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CASE REPORT

Enterocutaneous fistula associated with ePTFE mesh: case report and review of the literature

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Abstract A case of enterocutaneous fistula secondary to the erosion of an expanded polytetrafluoroethylene (ePTFE) prosthesis into the jejunum is described. This case is unusual secondary to the long experience with ePTFE and the lack of published cases similar to this one. The technical details of this case reveal extenuating circumstances associated with the fistula formation, and it is concluded that this particular case does not provide sufficient evidence to implicate ePTFE, by itself, as an etiologic agent for gastrointestinal fistulization. In addition, the published safety record of ePTFE in abdominal wall surgery is reviewed.

Keywords ePTFE · Expanded polytetrafluoroethylene · Mesh prosthesis · Incisional hernia · Enterocutaneous fistula · Gastrointestinal erosion · Prosthetic complication

Introduction

Polymeric prosthetic mesh, such as Teflon (polytetrafluoroethylene) or polypropylene, was initially used for the repair of abdominal wall hernia in the late 1950s [1, 2]. Data from randomized controlled trials has generally supported the tenet that the use of prosthetic mesh in abdominal wall hernia repair lowers the risk of hernia recurrence [3–8], therefore, the utilization of prosthetic mesh has currently been quite common in the repair of ventral and inguinal herniorrhaphy. There are well-known complications of mesh hernia repair, however, including infection, seroma, adhesion formation, bowel obstruction, and erosion into the hollow viscera [9–12]. In particular, the positioning of older formulations of polypropylene and polyester in proximity to the bowel has been associated with increased risk of luminal erosion, especially in the presence of ongoing inflammation (see review by Losanoff et al. [13] and other references [9, 11, 12, 14–19]). The precise risk of mesh erosion has been difficult to quantify. In contrast, the use of expanded polytetrafluoroethylene (ePTFE) is generally associated with a decreased risk of erosive complications [11, 13, 20]. In fact, the authors' search of the literature revealed little documentation [21, 22] of any erosive complication associated with an ePTFE herniorrhaphy. In conversations with colleagues over the past decade, however, the authors have heard anecdotes of fistula "caused" by ePTFE mesh. Recently, the authors were referred a patient who had developed an enterocutaneous fistula associated with ePTFE mesh. Since this type of complication has not been frequently reported, and since the mechanism of erosion in this particular patient appeared to be unusual, we decided to report this case of enterocutaneous fistula in a patient with a remote ePTFE incisional herniorrhaphy.

Case report

A 50-year-old man was admitted to the hospital with a two-day history of a fever and abdominal pain. Seventeen years prior to admission, the patient had a midline laparotomy after a motor vehicle accident. He subsequently developed a midline incisional hernia and underwent an open

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incisional hernia repair (suture only) 6 years prior to admission. The patient's hernia recurred, so he underwent an open redo hernia repair with ePTFE mesh 5 years prior to admission. Subsequent to this, the patient developed a laxity in his abdominal wall, which was attributed to redundant mesh. About 3 years prior to admission, the patient underwent an open excision of the redundant portion of the ePTFE mesh. Per the operative note, the central portion of the mesh was cut out and the remaining lateral leaves of mesh were stitched together with 1-0 polypropylene suture.

On physical examination in the admitting area, the patient had temperature of 98°F and, otherwise, was in no acute distress. There was a supraumbilical area of induration about 3–4 cm in diameter, with erythema and tenderness. The patient's white blood cell (WBC) count was 8,300/μl. An ultrasound did not reveal any fluid in this region. The patient was admitted with a diagnosis of possible mesh infection, and he was given intravenous antibiotics. A several centimeter area of fluctuance was noted in the affected area on hospital day 3; this was incised and drained, and grew *Escherichia coli*. The patient subsequently developed low-output (<50 cc per 24 h) bilious drainage from the wound. A computed tomography (CT) fistulogram demonstrated an enterocutaneous fistula to a loop of small intestine directly underneath the mesh. The patient's condition was stable.

