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

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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). It is a condition that affects approximately 1 in 3 women (2). There are several risk factors which can cause SUI, including the weakening of the pelvic floor muscles due to childbirth and aging (1). SUI and the stigma attached to it can leave women feeling embarrassed, debilitated and can severely impact their confidence and quality of life (2).

While conservative treatments for SUI include pelvic floor muscle training, pessaries and bulking agents, which can be good management tools for those not suitable for surgery, oftentimes they do not offer effective cures to patients experiencing severe symptoms. SUI has historically been treated using surgical mesh products, such as the mid-urethral sling (MUS) which offers mechanical support to the pelvic organs in the form of a woven or knitted mesh implant through minimally invasive surgery (3). While these procedures were largely successful, in a small number of cases major complications arose. Predominantly made from a polypropylene mesh, these products can cause cutting and erosion to the surrounding organs (3). Erosion is estimated to occur in 3% of cases of SUI repair (4).

The safety and efficacy of polypropylene as an appropriate mesh material has been called into question, with the tendency of the material to induce visceral adhesions and erode surrounding organs being noted (5). These complications resulted in widespread restrictions on the use of mesh implants globally with the Health Service Executive (HSE) in Ireland, pausing the use of vaginal meshes in the treatment of SUI and POP in 2018 (6). Hundreds of women were left in a chronic condition due to the vaginal mesh injuries, experiencing chronic pain, relentless infections, incontinence, bleeding and depression from those who experienced mesh complications (7).

This pause remains in place today in Ireland and has inadvertently left another cohort of female patients who are now unable to access adequate treatment for their debilitating SUI symptoms. Some of these Irish women are now travelling abroad in order to access MUS procedures as Ireland remains the only EU country not to have resumed the procedure under strict regulations (8). There is a clear need for an alternative material to Polypropylene mesh, which offers patients an effective treatment option for SUI, without requiring them to take on the risk of erosion that is associated with current mesh products.

My Summer 1 Research Project aims to understand the effect of different sling materials on pelvic organ tissue. This is done by developing a new testing setup which simulates the erosion of soft tissue by PP mesh. PP mesh is tested and the impact of loading the mesh, as happens while coughing or running, on the rate of erosion was investigated.

Methods

For this research project, an erosion-testing rig previously developed by Prof. David Taylor in Trinity College Dublin in (4), was adapted. Taylor had been investigating the erosion of soft tissue by the edge of a PP mesh. This is a worst-case scenario setup which would only occur if the mesh were to become twisted inside the woman's body, resulting in the edge of the mesh cutting into the surrounding pelvic organ tissue (3).

For this project, the rig was adapted to investigate erosion in the more likely in-vivo scenario, where the face of the mesh is in contact with the pelvic organs e.g. the urethra and vaginal wall. The adapted rig setup is illustrated in Figs. 1-3.

