

Biomechanical properties of raw meshes used in pelvic floor reconstruction

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Abstract Female urinary incontinence and pelvic organ prolapse are common conditions. The aim of this study was to assess the biomechanical properties of raw meshes commonly used in pelvic floor surgery, particularly the effects of cyclical loading on these meshes. The material properties of nine different types of surgical meshes were examined using uniaxial tensile tests. The strength and extensibility of the mesh designs differed considerably. Most mesh types exhibited curvilinear loading curves. Cyclical loading of mesh samples produced significant permanent deformation in all mesh designs. This non-recoverable extension ranged from about 8.5% to 19% strain. Hysteresis also varied considerably between materials from 30% to 85%. All mesh groups tested for their biomechanical properties displayed differences in results for failure load, stiffness, non-recoverable extension and hysteresis.

Keywords Biomechanics · Hysteresis · Polypropylene · Surgical mesh · Viscoelasticity

Introduction

Female urinary incontinence and pelvic organ prolapse are common conditions. Unfortunately, traditional native tissue surgery for these conditions, in particular pelvic organ prolapse, is associated with significant recurrence rates [1, 2]. In an attempt to improve outcomes and durability of surgery, synthetic meshes are becoming more popular. Various types of meshes are commercially available, and the risks and benefits have been previously documented [3]. Mechanical properties to failure of some meshes have been reported [4] and uniaxial tensile and flexural stiffness properties also assessed [5]. Cosson et al. [6] reviewed mechanical properties of available synthetic implants and demonstrated that no perfect product currently exists.

Although there is a paucity of data, a trend is emerging, linking the mechanical properties of meshes to the likelihood of post-operative mesh complications [6]. Understanding the mechanical properties of synthetic meshes may become an important consideration in their selection. Like connective tissues, polymers exhibit viscoelastic behaviour, and the ability of meshes to support the pelvic floor may depend on their degree of viscoelasticity under cyclic loading as much as their ultimate properties.

The aim of this study was to assess the biomechanical properties of raw meshes commonly used in pelvic floor surgery. In particular, we examined the effects of cyclical loading on these meshes. While mechanical testing to failure does provide information on tissue strength, cyclical loading may help identify ideal stress-shielding profiles.

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Methods

The material properties of nine different types of surgical meshes, Gynemesh, tension-free vaginal tape (TVT), Prolene, suprapubic arc (SPARC), Vypro, Dexon, Vypro II, Atrium, and intravaginal sling (IVS; Table 1) used in pelvic floor surgery were examined using uniaxial tensile tests. Each sample comprised a rectangle of mesh, each ends of which were gripped between two flat steel plates and mounted on a servo-hydraulic materials testing machine (8872, Instron, UK). Four samples of each material were prepared for testing.

A 250-N dynamic load cell was used to measure the forces applied to the samples subjected to cyclical length change and ramp tested to failure. The gauge length (distance between clamps) was standardised at 32 mm for all samples.

Individual specimens of each mesh type were of the same width. However, widths varied between different mesh types as some mesh types, including TVT, SPARC and IVS are manufactured with predetermined widths.

Tensile ramp loading to failure was conducted at an actuator displacement rate of 2 mm s^{-1} , providing a strain rate of 6.25%. The first major failure event was defined as an abrupt $\geq 10\%$ reduction in load, with the ultimate load defined as the peak force attained during extension to complete failure of the material.

Cyclical loading was achieved by subjecting each mesh sample to 15 sinusoidal cycles at 1 Hz. Sample strain was $20 \pm 5\%$. Post-test non-recoverable extension, the permanent set, was expressed as percent strain.

Testing to failure and cyclical loading was repeated on aged mesh samples (Gynemesh, TVT, Prolene, SPARC, Vypro, Dexon, Vypro II, Atrium and IVS) which had been exposed to air and stored at room

temperature for 12 months. The gauge length was 25 mm for all aged samples.

