Effect of the Sterilization Procedures of Different Surgical Meshes for Abdominal Surgery

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The surgical meshes selection, according to the structure and porosity of the biomaterial type and meshes design, is directly dependent on the surgical procedure used and interaction between biomaterial type and abdominal viscera. Surgical mesh must provide sufficient biomechanical strength in order to assure the physiological requirements in order to protect the soft tissue defects. The large variety of biomaterials used in abdominal surgery and the multitude of surgical fixation procedures show that we are still far from the ideal prosthesis. The main objective of this paper is to determine the effect of the sterilization procedures of some surgical meshes, with different design and made of different materials, on their structure and properties of interest. Experimental research was conducted on three types of surgical meshes, different from material and design point of view. Fourier Transform Infrared (FTIR) Spectroscopy was used to evaluate the structural characteristics of the samples. In the evaluation of the surface properties, scanning electron microscopy (SEM) was used for the qualitative assessment of surface morphology and contact angle determinations (CA) to determine the wettability properties. The sterilization process used was chemical sterilization with ethylene oxide, a procedure used by surgeons in clinical practice. According to the experimental research, the negative effects of the sterilization process on surgical meshes used in abdominal surgery are accentuated for the samples sterilized with ethylene oxide for three times, while their sterilization only one cycle does not significantly affect the surface properties and tensile strength of surgical meshes, regardless of the design and material of which they are composed.

Keywords: sterilization, surgical mesh, polymers, surface, microscopy.

The main purpose of a surgical mesh implant is to provide biomechanical strength to the attenuated fascial structures, being designed to withstand the tension forces who act on the abdominal wall. Also, the ideal mesh must not impede and should facilitate the healing process of the tissue defect by encouraging ingrowth of the tissue around the mesh fibers [1]. Evolution of abdominal surgery has led to polymeric biomaterials for replacement or reinforcement of the abdominal wall. The surgical meshes selection, according to the structure and porosity of the biomaterial type and meshes design, is directly dependent on the surgical procedure used and interaction between biomaterial type and abdominal viscera [2, 3].

Although the reinforcement and strengthening of the abdominal tissues to prevent recurrence is the main task of a mesh, functional restrictions can improve the quality of patient life. According to recent studies, many patients with a large mesh within the abdominal tissue express complaints such as physical restriction of abdominal mobility [4-9]. Restoring the physiological properties of the abdominal tissue must take into account the interactions of the human structures and the resulting elasticity or tensile strength [2]. The flexibility of the abdominal tissues is restricted by implantation of extensive biomaterial and to a greater degree by scar tissue formation [4].

Surgical mesh must also provide sufficient biomechanical strength in order to assure the physiological requirements in order to protect the soft tissue defects. From mesh design point of view, there are meshes with small or large pore size. The advantage given by the large pore size mesh is that the tissue is able to grow through the large pores of the mesh [2, 6]. Latest technological advances have allowed the use of specific materials to develop different types of meshes of create new construction methods that allow adequate support to the tissue while substantially reducing the amount of implant in the patient.

The large variety of biomaterials used in abdominal surgery and the multitude of surgical fixation procedures show that we are still far from the ideal prosthesis [6, 7, 10-17]. Their polymeric characteristics involve different conditions of fixation in the parietal region, the host tissue being different; or different surgical procedures involve different properties of the surgical meshes. Three polymeric biomaterials and their combinations are most commonly used today for surgical mesh: polypropylene, polyester and ePTFE [2, 8, 12].

The most common fixation procedures for a surgical mesh, depending on the muscle planes are: onlay, sublay, retromuscular and intraperitoneal. Each procedure are used in correlation with the polymeric characteristics of the biomaterial that comes in contact with the host tissue, and is directly dependent on the porosity and type of surgical mesh [14-17].

The main objective of this paper is to determine the effect of the sterilization procedures of some surgical meshes, with different design and made of different materials, on their structure and properties of interest. Because of the intraoperative clinical features, surgeons

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do not usually use the entire surgical mesh for hernia repair, and there are many situations in which parts of the surgical meshes are resterilized and clinically used in other surgeries. Currently, there are only a few studies and research on this issue, which are not covered by any international standards or medical requirements, the reason why these preclinical studies have been performed.

