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In vivo study of meshes implanted over the inguinal ring and external iliac vessels in uncastrated pigs

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Abstract
Background: The effects of placing a prosthesis directly on the internal inguinal ring and external iliac vessels in inguinal hernia repair are unknown. We compared tissue responses to five prostheses implanted in this position in uncastrated male pigs.
Methods: Three types of polypropylene and two types of expanded polytetrafluoroethylene (ePTFE) mesh were implanted in 20 pigs ($n = 8$ for each prosthesis type). Specimens of the implants and surrounding tissue were obtained 30 and 90 days after implantation and assessed histologically.
Results: The polypropylene implants had more adhesions, more surface area covered by adhesions, and more tenacious adhesions than did the ePTFE implants. Perivascular cuffing was observed in eight polypropylene and one ePTFE specimen; ossification, necrosis, and testicular venous congestion were seen in polypropylene specimens.
Conclusions: Abnormal healing processes after implantation of polypropylene mesh may increase complications of the transabdominal preperitoneal and total extraperitoneal approaches in laparoscopic inguinal hernia repair, whereas the minimal response to ePTFE meshes may make them safer for use in the preperitoneal space.

Key words: Laparoscopic hernioplasty — Inguinal hernia — Expanded polytetrafluoroethylene — Polypropylene — Adhesions — Transabdominal preperitoneal approach — Total extraperitoneal approach — Intraperitoneal onlay mesh approach

Laparoscopic inguinal hernia repair often uses either the transabdominal preperitoneal (TAPP) or the total extraperitoneal approach (TEP) and a prosthetic material, most commonly a polypropylene or expanded polytetrafluoroethylene (ePTFE) mesh. However, little is known about the effects of placing a prosthesis directly on structures in the preperitoneal space and the ultimate outcome of any abnormalities that may develop. Ischemic orchitis, which can result in testicular atrophy, is a rare but serious complication of inguinal herniorrhaphy [18]. Its causes have not been clearly identified, but it is possible that tissue reaction to placement of a prosthetic mesh may be one etiologic factor.

In many studies in animals [1, 2, 6–8, 10, 15], researchers have observed formation of adhesions between polypropylene mesh and various tissues, an extensive foreign-body reaction, or both, after placement of the mesh according to approaches used in laparoscopic inguinal hernia repair. For example, Eller et al. [7] observed adhesions to the left inguinal region in 12 of 21 pigs in which polypropylene mesh was implanted during laparoscopic herniorrhaphy. Other experimental studies [3, 4, 9, 11, 13] compared polypropylene mesh and ePTFE mesh used for abdominal wall reconstruction and found that, in general, ePTFE meshes produced a less intense inflammatory reaction and fewer, less tenacious adhesions than did polypropylene meshes.

The purpose of our study was to compare the tissue response to several polypropylene and ePTFE meshes placed in the preperitoneal space to repair an inguinal hernia. Specifically, in a pig model of inguinal hernia repair, we compared the effects on spermatic cord structures and blood vessels of the following materials: a monofilamented, macroporous polypropylene mesh (Marlex, C.R. Bard, Inc., Murray Hill, NJ), a monofilamented, macroporous double-weave polypropylene mesh (Prolene, Ethicon, Inc., Somerville, NJ), a multifilamented, knitted polypropylene mesh (Surgipro, United States Surgical Corp., Norwalk, CT), a two-surfaced (ingrowth and noningrowth) ePTFE mesh (Gore-Tex DualMesh Biomaterial, W.L. Gore & Associates, Inc., Flagstaff, AZ), and a perforated ePTFE mesh (Gore-Tex MycroMesh Biomaterial, W.L. Gore & Associates).

Methods

All animals were used and cared for in accordance with the *Guide for the Care and Use of Laboratory Animals* (NIH Publication No. 86-23, revised

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Table 1. Adhesion results at 30 days

Mesh (n = 4 for each)	Number of implants with adhesions	Mean % of implant surface covered with adhesions	Mean tenacity[a] of adhesions
Marlex	4	100	3
Prolene	4	94	3
Surgipro	1	75	3
DualMesh	1	50	2
MycroMesh	0	0	0

[a] Tenacity was scored according to the following system: 1 = adhesion easily separable with light pressure; 2 = adhesion requires blunt dissection for separation; or 3 = adhesion requires sharp dissection for separation

1985) and the Louisiana State University Policy for the Care and Use of Animals. Twenty uncastrated male pigs were divided randomly into two groups: one in which all animals were sacrificed 30 days after mesh implantation and one in which sacrifice occurred 90 days postoperatively. Each pig received two implants, one on each side, so that each of the five prosthetic materials studied was implanted four times in both the 30-day and the 90-day group.

