Introduction

Surgical drain tubes are commonly used devices that decrease pressure build-up inside wounds after surgical procedures. The drain tubes are generally composed of silicone and include flutes to help evacuate fluid from the wound to a bulb outside the body. Although surgical drain tubes are very useful, they create a constant opening in the skin where bacteria can proliferate, often leading to surgical site infections. Dr. Poore, a surgeon at the University of Wisconsin – Madison hospitals and clinics, focuses on mastectomies and breast reconstruction surgeries. As a result, Dr. Poore frequently encounters infected sites around surgical drain tubes and has requested a new device to decrease the infection rate. The goal of this project is to design a device that will interface with a surgical drain, and will effectively prevent bacterial invasion of both the wound site and the surrounding skin area.

Background

Over 200,000 patients are diagnosed with breast cancer every year. Breast cancer is caused by an abnormal amount of cell growth in the breast tissue and/or the surrounding ducts. In order to control the spread of the cancer many patients undergo a mastectomy, a surgery that removes part, or all, of the breast tissue. A mastectomy is a routine, yet invasive procedure that causes excess fluid drainage from the wound site (American Cancer Society, 2009).

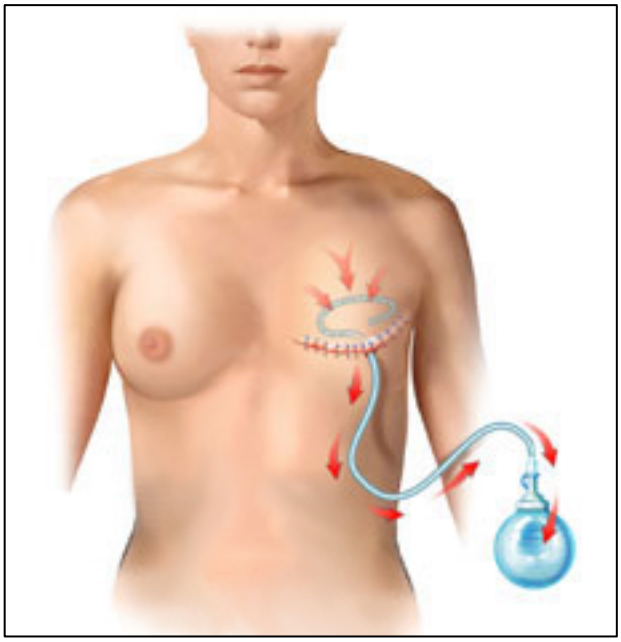


Figure 1: Diagram of surgical drain tube used in reconstructive surgery (SutterHealth, 2010).

A surgical drain tube is used to prevent a build-up of this fluid within the wound cavity. A drain tube, pictured in figure 1, is a small tube that allows excess blood and fluid to drain from the wound site into a bulb on the outside of the body. This decreases the pressure inside the wound and allows the body to heal faster. The most common type of drain tube, a fluted drain tube (Figure 2), utilizes slits along the section of tubing that is inside the body, which allow the fluid to flow into the tube and outside the body. The drain tube is worn for up to 14 days to allow complete fluid drainage.

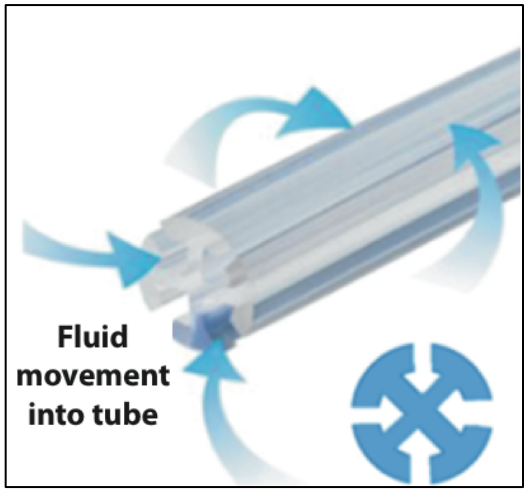


Figure 2: Fluted end of drain tube that is inserted into the wound site (C. Daniel Medical, Inc., 2010)

In order to keep the inside of the drain tube clean and prevent infection, the patients are instructed to clean and remove fluid from the bulb of the drain tube. Furthermore, the patients track the drainage each day (Louis, et al., 2003) to provide physicians with information that may serve as an early warning for complications, such as leaks and hemorrhages, which often result in a large accumulation of fluid within the wound (SutterHealth, 2010).

The drain tubes are very useful for removing fluid from wound sites; however, since the drain tube creates an opening for bacteria to infiltrate the body, they are associated with a high rate of infection. Dr.

Problem Statement

According to Dr. Poore, upwards of 20% of his mastectomy patients develop an infection during the period of drain tube usage, and 5% require drain tube removal due to the severity of the infection. The Mayo Clinic conducted a study on infections after breast surgery from 2003 – 2006 and found that 26% of patients developed a surgical site infection. Of those patients, 28% required re-admittance to the hospital to receive antibiotics. Moreover, 10% of the patients with an infection underwent an operation to replace the infected drain tube (Throckmorton, et al., 2009). Extra operations result in longer recovery times, more complications, increased stress and trauma, and more medical bills for the patients. In an effort to reduce these inconveniences Dr. Poore has requested a surgical drain tube device that will release a microcidal agent to fight and prevent infections in his breast reconstruction patients.

