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ORIGINAL ARTICLE

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Mechanical properties of urogynecologic implant materials

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Abstract Synthetic suburethral slings have recently become popular despite the risk of erosion commonly associated with synthetic implants. Some of these materials seem to have unexpectedly low erosion rates. Based on the hypothesis that erosion is due, in part, to biomechanical properties, we undertook an in vitro study. The biomechanical properties of eight non-resorbable synthetic implant materials, stiffness (slope, N/mm) and peak load (N) were determined from load vs. displacement curves. Open-weave Prolene mesh showed unique biomechanical properties compared to other tested materials. The tension- free vaginal tape had the lowest initial stiffness (0.23 N/mm), i.e. low resistance to deformation at forces below the elastic limit, whereas the stiffest implant tested, a nylon tape, reached 6.83 N/mm. We concluded that the TVT and other wide-weave Prolene tapes have unique biomechanical characteristics. These properties may be at least partly responsible for the apparent clinical success of the implants.

Keywords Biomechanics · Implant materials · Incontinence surgery · Prolene mesh · Stiffness · TVT

Introduction

Surgical mesh is widely used to replace or support native tissues in incontinence and prolapse surgery. The advantage of superior strength and durability, easy availability and versatility compared to autografts such as rectus sheath or fascia lata has to be balanced against an increased risk of infection and erosion [1]. Anecdotally, material stiffness has been associated with the likelihood of tissue erosion [2]. The stress transmission at the tissue–implant interface will be influenced by the biomechanical properties of implant and native tissue, respectively. Surprisingly, this issue seems so far not to have received any attention. An investigation of the biomechanical properties of implant materials seems timely in view of the recent resurgence of synthetic slings such as the tension-free vaginal tape (TVT).

This study examined the static uniaxial tensile stiffness and ultimate load of commonly used non-resorbable mesh biomaterials, including some specifically designed for suburethral sling placement.

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Materials and methods

The uniaxial tensile properties of the materials listed in Table 1 were measured using an MTS Mini-Bionix testing machine (MTS Corporation, Minneapolis, Mn, USA). The Mini-Bionix is a materials testing system designed to evaluate both synthetic and biomaterials for yield and ultimate strength, creep and viscoelastic characteristics, fatigue characteristics, elasticity and other biomechanical properties. Such systems are widely used in orthopedic and dental medical research and wherever the mechanical characterization of implant materials is of importance. In essence, its use for this study was limited to the stretching of samples at a steady rate until breakage while allowing constant electronic registration of load and displacement.

Eight materials were selected that are in current use for implants in urogynecology and which were locally available. Roller grips were designed and fabricated specifically for this purpose to avoid failure at the fixation line (Fig. 1), and this was successful in that all samples failed in the central part of the setup. Samples that slipped from the grips owing to inadequate fixation were discarded and not used in the evaluation.

A minimum of six samples were cut from all materials along the long axis of the material, i.e. the direction of greatest rigidity, with the standard width being 11 mm except for IVS (intravaginal slingplasty) and nylon tape, which were 8 mm and 6 mm respectively (as supplied). For implant materials that were not precut the meshes were fixed between layers of adhesive tape for fixation and then cut with a scalpel. Figure 2 shows microphotographs of the four materials that appeared to be of most clinical interest (TVT, IVS, Sparc and Nylon 66). Samples were initially tested in air at room temperature with a gauge length of 46 mm and a displacement rate of 1200 mm/min in order to

Table 1 Tested biomaterials (trade name and material) and suppliers

Product trade name	Material	Supplier
TVT	Polypropylene	Ethicon, Somerville, NJ, USA
Sparc tape	Polypropylene	American Medical Systems, Minnetonka, MN, USA
Prolene	Polypropylene	Ethicon
Mersilene	Polyester	Ethicon
IVS tape	Polypropylene	TYCO Healthcare International, Exeter NH, USA
Gore-Tex Mycro Mesh	Expanded polytetrafluoroethylene	WL Gore Associates Flagstaff, AZ, USA
Gore-Tex Soft Tissue Patch	Expanded polytetrafluoroethylene	WL Gore
Nylon 66	Nylon	Ethicon