In this paper, we studied the effect of the process of sterilization of surgical meshes used in current clinical practice, made from different biomaterials and with different design, on their surface properties, tensile strength and on the structural characteristics of the biomaterial from which they are made.

Experimental part

Materials and methods

Although, the manufacturer does not recommend partial reuse of surgical meshes for hernia repair, many surgeons are forced, due to economic problems, to reuse pieces of surgical meshes. Experimental research was conducted on three types of surgical meshes, different from material and design point of view. The types of surgical meshes for hernia repair taken in the study are shown in the table 1.

To avoid any inconsistencies due to the manufacturer, experimental samples from the same surgical mesh for hernia repair, were used. The form of the experimental samples taken in aseptic conditions (in the operating room) with the surgical scalpel were rectangular in shape, each sample having the size of 10 x 70 mm. Five experimental samples of each type of mesh were obtained for each sterilization cycle (each piece was packaged and sterilized separately). The control samples, from each type of surgical mesh, were obtained in the same manner but were not subjected to sterilization.

The encoding of the experimental samples used in this paper is presented in table 2.

The experimental investigations were performed on experimental samples in the initial state and after being subjected of one, respectively three sterilization cycles.

Fourier Transform Infrared (FTIR) Spectroscopy was used to evaluate the structural characteristics of the samples. Each spectrum was recorded in the 600-4000 cm^{-1} spectral range with a resolution of 4 cm^{-1} using a FTIR JASCO 6200 spectrometer operating in the ATR (Attenuated Total Reflectance) mode. In the evaluation of the surface properties, scanning electron microscopy (SEM) was used for the qualitative assessment of surface morphology and contact angle determinations (CA) to determine the wettability properties. Electron microscopy determinations were performed using an electronic scanning microscope type Philips XL 30 ESEM, while for contact angle determinations we used a Drop Shape Analyzer DSA30 device manufactured by KRUSS GmbH.

The sterilization process used was chemical sterilization with ethylene oxide, a procedure used by surgeons in clinical practice. The parameters of the sterilization process were according to clinical practice, aiming at reproducing as much as possible the situations involved in clinical practice. Ethylene oxide was used for 4 hours at 54ºC for each sterilization process. After the sterilization phase, the experimental samples were kept, in a desiccator, for 12 hours for drying. In the case of the three sterilization cycles, the same procedure was applied at one-day intervals, being practically a repetitive process. Sterilization with ethylene oxide was performed using a sterilizer AMSCO EAGLE 3017 type, similar to the sterilizer used in clinical practice.

Results and discussions

Fourier Transform Infrared Spectroscopy (FTIR)

The FTIR spectra recorded on investigated experimental samples made by polypropylene before and after resterilization, are shown in figure 1.

In the case of P1 surgical mesh, FTIR spectra did not reveal significant compositional changes after resterilization. All spectra exhibit the same absorption bands characteristic to polypropylene in the range of 2830-2960 cm^{-1} peaks which are attributed to the C-H stretching vibrations in CH2 and CH3 groups, at 1455 cm^{-1} peak due to the asymmetric bending vibration of the methyl group, at 1375 cm^{-1} peak due to the symmetrical bending vibration of the methyl group. Along with this characteristic peaks of polypropylene, the spectra reveal the peaks due to in-plane and out of plane bending vibrations of the C-H bonds of the methyl, methylene and methine groups.

The FTIR spectra recorded on investigated experimental samples made by polyethylene terephthalate before and after resterilization, respectively are presented in figure 2.

