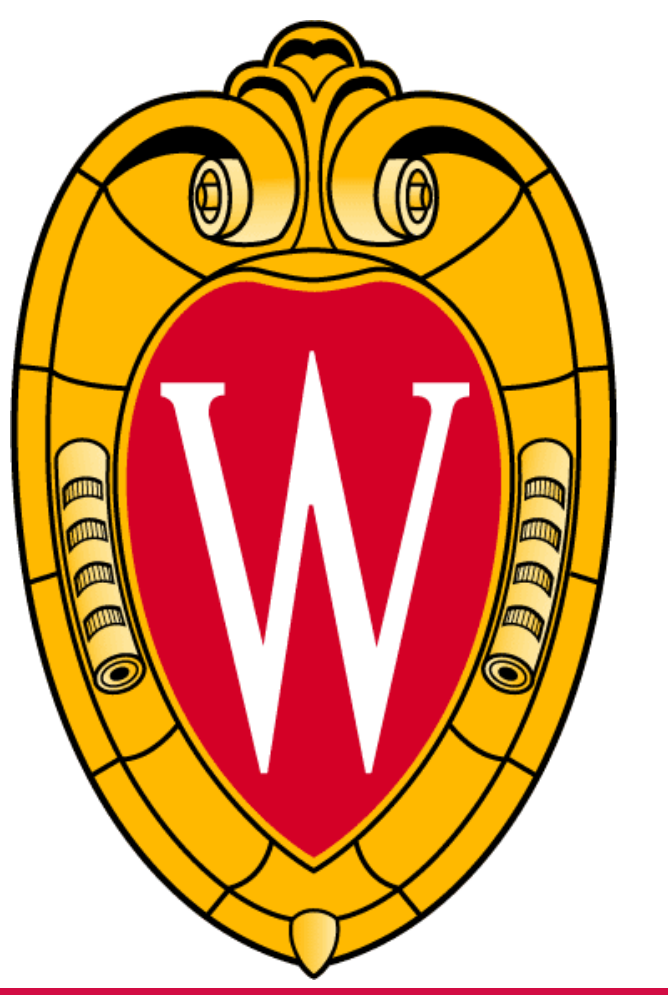




Development of a biocidal surgical drain tube



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Client: Dr. Samuel Poore, Plastic and Reconstructive Surgeon, University of Wisconsin Hospital
 Advisor: Professor Mitch Tyler, Biomedical Engineering Department, University of Wisconsin-Madison

1. Introduction

- 200,000 patients diagnosed with breast cancer/year^[1]
- After mastectomy, patients wear surgical drain tube
 - Surgical drain tubes used to drain fluid from wound
 - Drain tubes worn 14 days following mastectomy
 - Patients clean and record fluid amount drained