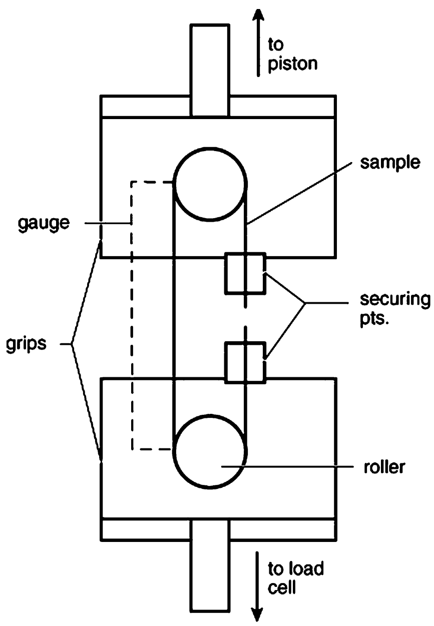

Fig. 1 Roller grips designed for the testing of implant materials

simulate physiologic conditions. Four materials (TVT, Sparc, IVS and Nylon) were also tested in a waterbath at 37°C. The stiffness (slope, N/mm) and peak load (N) for each sample were determined from the load versus displacement curves (Fig. 3). The investigators were not blinded against sample type.

Kruskal–Wallis statistics on Minitab version 13 were used to determine statistical significance, with the significance level set at $P<0.05$. Power calculations using http://calculators.stat.ucla.edu/powercalc/ demonstrated a power >0.9 to detect a statistically significant difference between the TVT and all other samples for the parameter 'mean stiffness', based on our own pilot studies and the assumption of six samples for each material.

Results

Table 2 summarizes results for the eight tested materials and the initial stiffness (load vs deformation of material prior to reaching the elastic limit, i.e., the point at which irreversible deformation occurs) and mean peak load (load at which rupture of material occurs) both at room temperature and in air. The load vs displacement curves revealed a wide variation of measurements for the different materials tested, but the variations within each group were much smaller.

Nylon tape showed the highest ultimate load at failure and linear behavior over the entire displacement. Mersilene and IVS were among the weakest materials tested and had a linear behavior with no plastic deformation (structural change with accompanying change in load/ displacement characteristics) prior to failure. The Gore-Tex materials also demonstrated an initial linear region but had a characteristic plastic deformation prior to failure with a reduction in stiffness. SPARC, Prolene and TVT demonstrated very low stiffness values in the initial part of the load vs displacement curve and a non-linear behavior with a well defined failure point.

Overall, the TVT had the lowest initial stiffness (0.23 N/mm), i.e. the lowest resistance to deformation at forces below the elastic limit. The differences between TVT and all other tested materials were highly significant for this parameter ($P=0.001$ or lower). The differences between SPARC and all other materials were also highly significant ($P=0.001$ or lower), except between Sparc and Prolene mesh.

Testing conditions (room temperature in air vs 37°C in water) did not significantly influence the mechanical properties of the materials tested. Characteristic load-deformation curves of the evaluated materials are shown in Fig. 4.

Discussion

The mechanical properties of synthetic materials used to replace or support native tissues play a vital role in their in-vivo function. Understanding such properties would appear to be an important factor in choosing the most appropriate material. To date, little engineering testing has been considered regarding the choice of the materials to be used in incontinence and prolapse surgery. This study examined the static tensile properties of some non-resorbable materials used for suburethral sling placement.

Although a multitude of synthetic materials have been used in fashioning a suburethral sling for the treatment of stress incontinence, none has become as widely accepted worldwide as the TVT. One reason for

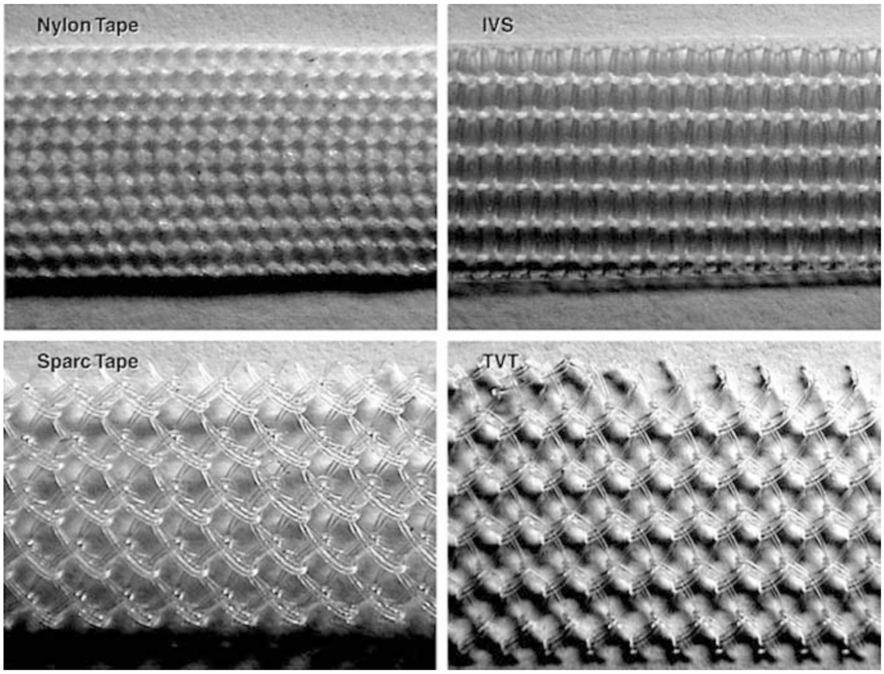

Fig. 2 Microphotographs of four tape implant materials (Nylon 66 *top left*, IVS *top right*, Sparc *bottom left* and TVT, *bottom right*). Magnification approx. 5–6-fold