The prosthetic materials were implanted at laparotomy with the pigs under general anesthesia. A peritoneal flap was raised on each side and a mesh was placed under the flap, directly on the deperitonealized external iliac vessels and the internal inguinal ring. The peritoneal flap was closed with surgical staples. After the animals recovered from the procedure, they were returned to their pens and fed a normal diet. At 30 or 90 days postoperatively, they were sacrificed by electrocution and specimens of the implants and surrounding tissue were obtained for study.

All specimens were examined grossly and microscopically by one pathologist. Adhesions between the explanted mesh were classified according to a modified Diamond scale [5] with respect to the number of implants with adhesions, the extent of adhesions (percentage of implant covered by adhesions), and the tenacity of adhesions (1 = easily separable with light pressure; 2 = separable by blunt dissection; and 3 = separable by sharp dissection only). Histologic evaluations assessed the condition of the spermatic vessels and cord, lymph nodes, and testes adjacent to the implant.

Results

The results of the adhesion assessment in the specimens obtained 30 days after mesh implantation are shown in Table 1; Figs. 1–6 show representative gross and microscopical studies. More polypropylene implants than ePTFE implants had adhesions, and those adhesions covered more of the implant and were more tenacious than the adhesions to ePTFE mesh. All three polypropylene meshes had adhesions to the omentum. The Surgipro and Marlex implants had adhesions to the spermatic cord; all three types of polypropylene meshes had adhesions to the spermatic vessels. Nonspecific lymphadenitis was observed in enlarged lymph nodes adjacent to all the Marlex specimens and two of the Prolene specimens. Follicular hyperplasia with sinus histiocytosis was present in one Prolene specimen; a hematoma was observed in another. A ''cuffing'' of lymphocytes around the spermatic vessels was seen in three Surgipro specimens, one Prolene specimen, and one Marlex specimen.

In the ePTFE specimens, there was one omental adhesion to a DualMesh implant and one enlarged lymph node with nonspecific lymphadenitis adjacent to a DualMesh implant. There were no adhesions to the MycroMesh implants. One node adjacent to a MycroMesh implant showed nonspecific lymphadenitis. Perivascular cuffing was not observed in any ePTFE specimen.

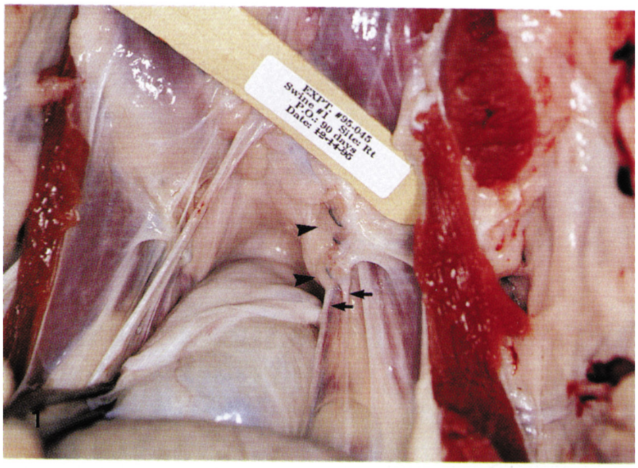
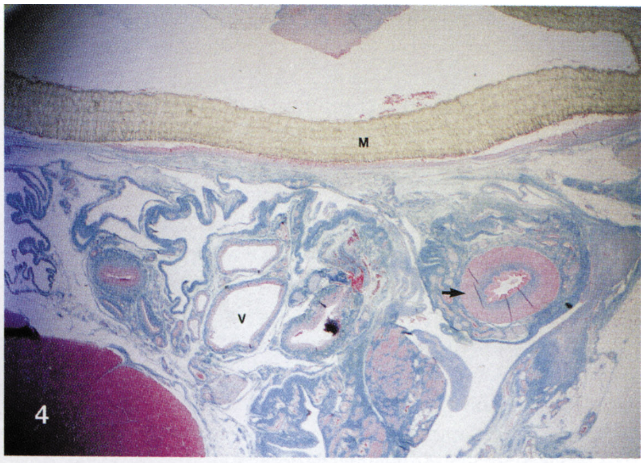


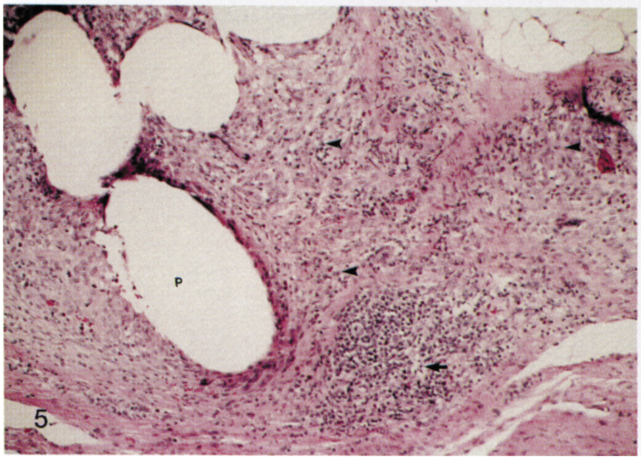
Fig. 1. Gross appearance of polypropylene mesh (*arrowheads*) at 90 days after implantation. The spermatic vessels (*arrows*) are adherent to the edge of the mesh, which is covered by a dense fibrocollagenous tissue.

