



PURPOSE

The risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) has largely restricted surgeons to using smooth surfaced breast tissue expanders and implants, making the process of tissue expansion less predictable and obviating the application of anatomically shaped devices. Our group has developed a novel smooth breast implant surface that promotes tissue ingrowth into pores (2-4mm in diameter within the implant surface) which facilitates tissue ingrowth into the shell of the implant and fixes the implant into position without the associated risks of microtextured devices.

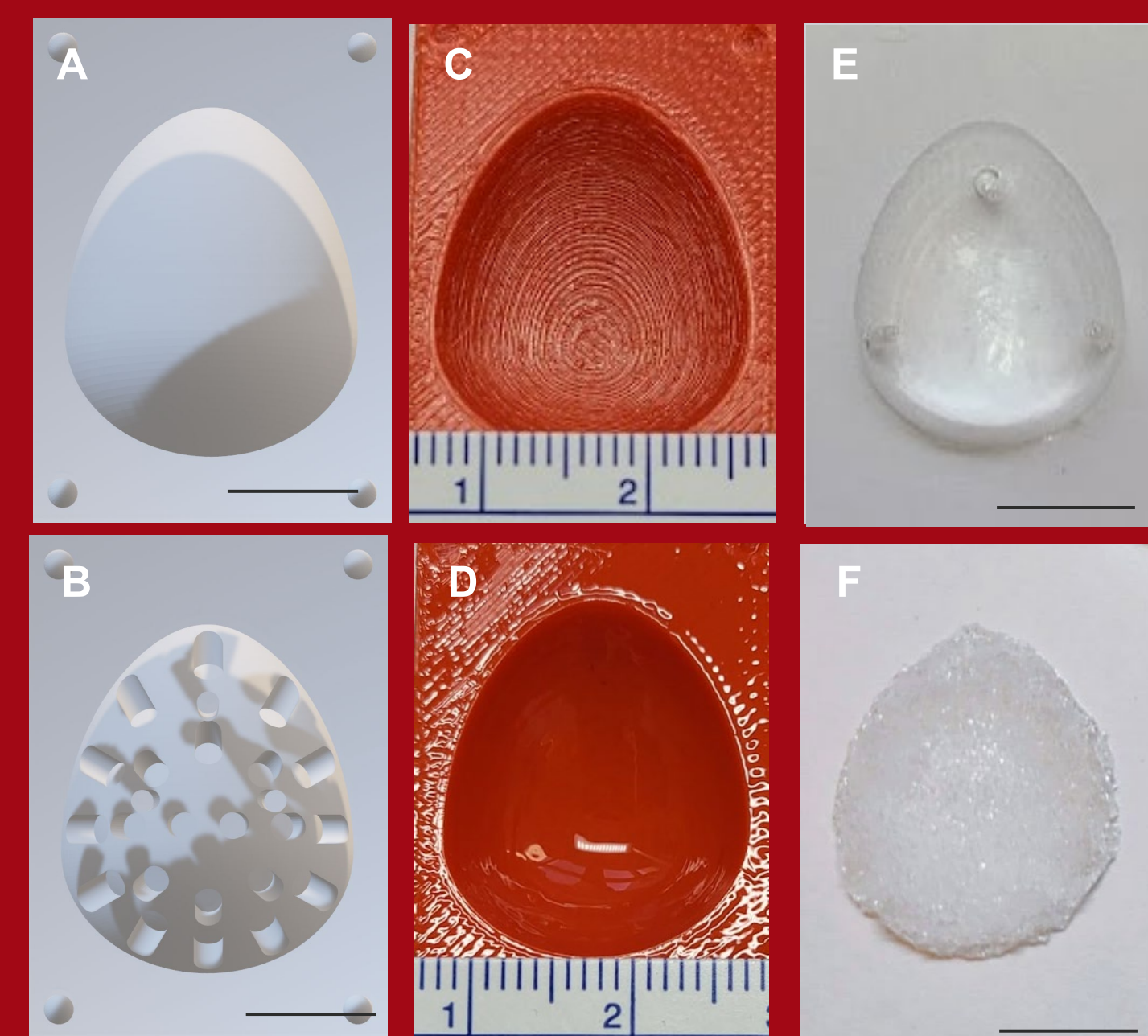


Figure 1: A)CAD Model of Smooth Implant Negative Mold, B) W2D3 implant CAD model negative mold, C) Smooth implant negative mold, D)Ethanol-smoothed negative implant mold, E)Smooth Implant, F)Textured Implant

METHODS

Miniature anatomically (breast) shaped smooth implants (2cc) made from polydimethylsiloxane were designed with pores invaginating into the surface. A range of pore number (peri-implant), widths and depths were tested. Textured and smooth implant controls with no pores were included. Implants were placed on the dorsum of wild-type rats (N=4 per group), implant rotation was evaluated monthly, and at explantation, implants were evaluated by gross visualization, histology, and Micro-CT.