Several days later, the patient underwent an exploratory laparotomy with mesh explantation and enterectomy. A single piece of ePTFE was found directly beneath the fascia. The mesh was involved in an inflammatory process with the underlying intestines, with dense vascular adhesions. After a prolonged dissection, the ePTFE mesh was found to be in a ring-shaped configuration (see Fig. 1). The events which produced this ring are not clear, but it is possible that

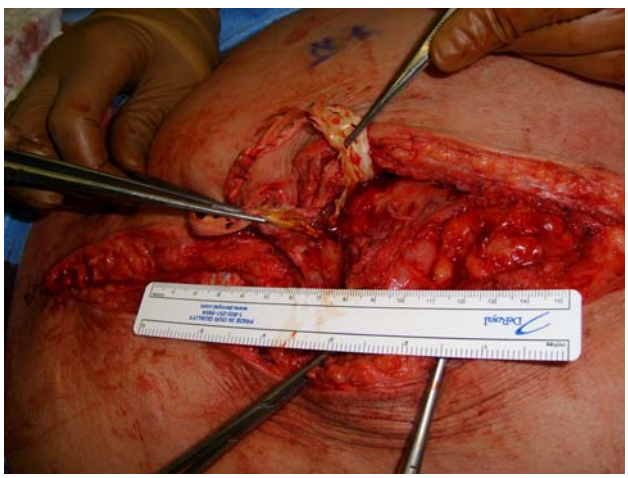

Fig. 1 Expanded polytetrafluoroethylene (ePTFE) mesh in situ. Shown is an intraoperative photo of the patient's partially opened midline incision. The patient's head is to the right. The two forceps are grasping the ePTFE mesh, which was in a ring-shaped configuration

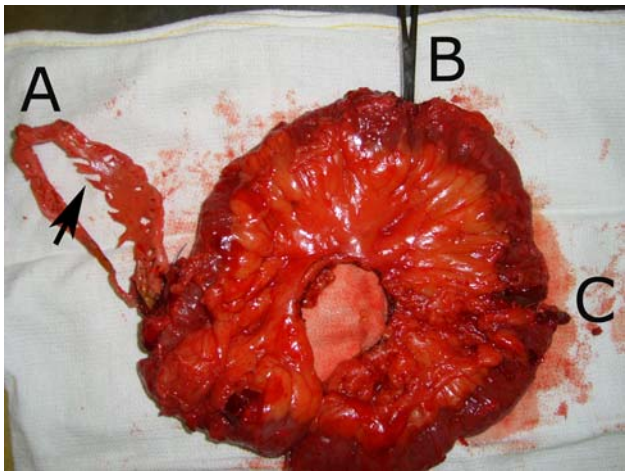

Fig. 2 Explanted mesh with resected segment of involved jejunum. (A) ePTFE mesh, in its entirety. The mesh still is adherent to the jejunum. The *arrow* points to a "spike" of ePTFE, which apparently resulted from the previous dehiscence of the mesh. One of these spikes had penetrated the bowel lumen at the point indicated by the surgical clamp (B); this was the origin of the fistula. Another region of the jejunum (C) had been compromised by the associated inflammatory process

the suture used to close the ePTFE after the previous excision of its redundant portion (described above) pulled through the edges of the prosthetic, resulting in a large central defect. This "dehiscence" of the ePTFE unfortunately resulted in the formation of tapered "spikes" of ePTFE (see Fig. 2a), some of which were stiff and sharp. One of these "spikes" had pierced the antimesenteric surface of the midjejunum (see Fig. 2b), and this was the site of the fistula. After explantation, resection, and a jejunal anastomosis, the patient's midline incision was irrigated and closed with suture. His recovery was uneventful. The pathology report on the surgical specimen described a fistula tract where the PTFE pierced the intestine, with associated acute and chronic inflammatory changes.

Discussion

ePTFE has been used for the repair of abdominal wall defects since the 1980s [23]. Other formulations of PTFE had been used for surgical implantation (e.g., Teflon felt for hernia repair or for vascular pledgets) prior to this point. In animal models, ePTFE mesh has been shown to develop fewer adhesions to the bowel than macroporous prosthetics; however, the tissue incorporation of ePTFE is comparatively less [24–27]. In a review of 252 adverse events (unknown denominator) related to mesh herniorrhaphy that were reported to the Food and Drug Administration (FDA) from 1996 to 2004 [28], there were 13 "intestinal" complications involving PTFE. The details of these complications were not reported in that review [28].

A new search of the FDA database (1992–2008) was performed for the present report (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm) using various combinations of the following simple terms: PTFE, ePTFE, polytetrafluoroethylene, fistula, erosion. This search returned three cases involving PTFE and hernia surgery, and the mesh type in all three was a proprietary polypropylene–PTFE composite with a polyester expander ring (Bard® Composix® Kugel® mesh [29, 30]) . In one of these cases, a sharp edge of the PTFE was noted to have penetrated the small intestine, producing a fistula; in the other two descriptions, it was difficult to know the relative contribution of the PTFE in causing the complication with respect to the contribution of the polypropylene and/or the polyester ring. This composite mesh has been recalled (http://www.fda.gov/cdrh/recalls/recall-122205.html) secondary to the fracture susceptibility of the expander ring. A search of the term "DualMesh" (the popular PTFE formulation for hernia repair manufactured by W.L. Gore and Associates, Inc.) in the same database returned 28 hits, almost all of which involved infection. No fistula or erosion with DualMesh was documented.

