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Purpose

The etiology of breast implant-associated pathologies not caused by rupture remain poorly understood. Particulate shedding is a recognized phenomenon of silicone breast implants and hypothesized to perpetuate chronic peri-implant inflammation. Prior research quantifying particulate size focuses on the microparticle range ($>1\mu\text{m}$). As recent technological advancements permit interrogation of the nanoparticle (NP) range ($<1\mu\text{m}$), we sought to examine nanoparticulates released from commercial implant shells.



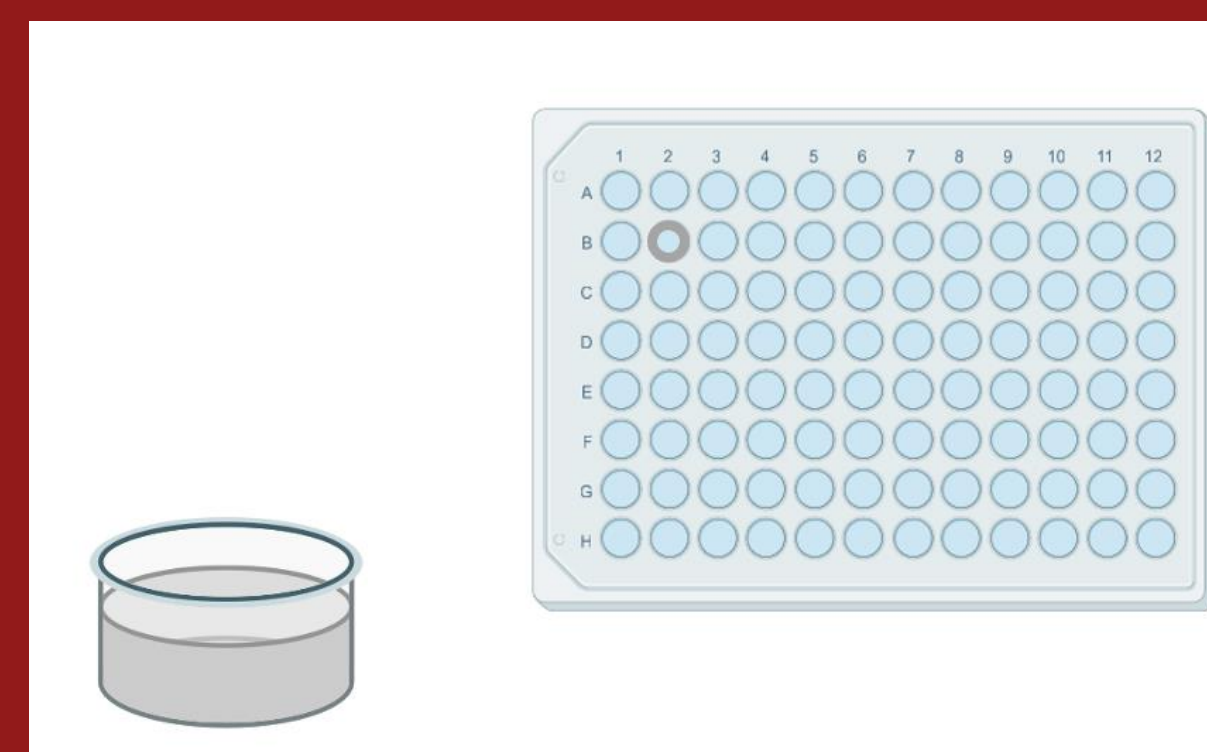
Fig. There are two major types of breast implant surfaces: smooth and textured.

Methods

Silicone textured and smooth implant shells from AllerganTM and MentorTM were thoroughly cleaned, sterilized, cut to line individual wells within a 96-well plate, and incubated in serum-free cell culture media for 48 hours. This ‘conditioned’ media (CM) was collected from textured (TCM) and smooth (SCM) implant shells and analyzed through the NanoSight Pro Nanoparticle Tracking Analyzer (Malvern Panalytical, Malvern, UK).