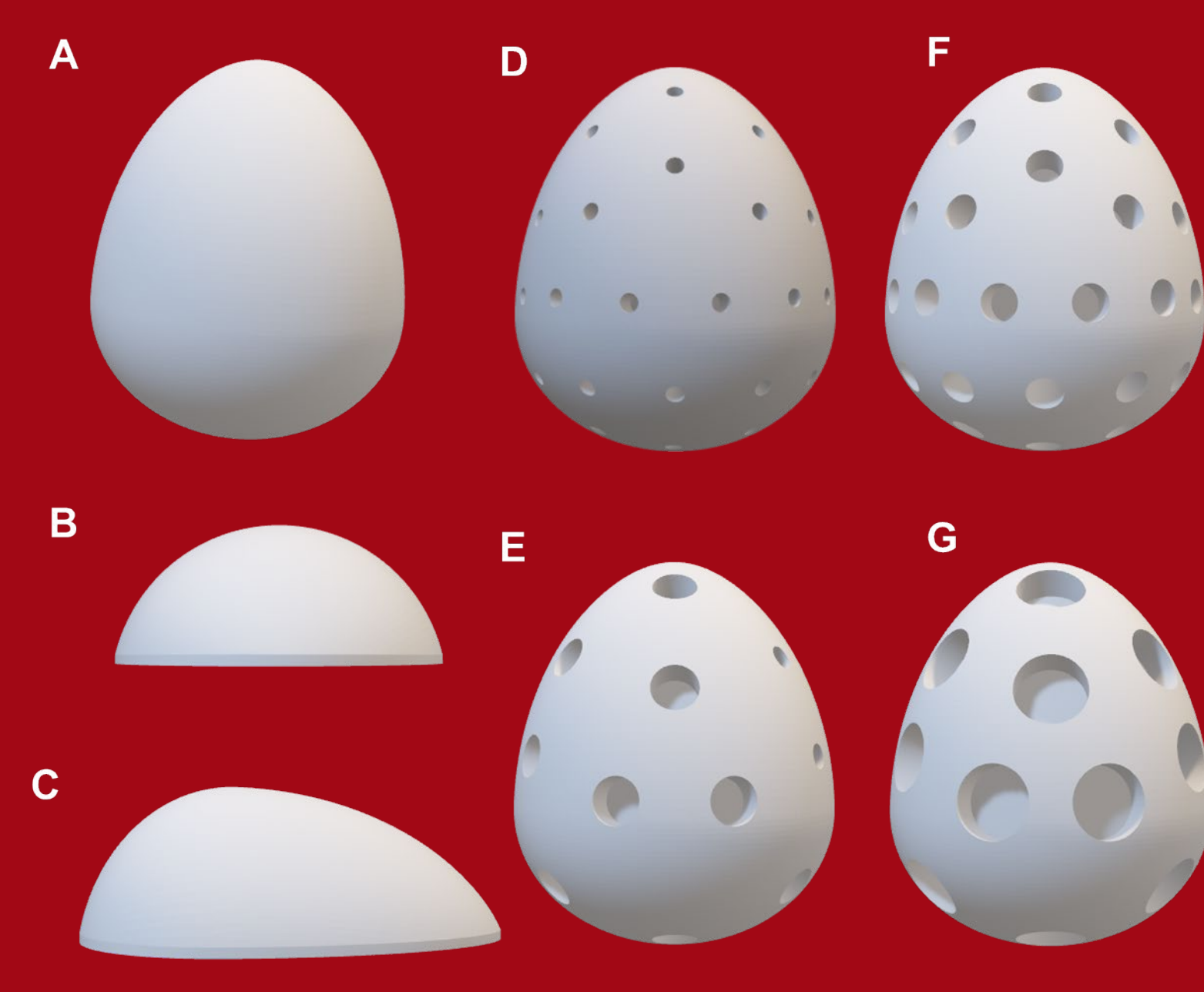


Figure 2: Representative implant designs of A) Smooth implant top view, B) Smooth Implant Front View, C) Smooth Implant, Side View, D)W1D1 22Pores, E) W2D2 11 Pores, F) W2D2 22 Pores, G) W4D2 22 Pores. W: Width (mm), D: Depth (mm)