Client Specifications

A device has been requested that effectively prevents bacterial growth around the drain tube entrance site for up to 2 weeks. The device should also interface with the existing drain tube such that minimal extra dressings are necessary to secure the position of the device. Lastly, the product must be economically feasible to produce on a large scale for mass use throughout hospitals.

Competition

There are two major competitors for the proposed device available commercially. The first is the BIOPATCH® and is the device currently in use by surgeons in conjunction with the surgical drain tube. The BIOPATCH® is a polyurethane disc with a microcidal agent known as Chlorhexidine Gluconate (CHG), used to fight infection on the surface of the skin. There is a smaller hole concentric with the disc that allows room for a catheter or drain tube. A radial slit from the circle allows the disc to slide around the drain tube. Figure 3 displays the BIOPATCH® as it is used with catheters or drain tubes. The arrows represent the release of CHG to the wound site. After the drain has been situated, the client places surgical dressing around the BIOPATCH® to secure the patch and tube to the skin. The main reason the BIOPATCH® method is not effective is that it requires extra work during the procedure. In order to prevent the tube from sliding in and out of the wound site, the BIOPATCH® must also be attached to the tube via suture. The biggest issue with the BIOPATCH® is that it is only effective for up to 7 days. Since Dr. Poore would like the device to remain in use for up to two weeks, the BIOPATCH® is insufficient for this application. Avoiding the necessity of replacing the device during the draining period would decrease risk of infection. The shortcomings of the BIOPATCH® are a few of the main reasons the client has requested a new device.

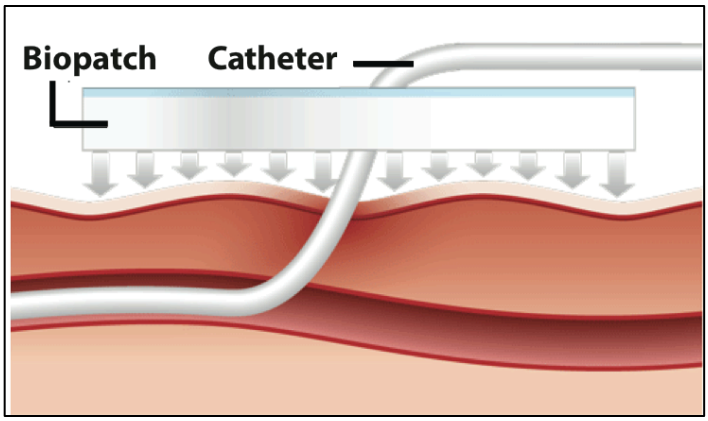


Figure 3: The BIOPATCH® releases CHG around the wound site (Ethicon 360, 2011)

A second competitor on the market is the Elutia™ (Bactrin International, Inc). This drain tube consists of a treated hydrogel coating the helps prevent contamination of the drain tube as well as infection. This device features the microcidal hydrogel all along the drain tube as opposed to only at the site of incision, where most

A major component missing from this device is the lack of a cuff to serve as a suture tab for the surgeon (Bacterin International, Inc., 2008)

Design Options

There are two main aspects of the design, a CHG-impregnated foam pad and a silicone cap. The cap will also have tabs to allow the surgeon to easily suture the drain tube to the patient's skin. The structure of the foam piece and cap are shown in Figure 5.

Foam Designs

The foam is impregnated with CHG, which provides the device with antimicrobial properties. The foam pad lies directly on the skin, therefore it must be biocompatible. Properties of the foam material include being open-celled and high hydrophilicity. These properties determine the extent to which the foam absorbs and releases the microcidal agent. The first design is shown in Figure 4. The foam features a circular disc with a diameter of 25mm and a cylindrical attachment that penetrates into the wound slightly to provide microcidal agent to the bottommost layers of the skin. This will provide more surface area for the release of the microcidal agent. The next design is very similar to the first design, and is depicted in Figure 5. However, this design features fillets (r=3 mm) to provide structural stability of the foam piece that penetrates into the wound. Finally, there is the simple disc design, which does not contain a cylindrical attachment; this is shown by Figure 6.

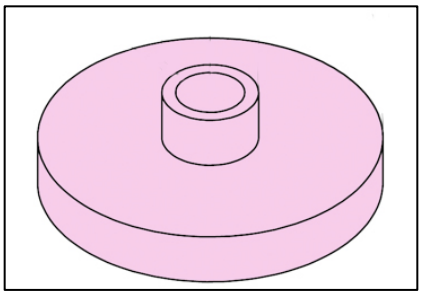


Figure 4: Foam design with cylindrical attachment. Bottom, isometric view. outer diameter of 25mm.

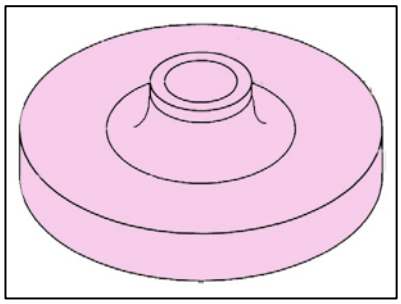


Figure 5: Foam design with conical attachment. Bottom, isometric view. outer diameter of 25mm.

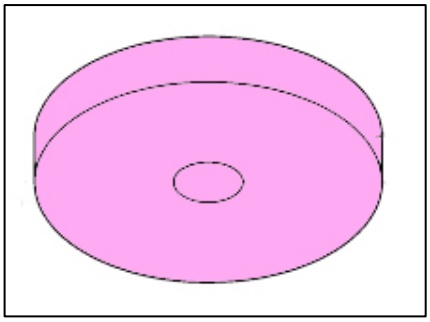


Figure 6: Simple disc design, outer diameter of 25mm.