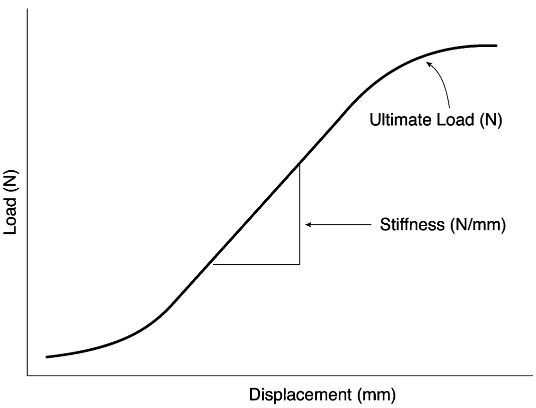

Fig. 3 Schematic load-deformation curve defining stiffness (N/mm)

this may be the reportedly very low likelihood of erosion [3, 4, 5], which is surprising given previous experience with synthetic slings [1].

The TVT, Sparc and Prolene materials demonstrated a non-linear behavior with a well-defined low stiffness region followed by a rise in stiffness and linear behavior. The elastic limit for these implants is only reached at an elongation of almost 50% of their initial length, although at relatively low forces. The TVT has the lowest initial stiffness, i.e. it exhibits less resistance to deformation at forces below the elastic limit. The one implant designed for suburethral placement that appears most similar in mechanical properties is the Sparc tape, which also is closest to the TVT in terms of macroscopic appearance (see Fig. 2). Both are mechanically similar to original Prolene mesh, which is not surprising given the close resemblance in material and specimen architecture.

A potential criticism of this study is that two pre-fashioned synthetic tapes, i.e. Nylon and IVS, were tested at a smaller width than all other samples, i.e. at 8 and 6 mm, as this is how they are sold. However, any potential correction for this difference in width would tend to accentuate the marked difference in stiffness observed in this study. This factor should not therefore influence our findings.

Another criticism may be aimed at the use of 'initial stiffness' versus stiffness beyond the elastic limit. The non-linear behavior of samples is probably due to alteration of their architecture, i.e. unraveling of the weave. However, the phenomenon is unlikely to be clinically relevant, as the forces exerted by intra-

Table 2 Mean stiffness and mean peak load for tested permanent materials. The differences between TVT and all other materials are highly significant ($P = 0.001$ or higher on Kruskal–Wallis test) for mean stiffness

Material	Mean stiffness (N/mm)	Mean peak load (N)
TVT ($n = 8$)	0.23 (StD 0.05)	68.1 (StD 25.8)
Sparc tape ($n = 8$)	0.53 (StD 0.15)	52.1 (StD 15.0)
Prolene ($n = 8$)	0.53 (StD 0.06)	56.4 (StD 5.9)
Mersilene ($n = 6$)	1.17 (StD 0.14)	50.3 (StD 6.3)
IVS tape ($n = 7$)	1.58 (StD 0.31)	46.2 (StD 4.2)
Gore-Tex Mycro Mesh ($n = 6$)	2.61(StD 0.11)	71.3 (StD 8.3)
Gore-Tex Soft Tissue Patch ($n = 8$)	2.68 (StD 0.24)	84.1 (StD 2.2)
Nylon 66 ($n = 8$)	6.83 (StD .28)	422.0 (StD 28)

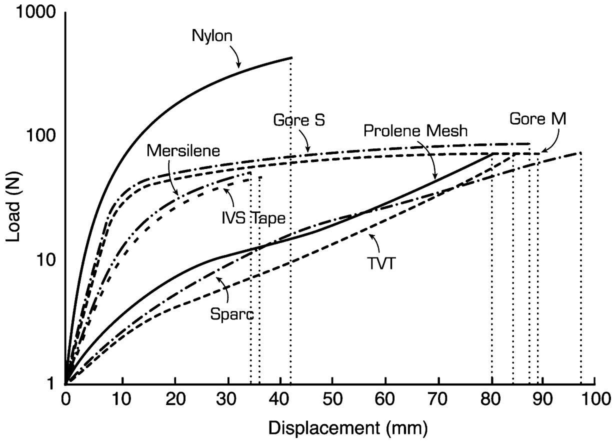

Fig. 4 Typical load-deformation curves for the eight tested permanent materials (log scale). The *vertical dotted lines* indicate the displacement at which failure occurred

abdominal pressure increases are thought not to exceed 10–16 N [6]. The elastic limits of all tested materials were well above this range.

