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Effects of Ethylene Oxide Resterilization and In-vitro Degradation on Mechanical Properties of Partially Absorbable Composite Hernia Meshes*

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Rezumat

Efectele resterilizării cu oxid de etilen și degradării in-vitro asupra proprietăților mecanice ale plaselor chirurgicale din material mixt parțial absorbabile

Principiul și scopul lucrării: Protezarea cu plase chirurgicale a herniilor de perete abdominal este o tehnică extensiv utilizată datorită simplității sale și ratelor scăzute de recurență aferente. Cele mai utilizate materiale sunt plasele din polipropilenă, însă noi materiale mixte sunt recomandate de unele centre datorită avantajelor pe care le prezintă. Aceste plase sunt, însă, mai costisitoare decât cele realizate exclusiv din polipropilenă. Resterilizarea unei plase de polipropilenă pură s-a dovedit a fi o procedură destul de sigură, iar multe centre preferă să taie o plasă de dimensiuni mari în mai multe plase mai mici, ce pot fi folosite pentru orice tip de hernie sau orice dimensiune a defectului. Cu toate acestea, nu există date privind gradul de siguranță al resterilizării plaselor din material mixt. Studiul curent a fost desfășurat în vederea evaluării efectelor resterilizării și degradării in-vitro cu fosfat tamponat cu soluție salină asupra structurii fizice și a proprietăților mecanice ale plaselor chirurgicale ușoare parțial absorbabile.

Materiale și metode: Două tipuri de plase din material mixt au fost utilizate în acest studiu: o plasă alcătuită din monofilamente de polipropilenă și monofilamente de poliglecapronă – un copolimer din glicolid și epsilon (ε)– caprolactonă (Ultrapro®, 28 g/m^2, Ethicon, Hamburg, Germania), iar cealaltă din multifilamente de polipropilenă și multifilamente de poliglactină (Vypro II®, 30 g/m^2, Ethicon, Hamburg, Germania). Două plase de dimensiuni mari au fost tăiate în probe rectangulare de 50x20 mm pentru testarea mecanică și de 20x20 mm pentru experimentele de degradare in-vitro. Plasele au fost distribuite în grupuri de control, fără sterilizare, și de resterilizare cu gaz. Sterilizarea gazoasă cu oxid de etilen a fost efectiată la 55°C timp de 4,5 ore. Câte un subgrup din fiecare grup de plase a fost supus degradării in-vitro cu 0,01 M fosfat tamponat cu soluție salină (PBS, pH 7,4) la 37 ± 1°C timp de 8 săptămâni. Măsurătorile tensiometrice și de microscopie electronică au fost efectuate pentru probele de control și cele resterilizate.

Rezultate: Indiferent de resterilizare, la expunerea plaselor la degradarea in-vitro, toți parametrii mecanici au scăzut semnificativ. Cea mai mare scădere în termeni de proprietăți mecanice a fost observată la plasele Ultrapro, din cauza degradării componentelor de poliglecaprona și poliglactină absorbabile ale acestor plase. S-a observat că resterilizarea cu oxid de etilen nu a determinat diferențe semnificative în ce

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privește caracteristicile de degradare, iar structurile fizice analizate au fost foarte asemănătoare atât în cazul protezelor resterilizate, cât și a celor ne-resterilizate. În cazul plaselor Vypro II nu s-au înregistrat diferențe semnificative între probele resterilizate și cele ne-resterilizate după degradare, în timp ce plasele Ultrapro resterilizate prezintă caracteristici mai puternice în comparație cu cele ne-resterilizate.
Concluzii: Resterilizarea cu oxid de etilen nu a afectat proprietățile mecanice ale plaselor din material mixt absorbabil. Nu au fost observate modificări de suprafață la microscopia electronică după resterilizare.

Cuvinte cheie: plasă chirurgicală, hernie, plasă din material mixt, resterilizare, degradare, proprietăți mecanice, tensiometrie, rezistență la tracțiune, polipropilenă, poliglecapronă, poliglactină

meshes. It was observed that resterilization by ethylene oxide did not determine significant difference on the degradation characteristics and almost similar physical structures were observed for resterilized and non-resterilized meshes. For Vypro II meshes, no significant mechanical difference was observed between resterilized and non-resterilized meshes after degradation while resterilized Ultrapro meshes exhibited stronger characteristics than non-resterilized counterparts, after degradation.
Conclusion: Resterilization with ethylene oxide did not affect the mechanical properties of partially absorbable composite meshes. No important surface changes were observed in scanning electron microscopy after resterilization.