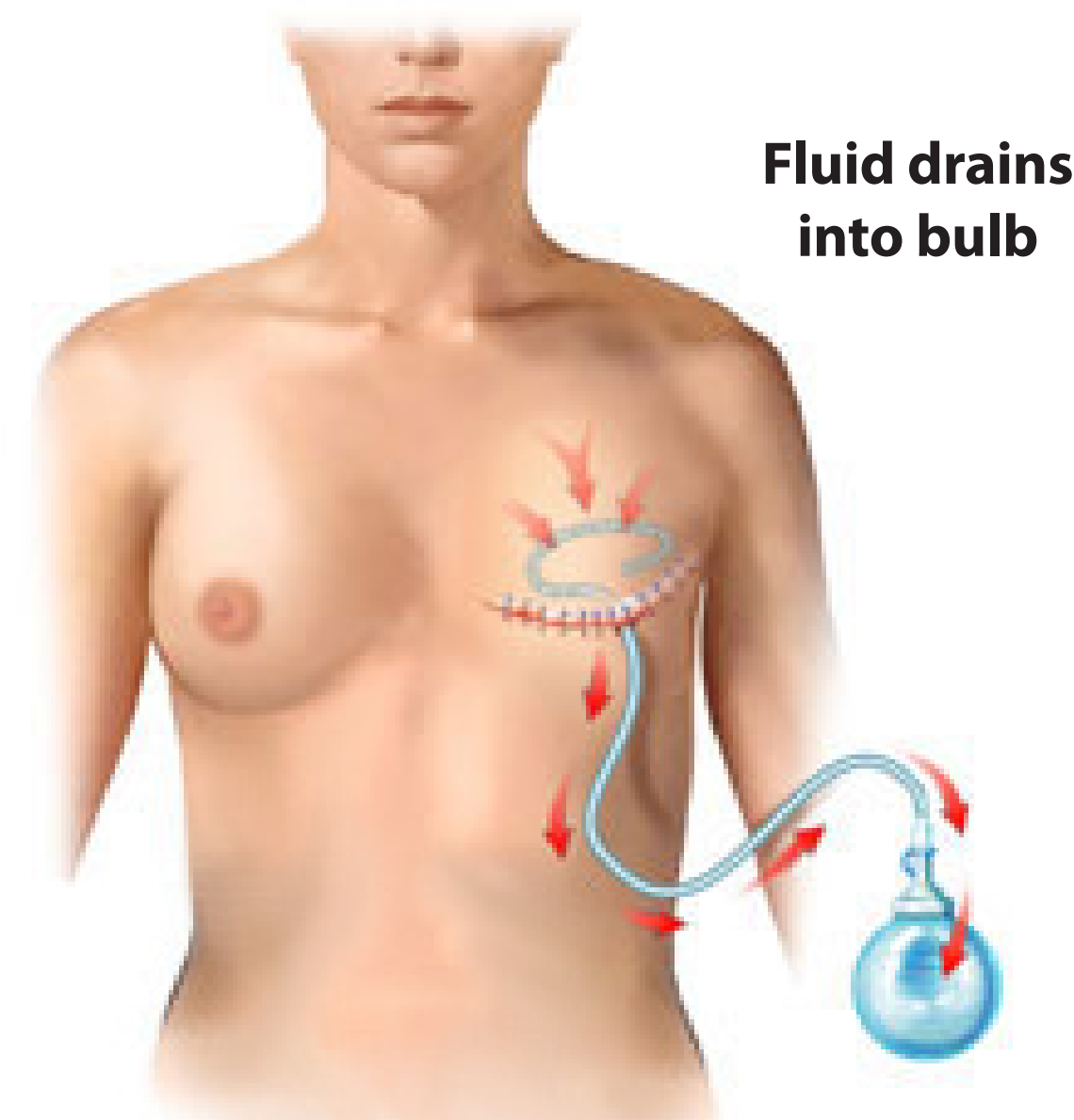
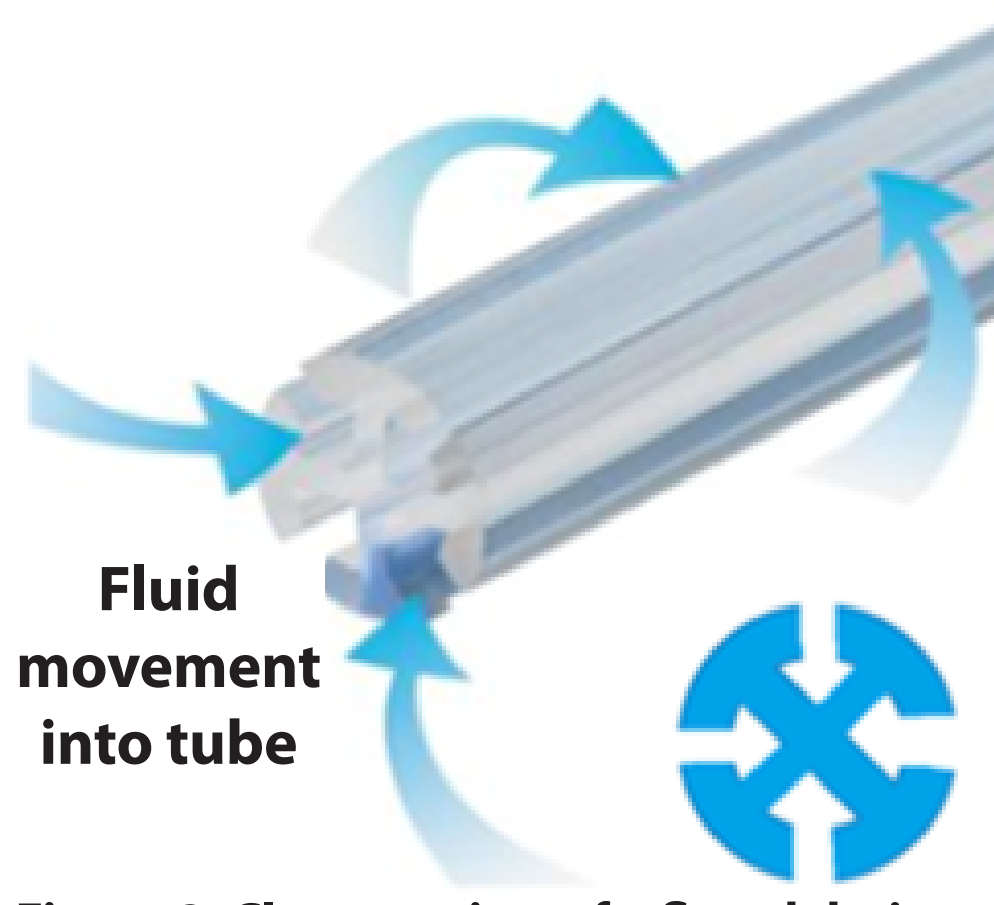


