A Novel Mid-Urethral Sling Demonstrates Biocompatibility and Ease of Removal in a Porcine Model

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The standard surgical treatment for stress urinary incontinence (SUI) involves placement of a polypropylene (PP) mid-urethral sling (MUS).

Problem: While effective, PP implants are associated with tissue ingrowth, difficult mesh removals and increased morbidity when revision or explantation is required.

Innovative Solution: A novel, application-specific, expanded polytetrafluoroethylene (ePTFE) , developed specifically as a MUS device (**Figure 1**) has pore size cross-section < 1 μm, making it impervious to bacteria, minimizing infection & erosion, and easing extraction.

Goal: Evaluate tissue response, positional stability, and removability of this novel sling in a clinically relevant porcine model.

METHODS

Fluorinated ethylene propylene (FEP) was used as pledgets on both types of MUS as anchors.

Female Yucatan mini-pigs (30–50 kg) underwent implant of either an ePTFE (n=6) or a PP (n=6) MUS.

The MUS was positioned in the mid-urethral region through a small vaginal incision and anchored bilaterally to the obturator membrane using the pledgets (**Figure 2**).

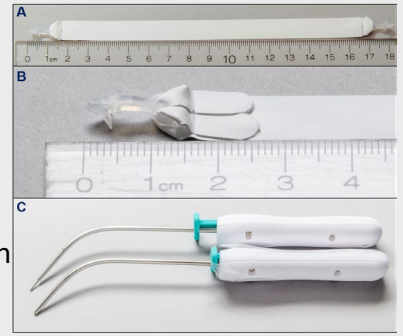

Figure 1. The novel ePTFE sling (**A**) showing the FEP pledgets (**B**) and insertion tools (**C**).

Excess MUS length was rolled into the periurethral space to simulate clinical placement. After 12 weeks, slings were explanted, and the time required for removal was recorded.

Tissue specimens surrounding the MUS body and anchor sites were collected for histologic assessment.

Study endpoints included technical feasibility of implantation, evidence of migration, ease of removal measured by explantation time and biocompatibility assessed as evidence of inflammation and fibrosis.

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RESULTS

Removal time for ePTFE slings (12.5 ± 2.8 sec), significantly lower than removal time for PP slings (714.2 ± 382.5 sec).

No migration of the slings occurred although approximately half of the ePTFE and half the PP slings were extruded into the vagina due to excess MUS length.

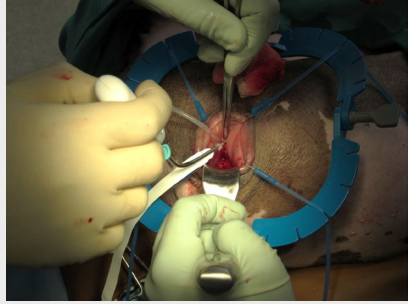

Figure 2. Surgical Implant Procedure.

The ePTFE sling implant resulted in unremarkable inflammation and fibrosis in the urethra near the MUS body and at the anchor site (**Figure 3**)

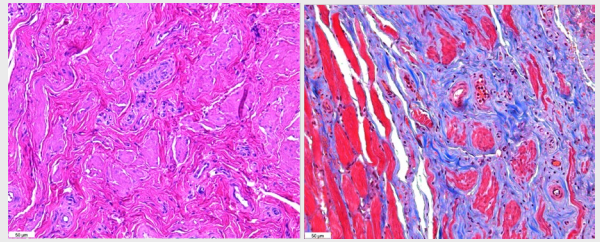

Figure 3. Histology of urethra near body of ePTFE MUS stained with H&E (left) and Masson's trichrome (right).

Quantification of muscle to collagen ratio in the urethra near the MUS body demonstrated less fibrosis with the ePTFE sling than the PP sling. No difference in muscle to collagen ratio was seen near the anchor **(Figure 4)**.

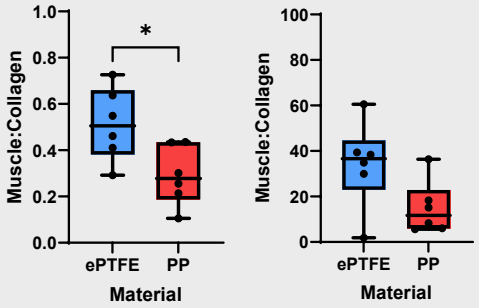

Figure 4. Quantification of muscle to collagen ratio from Masson's Trichrome in the urethra near the MUS body (left) and near the anchor of the sling (in muscle) for both ePTFE & PP slings. A significant difference between the two slings indicates reduced fibrosis at the urethra with the ePTFE sling. Note that the muscle to collagen ratio is much higher in muscle than in the urethra, as expected

CONCLUSIONS

The novel ePTFE sling, developed specifically as a MUS device, holds potential as a biocompatible, easily removable alternative to PP.