Fig. 2. At 90 days after implantation, the polypropylene mesh (*arrowheads*) is covered by a dense fibrous scar (*S*) that entraps the large blood vessels. The omentum (*O*) is adherent along the visceral surface (Verhoeff-van Gieson stain; 2.5×).

Table 2 shows the adhesion assessment results in the specimens obtained at 90 days. Again, the ePTFE specimens generally had fewer, less extensive, and less tenacious adhesions. All three polypropylene meshes had adhesions to the omentum and spermatic vessels; the Prolene specimens also had adhesions to the spermatic cord. Perivascular cuffing was seen in one Prolene and one Marlex specimen. A Surgipro specimen had calcification in the scar tissue around the mesh. The Prolene and Marlex specimens showed calcification, ossification, and necrosis of soft tissue, and hemorrhage around the mesh. Venous congestion of the testis was observed in one specimen each of the Prolene and Marlex implants.

The DualMesh specimens had no adhesions and showed an unremarkable tissue response. One MycroMesh specimen had a lymph node adhesion to the cranial edge of the periimplant membrane that showed follicular hyperplasia. Another specimen had perivascular cuffing. No evidence of calcification, ossification, necrosis, hemorrhage, or testicular venous congestion was observed in any ePTFE specimen. Lymphadenopathy was not observed in any specimen—either polypropylene or ePTFE—obtained 90 days





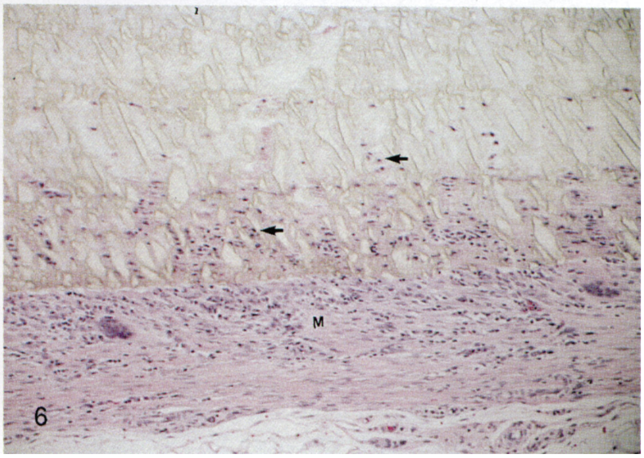


Fig. 3. Gross appearance of an ePTFE mesh (*arrowhead*) at 90 days after implantation. The ePTFE mesh is covered by a thin translucent membrane. The vessels maintain their normal anatomical position.

Fig. 4. At 90 days after implantation, a thin, bland-appearing fibrous membrane covers the ePTFE mesh (*M*). The spermatic cord (*arrow*) and the vessels (*V*) appear unremarkable (Milligan's trichrome; 2.5×).

Fig. 5. At 90 days after implantation, an intense inflammatory response consisting of lymphocytic (*arrow*) and histiocytic (*arrowheads*) infiltration around the polypropylene mesh (*P*) is present (H & E; 2.5×).

Fig. 6. At 90 days after implantation, the periimplant membrane (*M*) around the ePTFE mesh appears bland, with minimal inflammation. Cellular migration of fibroblasts and histiocytes (*arrows*) into the interstices is evident (H & E; 2.5×).

after implantation. In all specimens examined in the study, the testes were partly or well differentiated.

Discussion

Our results indicate that a prosthetic mesh, particularly a polypropylene mesh, can invoke an intense tissue reaction when placed in the preperitoneal space, as is done in the TAPP and TEP approach in laparoscopic inguinal hernia repair. Our findings at 90 days postoperatively are more relevant than those at 30 days with respect to the reaction to the implanted materials themselves, since tissue responses observed 30 days after implantation may still partly represent the reaction to surgical trauma. By 90 days, normal wound healing should have occurred. In the polypropylene specimens, however, we observed pronounced adhesion formation, ossification and necrosis of soft tissue, and venous congestion of the testes.

