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Scientific paper

Effects of resterilization on mechanical properties of polypropylene meshes

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Abstract

Background: The re-use of sterile packaged polypropylene meshes in hernia surgery is not recommended by the manufacturers. However, especially in developing and underdeveloped countries, many surgeons are obliged to re-use the mesh pieces after resterilization because of economic problems. The purpose of this study was to determine the effects of ethylene oxide and autoclave resterilization on the mechanical properties of polypropylene meshes.

Methods: Repetitive ethylene oxide gas and autoclave sterilizations were applied to polypropylene meshes (Herniamesh S.r.l., San Mauro, Italy) up to 3 times and the effects on the mechanical properties were examined. Gas resterilizations were applied for 4.5 hours at 55°C, whereas for autoclave resterilizations the specimens were kept at 134°C and 3 atm pressure for 64 minutes. Ethylene oxide gas–sterilized samples were labeled as G_n and autoclave-sterilized samples were labeled as A_n. Effects of the resterilizations on maximum load (Fmax), elongation at maximum load (ΔL), and energy required for complete failure of the specimen (E) were measured.

Results: Fmax in the groups showed no significant differences. ΔL values of groups A2, A3, and G3 were found to be significantly lower in comparison with the control group, whereas differences between the control group and other groups were not statistically significant. E values of A2 and A3 groups were significantly lower than that in the control group ($P < .05$), whereas the differences between the control group and other groups were not found to be statistically significant. No significant variations were determined between samples sterilized 1, 2, or 3 times in scanning electron microscopy micrographs, however, small irregularities were observed on autoclaved samples.

Conclusions: Single use of polypropylene meshes is always recommended because of biocompatibility and infection risks. However, if re-use of the open packages is needed, ethylene oxide sterilization is preferred over autoclave sterilization. If ethylene oxide sterilization is not available then 1 cycle of resterilization with an autoclave can be used.

Keywords: Hernia; Mesh; Polypropylene; Sterilization; Autoclave; Ethylene oxide; Re-use

Implantation of prosthetic materials in hernia surgery has become popular worldwide. Polypropylene meshes, first proposed by Usher et al [1] in the early 1960s, are the preferred material for prosthetic repair today [2]. It also commonly is used in many applications such as urinary incontinence slings, vaginal prolapse suspension, and other soft-tissue surgical mesh support. In general, the required strength for the meshes is at least 50 N. Dora et al [3] investigated various materials used for transvaginal anti-incontinence surgery on rabbits and examined the time-dependent variations in tensile strength and stiffness after implantation for up to 12 weeks. They reported that polypropylene mesh did not differ in tensile strength from baseline and even gained stiffness in time. Muller et al [4] used different mesh materials to repair ovine infraspinatus tendons and reported that polypropylene mesh failed at a mean ultimate tensile strength of 75 ± 14 N.

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These meshes are available commercially in sterile packages for single use, and re-use of the remaining pieces is not recommended by the manufacturers: "The Herniamesh range of hernioplasty products comprises several kinds of surgical implants in monofilament polypropylene mesh. All the meshes are ethylene oxide sterilized, disposable and cannot be re-sterilized. The product is valid for 5 years from the packaging date (www.herniamesh.com)."

In the product manual, warning 4 states that "If packaging is open or damaged it is no longer considered sterile and should not be used." Warning 5 states that "Meshes are intended for single use only, discard any unused product and do not resterilize" (Monofilament Polypropylene Surgical Mesh, Instructions for Use; HerniaMesh S.r.l., San Mauro T.se (To), Italia).

The main problem when a mesh is unpackaged and then resterilized is infectious complication risk, however, this does not seem to be the only concern with the resterilization procedure. The size of the prosthetic meshes may change and they may shrink because of repetitive steam or autoclave sterilizations. In fact, this problem is known already by the manufacturers and some of them warn surgeons to avoid those sterilization techniques and instead to resort to ethylene-oxide or gamma-ray sterilizations [5].