Key words: mesh, hernia, composite mesh, resterilization, degradation, mechanical properties, tensiometry, tensile strength, polypropylene, polyglecaprone, polyglactine

Abstract
Background and Aim: Prosthetic mesh repair for abdominal wall hernias is widely used because of its technical simplicity and low hernia recurrence rates. The most commonly used material is pure polypropylene mesh, although newer composite materials are recommended by some centers due to their advantages. However, these meshes are more expensive than pure polypropylene meshes. Resterilization of a pure polypropylene mesh has been shown to be quite safe, and many centers prefer slicing a large mesh into smaller pieces, suitable for any hernia type or defect size. Nevertheless there is no data about the safety after resterilization of the composite meshes. The present study was carried out to investigate the effects of resterilization and in vitro degradation in phosphate buffered saline solution on the physical structure and the mechanical properties of partially absorbable lightweight meshes.
Methods: Two composite meshes were used in the study: One mesh consists of monofilament polypropylene and monofilament polyglecaprone -a copolymer of glycolide and epsilon (ε) - caprolactone - (Ultrapro®, 28 g/m^2, Ethicon, Hamburg, Germany), and the other one consisted of multifilament polypropylene and multifilament polyglactine (Vypro II®, 30 g/m^2, Ethicon, Hamburg, Germany). Two large meshes were cut into rectangular specimens sized 50 x 20 mm for mechanical testing and 20 x 20 mm for in vitro degradation experiments. Meshes were divided into control group with no resterilization and gas resterilization. Ethylene oxide gas sterilization was performed at 55°C for 4.5 hours. In vitro degradation in 0.01 M phosphate buffered saline (PBS, pH 7.4) solution at 37 ± 1°C for 8 weeks was applied to one subgroup in each mesh group. Tensiometric measurements and scanning electron microscopic evaluations were completed for control and resterilization specimens.
Results: Regardless of resterilization, when the meshes were exposed to in vitro degradation, all mechanical parameters decreased significantly. Highest reduction in mechanical properties was observed for Ultrapro due to the degradation of absorbable polyglecaprone and polyglactin parts of these

Introduction

Prosthetic mesh repair for abdominal wall hernias is widely used because of its technical simplicity and low hernia recurrence rates (1,2). The most commonly used material is pure polypropylene mesh, although newer composite materials are recommended by some centers due to their advantages shown in clinical and laboratory studies (3-6). Meshes comprising together non-absorbable and absorbable materials have been presented to be strong enough to protect the recurrence and lighter to provide less complications related to biocompatibility (3,4,7,8).

Two types of composite meshes have frequently been used in the literature: a composition of monofilament polypropylene and monofilament polyglecaprone, and a composition of multifilament polypropylene and multifilament polyglactine. These two meshes are more expensive than pure polypropylene meshes. Besides, resterilization of a pure polypropylene mesh has been shown to be quite safe (9,10), and many centers in developing countries in Africa, Asia and the Middle East prefer slicing a 30 x 30 mesh into smaller pieces suitable for any hernia type or defect size. Nevertheless there is no data about the safety after resterilization of composite meshes.

In the product manual of all the commercial meshes an official warning states "do not sterilize". We previously reported that pure polypropylene mesh can be resterilized with autoclave or ethylene oxide at least once without significant changes in their mechanical properties and physical structures, however gas sterilization with ethylene oxide should be the preferred method (9). In continuation of our previous study we aimed to investigate the effect of ethylene oxide resterilization on composite meshes.

Materials and Methods

"None of the authors has any conflict of interest or disclosure at all".

"The meshes used in this study were not supplied by any manufacturer".

Mesh

A 30 x 30 cm composite mesh consisted of monofilament polypropylene and monofilament polyglecaprone - a copolymer of glycolide and epsilon (ε) - caprolactone - (Ultrapro®, 28 g/m^2, Ethicon, Hamburg, Germany), and a 30 x 30 cm composite mesh consisted of multifilament polypropylene and multifilament polyglactine (Vypro II®, 30 g/m^2, Ethicon, Hamburg, Germany) were used in the study.

Sample preparation

The two large meshes were cut into rectangular specimens sized 50 x 20 mm for mechanical testing and 20 x 20 mm for in vitro degradation experiments.

Ethylene oxide sterilization

Ethylene oxide gas sterilization was performed in the eto. krt 135 device (Ekol Medical, Ankara, Turkey). Ethylene oxide gas was applied to the specimens at 55°C for 4.5 hours. After the sterilization phases, aeration was applied to the samples for 12 hours.

Mechanical testing

The specimens were tested mechanically by using the Lloyd LRX5K mechanical testing machine (Lloyd Instruments Limited, Fareham, England). Gauge lengths of the specimens were adjusted to 20 mm. Tensile tests were performed at a strain rate of 20 mm/min (100% strain per minute). Each tensile test ended when the specimen tore completely. The mesh-structured specimens did not have solid cross-sectional areas and therefore tensile strength and elastic modulus values of the materials could not be calculated. Instead, maximum load before rupture (Fmax, N), elongation at maximum load (ΔL, mm), and quantity of energy required for complete failure of the specimens (E, Nmm) were measured and calculated to investigate the mechanical strength of the specimens.