Results

All Positionally Stable Smooth Implants (PSSI) with cylindrical pores demonstrated tissue ingrowth into pores by 1 month, and were evaluated by gross visualization, histology, and Micro-CT. Smooth implants experienced ~80 degrees more rotation than pore implants at 3 months, and there was no significant difference between PSSI and textured implant stability. Decreased stability and rotation were noted when the macropore density and width decreased.

Conclusions

We present an innovative design of PSSI implants which enhance implant positional stability without using the traditional microtextured surface linked to BIA-ALCL. These promising early results have led to ongoing follow-on studies to further identify the optimal macropore configuration that maximizes implant stability.

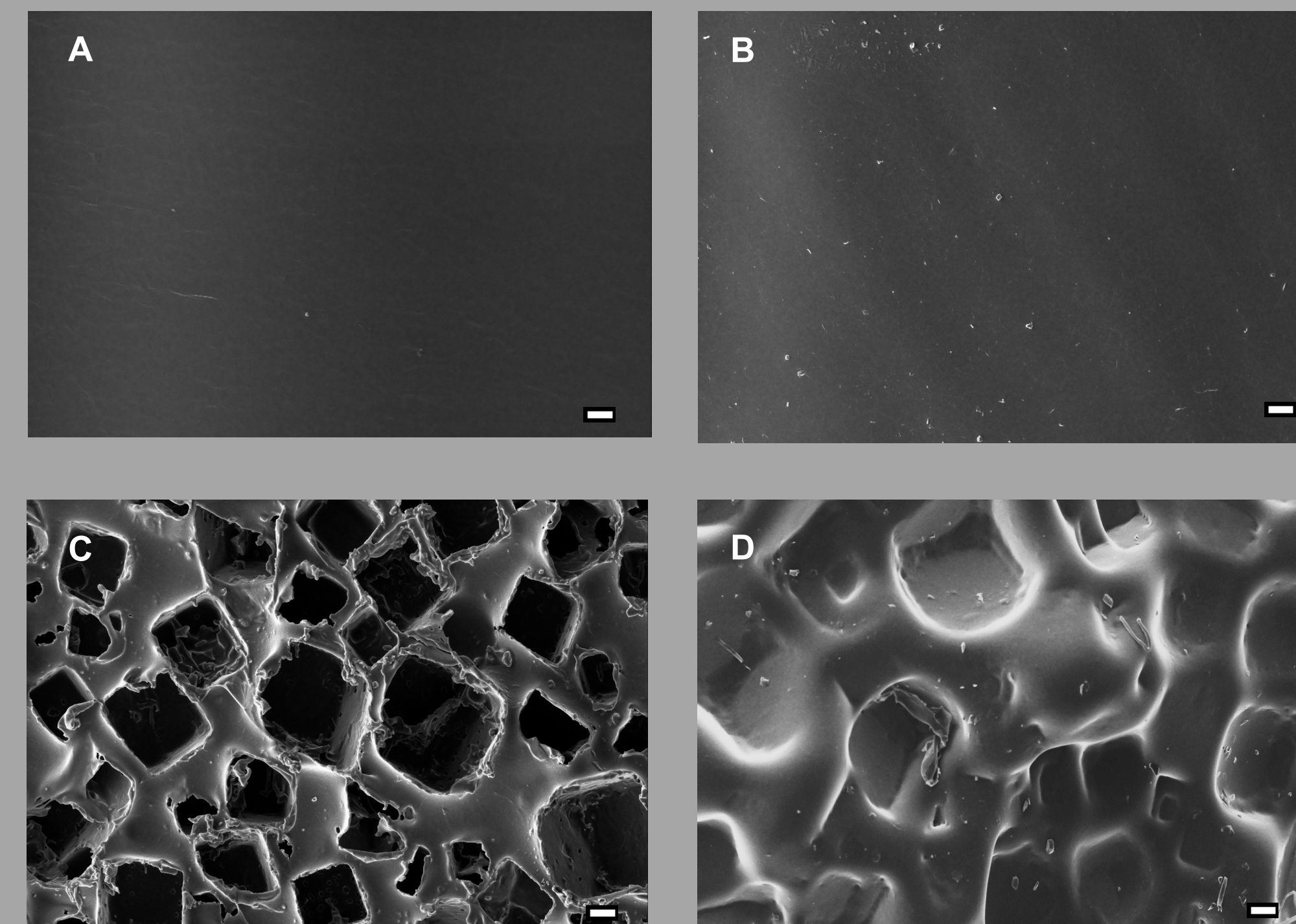


Figure 3: 100x SEM imaging of A) Allergan Smooth, B) Lab-fabricated smooth PDMS implant surface, C) Allergan Textured, D) Lab-fabricated salt imprinted textured implant. Scale bars = 0.1mm

