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ORIGINAL ARTICLE

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Comparison of two composite meshes using two fixation devices in a porcine laparoscopic ventral hernia repair model

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Abstract *Introduction*: Laparoscopic ventral hernia repair uses tacks to secure mesh. The mesh is designed to maximize tissue ingrowth while minimizing adhesions. We hypothesized: (1) a collagen-coated polyester mesh (PCO) will form fewer adhesions than an ePTFE-polypropylene composite (BC) and (2) absorbable tacks are equivalent to metal tacks. *Methods*: In a porcine model of adhesion formation, three pieces of 10×15-cm mesh were placed on the anterior abdominal wall. PCO was secured with absorbable (PLA) or metal tacks (PT), BC with PT. At 28 days, adhesion formation, abdominal-wall adherence, and tissue ingrowth were analyzed. *Results*: PCO induced fewer adhesions (14.5% vs 53.4%, $P=0.007$). On an adhesion scale (0–5), BC scored 3.6 vs 1.75 for PCO ($P<0.03$). There was no difference in adhesion strength, tack adhesions, or abdominal-wall peel force. Histology showed equal ingrowth. *Conclusions*: PCO induces fewer adhesions than BC. There is no difference in the ingrowth of the two mesh types. The PLA achieves equivalent mesh incorporation to the PT.

Keywords Laparoscopy · Ventral hernia · Adhesions · Surgical mesh · Prosthesis implantation

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Introduction

Incisional hernias are a significant source of morbidity for patients who have undergone abdominal surgery. Incisional hernias develop after 2–11% of all laparotomies [1], resulting in an estimated 90,000 incisional hernia repairs annually [2]. Unfortunately for many of these patients, recurrences after operative repair are common. As a result, surgeons have developed many different techniques and approaches for repairing these hernias.

Options for ventral or incisional hernia repair include open primary sutured repair, open prosthetic mesh repair, and, most recently, laparoscopic repair with intraperitoneal placement of prosthetic mesh. Lifetime risk of recurrence after an initial primary repair of an incisional hernia is as high as 41% or more [3]. A review of multiple prospective, randomized trials comparing primary suture repairs with open prosthetic mesh repairs demonstrated 3-year recurrence rates of 43% for primary repairs and 24% for repairs using mesh [4]. The results using mesh are better than primary repairs, but they still demonstrate significant recurrence.

Recent publications have compared open mesh and laparoscopic mesh repairs by using both hernia recurrence rates and overall complication rates as primary end points. In general, operative time and length of stay are shorter [5, 6, 7] and complication rates are lower with the laparoscopic approach [6, 7, 8]. In published series, the recurrence rate of laparoscopic ventral hernia repair ranged from 2.5 to 4.7% [2, 6, 9, 10].

The typical laparoscopic incisional hernia repair technique involves the complete reduction of herniated abdominal viscera back into the abdominal cavity and placement of a nonabsorbable prosthetic mesh over the defect with a significant (3–5-cm) overlap onto the peritoneal surface of the abdominal wall. The success of this technique is dependent on two critical properties of mesh: (1) adherence of the mesh to the abdominal wall as a result of fibrous ingrowth and (2) reduction or elimination of the risk of significant intra-abdominal adhesion formation, bowel erosion, and fistula formation. Additionally, the type of fixation device may impact the strength of the adherence to the abdominal wall and the formation of adhesions. Multiple types of mesh are currently available, and each is a result of a strategy to meet these goals. Currently available types of mesh include a prosthesis composed of two layers of ePTFE, a composite mesh of ePTFE for the visceral side and polypropylene for the parietal side, and mesh with polypropylene or polyester for the parietal side and an antiadhesive film for the visceral side.

The technique for fixation of the prosthetic mesh to the parietal surface of the abdominal wall remains a controversial issue. Although surgeons have traditionally fixed the mesh with a combination of transfascial anchoring sutures and metal tacks, the fixation tacks and sutures themselves may be a nidus for adhesion formation.