Figure 1. Diagram of a surgical drain tube. http://www.cancer.sutterhealth.org/information/bc_notebook/postoperative_care.html



- 20% develop infection
- 5% need second operation
- Extra operations leads to:
 - Longer recovery
 - More complications
 - More medical bills

Figure 2. Close up view of a fluted drain tube with exploded cross-section. <http://www.ctsnet.org/petersurgical>

2. Design Criteria

- Operate *in vivo* for 2 weeks
- Small and flexible
- Integrated for drain tubes
- Reduce wound dressing
- Biocompatible
- Easily manufactured

3. Competition

Biopatch®

- Releases CHG up to 7 days^[2]
- Successfully fights infection
- Tailored for catheters, *not* drain tubes
- Replace Biopatch® = Additional work & trauma

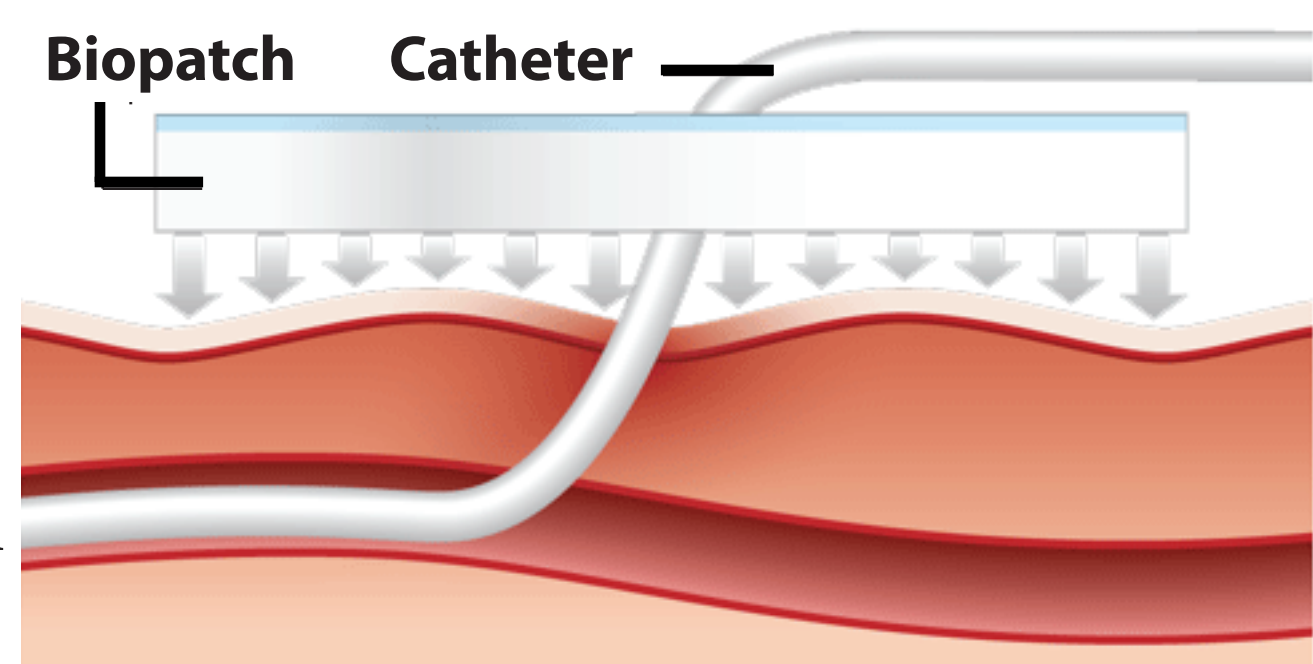


Figure 4. Diagram of a Biopatch® used on skin with a catheter. <http://www.ethicon360.com/products/biopatch-protective-disk-chg>