Foam Materials

The material type in question must satisfy several criteria to meet the design's needs. First, and perhaps the most essential, is that it must be capable of absorbing a large amount of liquid. Foams of this type are said to be "open cell." The cell walls, or bubbles, of these foams are broken, creating a sponge-like material in which liquid is able to flow into and/or through the material Additionally, the foam must not be an irritant to human skin. The foam that has proven to be most viable is reticulated polyurethane foam. It is widely used for clinical applications involving antimicrobial impregnation and release (CareFusion, 2011). Products that utilize a polyurethane foam material include BIOPATCH® and Chloraprep (Ethicon 360, 2011). However, what remains to be determined is the level of absorptivity of the polyurethane foam.

Polyurethane foams come in a wide variety of densities and porosities. A few of these stood out as being candidates for further research regarding their absorptivity. Two were polyurethane memory foams, in which they had been treated to increase viscosity. These were both listed as having equal foam densities (92.9 kg/m^3), but differed in their firmness. Firmness is a measurement

foam in question is deflected 25% of its total length and the pressure required is measured (Information on flexible polyurethane foam, 1994). The two memory foams had firmness measurements of 1 (considered 'soft') and 4 (considered 'firm'). Two other non-memory polyurethane foams were also used. The first has a density of 49.28 kg/m^3. The other is less dense at 23.2 kg/m^3, yet seems to have a higher amount of pores per inch. These four foam types will constitute the first round of testing. Additionally, a foam that has extremely promising qualities has been located which has a density of 28 kg/m^3 but can store up to 30 times its own weight in liquid. This has been included in testing at the hospital and is planned on being included in the next round of testing

Cap Designs

The cap has three main objectives—providing structural stability for the patch, attachment of the foam to the drain tube, and providing suture points for the surgeon to secure the drain tube to the patient. The cap will be made of silicone for ease of attachment as silicone bonds well to itself. Silicone is a polymer containing silicon, carbon, hydrogen, and oxygen (Greenwood & Earnshaw, 1997). Because this compound is highly inert and shows flex fatigue resistance, medical devices and implants are commonly made out of silicone (Shin-Etsu Silicone, 2005). The ease of fabrication is another benefit to this material, as silicone can be formed into virtually any shape and bond very well to other silicone parts.

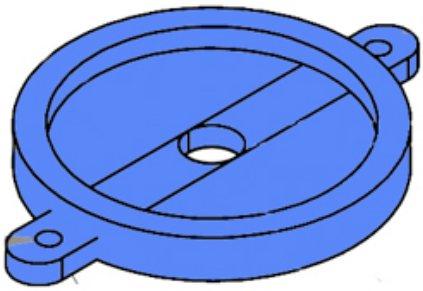


Figure 7: Cap design with tabs, bottom isometric view. Inner diameter of 25mm

The first design is shown in Figure 7. This cap covers all of the foam above the skin. Because of the depth of the cap, there is some worry about the pressure on the patient's skin as it may cause discomfort. The silicone cap provides attachment to the drain tube at the 5-mm opening at the top. Another design of the cap has suture tabs as shown in Figure 8. These tabs provide a way of attachment of the drain tube to the patient. The surgeon will suture through the holes in the tab and into the skin. This will minimize movement of the drain tube when on the skin. In addition, there is room between the skin and the cap to minimize pressure on the skin. The third design is displayed in Figure 8. This ovoid design provides better structural integrity to the design and increases the strength of the suture tabs.

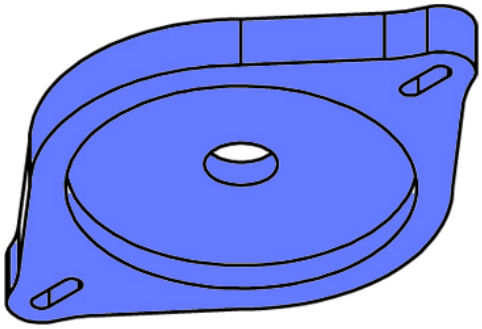


Figure 8: Ovoid cap design, the ovoid shape increases mechanical strength around the suture tabs.

The next cap design is shown in Figure 9. This cap also employs the suture tabs. However, with this design, the silicone core would extend into the skin. The foam would be a disc without a cylindrical attachment as shown in Figure 10. This core would also be impregnated with silver ions. This would be beneficial as the silver would prevent different strains of bacterial infection (Beam, 2009).

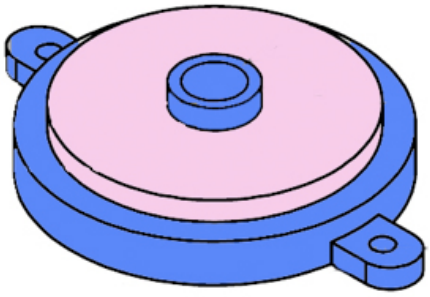


Figure 9: Cap design with inner core integrated with disc (pink).

