BME 301

# Design of a Cuffed, Microcidal Surgical Drain Tube to Prevent Surgical-Site Infections

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**Client: Dr. Samuel Poore, Department of Surgery, UW School of Medicine and Public Health**
**Advisor: Professor John Webster, Department of Biomedical Engineering**

## Table of Contents

# Introduction

Surgical drain tubes are commonly used devices to decrease pressure buildup inside wounds after surgical procedures. Surgical drains are fluted Silicone tubes that drain fluid from the wound into a bulb on the outside of the body. Although surgical drains are very useful, they commonly become infected because they leave a constant opening for bacteria to get into the tissue or blood streams surrounding the drain. Dr. Poore is a surgeon at the University of Wisconsin –Madison Hospital and

focuses on mastectomies and breast reconstruction surgeries. Thus, Dr. Poore deals with a lot of infected surgical drain tubes and would like a new design to decrease the infection rate. He submitted a design proposal to the biomedical engineering design course and this team chose to work on his project. Dr. Poore will be mentoring the team throughout the semester as well as funding the project. The goal of the research project is to design a surgical drain that has an antimicrobial agent to keep the skin around the drain tube clean and prevent bacteria from getting inside the body.

## 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 breast cancer many patients undergo a mastectomy, or a surgery that removes either part, or all of the breast tissue. Mastectomies are a routine procedure but are very invasive and cause a lot of fluid drainage from the wound site (American Cancer Society, 2009).

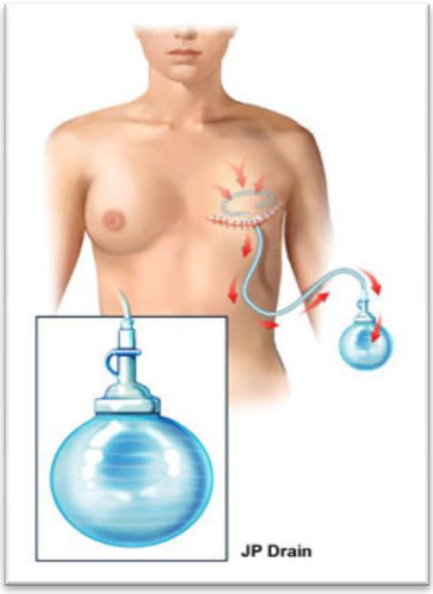


**Figure 1: Diagram of surgical drain tube used in reconstructive surgery (SutterHealth, 2010).**

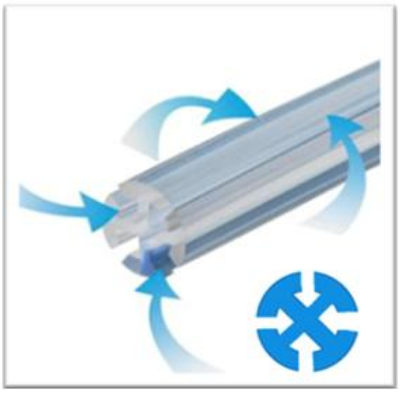

**Figure 2: Fluted end of drain tube that is inserted into the wound site (C. Daniel Medical, Inc., 2010).**

To prevent fluid buildup inside the wound doctors use a surgical drain tube. 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 is called a fluted drain tube, pictured in Figure 2. It contains slits all the way down the section of tubing that is inside the body. The fluid follows the slits until it reaches the skin, where the slits close and form normal cylindrical tubing. Drain tubes are usually worn for an average of 14 days and need to be cleaned regularly to keep the wound infection free.

In order to keep the inside of the drain tube clean, the patients are instructed how to clean and remove fluid from the bulb of the drain tube. The patients keep track of the amount of fluid that is drained each day so the doctors can tell if the wounds are healing properly. The doctors can predict leaks or hemorrhages if there is a large amount of fluid draining out of the wound (Louis, et al., 2003). Drain tubes are very useful for removing fluid from wound sites; however, since the drain tube creates a

constant opening for bacteria to get inside the body they have a high rate of infection associated with them. Dr. Poore would like a redesigned drain tube that can reduce infection rates.

