

Introduction & Objectives

Silicone-based implants are commonly used in breast augmentation, yet approximately half of patients who undergo the procedure utilizing silicone-based implants will experience complications, including capsular contracture, for poorly understood reasons. An easier and more accessible method to produce and study silicone implant biointeractions in the lab is needed. Utilizing computer-aided design and 3D-printing technology, resin-based negative implant molds were created to produce silicone-based implants in any size range for animal studies. Silicone implants were then characterized using Rheometry and tested in a rodent model for capsule formation and toxicity.

Materials and Methods

Two-piece negative molds were developed through computer-aided design and 3D-printed using stereolithography of Grey Photoreactive Resin on a Formlabs 3B+ printer (Formlabs). Polydimethylsiloxane (Slygard 184, Dow Corning, Midland, Mich) was mixed at 40:1 silicone base to cure ratio and poured into the molds. After 48 hours, implants were dip-coated in the same silicone mixture, now at a 1:1 base to cure ratio, at two 24-hour intervals, then dry heat sterilized for 48 hours before use in animals. Implants were placed in a female Lewis rat both sub- and pre-pectoral, then harvested en bloc after twelve (12) weeks for histologic analysis to evaluate capsule biology.

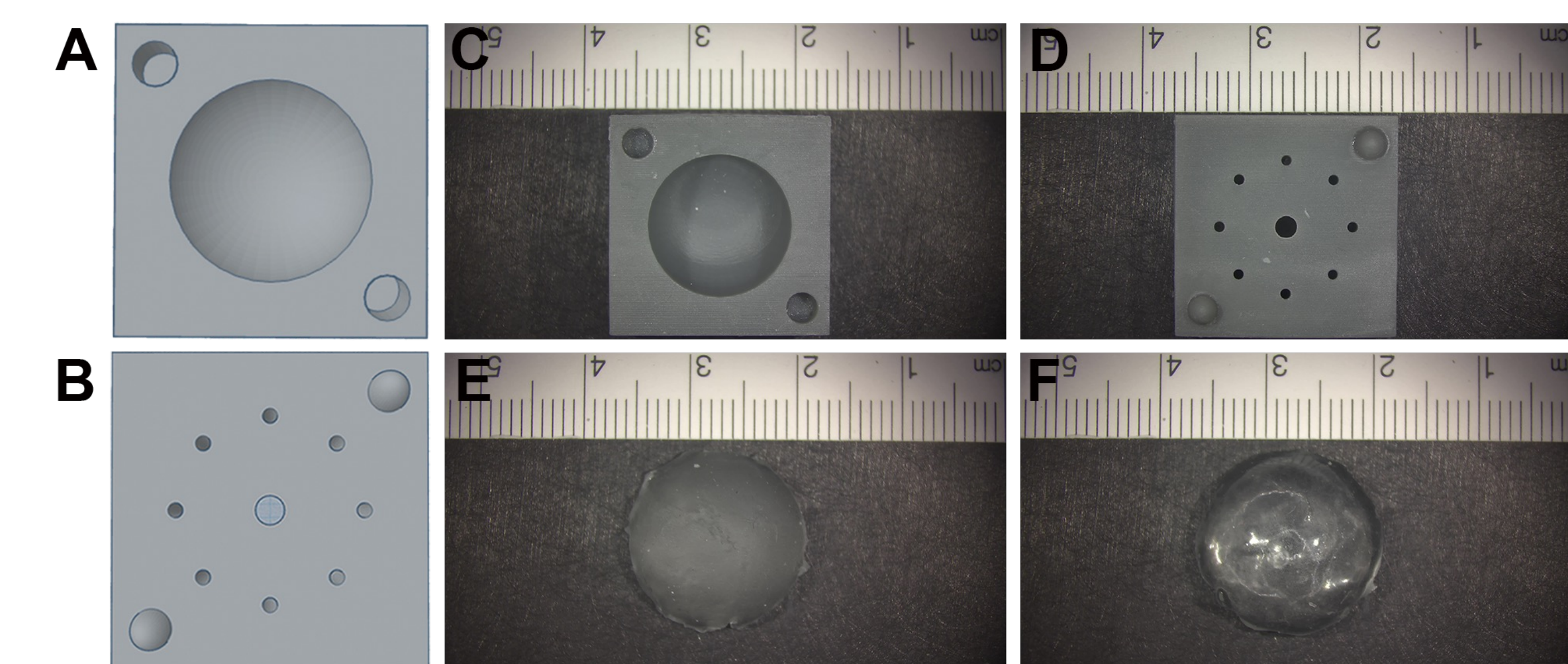


Figure 1 (A-B) CAD of implant molds. (C-D) 3D-printed resin molds. (E) Silicone implant before dip-coating. (F) Silicone implant after dip-coating.