Results

Of the nine mesh types, six tended to fail in a single catastrophic event (Atrium, IVS, Prolene, SPARC, TVT and Vypro II), whereas three (Dexon, Gynemesh and Vypro) tended to undergo multiple failure events prior to finally parting (Fig. 1). Table 2 presents the mean load at which the first major failure event occurred (defined here as an abrupt $\geq 10\%$ reduction in load), the ultimate load achieved by each mesh type and the strains at which these events occurred.

It is obvious that the strength and extensibility of the mesh designs differed considerably. Prolene was the strongest, at about five times the strength of Vypro II. IVS and Vypro were the least extensible mesh designs, only able to increase in length by about 50%, whereas TVT, Dexon and SPARC were able to withstand a doubling of their original length without failing.

Most mesh types exhibited curvilinear loading curves, in which the material stiffness started at relatively low levels, increased with increasing extension to finally become linear and displaying a relatively high stiffness. Prolene and IVS were the exceptions, with IVS displaying an initial, relatively high stiffness that gradually declined with further extension and Prolene had the same initial pattern, but changed to a high linear stiffness above about 50% of its failure strain (Fig. 2).

Cyclical loading of mesh samples at $20 \pm 5\%$ strain, 1 Hz, and for 15 sinusoidal loading cycles produced significant permanent deformation in all mesh designs. This non-recoverable extension ranged from about 8.5% (SPARC) to 19% strain (Dexon). At the levels of strain applied to the

Table 1 Biocompatible mesh material types

Product name	Material	Mesh type ^a	Company
Atrium	Monofilamentous polypropylene	Type 1	Atrium Medical Corporation, Hudson, NH, USA
Dexon	Multifilamentous polyglactin	Type 3	Davis and Geck, Montreal, Quebec, Canada
Gynemesh	Monofilamentous polypropylene	Type 1	Ethicon, Somerville, NJ, USA
IVS	Multifilamentous polypropylene	Type 3	Tyco Healthcare, Mansfield, MA, USA
Prolene	Monofilamentous polypropylene	Type 1	Ethicon
SPARC	Monofilamentous polypropylene	Type 1	American Medical Systems, Minnetonka, MN, USA
TVT	Monofilamentous polypropylene	Type 1	Ethicon
Vypro	Combined multifilamentous polypropylene and multifilamentous polyglactin	Type 3	Ethicon
Vypro II	Combined multifilamentous polypropylene and multifilamentous polyglactin	Type 3	Ethicon

IVS Intravaginal sling, SPARC suprapubic arc, TVT tension-free vaginal tape

^a After amid [15]

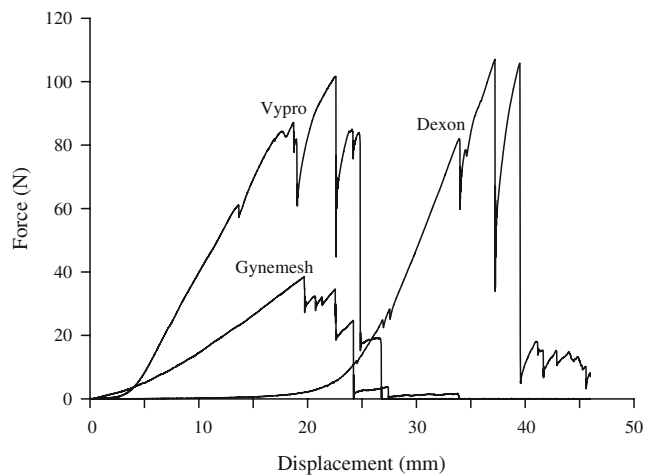


Fig. 1 Tensile ramp loading to failure of Vypro, Gynemesh and Dexon (Example of single typical curve for each material)