## Problem Statement

Dr. Poore is a surgeon at the University of Wisconsin Madison and came up with the idea of creating a surgical drain tube with a section that has antimicrobial layer to stop bacteria from getting inside the body. According to Dr. Poore, upwards of 20% of his mastectomy patients develop an infection during the two weeks that they wear the drain tubes, and 5% have to get the drain tube removed because of the severity of the infection (Poore, 2011). The Mayo clinic conducted a study on infections after breast surgery during 2003-2006 and found that 26% of patients that underwent breast surgery developed a surgical site infection. Of those patients, 28% had to be readmitted to the hospital to receive antibiotics. Moreover, 10% of the patients with an infection had to undergo an operation to replace the infected drain tube (Throckmorton, et al., 2009). Extra operations cause the patient to have a longer recovery time, more complications, and more medical bills. Dr. Poore has requested a cuffed surgical drain tube that will release a microcidal agent to fight and prevent infections in his breast reconstruction patients.

## Client Specifications

Dr. Poore requires that the device decrease the rate of infection in his patients. In addition to this, a few other requirements were proposed. The 3 mm diameter drain tube's overall form must be small and flexible enough to fit through a 5 mm diameter incision at the site of entry for the drain tube. The microcidal agent in the tube must be able to be effective in vivo for up to two weeks. Dr. Poore would like the microcidal agent to be a part of the tube. In hopes that the device is effective, Dr. Poore wishes the device to be able to reduce the amount of dressing needed to cover the wound site. By this, Dr. Poore means that the tube should be effectively secure on its own to avoid the necessity of additional bandages around the area. As with all drain tubes, the materials used in the design must be

biocompatible. Also, the client would like this product to be economical enough so it may be mass-produced for use throughout many hospitals.

## Competition

There are two major competitors for the proposed device currently out on the market. The first is known as the BIOPATCH®. The BIOPATCH® is the device currently in use by Dr. Poore 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 drain tube. There is a slit from the outer circle to the inner circle to allow 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 the disc around the tube, sutures the disc to the drain tube, and places additional dressing around the BIOPATCH® to secure the path and tube to the skin. The main reason that the BIOPATCH® method does not work very well for the client is that it requires extra work to be done 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 in addition to being secured to the skin. The BIOPATCH® is also only effective for up to seven days – Dr. Poore would like the device to remain in use for up to two weeks, thus 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 why the client requested a new device (Ethicon 360, 2011).

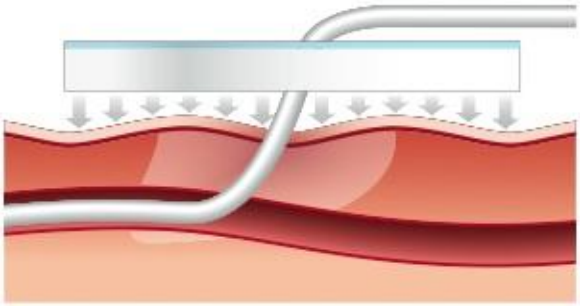

**Figure 3: The BioPatch releases CHG around wound site with drain tube (Ethicon 360, 2011).**

**Figure 4: Elutia fluted drain tube (Bacterin International, Inc., 2008).**

A second competitor on the market is the Elutia™ from the company Bactrin International, Inc. This drain tube consists of a treated hydrogel coating that 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 just at the site of incision, where most infections occur. The microcidal agent used in the hydrogel is silver sulfadiazine. The product has been tested over a period of 7 days and kills greater the 99.99% of bacteria. The cost of the product is $300.00 for a box of 10 drain tubes. 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

Three design options have been constructed for the final shape of the design.

### Tube Design

The tube design is modeled after the existing fluted drain tube as shown in Figure 5. During manufacturing, the silicone would be impregnated with

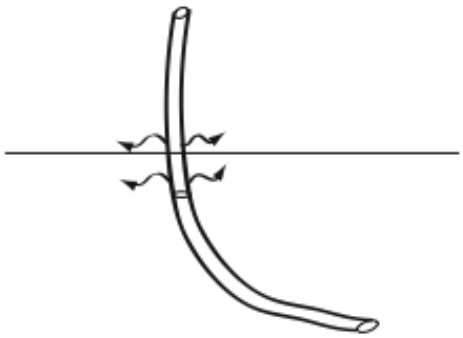

**Figure 5: Tube design.**

the microcidal agent CHG. However, the CHG would only be impregnated in the silicone to a certain point in order to prevent interaction between the microcidal agent and layers under the skin. There is a possibility that this interaction could cause complications for the patient.