In this study, we utilized a previously described model for adhesion formation in pigs [11] to evaluate two types of commercially available mesh types. We studied collagen-coated polyester (PCO, Parietex Composite, Sofradim Corporation, Trévoux, France) and composite ePTFE/polypropylene mesh (BC, Composix E/X, Bard, Murray Hill, N.J. USA) for adhesion formation and tissue incorporation. In addition, we evaluated two methods of sutureless mesh fixation utilizing helical metal tacks (PT, Protacker, United States Surgical Corporation, Norwalk, Conn. USA). and a novel absorbable tacking system (PLA, Pariefix absorbable tacks, Sofradim Corporation, Trévoux, France).

Materials and methods

The experimental protocol underwent review and approval by the IACUC (institutional animal care and use committee). Female Yorkshire swine weighing approximately 30–40 kg were obtained from Animal Biotech Industries, Inc. (Danboro, Penn. USA) and allowed to acclimate in our animal husbandry unit for 3–5 days. Animals were cared for in accordance with USDA (United States Department of Agriculture) and IACUC regulations. After acclimation, the animals received general anesthesia and underwent bowel abrasion via a mini-laparotomy. This was followed by laparoscopic placement of three pieces of dual-sided mesh, as described below.

Operative technique

Mechanical abrasion of the bowel was performed using a surgical scrub brush via a mini-laparotomy to induce the formation of visceral adhesions in the peritoneal space. Following bowel abrasion, eight animals underwent laparoscopic placement of three pieces each of 10×15-cm mesh to the anterior abdominal wall. Two pieces of PCO mesh were placed and secured with either PLA absorbable tacks or PT helical tacks. The third piece of mesh, BC, was secured with PT helical tacks.

Mesh was fixed to the anterior abdominal wall by tack fixation alone. The PT helical tacks were placed around the periphery of the mesh, approximately 1 cm apart. PLA absorbable tacks were placed, ten per mesh, at the corners and equally along the sides of the mesh. This was performed as per the PLA manufacturer's recommendations for fixation of the PCO mesh.

At necropsy after 28 days' survival, each piece of implanted mesh was examined for adherence to the abdominal wall, signs of tack failure, adhesion formation to the mesh, tissue ingrowth on the parietal surface of the mesh, and adhesions to the tacks. A veterinary pathologist performed histologic analysis on all specimens.

The relative location of the three implants (with the varied fixation techniques) was randomized in each animal, with each animal receiving one of each of the three mesh/fixation combinations. All numerical data were analyzed by calculating the mean from the necropsy data on all eight animals. Statistical significance was determined utilizing a paired *t*-test with a 0.05 two-sided significance level. All specimens underwent histologic analysis by a veterinary pathologist, who was blinded to the adhesion and peel-strength data.

Results

The procedure was well tolerated by six of the eight animals. These animals were ambulatory and taking fluids and feed within 12 h of the procedure. Two animals demonstrated signs of ileus for approximately 48 h. These animals were hydrated intravenously until they tolerated oral intake.

At necropsy, all animals demonstrated some degree of visceral adhesion formation, both interloop adhesions and adhesions of the bowel, liver, and spleen to mesh. A representative image of a gross necropsy specimen is shown in Fig. 1. In this figure, a large amount of bowel adhesions are present to the BC mesh. The PCO mesh demonstrates significantly fewer adhesions.

There were no episodes of herniation or bowel entrapment around the edges of the mesh. The PT and PLA tacks appeared grossly to be adequately anchoring the mesh to the abdominal wall with the exception of one PT tack in one animal that had pulled out of the abdominal wall and allowed the corner of one piece of PCO mesh to fold over.

PCO induced a significantly smaller area of adhesions than BC ($14.5 \pm 12.4\%$ for PCO/PT and $7.5 \pm 10.4\%$ for PCO/PLA vs $53.4 \pm 9.8\%$ for BC/PT, $P = 0.007$) (Fig. 2). There was no significant difference between the area of adhesion formation to the PCO/PT and the area of adhesion formation to the PCO/PLA combination. Some adhesion formation was noted to both PT and PLA tacks on the gross specimens.

