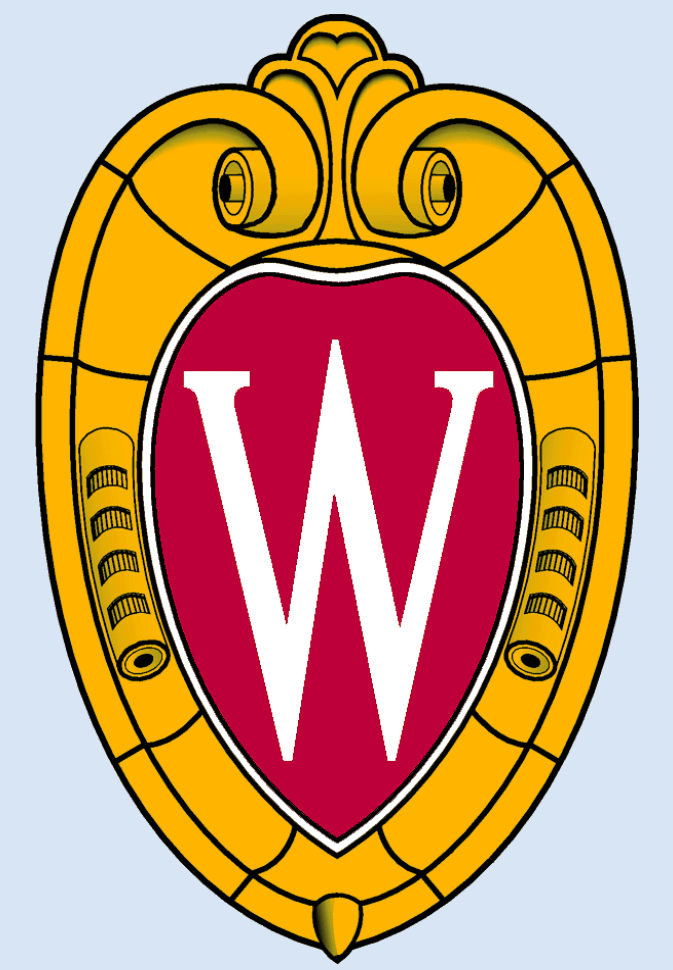


Design of a Cuffed, Microcidal Surgical Drain Tube to Prevent Surgical-Site Infections



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Client: Client: Dr. Samuel Poore– Plastic Surgeon, UW Hospital

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Abstract

Dr. Samuel Poore, a surgeon at the UW hospital, is a specialist in breast reconstruction operations. This operation typically results in an accumulation of fluid within the body cavity. Surgical drain tubes are used to drain this fluid. Unfortunately, the patients are then prone to infection. Infection rates are upwards of 20% with 5% requiring the tube to be taken out and replaced. Dr. Poore asked the design team to develop a drain tube which will be effective for two weeks, will not alter the current drain tube procedure, will not result in harmful interactions with the body, and will reduce the infection rate. Testing was done on a variety of materials to determine what would absorb the microcidal agent the best, and what would release the agent at a rate slow enough to allow for prevention of bacterial growth for 7 days. The team has designed a device called antibiody to accomplish this goal. This device is made out of polyurethane foam and is impregnated with Chlorhexidine Gluconate as a microcidal agent. The team is hoping to test this final design on animals before moving to market it as a final product.

Motivation/Current Designs

Motivation

- 200,000 breast cancer diagnoses each year
- Mastectomy is a common treatment
- After mastectomy, patients wear a surgical drain tube that:
 - Drains fluid from the wound
 - Stays in place for 14 days following the procedure
- 20% of Dr. Poore's patients develop an infection
- 5% require drain removal and another surgery
 - Extra operations require longer recovery, more complications, and more medical bills

