# **#781 A NOVEL ENGINEERED SLING TREATS STRESS INCONTINENCE WITHOUT ADHESION FORMATION IN A RAT MODEL**



LAB

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# Background

Polypropylene (PP) mesh mid-urethral sling is currently the gold standard surgical repair for stress urinary incontinence (SUI)



- Novel proprietary mesh utilizing expanded PTFE as a base polymer
  - completely redesigned microstructure compared to previously published PTFE slings
  - sintered material; not fiber based
  - inert; will not shrink after implantation like PP
  - mimics PP tensile strength &





# Methods & Results cont.

**1 Week Study** 

<b>Timed Removal</b> t-Test: Two-Sample Assuming Unequal Variances				
	Mean (S)	STD		
PP	428.8	109.9		
PTFE	2.7	1.0		
P(T<=t) two-tail		0.002		
Adhes Chi-s	ion Scoring			
Adhes Chi-s	ion Scoring square Test Median	IQR		
Adhes <sub>Chi-s</sub> PP	ion Scoring square Test Median 2	IQR 0		
Adhes <sub>Chi-s</sub> PP PTFE	ion Scoring square Test Median 2 0	IQR O O		

PNT / Sham Implant

**PNT** 

PTFE Implant (n

Sham Implant (n

PP Implant (n=5

1 week

(1) timed implant

(2) Adhesion scoring

removal

(3) Histology

PTFE





- compliance
- microporous; <2 x <1µm pores

# Aims

- To compare the novel PTFE implant to PP in the treatment of SUI 1. in a pre-clinical rat model both acutely & 6 weeks after implantation
- To compare the novel PTFE implant to PP in the ease of implant 2. extraction, adhesion formation, & induced histological changes 1 week & 6 weeks after implantation

# **Hypothesis**

- Both implants will improve leak point pressure (LPP) in our SUI 1. model both acutely & at 6 weeks.
- The novel PTFE implant will form less adhesions than PP with 2. easier extraction at 1 & 6 weeks.

# **Methods & Results**

- Bilateral pudendal nerve transection (PNT) induced SUI rat model
- ✤ Mesh was prepared to 4x25x0.25 mm & placed under the midurethra via midline laparotomy
- Cystometry (CMG) & LPP were measured via suprapubic catheter
- ✤ Adhesions: scored 0-4 from no adhesions to dense widespread adhesions
- Implant removal was timed
- ✤ Histology: inflammatory response assessed using a 3-point scoring system (H&E). Fibrotic reaction was quantified by collagen infiltration area using ImageJ (Masson's Trichrome).

#### **Acute Study**

### **6 Week Study**

#### Sham PNT PNT Sham PTFE Implant (n=12) Implant PP Implant (n=12) Sham Implant (n=12) (n=12) (1) CMG & LPP (2) Timed implant removal (3) Adhesion scoring (4) Histology



Timed Removal t-Test: Two-Sample		Adhesion Chi-squar	Adhesion Scoring Chi-square Test		
	Mean (S	) STD		Median	IQR
PP	683	132	PP	3	0
PTFE	42	23	PTFE	1	0.75
P(T<=t) two-tail	<0.00	001	P(T<=t) two-tail	<0	.0001



# **Conclusions**

- PTFE & PP implants comparably restored the PNT-induced SUI both acutely & after 6 weeks
- PTFE implants created significantly less adhesions after 1 & 6 weeks, enabling faster removal
- PP & PTFE induced similar histologic changes



- Overall, PP & PTFE induced similar histologic changes with increased collagen infiltration and inflammatory response compared to sham.
- PTFE did have the highest inflammatory scoring histologically at 6 weeks; however, these findings did not translate into appreciable clinical differences.
- This novel PTFE implant has the potential to improve SUI, while allowing easy extraction when necessary

## References

- 1. Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J. 2013 Aug;24(8):1265-9. doi: 10.1007/s00192-013-2090-2. Epub 2013 Apr 6. PMID: 23563892
- 2. Karlovsky ME, Kushner L, Badlani GH. Synthetic biomaterials for pelvic floor reconstruction. Curr Urol Rep. 2005;6:376-84.
- 3. Sangster P, Morley R. Biomaterials in urinary incontinence and treatment of their complications. Indian J Urol. 2010 Apr;26(2):221-9. doi: 10.4103/0970-1591.65394. PMID: 20877601; PMCID: PMC2938547.
- 4. Nanoscopic mesh imaging was performed in part at the Montana Nanotechnology Facility, an NNCI member supported by NSF Grant ECCS-2025391