Results

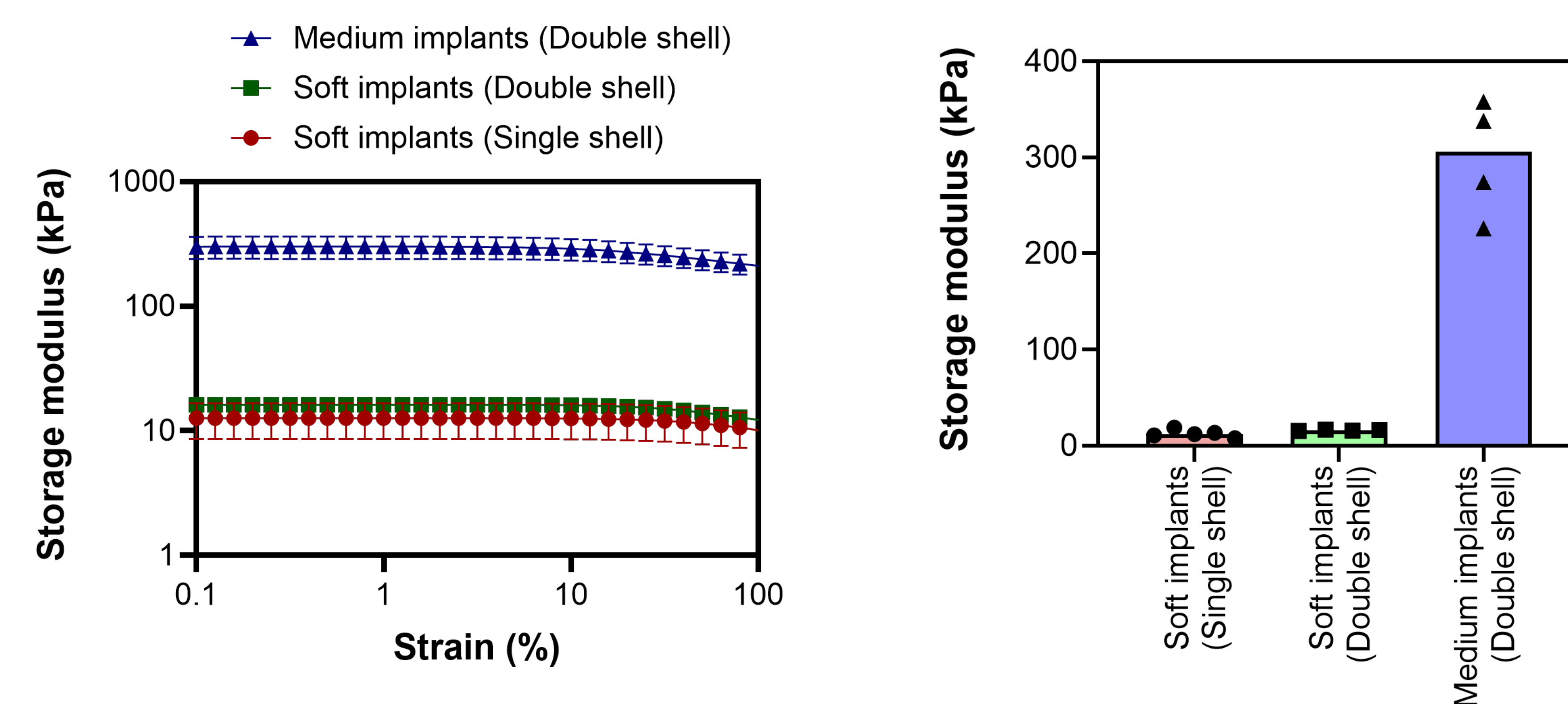


Figure 2 Rheological techniques were used to understand the mechanical properties of the implants. The storage modulus was measured as a function of strain rate. The medium implants (used in the rat studies), which were constructed at lower silicone base to cure ratio (40:1), were demonstrated to have a greater storage modulus compared to implants made with a higher silicone base to cure ratio (50:1).

