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SOLID MECHANICS

EXPERIMENTAL INVESTIGATION OF LONG-TERM MECHANICAL RESPONSE OF SURGICAL MESHES

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ABSTRACT: The repair of the abdominal wall defects with surgical meshes is a universally procedure worldwide. This paper aims to investigate the influence of aging on the mechanical properties of three types of meshes made of polypropylene, like basic material and different additional materials. Quasi-static tensile test was performed on samples of baseline meshes and simulated aging samples. Our results showed that all basic meshes were orthotropic and presented different mechanical behaviour. It is not possible to conclude that one of the meshes has better properties than the others. The main observation was that when the meshes were exposed to aging, all investigated mechanical parameters decreased or increased in both directions according to different compositions and architectures of meshes. The changes in mechanical properties over time necessitate the creation of a guide for surgeons including results obtained after mechanical experiments. They can use it to choose the proper mesh according to type of hernia, age and condition of the patient.

KEY WORDS: Surgical mesh; Mechanical properties; Experimental study.

1 INTRODUCTION

The use of synthetic meshes for hernia repair is an accepted procedure worldwide. Hernia meshes and their qualities are described in the literature [1, 2]. Although the synthetic meshes have high tensile strength, several complications such as hernia recurrence, infection, pain and adhesions still prevailed.

In order to overcome the issues related to the application of synthetic meshes, composite surgical meshes were developed [3]. The composite meshes combine more than one type of material into their composition. These meshes are manufactured by some of three basic materials: polypropylene (PP), polyethylene terephthalate (PET) and expanded polytetrafluoroethylene (ePTFE), which are used in combination

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with additional materials such as titanium (Ti), omega 3, monocryl, polyvinylidene fluoride (PVDF) and hyaluronate.

Some composite meshes are partially absorbable – they are composed by a non-absorbable structure and biodegradable elements such as polyglactine (Vypro II mesh, Ethicon, Johnson&Johnson, USA). This type of composite hernia meshes are used in the clinical practice in cases of large defects or damaged tissues. The process of absorbsion reduces the final mass of a mesh and inflammatory response, while also maintaining sufficient mechanical strength [4].Other available composite meshes are covered with low tissue reaction material to remain in direct contact with the viscerae. This is due to the better biocompatibilities of these materials, and thus induces less foreign body reaction than pure nonabsorbable meshes.

Hernia meshes stay in the patients' body for years after implantation and is obligatory to know what the effects of aging on them are. The long-term performance in mesh materials can be characterized by *in vivo* or *in vitro* experiments. *In vitro* tests of mesh material are: investigation of explanted meshes or samples placed in the chamber of the thermostatic bath full of buffer solution, or comparison of the mechanical behaviour of meshes before and after their expiration date. In this study we investigated the long-term mechanical behaviour of hernia meshes placed in the chamber of the thermostatic bath full of buffer solution. Long-term mechanical properties of three different hernia meshes which basic material is PP were chosen-composite partially absorbable mesh (Vypro II), not absorbable mesh (TiO_2Mesh) and standard PP mesh (Microval). The chosen meshes are one of the most used meshes in surgical practice in Bulgaria [5].

Currently, there are two titanized polypropylene meshes in the market: TiMesh (GFE Medizintechnik, Germany) and TiO_2Mesh (BioCerEntwicklungs-GmbH, Germany). In TiMesh the polypropylene filament is coated with titanium layer and in TiO_2Mesh the polypropylene filament is coated with titanium dioxide. Titanium is known for its good biocompatibility and lead to reduce adhesions. Most experimental and clinical studies in literature have been performed on TiMesh [6]. As far as we know to date no long-term biomechanical studies have been carried out on TiO_2Mesh.

Numerous experimental and clinical studies in animal hernia models were conducted to investigate for Vypro II [7–9]. They were focused on the histologic properties, biocompatibility, inflammatory reaction, adhesion formation, tensile strength and shrinkage. As these are complex and expensive tests there are studies using in vitro degradation for Vypro II [10]. The authors investigated the effect of in-vitro degradation on mechanical properties of partially absorbable composite meshes and standard PP meshes.

