

Structural and thermal properties of polypropylene mesh used in treatment of stress urinary incontinence

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Besides material biocompatibility, it is possible to infer that both vaginal and urethral erosion rates associated with sub-urethral synthetic slings may be related to the mechanical properties of the meshes and also to their other properties. With the aim of understanding what distinguishes the different polypropylene meshes, used for the treatment of the stress urinary incontinence (SUI), their structural and thermal properties were investigated. Five different mesh types were tested (ArisTM, Auto SutureTM, AvaultaTM, TVTOTM and UretexTM). Differential scanning calorimetry (DSC) and infrared spectroscopy (FTIR) tests were performed. Furthermore, geometry (electron microscope), linear density and relative density (pycnometer) of the meshes were investigated. The meshes are made of the isotactic polypropylene homopolymer. ArisTM mesh presented the smallest fibre diameter, linear density and the level of crystallinity among all the meshes used for the treatment of the SUI. This study shows that there is a direct relationship between the fibre diameter, linear density, level of crystallinity and flexural stiffness of the polypropylene meshes used for the treatment of the SUI.

Key words: polypropylene mesh, stress urinary incontinence, stiffness

1. Introduction

Besides material biocompatibility, it is possible to infer that both vaginal and urethral erosion rates associated with sub-urethral synthetic slings may be related to the mechanical properties of the meshes and also to their other characteristics, e.g. the pore size at the fibre crossing [1]–[5]. Rigid meshes may not accommodate the surrounding tissue as a more flexible mesh would, which affects the mesh–tissue integration [4].

The urogynecologic meshes present a huge diversity of geometrical designs, knots [4]–[6] and morphology of the monofilament fibre [7]. Different

meshes may present different flexibilities. The stiffness may be determined by calculation of the slope of the stress–strain curve, using the data of uniaxial tension tests. Using this approach, DIETZ et al. [3] tested several meshes commonly used in urogynecology.

The stiffness of different materials can be compared, provided that the fibres used in the uniaxial tension tests have the same thickness [7]. For complex structures like meshes or nets, other variables such as geometry or thickness should be considered. This means that for meshes the tension test (tensile stiffness) does not provide enough information about the flexural stiffness. Comparative tests may reveal a tensile stiffness hierarchy different from the flexural stiffness hierarchy [8].

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Nowadays, polypropylene is considered to be the most adequate material for pelvic floor repair. When compared with other meshes, polypropylene meshes display the best mechanical characteristics, namely durability and flexibility [2], [6]. The polypropylene polymeric chain reveals a huge diversity, therefore both the structural variability of the polymeric chain and the eventual presence of chemical additives should be investigated. These factors may have an impact on the material's mechanical properties such as stiffness and durability [9]. During mesh fabrication from extrusion to knitting, the material undergoes some structural changes. There are some reports available in the literature on changes in the internal morphology of the surgical sutures and inguinal meshes. For surgical meshes the industrial processes, extrusion (fibre quality) and knitting (linear weave, fabric end and thermal treatment), require custom technology [7], [10].

There is a direct relationship between the mesh stiffness and crystallinity. The crystallinity levels depend on the stereochemical structure, polymerisation conditions and the presence of additives [9].

A surgical mesh must be compared with other surgical meshes. This is a difficult task due to the lack of standards and material specifications concerning both the polypropylene and the additives used. As an example, DIETZ et al. [3] performed uniaxial tension tests with 4.6-cm (length) samples and at a displacement velocity of 1200 mm/min. AFONSO et al. [8] carried out the uniaxial tension test with 4-cm (full length) samples and an actual 2-cm test body, at a displacement velocity of 5 mm/min. These authors also introduced the tape ring compression test (for flexural stiffness) with 8-cm samples (ring perimeter), at a displacement velocity of 5 mm/min. It is worth noticing that the displacement velocity, due to polypropylene viscoelastic nature and sample size, influence the results of the test.