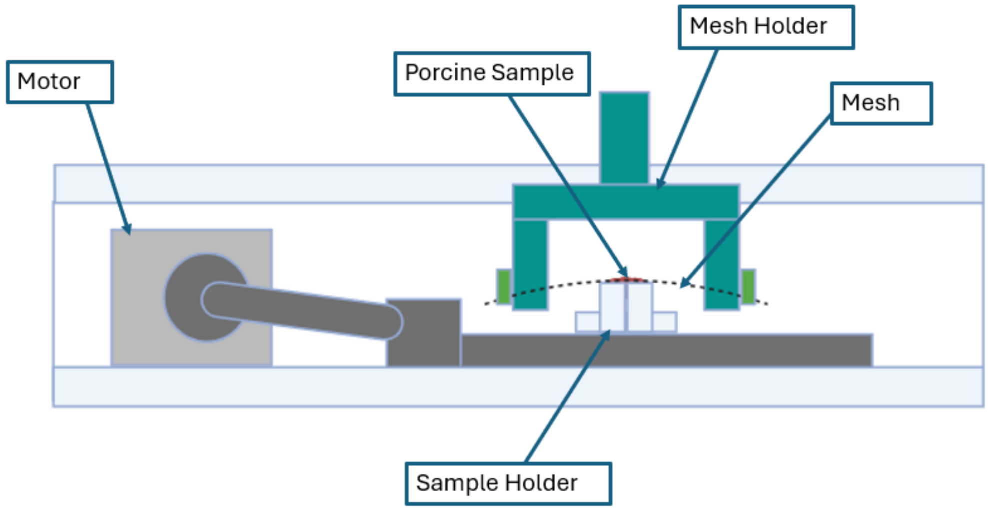

Figure 1. Schematic of the adapted erosion rig setup showing the porcine sample sitting in the sample holder with the mesh resting on top. The motor pushes the samples back and forth, moving in contact with the face of the mesh which remains still. Made using BIoRender.

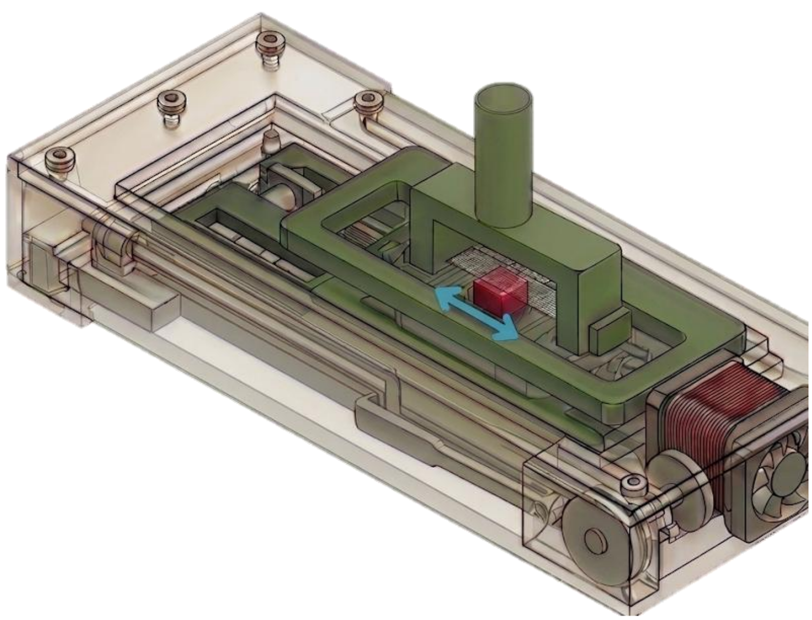

Figure 2. Isometric schematic of the adapted erosion rig showing the mesh in contact with the porcine tissue sample which is moved back and forth by the motor. Made using Gemini.

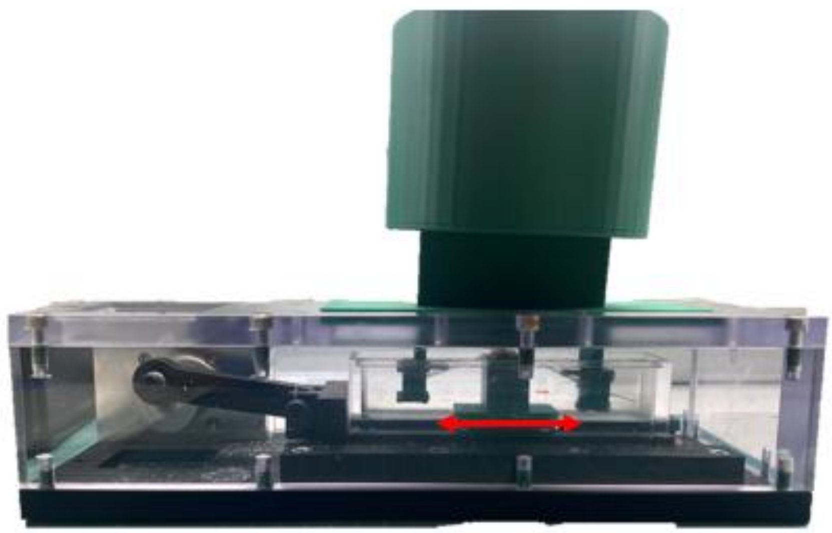

Figure 3. Side view of the adapted erosion rig. The motor moves the sample back and forth along the red arrow. The mesh rests on top of the sample. Weights are added into the bucket in order to apply different loads to the mesh.