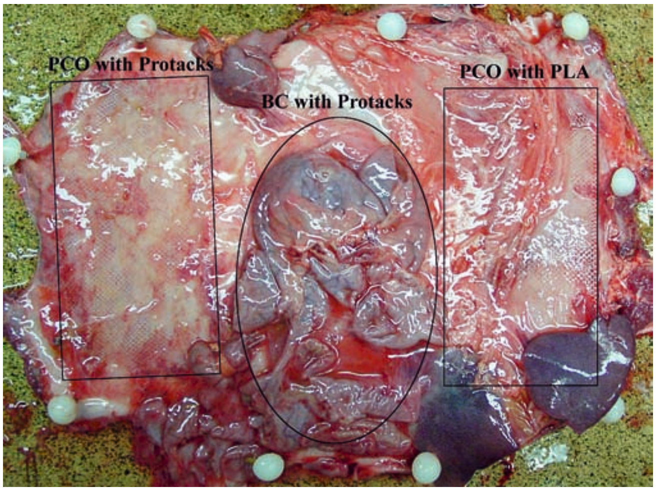

Fig. 1 A representative gross specimen at necropsy, demonstrating three pieces of mesh on the anterior abdominal wall. There are dense bowel adhesions to the BC mesh (ePTFE-polypropylene composite). PCO mesh (collagen-coated polyester mesh) has demonstrably fewer visceral adhesions

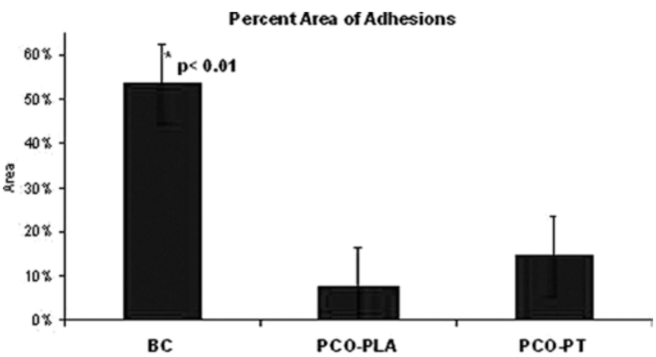

Fig. 2 Percent area of adhesions. A significantly larger area of the BC mesh (ePTFE-polypropylene composite) was involved with visceral adhesions than with PCO (collagen-coated polyester mesh)

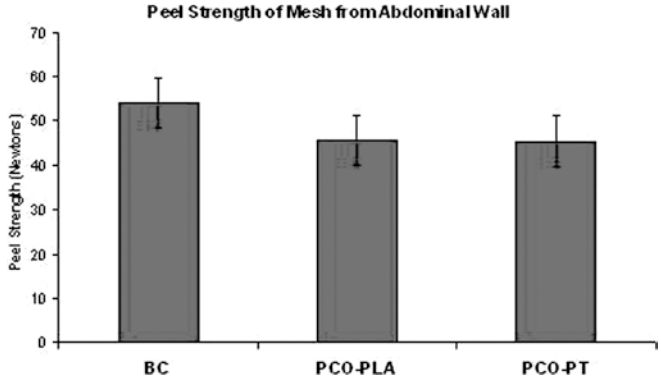

Fig. 3 Peel Strength. The force required to shear the BC (ePTFE-polypropylene composite) or PCO (collagen-coated polyester mesh) from the abdominal wall was not significantly different

On a scoring system based on adhesion density (0–5), BC scored 3.6 ± 0.51 vs 1.75 ± 0.56 for PCO ($P < 0.03$). There was a trend toward higher adhesion peel strength with BC (mean of 12.14 ± 2.52 N vs 5.82 ± 2.67 N for PCO/PT and 7.34 ± 3.19 N for PCO/PLA); these results were not statistically significant.

There was no significant difference in the peel strength from the abdominal wall between BC and PCO with either fixation method (Fig. 3). BC required a mean peak force of 54.0 ± 5.7 N to separate it from the abdominal wall. PCO with PLA required 45.6 ± 5.7 N, and PCO with PT required 45.5 ± 5.7 N.

Histology showed equal tissue ingrowth to both the PCO and the polypropylene component of the BC mesh. There was no evidence of tissue ingrowth to the ePTFE layer of BC. There were no histologic differences noted between the two modes of PCO fixation.

Neovascularization was present in sections of both mesh types. A neomesothelial layer was noted in specimens of PCO but not in specimens of BC. BC demonstrated inflammatory encapsulation of the ePTFE layer. There was delamination of the ePTFE from the polypropylene (PPM) in specimens of BC. Grossly this correlated with seroma formation between the ePTFE and PPM layers of BC. Light microscopy (Fig. 4 and Fig. 5) demonstrates that connective and inflammatory tissue encircles both the polyester fibers of the PCO and the polypropylene fibers of the BC. Electron microscopy (EM) demonstrates this in even more detail (Fig. 6 and Fig. 7).

