Twelve-Year Experience with Expanded Polytetrafluoroethylene in the Repair of Abdominal Wall Defects

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Abstract

Background: A prosthetic device must be used to repair ventral hernias in patients with insufficient tissue for a tension-free primary closure. Several prosthetic materials have been employed for this purpose, with varying results. We here review a long experience with the use of expanded polytetrafluoroethylene (ePTFE) patches in the open repair of large abdominal wall defects.

***Methods*:** Demographic, operative, follow-up, and histologic data were recorded and analyzed for all patients in a surgical practice who were treated for large abdominal wall defects with open repair using ePTFE patches between November 1983 and March 1996.

Results: Ventral hernia repairs using an ePTFE patch were performed in 98 patients. In 48 (49%), the patient had already undergone at least one previous ventral hernia repair. Of the 98 operations, 78 were full-thickness repairs, 11 were Rives-Stoppa procedures, and 9 were onlay operations. Complications included 5 seromas, 3 fistulas related to removal of a previously implanted prosthesis, and 9 infections. In addition, 10 patients developed recurrent hernias not related to explantation of the patch because of infection or fistula. In 3 patients, infections were treated successfully without removal of the patch. There were no complications related to adhesions, erosion of the patch into the viscera, or bowel obstruction. Histologic studies of long-term ePTFE implants showed excellent fibrous tissue ingrowth and minimal foreign body response.

***Conclusions*:** Our long-term clinical experience indicates that prosthetic patches of ePTFE are safe and effective when used in the repair of large abdominal wall defects that cannot be closed primarily. Operative complications were within acceptable limits, as was the reherniation rate.

Key Words: Hernia, ventral, incisional, polytetrafluoroethylene, herniorrhaphy.

The exact incidence of ventral or incisional hernia occurring after surgical procedures is unknown, but probably ranges between 2% and 11% (1). Therefore, repair of incisional hernias remains a common surgical procedure. Most of these hernias can be closed primarily, but use of a prosthesis is indicated in cases where there is insufficient viable tissue to permit a repair that does not place excessive tension on the suture line. Recurrence rates as high as 30% have been observed among patients in whom abdominal wall hernias were repaired without a prosthetic material (2).

Since 1983, we have used expanded polytetrafluoroethylene (ePTFE) patches (GORE-TEX® Soft Tissue Patch or, most recently, GORE-TEX® MycroMesh Biomaterial, W.L. Gore & Associates, Flagstaff, AZ) in the open repair of abdominal wall defects that could not be closed primarily. Our initial experience with these prostheses in 28 patients (3) was favorable. We have continued to employ ePTFE patches for ventral and incisional hernia repair, and here describe our entire 12-year experience with those materials.

Methods

All procedures were performed after administration of a broad-spectrum antibiotic. The fascial margins of the hernia were identified before entry into the peritoneal cavity. After entry, any loops of intestine adherent to the parietal peritoneum near the fascial margin were dissected free. Possible tension on the wound was then assessed, and if a tension-free repair could be performed, the wound was closed with interrupted sutures. If not, an ePTFE patch was implanted.

Three principal types of repairs were performed: full-thickness replacement of the abdominal wall (3), in which the prosthesis was sutured to the edges of the fascial defect; onlay operations, in which the fascia was closed and the prosthesis laid on top of it; and Rives-Stoppa repairs, in which the patch was placed between the rectus abdominis muscle and the posterior sheath (4). All patches were trimmed to bridge the defect. When full-thickness replacement was performed, no attempt was made to reestablish the peritoneum between the patch and the underlying viscera. The patch was tailored so that normal abdominal contours were restored, with minimal tension placed on the repair. No drains were used. Antibiotic therapy was discontinued three to five days after surgery unless there was evidence of wound infection. The surgical wound was examined daily during the patient's hospital stay, to monitor the progress of healing and to check for evidence of infection, erythema, induration, tenderness, seroma, hematoma, or abscess formation.

Demographic, operative, and follow-up data on all patients were collected retrospectively and for analysis. Specimens of an implanted ePTFE patch obtained by biopsy during subsequent abdominal procedures, performed for indications not related to the abdominal wall defect repaired with the patch, were examined histologically and with transmission electron microscopy.

Results

A total of 98 abdominal wall repairs using an ePTFE patch were performed between November 1983 and March 1996. The age of the patients ranged from 24 to 79 years (mean, 58

heyears); 47 were men and 51 were women. In 48 cases (49%), the patient was undergoing repair of a recurrent ventral hernia. Of the 98 operations, 78 were full-thickness repairs, 11 were Rives-Stoppa procedures, and 9 were onlay operations. The sizes of the patches used ranged from about 2 × 2 cm to 30 × 20 cm.