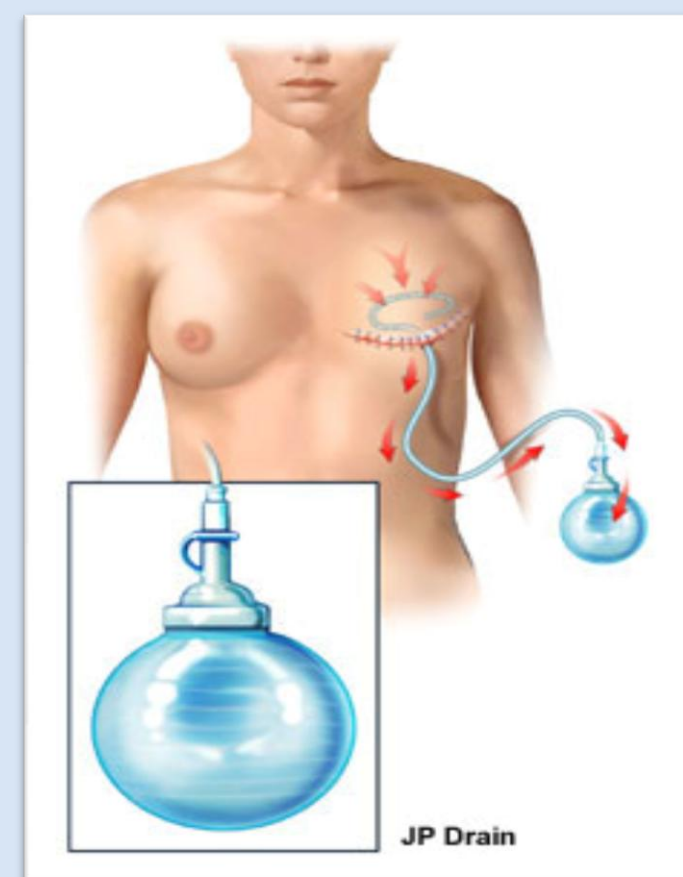


Figure 1: Diagram of a surgical drain tube. http://www.cancersutterhealth.org/information/bc_notebook/postoperative_care.html

Current Designs

- Biopatch
 - Releases CHG up to 7 days
- Elutia (2007)
 - Surgical drain tube with a hydrogel
 - Silver Silfadiaine
 - FDA approved
 - Effective for 7 Days
 - No clinical data to show in vitro effectiveness

[1] <http://www.ethicon360.com/products/biopatch-protective-disk-chg>

Design Criteria

Problem Statement

- Design cover surrounding the point of entry of a common surgical drain
- Incorporate microcidal agent to prevent infection



Figure 2: The "fluted" end that is inserted into the wound site, the openings help to siphon any fluid out of the site

Design Specifications

- Effectively operate in vivo for up to 2 weeks
- Interface with or incorporate a standard fluted drain tube
- Microcidal agent impregnated into device
- Reduce wound dressing needed to hold drain tube
- Must be biocompatible
- Manufacturable for mass production
- Release microcidal agent at wound site