Discussion

The main purpose of our study was to identify any significant differences in either the abdominal-wall incorporation or adhesion formation between the two mesh types. In addition, we wanted to evaluate sutureless fixation with absorbable and nonabsorbable tacks and compare the fixation strength and direct adhesion formation with two types of tacking devices. The data show that the collagen-coated polyester mesh is more effective at limiting adhesions than the ePTFE/polypropylene mesh, while exhibiting equivalent abdominal-wall incorporation. Sutureless fixation provided for strong connective-tissue ingrowth without any clear advantage for either absorbable or nonabsorbable tacks.

In our porcine model of adhesion formation, significantly fewer visceral adhesions formed to PCO than to BC. These differences were not related to the type of fixation device; most adhesions formed directly to the mesh and not to the tacks. Our findings with light and electron microscopy may explain this phenomenon. Both types of microscopy show a new mesothelial layer on the visceral surface of the PCO but mainly inflammatory tissue with only a little mesothelium covering the visceral surface of the BC.

One of the benefits of laparoscopy is that fewer adhesions form postoperatively [12]. Likewise, numerous vendors have developed new composite mesh types developed for laparoscopic intraperitoneal placement

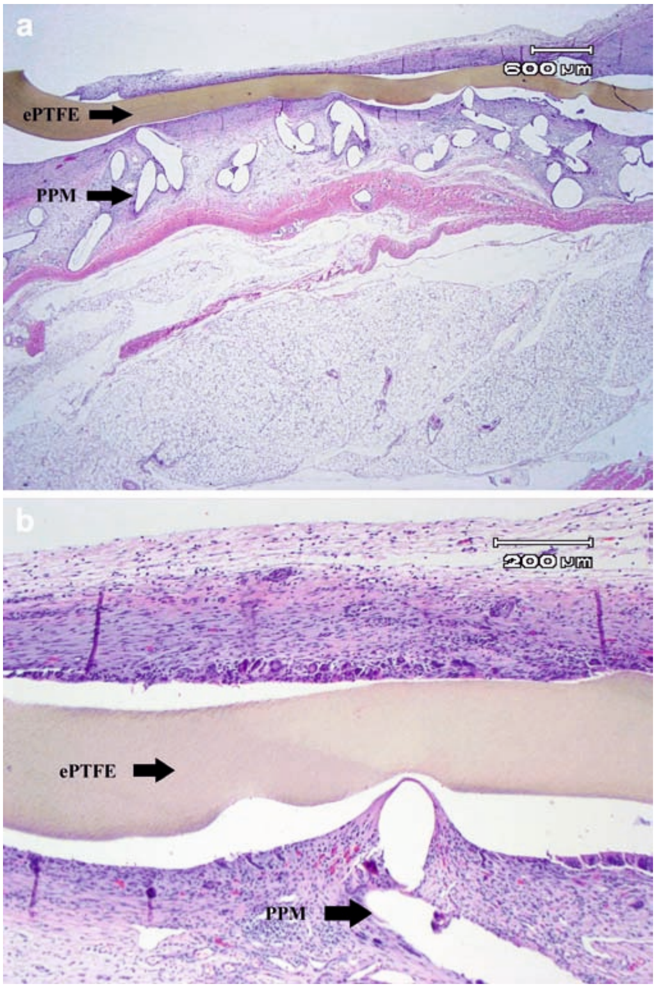

Fig. 4 A A low-power micrograph of BC mesh (ePTFE-polypropylene composite). Connective tissue ingrowth and inflammatory response are noted around the PPM (polypropylene) fibers. **B** High-power view of BC mesh. Superficial to the ePTFE layer is an inflammatory layer. The ePTFE layer is delaminated from the PPM and displays no tissue incorporation