Neither for surgical mesh made by polyethylene terephthalate, FTIR spectra did not reveal compositional changes after resterilization. All spectra highlight the same absorption bands characteristic to polyethylene terephthalate at about 1712 cm^{-1} peack assigned to the ester carbonyl bond stretching, at about 1406 cm^{-1} peack due to the bending vibration of the methine group coupled with the to stretching vibration of the C-C from the benzene ring, at 1242 cm^{-1} due to the ester group stretching, at 1016

Surgical meshes encoding	Surgical meshes material	Surgical meshes type
P_1	Polypropylene	Non-resorbable, multifilament
P_2	Polyethylene terephthalate	Non-resorbable, multifilament
P_3	Poly(propylene-co-ε-caprolactone) copolymer	Resorbable, multifilament

Table 1
SURGICAL MESHES TAKEN IN THE STUDY

Surgical meshes encoding	Control samples	Samples afer one sterilization cycles	Sample after three sterilization cycles
P_1	P_1M	P_11	P_12
P_2	P_2M	P_21	P_22
P_3	P_3M	P_31	P_32

Table 2
THE ENCODING OF THE EXPERIMENTAL SAMPLES

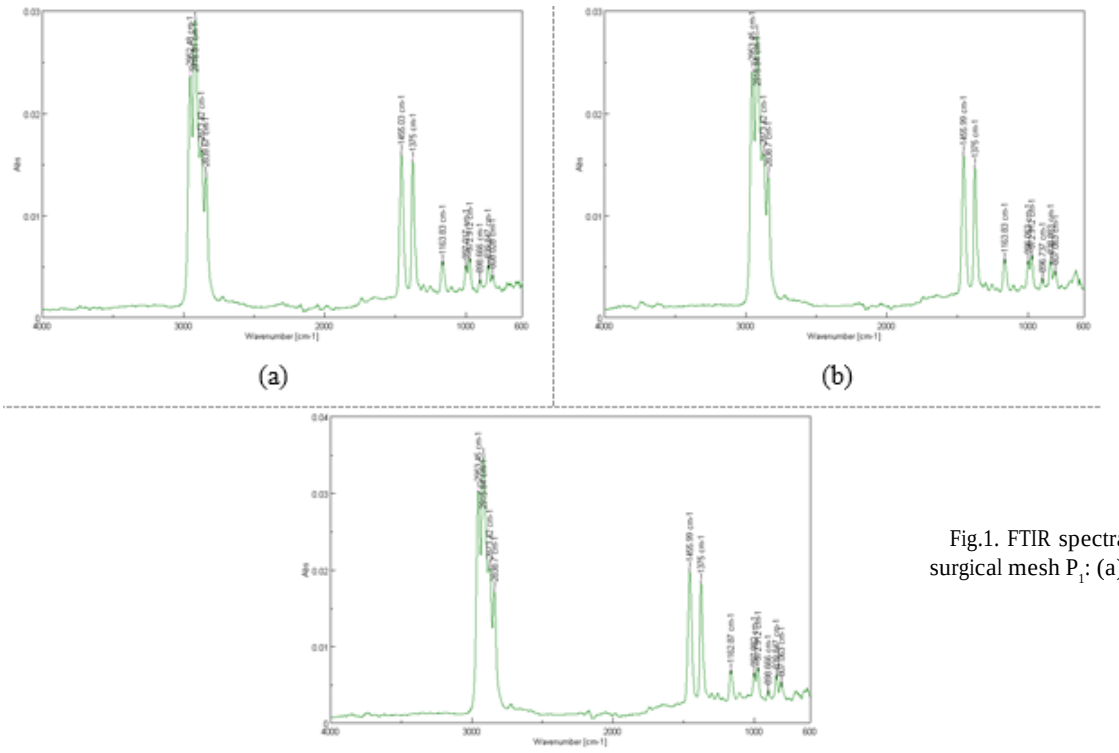

Fig.1. FTIR spectra on polypropylene surgical mesh P_1: (a) P_1M, (b) $P_1 1$, (c) $P_1 2$.