Final Design

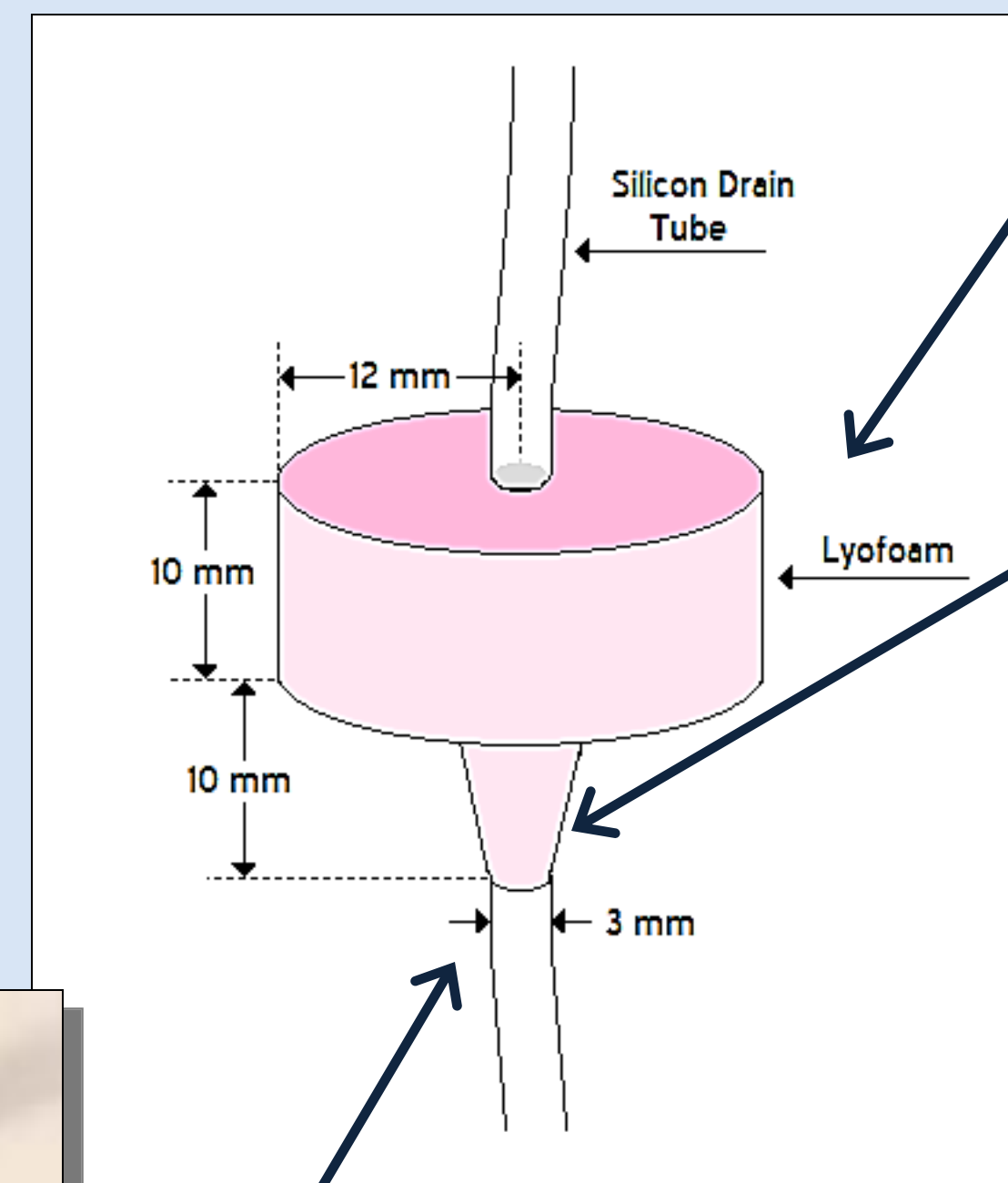
Antibiody

Material: Lyofoam

- Soft texture helps prevent rubbing and consequent skin irritation

Microcidal Agent: Chlorhexidine Gluconate