In vitro degradation

In vitro degradation tests were carried out in 0.01 M phosphate buffered saline (PBS, pH 7.4) solution at 37 ± 1°C (11). For this purpose, 20 x 20 mm meshes were prepared and the samples were incubated in PBS up to 8 weeks. At the end of 1 month and 2 months, samples (n = 4) were taken out, rinsed with distilled water and dried in vacuum oven at 40°C. Weight loss percentages were calculated from the dried weight obtained before and after degradation using gravimetrical method. Weight loss percentages were obtained using the following equation:

$WL\% = (W_0 - W_t) / (W_0) \times 100$, where WL is weight loss, W_0 and W_t are the dry weights of the samples before and after degradation, respectively.

Scanning electron microscopy

Topographic images of the meshes were obtained by scanning electron microscopy (SEM) (FEI Quanta 400 FEG, USA), after coating the samples with gold-palladium under vacuum.

Statistical analysis

Determination of the significance of the differences for the obtained values for Ultrapro and Vypro II was performed by the Mann-Whitney U test. Two-way Anova test was used in order to investigate the significance of resterilization and time effects. Tukey and Tamhane tests were used as post-hoc for time effects. Two-tailed "p" values below 0.05 were accepted for statistical significance.

Results

Tensile properties of Ultrapro mesh and Vypro II mesh after resterilization and degradation were examined. The maximum load before rupture (Fmax), energy required for complete failure (E) and elongation at maximum load (ΔL) values of each group before and after degradation are given in *Fig. 1, 2, 3*, respectively. And all the obtained results are summarized in *Table 1*.

No statistically significant differences were observed between the Fmax and E values of Ultrapro mesh and Vypro II mesh control groups. Fmax values of Ultrapro control and Vypro II control groups were found as 113.12 N and 113.28 N ($p=0.873$), while E values were 1572.83 Nmm and 1504.17 Nmm ($p=0.699$), respectively. ΔL values of Vypro II mesh were found to be significantly larger than Ultrapro mesh regardless of resterilization or degradation time ($0.001 < p < 0.030$).

When resterilized meshes were examined it was observed that resterilization had no significant effect on Fmax ($p=0.779$

