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ORIGINAL ARTICLE

On the relevance of uniaxial tensile testing of urogynecological prostheses: the effect of displacement rate

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Abstract
Introduction and hypothesis Uniaxial tensile testing is commonly used to calculate values of mechanical properties of urogynecological prostheses used in stress urinary incontinence and pelvic organ prolapse surgery in women. Clinical behavior of these products has been linked to their mechanical properties, hence influencing the clinician's preference for one brand or another. The objective of this study is to assess the effect of displacement rate used in uniaxial tensile testing on peak load, extension at peak load, and initial stiffness of Prolene® mesh, used as a proxy for urogynecological prostheses.
Methods Strips of Prolene® mesh measuring 10×30 mm were submitted to uniaxial tensile testing at the following rates: 1, 10, 50, 100, and 500 mm/min. Peak load, elongation at peak load, and initial stiffness were computed from load vs displacement curves at all displacement rates. The effect of displacement rate on these parameters was estimated by fitting linear trend lines through the data.
Results The displacement rate at which uniaxial tensile testing is performed has significant effects on the values of extension at peak load and initial stiffness, but not on the peak load.
Conclusions When urogynecological prostheses are submitted to uniaxial tensile testing, studies at more than one displacement rate should be performed. More importantly, these displacement rates should be within the range of applicability.

Keywords Mechanical properties · Mesh · Midurethral tape · Pelvic organ prolapse · Uniaxial tensile testing · Stress urinary incontinence

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Introduction

Synthetic midurethral tape (MUT) is now the most frequently performed surgical treatment for stress urinary incontinence in women. Different MUT brands are constantly being developed, whether retropubic, transobturator, or of the "minisling category." Polypropylene (PP) is now the exclusive material found in MUT [1], knitted as macroporous Amid type I [2].

Pelvic organ prolapse (POP) has a prevalence of 5–10 %, based on the finding of a bulge through the vagina [3]. POP traditional surgical repair using native tissue has been plagued with a relatively high recurrence rate, as almost one third of treated women would require reoperation [4]. In an attempt to improve success, synthetic mesh reinforcement was introduced in POP repair in 1996, long after its use in herniorrhaphy [5]. Since then, this practice has gained traction, as a recent Cochrane review concluded that mesh use reduces the risk of recurrent anterior vaginal wall prolapse on examination [6]. In the UK, gynecologists use a synthetic mesh in 75 % of recurrent anterior vaginal wall prolapse repair [7]. In the USA, the Food and Drug Administration (FDA) reported that, according to industry estimates, approximately one of three POP surgeries in 2010 used mesh [8]. Currently, the vast majority of POP meshes are PP based, Amid type I [9–11].

Contrary to the low risk of foreign body-related complications in MUT, the incidence of erosion in mesh reinforced POP repair was found to be 10.3 % in a recent meta-analysis [12]. As this rate is far from acceptable, manufacturers have continued to supply the market with “newer generation meshes” claimed to have better in vivo performance [11]. Distinct textile manufacturing of a mesh yields peculiar architecture for each product, which depends on its knitting, and, when present, its weaving or construct [13]. Such architecture will define the pore size, thickness, density, contact surface area, and individual mechanical parameters.

In this paper, we shall refer to MUT and POP meshes collectively as urogynecological prosthesis (UP). Most available data about mechanical or biomechanical (i.e., after implantation in the living) properties may be found in peer-reviewed publications where such products were tested after they became available in the market. Tests include uniaxial tensile testing, suture pull-through strength, burst strength, and tear resistance. Uniaxial tensile testing, whether cyclical or not, has been the most commonly used tool to compare mechanical properties of UP. Briefly, it consists of loading the ends of UP (or a cut piece) into opposing grippers. Force is then applied in one direction at a certain constant preset displacement rate until irreversible damage occurs, followed by the breakage of the UP. The test yields a load vs displacement curve that allows for the computation of peak load, extension at peak load, and initial stiffness. The definition and significance of these parameters were detailed elsewhere [14]. Conceptually, extension at peak load refers to “how loose” the mesh gets as it “starts breaking.” Initial stiffness is a measurement of “how quickly” a specimen is deformed under increasing load. Although stiffness refers to the relative resistance to stretching, it does not provide information on the ultimate strength of the mesh, which can only be measured at peak load. The association between mechanical parameters on the one hand and efficacy and complications of UP on the other has been consistently emphasized in the introduction and discussion sections of most publications addressing in vitro mechanical testing of UP [15–18]. By constantly introducing “newer” POP with modified mechanical characteristics, manufacturers have attempted to achieve a balance between improved host tolerability and a low risk of anatomical failure [17].