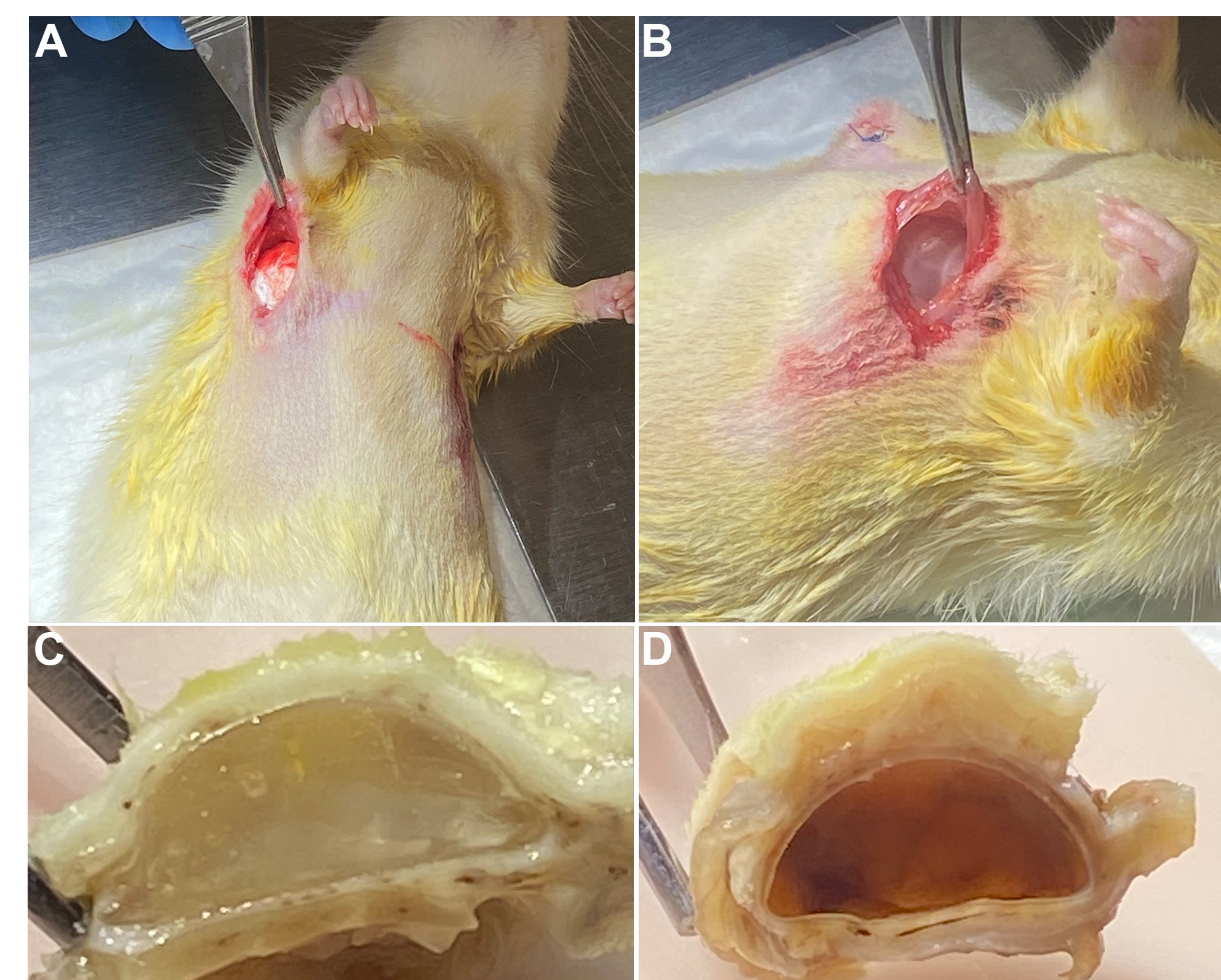


Figure 3 Two (2) hemispherical silicone breast implant prototypes were inserted bilaterally into the rat. (A) The right implant was placed in the pre-pectoral plane. (B) The left implant was placed in the sub-pectoral plane. Both implants were harvested at a 12-week endpoint for histological evaluation. (C-D) Pre-pectoral and sub-pectoral harvested implants.

