Alternative to Silicone Rubber: Realizing Promises

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Statement of Purpose: Breast cancer is by far the most common cancer among American women across all ethnic groups. One in eight American women develops breast cancer, and over 100,000 patients in US require mastectomy. Of these patients, 75% elect some form of breast reconstruction. Since 2006, only silicone rubber breast implants filled with saline or silicone gel are approved by FDA. These breast implants do not last forever, and can be subjected to failure. Unfortunately, 34% of women with implants experience complications including capsular contracture, calcification, hematoma, and necrosis. Our group has been working on developing alternatives to silicone rubber based on polyisobutylene (PIB). The linear triblock poly(styrene-*b*-isobutylene-*b*-styrene) (SIBS), the first representative of PIB-based biomaterials is approved by the FDA for use in the Taxus® Drug Eluting stent.[1] This is a self-assembling nanostructured thermoplastic rubber. The third generation with a branched (dendritic) PIB core (D_IBS) [2] is a promising biomaterial. This paper presents the first results of a double-blind implantation study with this material in rabbits.

Materials and Methods: The D_IBS (TPE1) used in this study was made as reported. [3] It was compression molded into 1-mm sheets. Medical grade silicone rubber sheet (MED-4050, 1.5 mm thick) was received as courtesy of Nusil Co. Before the implant surgery, the microdumbbell specimens cut from the sheets (Fig. 1[4]) were soaked in ethanol and then deionized water, each for 24 hrs, and dried for a week before subjected to ethylene oxide sterilization. These conditioning procedures were performed in a biohazard hood to avoid contamination. Two sets of 2-week implantation were performed on surgical rabbits to asses the short-term *in-vivo* biocompatibility of the materials. Tensile testing of pristine, and harvested and cleaned specimens was performed with an Instron 5567. [5] After explantation, tissue samples were sectioned (two pieces per sample) and submitted for histological examination. A blinded pathologist reviewed the slides and evaluated the tissues. The slides were graded on a 0 to 4 scale with 0 being no and 4 being extensive evidence.

Results: The silicone rubber, which is reinforced with SiO_2, had slightly higher tensile strength than TPE1 before implantation (Fig. 1). After the 2-week implantations, the results in Fig. 1 indicate that the tensile properties of Silicone somewhat decreased, similarly to that reported previously. [6,7] Remarkably, the tensile response of TPE1 showed improvement. This can be attributed to improved phase separation between the PIB and polystyrene domains in D_IBS under the implant conditions (38.3 – 39.4 °C in rabbits). It should also be noted that TPE1 is self-reinforcing upon extension, due to the strain-crystallization of the PIB segment.

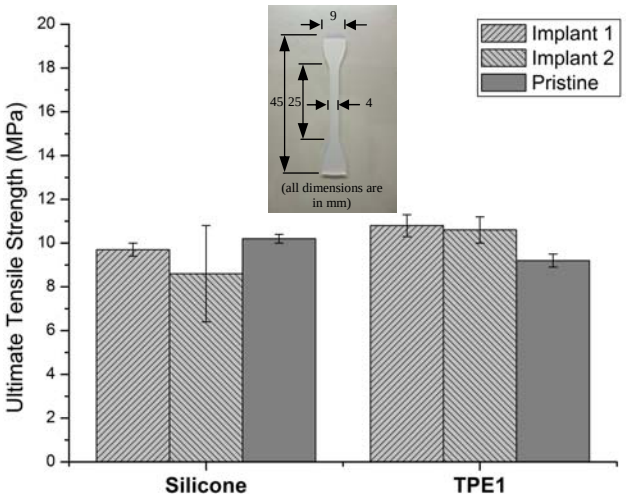

Figure 1. Tensile performance before and after implantation.

The histological examination found no significant differences between TPE1 and Silicone rubber in any of the six categories of acute inflammation, chronic inflammation, granulation tissue formation, foreign body giant cell reaction, fibrous capsule formation, and evidence of infection (including bacterial overgrowth).

Conclusions: Our pathology study after 2-week implantation in rabbits revealed that the new dendritic SIBS (TPE1) and medical grade silicone rubber had similar biocompatibility. Furthermore, TPE1 showed higher strength than Silicone after the implantation. Hence, this new biomaterial has great potentials for its excellent biocompatibility and good mechanical properties to be considered as alternatives for the materials in breast implants.

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