- 4% solution effectively prevents infection, but does not harm skin

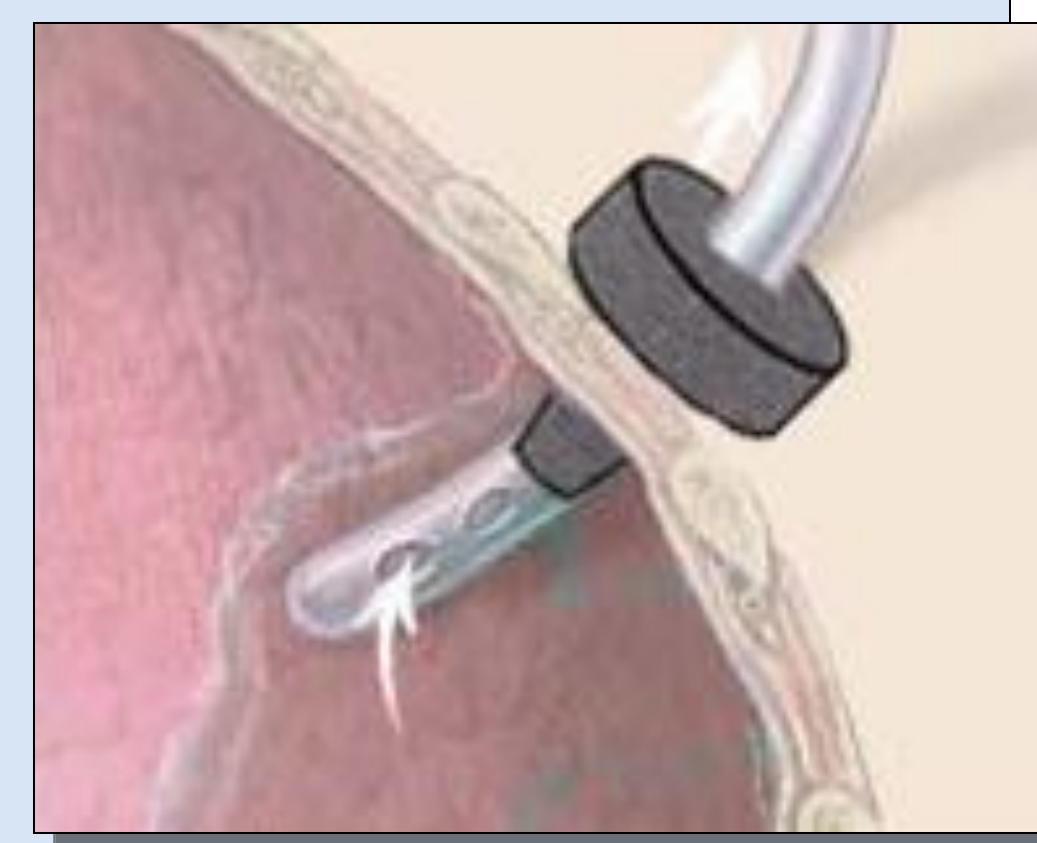


Disk Section

- Lays flat over skin surrounding incision site
- Serves as a suture tab for easy securement

