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ORIGINAL ARTICLE

Polyvinylidene fluoride: a suitable mesh material for laparoscopic incisional and parastomal hernia repair!

A prospective, observational study with 344 patients

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Abstract

Background Today, the laparoscopic approach is a standard procedure for the repair of incisional hernias. However, the direct contact of visceral organs with mesh material is a major issue.

Patients and methods This prospective observational study presents the data of 344 patients treated for incisional and parastomal hernias with a new mesh made of polyvinylidene fluoride (PVDF; Dynamesh IPOM®) between May 2004 and January 2008 with a minimum follow-up of 6 months. The median follow-up of 297 patients after incisional hernias totaled 24 months and 20 months for 47 patients with parastomal hernias. Incisional hernias were repaired using an IPOM technique. For parastomal hernias, a recently described sandwich technique was used with two meshes implanted in an intraperitoneal onlay position.

Results The recurrence rate for incisional hernias was 2/297 = 0.6% and 1/47 = 2% for parastomal hernias. Three patients developed a secondary infection after surgical revision or puncture of a seroma. One patient had a bowel fistula through the mesh, with an abscess in the hernia sac. In all cases, the infection healed and the mesh could be preserved. No long-term mesh-related complications have been observed.

Conclusion The laparoscopic repair of incisional and parastomal hernias with meshes made of PVDF (Dynamesh IPOM®) revealed low recurrence and, overall, low complication rates. Especially in cases of infection, the material proved to be resistant without clinical signs of persistent bacterial contamination. Mesh-related complications did not occur during the follow-up.

Keywords Polyvinylidene fluoride · Incisional hernia · Parastomal hernia · Laparoscopic repair · IPOM

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Introduction

Incisional hernias are a common problem after major abdominal surgical procedures. The frequency sometimes exceeds 20% [1, 2]. Closure of the fascial defect by suture alone is followed by high recurrence rates as it was shown not only for major hernias, but also for small ones [3, 4]. Therefore, it is generally accepted that the abdominal wall needs an augmentation by a nonresorbable mesh for effective and long-lasting repair of incisional hernias. Another aspect underlining the importance of a mesh-based repair is represented by the pathogenesis of the hernia disease itself. It was clearly demonstrated that a defect of the collagen synthesis is associated with the occurrence of incisional hernias [5, 6].

Open techniques use meshes in an onlay, sublay, or intraperitoneal position. Onlay and sublay techniques need a wide mobilization and separation of the layers of the abdominal wall, resulting in large wound areas. Therefore, wound complications are common problems after an open repair [7]. The laparoscopic approach, on the other hand, is based on the intraperitoneal positioning of the mesh without the necessity of abdominal wall separation. The precondition of laparoscopic repair is the availability of a mesh structure that provides incorporation into the abdominal wall, as well as preventing adhesions between the mesh and the bowel. Up to now, expanded polytetrafluoroethylene (ePTFE)-derived meshes are the most common structures described in the literature which deal with laparoscopic incisional hernia repair [8]. However, there are some other materials available, such as coated polypropylene or polyester [9]. Ideally, the resorbable coating material should prevent adhesions to the bowel and the mesh material itself should provide incorporation into the abdominal wall. It is a completely different approach using an inert mesh material which does not adhere to abdominal structures, such as polyvinylidene fluoride (PVDF). Dynamesh IPOM® also contains a small amount of polypropylene on the parietal side, inducing ingrowth and incorporation.

This prospective observational study summarizes the clinical outcome and eventual mesh-related complications of 297 laparoscopic procedures for incisional hernias and 47 laparoscopic procedures for parastomal hernias performed by a single surgeon (D.B.) between May 2004 and January 2008. Dynamesh IPOM®, a real mesh structure with large pores made of PVDF, was used in all cases.

Patients, materials, and methods

Patients

A total of 297 unselected consecutive patients with an incisional hernia and 47 patients with parastomal hernias, except emergency cases, were enrolled in a prospective observational study. Only patients with a fascial gap which did not allow a lateral overlap of at least 5 cm were excluded. The demographic data are summarized in Table 1. The patients were clinically followed at 1, 3, 6, and 12 months, and yearly thereafter.

