Rethinking the Mesh: Erosion Testing of Polypropylene used in the Surgical Treatment of Female Stress Urinary Incontinence

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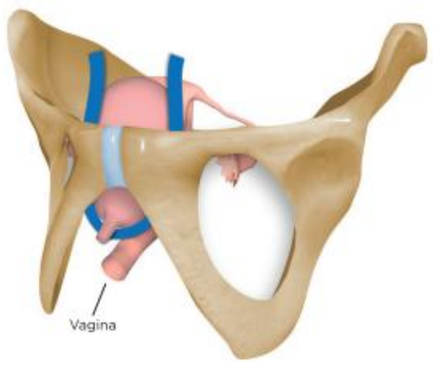

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AIM: To provide women worldwide with a better treatment option for stress urinary incontinence that avoids the risks of current vaginal mesh products.

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Introduction

Stress Urinary Incontinence (SUI) is the involuntary loss of urine caused by physical activity or abdominal pressure due to coughing or sneezing [1], affecting approximately 1 in 3 women and their quality of life [2].

The mid-urethral sling (MUS) offers mechanical support to the pelvic organs and has historically been used to treat SUI but in ≈ 3% of cases major complications arose [3]. Made from polypropylene (PP) mesh, these products can cause erosion to the urethra and vaginal wall tissue which resulted in widespread restrictions on the use of mesh implants globally [4].

This project aims to understand the effect of different sling materials on pelvic organ tissue by testing the erosion of soft-tissue by PP mesh with a new testing setup and investigating the impact of loading the mesh on the rate of erosion.

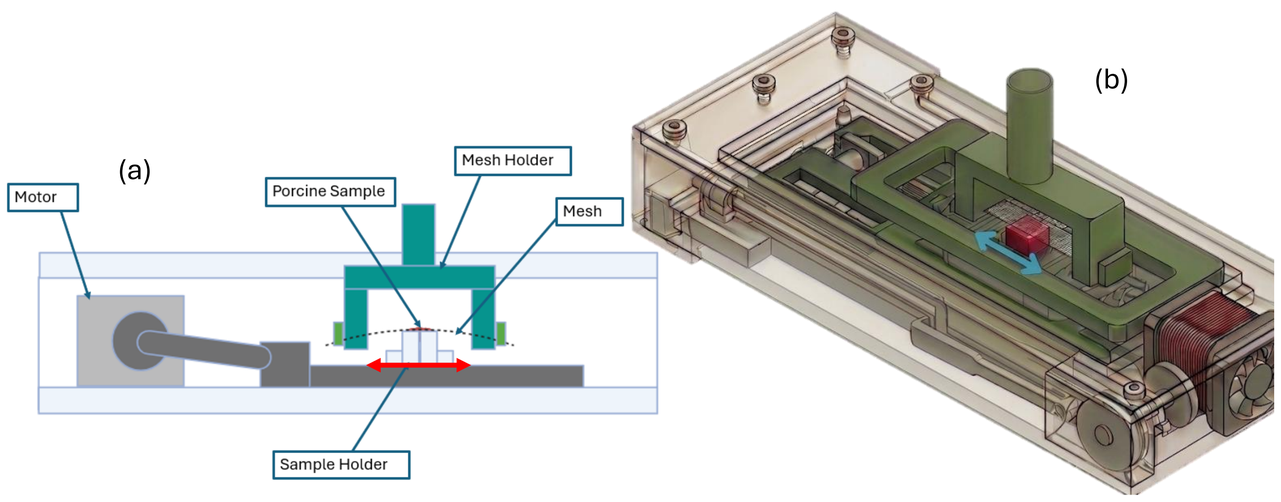

Fig 1. The adapted erosion rig used for testing for this project. The porcine sample was moved back and forth with a cycle rate of 1Hz while in contact with the face of the PP mesh. (a) was made using BioRender. (b) generated using Gemini.

Methodology

An erosion-testing rig previously developed by Schmidt & Taylor in [4] was adapted for use in this experiment (Fig. 1). The soft tissue was moved back and forth in the rig whilst in contact with the face of the constrained mesh. Porcine tissue was the soft tissue used in this experiment.

The number of back and forth cycles required for the porcine sample to decrease in height by 1 mm and 2 mm was measured with three different load applications to the mesh; 5.9, 10.8 and 15.7 N.

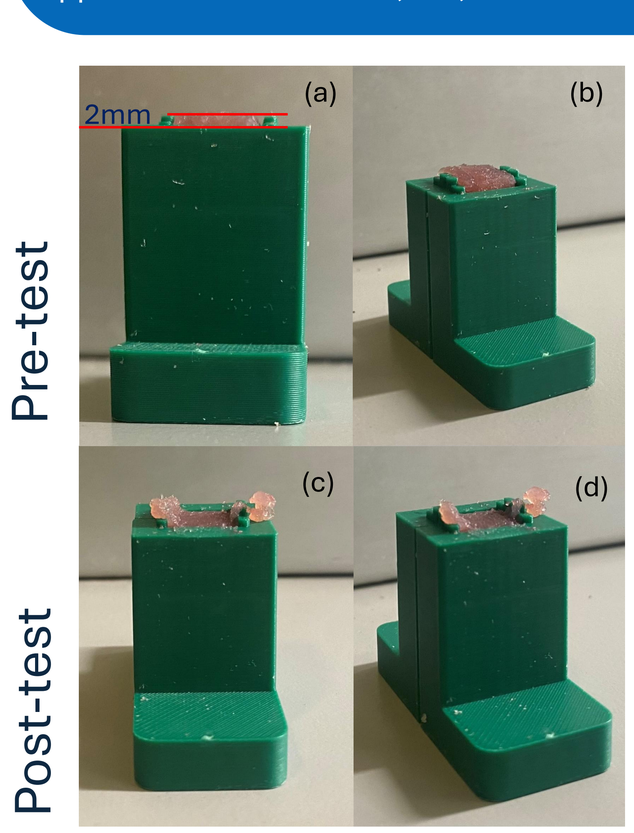

Fig 2. (a) & (b) The 1cm³ porcine sample sitting 2mm above the edge of the sample holder. (c) & (d) Porcine sample decreased in height by 2mm following testing.