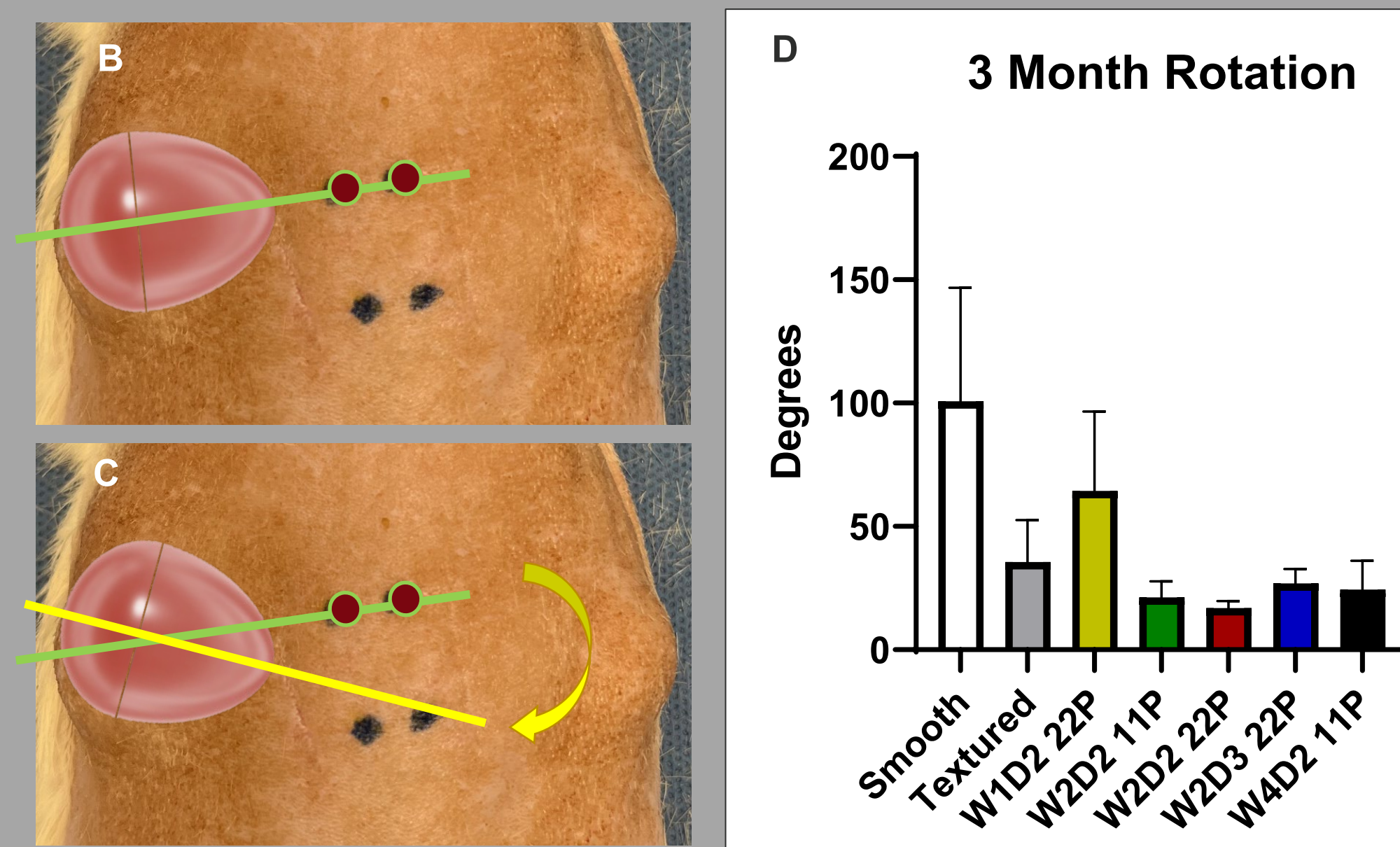


Figure 4: A) Representative image of implant location on rat, B) original implant location relative to two tattoo markers, C) Implant rotation measurement, D) Implant rotation measurements over 3 months.

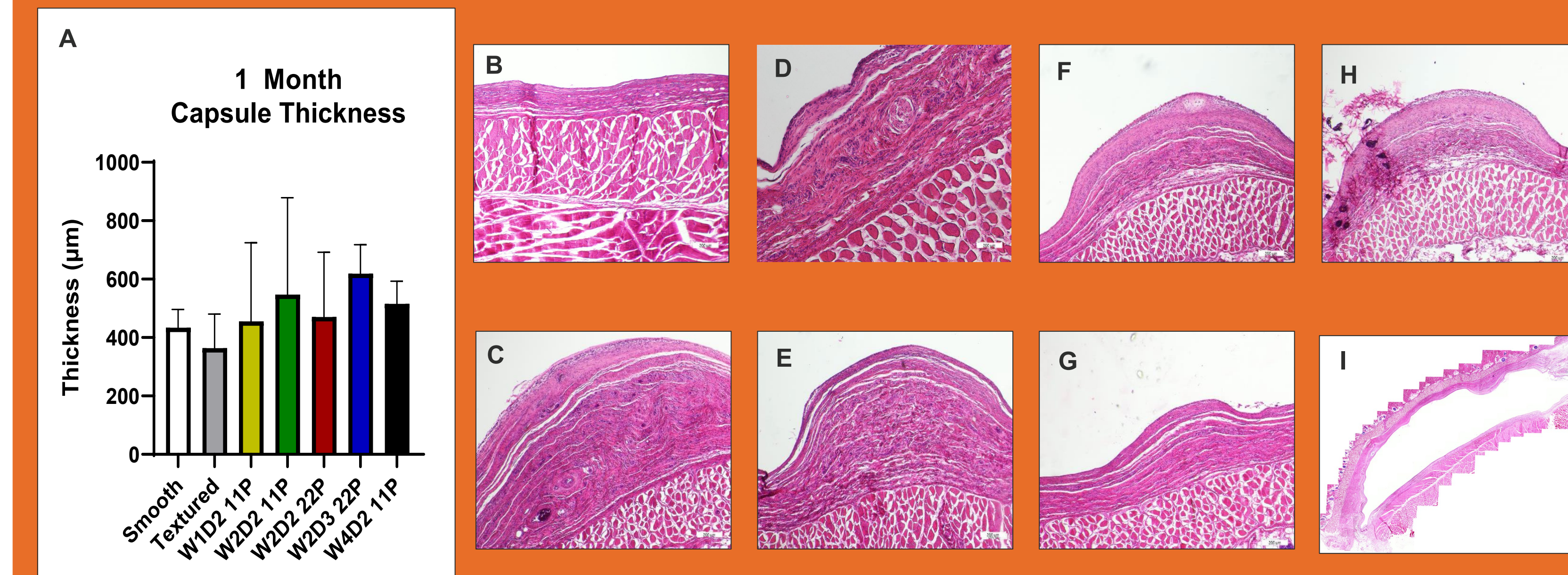


Figure 5: 1 month A) Capsule thickness measurements, B) Smooth implant capsule, C) W4D2 11 pores implant capsule, D) Textured implant capsule, E) W2D3 22 pores implant capsule, F) W2D2 22 pore implant capsule, G) W1D2 22 pores implant capsule, H) W2D2 11 pore implant capsule, I) Stitched W4D2 11 pores complete capsule. W: Width (mm), D: Depth (mm)

Future Directions

In subsequent studies, we aim to increase the sample size to further validate our findings and enhance the generalizability of our results. Additionally, we plan to investigate the performance of soft gel-filled implants with the novel smooth surface design, as this may more closely mimic the properties of commercially available breast implants.