Because this design is modeled after the existing tube, it has a few advantages. Mass production of the tubes would be relatively easy as only one step in the process is changed. In addition, the surgeons would not have to alter the procedure. However, because the tube does not cover the wound site, infection could still be a common occurrence. Lastly, the tube does not provide a convenient method of securing to the skin to prevent movement of the tube.

## Cuff Design

The second design option is a cuff design. The cuff design would have polymer foam wrapped around the silicone fluted drain tube, as shown in Figure 6. The foam would be impregnated with CHG using a similar process used in the production of the BIOPATCH®. The foam would act as a barrier to seal around the wound site, thus preventing bacteria and other foreign bodies from entering through the incision. Because the microcidal agent is localized to the cuff, there should not be any interaction between the cuff and the deeper layers of tissue.

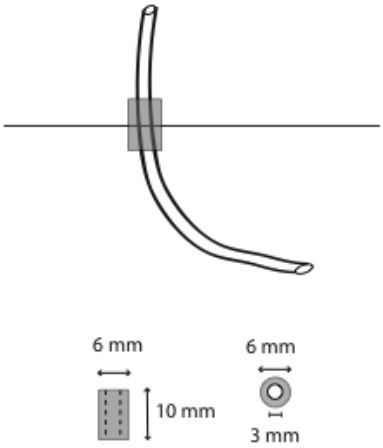


**Figure 6: Cuff design with dimensions.**

## Suture Tab Design

The final design the team constructed was the suture tab design. This design would use a polymer foam disc impregnated with the CHG agent, similar to the concept of the BIOPATCH® (Figure 7). This design would differ from the BIOPATCH® in that

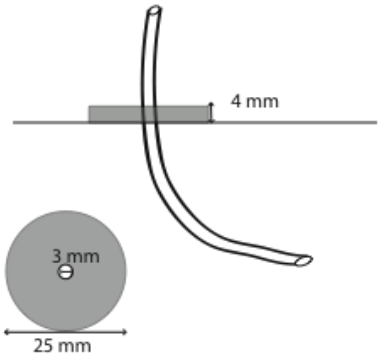


**Figure 7: Suture tab design.**

the foam would be attached to the silicone tube using a silicone-bonding polymer. The disc would be small and flexible enough to fit through the 5 mm incision.

This design has many advantages. Because of the additional surface area around the wound site, it not only provides protection from entering foreign bodies, but also acts as a place for surgeons to secure the tube to the skin of the patient. Additionally, the CHG only acts on the surface, minimizing any interaction between the microcidal agent and the deeper layers of tissue. However, mass production could be difficult or inefficient. In addition, the surgeon may have to alter the procedure to make sure the disc fits on top of the skin.

## Materials

After the form of the design is decided upon, the team will still have to determine what type of material to use for the design. There are two primary options at this point of time: silicone or reticulated polyurethane foam.

Silicone is a polymer containing silicone, carbon, hydrogen, and oxygen (Greenwood & Earnshaw, 1997). Because this compound is highly inert, medical devices and implants commonly use silicone (Shin-Etsu Silicone, 2005). Silicone also shows flex fatigue resistance (Shin-Etsu Silicone, 2005). The ease of fabrication is another benefit to this material, as silicone can be formed into virtually any shape. In addition, silicone bonds very well to other silicones, creating a very durable product.

Polyurethane is another type of polymer that is commonly used in medical equipment, including the BIOPATCH®. Because polyurethane remains durable and relatively inexpensive, it is commonly found in polymer foams that release drugs in a biological environment. Polyurethane also comes in various textures, all exhibiting different properties (McMaster-Carr, 2010). However, reticulated polyurethane foam would work the best for the drug delivery system. One concern is the bonding strength of silicone and polyurethane foam.

## Design Matrix

A design matrix was used to determine both the shape of the final design and the type of material to be used (Tables 1 and 2). The categories that were used were determined from Dr. Poore's specifications (see appendix). The categories that were chosen for the final design are as follows: feasibility, cost, durability, safety, ergonomics, surface area, and flexibility. Each category was weighted (0-1) and multiplied by its score out of 4.

