SATURDAY, MAY 6, 2017
SESSION 8 GROUP C
10:30 AM – 12:00 AM

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Better Living Through Chemistry: A Novel Breast Implant Surface Coating Significantly Reduces Peri-Prosthetic Capsule Formation

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PURPOSE: The body responds to synthetic surfaces on implanted prosthetic devices with an inflammatory foreign body response (FBR), which results in the gradual deposition of a fibrous collagenous capsule. Capsular contracture (CC), the progressive growth and contraction of this peri-prosthetic capsule, is the most common complication of aesthetic and reconstructive breast surgery, affecting up to 47.5% of patients (1). CC causes breast pain, hardening, and deformity and is the most common indication for revision surgery. CC is thought to be due to an excessive FBR, however the etiology and pathophysiology of this process is poorly understood, and CC can occur in the absence of any putative risk factors. As such, there are no clinically approved therapies for prevention or treatment of CC. Rather, the complication is mitigated with re-operation and capsule excision, which often necessitates implant removal and replacement. Herein we altered the surface chemistry of silicone implants with Sigilon's proprietary anti-inflammatory molecules, E9 and RZA15. These compounds are biocompatible small organic molecules which are covalently grafted to the surface of the implant. They are designed to reduce immune cell adhesion to the implant, leading to a truncated FBR and reduced fibrosis.

METHODS: Round silicone implants were created from polydimethylsiloxane (PDMS). RZA15 or E9, two novel, biocompatible, non-toxic, anti-inflammatory proprietary molecules were covalently bonded to the implants. Uncoated, RZA15- and E9-coated implants were implanted subcutaneously into the dorsa of wildtype C57Bl/6 mice. After 21 and 90 days, peri-prosthetic tissue was removed for histologic analysis, and stained with Hematoxylin & Eosin and Masson's Trichrome. The capsule was identified at five equidistant regions throughout the implant and outlined in ImageJ software. Capsule area was calculated, and divided by capsule length to determine the average capsule thickness per implant.

RESULTS: We compared mean capsular thickness at two time points across the three groups: E9-coated, RZA15-coated, and uncoated implants. After 21 days, there was a statistically significant reduction in capsule thickness of RZA15- (71.12 microns; $p = 0.0194$) and E9-coated implants (76.84 microns; $p = 0.0463$) compared to uncoated implants (103.80 microns). Similarly, after 90 days, there was a statistically significant reduction in capsule thickness E9-coated implants (40.51 microns; $p = 0.023$) compared to uncoated implants (59.16 microns).

CONCLUSION: Coating the surface of silicone implants with RZA15 and E9 significantly reduced both acute (3 weeks) and chronic (3 months) capsule formation in a mouse model for implant-based breast augmentation and reconstruction. As capsule formation obligatorily precedes capsular contracture, these results suggest contracture itself may be significantly attenuated. Furthermore, as peri-prosthetic capsule formation is a complication without anatomical boundaries, the chemistry of this novel compound may have additional applications beyond breast implants, to a myriad of other implantable medical devices.

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Quality and Quantity Control Cell Culture with Microgravity increases CD34-positive fraction and angiogenic potential of endothelial progenitor cells

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