The aim of the study is to examine the long-term mechanical behaviour of Vypro II, TiO_2Mesh and Microval hernia meshes placed in the chamber of the thermostatic bath full of buffer solution and to propose the recommendations for their application.

2 Materials and Methods

2.1 Materials

Three commercially available hernia meshes, namely Microval, TiO_2Mesh and Vypro II were compared (Table 1). Information sources for Table 1 are product sheets furnished by the manufacturers. As well as indicating the manufacturer, the type of material and filament for each is given. For further convenience, they will be called MV (Microval), TM (TiO_2 Mesh) and VP (Vypro II), respectively.

Table 1: Commercially available composite meshes for hernia repair

Brand name	Manufacturer	Type of material	Filament	Characteristics
Microval 2D Mesh	MicroVal, France	Polypropylene	Mono-filament	No absorbable
TiO_2Mesh	BioCer Entwicklungs GmbH, Germany	Polypropylene/ Titanium dioxide layer	Mono-filament	No absorbable
Vypro II	Ethicon, Johnson & Johnson, USA	Polypropylene/ Polyglactin 910	Multi-filament	Polyglactin is absorbable

2.2 Structural characteristics

Optical microscopy (Leica DM 750, Leica Microsystems, Germany, at magnifications up to $\times 5$) was used to perform a morphometric analysis to measure both the pore size and the filament diameter. A sample of each mesh material was photographed using a digital camera of light microscope. The sample thickness was determined by averaging five values acquired at different locations on each specimen using a digital callipers gauge (accuracy 0.01 mm). A known area of mesh was cut in a dry condition and weighed on an electronic balance (Mettler AJ150, resolution 0.0001 g). The density was then calculated by dividing the mass of each mesh specimen (g) by the area of the specimen (m^2).

2.3 Long term mechanical simulation

Long term mesh mechanical properties were determined following under simulated physiological conditions to expedite processing. The meshes were cut into pieces for these experiments. The meshes were cut into rectangular specimens of 150×70 mm size.

To mimic a biological environment similar to human physiology, mesh specimens were soaked in Buffer Solution (PBS, pH 7.4) at 37 ± 1°C in the chamber of the digital thermostatic bath DIGIBATH-2 (Raypa, Spain). All samples were taken out after 70 days. The initial weight of each specimen was measured before the immersion into PBS. At the end of process specimens were rinsed with distilled water, dried at room temperature during 24 hours. Dried samples were subjected to mechanical tensile test.

The meshes were measured to determine the degree of contraction. Shrinkage of each mesh was expressed as a percent change of the surface area of the explanted meshes. A digital calliper gauge was used to precisely calculate the cross-sectional area and the shrinkage of the meshes.

2.4 TENSILE EXPERIMENT

The uniaxial tensile test is the most common method for mechanical testing and to determine some material characteristics. Five specimens, each 70 mm long $\times$ 10 mm wide, were cut in two orthogonal directions – longitudinal (along the loop columns; L direction) and transverse (across the loop columns; T direction) for mechanical evaluation. TM mesh has blue orientation stripes and it was easy to control the orientation. A total of 20 samples were obtained for each mesh – 10 before exposed in PBS and 10 after exposed in PBS.

The strips were submitted to quasi-static tensile loading at 23°C room temperature using an universal testing machine (Fu1000e, Germany) equipped with a 500 N load cell (0.2 N resolution) operated at a crosshead speed of 0.13 mm/s. The specimen was clamped to the tensile fixture of the machine vertically and tested to failure. The initial clamp-to-clamp distance was measured using the digital callipers gauge and it was 40 mm.