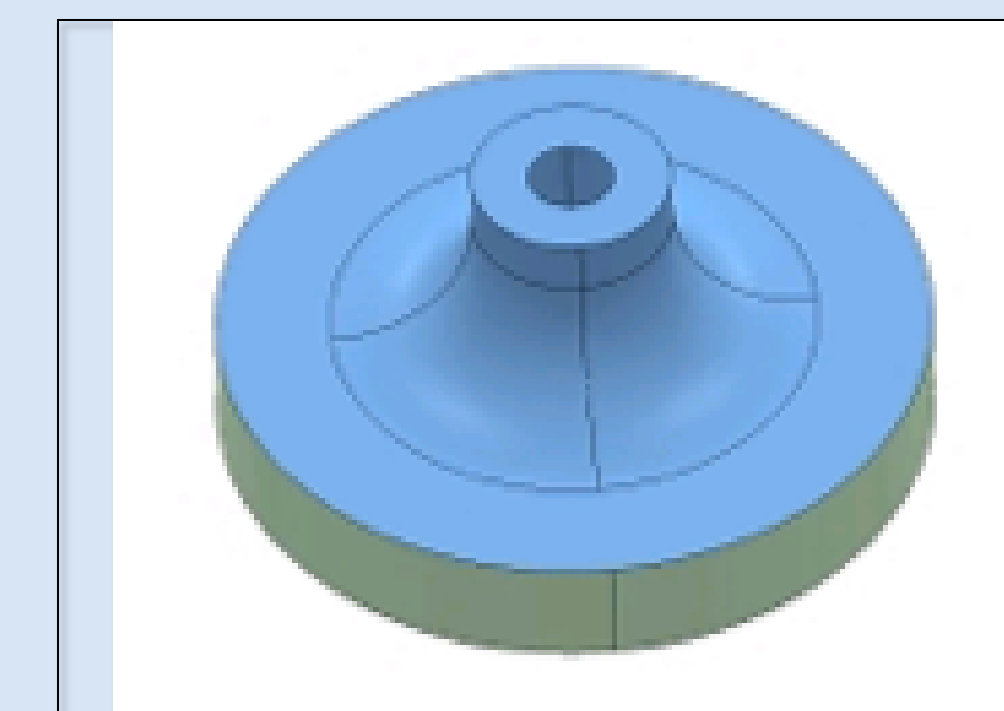
Tapered Section

- Inserts 1 cm into incision
- Applies microcidal agent in the section of the wound closest to the outside environment
- Tapered shape allows for easy application



3 mm Diameter Opening

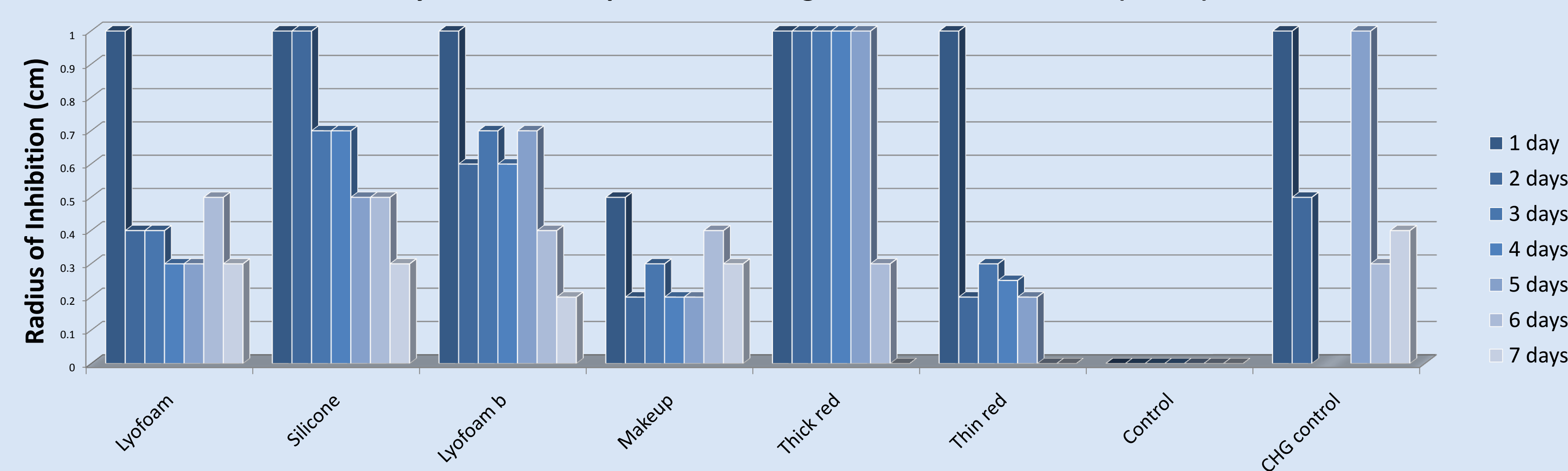
- Fits over general 3 mm diameter drain tube
- Grips drain tube to prevent movement of the foam along the drain tube



