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Authors: Dietz, H.P., Vancaillie, P., Svehla, M., Walsh, W., Steensma, A.B., Vancaillie, T.G.
Institution: Pelvic Floor Unit, Royal Hospital for Women, and Orthopaedic Research Laboratory, Prince of Wales Hospital
Title: MECHANICAL PROPERTIES OF IMPLANT MATERIALS USED IN INCONTINENCE SURGERY

Aims of Study

Surgical mesh is widely used to replace or support native tissues in incontinence and prolapse surgery. The advantage of superior strength and durability 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), and it appears plausible that the interaction between implant and surrounding native tissues would partly be determined by their relative biomechanical properties. In this study we planned to quantify the initial stiffness and peak breaking load of commonly used implant materials, including some specifically designed for suburethral sling placement.

Methods

In an in vitro observational pilot study, the following implant materials were subjected to mechanical testing: Prolene, Mersilene (all Ethicon, Somerville, NJ, USA), Tension- free vaginal tape (Gynecare, a division of Ethicon), IVS tape (Tyco Healthcare International, Exeter, NH, USA), Nylon tape (Ethicon), GoreTex Mycro Mesh and Gore Tex Soft Tissue Patch 1 mm (WL Gore & Associates, Flagstaff AZ. USA). An MTS Mini- Bionics servohydraulic testing apparatus was employed, using the software 'Testware SX®' to program the setup. Roller grips were designed and fabricated specifically for this purpose to avoid failure at the fixation line. At least six samples were cut from all materials, with the standard width being 11 mm except for IVS and nylon tape which were 8mm and 6mm respectively. The gage length was 46mm. Materials were tested at 1200mm/min to simulate the commonest loading rate encountered, e.g. on walking. Load-deformation data was captured and initial stiffness and peak load data were measured.

Material	Mean Stiffness (N/mm)	Mean Peak Load (N)
Nylon 66	6.83 (StD .28)	422.0 (StD 28)
IVS	1.58 (StD.31)	46.2 (StD 4.2)
TVT	0.23 (StD .05)	68.1 (StD 25.8)
Gore-Tex Soft Tissue Patch	2.68 (StD.24)	84.1 (StD 2.2)
Gore-Tex Mycro Mesh	2.61 (StD.11)	71.3 (StD 8.3)
Mersilene	1.17 (StD .14)	50.3 (StD 6.3)
Prolene	0.53 (StD .06)	56.4 (StD 5.9)

Table 1: Mean stiffness and mean peak load for tested permanent materials. The differences between TVT and all other materials are highly significant ($p<0.001$) for mean stiffness.

Results

Table 1 shows results for the 7 tested materials and 2 main parameters initial stiffness (initial elasticity of material prior to reaching the elastic limit) and mean peak load (load at which rupture of material occurs). Characteristic load-deformation curves of the evaluated materials are shown in Fig. 1.

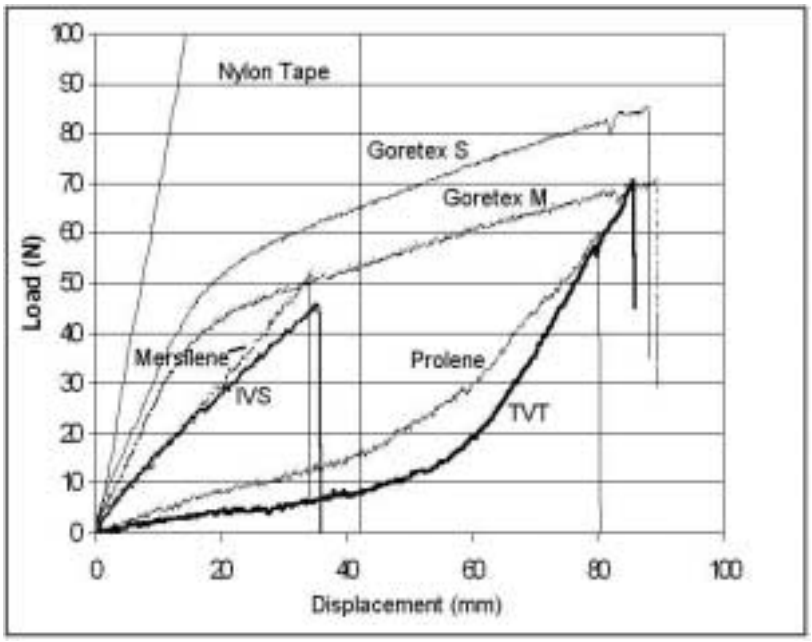

Fig. 1: Typical load- deformation curves for the seven tested permanent materials (n= 6).

Conclusions

One of the most interesting developments in incontinence and prolapse surgery over this last decade has been the introduction of the tension- free vaginal tape (TVT). While a multitude of synthetic materials has been used in fashioning a suburethral sling for the treatment of genuine stress incontinence, none has become as widely accepted worldwide. One reason for this may be the reportedly very low likelihood of erosion (3,4,5) which is surprising given previous experience with synthetic slings. As demonstrated in this study, the TVT shows unusual biomechanical properties when tested against other routinely used implant materials. Of the tested permanent mesh products it has by far the lowest initial stiffness, i.e., it exhibits less resistance to deformation at forces below the elastic limit. The elastic limit is only reached at an elongation of almost 50% of its initial length although at relatively low forces. The fracture point is reached at very high elongation and on exertion of a relatively high force. In terms of biomechanical properties the TVT stands out for its high elasticity.

It is hypothesized that the unusual biomechanical properties of the tension- free vaginal tape may help explain the fact that the material seems unusually biocompatible in its current use as a suburethral sling. If proven true, this hypothesis may have wider implications for the design and development of implant materials for use in the human body generally.

Literature

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