On the other hand, the resterilization procedure may alter the mechanical properties of the prosthetic material as a result of polypropylene macromolecular chain degradation. Therefore, meshes may become less resistant to pressure after resterilization. There is at least one known hernia recurrence case caused by mesh disruption after a prosthetic material repair with a resterilized mesh piece [6]. Unfortunately, the re-use of mesh pieces after resterilization is a reality for some surgeons today because of economic problems, especially in developing and underdeveloped countries. This study was designed to investigate the influences of repetitive ethylene oxide and autoclave resterilizations on the mechanical properties of polypropylene meshes.

Materials and Methods

Mesh

An undyed, knitted, pure polypropylene mesh piece, 30 × 30 cm in size, that originally was sterilized by the manufacturer (Herniamesh S.r.l.), was used.

Gas sterilization

Gas sterilizations were performed in the eto.krt 135 device (Ekol Medical, Ankara, Turkey). Ethylene oxide gas was applied to the specimens for 4.5 hours at 55°C for each sterilization process. After the sterilization phases, aeration was applied to the samples for 12 hours. For repetitive sterilizations, the same procedure was performed on the samples at 1-day intervals. The packed samples were kept on the shelf at room temperature between the sterilization phases.

Autoclave sterilization

Autoclave sterilization was performed by using the Trans T06 Autoclave device (Trans Medical Equipment Inc., Ankara, Turkey). For each sterilization process, the specimens were kept at 134°C temperature and 3 atm pressure for 64 minutes. Two or 3 sequential sterilizations were performed at about 1-day intervals by using the same procedure. The packed samples were kept on the shelf at room temperature between the sterilization phases.

Specimen preparation

To avoid differences between mechanical properties of meshes produced from different batches, only 1 square polypropylene mesh piece that was 30 × 30 cm was used. Test samples were prepared by cutting the mesh into rectangular specimens that were 100 × 14 mm. Seven test groups were arranged. Each group had 7 specimens chosen randomly.

The control group contained original samples that were not treated with further sterilizations. Groups A1, A2, and A3 samples all were autoclave resterilized for 1, 2, or 3 times, respectively, and packed separately. For A1 samples, autoclave sterilization was applied only once and the samples were packed and kept at room temperature after the sterilization process until the mechanical tests were completed. For repetitive sterilization to the A2 and A3 samples the coverings of these samples were opened after 1 day and autoclave sterilization was applied for the second time; the samples were packed separately and kept at room temperature. Coverings of A3 samples were opened after 1 day and autoclave sterilization was applied for the third time; the samples were packed and kept under the same conditions as the other samples.

Groups G1, G2, and G3 were gas sterilized once, twice, and 3 times, respectively, and the samples were packed separately after each sterilization process. Gas sterilization was applied only once to group G1 samples. For groups G2 and G3 samples, the coverings were opened after 1 day, gas-sterilization was applied to the samples for the second time, and then the samples were packed separately. For G3 samples the coverings were opened after 1 day and gas sterilization was applied for the third time. All the packed samples were stored on a shelf at room temperature until they were used. Mechanical tests were completed the day after the resterilization processes were applied. Therefore, the samples can be considered freshly resterilized during the application of tension tests.

Mechanical testing

The specimens were tested mechanically by using the Lloyd LRX5K mechanical testing machine (Lloyd Instruments Limited, Fareham, England). Gage lengths of the specimens were adjusted to 40 mm. Tensile tests were performed at a strain rate of 40 mm/min (100% strain). Each tensile test ended when the specimen tore completely. For the mesh-structured specimens a solid cross-sectional area could not be obtained, therefore, tensile strength (force/area) of the materials could not be calculated.

Maximum load before rupture (Fmax), elongation at maximum load (ΔL), and quantity of energy required for complete failure of the specimens (E) were measured and calculated to investigate the mechanical characteristics of specimens. The units are given as Newton, mm, and N.mm for Fmax, ΔL, and E values, respectively.

Scanning electron microscopy

Topographic images of the meshes were obtained by scanning electron microscopy (SEM) (JEOL, JSM-6400; NORAN Instruments, Tokyo, Japan), after coating the samples with gold under vacuum.

Statistical analysis

Determination of the significance of the differences between the groups was performed by the Mann-Whitney U test. All data are reported as means and SDs.