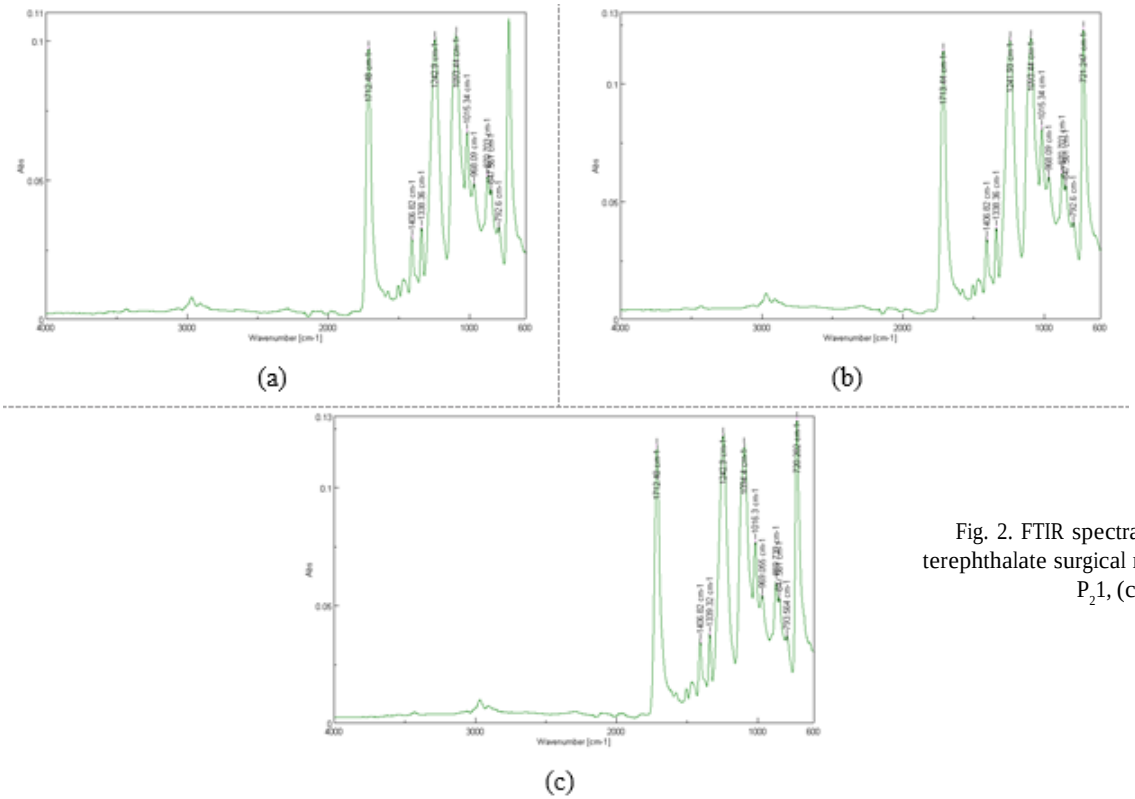

Fig. 2. FTIR spectra on polyethylene terephthalate surgical mesh P_2: (a) P_2M, (b) $P_2 1$, (c) $P_2 2$

and 720 cm^{-1} due to the in-plane/out-plane bending of the aromatic group.

The FTIR spectra recorded on investigated experimental samples made by poly(propylene-co-ε-caprolactone) copolymer before and after resterilization, respectively are presented in figure 3.

FTIR spectra shows absorption bands specific to polypropylene and polycaprolactone due to the C-H stretching vibrations from the methylene group, absorption bands specific to polypropylene assigned to the stretching and bending vibrations of the methyl groups and absorption bands specific to polycaprolactone due to the carbonyl bond stretching (~1738 cm^{-1} - P_3M, ~1739 cm^{-1} - $P_3 1$, ~1741 cm^{-1} - $P_3 2$) and C-O bond stretching vibration coupled with the C-C stretching vibration (~1149 cm^{-1} - P_3M, ~1151 cm^{-1} - $P_3 1$, ~1153 cm^{-1} - $P_3 2$).

Determination of Contact Angle

According to experimental studies conducted by other researchers on similar biomaterials, the fluid used to determine the contact angle for the experimental samples was deionized water [18]. The comparative aspect between the contact angle values for the all investigated samples are shown in figure 4.

