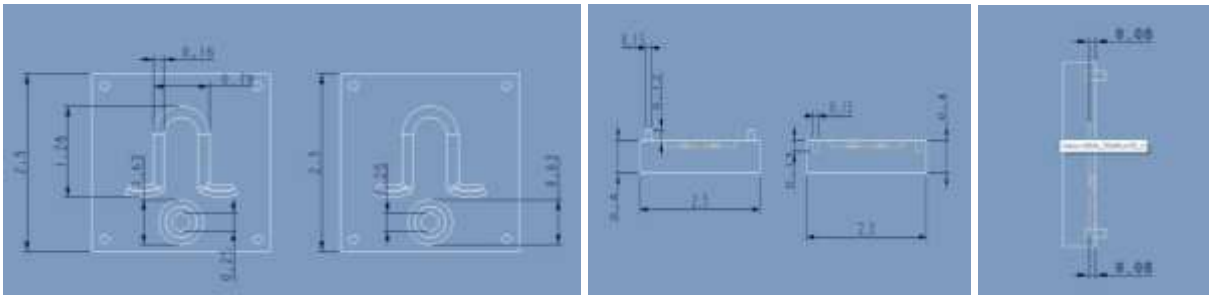
a. Surgical drain - Patent 5053021

b. FLAT DRAIN - Patent 3860008

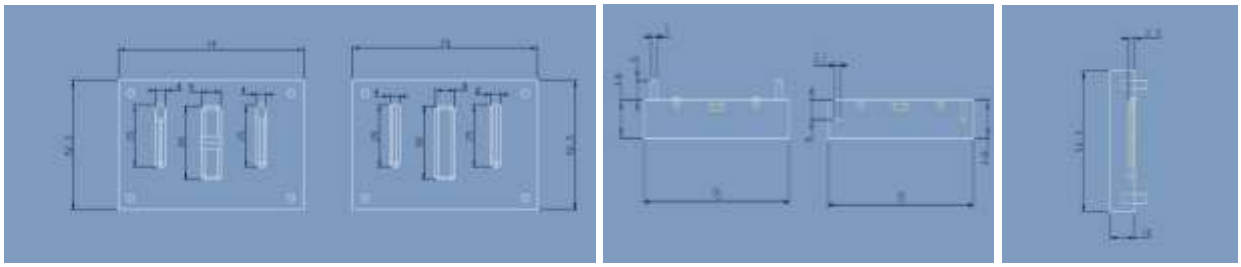
c. SURGICAL DRAIN - Patent 3823720

d. Method and device for draining abscess - Patent 5232440

3D printer CAD designs



CAD A-drain for 3D printer



CAD scissor frame for 3D printer

Silicone properties

Material properties

Materials in the default library can not be edited. You must first copy the material to a custom library to edit it.

Model Type: Linear Elastic Isotropic

Units: SI - N/m^2 (Pa)

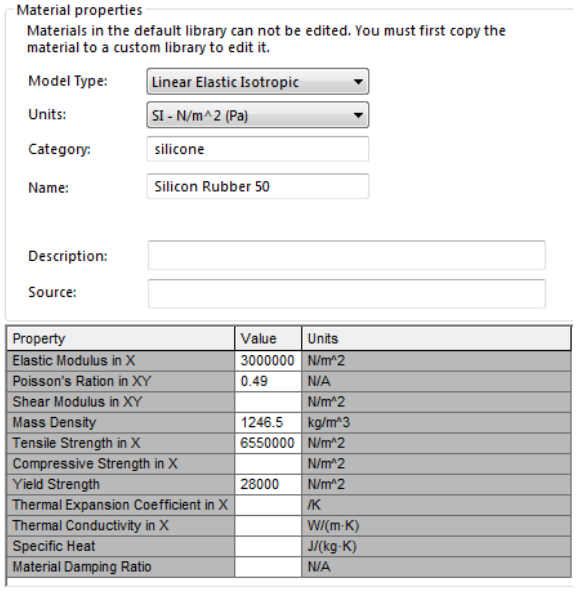
Category: silicone

Name: Silicon Rubber 30

Description:

Source:

Property	Value	Units
Elastic Modulus in X	2000000	N/m^2
Poisson's Ration in XY	0.49	N/A
Shear Modulus in XY		N/m^2
Mass Density	1246.5	kg/m^3
Tensile Strength in X	5520000	N/m^2
Compressive Strength in X		N/m^2
Yield Strength	21000	N/m^2
Thermal Expansion Coefficient in X		/K
Thermal Conductivity in X		W/(m·K)
Specific Heat		J/(kg·K)
Material Damping Ratio		N/A



Material properties

Materials in the default library can not be edited. You must first copy the material to a custom library to edit it.

Model Type: Linear Elastic Isotropic

Units: SI - N/m^2 (Pa)

Category: silicone

Name: Silicon Rubber 50

Description:

Source:

Property	Value	Units
Elastic Modulus in X	3000000	N/m^2
Poisson's Ration in XY	0.49	N/A
Shear Modulus in XY		N/m^2
Mass Density	1246.5	kg/m^3
Tensile Strength in X	6550000	N/m^2
Compressive Strength in X		N/m^2
Yield Strength	28000	N/m^2
Thermal Expansion Coefficient in X		/K
Thermal Conductivity in X		W/(m·K)
Specific Heat		J/(kg·K)
Material Damping Ratio		N/A

Material properties

Materials in the default library can not be edited. You must first copy the material to a custom library to edit it.

Model Type: Linear Elastic Isotropic

Units: SI - N/m^2 (Pa)

Category: silicone

Name: Silicon Rubber 70

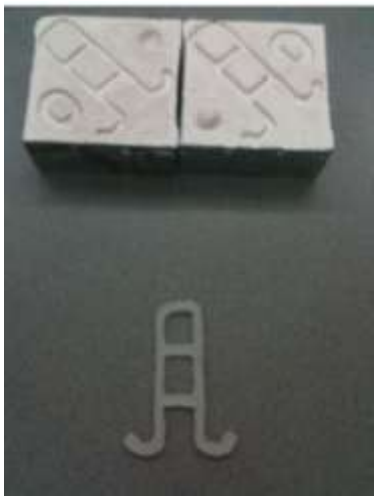
Description:

Source:

Property	Value	Units
Elastic Modulus in X	4000000	N/m^2
Poisson's Ration in XY	0.49	N/A
Shear Modulus in XY		N/m^2
Mass Density	1246.5	kg/m^3
Tensile Strength in X	6900000	N/m^2
Compressive Strength in X		N/m^2
Yield Strength	33000	N/m^2
Thermal Expansion Coefficient in X		/K
Thermal Conductivity in X		W/(m·K)
Specific Heat		J/(kg·K)
Material Damping Ratio		N/A

Progression of molds and prototypes

1st and 2nd generation prototypes



2nd generation prototype packed by Greg for better quality

3rd generation prototype wax molds and vel-mix

3rd generation molds and silicone prototypes employing circular bar in two configurations

4th generation prototype wax model and dental stone mold

3rd generation prototypes in 70A (top) and 70A/30A 50:50 mix (bottom)