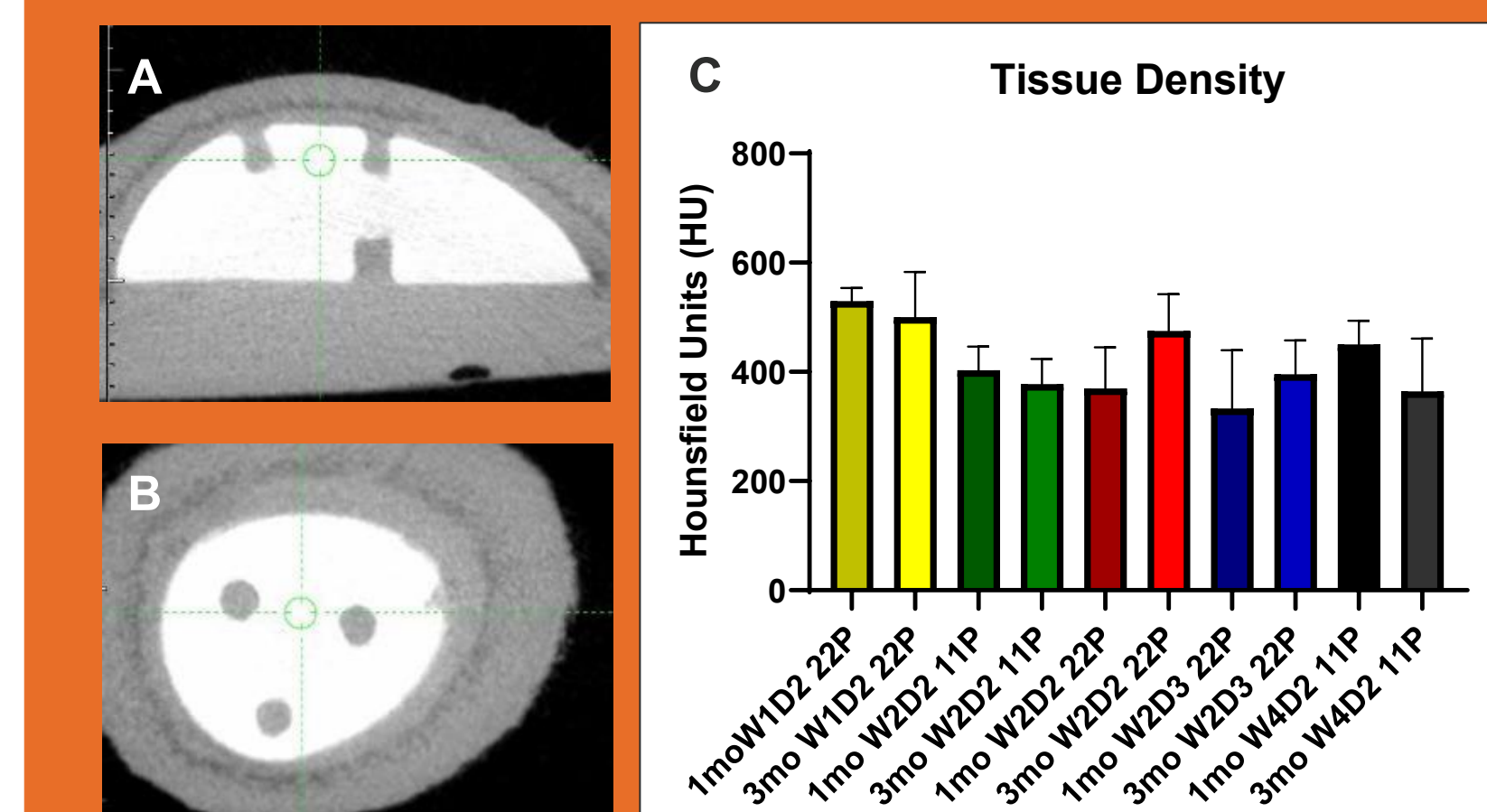


Figure 7: A) MicroCT imaging of W2D2 11 pore implant (side-view), B) MicroCT imaging of W2D2 11 pore implant (top-view), C) Density of tissue in pores measurements