The results obtained in the case of surgical meshes made by polypropylene (P_1M, $P_1 1$, $P_1 2$) and polyethylene terephthalate (P_2M, $P_2 1$, $P_2 2$) show an increase in the

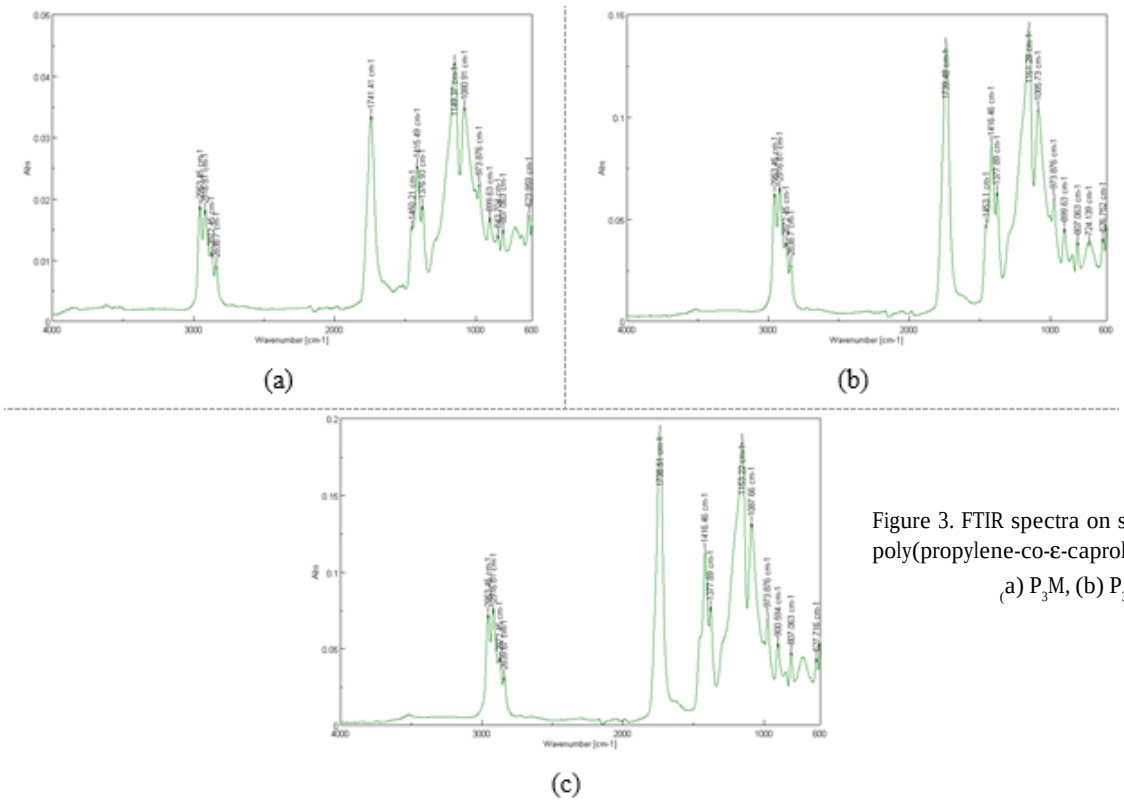

Figure 3. FTIR spectra on surgical mesh made by poly(propylene-co-ε-caprolactone) copolymer P_3: (a) P_3M, (b) $P_3 1$, (c) $P_3 2$