An important observation regarding the published experiments of uniaxial tensile testing is that the displacement rate at which testing is performed has not been consistent among different studies. In fact, rates of 5, 10, 50, and 120 mm/min have all been used, with mostly no attempted justification [9–11, 15–17]. Well outside this range, a displacement rate of 1,200 mm/min was used in only one study [18].

Type I knitted PP, the constituent of most UP, is considered a viscoelastic material. When subjected to uniaxial tensile testing, it is expected to exhibit a response that combines viscous (fluid-like) and elastic (solid-like) properties. Under a load, the corresponding stretch has an elastic component as well as a viscous component. While the mechanical characteristics of elastic materials do not generally depend on the deformation rate (or the speed by which the sample is stretched while tested), those of viscous materials do.

We took Prolene® hernia repair mesh (Ethicon, Gynecare, Somerville, NJ, USA) as a proxy for UP and evaluated the following hypothesis: that the values of mechanical parameters generated by uniaxial tensile testing significantly depend on the displacement rate used during the experiment. If proven, such a theory may challenge the numerical comparative results tabulated in many publications, with consequent impact on expected or previously assumed differential clinical outcome.

Methods

Strips of Prolene®, 30 mm in length and 10 mm in width, were cut along the same axis directly from the packaged product. The specimens were tested using the Hounsfield H100K-S universal testing machine (UTM). The machine has a 0.5 % accuracy of the applied force, 0.005 % speed accuracy, and 0.01 mm extension accuracy. A small, 1 kN load cell was used since the ultimate force of the material being tested is relatively low. Dual action pneumatically operated grips with rubber faced jaws (Hounsfield HT45) were used to hold the samples in place. These grips clamp the specimen on centerline and maintain position even when the specimen reduces thickness during testing. Following slack removal, uniaxial tensioning of the test samples was carried out until fracture, while force and extension data were collected for analysis. Three specimens were tested at 1 mm/min and six specimens were tested at each of the following displacement rates: 10, 50, 100, and 500 mm/min.

Raw data were collected in the form of load versus displacement plots. From these data, peak load, elongation at peak load, and initial stiffness for different displacement rates were calculated for all specimens. Initial stiffness was determined by calculating the slope of the linear region of the load versus displacement curvilinear plot. Interactions between these properties and the displacement rates were statistically examined. The two-tailed, paired Student's t test (ProStat version 2.5, Poly Software International, Inc., Pearl River, NY, USA) was used to compare the mean values of raw data for all cases tested. A $p<0.05$ was considered statistically significant.

To study the effect of displacement rate on peak load, extension at peak load, and initial stiffness, the raw data were plotted versus the displacement rate (common or base 10 log scale). Linear trend lines were fitted through the data and their equations were calculated in the form of: $y = a\ ln(x) + b$, where a' is the slope of the trend line and b' is its y intercept.

As this is a mechanistic study, it was exempt from Institutional Review Board review and approval.

Results

The values of peak load, elongation at peak load, and initial stiffness for all displacement rates tested are listed in Table 1. Our results are consistent within each group (for each displacement rate), as indicated by the acceptable value of standard deviation.

There is negligible effect of displacement rate on the peak load. A Pearson's product–moment correlation coefficient, R, is found to be near zero for such a trend line, indicating that peak load is independent of displacement rate (p=0.97) (Fig. 1).

There is a clear decreasing trend for the values of extension at peak load as a function of displacement rate. The goodness of fit of the trend line that connects the 5 data points is reflected by a correlation coefficient, R, of −0.9, yielding a two-tailed p value = 0.037 (statistically significant). Increasing the displacement rate from 1 to 500 mm/min corresponds to a 22 % decrease in the relative elongation of the mesh (Fig. 2).