Porcine tissue is used in this experiment due to its wide availability as a soft tissue. The setup of the erosion testing rig is such that a 1cm^3 porcine sample is moved back and forth at a cycle rate of 1 Hz while it is in contact with the face of the mesh. The sample sits 2mm above the edge of the sample holder as is shown in Fig. 4 (a) & (b), with tabs on the sides of the sample holder indicating 2mm and 1mm above its edge. The number of cycles in the rig, required for the sample to decrease in height by both 1mm and 2mm, were recorded. This 2mm decrease in height following testing can be seen in Fig.4 (c) & (d).

Three different loads of 5.9, 10.8, and 15.7N were applied in this experiment as this is the range of expected in-vivo loads (9). The lower end of this range (≈5N) is estimated to be the load experienced by the mesh while standing, while the higher end of this range (≈15N) relates to the loads experienced while coughing or sneezing. However, it is worth noting that very limited work has been done in this area, and more work is required in order to accurately determine the loads experienced in-vivo by an MUS.

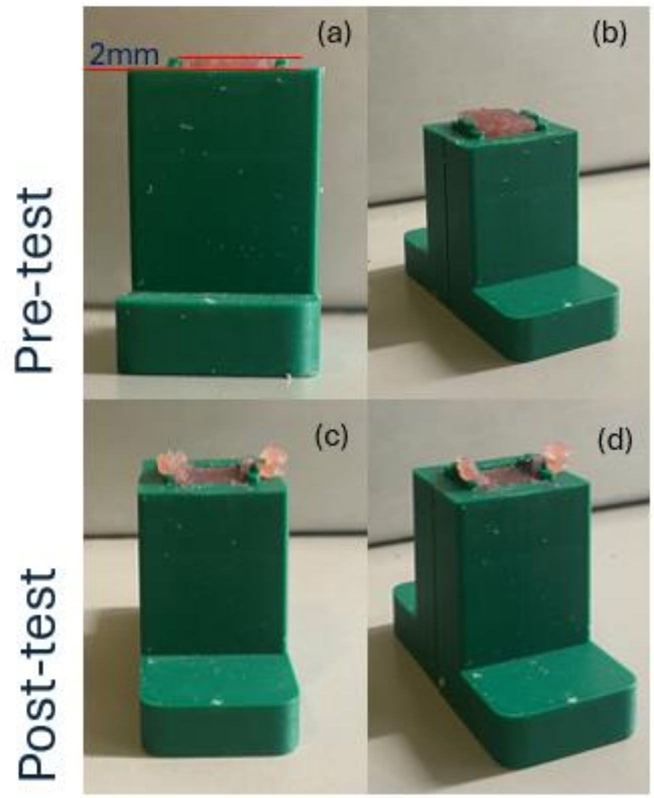

Figure 4. (a) & (b): The 1cm³ porcine sample sitting 2mm above the edge of the sample holder. (c) & (d): Porcine sample decreased in height by 2mm following testing.