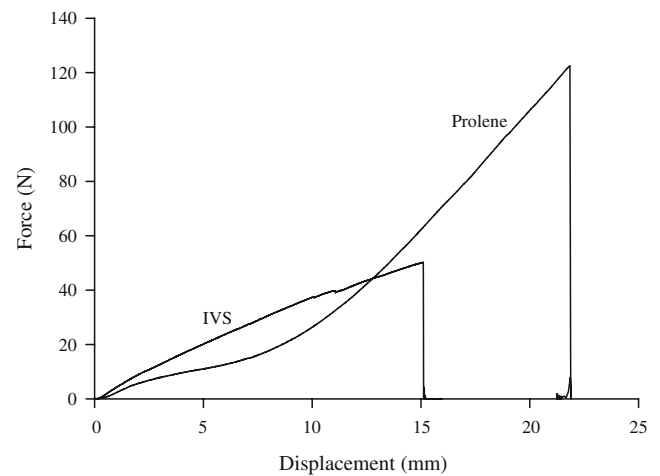


Fig. 2 Loading curves of IVS and Prolene. A displacement of 32 mm was equivalent to a strain of 1 (=100% elongation)

mesh samples the minimum loads experienced by the samples were broadly similar (range 0–3 N), whereas the peak loads varied markedly (Table 2). Hysteresis also varied considerably between materials, approaching 85% in Vypro II and as little as about 30% in IVS.

Discussion

Biomechanical properties of biological materials are determined by elasticity, viscosity and plasticity. Vaginal tissue is more viscoelastic [7, 8] in comparison to tissues such as tendons [9]. Viscoelasticity can be defined by the degradation of stress under constant deformation (stress relaxation) or the increase in deformation for a constant stress (creep). The degree to which these occur may be characterised by

the amount of energy lost during a loading–unloading cycle or hysteresis [10]. A stiff material with low viscoelasticity could provide excessive stress-shielding to the tissues, while one that loses large amounts of energy during normal cyclic loading, or displays excessive creep, may fail to adequately support the pelvic floor. It is expected that in vitro tests of raw synthetic mesh will display different properties compared to in vivo implanted mesh which has undergone tissue incorporation.

All mesh groups tested for their biomechanical properties displayed differences in results for failure load, stiffness, non-recoverable extension and hysteresis. The hysteresis loop represents the energy lost during cyclical loading. Polymers exhibit viscoelastic behaviour. The behaviour is rate dependent with the strength or stiffness subject to loading rates. Elastic material is independent of rate, with no resulting hysteresis loop. A small loop,

Table 2 Physical and mechanical properties of the nine mesh types studied

Mesh type	Mean mesh width (mm)	Load (N)		Strain (e/l %)		Load at 25% strain (N)	Offset (mm)
		Ultimate	First major failure	Ultimate	First major failure		
Gynemesh	12.0	37.5±1.0	37.5±1.0	63.4±0.8	63.4±0.8	10.0	3.2
TVT	11.5	77.0±3.7	70.8±9.3	113.4±3.0	111.6±4.6	3.0	3.5
Prolene	12.4	122.0±2.8	122.0±2.8	66.6±1.8	66.6±1.8	16.0	4.0
SPARC	10.9	66.8±6.7	66.8±6.7	135.3±7.2	135.3±7.2	4.1	2.7
Vypro	14.2	100.0±1.4	81.7±2.9	74.1±2.3	57.2±2.3	25.0	5.0
DEXON	14.0	105.8±7.0	78.0±11.5	125.3±5.6	110.0±7.9	0.1	6.0
VYPRO II	12.2	24.5±1.0	24.5±1.0	81.3±5.4	81.3±5.4	0.7	4.0
ATRIUM	12.5	95.4±7.3	95.4±7.3	80.3±2.6	80.3±2.6	13.0	4.0
IVS	8.1	50.8±3.4	50.8±3.4	47.8±2.9	47.8±2.9	3.0	3.8

N=4 for all tests

e Extension, l original specimen length

therefore, indicates more elastic than viscous properties, and a large loop indicates more viscous properties.

Despite many mesh groups being composed of the same polymer, their biomechanical characteristics vary considerably. These variations may be due to differences in weave and mesh architecture, polymer size and pore size. In our study, mesh samples exhibited consistent intra-group results, in contrast to the findings of Dietz et al. [4] where some samples within each mesh group displayed moderate variance in stiffness and peak load. While there may be some variation in manufacturing, synthetic materials are more likely to be more uniform in quality than biological materials.