There are no direct measurements of the stress suffered by the material in the sub-urethral region. The values of intra-abdominal pressure found in the literature concerning abdominal hernias [3] are, in fact, only estimations. The hypermobility of the bladder neck (linear dorsocaudal movement with >15 mm) verified after the surgical treatment is linked with an increase in failure rates and other problems [11]. The mesh collocation technique is tension free; however, there are hypothetical limits (in urogynecology) for the mesh flexibility. Those limits would be established by the preservation of prostheses' durability and resistance, which means that a sufficient tension is maintained over time to guarantee the support func-

tion expected. However, those limits are unknown and may not be unique.

Therefore, for the purpose of understanding what determines the mechanical behaviour [8] of the different polypropylene monofilament meshes used as implants for the treatment of stress urinary incontinence (SUI), the present study is focused on the analysis of their structural and thermal properties.

2. Materials and methods

The meshes studied in the current work were: Aris™, TVTO™, Uretex™, Avaulta™ and Auto Suture™. Aris™, TVTO™ and Uretex™ are indicated for the treatment of female SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

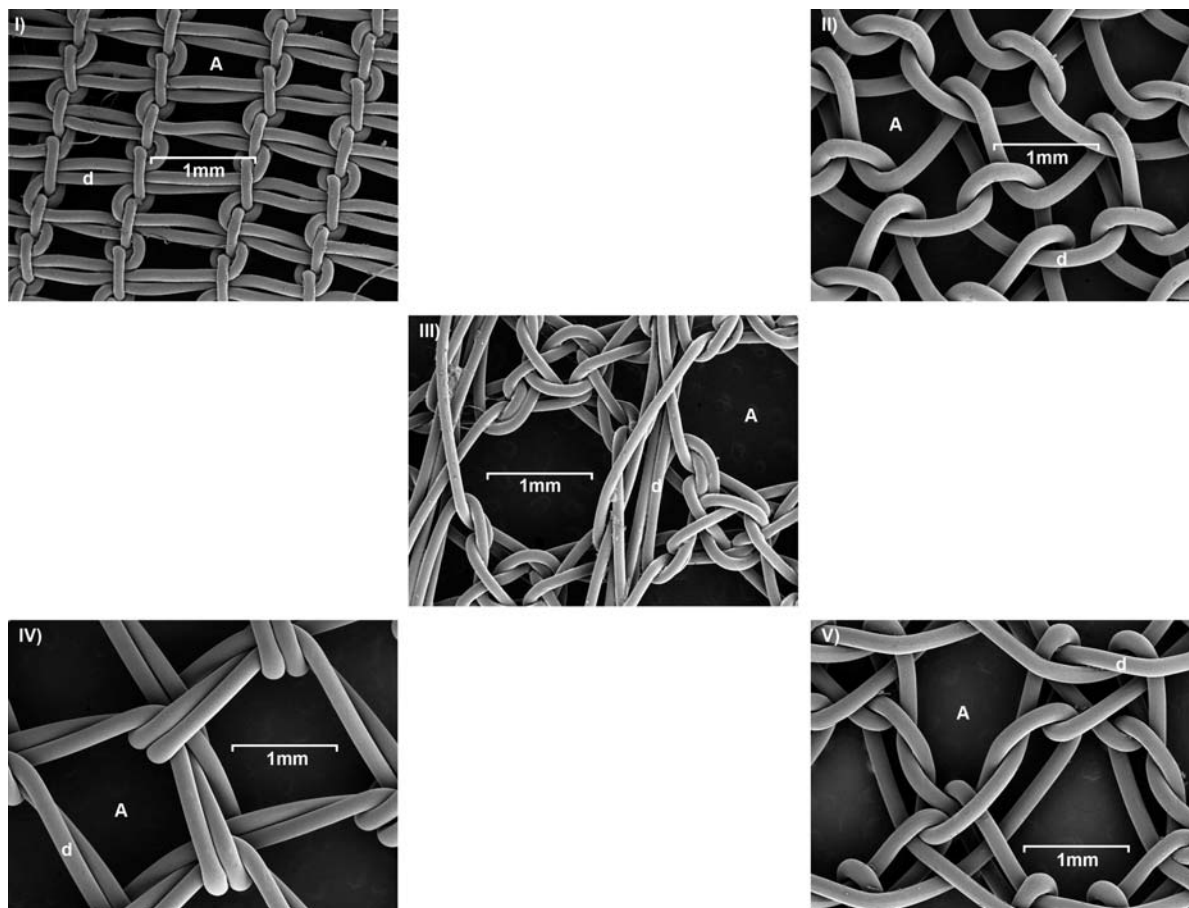
Two meshes were analysed for comparison purposes: the Avaulta™ used for tissue reinforcement and stabilization of the pelvic floor fascias associated with vaginal wall prolapse and, although not clinically tested for pelvic floor repair, the Auto Suture™ (Surigipro mesh, ref. SPMM35).