There is a definite increasing trend for the initial stiffness vs displacement rate. The goodness of fit of the trend line that connects the 5 data points is reflected by a Pearson's product–moment correlation coefficient, R, of +0.98, yielding a two-tailed p value = 0.0025, i.e., highly statistically significant according to accepted statistical norms. Initial stiffness increases 26 % when changing the displacement rate from 1 to 500 mm/min (Fig. 3).

Discussion

Many researchers have questioned the clinical relevance of peak load, as testing to failure results in loads far beyond what is required of a mesh in vivo [18–20]. Interestingly, in our study, the peak load was the only parameter that is not affected by the displacement rate.

Although peak load of most UP is considered to be above physiological levels, it has been customary to compare extension at peak load (a reference point) of different UP, as a proxy to dimensional alterations under stress. Mesh extension, especially when calculated in cyclical loading, is considered a parameter of clinical relevance, as an elongated mesh is unlikely to protect the incorporated tissues [17, 19]. Consequently, our finding that extension significantly varies as a result of the displacement rate carries particular importance. In many studies, statistically significant differences in mesh extension of tested products were not far from the 22 % decrease we calculated as a result of changing the displacement rate [11, 15, 17].

Stiffness (or rigidity) is linked to many UP-related complications. Postoperative voiding dysfunction has been claimed to be related to a "stiffer" MUT [15]. In addition, erosion, a rather serious complication of UP, was cited to be a direct function of stiffness [11, 15, 18, 21]. At the other end of the spectrum, some researchers attributed "lower" stiffness of newer generation POP meshes to wrinkling and irreversible deformation, possibly leading to inefficacy and clinical failure [16, 17]. Yet, stiffness of all these products was calculated in an experimental setup where the speed rate is arbitrary. The threshold for difference in stiffness values of two UP specimens, above which efficacy or complication rate is affected, has not been determined. Consequently, the 26 % increase in stiffness seen with the extremes of rates used in our experiment continues to be relevant.

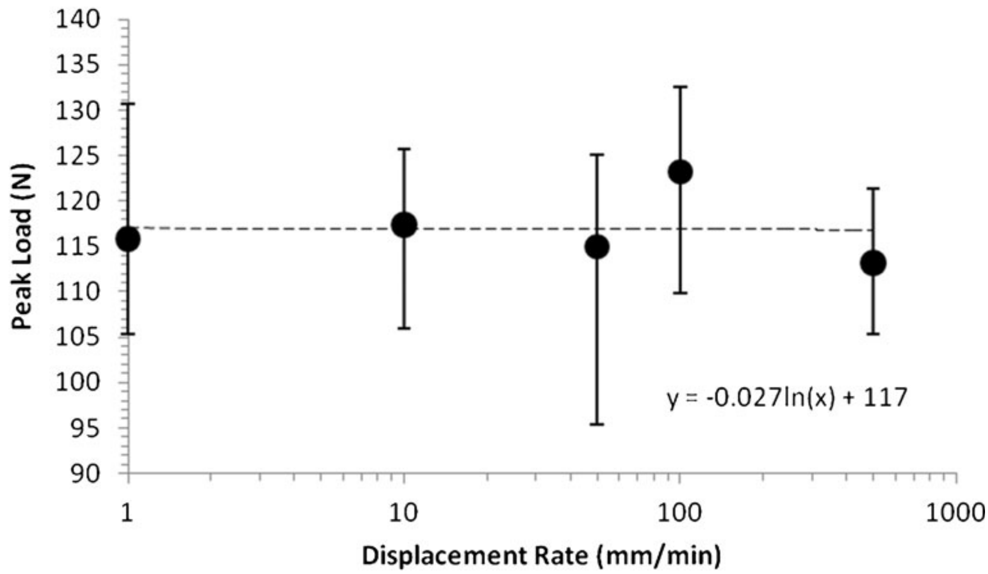
A seemingly reasonable argument is that results from studies addressing uniaxial mechanical properties are only valid for UP within a single study, i.e., when all studied products are subjected to the same experimental conditions [11]. We do not agree with this assumption, even when all products are tested at the same displacement rate. The change in the values of mechanical properties as a function of displacement rate cannot be assumed to be identical for all products. Put in simple terms, this change reflects the viscous element component in