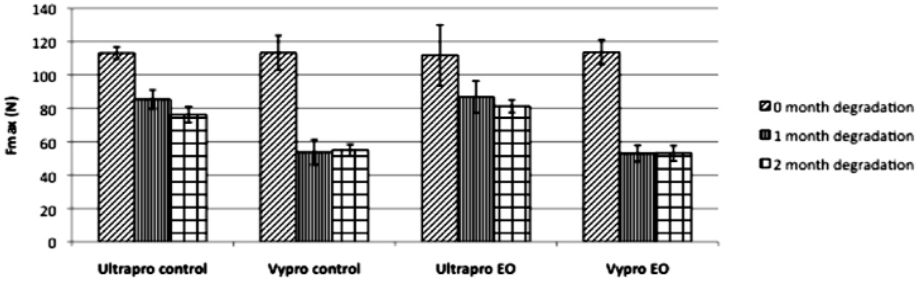

Figure 1. *Maximum force values of meshes*

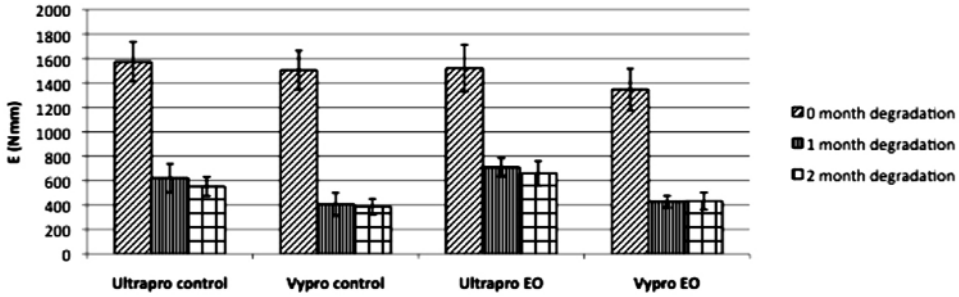

Figure 2. *Energy values required for complete failure of meshes*

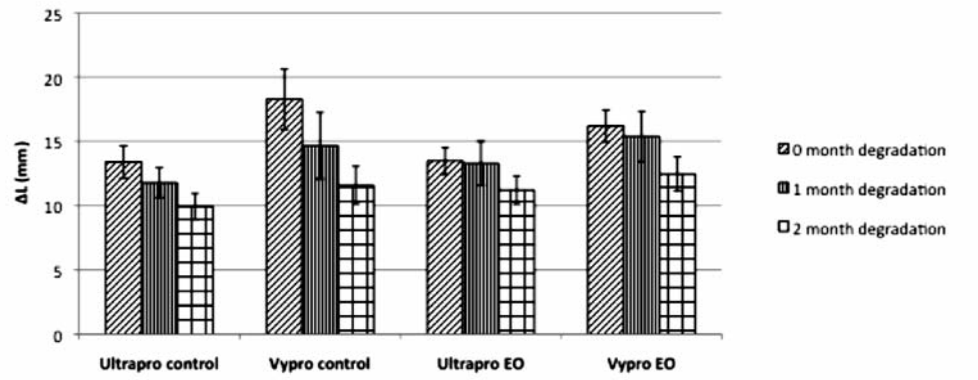

Figure 3. *Elongation at maximum force values of meshes*

Table 1. *Fmax, E, and ΔL values of all groups*

	Fmax (N)	E (Nmm)	ΔL (mm)
Ultrapro control	113.12 ± 3.72	1572.83 ± 160.81	13.39 ± 1.24
Ultrapro control 1 month deg.	85.41 ± 5.66	621.89 ± 116.06	11.78 ± 1.16
Ultrapro control 2 month deg.	76.28 ± 4.70	552.52 ± 79.43	9.92 ± 1.03
Vypro II control	113.28 ± 10.39	1504.17 ± 158.20	18.26 ± 2.34
Vypro II control 1 month deg.	53.73 ± 7.53	407.33 ± 92.23	14.66 ± 2.59
Vypro II control 2 month deg.	54.89 ± 3.45	386.93 ± 65.01	11.58 ± 1.47
Ultrapro EO	111.77 ± 18.30	1520.75 ± 191.85	13.48 ± 1.04
Ultrapro EO 1 month deg.	86.83 ± 9.55	709.99 ± 73.28	13.29 ± 1.72
Ultrapro EO 2 month deg.	81.33 ± 3.78	660.01 ± 102.26	11.21 ± 1.10
Vypro II EO	113.65 ± 7.3	1346.67 ± 170.2	16.19 ± 1.22
Vypro II EO 1 month deg.	52.89 ± 4.92	429.43 ± 48.58	15.38 ± 1.95
Vypro II EO 2 month deg.	53.09 ± 4.82	433.50 ± 68.82	12.46 ± 1.33

for Ultrapro, p=0.873 for Vypro), E (p=0.779 for Ultrapro, p=0.109 for Vypro) and ΔL (p=0.708 for Ultrapro, p=0.109 for Vypro) values of both control group meshes. In addition, when resterilized and non-resterilized meshes were compared after degradation processes there were no statistically significant differences between tensile properties of control and resterilized Vypro II meshes after 1 month and 2 month degradation ($0.149 < p < 0.665$ for all mechanical parameters).

For Ultrapro meshes, after one month of degradation, the mechanical properties remained unaffected by resterilization ($0.060 < p < 0.736$ for all mechanical parameters). But, after 2 months of degradation, all mechanical properties of resterilized meshes were significantly better than non-resterilized ones ($0.013 < p < 0.031$ for all mechanical parameters).

Regardless of resterilization, when meshes were exposed to in vitro degradation, all mechanical parameters decreased

significantly. Significant reduction in mechanical properties was observed due to degradation of absorbable polyglecaprone and polyglactin parts of the meshes. Energy values in all groups decreased by more than 50%.

After 1 month and 2 month degradation regardless of resterilization Ultrapro mesh was found to be significantly stronger than Vypro II mesh in terms of Fmax and E values ($0.000 < p < 0.005$ for all related Fmax and E values).

After one month degradation, excepting ΔL values of resterilized meshes, all other mechanical parameters decreased for all control and resterilized meshes ($0.000 < p < 0.05$). After one month degradation, the decrease in ΔL values of resterilized meshes was not significant ($p=0.887$ for resterilized Ultrapro and $p=0.409$ for resterilized Vypro). After two month degradation, regardless of resterilization and the type of the mesh, all mechanical parameters decreased for all control and resterilized meshes compared to initial parameters ($0.000 < p < 0.001$ for all mechanical parameters).