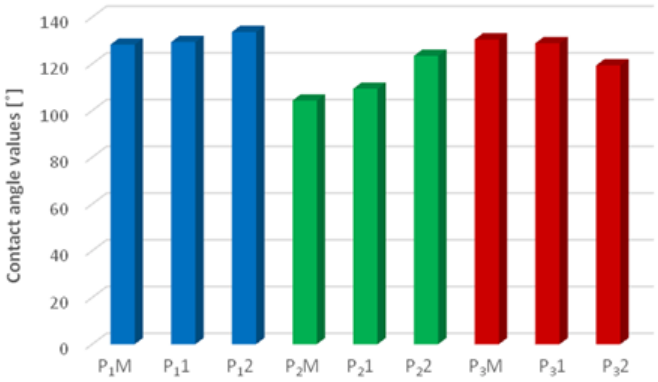

Fig. 4. Contact angle values for the all experimental samples

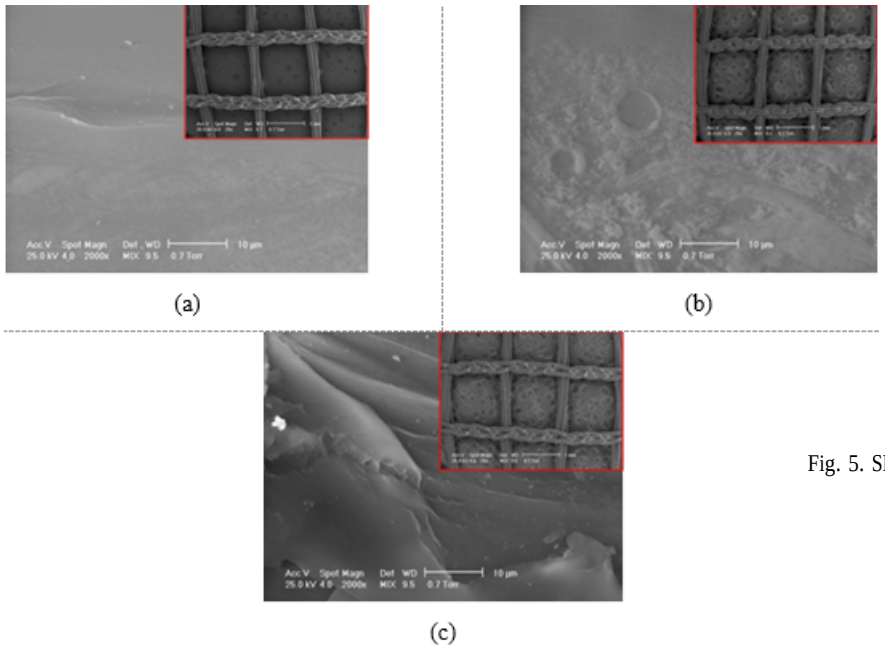

Fig. 5. SEM images on polypropylene surgical mesh P_1: (a) P_1M, (b) $P_1 1$, (c) $P_1 2$

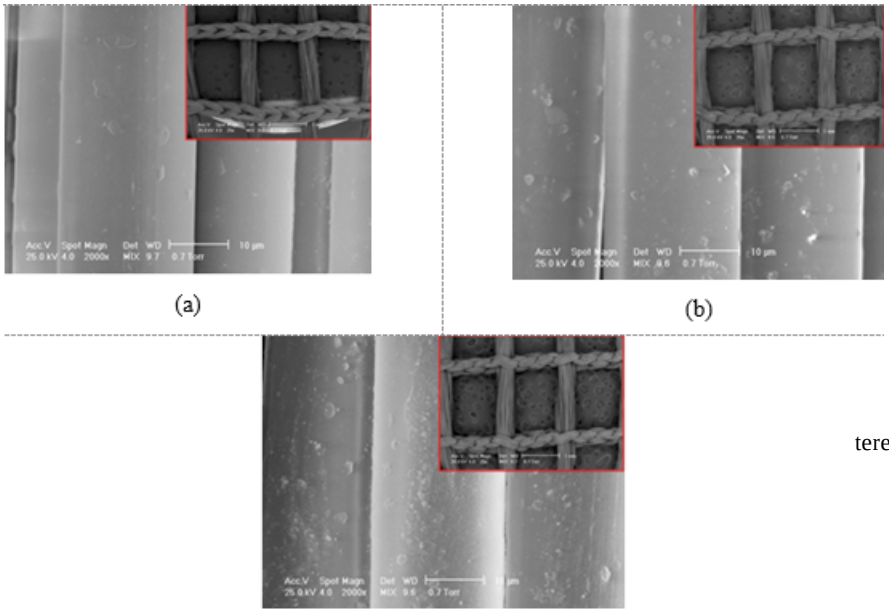

FIg. 6. SEM images on polyethylene terephthalate surgical mesh P_2 (a) P_2M, (b) P_21, (c) P_22