Table 1 Mean values of peak load, extension at peak load, and initial stiffness for different displacement rates

Displacement rate, mm/min	Peak load, N	Extension at peak load, %	Initial stiffness, N/mm
1	115.8 (13.3)	266.1 (20.1)	4.2 (0.5)
10	117.4 (7.3)	237.8 (14.8)	4.7 (0.3)
50	115.0 (12.7)	220.8 (11.9)	4.8 (0.4)
100	123.2 (9.1)	229.1 (17.1)	5.1 (0.3)
500	113.2 (5.3)	223.2 (9.7)	5.3 (0.3)

Numbers in parentheses are the standard deviation values

Fig. 1 Semilogarithmic plot of the peak load vs displacement rate



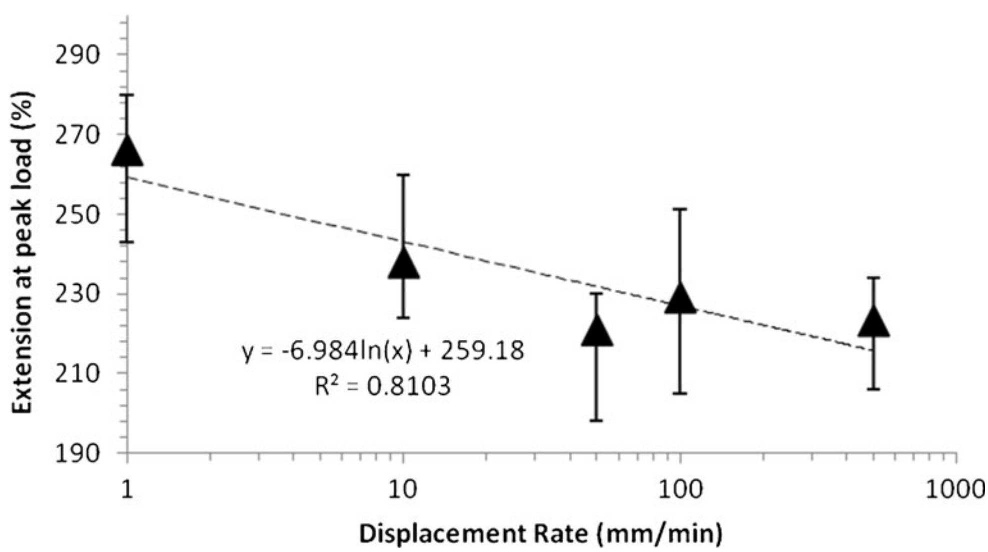
the viscoelastic material. To illustrate this point, assumed stiffness of a virtual product X is plotted as a function of displacement rate on the same graph as Prolene® (Fig. 4). An experiment where product X and Prolene® undergo uniaxial tensile testing at a displacement rate of 10 mm/min (where the two graphs intersect) would yield identical initial stiffness—and theoretically comparable potential erosion rates—all other factors being equal. Such results, however, are not reproducible at a different displacement rate, as the graph clearly shows. Product X has lower stiffness than Prolene® at 5 mm/min, but higher stiffness when the 100 mm/min rate is used.

Our results do not allow us to recommend against the use of uniaxial tensile testing of UP, although other methods of mechanical testing were suggested to provide a better correlation with clinical performance [20]. Specifically, as UP do not usually achieve failure in vivo, permanent (irreversible) elongation with cyclical loading could be more relevant than testing to ultimate failure [15]. Nevertheless, our data call for scientific justification of the conditions of uniaxial tensile testing of UP, specifically the displacement rate.

From a mechanical point of view, testing a product, whether it is a car seat or a car bumper, is performed within the “range of applicability” of the product. Obviously, these two cited examples, which are components of the same vehicle, are not subjected during their “applicability” to identical conditions. This leads to the following question: what is the range of applicability of UP? What is the “expected” displacement rate of UP after implantation in the human?