Sample length and area were measured with 2× optical magnification using a calliper (Mitutoyo). The weight and the relative density were measured using an electronic scale (Mettler Toledo, model AG 204; 0.1 mg precision) and a 5-ml pycnometer (Equilabor).

The measurements were taken using redistilled water at 25 °C. Polypropylene weight per area ratio (mg/mm²) as well as the linear density (mg/mm) were determined. The relative density of the polypropylene was measured based on the Archimedes principle (weight of displaced fluid).

The measurements of glass transition temperature (T_g), the level of crystallinity and the melting temperature (T_m) were performed using a differential scanning calorimeter (DSC), model Shimadzu DSC-50. The polymer crystallinity, commonly varying between 20% and 70%, was determined by DSC using the relation between the heat of fusion of the sample studied and the theoretical heat of fusion (209.2 J/g) of a polymer with a crystallinity of 100% [7].

The vibrational spectroscopy is a powerful tool for the identification of functional groups and macromolecular structural and conformational studies [12], [13]. The equipment used was the Fourier Transform Infrared (FTIR) spectrometer, Perkin Elmer 16PC, and the software Grams/AI 8.0 for spectral data analysis. The polypropylene samples were heated to prepare a film which was used for the analysis. The analysis of transmission FTIR results was performed under the



Details of five different meshes; A – area, d – fibre diameter; I – Aris™, II – Auto Suture™, III – Avaulta™, IV – TVTO™, V – Uretex™. Based on the study of AFONSO et al. [8]

following conditions: resolution of 4 cm^{-1} at the band of $4000\text{--}400 \text{ cm}^{-1}$. The absorption FTIR analysis was performed using the band of $1500\text{--}700 \text{ cm}^{-1}$.

The chemical tests were conducted according to the American Society for Testing and Materials (ASTM standards).

Based on the study of AFONSO et al. [8], the area of pore was measured using the electron microscope images (the figure).

3. Results

The relative density results of the polypropylene meshes are shown in table 1.

The values of polypropylene weight per area ratio (mg/mm^2), volume per area ratio, volume per length ratio and linear density (mg/mm) are shown in table 1. The weight and volume per unit length are given only for the SUI meshes (Aris™, Uretex™ and TVTO™).

To determine the thermal characteristics of the materials, the DSC curves were analysed. A compilation of the results is shown in table 2.

The FTIR spectra of all the samples (data not shown) exhibited the bands at 2870 and 2954 cm^{-1} belonging to methyl ($-\text{CH}_3$) chemical groups, the bands at 2839 and 2918 cm^{-1} belonging to $-\text{CH}_2$ and the bands at 972 and 1376 cm^{-1} belonging to $-\text{CH}_3$. Band at 1459 cm^{-1} belongs to $-\text{CH}_3$ or $-\text{CH}_2$. Band at 1158 cm^{-1} belongs to $-\text{CHCH}_3$ [12], [13]. The bands at 840 , 1000 and 1170 cm^{-1} were detected. None of the samples tested presented bands at 870 cm^{-1} (syndiotactic polypropylene), or at $720\text{--}725 \text{ cm}^{-1}$ (ethylene-propylene copolymer) [12], [13]. From these considerations it is possible to infer that the spectra of all the samples analyzed are typical of isotactic polypropylene homopolymer.