One difficulty when trying to determine optimal mesh properties for use in vaginal prolapse is that the biomechanical properties of normal unprolapsed vaginal tissue are not documented. Although Goh [8] proposed studies to assess such tissue, human ethics committee approval has not been granted and consequently the benchmark for what constitutes ideal biomechanical properties of mesh for use in vaginal surgery is unknown. Despite this, some understanding of vaginal tissue has been gained from studies on prolapsed tissues. Ettema et al. [7] compared the biomechanical properties of pre- and postmenopausal vaginal tissue from women with prolapse. There were few differences in biomechanical assessment between the groups apart from a significantly higher elastic modulus observed in the postmenopausal vaginal group. The elastic modulus is the relationship between stress and strain, and the higher the modulus, the steeper the stress–strain curve. Thus, in postmenopausal tissue the tissue was stretched less for a given increase in tension compared with pre-menopausal tissue. This appeared to be an age-related phenomenon, possibly related to tissue hydration and maturation of collagen-cross-links [11, 12].

Recent biomechanical testing on prolapsed vaginal tissues excised at prolapse surgery and cadaveric non-prolapsed vaginal tissue demonstrated a non-linear relationship between stress and strain, and very large deformation before rupture [13]. This indicated the vaginal tissue to be hyperelastic with a large deformation.

Previous examinations of full thickness anterior vaginal wall samples have demonstrated tensile strains of between 19% and 31% under applied stresses of 0.4 MPa (a stress that all tissues could withstand) [7]. It has been suggested that further insight into the biomechanical properties of normal human vagina may lead to the production of more functional prosthetics for use in surgery for pelvic organ dysfunction [14].

The results from the initial tensile tests at 32 mm on these nine meshes indicate that all are capable of such deformations without compromise. The stiffness profiles of some mesh types do, however, differ significantly from those for the vagina. As tested here when comparing load at 25% strain, IVS and Vypro would appear to provide high levels of stress-shielding to repaired tissues. Dexon, SPARC,

TVT and Vypro II appear to be very compliant at low loads, with Gynemesh, Prolene and Atrium having intermediate properties. Stress-shielding is defined here as the ability of the prosthesis to protect the weakened tissue from external loads. When mesh is used to augment prolapse surgery or as a midurethral sling, the mesh–tissue interface will help to determine the behaviour of the implant. An overly elastic mesh provides inadequate support when external forces are applied. Conversely, if a mesh is very rigid, the dynamic and functional properties of the vagina and pelvic supports may be compromised. Thus high levels of stress-shielding may mean a stiffer and possibly less functional vagina, and very low stress-shielding may provide inadequate support.

While the initial 32-mm mesh sample testing was performed with new samples recently removed from their sealed manufacturer packaging, subsequent testing of 25-mm non-implanted, aged mesh samples gave reproducible results with the exception of Dexon and Prolene. The peak load that Dexon could withstand was significantly reduced in these tests. In addition, the mean strain of Prolene at ultimate failure increased with aging of the mesh. These mesh samples had all been kept at room temperature in unsealed plastic bags for 12 months following the first analysis of the meshes. It would appear that the Dexon and Prolene meshes had deteriorated and weakened over time in the given environment. Further testing would need to be conducted of the Dexon and Prolene meshes at various times after removal from the manufacturer's packaging in order to confirm this observation. While these results indicate that the manufacturer's guidelines should be adhered to prior to implantation of the mesh if the intended biomechanical characteristics are to be realised, there is a suggestion that some mesh-types, especially polyglactin, may deteriorate over time and may be indicative of changes that would occur post-implantation.

Conclusions

This paper provides further information on the mechanical properties of each of these nine mesh designs. Further in vivo studies are required to assess the effect of implanted meshes on biomechanical properties of tissues.

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Conflicts of interest None.

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