Acknowledgments

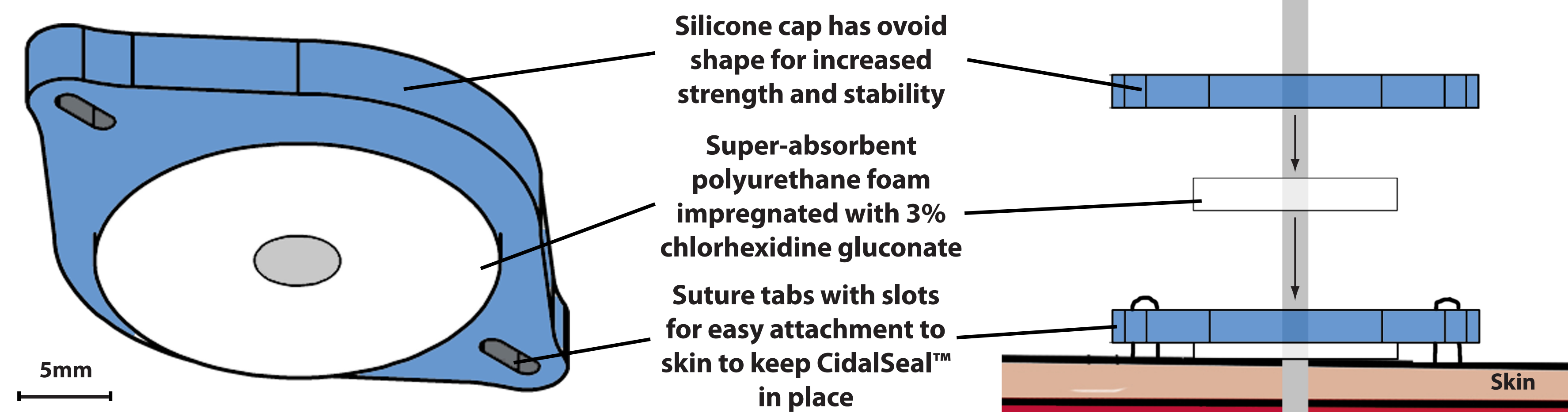
Dr. Andrew Navarrete, Plastic & Reconstructive Surgery, University of Wisconsin Hospital