Using ultrasound imaging, the posterior urethra in stress incontinent women was found to move caudally, during a cough, at a velocity of 5.8±2.4 cm/s, while the anorectal angle moves at 4.1±1.5 cm/s [22]. This is equivalent to

Fig. 2 Semilogarithmic plot of the extension at peak load vs displacement rate



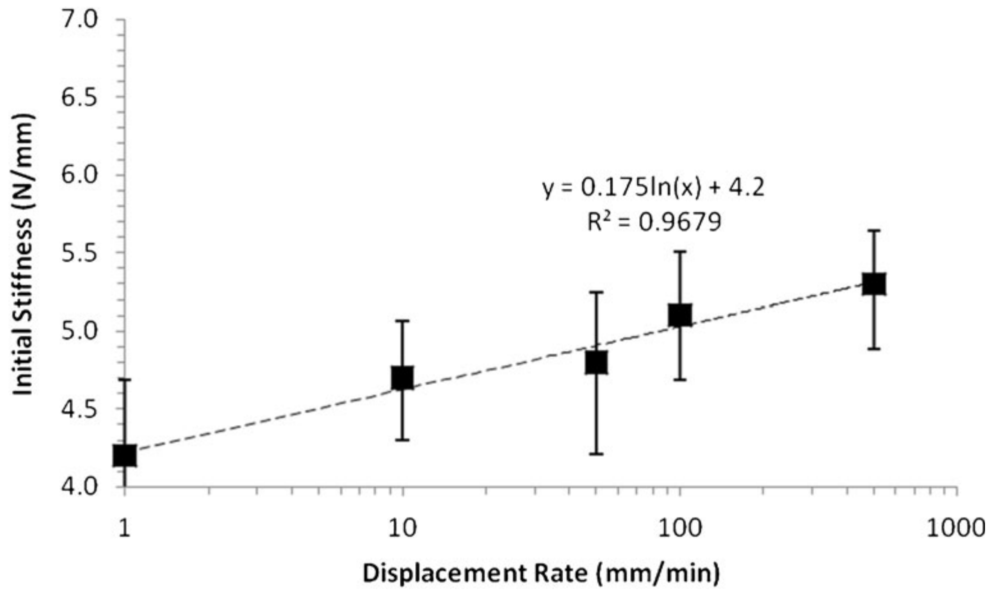


Fig. 3 Semilogarithmic plot of the initial stiffness vs displacement rate

velocities of 3,480 and 2,460 mm/min, respectively. These values are orders of magnitude larger than displacement rates used in most studies (5–120 mm/min), which is a cause for concern. Although there are no accurate data about rate of displacement of pelvic floor organs during different daily life maneuvers, cough-induced displacement is definitely within the spectrum of physiological loading conditions.

The very first publication addressing uniaxial tensile properties of UP was the only one, to the best of our knowledge, to present a justification for the implemented displacement rate [18]. At 1,200 mm/min (the largest rate ever reported in UP testing), Dietz et al. claimed simulation of "physiological conditions." Prior to the publication of this study, there was evidence that the bladder neck moves 2.9–5.4 mm caudally during a cough [23]. This translates into a rate comparable to that used by this group of researchers.

We believe that Prolene® is an acceptable proxy to UP, as it is an Amid type I knitted PP. In addition, its stiffness was found to be very close to that of Sparc™ (American Medical Systems, Minnetonka, MN, USA), a commonly used MUT [18]. We recognize that the change in mechanical characteristics as a function of displacement rate cannot be assumed to be identical for other UP. However, this actually highlights the relevance and accentuates the problem, as discussed above and shown in Fig. 4.