Gravimetric analysis demonstrated that, generally, there is no significant difference in weight loss percentage values of resterilized and non-resterilized samples ($p > 0.05$ for Ultrapro at 2 to 8 weeks and for Vypro at 5 to 8 weeks). Although up to 5 weeks Vypro II resterilized mesh seems to degrade more than the Vypro II control group, at the end of 8 weeks of degradation weight loss values were almost the same ($p = 0.343$). In general, it can be concluded that ethylene oxide sterilization did not affect degradation behaviour of Ultrapro and Vypro II meshes. When Ultrapro and Vypro II meshes are compared, in both resterilized and non-resterilized groups, Vypro II degraded slower than Ultrapro up to 3 weeks. However after 4 weeks, Vypro II started to degrade faster and at the end of 8 weeks, weight loss of Vypro II EO (57.01%) was higher than weight loss of Ultrapro EO (44.60%).

If the chemical compositions of two meshes are compared, Ultrapro consists of polypropylene monofilaments that are closely tangled with a copolymer of glycolide and ε-caprolactone (named as polyglecaprone), and Vypro II is made up of multifilaments of polypropylene with glycolide and lactide copolymer (named as polyglactin).

It was observed that Vypro II mesh degraded faster than Ultrapro ($p = 0.001$ at 8 weeks). Since polypropylene is rather stable, it is expected that degradation would be controlled by the chains which are polylactide and polycaprolactone for Vypro II and Ultrapro, respectively. Both of these chains can have a semi-crystalline organization, and when semi-crystalline materials are immersed in aqueous media the diffusion of water and therefore degradation by hydrolysis take place in two steps. The first step is the diffusion of water in the amorphous parts where the initial and faster degradation by hydrolysis starts; and the second step is the diffusion of water to the more organized crystalline domains where slower degradation continues. The process for degradation occurs as reduction in molecular weight combined with weight loss. In some cases degradation starts from the surface and causes a rapid weight loss but does not affect the molecular weight, in other cases degradation results in significant decrease in molecular weight, but not in total weight. These depend on the initial preparation conditions of the materials such as crystallinity, shape and molecular weight.

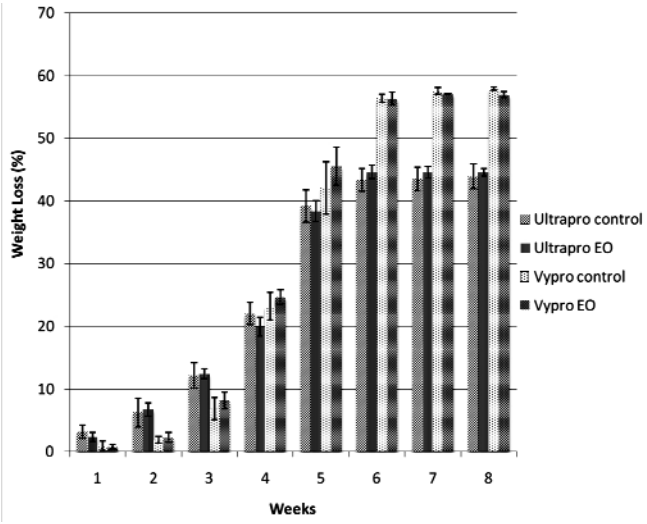

Figure 4. *Weight loss percentage values of meshes after incubating in PBS*

In this study, it was observed that Vypro II mesh degraded faster than Ultrapro mesh indicating that the copolymeric structure of lactide with glycolide is more sensitive to water hydrolysis than that of polycaprolactone existing in Ultrapro mesh. Weight loss percentage value of meshes after incubating in PBS is given in *Fig. 4* and *Table 2*.

SEM

The SEM micrographs of control and resterilized Vypro II

Table 2. *Weight loss (%) of meshes after incubating in PBS up to 8 weeks*

	Ultrapro control	Ultrapro E.O.	Vypro II control	Vypro II E.O.
1 week	3.22 ± 1.07	2.34 ± 0.79	0.94 ± 0.77	2.19 ± 2.79
2 weeks	6.26 ± 2.28	6.74 ± 1.09	1.90 ± 0.53	3.60 ± 2.71
3 weeks	12.17 ± 2.04	12.44 ± 0.79	6.87 ± 1.75	9.92 ± 3.61
4 weeks	22.07 ± 1.77	19.98 ± 1.52	23.21 ± 2.22	26.73 ± 4.25
5 weeks	39.20 ± 2.57	38.39 ± 1.69	42.12 ± 4.17	48.25 ± 5.93
6 weeks	43.38 ± 1.80	44.60 ± 1.07	56.39 ± 0.64	56.94 ± 1.46
7 weeks	43.57 ± 1.87	44.59 ± 0.86	57.55 ± 0.53	57.94 ± 1.59
8 weeks	43.94 ± 1.99	44.60 ± 0.60	57.97 ± 0.26	57.53 ± 1.14

mesh before and after degradation are given in *Fig.* 5. Vypro II mesh is made up of multifilamentous polypropylene combined with an absorbable component made of vicryl. Significant differences were not observed between resterilized meshes and the control groups. It was observed that fibres of meshes were broken homogeneously after degradation.