TABLE

Complications after 98 Open Ventral Hernias Repairs Using an Expanded Polytetrafluoroethylene Patch

	No. of Cases
Seroma	5
Fistula	3
Infection	9
Recurrences	19
Explantation after infection or fistula	9
Explantation in patients with no infection	10*

***** In patients who had undergone at least one previous ventral hernia repair.

Postoperative complications are shown in the **Table**. Two patients with parastomal hernias developed infections which were thought to be due to contamination. The 3 patients in whom a fistula developed all had a previously implanted prosthesis (polypropylene mesh in two patients and an ePTFE patch in one) removed during the repair. In one of these patients, a remnant of polypropylene mesh was found at the site of the fistula. Of the 9 patients with infections, 3 were successfully treated without removing the patch.

With a mean implant duration of 6.2 years (range, 56 days to 12.5 years), there were 19 reherniations (19% overall recurrence rate). However, 9 of these occurred after removal of the ePTFE patch because of infection or fistula. Recurrence occurred with the patch in place in 10 patients, all of whom had undergone at least one previous ventral hernia repair. Other than the 3 patients in whom removal of a previously implanted prosthesis led to a small bowel injury and subsequent development of a fistula, no patient had complications related to adhesions, erosion of patch material into the viscera, or bowel obstruction. Seromas developed in 5 patients.

Figs. 1–4 show portions of the ePTFE patch in one patient obtained by biopsy during two subsequent abdominal procedures performed for indications not related to the wall defect repaired with the patch. There was no recurrence of the hernia and the patch itself was not removed. Only biopsy specimens of the patch were obtained. **Fig. 1** shows the histology of the specimen obtained after 7.5 years of implantation. **Fig. 4** illustrates the histology of a specimen of the same patch acquired 2.5 years later, or 10 years after the original procedure. Both specimens show minimal tissue reaction to the ePTFE at the interface with the device. There are a few macrophages, some rare giant cells, and no evidence of any focal or diffuse cellular response. The extent of the host reaction appears to be less in the specimen obtained after 10 years, as compared to that obtained after 7.5 years. The connective tissue formed around the implant is nonprogressive.

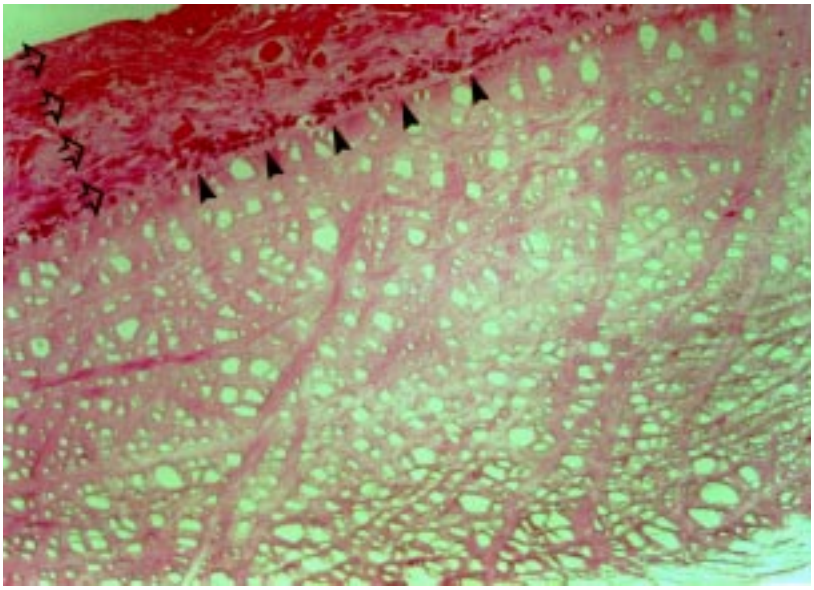

Fig. 1. Histologic study of a biopsy specimen of an ePTFE patch implanted during a ventral hernia repair 7.5 years earlier. There is a minimal cellular layer at the tissue interface (arrowheads) that consists primarily of fibroblasts, macrophages, and a rare foreign-body giant cell. The stroma is well-organized fibrovascular connective tissue (open arrows) (hematoxylin & eosin, original magnification × 25).