To the best of our knowledge, no previously published study addressed the effect of displacement rate on

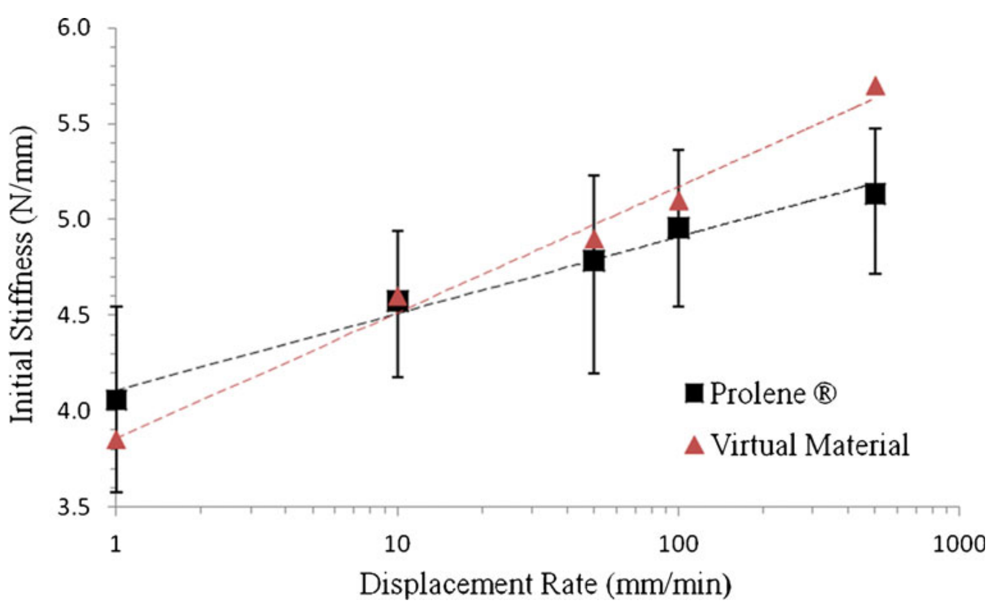


Fig. 4 Semilogarithmic plot of initial stiffness of Prolene® and that of a virtual material vs displacement rate

mechanical behavior of UP. Rubod et al. [24], in an attempt to standardize uniaxial tensile testing of vaginal tissue, used three different displacement rates in an animal experiment. They concluded that, at 1.2 and 12 mm/min, stiffness was 30 % lower than that calculated at 0.12 mm/min. This finding is in agreement with the viscoelastic nature of vaginal tissue.

One weakness of our study is not testing at rates proven to exist in the upper range of physiological conditions (2,460–3,480 mm/min). We do not believe, however, that this greatly affects the significance of our conclusion. It is most likely that the trends clearly demonstrated when increasing the displacement rate 500-fold would still exist when projected to a rate higher by less than one order of magnitude.

At present, it is safe to assume that MUT shall remain, in the foreseeable future, the treatment of choice for stress urinary incontinence in women [1]. As for POP surgical repair, the FDA safety communication regarding mesh use [8] is not expected to eliminate altogether the practice of mesh augmented repair, but rather to frame its use within benefit-risk boundaries according to individual cases. Therefore, one may assume continuous innovation (and mechanical testing) of new UP types. While studies about drug bioavailability, peak level, and half-life are performed through standardized methodology, mechanical testing of UP continues to lack uniformity. Not uncommonly, UP vendors have referred to mechanical characteristics as an argument for the superiority of a "most recent product" over a "not so recent product." The ideal mechanical characteristics of a UP, for best efficacy and lowest complication rate, are far from known. They most likely depend on the function and location of the UP in vivo: whether it is an anti-incontinence mesh or one that is used for support of the anterior vaginal wall, posterior vaginal wall, or vaginal apex. There is strong likelihood that data generated by mechanical testing, in the past as well as in the future, would influence the clinician's decision regarding the preference of one UP brand over another, hence the importance of our findings.

Conclusion

We demonstrated that the displacement rate at which uniaxial tensile testing of UP is performed has significant effects on the values of extension at peak load and initial stiffness. It is safe to assume that any peculiarity of mechanical characteristics of different UP depends on the displacement rate. When uniaxial tensile testing is performed, we recommend studies at more than one displacement rate (speed) of the UTM jaws, and most importantly within the range of applicability. The latter reflects movement of pelvic floor organs during daily life conditions. The upper end of this range is higher, by orders of magnitude, than what has been used in most studies.

Conflicts of interest None.

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