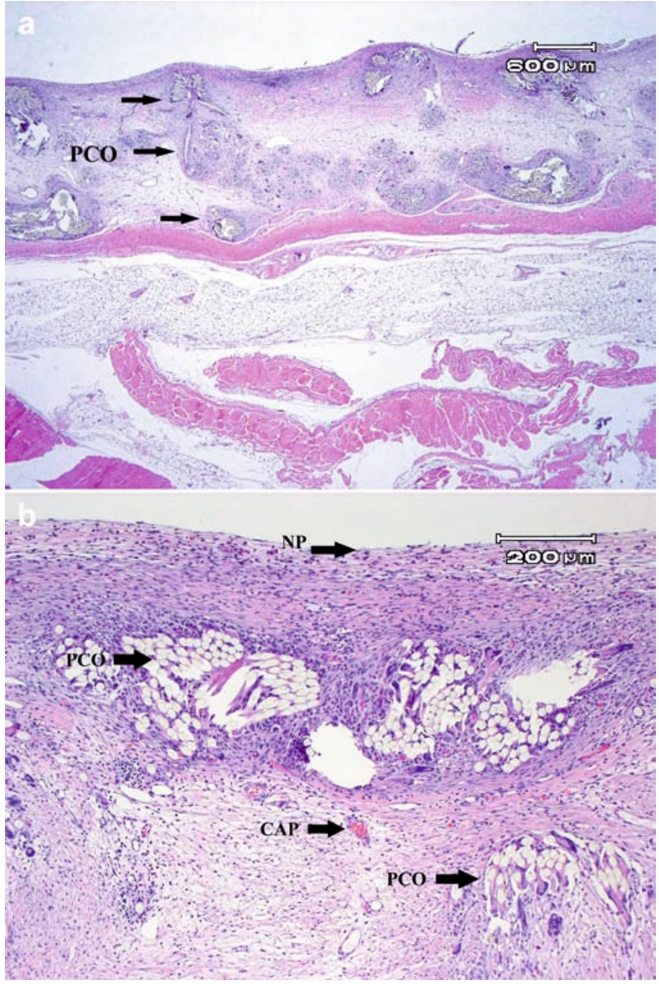

Fig. 5 A A low-power micrograph of PCO (collagen-coated polyester mesh). Connective tissue ingrowth and inflammatory response are noted around the polyester fibers. **B** High-power PCO with capillary neovascularization (CAP) and a neoperitoneal layer (NP)

that are designed to induce fewer adhesions than a standard nonabsorbable mesh, such as polypropylene. Harris et al. have demonstrated in a rat model that adhesion formation occurs promptly in the postoperative period, generally within the first 36 h [13]. Most antiadhesive mesh products on the market provide some kind of barrier to separate the mesh from the visceral tissues through this early period of adhesion formation. Several comparative studies are available for these products in animal models [11, 14, 15, 16, 17, 18]. The most studied of these and the mesh most widely used in clinical practice is a dual-textured ePTFE mesh (Dual Mesh, W.L. Gore & Associates, Flagstaff, Ariz. USA).

Comparisons of polypropylene to the dual ePTFE mesh in a rabbit model of laparoscopic ventral hernia repair demonstrated a significantly smaller area of adhesion formation with the ePTFE product, 55% vs 20% [14]. Several rabbit studies using open surgery compared PCO with PPM and BC. The degree of tissue incorporation for PCO and PPM was similar, but significantly fewer adhesions formed and a more complete neoperitoneal layer formed over the PCO [17, 18]. Another open-surgery rabbit study compared PCO with BC and found fewer adhesions, equivalent tissue integration, and a more complete neoperitoneum with PCO [16]. Our results agree with these findings regarding the antiadhesive effects, neoperitonealization, and tissue ingrowth properties of PCO.

While use of PCO has been shown to be safe and effective in human studies [19], attempts to quantify adhesion formation in patients have shown a similar degree of adhesion formation to those in the animal studies. One study proposes an intriguing method of evaluating adhesions to mesh using abdominal ultrasound. The technique was validated using ultrasonic imaging of preoperative hernia patients and correlating the results with intraoperative findings. Patients with implanted mesh were then studied postoperatively and