Because the meshes had a woven structure, the area of the specimens changed considerably because of high elongations resulting from the application of force. Therefore, an exact cross-sectional area calculation was not possible. The modulus of elasticity values therefore were unknown. However, because the dimensions of all specimens were the same, the slopes of the force/elongation graphs gave at least a rough idea about the changes in elastic characteristics of the specimens, and a meaningful comparison between the samples was possible.

Results

The Fmax values of each group are shown in Table 1. Although the values in the control group and the other groups were somewhat different, these differences were not found to be statistically significant ($P > .05$).

The ΔL values of each group are shown in Table 1. Groups A2, A3, and G3 were found to have significantly lower values in comparison with the control group ($P < .05$), whereas differences between the control group and other groups were not statistically significant ($P > .05$).

The E values of each group are shown in Table 1. The E values of A2 and A3 groups were significantly lower than that in the control group ($P < .05$). Differences between the control group and other groups were not found to be statistically significant ($P > .05$).

SEM micrographs

Although significant variations were not observed between samples sterilized 1, 2, or 3 times and the control samples, small irregularities were observed on autoclaved samples (Figs. 1 and 2).

Comments

Polypropylene meshes are the preferred material for tension-free inguinal hernioplasties and ventral hernia repairs in many centers today [7–10]. These meshes are available in sterile packages for single use. However, because it is cheaper, some surgeons prefer cutting 1 large piece of mesh into several smaller pieces and to re-use the pieces after resterilization. Although it is not recommended by the manufacturers mainly because of the risk for infection, recent studies have shown that it also is inconvenient because of another reason: mesh shrinkage after repetitive sterilizations [5].

Furthermore, at the 1999 Incisional Hernia Symposium in Aachen, Germany, a central mesh recurrence case caused by mesh disruption was reported after a prosthetic material repair with a resterilized mesh piece [6].

Therefore, it should be kept in mind that resterilization techniques may alter the mechanical properties and strength of the prosthetic materials and render them less reliable in hernia repair.

In the present study we found that energy (E) values of the A2 and A3 groups were significantly lower than values in the control group. This means that a lesser amount of energy is needed for mesh failure or disruption after 2 or more autoclave resterilization procedures, compared with the original sample. In addition, Fmax values, reflecting the resistance of the mesh to maximum load before disruption,

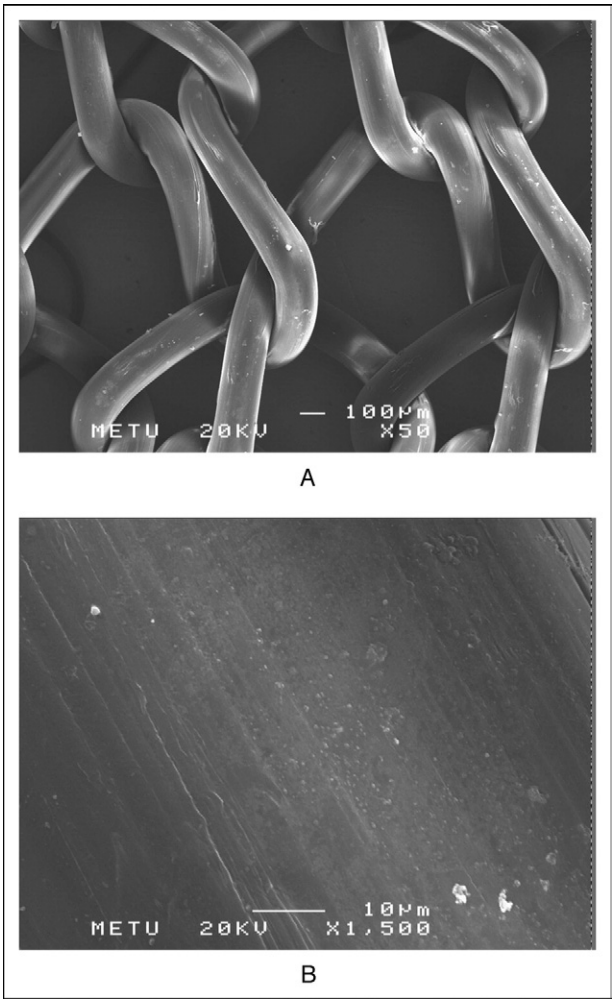

Fig. 1. SEM micrographs of polypropylene mesh control group. (A) ×50 (general appearance). (B) ×1500 (fiber surface).