Safety was weighted the highest; the design's impact on the patients' health is of the utmost importance. Care must be taken to be sure that nothing, especially the antimicrobial agent, will inflict any harm upon the patient for its duration in use. The second highest weight was the designs flexibility. This is because it is vital that the design is able to fit through the 5 mm diameter incision. Without being capable of fitting through the incision, the design is essentially unusable. The third highest weighted category was ergonomics, followed closely by durability. 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. 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. Surface area played a small role in the decision matrix, it is important for the release of the microcidal agent; however, much of this mechanism rests in the overall design. Finally, cost was weighted the lowest; this is because the materials for production are relatively cheap. They would not cost significantly more than what is used now (drain tube and BIOPATCH®).

Of the three designs: tube, cuff, and disk, the disk scored the highest, followed closely by the cuff design, and then the tube in last. The disk scored the highest because of its large umbrella-like covering of the incision site. This design is extremely similar to the shape of the BIOPATCH®, except that instead of being its own separate piece, it is attached to the tube directly. The cuff design came in a very

close second; this is mostly due to its possibility of slipping down into the wound site. Unlike the disk, it is simply larger diameter version of the old tube, and will likely need to be secured the same way as the tubes are now. The impregnated tube design scored the lowest due to the feasibility of the design and its lack of safety. With this design, it would be difficult to impregnate the specific portion of the tube with the microcidal agent. If this was accomplished, the next task would be to make sure too much microcidal agent wasn't released too deeply into the wound site; this could cause further complications and is generally avoided if possible.

**Table 1: Design matrix of shapes in design.**

| | Weight | Tube | Cuff | Disc |
|---|---|---|---|---|
| Feasibility | 0.50 | 1 | 3 | 4 |
| Cost | 0.10 | 2 | 2 | 2 |
| Durability | 0.70 | 4 | 3 | 2 |
| Safety | 1.00 | 1 | 3 | 4 |
| Ergonomics | 0.85 | 1 | 2 | 4 |
| Surface Area | 0.40 | 1 | 2 | 4 |
| Flexibility | 0.90 | 4 | 3 | 2 |
| **Total** | | **9.35** | **12** | **14.4** |

The second criterion that was discussed is the material that the final design will be composed of. After extensive research, two recurring types of foam were repeatedly used in a clinical setting. The first type, and more widely used, is reticulated polyurethane foam. The other type is silicone-based foam. The categories to score these were the same used for the form of the design, with the added categories of absorbency, manufacturability, and bonding. Absorbency and bonding were both weighted quite heavily. The ability to absorb the microcidal agent is quintessential to the design, as well as the ability of the foam to adhere to the surface of the tubing. Research and experience proved that materials bond

better when they are of similar structure. Therefore, the silicone foam scored high in its ability to bond to the silicone rubber tubing. However, what also is a large governing factor is the ability for the foam to absorb and release the antibacterial agent. In this category the reticulated polyurethane foam was best. The polyurethane is more porous and is used more widely in the application of microcidal agent, and will be the material of choice for the final design.

**Table 2: Design matrix of materials.**

| | Weight | Silicone | Polyurethane |
|---|---|---|---|
| Feasibility | 0.50 | 2 | 2 |
| Cost | 0.10 | 2 | 3 |
| Durability | 0.70 | 4 | 3 |
| Safety | 1.00 | 4 | 4 |
| Absorbency | 0.85 | 2 | 4 |
| Flexibility | 0.70 | 2 | 3 |
| Manufacturability | 0.50 | 3 | 3 |
| Bonding | 0.90 | 4 | 3 |
| **Total** | | **15.7** | **17.1** |

## Final Design

Due to the high scoring aspects of two designs, the final design will incorporate aspects of both the disk and cuff designs, the AntiBioDuct. A SolidWorks rendering of the design is shown in Figure 8.