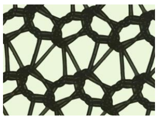
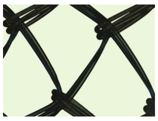
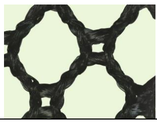
Force (F, in N) – extension (L, in mm) data was extracted from the system software and used to create force–extension curves. The relationship between the Lagrangian stress T_L and stretch ratio λ of each specimen was obtained by dividing the applied force F by the initial cross-section area S_0 and by taking the ratio of the obtained displacement L to the initial testing lengthL_0.

Several parameters, which characterize elastic response of hernia mesh, were derived from stress-stretch curves for each specimen: maximum tensile stress $T_{\max}$, stretch at maximum stress $\lambda_{\max}$ and elastic secant modulus of mesh E_5 defined as a ratio of the Lagrangian stress T_L and 5% strain.

3 RESULTS

Before soaked in PBS solution, we measured the main baseline structural characteristics of the investigated hernia meshes – filament diameter, thickness, pore size and density (Table 2). The investigated meshes are different with respect to composition (Table 1) and architecture (Table 2).

Table 2: Basic parameters of the investigated baseline meshes

Mesh	Microscopic view	Filament diameter, [μm]	Thickness, [mm]	Max pore size, [mm]	Mesh density, [g/m^2]
MV		150	0.56	1.3	90
TM		150	0.60	3.0	45
VP		40	0.50	3.0	50

Two out of three meshes are manufactured from monofilament fibres with filament diameter of 150 μm. Only VP mesh has a multifilament structure. Its filament diameter is 40 μm.

According to Amid's classification [11] on the basis their pore sizes, all investigated meshes are the representative of macroporous meshes. Based on the classification by Earle et al. [4], MV is mesh with large pore and TM and VP are meshes with very large pore. A larger pore diameter allows easy entry of macrophages, fibroblasts, collagen fibres, which constitute the new connective tissue and integrate the prosthesis to the organism. But there also be a greater risk of adhesions, promote erosion and fistula formation [12].

According to Earle's classification on the basis of the weight [4], TM and VP are lightweight meshes and MV is mediumweight mesh. Based on the classification by Coda et al. [13], TM and VP are lightweight meshes and MV is standard mesh.

The average stress–stretch curves of baseline meshes are given in Figs. 1(a) and 1(b). The all meshes present orthotropic behaviour, but MV is isotropic up to $\lambda = 1.45$.

Figures 2, 3 and 4 illustrate the average values of mechanical characteristics before and after exposed in PBS of the investigated meshes tested in both the longitudinal and the transverse directions.

The results presented in Fig. 2 show that the TM mesh has the lowest maximum tensile stress $T_{\max}$ (2.54 ± 0.51 MPa) and VP mesh the highest $T_{\max}$ values – 10.41 ± 0.64 MPa among the investigated baseline meshes before PBS in the longitudinal direction. The sequence of tensile strength in the longitudinal direction is in

(a)

(b)