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

Sample	Fmax, N	ΔL, mm	E, Nmm
Control	62.78 ± 4.14	83.84 ± 6.44	1991 ± 306
A1	68.63 ± 5.64	78.10 ± 6.52	2081 ± 287
A2	56.82 ± 8.78	73.80 ± 7.15*	1563 ± 327*
A3	56.23 ± 11.73	72.42 ± 7.13*	1556 ± 451*
G1	61.96 ± 10.86	74.61 ± 1.36	1888 ± 349
G2	69.34 ± 4.97	76.50 ± 5.36	2028 ± 208
G3	59.95 ± 15.26	73.73 ± 11.14*	1741 ± 663

* $P < .05$ in comparison with control group.

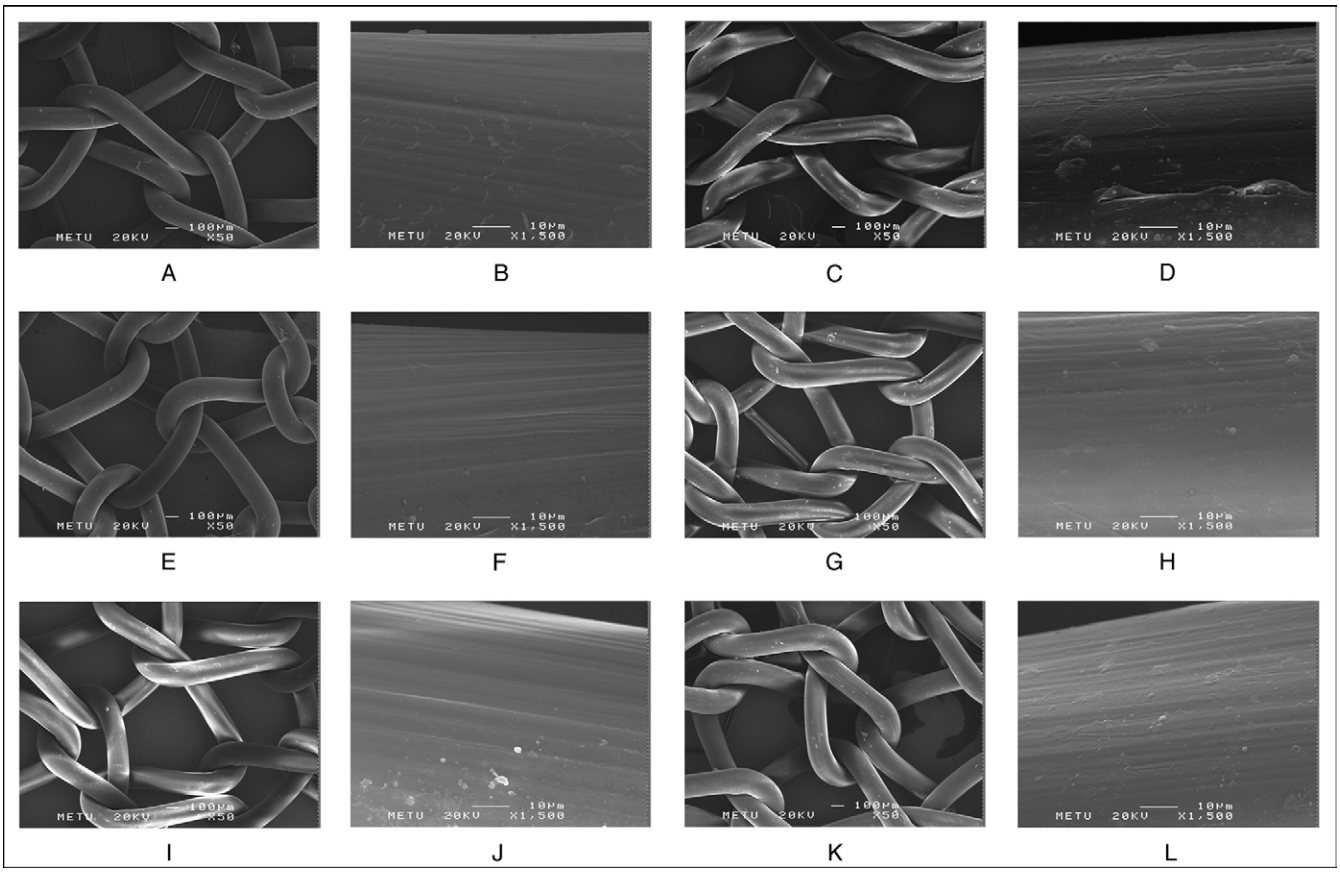

Fig. 2. SEM micrographs of resterilized polypropylene meshes. (A) G1 ×50 (general appearance). (B) G1 ×1500 (fiber surface). (C) A1 ×50 (general appearance). (D) A1 ×1500 (fiber surface). (E) G2 ×50 (general appearance). (F) G2 ×1500 (fiber surface). (G) A2 ×50 (general appearance). (H) A2 ×1500 (fiber surface). (I) G3 ×50 (general appearance). (J) G3 ×1500 (fiber surface). (K) A3 ×50 (general appearance). (L) A3 ×1500 (fiber surface). G1 = gas sterilized once, A1 = autoclaved once, G2 = gas sterilized twice, A2 = autoclaved twice, G3 = gas sterilized three times, A3 = autoclaved three times.

showed a decrease after the second sterilization in the autoclaved groups, an increase after the first autoclave sterilization and a significant decrease after the second treatment. This can be explained by the formation of some degree of cross-linking between the polypropylene macrochains in the mesh structure. A similar behavior was reported in the study by Staggers and Margeson [11] even for orthodontic nickel titanium wires. They found a significant increase in tensile strength of the wires after 1 resterilization cycle with an autoclave, but no decrease was recorded after even the fifth resterilization cycle. On the other hand, it also has been reported that no changes on surface physical topographies were observed with SEM for different orthodontic wires after autoclave sterilization [12].

Although the earlier-described results are given for metallic wires, this might not be the case for plastic polypropylene material. Both gas and autoclave sterilizations may affect the molecular structure and/or fabric of polypropylene meshes either by forming cross-links between the polypropylene chains or by breaking them and creating smaller chains and/or oligomers. SEM micrographs in the present study showed small irregularities for the autoclaved meshes, but no abnormalities were seen in the gas sterilization group. These structural changes may be responsible for crack initiation before mesh failure.