Design Matrix

A design matrix was made to review the three different foam

Safety was weighted the highest; the design's impact on the patients' health is of the utmost importance. Care must be taken to ensure that nothing, especially the antimicrobial agent, will inflict any harm upon the patient for its duration in use. The second highest weighted category was ergonomics, followed closely by manufacturability. Ergonomics is extremely important in that it must not significantly detract from the surgeon's normal procedure, as surgeons are often wary of deviating from a specific procedure. The third highest weight was manufacturability. The design should be mass-producible. It should also conform to a certain degree to the incision, thereby further preventing the entry of bacteria. Durability goes hand in hand with these, it should be able to stay functional for up to 2 weeks, as well as withstand the insertion procedure of the drain tube. Feasibility was included as a way to determine if it could be fabricated. Finally, cost was weighted the lowest; this is because the materials for production are relatively inexpensive. They would not cost significantly more than what is used now (drain tube and BIOPATCH®).

Table 1: Design matrix of foams shapes. The simple disc received the best score.

Category	Weight	Cylindrical with Fillets (Figure 5)	Cylindrical (Figure 4)	Simple Disc (Figure 6)
Feasibility	0.5	1	3	4
Cost	0.1	2	3	4
Durability	0.7	3	3	3
Safety	1	4	3	3
Ergonomics	0.9	3	4	4
Manufacturability	0.85	2	1	4
Total		11.2	11.35	14.5

Of the three foam shapes, the simple disc scored the highest. The disc scored the highest in manufacturability and cost. This is because a simple disc is much more easy to construct out of a sheet of foam instead of with a fillet or cylinder. In addition to this, the simple disc leads to less use of material that will lower the cost of the device. The simple disc also scored higher in feasibility and ergonomics. Because of the results, the simple disc seems to be the most desirable for use with our device.

Another design matrix was created to analyze the different cap designs. The same categories were used in both matrices, but with different weights. This is shown in Table 2. Safety remains the most important with both feasibility and ergonomics the second most important.

The three different designs all scored the same in feasibility, manufacturability, and cost. This is due largely to the fact that they are all made from the same material and this material costs the same amount. The method used to manufacture each of these silicone cap designs was the exact same, so it was impossible to score them differently in the feasibility and manufacturability categories. Therefore, the main differences between the designs stem from the safety, ergonomics, and durability categories.

The ovoid design scored the highest in safety, durability, and ergonomics. This is because the larger ovoid

higher strength and stability. These efficient tabs would also aid the surgeon in attaching the drain tube. This would minimize the need for dressings and adhesives to the drain tube.

The cap with tabs and cap with fillet tabs scored lower in the safety, durability, and ergonomics categories. This is largely due to their lack of successful performance in the strength testing as well as having smaller holes for the surgeon to suture through. In the mechanical testing, the cap with tabs and cap with fillet tabs broke at a much lower strength than the ovoid design, thus decreasing their ratings in durability and safety. The small holes in the two low scoring designs lead to added difficulty for the surgeon and ergo lowering their score in ergonomics.

To summarize the findings of the design matrices, the ovoid with simple disc foam scored the highest among the designs and therefore will be included in the final design.

Table 2: Design matrix comparing cap designs. The ovoid received the highest score.

Category	Weight	Cap With Tabs	Cap With Fillet Tabs	Ovoid
Feasibility	0.8	3	3	3
Manufacturability	0.6	3	3	3
Cost	0.5	2	2	2
Safety	1	3	3	4
Durability	0.7	2	3	4
Ergonomics	0.8	2	3	4
Total		11.2	12.7	15.2

Testing

There are two stages of testing for this device, starting with a small-scale experiment to understand the feasibility of the device, then a larger scale experiment in the microbiology lab. This first round is intended to determine the appropriate material to be used in the design of the foam portion of the CidalSeal™. Four different types of foams were tested in the first round. They include foams of varying density: 23.2 kg/m3, 49.28 kg/m3, and two memory foams with a density of 92.907 kg/m3. The memory foams are differentiated by there firmness levels. The active agent used was chlorhexidine gluconate (Sigma- Aldrich, C9394).

The first step of the procedure is to collect all necessary materials need to be collected. These include:

- Foams: listed above
- Microcidal agent: 3% CHG, 97% H_20
- Agar plates (90 mm x 16 mm)
- Agar: LB, sterile, 125mL
- Deionized water
- E. coli

- 37 °C
- Maintained darkness

In order to prepare the foams, the first step is to cut the disks with a 25.4-mm diameter circular di-cut. Five circular disks should be cut of each foam type. Next, the foams need to be weighed and sterilized. This

is accomplished by collecting the dry weight and then soaking the disks in an ethanol solution for 10 minutes After soaking for the appropriate time, the disks are placed on weigh boats (or other sterile surface) in a sterile fume hood. This allows the foams to remain sterile and dry faster. After 10 hours of drying, the foams will be ready to be weighed and soaked in CHG. A 3% CHG, 97% H_2O solution is made. Four foams are soaked in the CHG for 10 min. Sterile forceps can be used to ensure complete saturation by pressing the foam against the beaker to ensure full foam absorption (this process eliminates any air bubbles inside the foam). Next, the foams are left to soak for 10 minutes in the solution. After, they are weighed and left to dry in a sterile weight boat placed in a fume hood. They should be left to dry for 10 hours.

After complete drying, the dry weight of the CHG and foam is collected and the amount of CHG absorbed by the foam is determined. The petri dishes should all be pre labeled with a number, type of foam, and whether or not it is a control. The dishes are autoclaved and kept as sterile as possible by not opening the lid for long periods of time. The LB agar is pre-mixed and poured into the petri dishes to a height of 8 mm. The agar should be refrigerated for 2 hours upside-down. Next, the petri dishes should be placed in an incubator at 37˚C for one hour to ensure constant temperature.