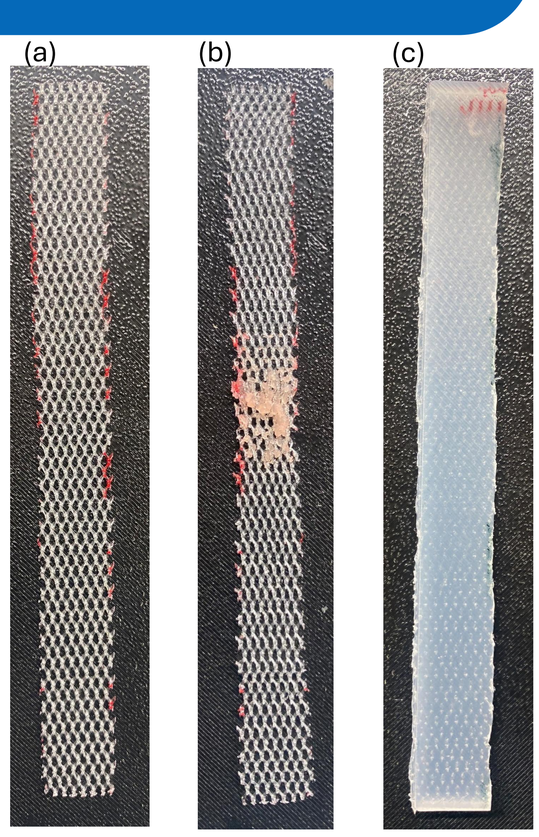

Fig 3. (a) PP mesh sample before testing. (b) PP mesh sample with tissue caught in the pores following testing. (c) Silicone-embedded PP mesh sample.

Results & Discussion

As mesh load increased, e.g. during coughing/sneezing, the rate of erosion increased. This was indicated by a significant decrease in the number of cycles for a 2 mm reduction in sample height due to the higher rate of erosion (Fig. 4). When the loaded mesh was applied to the soft tissue, initial compression of the sample resulted in a quick 1mm reduction in sample height for all load levels.

The mechanism of erosion involved tissue getting caught in, and pulled through, the pores in the PP mesh (Fig. 3 (b)). With the absence of pores on the surface of silicone-embedded PP, erosion was reduced. However, the silicone began to erode from the PP mesh, leaving the PP mesh exposed and risking further erosion.

Load ↑, Erosion ↑, number of cycles ↓

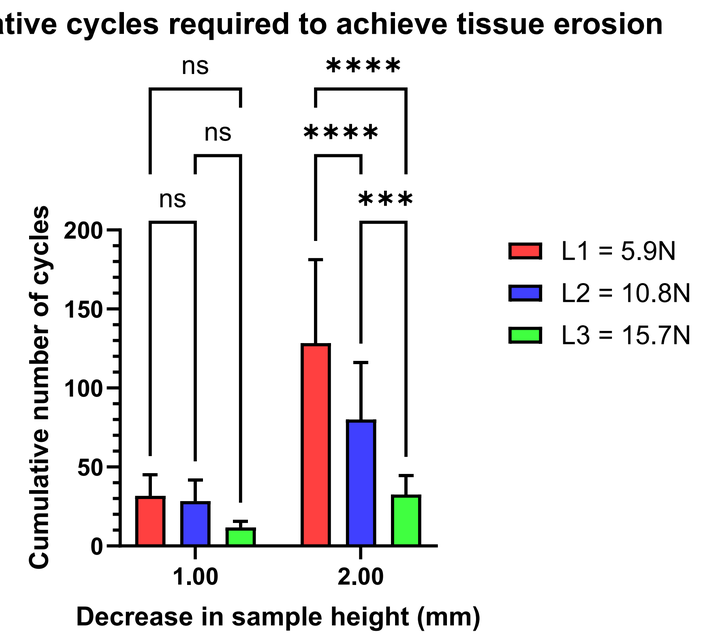

Fig 4. Graph illustrating the data shown in Table 1 where L1, L2 and L3 correspond to loads of 5.9, 10.8 and 15.7 N which includes the weight of the weight bucket in which the masses were held. (n = 36)

Table 1. Mean cumulative number of cycles required to achieve the given depth of tissue erosion, shown by load, with uncertainty given as the standard deviation and all values rounded to whole numbers.

Depth	Cycles at L1	Cycles at L2	Cycles at L3
1mm	32 ± 13	28 ± 13	12 ± 4
2mm	128 ± 53	80 ± 36	33 ± 12

Conclusion

- A parallel testing setup was developed which can be used to compare erosion by alternative sling materials with these PP mesh results as a benchmark.
- There was greater erosion at higher loads, indicating a higher risk of erosion during activities such as coughing or running.
- The mechanism of erosion by PP mesh indicates that a softer material with no surface pores could reduce erosion risk compared to PP mesh.
- This highlights the importance of matching the properties of a sling material to the properties of native tissue in the pelvic floor region.

Acknowledgements

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