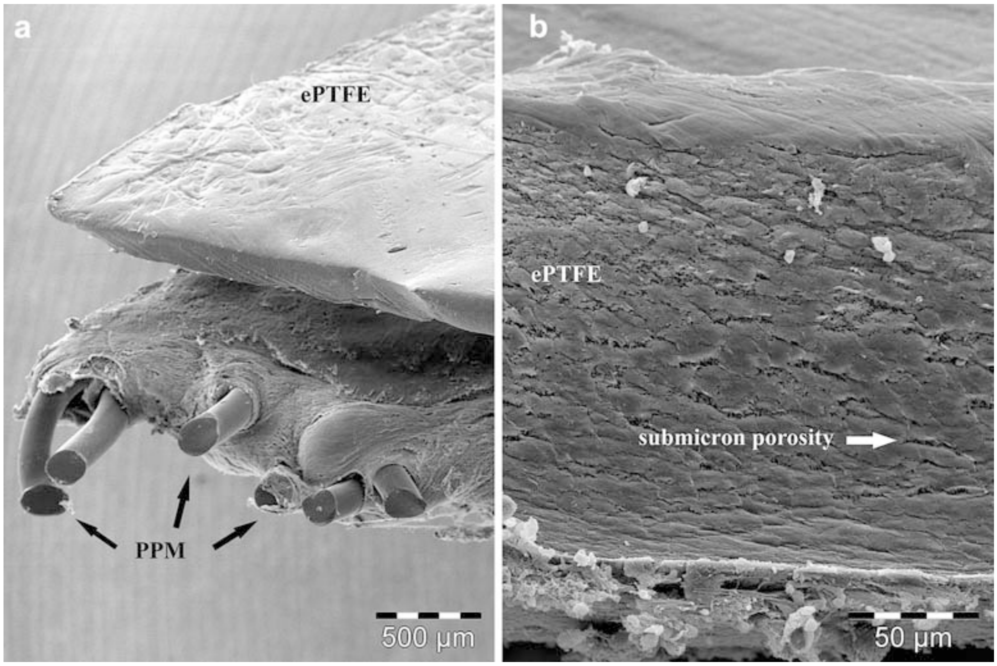

Fig. 6 **A** Low-power EM (electron microscopy) of BC mesh (ePTFE-polypropylene composite), demonstrating lack of tissue incorporation and delamination of the ePTFE layer. Significant ingrowth is noted around the polypropylene fibers (PPM). **B** High-power EM cross section of the ePTFE layer of BC, demonstrating submicron porosity and no cellular penetration

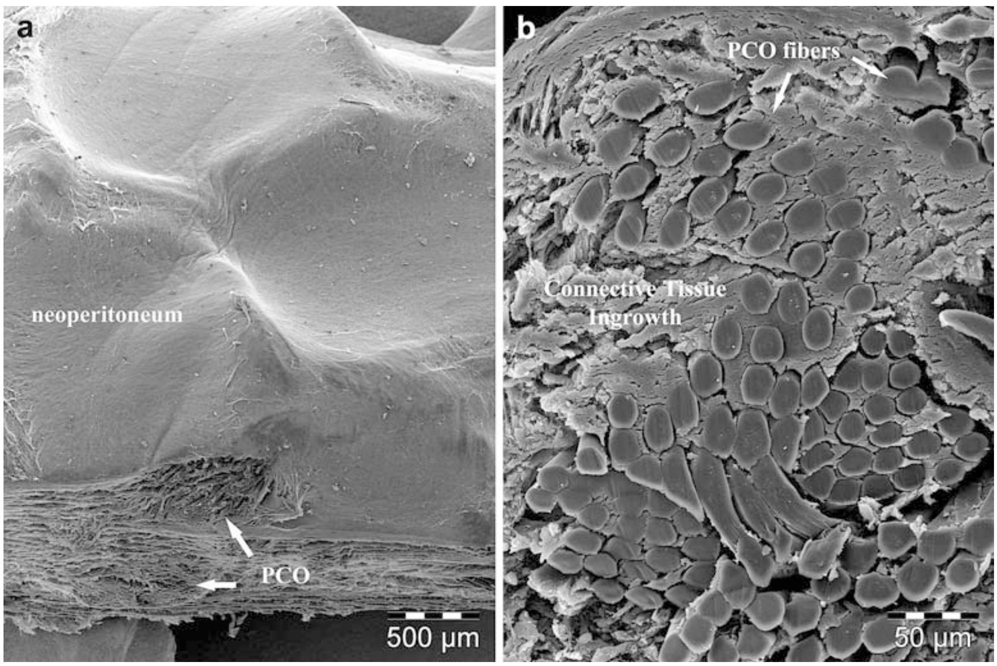

Fig. 7 **A** Low-power EM (electron microscopy) oblique surface view of PCO (collagen-coated polyester mesh), demonstrating a continuous neoperitoneal mesothelial layer over the 3D form of the mesh. Polyester fibers (PCO) are noted at the sectioned edge with complete tissue ingrowth. **B** High-power EM cross section of PCO demonstrating dense tissue ingrowth between the mesh fibers

