Post-Mastectomy Breast Reconstruction Radio-Implant

Matthew Eganhouse, Patrick Deck, Ryan McLaughlin, Briana Krueger

Field Mentor: (Yusung Kim, Radiation Oncology), BME Mentor: (Dr. Tae-Hong Lim)

Background & Motivation

- In 2015 alone, the American Cancer Society has projected 231,840 women will develop invasive breast cancer, and in the past decade, 35.5% of tumor-removal patients underwent a mastectomy.
- Brachytherapy is shown to have higher success rates than using other standard treatments, such as external beam radiation therapy (EBRT), seen to the upper right.
- Delivery of EBRT is limited by organs (heart, lungs) surrounding tumor. Higher dosages used for brachytherapy (120-145 Gy, compared to 75-81 Gy for EBRT) can be limited to the tumor and surrounding tissue.
- Risk of recurrence post-mastectomy is dependent on lymph node exposure to cancerous cells. Radiotherapy significantly decreases risk of recurrence.
- Reconstruction provides psychological benefit to patients. 29% of women receive reconstruction post-mastectomy per a 2013 study.

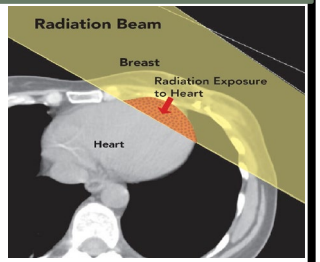


Figure 1. Example of affected areas exposed to EBRT

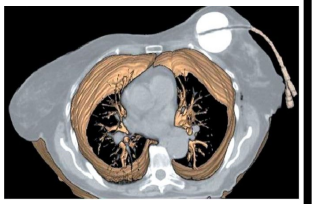


Figure 2. Brachytherapy device used to treat breast cancer

Design Objectives

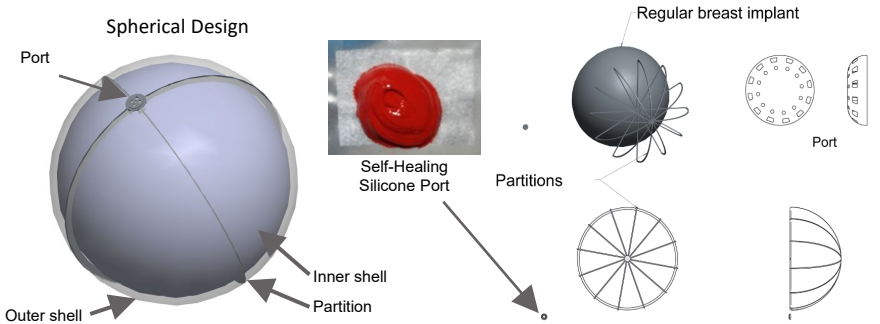
Overall Objective: The device will deliver a high-boost dosage of brachytherapy radiation and provide breast reconstruction after a mastectomy.

Specific Objectives:

- Effectively and uniformly deliver radiation to breast tissue.
- The device will meet ASTM standards for biocompatibility and pressure testing.

Our Approach

- Double-lumen breast implant
- Silicone inner and outer shell (inner lumen can be filled with silicone gel or saline)
- Outer lumen has partitions that divide radioactive hydrogel into multiple compartments
- Different compartments can be used to tailor dosage to a specific side of the implant
- Injection port with multiple injection sites (self-healing silicone or plastic)



Results and Conclusions

- Microsphere and hydrogel displacement test demonstrated the hydrogel's ability to keep microspheres stationary, ensuring a uniform distribution of radiation.
- Valve test demonstrated silicone mold and curing process was successful.
- Utilizing 3D printed molds is an adequate method of forming breast implant shells.

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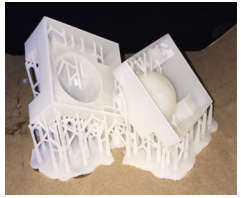
Engineering Skills and Tools Employed in this Project

Tools

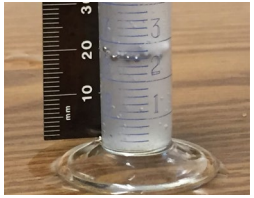
- Creo Parametric 2.0 – used to 3D model design of double-lumen breast implant, injection valves and implant molds
- 3D printer – used Form 1+ 3D printer for creation of breast implant molds and injection valve

Skills

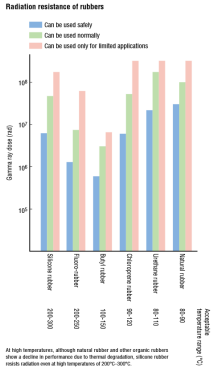
- Biomaterial molding and curing – pour-molding of silicone rubber into a negative shell mold and cure at room temperature
- Mechanical property tests (radiation resistance, pressure)
- Biocompatibility and ASTM Standards research



3D printed Inner shell molds



Hydrogel sedimentation test



Valuable Resources

- Smooth On Silicone material
- Blick Art Supply Store
- Biofluids Laboratory
- BME Senior Design Lab

Testing Our Design

- Microsphere displacement test – place similar density metal spheres in hydrogel and heat to in vivo conditions to simulate whether radioactive microspheres would be stationary in hydrogel
- Hydrogel displacement test – pressure hydrogel layer at in vivo conditions to determine possible non-uniform displacement of hydrogel
- Valve competence test – fill breast implant with saline and subject it to retrograde pressure for 5 minutes in accordance with ASTM international standards

Anticipated FDA Class

Silicone gel-filled breast prosthesis are Class III medical devices, and radionuclide brachytherapy source devices are Class II. Due to our device employing both of these attributes, it is safe to assume that our device will be Class III.

A date premarket approval application (PMA) is required to be filed with the FDA in order to obtain marketing clearance. The PMA must contain sufficient valid scientific evidence to assure that the device is safe and effective for its intended uses. FDA regulators have 180 days to review the PMA and make a decision.

Future Work

- Decrease filling costs by determining smallest functional volume of radioactive microspheres in hydrogel for outer lumen.
- Test silicone mechanical integrity after typical brachytherapy radiation dosage.
- Optimize layout of compartments between silicone shells to achieve a uniform filling distribution.
- Devise optimal means of manufacturing and attaching silicone shells.