A case of PTFE erosion into the gastroesophageal junction after buttressed hiatal hernia repair was reported in the pediatric literature [31]; upon close inspection of the figures in this paper, however, it was apparent that the responsible prosthetic was Teflon felt, and not ePTFE. Teflon felt is a coarse material, not soft and smooth like ePTFE. The senior author himself was previously referred a case in which Teflon felt had eroded into the gastric fundus after a prosthetic-reinforced hiatal herniorrhaphy (unpublished). In the gynecological literature, a case of ePTFE erosion into the bladder was reported after this prosthetic had been placed into the pelvis as an adhesion barrier [32]. In the general surgical literature, an anecdotal case of ePTFE erosion into the esophagus after paraesophageal hernia repair was mentioned in the discussion of one paper, but no details were given [33]. This same discussion also referred to a case of ePTFE erosion after paraesophageal herniorrhaphy in another paper [34], but a close reading here revealed this incident to be an esophageal perforation in the presence of ePTFE, which presented in the immediate postoperative period. In contrast to this data, recently, there was a report of two nonacute mesh erosions into the esophagus in a series of 15 tension-free hiatal hernia repairs with ePTFE [22]. It is difficult to gauge the significance of this small series from one institution, but it would suffice to say that the data on the safety of ePTFE in proximity to the gastrointestinal tract does not appear to be uniform.

In a recent review of over 6,000 minimally invasive ventral hernia repairs [35], ePTFE was, by far, the most common mesh utilized, having been employed in ~80% of all repairs. The reason for this heavy preference of ePTFE is probably multifactorial, but, presumably, includes the assumption that ePTFE is more benign to the surface of the bowel than macroporous mesh. This factor has increased relevance in minimally invasive ventral hernia repair, since the vast majority of surgeons use intraperitoneal placement of prosthetic mesh [35], in which the mesh is often in direct contact with the viscera. Interestingly, in the 6,000-plus cases described above, there was not one case of ePTFE erosion into the bowel [35]. So, with the exception of the one small series described above [22], previous documentation of enterocutaneous fistula cause by ePTFE has been scant.

As described in the introduction, there is ample evidence that macroporous, heavyweight polymeric mesh (e.g., Marlex®, Prolene™, Mersilene™) can erode into the gastrointestinal tract. Some authors have used this experience to caution against placing any type of prosthetic mesh close to the bowel. The authors of the present report have found it interesting that a single case of mesh erosion into the gastroesophageal junction after an open mesh-reinforced hiatal herniorrhaphy that the senior author previously reported [36] has been repeatedly referenced by others as a warning not to use nonabsorbable mesh at the gastroesophageal hiatus. The mesh used in this case was Marlex® (polypropylene), which is relatively stiff, and incites a considerable inflammatory response. In retrospect, it is surprising that there were not more cases of erosion in this series [36], which utilized Marlex® exclusively. Given the retrospective data of the 1980s and 1990s, it would be difficult to find any expert who would recommend the direct apposition of a dense, macroporous polymeric mesh against the viscera. On the other hand, currently, there is a relative proliferation of lightweight polypropylene and polyester mesh materials for hernia repair (not reviewed here), and their behavior in juxtaposition to the intestine might be quite different to the older iterations of these materials (e.g., Marlex®, Prolene™, Mersilene™). The data on this particular issue is pending.

In contrast to the macroporous materials, there is plenty of evidence to suggest that the use of ePTFE in proximity to the gastrointestinal tract is reasonably safe. With the exception of one small series [22], there has been a relative lack of documentation of gastrointestinal erosion associated with the use of ePTFE, whether in the repair of inguinal, ventral, or diaphragmatic defects. This situation suggests that the incidence of this complication is probably quite low, and, therefore, difficult to quantify. But it would be a stretch to claim that the incidence of erosive complications involving ePTFE is zero. The cases described in the present and prior [22] reports demonstrate that ePTFE can erode into the bowel. The circumstances surrounding the erosion in the present report seem unusual though. Through a collusion of events in the involved patient, the ePTFE was

fashioned into a virtual "harpoon" and pierced the jejunal lumen. The authors would suggest that, if an enterocutaneous fistula does occur in association with ePTFE mesh, then there will likely be extenuating circumstances, as there were in this case report. The preponderance of evidence in the surgical literature to date suggests that the intraabdominal positioning of ePTFE mesh is safe, even when the mesh is in direct contact with the viscera.

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