Dr. John Puccinelli, Biomedical Engineering, University of Wisconsin-Madison

Greg Gion, Medical Art Prosthetics

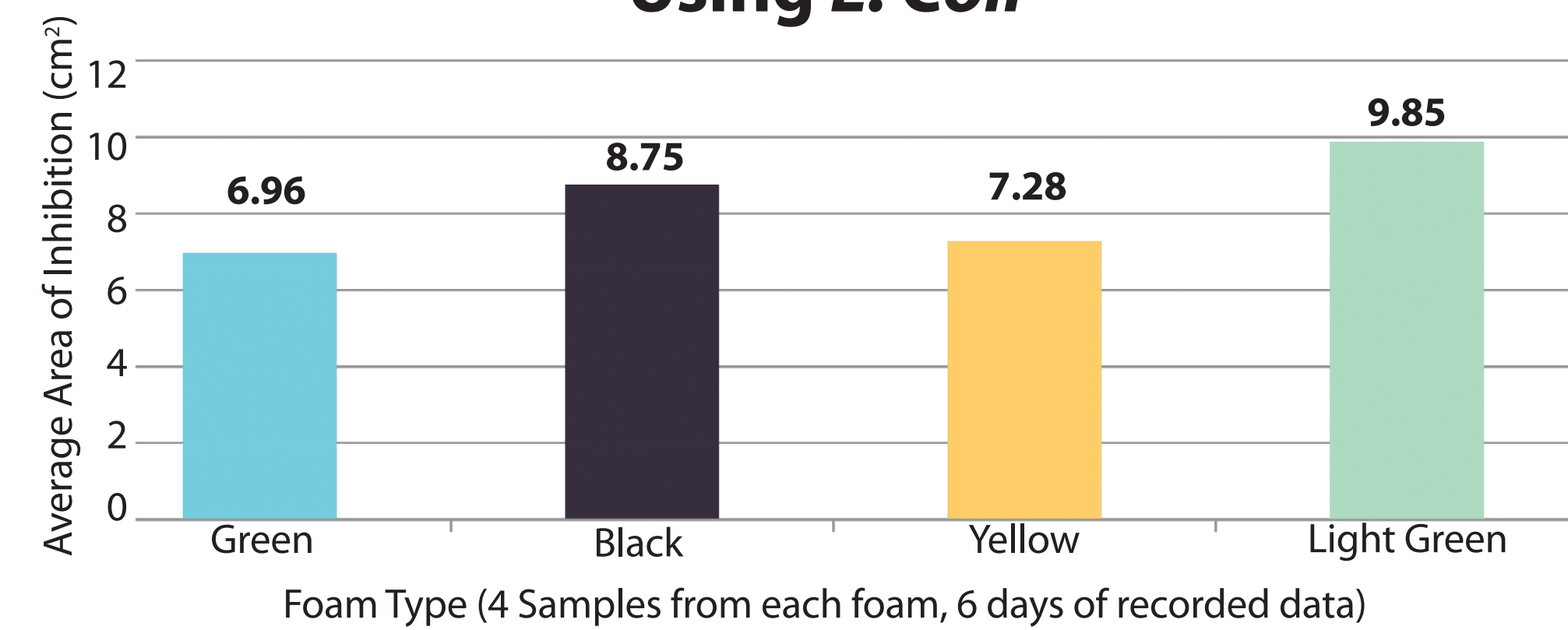
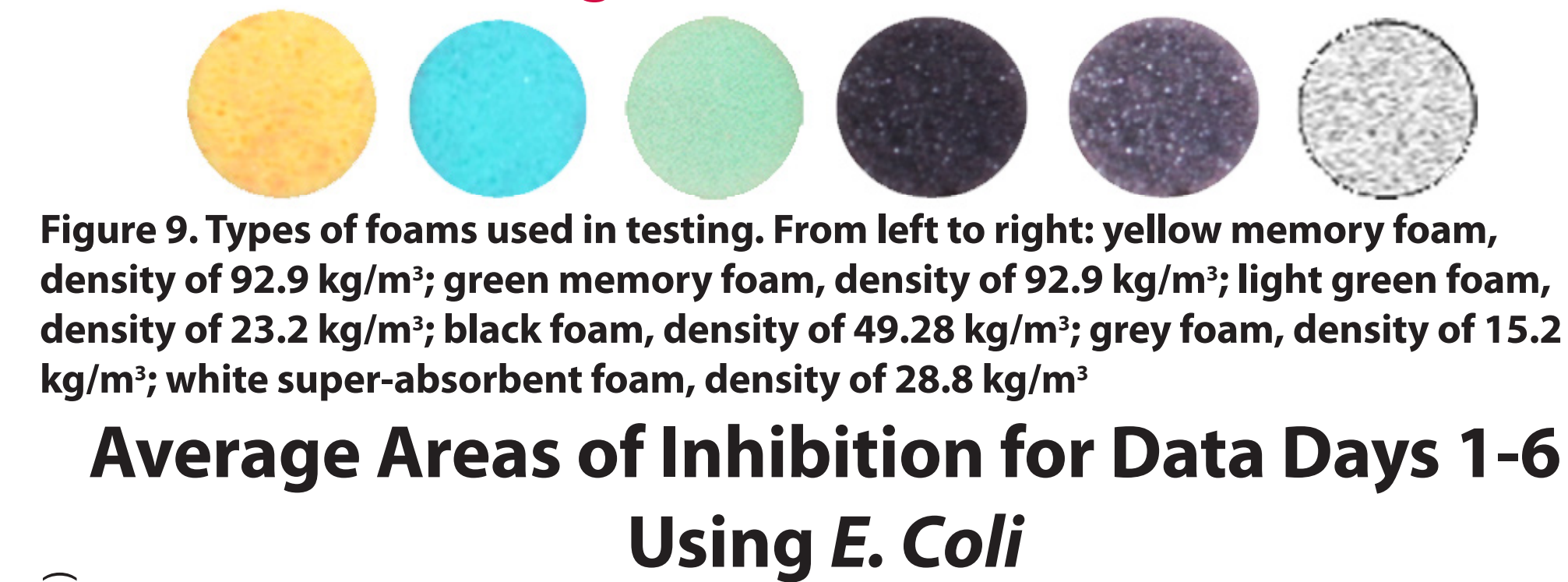
4. Final Design

CidalSeal™



6. Results and Conclusions

Antimicrobial Testing



Number of Days Foam Samples Maintained Area of Inhibition Using *Staphylococcus aureus*