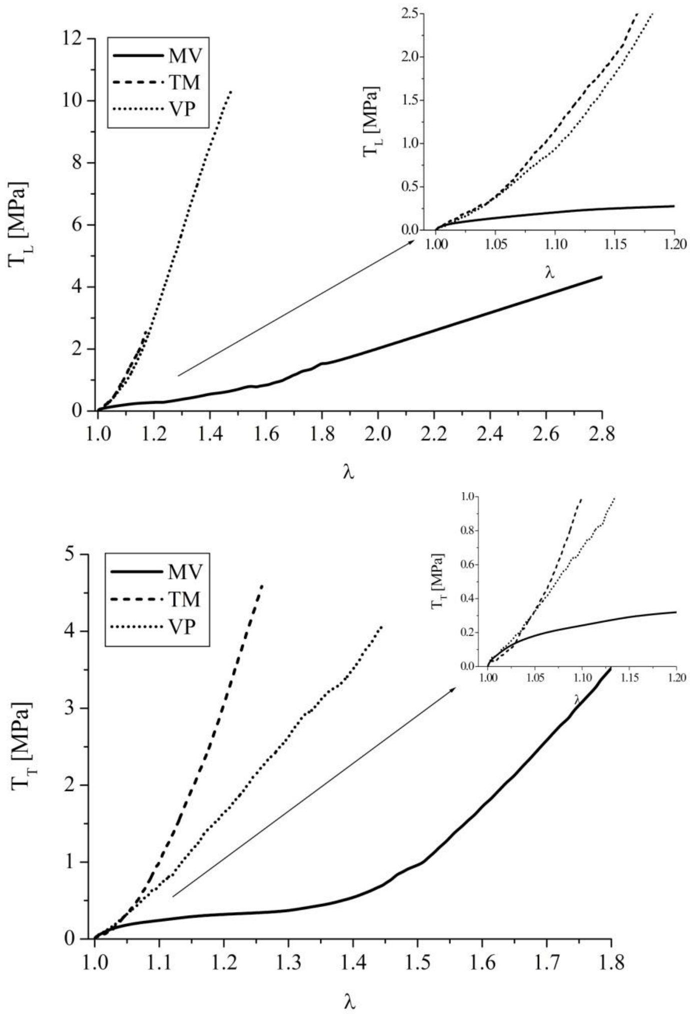


Fig. 1: Representative stress–stretch curves of baseline meshes in (a) the longitudinal direction and (b) the transverse direction.

the order VP $>$ MV $>$ TM. In the transverse direction, the MV mesh has the highest $T_{\max}$ (7.36 ± 0.71 MPa) while $T_{\max}$ of another two meshes are close – VP mesh (4.07 ± 0.26 MPa) and the TM mesh (4.57 ± 0.76 MPa). The sequence of tensile strength in the transverse direction is in the order MV $>$ TM $>$ VP.

The soaking of meshes in PBS for 70 days influences $T_{\max}$ values as follows: the $T_{\max}$ values of TM mesh in the L direction did not alter significantly (from 2.54 ± 0.51 MPa to 2.71 ± 0.58 MPa, which is 6.7%). The $T_{\max}$ values of VP

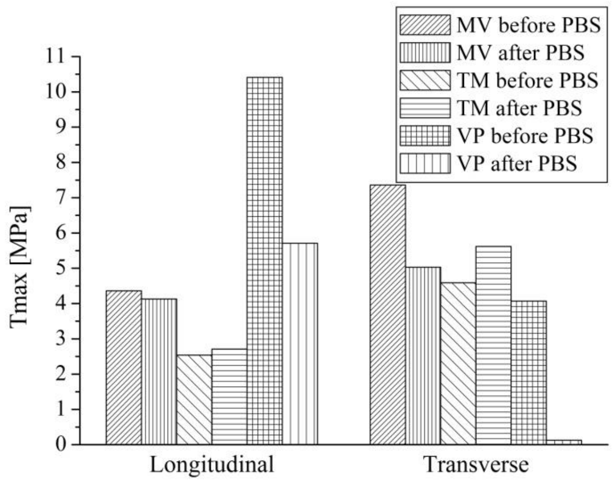


Fig. 2: Results of the maximum tensile stress measurements in the L and the T direction.

mesh decreased 45% and of MV decreased by 5.3% respectively after exposed in PBS. In the T direction, the TM mesh values of $T_{\max}$ increased by 22%, while the same parameter decreased by 97% and 32% for VP and MV meshes.

As shown in Fig. 3 the stretch at maximum stress $\lambda_{\max}$ is highest for MV in the L and T direction (2.81 ± 0.04 and 2.18 ± 0.02). After 70-days in PBS, the $\lambda_{\max}$