A non-pathogenic E. coli bacterium was used throughout these experiments. Measure out 1 µL of bacteria with a micropipette. Next, spread the bacteria with a toothpick in longitudinal zigzags across the agar. After spreading, the cap should be placed on the petri dish immediately and either a foam or control foam is placed directly in the middle of the petri dish. Next, repeat this step for all plates.

The samples are left in a dark, 37˚C incubator for 14 days. The samples are checked on every 24 hours and the areas of inhibitions are monitored. The area of inhibition is defined as the area where no live bacterial colonies are forming, shown in Figure 10 (d). Each sample will be photographed using the same camera at 4x zoom and a tripod is used so that the pictures are taken from the exact same height every time. Adobe Photoshop® is then used to convert the amount of pixels into centimeters so that an accurate area of inhibition can be found. Some examples of the photos are shown in Figure 10.

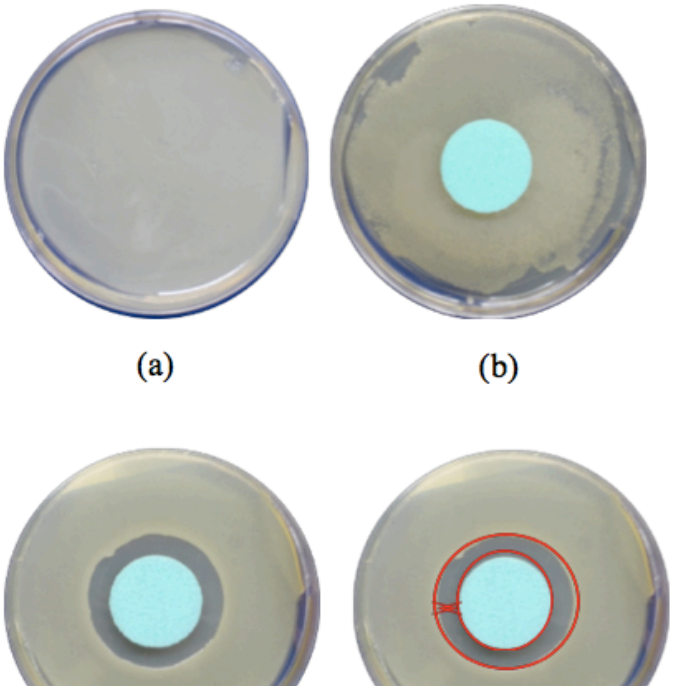
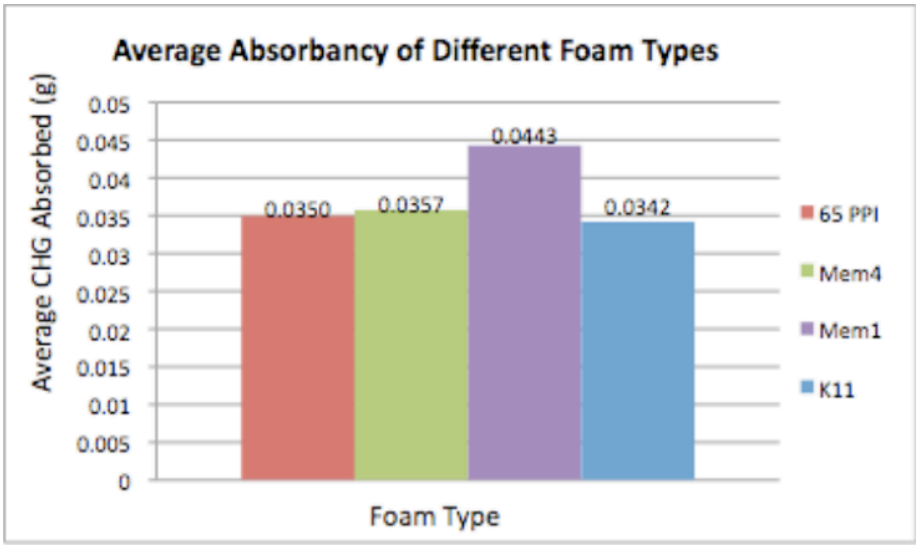


Figure 10: Petri dishes of experiment. (a) control with no foam and only E. coli. (b) control with untreated foam. (c) foam impregnated with CHG. (d) area between the red lines is area of inhibition observed and measured in Photoshop®.

In addition to the testing conducted by our team, the University of Wisconsin hospital conducted inhibition testing on six different types of CHG treated foams. To test the foams they placed 8 of each type of foam on separate plates of agar that had been seeded with *Staphylococcus aureus*. In addition to this, two controls (untreated foams) of each type were also tested. The samples were set on the bacteria cultures in ambient air for 18-24 hours. After this time period the foam samples were removed and the diameter of inhibition was measured. The samples were then placed on another bacteria culture and measured for diameter of inhibition after 18-24 hours. This procedure was repeated for a time period of 14 days. Daily movement of samples to new bacteria cultures ensured that the samples were continually releasing CHG.

Mechanical testing on the silicone tabs was also performed. All three of the cap designs were subjected to a tensile loading on the suture tabs. The maximum force of 20 N was implemented via spring gauge repetitively for a time period of 1 second on each type of suture tab. The sample was fixed along the center and force was applied on a 3.0 (metric) polypropylene suture that was tied to the tab. The force was repeated on the specimen until the structure broke. The number of successful repetitions and site of failure was recorded.