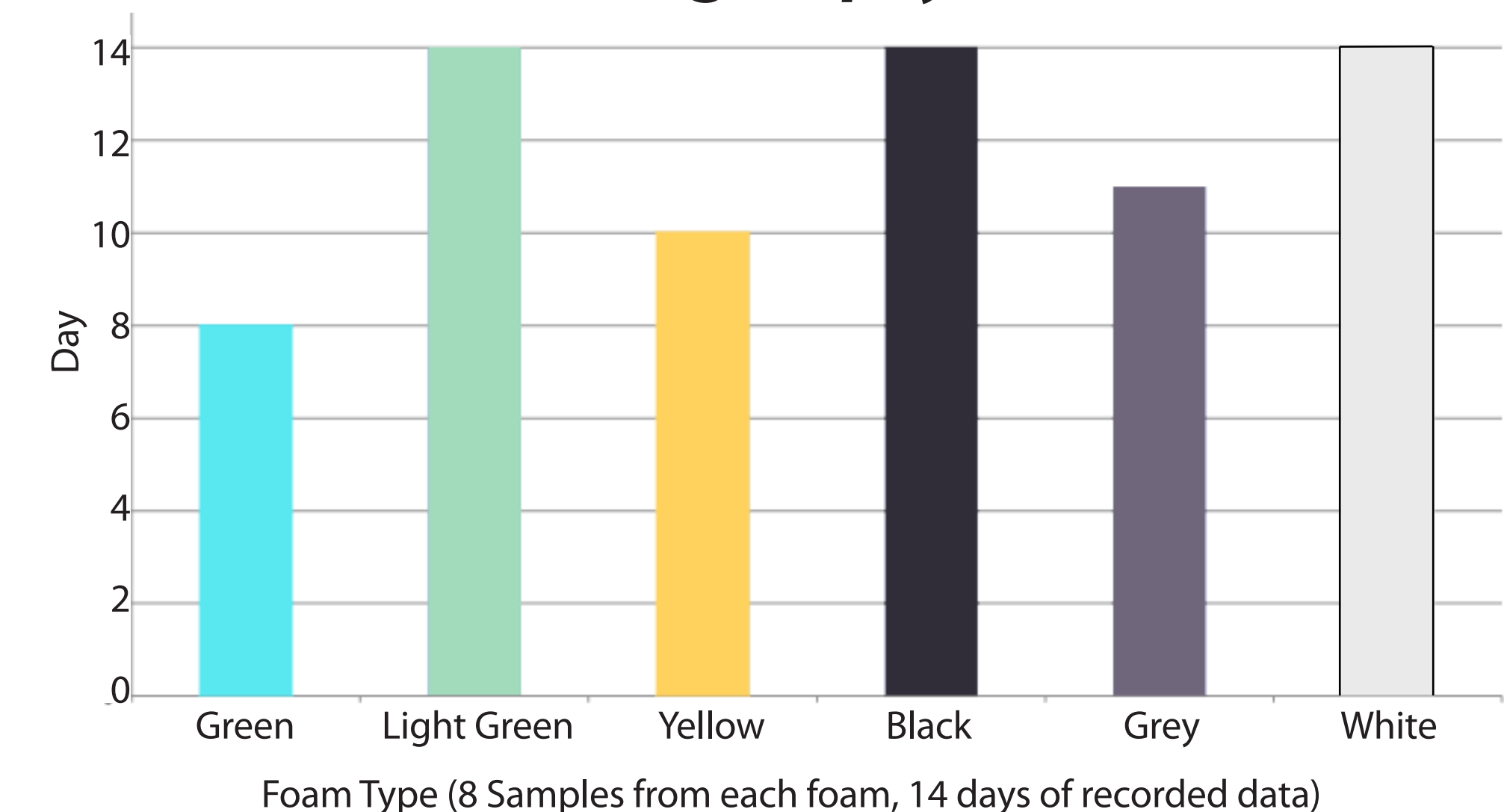


Figure 6. The number of days the impregnated foams maintained a visible area of inhibition for 14 days over testing period. This test was performed at UW Hospital.

