Development of a Novel Sheep Model of Human Implant-Based Breast Reconstruction: 12 month Experience with SeriScaffold®, a Silk-Derived Bioresorbable Scaffold (SBS), for the Provision of Soft-Tissue Support through Host Tissue Generation

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Purpose: To (i) develop a full-scale animal model (FAM) in sheep that emulates the mechanical and biological environment of 2-stage breast reconstruction, and (ii) evaluate the clinical, mechanical and biological performance of the SBS over 12 months *in situ*.

Methods: Twelve sheep underwent bilateral implantation of tissue expanders (TE) under the latissimus dorsi muscle with partial muscle coverage. The SBS was sutured between the latissimus dorsi and the chest wall creating an infra-mammary fold (IMF) and defining a soft tissue lower pole. Animals were evaluated 1, 3, 6 & 12 months post-surgery; those designated for the 6 & 12 month endpoints had TE/breast implant exchange at 3 months. Implant sites were assessed through clinical observation and imaged at 6 and 12 months using CT and MRI. At necropsy, lower pole samples were assessed for thickness and drapability, and biomechanical strength was determined using a standard ball-burst test. Early model development involved (i) drain optimization and (ii) the evaluation of a non-SBS sham group.

Results: There was 1 incident of surgical site infection (which resolved without requiring implant removal), 1 incident of TE rotation, and no incidents of implant migration or bottoming-out. SBS features were not palpable at any time point; SBS-suture line edges were minimally discernable up to 4 months. SBS position was visualized by MRI at 6 months. SBS was fully ingrown from 1 month onward with SBS-tissue thickness increasing initially and then maintained (0.9±0 mm at time=0 to 1.9±1.3 mm at 1 month to 2.2±1.0 mm at 12 months). All tissue explants were drapable (Figures 1 and 2). The tissue burst strength was consistent ($p>0.05$) over all time points (and stronger than sheep fascia) while the strength of the SBS alone, following complete extraction of ingrown tissue, steadily declined with complete strength loss by 12 months.

Conclusion: The FAM in sheep is a satisfactory means of evaluating implant based breast reconstruction. Results indicated a progressive transfer and maintenance of load-bearing responsibility from SBS to newly generated functional tissue capable of supporting the breast pocket through expansion and long-term implant reconstruction.

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Fig 1

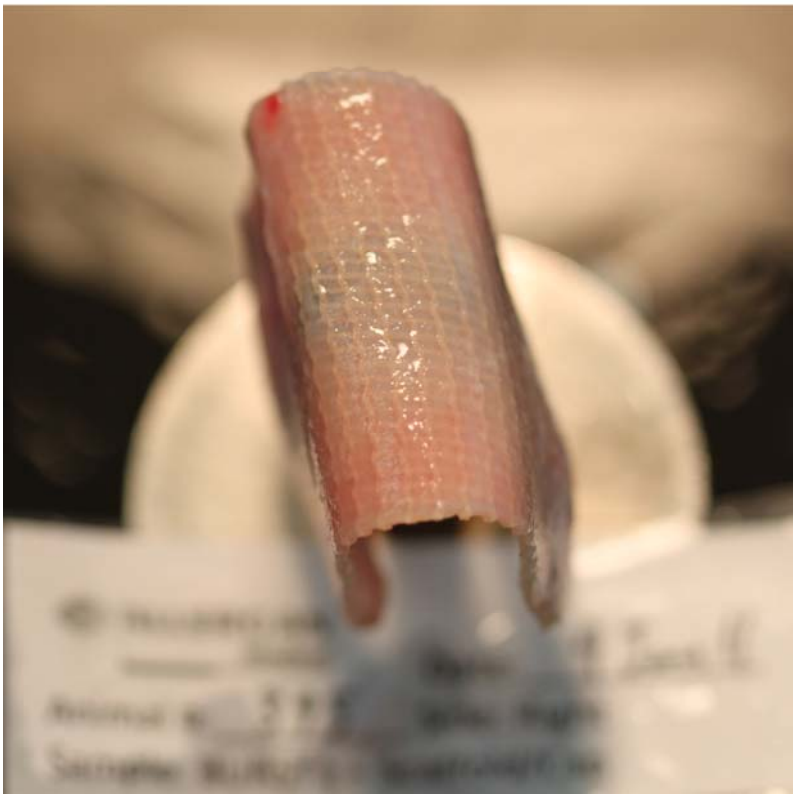

Fig 2