Development and Validation of a New Ultrasound Imaging Technique for Visualizing Polypropylene Surgical Mesh Under Simulated Use and *In Vivo* Conditions

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Introduction: Polypropylene (PP) is a common surgical mesh material that is knitted into flat patches and affixed to tissues for surgical repair of abdominal hernias. Unfortunately, mesh materials do not always remain flat *in situ* and there are persistent problems with hernia recurrence due to mesh contraction, curling of the mesh edges, and mesh slippage. There is urgent need for imaging modalities capable of visualizing mesh *in situ* to aid clinical detection of these mesh complications. The purpose of this study was to develop and validate an ultrasound imaging technique for visualization of PP mesh under simulated conditions and under *in vivo* conditions during an IACUC-approved animal study. It was hypothesized that PP mesh would be sufficiently echogenic to support use of common image segmentation algorithms for differentiating the PP mesh from tissues and detecting *in situ* changes in mesh size.

Materials and Methods: PP surgical mesh (Prolene Soft, Ethicon) was acquired and cut into 3x3 cm coupons. Images were acquired using a portable ultrasound system (LOGIQ E Veterinary, GE). Simulated conditions involved submerging the mesh coupons in water and embedding them in porcine cadaver tissues while manipulating the ultrasound settings and probe orientation to optimize mesh echogenicity in the acquired images. *In vivo* conditions involved six male rabbits, with 5 rabbits implanted with two pieces of PP mesh that were fixed with tissue adhesives in the upper quadrant and one sham operated rabbit without mesh. Images were acquired using three imaging sweeps over the mesh implants at two time points: immediately after implantation with the rabbit under anesthesia and after a 14-day *in vivo* duration immediately prior to explantation following euthanasia. Mesh margins were marked at the time of image acquisition and mesh size (length) was measured in each image using the calibrated measurement tool in the imaging software. Mesh shrinkage was calculated as the difference in length at explantation and at implantation.

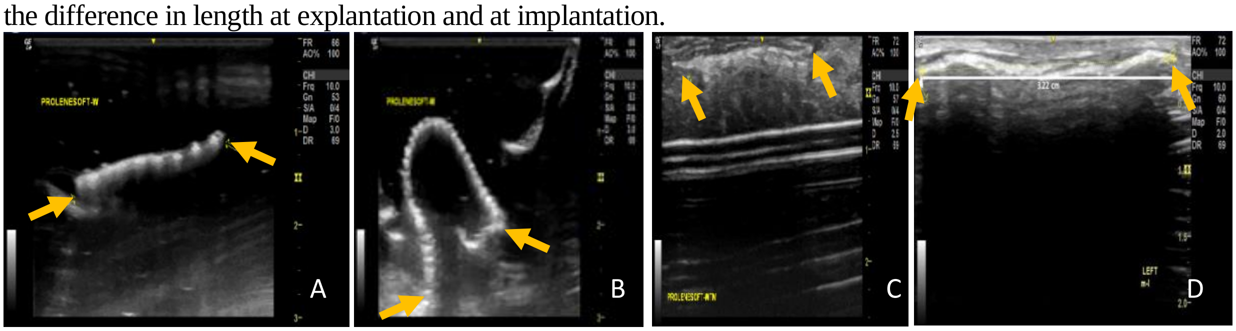

Figure 1: Flat and wrinkled PP mesh imaged in water (A,B), embedded in muscle under simulated use (C), and *in situ* at the time of implantation (D).

Results and Discussion: During simulated conditions, the PP meshes were highly echogenic and had clearly visible peripheral edges when submerged in water, with some image degradation in muscle and fat. During *in vivo* conditions at the time of explantation, mesh size contracted (shortened) an average of -0.9 ± 0.14 (range, +0.1 to -0.28) cm, representing a proportional change of +3.3% lengthening to -9.3% shortening relative to the initial 3 cm mesh lengths. This magnitude of contraction is within the average 3.93% to 41.35% previously reported for macroporous PP mesh after 14 days *in situ* in a rabbit hernia defect model.[1] Notable (>2 mm) changes in mesh length were evident in three mesh, consistent with gross wrinkling of the mesh and fluid-filled pockets in the mesh-tissue samples at resection.

Conclusion: This study provided initial validation of a newly developed ultrasound imaging technique for visualizing PP mesh under simulated conditions and *in vivo* conditions in a rabbit model. The PP mesh was suitably echogenic and supported use of common image segmentation algorithms to differentiate the PP mesh from the tissue tissues and detecting *in situ* changes in mesh size over a 14-day implantation time.

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Reference: [1] Ozog, et al. *Int Urogynecol J*, 22(9): 1099-1108, 2011