Mechanical Testing

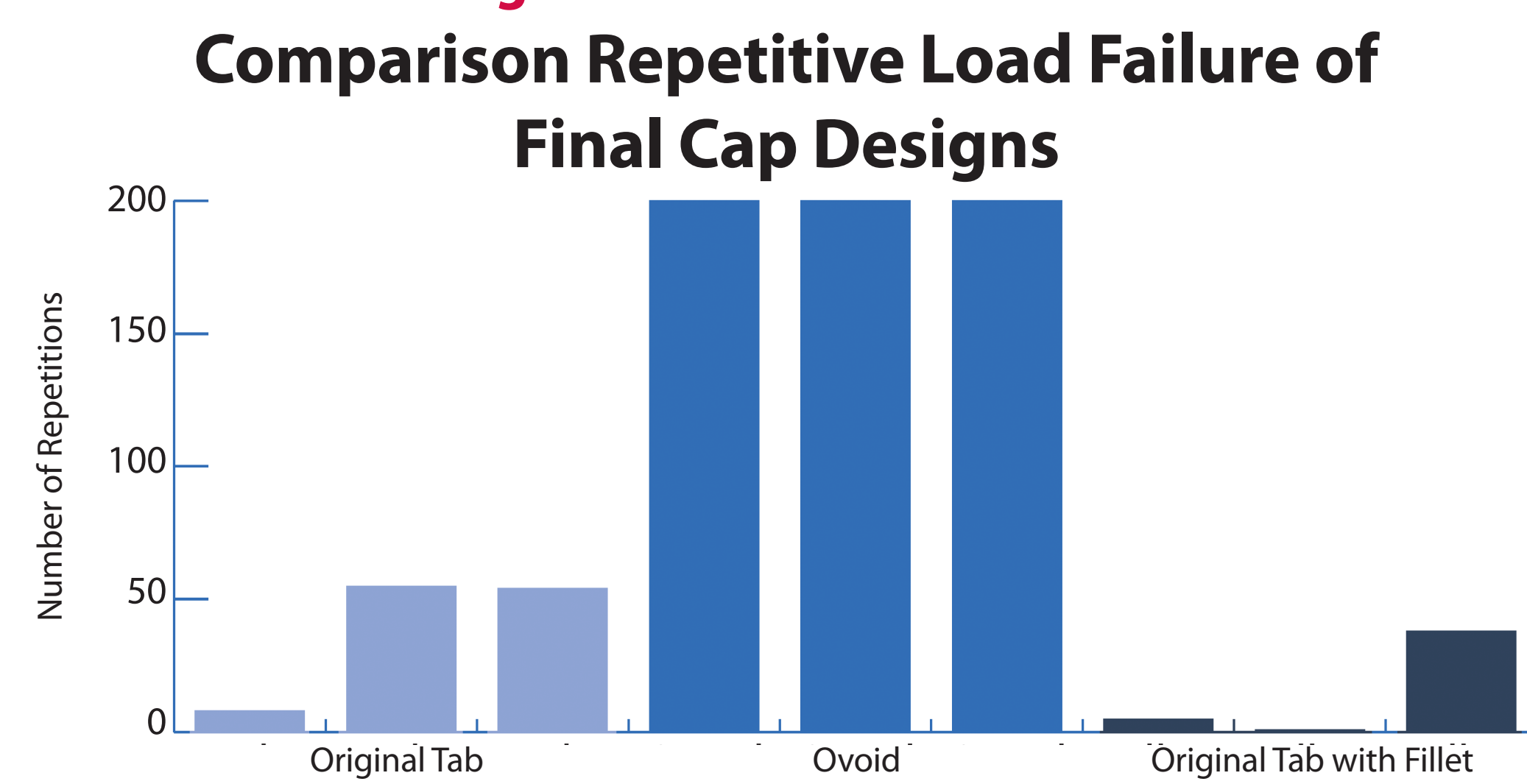


Figure 7. Comparison of possible designs for silicone cap. A force of 20 N was applied for 1 second repetitively until failure. The ovoid design, the current final design, did not fail after 200 repetitions.

Conclusions

Antimicrobial Tests

- Light green foam maintained a statistically significantly larger area of inhibition over the course of 6 days.

Day	1	2	3	4	5	6
Greatest Avg Area of Inhibition	Light Green	Light Green	Light Green	Light Green	Light Green	Light Green
2nd Greatest Avg Area of Inhibition	Black	Black	Black	Black	Black	Black
T-Test Statistic	0.1770	<u>0.0192</u>	0.1021	0.0705	0.1219	<u>0.0052</u>

Table 1. T-test statistic of areas of inhibition of foams. Numbers underlined show statistical significance.

- The white foam absorbed CHG significantly more than other foams, except the light green foam
- The white foam maintained a statistically significantly larger area of inhibition than other foams

Mechanical Tests

- Ovoid design proved to be the most structurally stable design compared to the other designs

5. Testing Protocol

Antimicrobial Testing

Testing on 6 different materials

- Control of each foam
- Control with no foam

Bacteria strain:

- E. Coli* (non-pathogenic)
- Staphylococcus aureus*

Measured the zone of inhibition over 14 day period

- Area of inhibition=area without live bacteria colonies

Performed additional trials at University of Wisconsin Hospital

Mechanical Testing

3 different cap designs needed to be compared based on structural strength

Samples tested to be able to withstand repetitive loading of 20 N

- Maximum force measured by the spring gauge
- Sample fixed along the center and force applied at suture tab using 3.0 (metric) Polypropylene Suture
- Over a period of 1 second force, was steadily applied to the suture tab up to 20 N
 - Repeated until failure of the silicone suture tab
- Number of successful repetitions and the site of failure was recorded