Results



Each foam sample was saturated with antimicrobial by submersion in a 3% CHG solution. The water absorbed. By the foam was then allowed to evaporate, theoretically leaving behind some CHG within the matrix of the foam pores. In order to quantify the amount of CHG held in each foam, dry weights were taken before and after soaking in CHG. Figure 11 displays the average CHG absorbed by each foam type.

Figure 11: Average CHG absorbed by various foam types.

Foam Population 1	Foam Population 2	p-value
K11	65PPI	0.824001
K11	Mem4	0.856143
K11	Mem1	0.335424
65 PPI	Mem4	0.909132
65 PPI	Mem1	0.334339
Mem4	Mem1	0.345437

Table 3: P-values for a 2-tailed paired student's t-test comparing the CHG absorbed by 2 populations of foam samples

It is observed that memory foam 4 (Mem4), the 65 pores per inch (65PPI) foam, and the K11 foam absorbed relatively similar amounts of CHG. Table 3 displays the p-values obtained by performing a student's t-test on paired populations of foam samples with the following hypothesis: HO: $\mu 1 = \mu 2$, H1: $\mu 1 \neq \mu 2$. In this table it can be seen that although memory foam 1 (Mem1) retained, on average, the greatest mass of CHG, statistically the differences in the values are not significant between any combination of foam types. The data from the first 6 days of testing have been recorded, analyzed, and compiled in figures 12 and 13, and Table 4 below.

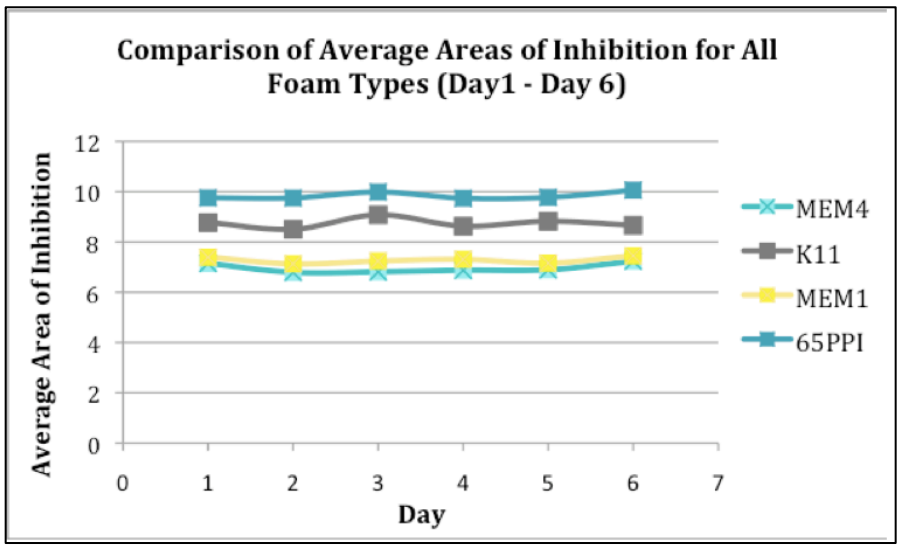


Figure 12: Tracking the average area of inhibition among all samples of all foam types for days 1-6. n=4 for each foam type.

Figure 12 tracks the average areas of inhibition for each foam type throughout the first six days of testing. From this data it can be noted that the relative average areas of inhibition stayed constant throughout this portion of the testing period. Figure 13 displays a similar set of information, but shows an average of the compilation of the areas of inhibition over this period. Again, it can be seen that the 65PPI foam outperformed all other foam options. A 2-tailed, paired student's t-test was performed to show the statistical significance of the differences seen between 65PPI foam and the next best performers: K11 and Mem1. Table 4 summarizes the information gained from this statistical test. If an alpha value of 0.1 is chosen to determine statistical significance, then the 65PPI foam has an area of inhibition significantly greater than all foams for days 2, 4, and 6 of testing, and an area of inhibition significantly greater than the third "best" foam option for all days during the testing period.

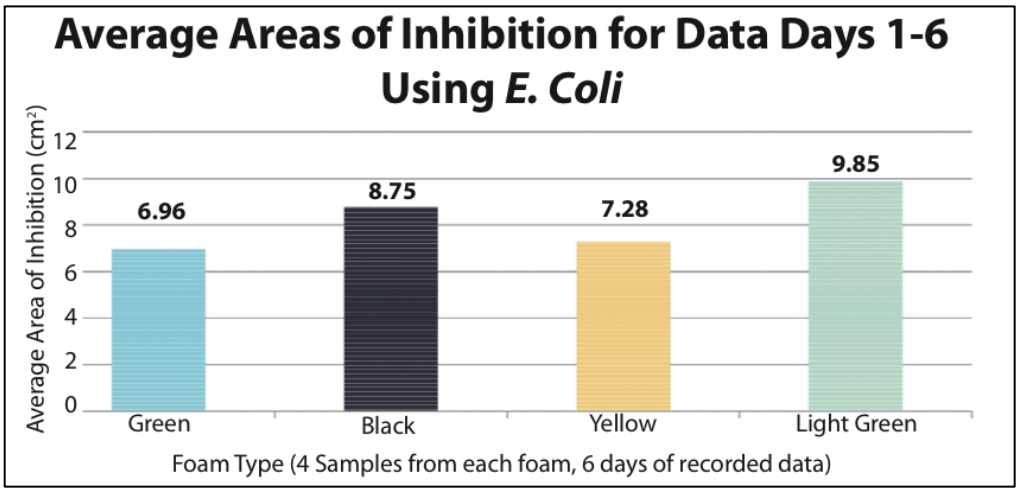


Figure 13: The overall average areas of inhibition for each foam type taken from all data over 6 days of testing. n=4 for each foam type.