In tables 3 and 4, the results of AFONSO et al. [8] (fibre diameter, pore size and stiffness) concerning meshes used in SUI treatment are compared with the results of the current study.

Table 1. Pycnometer. Polypropylene relative density. Weight and volume per area ratio and per length ratio of mesh. PP weight. Linear density of the mesh

	Aris™	Auto Suture™	Avaulta™	TVTO™	Uretex™
Relative density	0.880	0.884	0.692	0.878	0.880
PP weight (mg/mm ²)	0.065	0.083	0.058	0.093	0.078
PP volume (mm ³ /mm ²)	0.073	0.092	0.072	0.106	0.089
PP weight (mg/mm)	0.780	–	–	0.963	1.018
PP V (mm ³ /mm)	0.886	–	–	1.096	1.162

Table 2. Differential scanning calorimetry (DSC). T_g – glass transition temperature, T_m – melting temperature, Δhf – heat of fusion, Lc – level of crystallinity

DSC	Aris™	Auto Suture™	Avaulta™	TVTO™	Uretex™
T_g (°C)	-10.44	10.63	14.79	-10.75	-7.50
T_m (°C)	-154.27	172.11	168.95	169.10	170.14
Δhf (J/g)	-92.59	-113.99	-98.50	-102.77	-107.30
Lc (%)	44.2	54.4	47.0	49.1	51.2

Table 3. Relation between flexural stiffness, linear density of the mesh, fibre diameter and polypropylene's level of crystallinity. Fibre diameter in percentage relationship. Based on study of AFONSO et al. [8]

	Low stiffness	High stiffness	
	Aris™	TVTO™	Uretex™
Linear density of the mesh (mg/mm)	0.780	0.963	1.018
Fibre diameter (%)	0.63	1	0.94
PP level of crystallinity (%)	44.2	49.1	51.2

Table 4. Relation between tensile stiffness and pore geometry. Based on study of AFONSO et al. [8]

	High stiffness	Low stiffness	
	Aris™	TVTO™	Uretex™
Approximate area (mm ²)	0.120	1.409	1.790

4. Discussion

The decades have seen a trial–error process carried out to produce, using the same surgical technique (sub-urethral sling), the urogynecologic meshes currently used in SUI treatment. This left an historical footprint full of complications and a shot at problem [1]–[6]. Nowadays the frequency of adverse effects is tolerable [3]–[6], but the fundamental properties of mesh, both mechanical and chemical, are not well known and only roughly described in literature (U.S. patents 4911165 and 4520822).

The stiffness of the material has been associated with the possibility of tissue erosion. Flexible and macroporous, polypropylene monofilament meshes

made specifically for urogynecologic applications seem to provide a better integration with human tissues when compared with other synthetic materials [2]–[6], [14].

Polypropylene biocompatibility was proven by the Food and Drug Administration (FDA) with a set of rigorous standardized tests [9]. It presents a mechanical integrity equivalent to nylon and better biocompatibility [7] and flexibility [3]. The high biocompatibility and the low cost were the main reasons for using polypropylene in biological prostheses [15].

For each material, mesh stiffness is related to mesh geometry, thickness and fabrication process (extrusion and knitting). The stiffness may also be altered by the use of different material specifications and additives. It is a fair assumption that the fibre diameter and the

linear density of the mesh influence more deeply the results of the tape properties during ring compression test than during the uniaxial tension test. This means that a change in thickness and/or linear density affects more significantly the flexural stiffness than the tensile stiffness [8].