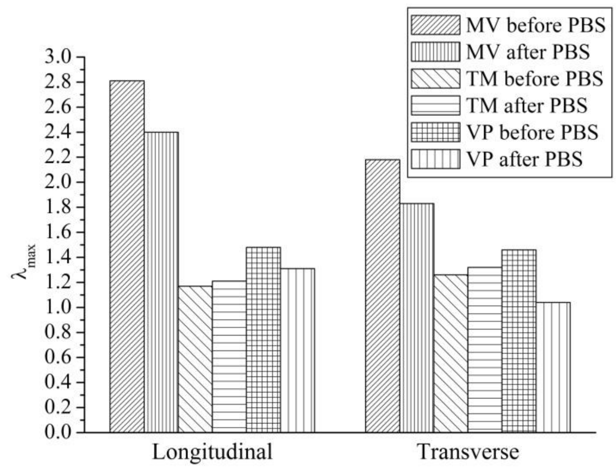


Fig. 3: Results from the stretch at maximum stress measurements in the L and the T direction.

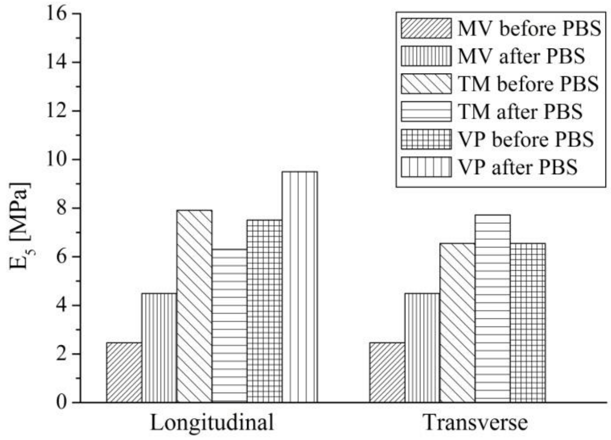


Fig. 4: Results from the elastic secant modulus measurements in the L and the T direction.

for MV were 2.4 ± 0.02 in the L direction and 1.83 ± 0.02 in the T direction. The $\lambda_{\max}$ of VP and TM mesh samples were in the interval 1.17–1.48 before soaking and 1.04–1.32 after soaking.

In the L direction, the E_5 modulus for the TM and VP meshes were about 6.5–7.5 MPa, while MV is less stiff – 2.46 ± 0.45 MPa (Fig. 4). After exposed in PBS, the E_5 modulus for the VP mesh increases up to 10 MPa, modulus for TM meshes were in the same interval 6.5–7.5 MPa, while the modulus of MV increased to 4.49 MPa.

The shrinkage of the meshes was as follows: The area of VP decrease by 2.1%, the area of MV increased by 2.5%, while no change was detected for TM mesh.

4 Discussion

Long term mechanical properties of three hernia meshes – two lightweight composite meshes and one standard mesh were compared before and after exposition in PBS solution for 70 days. The material is orthotropic and stiffer in the L direction compared with the T direction (Fig. 1). Before investigation we supposed that the properties of lightweight meshes (TM and VP) should be similar and this suggestion was partially valid as is seen from the results.

After soaking in PBS, VP mesh which consists of 50% absorbable material Polyglactin 910 reduced its mass and its mechanical strength [14]. Our results showed that VP mesh lost 40% of the weight after 70-days degradation. The VP mesh lost 57% of its weight after 56 days degradation according to Schug-Paß [15]. As a result, maximum tensile stress $T_{\max}$ of VP mesh decreased by 45% in the L direction and 97% in the T direction. The stretch ratio $\lambda_{\max}$ decreased by 11% in the L direction and 28% in the T direction. Endogan et al. investigated in vitro degradation of partially absorbable lightweight meshes – Ultrapro and Vypro II in phosphate buffered saline solution and the influence of PBS on the physical structure and the mechanical properties of these meshes [10]. The authors reported that mechanical parameters of meshes decreased significantly. Highest reduction in mechanical properties was observed due to the degradation of absorbable parts of these meshes. Our results confirm their observations.

Comparison of the highest value of $T_{\max}$, $\lambda_{\max}$ and E_5 in the L and T direction clearly showed that it is not possible to conclude that one of the meshes has better properties than the others before experiment. Only MV mesh is more stretchable than the other meshes. The highest value of the stretch ratio $\lambda_{\max}$ in the L direction is 2.81 (MV) and in the T direction is 2.18 (MV). The maximal strength and elasticity of meshes are too different according to tensile directions (Fig. 2 and Fig. 4).