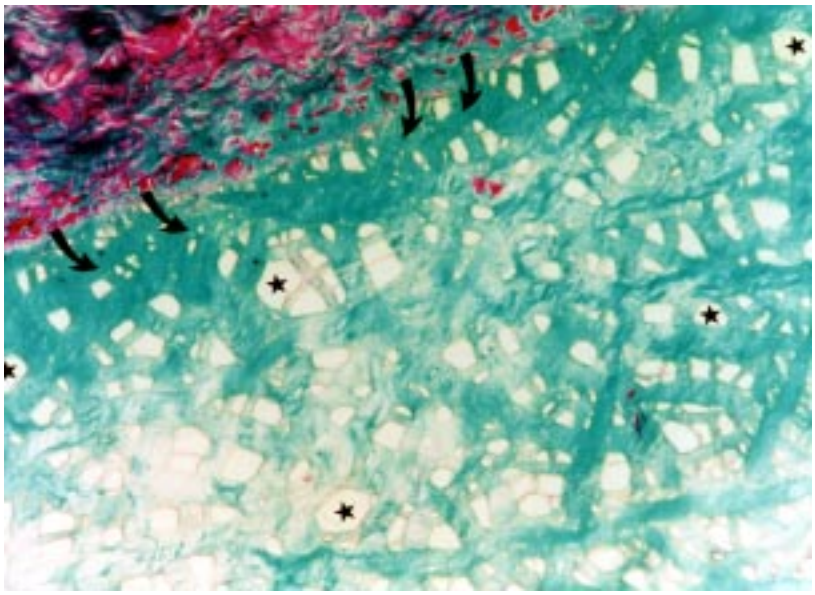

Fig. 2. Section of same specimen as in **Fig. 1**. Collagen formation (green) extends (curved arrows) from the periimplant stroma deep into the internodal spaces of the ePTFE, thereby creating a contiguous connective tissue matrix. The stars mark some nodes of ePTFE (Milligan's trichrome, original magnification × 25).

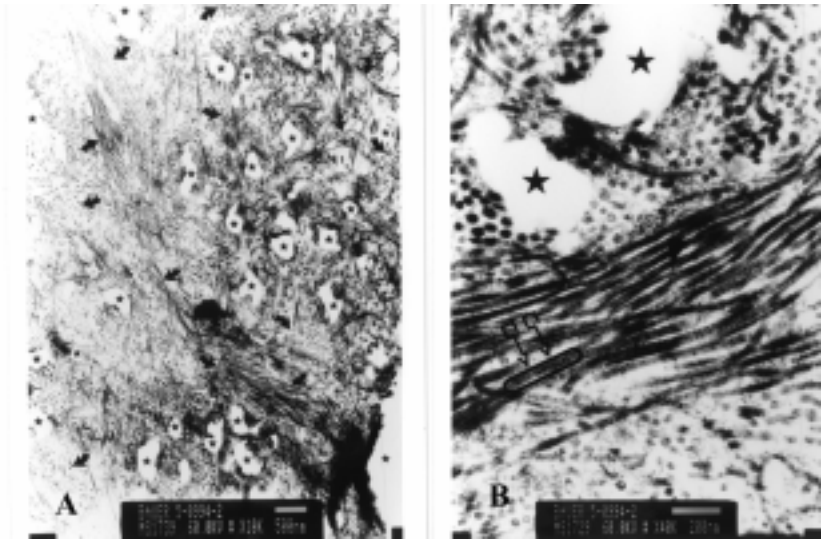

Fig. 3. Transmission electron micrographs of the same specimen as in **Fig. 1**. The specimen was deparaffinized and reprocessed in plastic for ultrastructural analysis. **A**. Extensive collagen fibril deposition (curved arrows) appears within the internodal spaces. Collagen, a fibrillar protein, appears in the longitudinal plane as elongated fibrils and fibril bundles and in the transverse plane as small dots or rods. The nodes of ePTFE (stars) are electron lucent and appear bright white (uranyl acetate and lead citrate, bar = 500 nm). **B**. Very high magnification shows the characteristic fibril periodicity (transverse banding along the fibril), constituting proof that these fibrils are collagen (bar = 200 nm). The periodicity is most evident in the area in which the fibrils are in the transverse plane (open arrows and oval), adjacent to two nodes of ePTFE (stars).