The erosion testing protocol is summarized as follows:

- A 1cm^3 sample of porcine tissue was cut, hydrated in Phosphate Buffer Saline for 2 minutes and placed in the sample holder where it sat 2mm above the edge of the sample holder as shown in Fig 4. (a) & (b).
- A pretension of 5% is applied to the mesh when it is clamped in place to remove any slack.
- Load was applied to the system using up to three 0.5kg weights, which combined with the weight of the weight bucket amounted to loads of 5.9 N, 10.8 N and 15.7 N being applied.
- At 20-cycle intervals, remove the sample from the rig & observe the change in height of the sample, recording the cumulative number of cycles when the sample has been eroded by 1mm

- Place the sample back in the rig and continue to observe the change in height at 20 cycle intervals until a 2mm decrease is observed. Record the cumulative number of cycles required for this 2mm reduction in sample height.
- The 20-cycle interval was reduced to 10 cycles for 15.7N as it was found that the height was decreasing much more rapidly than with the other two load levels. This results in a lower standard deviation in the values recorded at 15.7N.

Results & Discussion

Following the collection of data in this experiment, a descriptive analysis was first done on the dataset in GraphPad to calculate the mean and standard deviation of each group. This data is shown in Table 1. There was a total of 12 samples at each load level providing a total sample size of 36 (n=36).

A mixed-effects model was used to calculate statistical significance between the groupings in the dataset, looking at the effect of loading the mesh and erosion depth on the number of cycles required. As would be expected, the number of cycles increased with a greater change in sample height i.e. more cycles were required to erode the sample by 2mm than 1mm.

Tukey's Test for multiple comparisons was used to calculate statistical significance within the erosion depth groups. This compared the differences between the number of cycles at each load level within the 1mm and 2mm groupings. Once more, as would be expected, when a greater load was applied, the rate of erosion increased, resulting in a decrease in the number of cycles for a given reduction in sample height. This is illustrated by the graph in Fig. 6. There was found to be a significant difference between the number of cycles at each load level at a depth of 2mm, however this was not the case at a depth of 1mm. It is hypothesized that the 1mm decrease in sample height occurred quickly across all load levels due to the initial compression effects of the loaded mesh being placed on top of the sample. However, as erosion occurs, the increasing effect of loading the mesh on the rate of erosion becomes clear at a 2mm decrease in sample height. This suggests that there is a greater risk of erosion during higher load activities such as coughing or running.