The study of flexural stiffness in urogynecologic meshes was reported by AFONSO et al. [8] for the first time. Previous works were limited to tensile stiffness [3], therefore an available literature does not provide enough data to understand the effect of flexural stiffness (compared to tensile stiffness) on the erosion rate and on the SUI treatment success. It is still unknown which stiffness (tensile or flexural) is more important or whether one may compensate for the other to achieve the required performance concerning erosion rates and SUI treatment success. According to these authors the mechanical properties of the urogynecologic meshes are significantly different. Considering the SUI meshes, Aris™ presents a tensile stiffness significantly higher than Uretex™ and TVTO™; however, its flexural stiffness was significantly lower.

The polypropylene volume used for mesh fabrication, per length unit of mesh, may change the relationship between the fibre thickness, the number of fibres per area unit and mesh width. Using the same material specification, GAOMING et al. [10] reported that during the mesh knitting process, the linear density of a mesh is the principal factor affecting its mechanical properties, including the resistance and flexibility. The mesh with an inferior linear density has bigger inter-filament pores and greater flexibility.

For the meshes analysed, a reduction of the flexural stiffness is followed by a reduction in monofilament diameter. The same relation occurs in respect of the linear density (weight of mesh by length unit). An important remark about the current work, assuming the mesh width roughly the same, is that length-related parameters (linear density) can better explain the mechanical behaviour than the area-related parameters.

It can be said that in clinical practice the mesh length changes according to each patient needs, so that the whole area under pressure in the length direction (transversal), from the sub-urethral region to the anchoring point, is covered with the tissue. A different situation arises for mesh width, which is fixed and does not cover the entire length under pressure and has no anchoring points. So the mesh width is not taken under consideration because in the commercial products being available (mesh kits) it appears as a characteristic specific parameter of the product, and as a whole determines the mesh stiffness.

The previous geometric considerations cannot be applied to the Auto Suture™ and Avaulta™ meshes. In the case of these meshes, fibre thickness and mesh linear density cannot explain and/or compensate for the other factors involved. Therefore the load distribution through the mesh geometry, including the knots, the polypropylene polymeric structure, molecular mass, additives and thermal memory must be considered [7], [9].

In respect of the thermal memory during mesh knitting, the mechanical properties are influenced by temperature, which is the dominant factor, border adjustments and thermal exposure time. The heat adjustment during the knitting process allowed better mesh stability and flexibility [10]. After the mesh fabrication process (extrusion and knitting), the material can be sterilized with ethylene oxide, since thermal sterilization processes may alter the mechanical properties of the final product [7], [16].

According to Menezes and Steinheuser (U.S. patent 4520822), a random copolymer containing a small quantity of polymerized ethylene produced a desirable approximation of the mechanical properties of polypropylene monofilamentous surgical sutures. The resistance level (comparable to that of polypropylene homopolymer) was maintained with a smaller elastic modulus (or Young modulus).

The properties of the polypropylene homopolymer can be adjusted by the processing conditions and the catalysts, which change the level of crystallinity of the polymer. So, the mechanical properties of the polymer are connected with the level of its crystallinity and depend on its tacticity. It is worth noticing that the molecular mass also affects its mechanical properties [9].

The infrared absorption spectroscopy analysis allow us to infer that the samples analysed are isotactic polypropylene homopolymer, with or without an atactic portion [9], [17].

The thermal analysis (DSC) of the samples provided a variety of data: glass transition temperature (T_g), the level of crystallinity and melting temperature (T_m). This means that the polypropylene polymers used in mesh fabrication, although (hypothetically) chemically identical, may present differences in fibre morphology and thermal history due to the industrial processing. Moreover, chemical differences of molecular mass and polymeric structure [7], [9] are also possible.