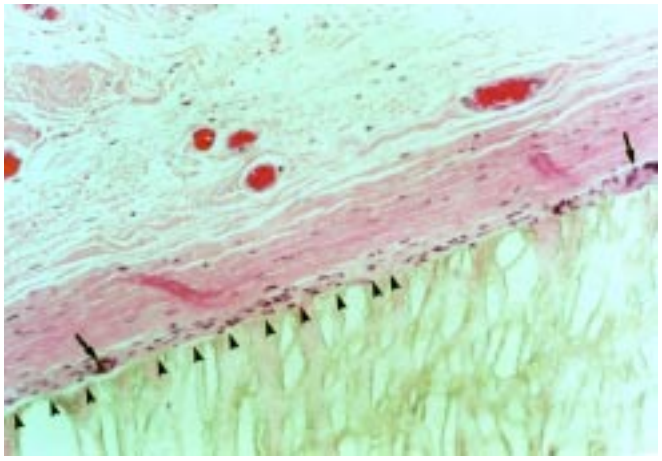

Fig. 4. Histologic study of a specimen of the same ePTFE patch as in **Fig. 1** but obtained 10 years after implantation of the patch. The specimen was obtained by biopsy during a ventral hernia repair lateral to the original implantation. It is remarkable for the bland, almost nonexistent, foreign body response at the implant–tissue interface. Large areas of the interface consist only of an oriented collagenous tissue (arrowheads). Two foreign-body giant cells (arrows) are present (H & E, original magnification × 50).

In **Fig. 2**, the same specimen as in **Fig. 1** shows extensive amounts of collagen (green stain) in the internodal spaces of the ePTFE, thereby indicating that the implant has been incorporated into the host tissue. This high degree of tissue ingrowth is consistent with a strong hernia repair. In addition, a comparison between this specimen and that shown in **Fig. 4** reveals that there was a diminution in the response to foreign body during the 2.5-year interval between biopsies. In **Fig. 4**, fewer cells appear to be present at the interface (the site of typical cell-mediated responses to a reactive material), although the stromal component (collagen) remains inside the ePTFE pores.

Fig. 3A and 3B are ultrastructural studies of the same specimen as in **Figs. 1 and 2**. They confirm that the trichrome staining in **Fig. 2** is indeed highlighting extensive collagen fibril deposition within the ePTFE.

Discussion

In our 12-year experience with ePTFE patches in the open repair of large abdominal wall defects, we have found these prostheses to be safe and effective. Complication rates were within acceptable limits and similar to those associated with the use of any prosthetic in patients with large ventral hernias. Our current findings support those of other clinical series that have been described since our earlier report in 1987 (3).

Deysine's (5) series included 47 ventral hernias, as well as 33 inguinal hernias, repaired with an ePTFE patch. In 13 of the ventral repairs, the graft was placed directly over the viscera. During the 18-month follow-up period, there were four recurrences and three infections. None of the patients had clinical evidence of adhesion formation. Moreover, during a reoperation for graft trimming in a patient who had undergone a ventral repair a year earlier, the ePTFE patch was found to have formed a posterior lining that could not be visually differentiated from normal peritoneum. There were no adhesions to this membrane, which was firmly bound to the graft.

DeBord (6) used ePTFE patches in full-thickness repairs of large ventral hernias in 64 patients during an 8-year period. In the 64 cases, 6 infections and 9 seromas developed postoperatively. One infected patch was treated successfully without removal. Although DeBord and colleagues generally did not attempt to shield intra-abdominal contents from the graft, they had no complications related to adhesions, erosion of the patch, or bowel obstruction.

In the series of Kennedy and Matyas (7), 40 ventral hernias were repaired with an ePTFE patch. With a mean follow-up of 49 months, there was one recurrence, one seroma, one wound infection, and one prolonged gastrocutaneous fistula, which developed in a patient in whom a suture had been placed too close to a gastrostomy tube. There were no other complications caused by adhesions, bowel erosion, or bowel obstruction.

Despite the good results achieved with ePTFE, polypropylene mesh remains the most widely used prosthesis for hernia repair, and some authors (8, 9) have reported success in employing it to repair abdominal wall defects. No randomized, controlled clinical trials comparing the use of ePTFE and polypropylene mesh in the repair of abdominal wall defects have been performed, although they are clearly needed. However, much experimental and clini-

cal evidence indicates that ePTFE has certain advantages over polypropylene with respect to bowel-adhesion, tissue-ingrowth, and infection (10–15).

For example, in studies in rats, Law and Ellis (11) found that the extent of adhesions to ePTFE patches was significantly less ($p < 0.05$) than that of adhesions to polypropylene mesh at 1–8 weeks after implantation. Histologic examination showed that the polypropylene mesh incorporated dense collagen fibers in the presence of a mild foreign-body reaction, that omental adhesions had enveloped the fibers of the mesh and become firmly attached to it, and that mesothelial cells were present in an irregular pattern. In contrast, examination of the ePTFE explants showed that collagen had penetrated the interstices of the ePTFE in a regular pattern, and, most important, that mesothelial cells had appeared in a continuous layer on the surface to form a neoperitoneum.