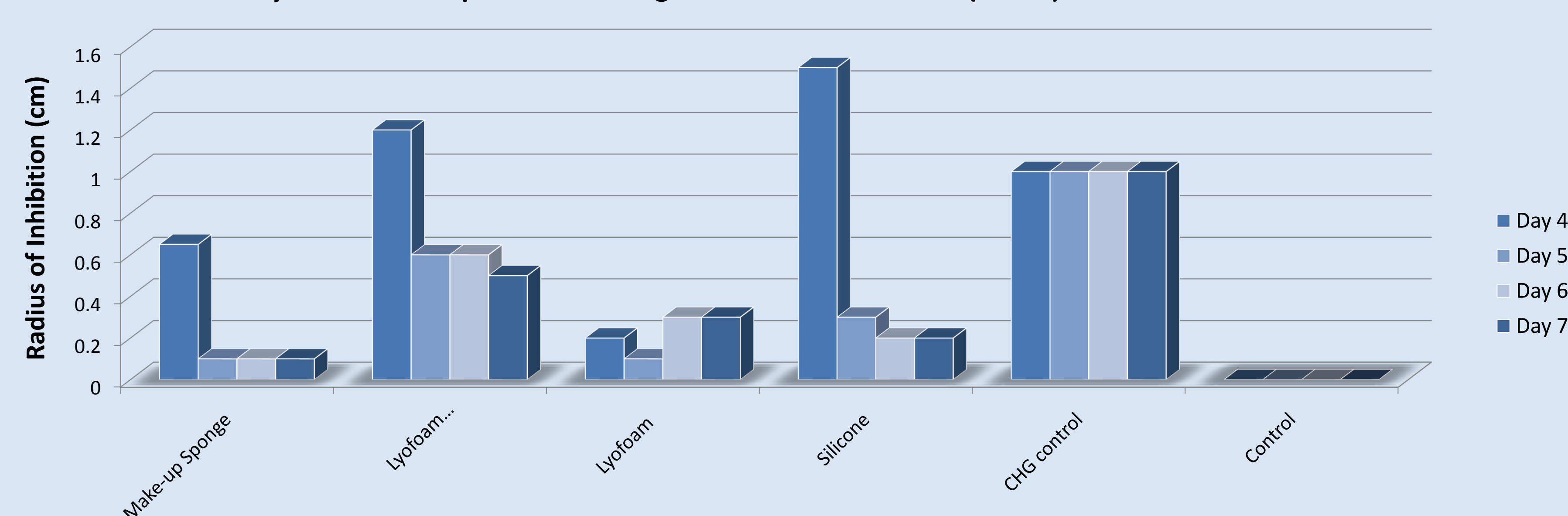
- A SolidWorks representation of the microcidal portion of the finished product

Testing

Ability of Foam Samples to Deter Against Bacterial Growth (Test 1)



Ability of Foam Samples to Deter Against Bacterial Growth (Test 2)



Cost Analysis

- Quotes indicate a relatively inexpensive manufacture cost:
 - An initial tooling cost estimated at \$1445.00
 - After tooling cost, each piece costs approximately \$2.11
- Polyurethane foam cost is relatively low as well, coming to approximately \$10.75/ft³
 - Assuming 8 cm³ blocks of foam for each piece, approximates to 0.3 cents per foam block, potentially very inexpensive
- Comparing to the Biopatch, which sells for \$113 per 10-pack of BioPatch's, or \$11.30/BioPatch, AntiBioDuct would be significantly cheaper

Future Work

Additions or Changes to Prototype

- Changes for Improvement of Overall Design
 - Addition of non-absorbent over layer
 - Soft over layer
- Changes to encourage ease for mass production
 - Incorporate foam manufactured with microcidal agent
 - Molds for half the form
 - Secure 2 halves to silicon drain tube with silicon sealant
 - Microcidal disk and silicon drain tube sold together in final design

Additional Testing

- In Vivo testing on animals
- In Vivo Testing with human clinical trials Multiple simple

References

[1] BioPatch: Protective disk with CHG. *Ethicon 360*. [online] Referenced Feb. 27, 2011. <http://www.ethicon360.com/products/biopatch-protective-disk-chg>.

[2] Conway, L. J., Conway, P. J., Fryar, D. 1992. *Microcidal Agent Releasing Catheter*. US Patent 5,269,770.

[3] "Postoperative Care; Wound Dressing and Drain Care." *Cancer Services at Sutter Health*. Web. 07 Mar. 2011. http://www.cancer.sutterhealth.org/information/bc_notebook/postoperative_care.html.

[4] <http://www.ctsnet.org/peterssurgical>

Acknowledgements

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