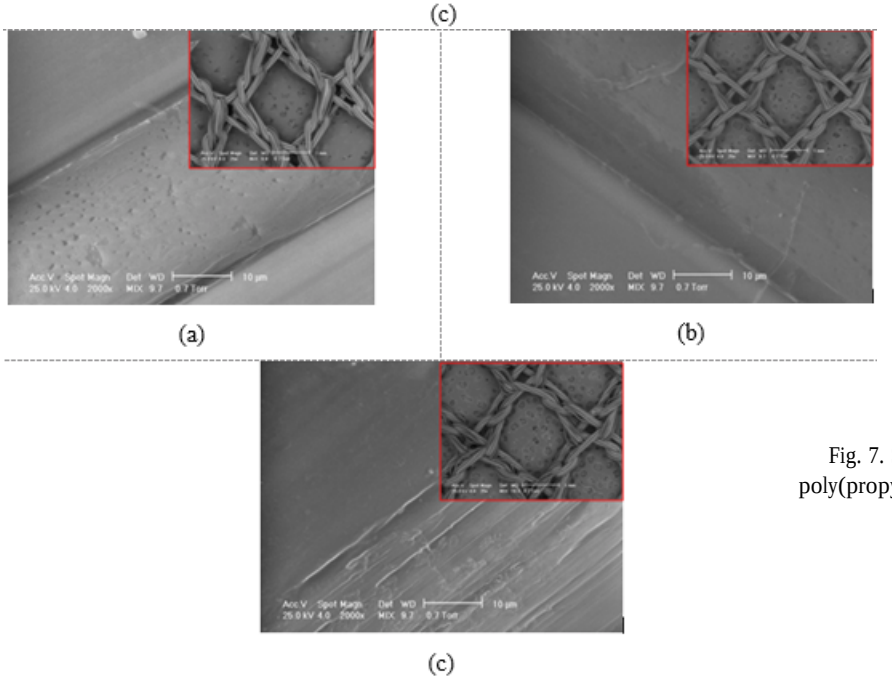

Fig. 7. SEM images on surgical mesh made by poly(propylene-co-ε-caprolactone) copolymer P_3 (a) P_3M, (b) P_31, (c) P_32

hydrophobicity of the meshes after resterilization. This, along with the results of FTIR spectroscopy, proves that polypropylene is a polymer with an excellent chemical resistance, and polyethylene terephthalate is a polymer with hydrolytic, thermal and oxidative resistance. Because an interface is formed at a contact of a polymeric biomaterial with an extracellular fluid, the hydrophobicity of a biomaterial is directly related to its biological properties.

In the case of surgical meshes made by poly(propylene-co-ε-caprolactone) copolymer (P_3M, P_31, P_32) there is a decrease in the value of the contact angle for the resterilized samples, that means a decrease in hydrophobicity.

Also, we could conclude that the significant changes in terms of contact angle values are observed after 3 cycles of sterilization for the all surgical meshes investigated in our study even there are from different materials.

Scanning Electron Microscopy (SEM) Analysis

Figures 5, 6 and 7 presents the SEM micrographs recorded on the experimental samples before and after different sterilization cycles.

Scanning electron microscopy images obtained after investigating the experimental samples reveal that after resterilization there is a qualitative increase in the degree of roughness of their thread and thus the deterioration of their surface. This is more evident in experimental samples which have been subjected to the sterilization process three times, aspect supported by the results obtained in the determination of the contact angle. Also, in the case of experimental samples subjected to a single sterilization cycle, regardless of the type of biomaterial from which they are made, there are no significant changes on the surface area in terms of their topography.

Determination of the Tensile Strength

From the experimental results obtained after testing the tensile strength of the experimental samples, in tension-elongation coordinates, the elongation values obtained using a force of 16 N were selected (the test area of the experimental sample being 1 cm^2). This value was selected because, according to literature data [19] surgical meshes, for hernia repair, should have a tensile strength of at least 16N/cm^2 (maximum intra-abdominal pressure generated by healthy adults is when they cough or jump, and is estimated to be 170 mmHg. Therefore, surgical meshes used for abdominal hernias should be able to withstand at least 180 mmHg pressures, i.e., have a tensile strength of