Small rectangular sections were cut from outer shells, cleaned of silicone gel interior, and sterilized via steam autoclave and UV light



Shells were used to line the inside of a cell culture plate, with the implant’s outer surface facing inward



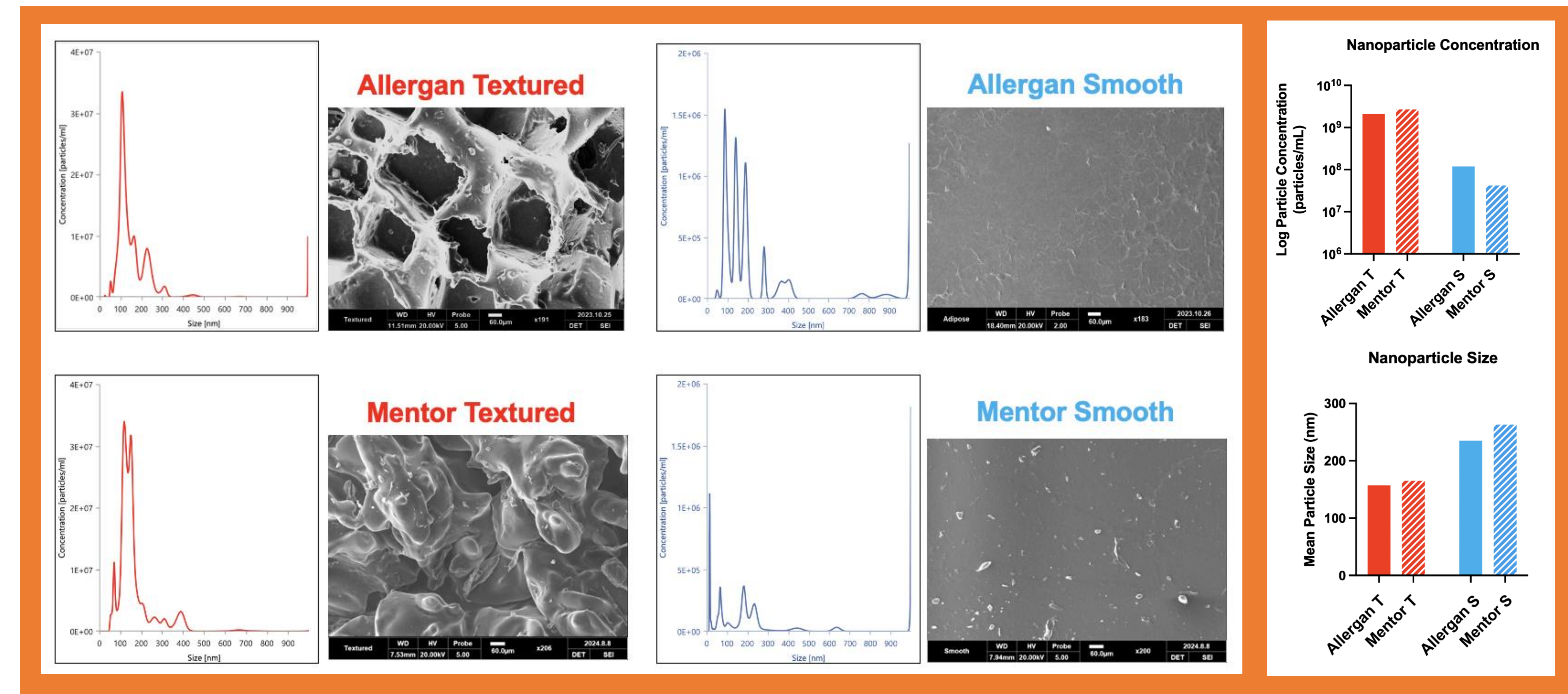
Serum free media was added and incubated for 48 hours to release any particles



Exposed media was run through the Nanoparticle Tracking Analyzer

Results

No NPs were detected in serum-free media. NPs were detected in all implant CM groups, with greater mean concentration in TCM (Allergan: 2.09×10^9 particles/mL, Mentor: 2.69×10^9) by over one order of magnitude compared to SCM (Allergan: 1.19×10^8 , Mentor: 4.18×10^7). Median NP size was smaller in CM from textured Allergan and Mentor (126nm and 141nm, respectively) compared to their smooth counterparts (152nm and 185nm, respectively). TCM NP size distributions peaked between 100-200nm, while SCM NP histograms spanned more broadly across smaller sizes with additional peaks between 600-1,000nm.



Conclusions

Breast implant shells incubated in media release nanoparticulates, with textured shells shedding over 10x more NPs than smooth. Further study is required to determine what, if any, role NPs play in inducing breast implant pathology, including BIA-ALCL.