In a study by Murphy et al. (12), either polypropylene or ePTFE was used to repair full-thickness abdominal wall defects in rats. There was a significant difference ($p < 0.005$) between the two groups with respect to bowel adhesions observed after sacrifice and explantation. Histologic examination of the tissue from the polypropylene group showed chronic inflammatory cells, fibroblasts, and rare giant cells, as well as collagen fibers encapsulating the prosthetic material. In the ePTFE group, there was a focal reaction of giant cells, with fewer fibroblasts and less collagen than in the polypropylene group. Nonetheless, abdominal wall reconstruction with ePTFE resulted in wound strength equal to that obtained with polypropylene mesh.

Clinical problems related to the types of tissue reactions to polypropylene mesh observed in these experimental studies have been well documented. Kaufman et al. (13), for example, described a patient in whom a fecal fistula to the skin developed as a result of incorporation of polypropylene mesh into the splenic flexure of the colon. They advised against using polypropylene in intraperitoneal hernia repairs. Schneider et al. (14) described an erosion of polypropylene into the intra-abdominal organs. In a recent article, Nagy and coworkers (15) reported formation of a fistula as a result of erosion into the small bowel and colon in 3 of 4 patients in whom polypropylene mesh had been used for abdominal wall closure. Two of the three fistulas in our series occurred after removal of polypropylene following an unsuccessful repair. Nagy et al. have abandoned the use of polypropylene for this application.

One report on an experimental study (16) has claimed that the moderate tissue reaction to ePTFE results in inadequate tissue attachment to the patch and subsequent reherniation. Our clinical experience, and that of others mentioned above, is in sharp contrast to these findings. The apparent discrepancy between our clinical results and the experimental work of Simmermacher et al. (16) may have arisen because of the surgical implantation technique and specimen sampling protocol used by those authors. An implantation method that leaves any dead space overlying the prosthesis will preclude mesenchymal cell attachment and migration onto and subsequently into the interstices of the ePTFE patch. The tissue incorporation process requires intimate and sustained contact between the surface of the implant and the adjacent muscle and fascia. Thus, samples obtained at necropsy from areas in which no such contact occurred will probably show little or no evidence of tissue ingrowth. In addition, normal wound healing and tissue ingrowth may be substantially muted by the presence of sepsis either in the

form of an overt wound infection or subclinical wound contamination.

In a review of the literature, Houck and colleagues (17) reported the rate of infection after incisional hernia repairs, with and without a prosthesis, to range from 15% to 45%, and expressed the view that these procedures should be considered "contaminated" for surveillance and reporting purposes. Although any infection is undesirable, our series infection rate of 12% seems low in comparison to these observations. Vascular grafts made of ePTFE have been found to be associated with low rates of infection in *in vitro* studies (18, 19). Moreover, in an investigation of abdominal wall reconstruction in guinea pigs with wounds contaminated with *Staphylococcus aureus* (20), significantly fewer ($p<0.05$) organisms adhered to ePTFE patches than to polypropylene mesh.

Interestingly, once an ePTFE patch does become infected, it is possible that the nature of the material contains the infection and makes it easier to treat. The node-and-fibril configuration of ePTFE may inhibit rapid and diffuse penetration of bacteria. Organisms may initially remain clustered in a section of the implant, rather than becoming uniformly dispersed throughout the prosthesis. In our series, we successfully treated 3 of the 9 infected patients, thereby avoiding possible morbidity associated with reherniation after patch removal.

In summary, our long-term clinical experience, as well as the findings of others, indicates that prosthetic patches of ePTFE are safe and effective when used in the repair of large abdominal wall defects that cannot be closed primarily. Operative complications with these devices are within acceptable limits, and the reherniation rate is low. Our long-term histologic and ultrastructural studies revealed that ePTFE evokes little foreign body reaction, even after extended periods of implantation, and that it allows tissue ingrowth to produce a strong repair. Our sequential histologic examination of biopsy specimens from an ePTFE patch offered the opportunity to observe the cytological response and progression at the device-tissue interface in a normal patient over the course of time. Our findings suggest that expanded polytetrafluoroethylene patches are an appropriate choice for full-thickness replacement of the abdominal wall.

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