The possible long-term effects of such abnormalities on testicular function are unknown. Nevertheless, thrombosis of the testicular veins with intense venous congestion of the testis is considered to be the basic pathological process in ischemic orchitis, which can result in testicular atrophy and infertility [18]. Wantz [18] has emphasized the importance of minimizing surgical trauma to the spermatic cord during hernia repair to help prevent ischemic orchitis. The spermatic cord adhesions and other tissue reactions observed in our study may also represent a damaging process that could increase the risk of orchitis. Lessening this risk in patients

Table 2. Adhesion results at 90 days

Mesh ($n = 4$ for each)	Number of implants with adhesions	Mean % of implant surface covered with adhesions	Mean tenacity[a] of adhesions
Marlex	3	75	3
Prolene	4	75	3
Surgipro	4	63	3
DualMesh	0	0	0
MycroMesh	1	25	2

[a] Tenacity was scored according to the following system: 1 = adhesion easily separable with light pressure; 2 = adhesion requires blunt dissection for separation; or 3 = adhesion requires sharp dissection for separation

undergoing laparoscopic groin hernia repair may depend partly on the choice of implantation technique and prosthetic material.

Currently, most laparoscopic inguinal hernia repairs are done with the TAPP, TEP, or intraperitoneal onlay mesh (IPOM) approach. Each method has its advocates, and experimental and clinical studies comparing the techniques have evaluated different factors and yielded various results. With respect to adhesion formation, Attwood et al. [1], in a study in pigs, found no difference between intraperitoneally and extraperitoneally placed polypropylene mesh. In a canine model, Schlechter and colleagues [15] found that approaches in which polypropylene mesh was implanted in a reperitonealized fashion resulted in less adhesion formation than did the onlay approach. In contrast, Durstein-Decker et al. [6] observed a significant decrease in the number of adhesions in pigs in which polypropylene mesh was simply placed over the defect and stapled in place (without being covered with peritoneum) compared with pigs in which the peritoneum was not reapproximated after mesh placement. Fitsgibbons et al. [8], in a study in pigs in which the IPOM method and polypropylene mesh were used to repair indirect hernias, found a significantly decreased incidence of adhesions with laparoscopic compared with open repair.

In clinical studies, Phillips et al. [14] reported a decreased number of postoperative small-bowel obstructions and cases of testicular pain in patients who underwent an IPOM procedure compared with those who had a TAPP or TEP repair. The total patient population in their series was 3,229. In a series of 1,514 patients who underwent laparoscopic inguinal hernia repair described by Tetik and colleagues [16], there were 23 testicular complications: 20 cases of testicular pain, two of epididymitis, and one of orchitis. None of these problems occurred in a patient who had IPOM surgery.

In none of the experimental or clinical studies comparing approaches for laparoscopic inguinal hernia repair was ePTFE mesh used. However, other investigations have assessed the use of ePTFE mesh in onlay repairs. In an experimental study comparing ePTFE, Marlex, and Prolene meshes, Layman et al. [10] used the onlay method in 30 male pigs and found only two major adhesions—both to polypropylene mesh. They theorized that the low adhesion rate was due to three factors: the rapid rate of proliferation of peritoneum over the surface of a biomaterial placed in close proximity to an undamaged peritoneal lining, decreased trauma to layers of peritoneum from use of laparoscopy instead of laparotomy, and placement of the patch so it was not in contact with the omentum. We [12] and others [17] have reported on series of patients in whom ePTFE mesh was used for inguinal IPOM hernia repair. Our series [12] included 264 repairs; that of Toy et al. [17] had 212. Neither series had any complications related to adhesions.

Additional studies are required to establish with certainty which technique and prosthesis provide the most safety and efficacy in laparoscopic hernia repair. However, we think that the findings in this study raise the possibility that abnormal healing processes may increase testicular complications of the TAPP and TEP approaches if polypropylene mesh is implanted. On the other hand, the minimal tissue response to ePTFE meshes may make them safer for use in the preperitoneal space.

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Discussion

Dr. Talamini: Based upon this work, what are you using clinically for hernia repairs currently?

Dr. LeBlanc: Gore-Tex. For the laparoscopic we are using the dual-mesh, and the micro-mesh for the open.

Dr. Talamini: Over the years it's been stated a number of times that when this repair is done laparoscopically, the repair depends upon a fibrotic reaction that is generated by whatever piece of mesh or graft is placed in the canal. Maybe you could comment upon that. Is there a material that may strike a better balance between inflammation, to actually help with the repair without creating all these adhesions?

Dr. LeBlanc: To us, the Gore-Tex is the most suitable material. I've been using it for ten years, and I've used it almost exclusively for laparoscopic repairs. The tissue incorporation that does occur is more of a normal type of tissue healing, and we have documented experimentally that this collagen ingrowth within the interstices of the Gore-Tex in its normal process, and you really don't see this, even with the other studies we've done.

Dr. Talamini: Thank you, Dr. LeBlanc.