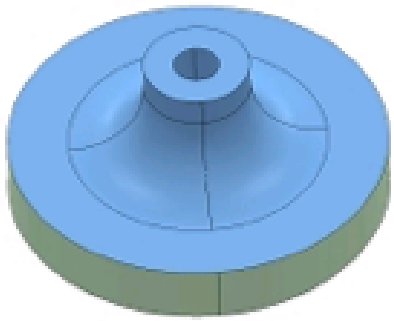

**Figure 8: SolidWorks rendering of final design.**

The final design developed by the team consists of important structural features as well as importance in selection of material. The final device still utilizes the existing silicone rubber surgical drain tube in unison with an active drain bulb to draw the fluids from the wound site. The most important component of the device added by the team is the microcidal cuff. The cuff itself consists of reticulated polyurethane foam treated with the microcidal agent CHG at a 4% solution. This concentration is the perfect amount of CHG in solution so as to still successfully protect against infection as well as avoiding harming the skin. As it shows in the testing, the treated reticulated polyurethane showed the greatest effectiveness in killing and protecting against bacteria on and around the wound site.

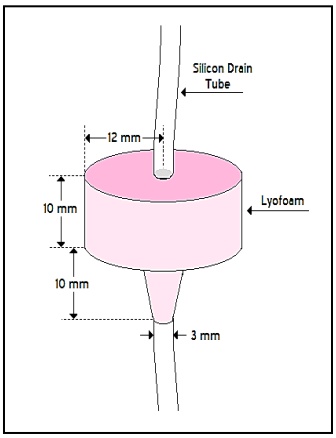


**Figure 9: Final design with dimensions.**

The structure of the cuff is a disk section that has a 12 mm radius and is 10 mm thick, as shown in Figure 9. This part of the cuff will lay over this skin and protect against infection and serve as a suture tab for the surgeon to attach the device to the skin. Underneath the disk portion of the device lies a tapered section that enters the incision up to 1 cm. This part of the device helps to fight infection inside the incision instead of simply fighting it at the surface. The tapered shape also allows for easy application into the incision. The drain tube itself is 3 mm in diameter. Therefore, the opening in the top of the disk section and bottom of the tapered section must be 3 mm. This close fit will aid in making sure that the cuff does not slide along the drain tube. In addition to this, Silicone bonding agent is applied between the polyurethane cuff and Silicone drain tube in order to ensure no sliding of the cuff along the drain is even possible.

## Testing

### Impregnating the Foam Materials with CHG

Six different types of foams were impregnated with the CHG solution: lyofoam (a reticulated polyurethane foam), lyofoam without the bottom layer, polyurethane foam (makeup sponges), silicone foam, and 2 industrial grades of silicone foam. This was done by soaking one side of the foam in 5 ml of CHG for 5 minutes, and then turning the foam over and soaking the other side for 5 minutes. Next, the foams were allowed to air dry for 5 days. The polyurethane foams became saturated with the solution because the foam was very absorbent. After drying, the samples were sticky, and the foam pores stuck together but were still useable. The silicone foams appeared to present the best characteristics after absorbing the CHG solution because they were not sticky and they maintained shape well.

### Bacterial Testing

In order to determine what the best material for the design is, a series of tests were conducted to determine the duration of antimicrobial properties of the foam. First, agar was placed in Petri dishes.

A powdered form of nutrient agar was used for the tests. To prepare the powdered agar, 2 Tablespoons of powder were mixed with 1 cup of cold water. The mixture was heated in a microwave in 30-second increments until the solution started to boil, or foam appeared on the top of the solution.

Next, the cultured bacteria were spread over the entire Petri dish and a foam sample was placed in the center of the dish. The bacteria came from Lake Mendota and from skin. Two controls were also used: a Petri dish with only cultured bacteria and no foam sample, as well as a Petri dish with a drop of CHG not associated with a foam sample. The area of inhibition was observed over the next 7 days to determine which foam sample best prevented against the growth of the bacteria.

## Results

The area of inhibition of the material is shown over a span of 7 days in graphical form in Figures 10 and 11. From the data collected, the lyofoam works the best after 7 days. Photographs from the data collection are in the Appendix.