The SEM micrographs of control and resterilized Ultrapro mesh before and after degradation are given in *Fig.* 6. Ultrapro consists of polypropylene monofilaments that are closely tangled with absorbable monocryl, a copolymer of glycolide and ε-caprolactone. Similar types of homogeneous breaks were observed after degradation.

Discussion

Resterilization of biomedical materials obviously lowers in-hospital care expenses. However, resterilization processes should be reserved for unused medical devices, where the expiration time has been surpassed, or which have a damaged package (12). When a mesh has been in contact with the patient tissues during the operation no piece of it should be considered for resterilization.

Resterilization can create two problems mainly: infection risk and violation of their mechanical and functional properties. Various allografts and prosthetic materials for dentistry, orthopedics, cardiovascular surgery and general surgery were studied for the effects of resterilization (13-15). Novel sterilization methods that are supposed to be harmless to mechanical and functional properties of the biomaterials have also been studied (15). There are three studies on the effects of resterilization of polypropylene meshes that are used in hernia repairs (9,10,16).

The only clinical study revealed that a single resterilization of the mesh with autoclave does not increase infection and recurrence rates in inguinal hernia repair (10). However, at least one central mesh recurrence caused by mesh disruption was reported after repair with a resterilized mesh (17). Our previous laboratory study introduced that single resterilization with autoclave or ethylene oxide did not result in significant changes in mechanical properties or electron microscopic features of the polypropylene meshes.

Dividing a 30 x 30 cm mesh into smaller pieces for hernia repairs (mostly for inguinal hernia) is an economic economical practice, especially in developing countries. Usually pure polypropylene meshes are used for Lichtenstein repair, however some better results with partially absorbable lightweight composite meshes have been reported (18). Although manufacturers strictly warn the surgeons about the use of commercial single use pre-sized materials, scientific data are not in complete agreement with them (9,10). A further economic advantage can appear, if newer composite lightweight meshes are also suitable for resterilization like their pure polypropylene counterparts.

Pure polypropylene mesh is generally accepted as thoroughly inert and is not affected by the bodily fluids (19).

