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UNIAXIAL TENSILE PROPERTIES PRIOR TO AND AFTER RESORPTION OF A PARTIALLY DELAYED ABSORBABLE MESH FOR VAGINAL REPAIR OF PELVIC ORGAN PROLAPSE

Hypothesis / aims of study

A recent vaginal mesh kit for pelvic organ prolapse, Prolift +M™ (Gynecare, Somerville, NJ), has been engineered to reduce host mesh burden by replacing a portion of the mesh with delayed absorbable fibers. As meshes with increased stiffness have been associated with increased rates of erosions and complications, we hypothesized that the resorption process would reduce mesh stiffness. Thus, we aimed to determine the uniaxial tensile properties of the mesh pre- and post- absorption.

Study design, materials and methods

Five separate sterile mesh samples of Prolift + M™ were divided in half, and one half underwent a resorption process as described by the manufacturer. The ex-vivo resorbed and unresorbed mesh specimens were loaded to failure to determine stiffness, failure load, and relative elongation at failure. Additional samples underwent 3 separate protocols for cyclic loading to determine permanent deformation with submaximal cyclic loading. Gynemesh PS™ as Prolift™ (Gynecare, Somerville, NJ) underwent the same resorption and testing as a control. Its permanent polypropylene fibers should not be affected by the resorption process.

Results

The load-elongation curves demonstrated a bilinear response with a period of lower stiffness (N/mm), followed by a period of higher stiffness (figure 1). The maximal load at failure was lower in Prolift +M™ after resorption (5.32 vs. 7.83N, p=0.008, figure 2). There were no other differences in the biomechanical properties between pre- and post-resorption specimens for Prolift +M™ including low stiffness, high stiffness, relative elongation at inflection point between low and high stiffness, and relative elongation at mesh failure. Gynemesh PS™ demonstrated no differences for any parameters before and after resorption. Prolift +M™ was significantly different from Gynemesh PS™ even prior to resorption.

Figure 1: Typical Load- Relative Elongation Curve with Bilinear Behavior

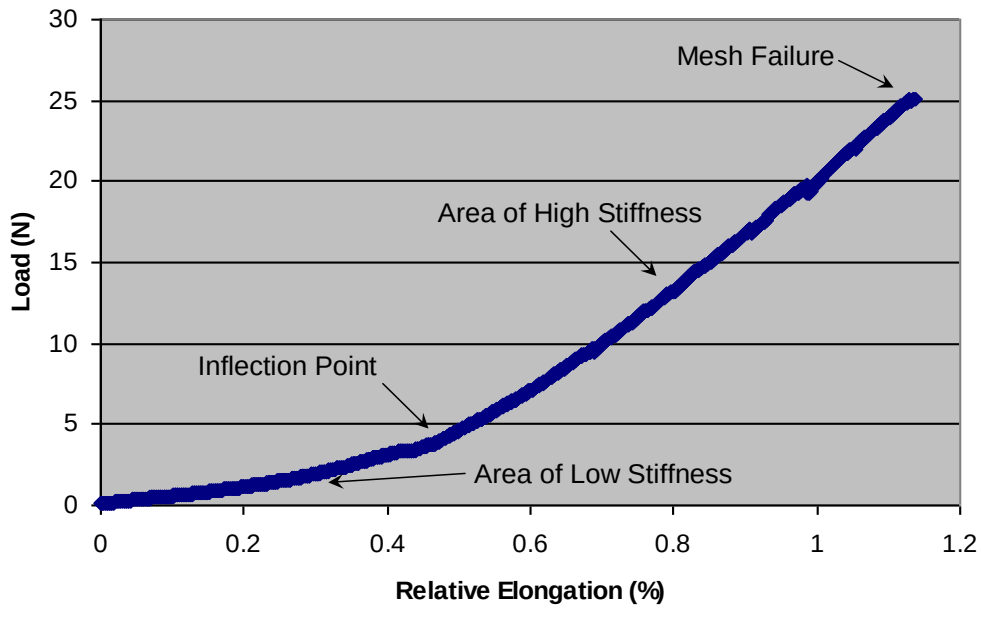
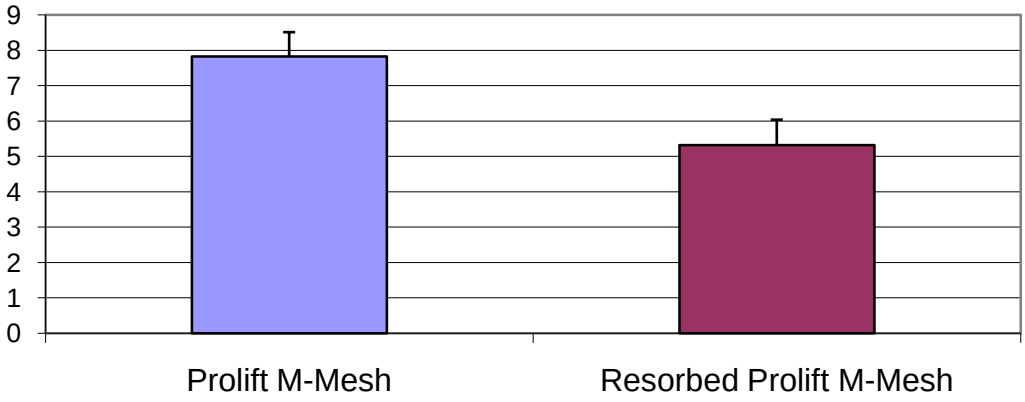


Figure 2: Maximal Load at Mesh Failure (N)



Note: There were no other significant differences between pre- and post-resorbed Prolift M-Mesh including low stiffness, high stiffness, relative elongation at inflection point, and relative elongation at mesh failure.

It was less stiff in both the high and low regions of the load-elongation curve (0.24 vs. 1.37N/mm, 0.01 vs. 0.29N/mm, p≤0.001) with a higher inflection point to high stiffness (46.5% vs. 25.0%, p=0.003). It had a lower failure load but higher relative elongation at failure (7.83N vs. 46.25N, 87.92% vs. 66.67%, p≤0.001). Compared to Gynemesh PS™, Prolift +M™ had higher permanent deformation with submaximal cyclic loading (44.29 vs. 5.66%, p≤0.001).

Interpretation of results

Resorption of the delayed absorbable portion of the Prolift +M™ mesh had little impact on the ex-vivo tensile properties of the material. However, it is significantly less stiff than Gynemesh PS™ regardless of resorption status, which may be predictive of lower patient morbidity. It is not clear whether the decrease in failure load will impact clinical outcomes such as surgical failure and recurrence of prolapse. Further experiments are underway to define in vivo behavior.

Concluding message

Although designed to reduce the resultant mesh burden experienced by the patient, there is little evidence that resorption of the delayed absorbable filaments of the Prolift +M™ mesh have any effect on the tensile properties of the mesh. The only difference after resorption is a reduction in the maximal load at mesh failure, a property with no clinical benefit. Prolift +M™ is significantly less stiff than Gynemesh PS™, the gold-standard pelvic mesh, which should help reduce mesh erosions when compared to this product.

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What were the subjects in the study?	**NONE**