There was a surprising degree of variation for both stiffness and peak load, especially between different samples of TVT and Sparc. As those samples were supplied by the manufacturers, this is probably not due to the methodology used in this study. Variations in manufacturing are a more likely explanation. However, the clinical relevance of this observation is doubtful, as peak loads and elastic limits invariably remained well above the physiologic zone defined above.

It has recently been stated that 'The particular innovation [of the TVT] was the concept of midurethral support without tension' [7]. Although this may well be true, the biomechanical properties of this new implant material may be contributing as much to its apparent success as placement, which appears to be quite variable [8].

To date, the focus as regards erosion has been exclusively on microscopic tissue reaction [9]. Although tissue reaction is clearly an important factor, common sense would suggest that any differential between the biomechanical properties of implant and surrounding tissue is likely to influence the likelihood of erosion. This introduces the concept of the tissue–implant interface, which plays an important role in all biomaterial interactions. A mismatch between implant and tissue properties does not allow for the appropriate transmission of loads at the interface and may attribute to the poor clinical results observed with some of these materials. A steel wire or band is clearly a highly inappropriate choice for a suburethral sling, considering the elasticity of the surrounding tissue. To take the analogy further, bolting this steel wire to the symphysis pubis would probably make matters even worse, creating a system with extremely stiff mechanical characteristics.

This study is limited in that we examined only the in-vitro static uniaxial tensile properties at one displacement rate. Considering that the ultimate load of all these materials requires deformations far beyond clinical relevance, it is likely that in-vivo failure occurs as a result of a fatigue mechanism, if at all. Fatigue of a material occurs under cyclical loading at a load level below the failure load. More complex multiaxis loading regimens may also reveal other differences between these materials.

Furthermore, the actual implant is only one component in the overall system put in place to achieve its aims clinically, in this case dynamic urethral compression. Suture material (if required) and anchoring tissues do contribute to the stiffness and failure mode of the system. Anchoring structures such as sutures may represent areas of increased stress, which could contribute to failure and help explain the phenomenon of suture pullthrough. In this context, the TVT and implants with similar properties may stand out even more, as the overall system of such a tape implanted into the retropubic space may be more elastic than the actual implant owing to the absence of anchoring sutures. Ultimately, the in vivo clinical performance will depend on many other factors, including surgical technique (especially extent of dissection), the mechanical properties of the native tissues, biological ingrowth/ongrowth to these implants, and not least on in-vivo loading characteristics.

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References

1. Iglesia CB, Fenner DE, Brubaker L (1997) The use of mesh in gynecologic surgery. Int Urogynecol J 8:105–115
2. Fenner DE (2000) New surgical mesh. Clin Obstet Gynecol 43:650–658
3. Ulmsten U, Johnson P, Rezapour M (1999) A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. Br J Obstet Gynaecol 106:345–350
4. Olsson I, Kroon UB (1999) A three year postoperative evaluation of tension-free vaginal tape. Gynecol Obstet Invest 48:267–269
5. Moran PA, Ward KL, Johnson D, Smirni WE, Hilton P, Bibby J (2000) Tension-free vaginal tape for primary genuine stress incontinence: a two-centre follow-up study. BJU Int 86:39–42
6. Schumpelick V, Klinge U, Welty G, Klosterhalfen B (1999) Meshes within the abdominal wall (in German). Chirurgie 70:876–887
7. Stanton S (2001) Some reflections on tension-free vaginal tape – a new surgical procedure for treatment of female urinary incontinence. Int Urogynecol J 12 [Suppl 2]:S1–2
8. Dietz HP, Mouritsen L, Ellis G, Wilson PD (2003) How important is TVT location? Acta Obstet Gynecol Scand (in press)
9. Falconer C, Soederberg M, Blomgren B, Ulmsten U (2001) Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women. Int Urogynecol J 12 [Suppl 2]:S19–23

Editorial comment

Understanding the biomechanical properties of synthetic meshes is important in choosing appropriate materials for a variety of urogynecologic procedures, particularly suburethral slings. Although this paper does not address histologic or in vivo findings, the biomechanical properties that seem to be important are mesh pore size, weave and stiffness. Although mesh may be made from similar materials, the final weave of the product may play a role in the ultimate outcomes or complications from slings. Further studies in animal or human models may be necessary to determine the importance of these biomechanical properties.