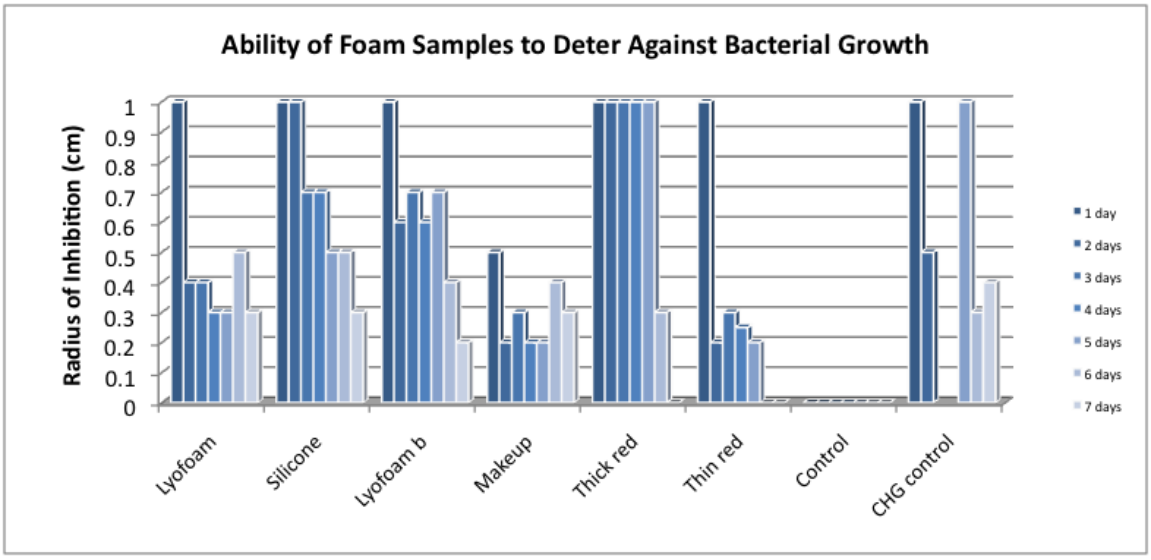


**Figure 10: Radius of inhibition comparison between materials.**

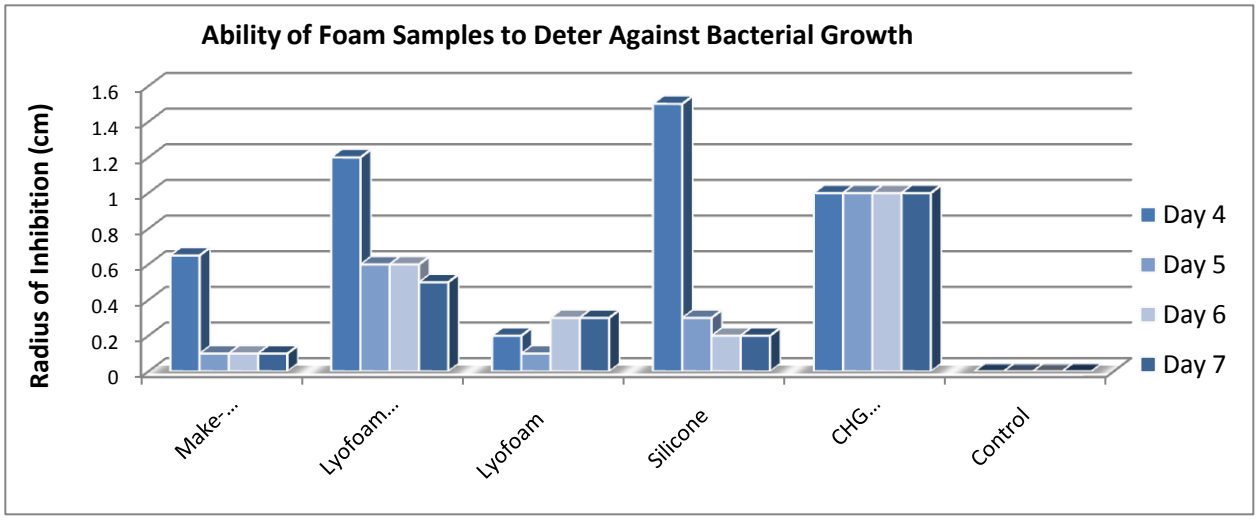


**Figure 11: Comparison of radii of inhibition between materials. The data starts at Day 4 as that was first day of visible bacteria growth.**