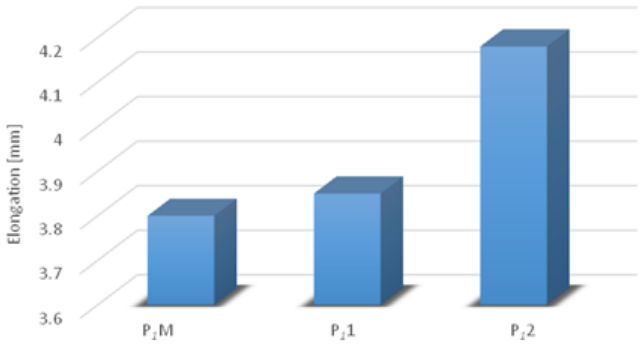

Fig. 8. Variation of elongation after tensile strength testing of P_1 samples made by polypropylene

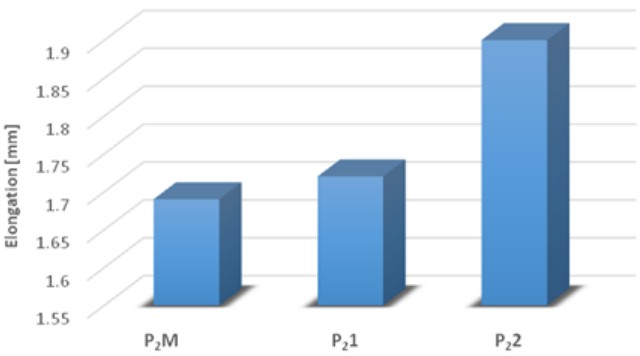

Fig. 9. Variation of elongation after tensile strength testing of P_2 samples made by polyethylene terephthalate

16 N/cm^2). The results obtained are presented in the following figures 8, 9, 10..

In the case of experimental samples made by polypropylene samples, a tensile force of 16 N shows an elongation of 3.8 mm for P_1M, 3.85 mm for $P_1$1 and 4.2 mm for $P_1$2.

For the experimental samples made by polyethylene terephthalate samples, a tensile force of 16 N shows an elongation of 1.69 mm for P_2M, 1.72 mm for $P_2$1 and 1.9 mm for $P_2$2.

For the experimental samples made by poly(propylene-co-ε-caprolactone) copolymer samples, a tensile force of 16 N shows an elongation of 2.7 mm for P_3M, 4 mm for $P_3$1 and 4.9 mm for $P_3$2.

It is noted that between the control and the once resterilized samples the variation in elongation is very small, which we cannot say about the control samples and the ones resterilized three times. The results obtained from this test reveal that the mechanical properties of the experimental samples are not significantly affected by the first sterilization cycle. The samples sterilized three times were affected from this point of view, the elongation value of the samples after the three sterilizations being almost double compared to control samples.

Conclusions

The results of the FT-IR investigations reveal that there are no structural changes in the investigated experimental samples, instead, there are small displacements of the absorption bands for the resterilized samples made by poly(propylene-co-ε-caprolactone) copolymer, because when the polymers are subjected to a heat treatment (the sterilization process is performed at 54 °C) small band shifts may occur. When the material is composed of a single polymer, these movements are insignificant.

The results of the SEM investigations are useful in assessing the effect of resterilization of the investigated surgical meshes on the morphology of their surfaces. Following SEM investigations, it was found that resterilized samples underwent a degradation highlighted by a roughness change, more pronounced degradation being noticed in the case of those who had been resterilized for three times.

From the contact angle values, it can be noticed that after every sterilization cycle, the hydrophobicity of the polymeric increases. The results obtained from the tensile strength test show that after sterilization, the mechanical properties of the experimental samples are not significantly affected, whereas samples sterilized three times were affected from this point of view, the sample elongation value after three sterilizations being almost double compared to the control samples.

According to the experimental research, the negative effects of the sterilization process on surgical meshes used in abdominal surgery are accentuated for the samples sterilized with ethylene oxide for three times, while their sterilization only one cycle does not significantly affect the surface properties and tensile strength of surgical meshes, regardless of the design and material of which they are composed.

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