Overall, the testing results gathered thus far show that the CHG absorbed by a particular foam type cannot be shown to be a predictor of that foam producing a large area of inhibition. The foams tested are not significantly different in their ability to retain CHG. The foams can be shown to significantly differ in the areas of inhibition produced when placed on a plate of *E. coli*. bacteria, with the 65PPI foam outperforming all other foams in this area consistently for the first 6 days of the testing period.

A second round of bacterial testing was performed at the UW hospital. In this experiment the areas of inhibition maintained by CHG soaked foam samples was measured when placed on an agar plate inoculated with *Staphylococcus aureus* ATCC 25923, a methicillin-susceptible organism. A full description of this experimental protocol can be found in the Appendix. Figure 18 shows the duration of antibacterial activity of each foam type. Light green, black, and white continued to release CHG for the full 14 days, whereas the other three were unable to maintain antibacterial activity. By using an alpha value of 0.1 to determine statistical significance the white, high absorbency foam performed statistically better than all other foam types.

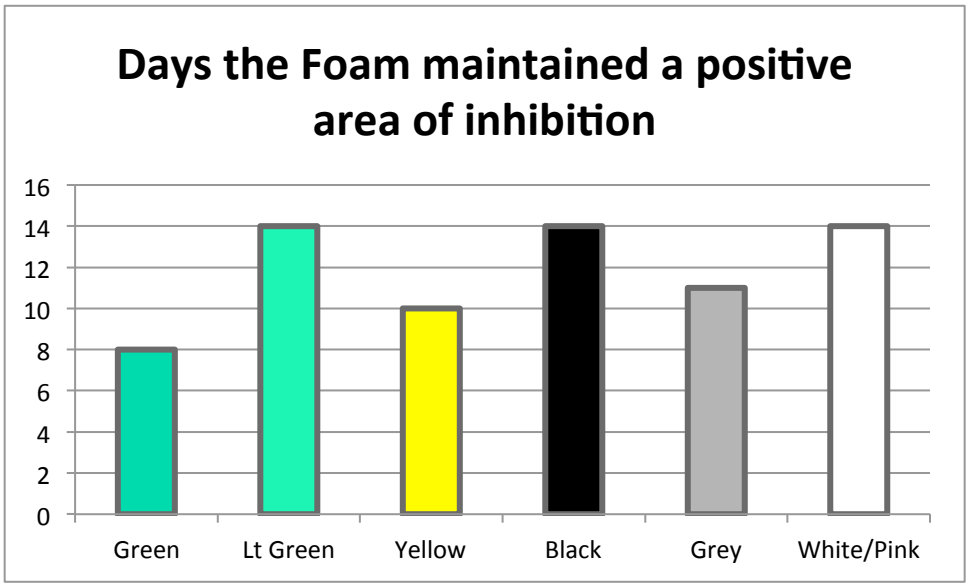


Figure 14: Foams shown by length of efficacy on *staphylococcus aureus.* The *y*-axis is shown in days, and n=8 for each sample type.

Product	Price
Washers	$11.60
10' Silicone Foam	$38.34
2.75 in. Polyurethane cubes	$18.73
100 mL CHG Solution	$79.29
Filter Foam: 20, 30, 65 PPI	$57.29
Recovery and Natural Gum Foam	$25.90
Polyurethane foam	$13.06
Agar and Plates	$64.24
Memory foams 2 and 3	$16.51

Table 5: Total of purchases made this semester.

Cost Analysis

In the initial stages of design of the device, price of the individual components was taken into account in order to make the device as cost effective as possible. A $5,000.00 budget was established for the product. Expenditures, however, have stayed well below that, as seen in Table 5.

The cost of the super-absorbent foam, which performed best in the trials, costs $2.85/sq. ft. (McMaster Carr, 2011). Assuming that 1 sq. in. is needed for the fabrication of just one piece of foam, the material cost per device would be approximately $0.02. A 3% CHG solution is used to treat the foam components. The cost for 100 mL of 20% CHG is $79.29. Since the solution must be diluted down to 3% concentration and only a small amount of the agent (~15mL) is needed to impregnate multiple

foams. Assuming each foam disc needs 10 mL of the 3% solution during fabrication, the cost per foam piece in terms of CHG will be $1.75. The silicone adds additional cost to the design. The silicone costs $79.67 for 454 g of the elastomer and catalyst. Only 3 g of silicone is used in the device, $0.52 per unit. Additional costs may arise in the future in response to the need for streamlining fabrication. Injection molding would be effective for manufacturing the silicone cap. With injection molding, an initial tooling cost is estimated at $1,445.00. Comparing this to the current technology, it does prove to be more cost effective. The cost of in individual BIOPATCH® is approximately $11.30 (Ethicon 360, 2011). The CidalSeal™ will cost only $2.31 per unit. This cost effectiveness proves that this product has a great potential to be marketable with an opportunity for a high profit margin.