## Cost Analysis

### Unit Cost

One of the most important components to this design is its cost effectiveness. The AntiBioDuct will theoretically be used with any patient requiring a drain tube. In most cases, a hospital will weigh the cost of a product heavily in their decision to use it or not. It should be equal to or close to the price of the current product, which in most cases is the simple drain tube apparatus, and in some other cases is both the drain tube and the BIOPATCH®. The Jackson-Pratt Round Drain sells online for around $150.00 for 10, equating to about $15.00/drain. This price won't deviate much between hospitals because the AntiBioDuct incorporates the Jackson-Pratt drain. However, for the hospitals that utilize the BIOPATCH®, they are paying an additional $11.30 per drain assembly used, and that doesn't count the replacement patches used when one fails. This comes to a total of approximately $26.30 per drain tube used with the BIOPATCH®. Tooling manufacturing was quoted at about $1445.00. After the tooling costs, individual devices were quoted at about $2.11 per piece to manufacture. The materials for the design include polyurethane foam and CHG solution. As a raw material, polyurethane foam can be purchased for roughly $10.75 per $ft^3$. The dimensions for the design would call for approximately 8 $cm^3$ blocks for each device, which would place each individual piece at 0.3 cents. As for the CHG solution, it

can be purchased for around $7.65 for an 8 oz. bottle. Assuming one of the devices requires 1.5 oz. of CHG, each piece will use approximately $1.43 worth of the solution. Totaling the costs of the raw materials, manufacture, and Jackson-Pratt drain, one gets about $19.98/device, assuming production of 1,000 units. Clearly this estimation is based on minimalist estimations on the cost of production, however it is still significantly cheaper than the current method with the BIOPATCH®, and only slightly higher than the method without the BIOPATCH®. With all things considered, it is very likely that the actual price of production of the AntiBioDuct will be less than or equal to the price of the Jackson-Pratt drain and the BIOPATCH®. The AntiBioDuct will provide hospitals with an effective solution to infection while remaining within a reasonable price range.

### Expenditures

Table 3 shows expenditures on project thus far. Most purchases were for experimental purposes.

**Table 3: Purchases for project.**

| Item | Price |
|---|---|
| FDA-Compliant Silicone Foam, 3/8" Thick, 6" X 6" | $12.49 |
| Super-Resilient Extreme-Temperature Silicone Foam, 1/8" Thick, 2" Width | $18.42 |
| Shipping for silicone samples | $4.22 |
| Agar and Petri dishes | $61.89 |
| Lyofoam Sample | $23.43 |
| Chlorhexidine Gluconate | $13.35 |
| Makeup Sponges | $24.75 |
| Silicone Samples, Donation from Medical Art Prosthetics Clinic | $0.00 |
| 3D Prototype | $18.30 |
| **Total** | **$176.85** |

## Future Work

Finally, A final design prototype will need to be developed. That design would likely be required to undergo more testing procedures to determine safe use for humans. If all these steps were taken the design could be marketed to hospitals as a product to incorporate into their surgical operations.

### Additions or changes to prototype

The next step in the design would be to make a final prototype in the desired shape and material. Testing on the final design would then need to be completed. However, finding a cost-effective way to manufacture the product is a big concern. Injection molding seems like a viable option, but more research needs to be completed. A methodology of manufacturing would also need to be put into place to market the product. This includes finding an efficient way to create the microcidal foam and then attach to silicone tube.

For additional patient comfort, a layer of a nonabsorbent material would be placed on the topside of the product. This would prevent the CHG from becoming sticky and releasing unnecessarily on the patient's skin. This would hopefully make the effectiveness of the AntiBioDuct last longer and increase patient comfort.

### Additional testing

Initially, more in vitro testing would need to be completed. A longer duration would be very helpful as the microcidal agent's release could be accurately measured until it no longer works. An in vitro test comparing the effectiveness of the AntiBioDuct to the BIOPATCH® would also be needed in continuation of the project. After in vitro testing, in vivo testing would begin on animals. If the results look promising, further in vivo testing could begin on humans in clinical trials.

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# Appendix

## Surgical Drain Tube (PDS)

**3/7/11**

Laura Platner, Taylor Powers, Danny Tighe, Kelsey Hoegh, Tanner Marshall

**Function:** Dr. Samuel Poore would like a surgical drain tube that consists of a standard round, fluted tube to prevent surgical site infections. He would like the tube to have a microcidal chemical, such as Chlorhexidine Gluconate, incorporated into the design.