compared to a group previously operated on with intraperitoneally placed unprotected polyester mesh. The authors concluded that unprotected polyester mesh induced adhesions in 77% of patients and that 14% of PCO patients developed adhesions [20]. While certainly not conclusive, this study was an interesting endeavor to show that the PCO antiadhesive barrier mesh works well in human patients.

Our data show similar amounts of force are required to separate the parietal side of both mesh types from the abdominal wall. These quantitative results correlate with our histologic findings of connective tissue ingrowth around and between the polyester and polypropylene fibers of either mesh. In addition, the degree of tissue incorporation we demonstrated was achieved without the use of transfascial sutures. In our porcine model, securing the mesh with just tacks provided more than adequate stabilization of the implant until connective tissue had infiltrated the fibers of the mesh.

Our comparison of absorbable (PLA) and nonabsorbable tacks (PT) did not demonstrate any clear advantage for either design. However, the PLA tacks were placed in a manner that differs from the standard recommendations of spacing for the PT tacks. For the BC mesh and the PCO that was anchored with PT, we spaced the tacks approximately 1 cm apart around the periphery of the mesh. With the PLA, we followed the recommendations of the manufacturer and secured the PCO mesh with a total of ten tacks. We placed one PLA device at each corner, and then placed two additional tacks along each long side and one along each short side. We found that with accurate placement of the tacks, it was relatively straightforward to position the PCO mesh flush to the peritoneal surface. In addition, the 7-mm length of these "I" shaped tacks allowed for fascial penetration. We observed no herniation of bowel between fixation devices in any of the animals.

Laparoscopic ventral hernia repair is a technique still in evolution. While currently published series show multiple benefits over open techniques and low recurrence rates [2, 6, 10, 21], these patients often have more postoperative pain than after other laparoscopic procedures. In our experience, the pain seems to be related to the presence of transfascial anchoring sutures, an observation also made by other authors [6, 21]. Perhaps as a result of these observations, management strategies for chronic pain at these suture sites have developed [22], and alternate modes of fixation have been attempted in animal models [23].

Although an ideal repair might eliminate the need for these sutures, most authors advocate their routine use to avoid hernia recurrence [2, 6, 10, 21]. A difference of opinion is expressed by the only group thus far to publish a prospective randomized trial comparing laparoscopic and open repair of incisional hernias [7]. These authors argue that equivalent recurrence rates can be obtained using only tacks by ensuring that there is adequate overlap of the hernia defect by the mesh (at least 5 cm) [9].

Advocates of routine transfascial suturing refer to a porcine cadaver model study as supporting their clinical experience. This study measured the shear strength of sutured and tacked polypropylene to the abdominal wall. The authors found that a 2.5× greater force was required to disrupt the mesh with suture fixation than with helical metal-tack fixation [24]. While certainly suggesting that the current design of the helical tack may be inadequate for strong abdominal wall fixation, these studies do not rule out the potential for a more effective tack that anchors the mesh more securely through the fascia.

Our study using only tack fixation suggests that mesh types that tend to allow rapid and complete connective tissue ingrowth may be adequately fixed to the abdominal wall by tacking devices. Additionally, absorbable tacks may provide sufficient mechanical support during the integration phase. Additional animal studies using a ventral hernia model are required to assess whether tacks can provide equivalent fixation to suture-based fixation, allow equivalent tissue ingrowth, and minimize hernia recurrence. With continued development of the materials and techniques used for laparoscopic ventral hernia repair, rapidly integrating, adhesion-resistant materials, such as PCO mesh, may be adequately secured without the use of transfascial sutures.

In conclusion, the collagen-coated polyester PCO ventral hernia mesh is more resistant to adhesion formation than the dual layer ePTFE-polypropylene BC mesh. When placed laparoscopically, both types of composite mesh sustained significant tissue ingrowth at the abdominal wall parietal surface. PLA absorbable tacks provided equivalent fixation to PT tacks with PCO mesh.

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