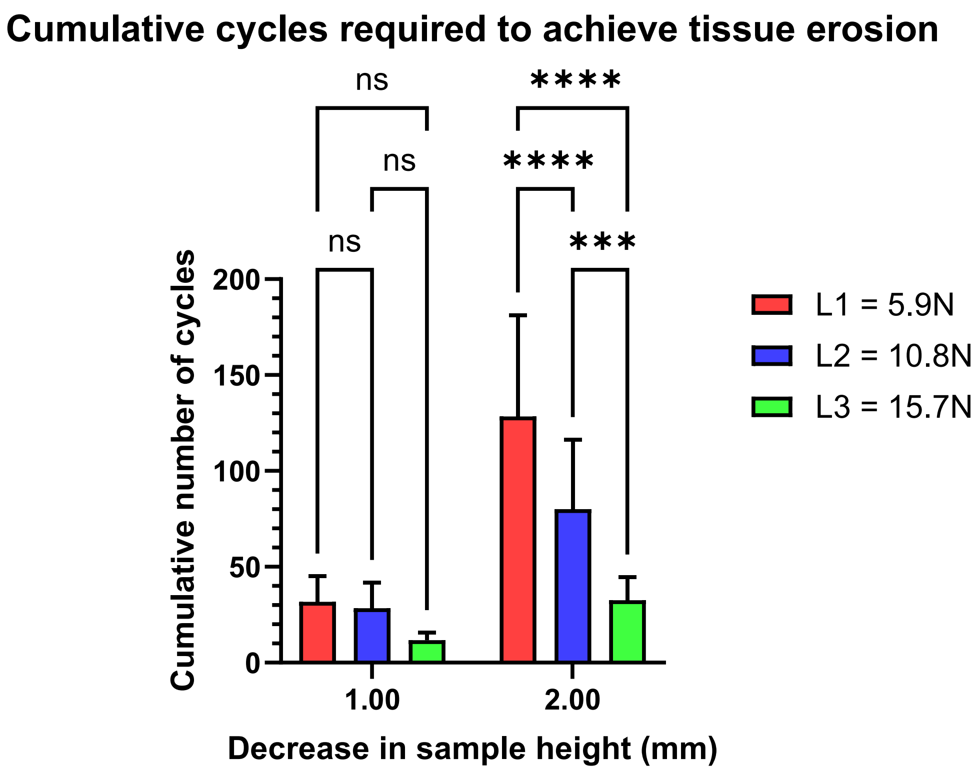

Figure 5. Graph illustrating the data shown in Table 1 where L1, L2 and L3 correspond to loads of 5.9, 10.8 and 15.7 N which includes the weight of the weight bucket in which the masses were held. (n = 36)

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

Erosion by the PP mesh was occurring as the soft tissue became caught in and pulled through the pores of the mesh. This can be seen in Fig. 5 (b) where the porcine tissue has become caught in the pores of the mesh following testing. Given this mechanism of erosion for the PP mesh, it was expected that a softer material without surface pores may reduce this risk of erosion. Some very initial testing of silicone-embedded PP (Fig. 5 (c)) found this to be the case. In contrast to the PP mesh, little to no porcine tissue remained on the silicone-embedded PP following testing. However, during this initial testing, the silicone itself began to erode. This was leaving some areas of the mesh exposed, with the potential to cause further erosion to soft tissue. It would be important that any material considered for use in the MUS, would not become damaged itself through contact with the soft tissue, as occurred with the silicone-embedded PP.

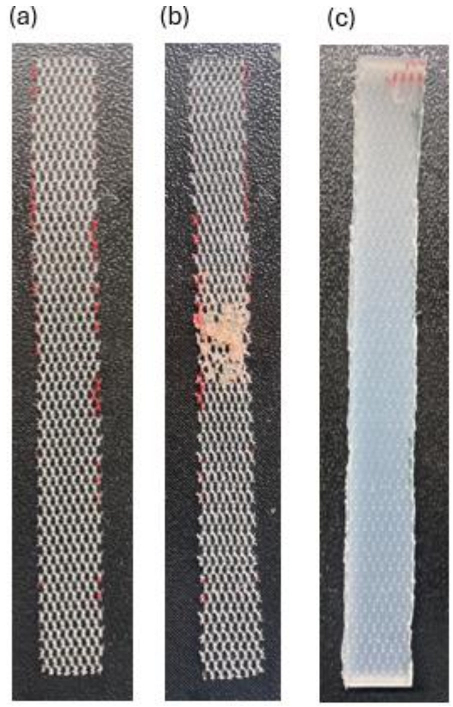

Figure 6. (a) PP mesh sample before testing. (b) PP mesh sample with tissue caught in the pores following testing. (c) Silicone-embedded PP mesh sample before testing.

Conclusion

This research project demonstrated an experimental erosion testing setup and protocol which can be used to quantify the erosive properties of materials while in contact with soft tissue. Alternative materials to PP mesh can now be tested using this setup and their results compared to these PP mesh results as a benchmark.

The effect of loading the mesh on the rate of erosion was demonstrated in this experiment. Higher rates of erosion at higher loads suggest an increased risk of erosion during activities which place additional loads on the bladder and urethra e.g. running.

The mechanism of erosion by PP mesh during this experiment suggests that a softer material without surface pores may reduce the risk of erosion. Future work would look to identify an alternative material to PP mesh which avoids this risk of erosion, which possesses similar strength to PP mesh to ensure efficacy in treating SUI, and which does not become damaged itself through contact with pelvic organ tissue.

SUI is a condition which is hugely debilitating to so many women in Ireland and across the world. It is vital to ensure that these women are presented with better treatment options which don't require them to make a choice between risking vaginal mesh injuries and continuing to suffer with the symptoms of SUI.

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Supervisor's signature: Tríona Lally

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