Poster 4 Executive Summary: BME Design Excellence Award, BME 402

Improved Method of Securing Surgical Drains

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Mastectomies are commonly performed to reduce the risk of breast cancer. Following these procedures, surgical drains are placed to prevent fluid buildup. Current methods involve securing the drain with a single suture, creating painful tugging or drain displacement. Many products are on the market to replace sutures, but these short-term solutions use adhesives that are only reliable for one week. Therefore, for longer-term drain usage, the development of an improved method for securing surgical drains is necessary to improve the lives of patients.

Prior to final design fabrication, MTS testing was conducted on elastic therapeutic tape, hydrocolloid, and silicone bandages to determine the most isotropic material. A clip design was decided as the securement method for its ease of use and straightforward fabrication. The current device is a hydrocolloid bandage with a 3D-printed clip, adhered by a waterproof adhesive. The clip secures the surgical drain tubing and distributes the pressure and tugging of the surgical drain away from the suture site. Many iterations of this clip were created with diameters ranging from 0.300 cm to 0.400 cm. Flow and force tests were performed on each iteration to determine the ideal clip diameter that secured the surgical drain tubing without decreasing fluid flow.

A successful design must prevent tube displacement within 3.16 +/- 1.0 cm and cannot compress the surgical drain tubing. It must last up to 1 week with limited signs of wear and without a decrease in functionality. To determine what clip could hold the most weight without displacement, a force test was conducted at varying diameters. The flow rate through the tube was characterized by placing one end of the drain in a mixture with a similar viscosity to blood, followed by attachment of the other end to a vacuum. The vacuum created negative pressure in place of the drain bulb, while the tubing was held in place by the clips. A decreased flow rate was attributed to drain tubing impingement, so a 0.325 cm clip diameter was selected. To test the lifespan of the bandage, the device was placed on imitation skin, alongside a Grip-Lok® for comparison to a market device. The imitation skin was sprayed with a saltwater solution to create sweat conditions during physical therapy routines, followed by a water rinse several hours later to mimic showering conditions. This test was run for 14 days, followed by ratings of the bandage on a predetermined scale of 1-5. This device was rated after application of the sweat solution, as well as after water application. Ratings were based on appearance and functionality. Removal strength was tested using an MTS machine to pull the material off the skin sample, to assess pain associated with removal. The hydrocolloid samples were tested alongside various tapes to compare removal strength with increasing removal strength associated with increasing pain.

Extensive simulation testing and prototype iterations have been utilized to assess the device's various criteria prior to human testing. Through force testing, it was shown that this device prevents significant displacement of the surgical drain and therefore decreases tugging on the sutures. Flow testing demonstrated that the clip does not block the surgical drain. Wear testing showed that this device is able to last at least 1 week on the patient, making it applicable for long-term drain use. This device is able to prevent drain displacement, tube blockage, and is effective for long-term use.