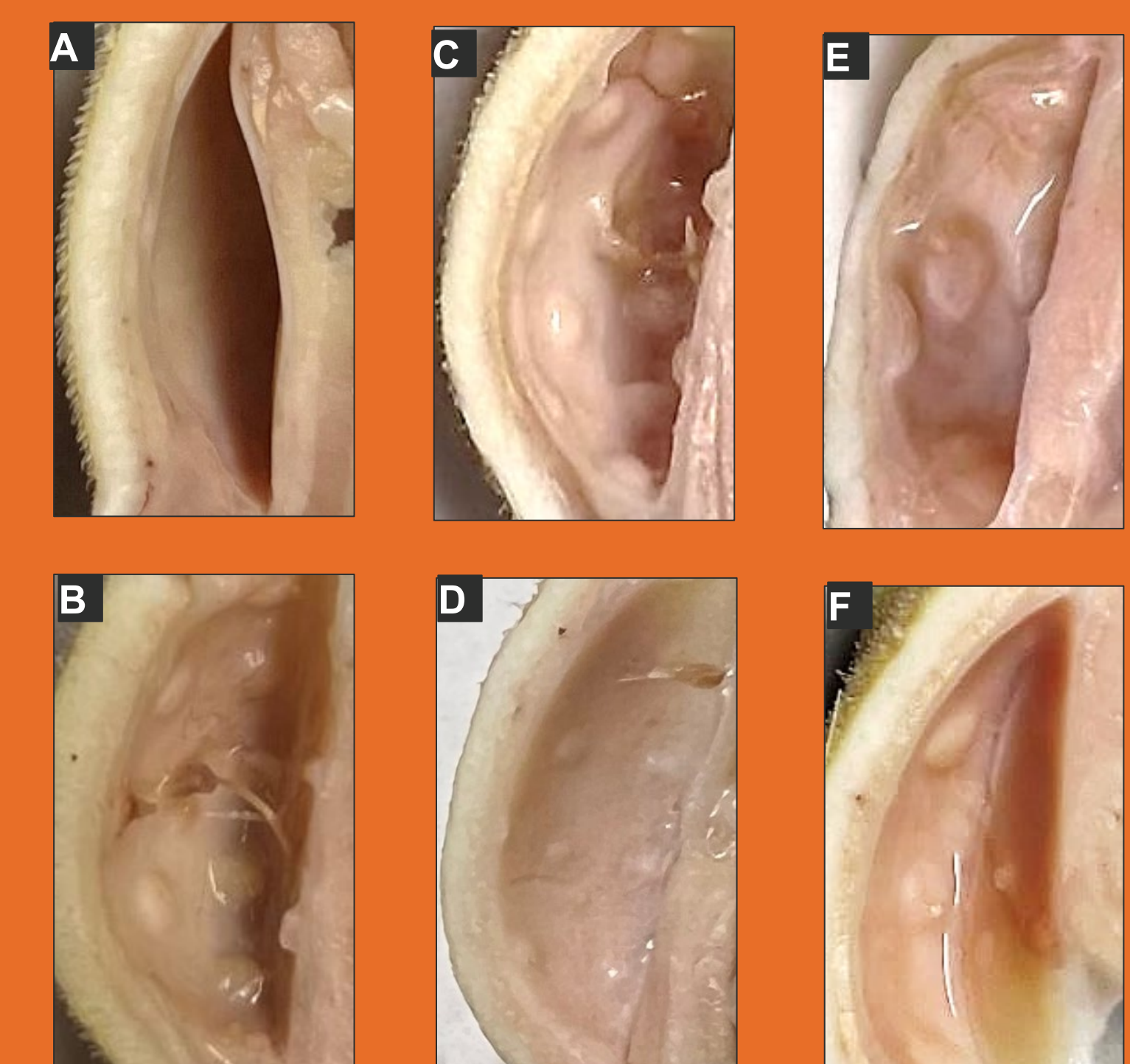


Figure 6: 1 month explanted capsule and surrounding tissue of A) Smooth implant, B) W2D2 22 Pores, C) W2D3 22 pores, D) W1D2 22 pores, E) W4D2 11 Pores, F) W2D2 11 Pores. W: Width (mm), D: Depth (mm)

Acknowledgments



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