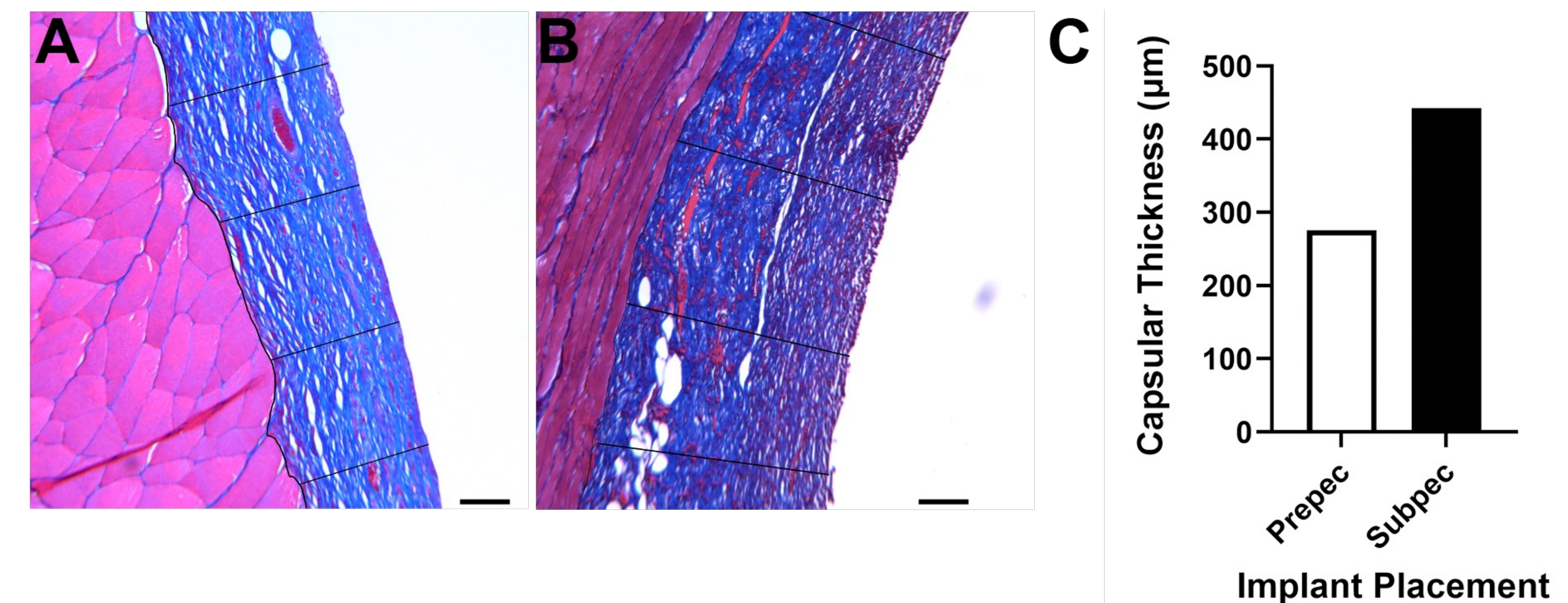


Figure 4 Observed differences in capsule thickness between (A) pre-pectoral (275 μm) capsule and (B) sub-pectoral (442 μm) capsule. (C) Graphical representation.

Conclusions

- Implants retained the original shape of the 3D-printed molds and qualitatively demonstrated a shell with an inner gel-like structure while still being deformable. These observations were reflected in data to characterize the mechanical properties.
- Lab-made implants were well tolerated for the duration of the twelve (12) week in-vivo study.
- Histological analysis revealed capsule formation and foreign body response that closely mirrored other results for implants used in animal studies.