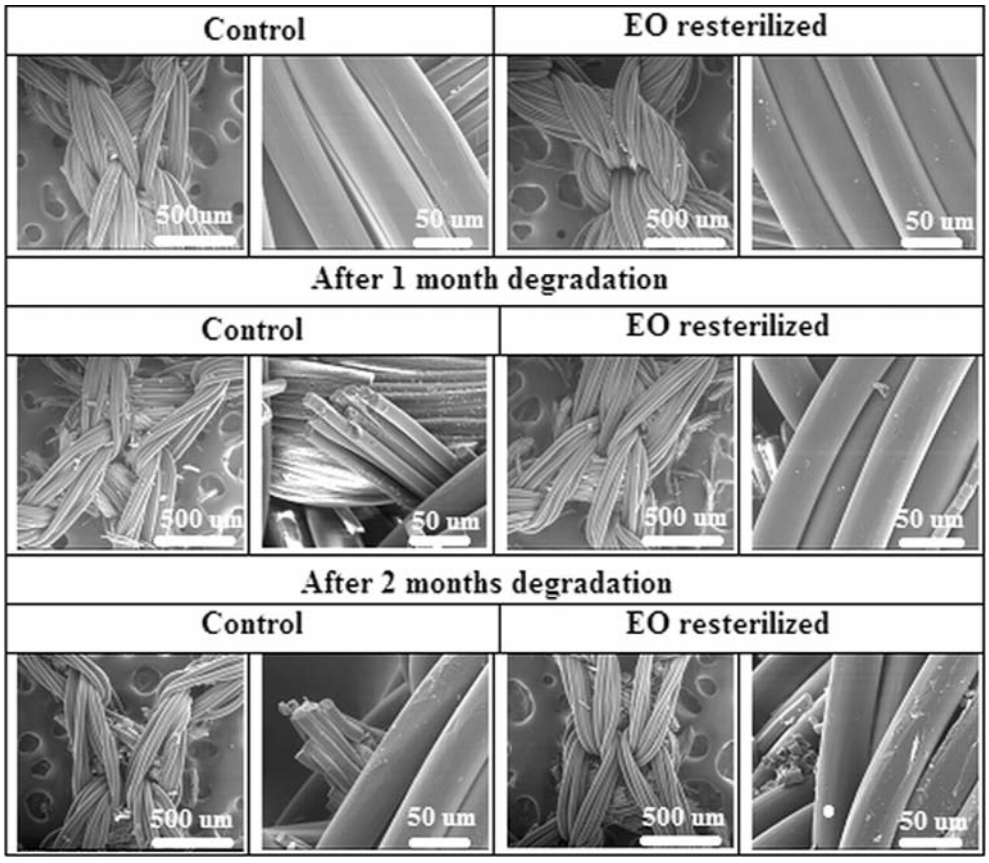

Figure 5. *SEM micrographs of Vypro II mesh*

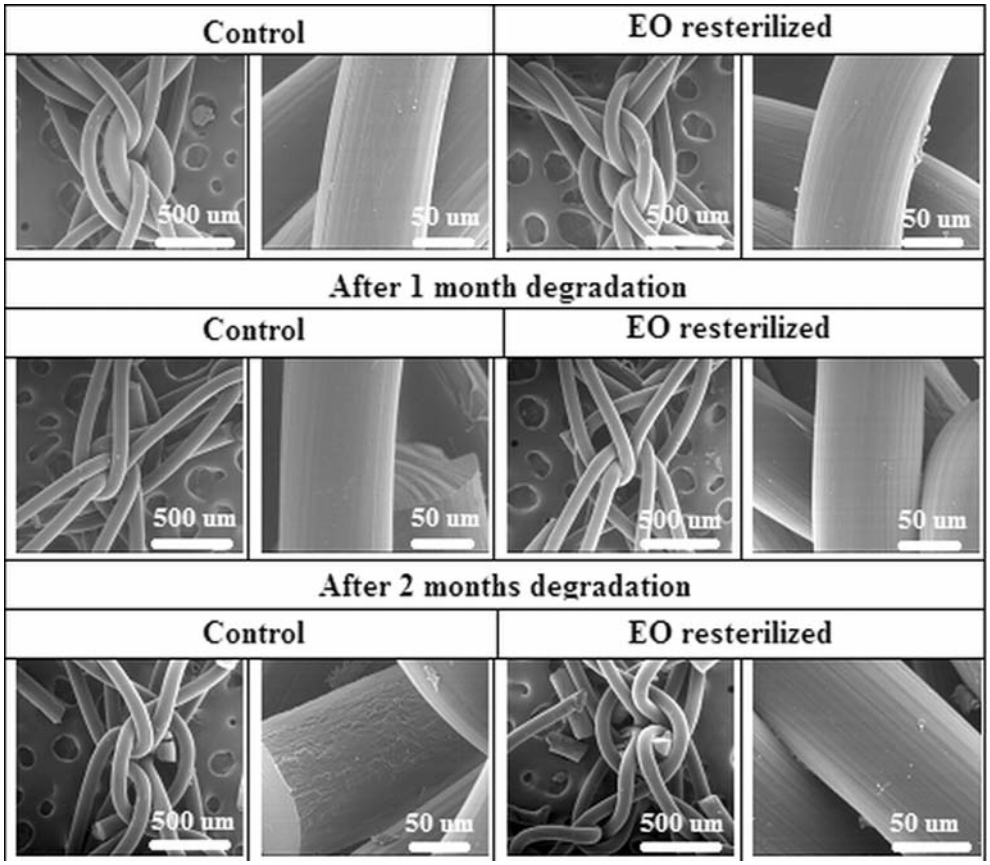

Figure 6. *SEM micrographs of Ultrapro mesh*

However, Coda et al discovered that structural alterations in the size of the mesh pores can be affected by distilled water, saline, blood, as well as in vivo implantation. Prosthetic meshes are, therefore, not the inert materials they are claimed to be and can expand as well as shrink (20). Composite meshes with their absorbable parts are naturally more prone to be affected by water, saline and bodily fluids. These meshes have an absorbable part that contains hydrolytically unstable, linear, aliphatic ester bonds and are resorbed within nearly 2 months. This is the advantage of this kind of lightweight meshes, but also that which may render the material susceptible to resterilization. For this reason, the present study included a 2-month in-vitro degradation phase to observe effects of both resterilization and saline media and it was observed that Vypro II mesh degraded faster than Ultrapro. Since polypropylene is rather stable, it is expected that degradation would be controlled by the chains which are polylactide and polycaprolactone for Vypro II and Ultrapro, respectively. Both of these chains can have a semi-crystalline organization, and when semi-crystalline materials are immersed in aqueous media the diffusion of water and therefore degradation by hydrolysis take place in two steps. The first step is the diffusion of water in the amorphous parts where the initial and faster degradation by hydrolysis stars; and the second step is the diffusion of water to the more organized crystalline domains where slower degradation continues. The process for degradation occurs as reduction in molecular weight combined with weight loss. In some cases degradation starts from surface and causes a rapid weight loss but does not affect the molecular weight, in other cases degradation results in significant decrease in molecular weight but not in total weight. These depend on the initial preparation conditions of the materials such as crystallinity, shape and molecular weight.