**Client requirements:**

- Must be flexible enough to fit through 5 mm incision
- Must be able to be left in the body and fight infection for 2 weeks
- Microcidal agent should be part of tube
- Reduce amount of dressing on wound
- Material must be biocompatible
- Have ability to be mass produced

**Design requirements:**

1. **Physical and Operational Characteristics**
    a. *Performance requirements:*
        i. Must be flexible enough to fit through 5 mm diameter incision
        ii. Must fight infection
        iii. Microcidal agent must be part of tube
        iv. Must fit tightly around the wound
        v. Must be disposable
    b. *Safety:*
        i. Materials cannot harm patient
        ii. Microcidal agent must not enter deeper anatomy
        iii. Must be sterile
    c. *Accuracy and Reliability*
        i. Deliver microcidal agent to only the skin
        ii. Microcidal agent should fight infection
    d. *Life in Service:*
        i. Microcidal agent should fight infection for 2 weeks
    e. *Shelf Life:*
        i. 2 years
        ii. Easily storable
    f. *Operating Environment:*
        i. Inside the body, between the skin and pectoralis major
        ii. Room Temperature and Body Temperature- 15-40° C
    g. *Ergonomics:*
        i. Comfortable for the patient to wear for 2 weeks
        ii. Easy to use for surgeons

iii. Decrease infection rates

h. *Size*
   i. Tubing
      1. 3 mm diameter
      2. 1 m total length
      3. 0.3 m of fluted tube
   ii. Disc
      1. 2.5 cm diameter

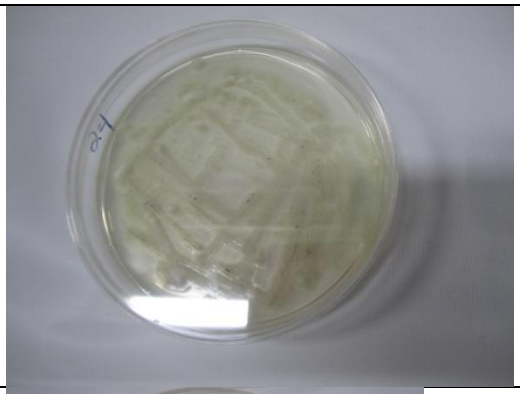
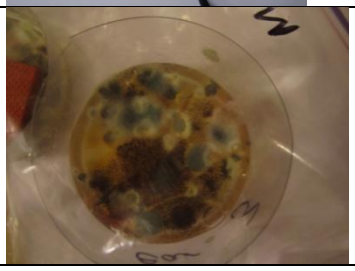
i. *Materials:*
   i. Silicone
   ii. Polyurethane
   iii. Chlorhexidine Gluconate

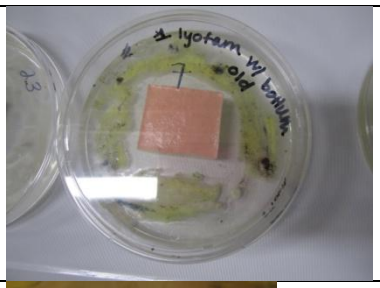
j. *Aesthetics, appearance, and finish:*
   i. Function over aesthetics

2. **Production Characteristics**
   a. *Quantity:*
      i. One prototype
      ii. Possibly mass produce
   b. *Target Product Cost:*
      i. $20 each

3. **Miscellaneous**
   a. *Standards and Specifications:*
      i. Follow hospital regulations, FDA regulations
      ii. Must be safe and comfortable for patients
      iii. Must decrease infection rates
   b. *Customer:*
      i. Easy to use for surgeons
   *c. Patient-related concerns:*
      i. Cannot get microcidal agent too deep into tissue
      ii. Must be comfortable for long-term use
      iii. Whole tube must be sterile
   d. *Competition:*
      i. Existing drain tube with BioPatch
      ii. Elutia drain tube with microcidal agents

## Photos from data collection

| | |
|---|---|
| Control- mendota |  |
| Silicone- mendota |  |
| Control with CHG- mendota |  |
| Makeup- mendota |  |
| Control mendota |  |

| | |
|---|---|
| Lyofoam mendota |  |
| Lyofoam mendota |  |
| Lyofoam-mendota |  |
| CHG control - toe |  |
| Makeup- toe |  |