Final Design

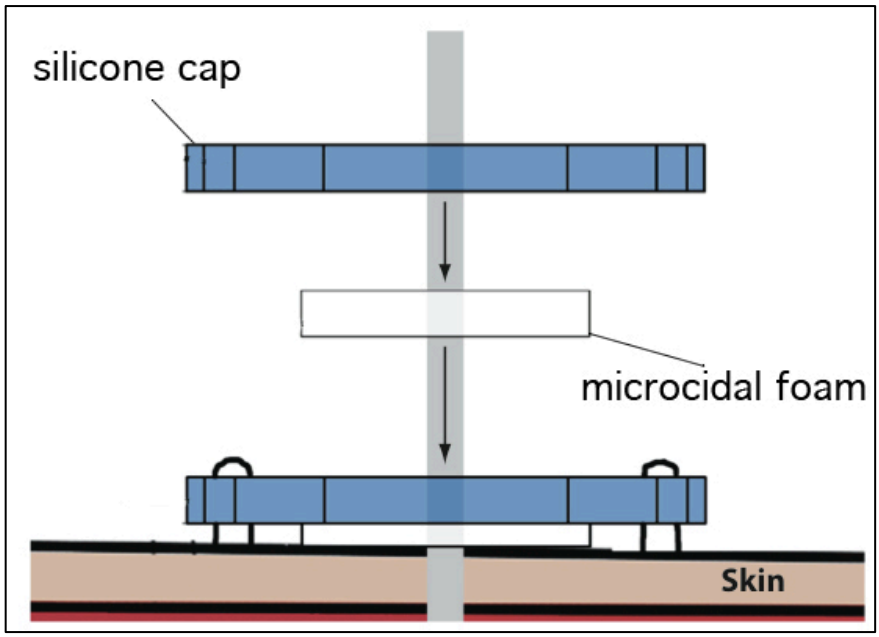


Figure 15: A depiction of the final product, the silicone cap integrates with the antimicrobial foam disc and then is sutured down onto the skin.

Our current design utilizes the white Aquazone® foam as the antimicrobial absorbing component. This foam performed best in comparison to the other three, with respect to CHG absorbance and average diameter of inhibition over 14 days. It remains to be tested on other strains of bacteria than *staphylococcus aureus*. The antimicrobial solution used is a 3% CHG solution, diluted from a 20% solution. This impregnated foam component is then covered with a silicone suture cap. The silicone used was a commercially available compound with product number A-2186F. This particular silicone is platinum cured, and therefore biocompatible. Assembly of these components in succession will constitute the CidalSeal®.

Future Work

There are several areas that require attention in the upcoming semester. First, more material testing will take place at the University of Wisconsin Hospital's microbiology lab. There, a similar test to the ones completed will take place to determine which CHG treated foam is the best at killing various types of bacteria. After successful *in vitro* testing, the next step would be to begin *in vivo* animal testing, potentially on porcine specimens. A protocol will be written for this experiment and conducted along the following parameters: the CidalSeal™ will be inserted on one side of the animal, and an untreated drain tube will be inserted on the other. This will hopefully prove the effectiveness of the device in comparison to its untreated counterpart as well as illustrate its longevity *in vivo*. If this test appears successful, the next step will be clinical trials.

While this testing is taking place, an investigation of the potential integration of silver ions into the device will be conducted. This addition will diversify the types of bacteria that the device is able to kill. For example, CHG has shown only limited effectiveness against pseudomonas, whereas silver ion anti-bacterials are quite

effective. Additionally, providing a method of attachment of the CidalSeal™ to the drain tube is another priority. The method should be easy for the surgeon to use, yet secure enough so the drain tube remains stationary.

Finally, a prototype must be fabricated and hopefully capable of mass-production by the end of the academic year. With this prototype, an application will be sent to WARF in hopes of patenting the CidalSeal™.

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Appendix

Chlorhexidine Foam Study																
Mean Diameter (mm) zone sizes of 14 daily replicates																Over-all Rank
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Green	22	11	13	9	11	11	8	(20)	(13)	0	0	0	0	0	0	6
Lt Green	22	19	17	15	18	16	15	16	15	14	12	14	12	9	(8)	3
Yellow	23	13	13	11	17	15	14	7	15	8	(20)	0	0	0	0	5
Black	24	16	15	14	15	15	14	14	14	13	12	11	12	13	(20)	2
Grey	21	16	14	14	14	13	13	12	12	11	10	(18)	0	0	0	4
White/Pink	23	19	16	17	17	16	16	16	17	17	16	15	15	15	(19)	1

Testing Protocol for round 2 testing – at the UW hospital

Materials and Methods

150 mm (diameter) agar plates containing cation-supplemented Mueller-Hinton agar (MHA; REMEL, Lenexa, KS) were brought to room temperature. A suspension of the test organisms was prepared in 0.85% sodium chloride (Becton-Dickinson, Sparks MD) to match an 0.5 McFarland barium sulfate turbidity standard, equivalent to 1.5×10^8 CFU/mL, and this suspension was used to inoculate the MHA plates using standard methods (1). Within 15 min of inoculation, the foam pieces were placed on the seeded agar. Those containing chlorhexidine were placed first followed a chlorhexidine-free control. Plates were incubated upright at 35 $\pm$ 1°C in ambient air for 18-24 hr. After the foam pieces were moved to a freshly inoculated MHA plate, the diameter of the zones of inhibition were measured and recorded.

For the first set, tested against *Staphylococcus aureus* ATCC 25923, a methicillin-susceptible organism, there were eight replicates and two chlorhexidine-free controls for each type of foam (green, light green, yellow, black, grey and white/pink).