Synthetic absorbable suture materials have been on the market for a long time. Experimental and clinical studies in different surgical branches introduced better results in favour of absorbable sutures (21-23). Resterilization of these suture materials has also been studied. Woods and Nagaraja found no statistically significant difference in tensile strength after ethylene oxide resterilization of polyglycolic acid and polyglactin sutures (24,25). The present study also displayed similar tensile strength measurements for the two meshes before and after ethylene oxide use. In fact, the tensile strengths of the composite meshes mostly rely on the non-absorbable polypropylene part.

Ethylene oxide sterilization can leave some residues in the treated material. Ethylene oxide itself and its breakdown products (ethylene glycol, ethylene chlorohydrin, dioxane) are toxic, and sterilized materials should be aired for a period of at least 7 days (12). However, as mentioned above, we previously have shown that ethylene oxide resterilization does not affect the mechanical properties of polypropylene. Hypothetically, similar results are expected for the tensile strength of the composite meshes. In this study, it was observed that ethylene oxide resterilization did not affect the meshes negatively. Furthermore, composite meshes could even display stronger

parameters after ethylene oxide resterilization.

The mechanical parameters of resterilized Ultrapro were stronger than non-resterilized Ultrapro during the degradation process. The increase in mechanical properties and the resistance to degradation after ethylene oxide resterilization can be explained by the formation of new intermolecular attractions and new crosslinks between chains. It was reported that degradation of semi-crystalline polymers takes place in two steps. First water diffuses into the amorphous regions of the polymer matrix and breaks the ester bonds and then the crystalline part becomes susceptible to hydrolytic attack. Upon collapse of the crystalline regions the polymer chain dissolves (26). Slower degradation of Vypro II compared to Ultrapro after 1-3 weeks shows its acceptability to hydrolytic degradation. On the other hand, Vypro II degradation accelerates after the 3rd week and weight loss of Vypro II is much higher than that of Ultrapro in the 8th week.

It should be reminded at this point that lightweight meshes with large pores have shown earlier tissue incorporation and collagen deposition in animal studies (27). The tensile strength values of Ultrapro meshes have been reported to improve after experimental abdominal wall implantation at 2 and 3 months (28). An in vivo degradation by bodily fluids is developing, but the strength of the mesh is increasing because of a good tissue integration in spite of an expected decrease in its mass after 2 months.

Some previous studies on sterilization of polygycolic acid polymers may be worth mentioning. Athanasiou and colleagues, in 1996, stated that the majority of currently available sterilization techniques are not suitable for thermoplastic materials such as polygycolic acid polymers and it may be desirable to develop new sterilization standards (29). The studied techniques in that work were autoclaving, ethylene oxide, and gamma irradiation. Recently, Shearer et al tried to find a new sterilization method that can eliminate the potential problems such as low polymer melting point, complex architectures and hydrolytic degradation mechanisms for the damage of copolymer materials (30). They employed different sterilization techniques (30 min in ethanol solution, 2 h ultraviolet light, and 24 h in antibiotic solution). Although antibiotic solution gave the mildest results, all methods resulted in surface damage and increase in pore sizes. However, both studies were conducted for polyglycolic acid scaffolds. The configurations of those scaffolds are quite different from hernia meshes. They are produced for cell culture or as drug carriers with more delicate morphologies.

Another concern about the resterilization of the meshes was presented by Broll et al (31). They found that autoclave resterilization of polypropylene mesh impaired fibroblast growth after mesh application. The investigators believed that a release of toxic substances from resterilized mesh could have this negative effect. This might be a direct result of autoclaving. Autoclave sterilization subjects the materials to high pressure steam at 121°C or more, for 15 to 20 minutes. On the other hand, ethylene oxide gas is applied to the specimens at 55°C for 4.5 hours. Its heat is less than half of autoclaving, but the duration is much longer. We think it will be useful to set an in-vivo model for resterilized composite meshes to observe fibroblast proliferation and other components of healing and tissue integration.

According to prospectus information and previous studies, composite meshes lose their absorbable part completely within 60-70 days after implantation (31). A similar pattern was recorded in the present study. The composite mesh with polyglecaprone part lost 44% of its weight in the 8th week. The other mesh with polyglactin part also lost 57% of the weight after the same period of time. Ethylene oxide sterilization did not accelerate or retard the absorption process. Therefore, resterilization seemed to be safe in respect of mass effect of these two meshes during the early phase of prosthetic hernia repair.

Conclusion

Ethylene oxide resterilization does not compromise the properties of composite meshes. These meshes can preserve their characteristics even after a degradation process. Eventual decision can be made by studying an in-vivo model. The authors have not used resterilized composite meshes in clinical setting yet. Each center should be setting for an institutional decision for the use of resterilized meshes after evaluating the medicolegal issues.

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