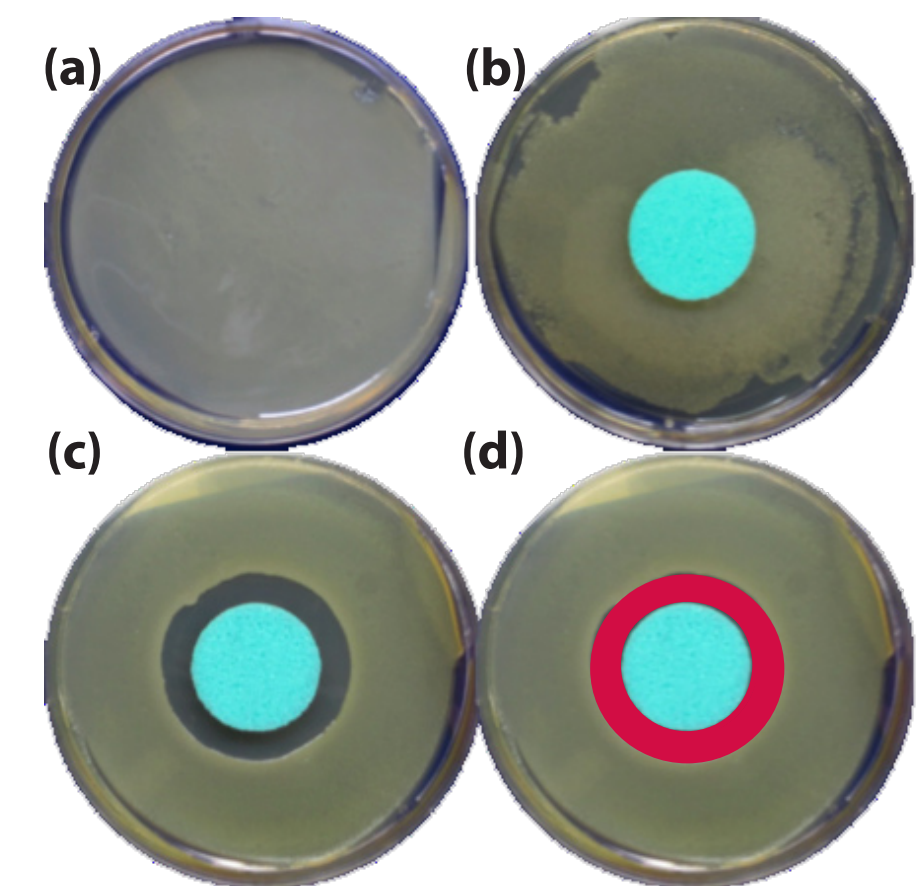


Figure 8. Petri dishes of experiment. (a) is control with no foam and only *E. coli*. (b) is control with untreated *E. coli*. (c) is foam impregnated with CHG. (d) is showing area of inhibition in red is observed and measured in Photoshop®.

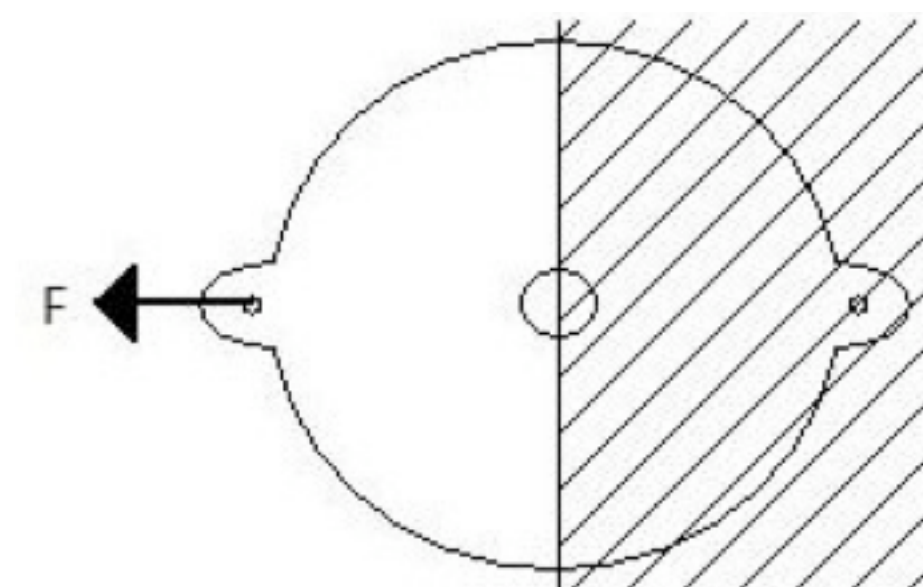


Figure 10. Diagram showing how the silicone cap was fixed, as well as the site of force application during testing.

7. Cost Analysis

Product	Price Per Unit
Biopatch®	\$11.30
CidalSeal™	\$1.92

8. Future Work

- Establish method of attachment of CidalSeal to drain tube
- Add silver ions to silicone cap to better prevent different types of infection
- Begin animal testing at University of Wisconsin Hospital
- Apply for patent with WARF
- Begin clinical trials on humans

References

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