peri-areolar region (6.6 mm, range 1.7 to 28 mm). Average cadaver tissue measurements were similar to those found on MRI.

**CONCLUSION:** Our radiographic and cadaveric findings of the breast fascial condensations correlate suggesting that the breast boundaries do not always extend to the IMF, rarely reach the latissimus and the clavicle and never extend medial to the sternal border. Working with breast oncologists to identify fascial condensations rather than previously established landmarks may lead to better soft tissue camouflage of pre-pectoral implants after mastectomy.

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6-Year Clinical Trial Results with the Structured Breast Implant

**Presenter:** Gregg Anigian, MD;  
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**INTRODUCTION:** The structured breast implant uses different technology than existing saline or silicone gel implants, making it a third type of implant. It was approved by FDA and Health Canada in November 2014. The 6-year results from the FDA Core clinical trial are presented. Comparison of data for the three types of implants reveals certain advantages of the structured implant over saline and silicone gel implants.

This third type of implant is filled with saline, but uses an internal structure to make it behave as if filled with silicone gel. It contains a series of nested shells that support the upper pole when upright and control fluid movement to prevent bouncing. The result is an implant that combines certain key features and benefits from both saline and silicone gel implants. Like the saline implant, the filler is only saline, which women like for peace of mind in case of a rupture/deflation. Like the silicone gel implant, it has a natural feel, but without the risk of silent rupture and FDA-recommended MRIs - women can simply look in the mirror and know their implants are intact.

**METHODS:** This US clinical trial began February 2009, with 502 women enrolled by February 2010: 399 for primary augmentation and 103 for replacement of existing saline or silicone gel implants. Investigators included 45 ABPS certified plastic surgeons at 35 sites.

**EXPERIENCE:** Of the 502 women enrolled, 438 completed their 6-year follow-up visits, a rate of 87.3%. This follow-up visit rate is higher than for any other breast implant clinical trial, providing robust clinical data for analysis.

**RESULTS:** For the 438 patients with 6-year follow-up, patient satisfaction with the outcome was 89.7% for primary and 91.6% for replacement augmentations; surgeon satisfaction with the outcome was 92.6% for primary and 94.0% for replacement augmentations. Adverse events per patient were tabulated by Kaplan-Meier risk rates of first occurrence: Baker class 3 & 4 capsule contracture – 5.7% for primary, 11.5% for replacements; rupture/deflation – 1.8% for primary, 4.7% for replacements.

**CONCLUSION:** 6-year results from 438 women show that the structured breast implant has a high rate of patient and surgeon satisfaction, a low rate of capsule contracture and a low rate of rupture/deflation.

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Tissue Engineering a Biomimetic Platform for the Study of Breast Cancer Metastasis

**Presenter:** Julia L. Jin, BS;  
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INTRODUCTION: Current tissue engineering efforts are aimed towards recreating tissues to repair those that have been lost or damaged – such as the development of in vitro 3D biomimetic platforms to recapitulate in vivo conditions. Specifically, in breast cancer research, surrounding ECM in vivo has a profound effect on malignant invasion of cancer cells and it has also been clinically observed that breast tumor tissue is denser than normal tissue. However, traditional cell culture systems employed to study tumor cell behavior are limited by the significantly different cell phenotype induced under 2D culture conditions. We have created intact functional vascularized channels in biocompatible collagen constructs with proper in vivo vascular physiology and alter collagen stiffness to study factors that influence tumor progression, and vascular remodeling.

METHODS: Type-I collagen was enzymatically stiffened with ribose solution to create a stock collagen solution. Pluronic F127 fibers, were sacrificed in the collagen, creating a central looped microchannel with a tumor spheroid embedded in the collagen bulk. A cell suspension of human aortic smooth muscle cells (HASMC) and human umbilical vein endothelial cells (HUVEC) was seeded into the microchannel. Mechanical compression testing was completed by ElectroForce-3200 Series III.

RESULTS: Confocal reflectance values showed no statistical changes of fiber length or pore area in enzymatically altered collagen, suggesting changing the stiffness would not affect bulk cell migration. Biomechanical testing of stiffened collagen revealed that 200mM of ribose dosed collagen increased the stiffness of the hydrogels to appropriate “tumor” stiffness (4kPa). After all time points, non-cancer containing constructs containing microchannels consisting of an anatomically correct robust vascular channel lining with increasing proliferation. However, in cancer constructs, degradation of the vascular lining and aberrantly organized HUVEC and HASMC were present. IHC and MPM imaging revealed the presence of breast cancer cells invading the endothelial lining. Permeability studies using TexasRed Dextran revealed an increase of neovessel permeability correlating with increasing stiffness, suggesting metastatic potential of cancer also increased.

CONCLUSION: This model overcomes the limitations of previous 2D and 3D culture models and may be used to investigate any type of tumor cell and can lead to the further understanding of breast cancer signaling pathways, as well as potentially provide an effective platform for high throughput analysis of patient specific breast cancer cells.

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Results of the XPAND II Multi-Center, Prospective Clinical Trial for the AeroForm Tissue Expander System used for Two-Stage Breast Reconstruction

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INTRODUCTION: Data from the XPAND II continued access clinical study are presented to confirm previously reported results for the AeroForm Tissue Expander System when used for two-stage breast reconstruction.

BACKGROUND: The XPAND II multi-center study was conducted as a continued access study under the U.S. FDA IDE regulations. The study was a multi-center, prospective, single arm study designed to confirm the results from the XPAND study, a multi-center, prospective, randomized study for breast reconstruction. In December 2016, the AeroForm device received clearance from the FDA based on the results of the XPAND trial, and adoption of this novel needle-free expansion system is underway in the U.S.