The only study in the literature of resterilized polypropylene meshes was reported recently by Broll et al [13] from Lübeck University. In fact, they did not investigate the mechanical properties of the meshes. However, their experiment studied another important point: fibroblast growth on the meshes. In their study, polypropylene mesh resterilized by steam autoclave (only once) inhibited the growth of fibroblasts significantly. The investigators believed that a release of toxic substances from the resterilized mesh could have a negative influence on cell proliferation. Because one of the main advantages of polypropylene mesh in hernia surgery is the stimulation of fibroblast growth, we believe the results of Broll's study should be considered as a recommendation against resterilization of the meshes.

SEM micrographs also showed almost no changes in the physical and topographic shapes of the meshes. Some minimal alterations were observed for the samples that were resterilized by autoclaving.

In light of these results, we could say that polypropylene meshes become less resistant and less reliable after the second autoclave sterilization. However, only 1 cycle of resterilization with an autoclave seems to be acceptable in respect to mechanical properties. During surgery, one can cut a large piece of polypropylene mesh into small pieces, package them separately, and resterilize the pieces once

more without any harm. On the other hand, repeated gas sterilization had almost no adverse effects on the mechanical properties of polypropylene meshes even after 3 consecutive cycles.

Conclusions

In summary, ethylene oxide sterilization results in minimal changes to the mechanical properties of polypropylene meshes according to our testing methods. It is preferable to use autoclave sterilization, which may be used for a single cycle if gas sterilization is not available. However, our findings apply only to the mechanical properties of polypropylene meshes and do not apply to the potential issues of infection or biocompatibility in patients.

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