We tried to find the main tendency in the long-term behaviour of investigated mashes according to their density as they all consists of PP after exposed in PBS.

Actually the three meshes presented a different mechanical behaviour. The maximum tensile stress $T_{\max}$ decreased in both directions for VP and MV samples and increased in both directions for TM. The highest reduction of maximum tensile stress $T_{\max}$ in both directions was observed in VP mesh – by 45% in longitudinally cut samples and by 97% in transversally cut samples within 70 days. VP meshes exhibited a clear trend of change in mechanical properties due to the degradation effect. The highest raise of $T_{\max}$ is obtained for TM mesh in the T direction – 22%.

As the next step we compared TM mesh and MV mesh which remained intact after 70 days in PBS. The long-term tendency of the investigated parameters is totally different. $T_{\max}$ of TM mesh increased in both directions (7% and 22%) but $T_{\max}$ of MV mesh decreased in both directions (by 5% and 32 %). The stretch ratio $\lambda_{\max}$ of TM mesh increased in both directions (by 3% and 5%) while the stretch ratio $\lambda_{\max}$ of MV mesh decreased by 14–16% in both directions after 70 days of aging in the PBS. MV underwent permanent deformation, which will induce decreased mesh flexibility over time. The value of the elastic modulus is about 6.5–8 MPa for the TM mesh and elastic modulus of MV mesh increased 1.8 times. The TM mesh did not shrink after 70 days but MV mesh expands by 2.5%. The properties of MV and TM changed although they are not absorbable meshes.

Rynkevic et al. reported results from three month in vitro study of the mechanical performance of three hernia meshes made from poliglecaprone and polypropylene, polyvinylidenefluoride and polypropylene only (Surgipro) [16]. The larger deformations occurred in Surgipro (25%). The lowest level of deformation (10%) exhibits resorbable mesh consists of poliglecaprone and polypropylene. In our study, larger deformations also occurred in the standard mesh (MV).

One of the complications in hernia repair is a shrinkage following the implantation of the mesh. Many authors evaluate post-implant shrinkage using an animal hernia model. The results are in the range 16–34% for different animal models and duration of the experiment. In a study of Bellon et al. VP mesh shrank after 90 days 16% implanted in rabbits [7]. In a dog model, Klinge et al. showed that VP mesh shrank 34% of its original size within 2 to 6 months after implantation [17]. In its review Brown et al. [18] indicate that VP mesh shrank – 29%. In our study, the VP mesh demonstrated a reduction of 2.1% of its initial surface area after 70-days in vitro degradation. The possible explanation is the difference in the experimental conditions. In vivo experiments are more harmful for the meshes.

The main observation for this study was that when the meshes were exposed to "aging" in the PBS solution (pH 7.3) at 37°C, the mechanical parameters $T_{\max}$, $\lambda_{\max}$ and E_5 decreased or increased in both directions according to different compositions and architectures of meshes. It must be noted that the "aging" practically affects all mechanical parameters in different way but the values of parameters are different from those obtained after animal models.

5 Conclusions

A study was performed to understand the aging process of the hernia meshes by soaking them in PBS (pH 7.3) solution. We studied the important mechanical characteristics of three of the popular commercial surgical meshes under physiological conditions. Based on the results of the in vitro tests, we can conclude that the changes that occur in these meshes with the aging affect their mechanical properties. Due to the increased risk of recurrence in these cases, careful planning for the treatment of patients is needed. The various changes in mechanical properties over time necessitate the creation of a guide for surgeons including results obtained after mechanical experiments. Thus surgeons will be informed about specific properties of meshes before and after implantation. They can use it to choose the proper mesh according to type of hernia, age and condition of the patient. Further in vivo studies are required to assess the influence of living tissue to the aging process of this type of surgical meshes.

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