It is worth stressing that in PUBMED indexed literature, polypropylene tacticity is not directly recognized as a biocompatibility factor and there is no reference to its stereoisomerism. The addition of atactic components to the isotactic polymer has, in principle,

the exclusively mechanical objective of reducing the elastic modulus by diminishing the level of crystallinity [9]. However, biological phenomena like polymer biodegradation [18] and acid–base properties [19] are associated with its tacticity.

The level of crystallinity of TVTO™ mesh made of Prolene™ suture fibre was 49.1% which is close to the value found in literature for Prolene™-0 (49.5%) [7]. This result is in a good agreement with manufacturer's claim that the Prolene™ fibre used in TVTO™ mesh has a diameter inferior to that of the fibres used in non-urogynecologic meshes.

The Auto Suture™ (Surgipro™) mesh has a level of crystallinity (54.4%) close to that of the Surgipro™ 4/0 suture fibre (51.5%) [7]. Currently, the technical specifications of these meshes are not available either in the literature or in manufacturer's instructions.

As shown in tables 1 and 2, relative densities of the PP meshes are not proportional to their levels of crystallinity. This relation may be due to different industrial processes (chemical additives and/or atactic components and/or effect of thermal treatments) [7], [9].

For the SUI treatment meshes (Aris™, TVTO™, Uretex™), the mesh geometrical data (fibre thickness and linear density) and the polymer chain chemical data remained compatible with the flexural stiffness findings of the present study. However, the mechanical behaviour of the Auto Suture™ and Avaulta™ meshes is still unknown. Auto Suture™ displays the geometry and knot design simpler than the other meshes, being the only one with low tensile and flexural stiffness [8].

It must be stressed that all factors make their contribution to the mechanical properties of the product and one factor may or may not compensate for the other in terms of the prosthesis required characteristics.

Furthermore, the rheology of polypropylene mesh may be understood in terms of its durability, function and perhaps future complications due to changes in mechanical properties caused by long-term usage. Polypropylene has been connected with mechanical erosion due to 'slippage', poor host tissues, or excessive scarring [20]. KOBELVEV et al. [21] report that one of the physiological functions of viscosity in living tissues is to prevent their breaking at fast deformations. Almost all biological tissues are viscous. The relaxation processes are influenced not only by the amplitude of the deformation, but also by the rate of deformation. Most living soft tissues, with several values of linear stiffness, are functioning in different ranges of physiological deformations. In the initial range of

deformations, soft elements are mostly involved. When deformation increases, stiffer elements play the main role preventing the tissue destruction.

The rheological properties of polypropylene are affected by mechanical and/or thermal fatigue. The continuous exposition to fatigue conditions may ultimately lead to failure. Some fundamental parameters affecting the fatigue process are the stress level, the load frequency, mesh geometry and the temperature. For the prostheses used in SUI, thermal fatigue and mesh geometry are very important issues. Polypropylene shows a large hysteresis in the stress–strain diagram, i.e. each load cycle produces a considerable heat output, making it vulnerable after successive loading. The meshes may deteriorate over time and may be indicative of changes that would occur as a result of implantation. To fully understand the effect of the coupling of mechanical fatigue (mesh geometry) with thermal fatigue on the rheological properties of in SUI prostheses, cyclic loading fatigue tests should be performed before the approval of a new mesh design [22], [23].

However, using the data available there is no way to know what would be the ideal mechanical properties of the synthetic prosthesis used in SUI treatment. The technical procedure or mechanical standards [3], [7], [8] remain to be defined.

The manufacturers do not provide stiffness or durability data for the meshes they produce and sell. Standardization could allow employing mechanical properties of the different meshes used in clinical practice for a critical and comparative analysis, thus providing the medical community with particular data to search for the ideal parameters and even personalized solutions. At the same time some knowledge about the industrial process could enable a faster product tuning.

5. Conclusions

Dealing with the polypropylene meshes used for the treatment of the SUI, this study shows that there is a direct relationship between fibre diameter, linear density, level of crystallinity and flexural stiffness.

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