Surgical procedure

Patients were in the supine position with the arms tucked in at the sides. A Foley catheter was inserted only in patients with an incision extending to the lower abdomen. In cases with an untouched upper quadrant, pneumoperitoneum was established with the Veress needle. In all other cases, an open approach was preferred. After inserting a 10-mm trocar and the angulated optic (30°), one 5-mm and one 10-mm trocar were inserted under direct vision on the same side. In hernias after transverse incisions, the trocars were also placed laterally and in the lower and, if possible, upper quadrants. The adhesiolysis was performed with scissors without any energy-driven device to prevent thermal injury. Bipolar coagulation was used for bleeding control. The falciform ligament was routinely cut in upper abdominal hernias. The fatty tissue between the plicae mediales was dissected in lower midline hernias in order to open the space of Retzius and to provide adequate fixation of the mesh in the fascia and the pubic bone. The mesh must overlap the fascial gap by at least 5 cm. The mesh was prepared by nonresorbable stay sutures (polypropylene) at the corners and in the midline between the corners in the longest extension. These sutures were grasped first to provide the correct position of the mesh. After grasping the sutures at the corners, the mesh is ideally held in place and can be finally fixed with spiral tacks (Protack®, Covidien, Mansfield, MA, USA) every 2–3 cm. The stay sutures are tied at the end of the procedure. Usually, meshes with a size up to 20 × 30 cm can be introduced via a 10-mm trocar, whereas for larger meshes, a 12.5-mm trocar must be used. After removal of the trocars under direct vision, the fascia at the 10-mm trocar sites was closed by a single suture.

In cases with a parastomal hernia, the recently described sandwich technique was used [10]. In brief, after complete adhesiolysis and opening of the space of Retzius, a 15 × 15-cm mesh was incised in a keyhole fashion and placed around the stoma. The incision was closed by suturing and the mesh was fixed with staples. An additional mesh covering the midline incision as well as the stoma site was introduced. The stoma loop is lateralized between the incised and the larger mesh for at least 5 cm.

A single dose of cefuroxime and metronidazol was generally given prophylactically. Postoperatively, the patients were allowed to do everything not associated with pain. Sport and all other activities were not restricted. Usually, no bandage was applied unless the patients felt safer with a belt.

Dynamesh IPOM® was used throughout. It is a real mesh structure warp-knitted from PVDF and containing a

Table 1 Demographic and surgical data of incisional and parastomal hernias

	Incisional hernias		Parastomal hernias	
	Median	Range	Median	Range
Age (years)	65	22–92	69	54–92
Body mass index	29	17–58	28	18–57
Hernia size (cm^2)	122.5	2–420	155	12–400
Mesh size (cm^2)	600	150–2,115	825	225–1,425
Operating time (min)	77.5	30–230	115	65–230
Hospital stay (days)	8	2–36	10	6–66
Follow-up (months)	24 (251/297 = 84%)	6–48	20 (43/47 = 91%)	6–48

small amount of polypropylene on the parietal side, providing effective incorporation into the abdominal wall. The lack of adhesive properties was proven in animal experiments [11]. The mesh has some elasticity, reflecting the original elasticity of the human abdominal wall, which was determined in cadaveric samples [12]. The mesh is produced by FEG Textiltechnik, Aachen, Germany, and is distributed by Dahlhausen Co., Cologne, Germany.

Results

Incisional hernias

The demographic and surgical data are summarized in Table 1. It should be pointed out that 67/297 patients (23%) had suffered from a recurrent hernia. The main results of our surgery are shown in Table 2. The recurrence rate is very low and the overall complication rate is promising. One out of two patients with recurrences developed a new hernia after the repair of a hernia of the upper midline between the umbilicus and the symphysis. The new fascial gap was at the lower border of the mesh at the midline stay suture. Another patient experienced a recurrence after mesh explantation. During excision of the original hernia sac, an enterotomy occurred and the mesh was immediately removed. Persistent seromas were observed in seven patients (2.1%), which had in common a major hernia sac and a small fascial defect with an area <30 cm^2. Three of these seven patients had major complications: two infections and one mesh explantation due to an enterotomy after puncture or local revision. However, all patients with a deep wound infection down to the mesh, as well as the patient with an unrecognized enterotomy, had a complete recovery without persistent mesh infection. No mesh had to be removed because of infection. The only bladder laceration finally healed after 3 weeks of bladder drainage. A conversion was necessary because of strong adhesions. This patient needed a mesh-augmented component separation technique because of the wide gap not allowing primary closure of the fascia.

Persistent pain longer than 3 months was observed in seven patients. A stay suture was finally removed in one of these patients.

One patient died on the seventh postoperative day because of pulmonary embolism.

Table 2 Main results—incisional hernias

Recurrences: 2/297 = 0.6%
One trocar hernia = 0.3%
One conversion = 0.3%
One bladder laceration
One relaparotomy due to hemorrhage
One bowel fistula which healed after local revision and VAC therapy
Four punctures due to seroma; one infection due to the puncture
Three further revisions with resection of the hernia sac because of persistent seroma or hematoma; one postoperative wound infection, one patient with intraoperative enterotomy leading to mesh explantation and recurrence
Delayed defecation in five patients
Six patients with strong pain and additional medical treatment during 3 months
One patient needed a local revision of a stay suture
One patient died because of pulmonary embolism

Parastomal hernias

Table 1 also demonstrates the demographic and surgical data. Due to the fact that two meshes were used, the median mesh size is bigger than in cases with incisional hernias. The median operating time is longer, which clearly shows the technical challenge of the procedure. Out of 47 patients, 12 (26%) were admitted with a recurrent hernia. As shown in Table 3, the recurrence rate is again very low; only one patient (2%) developed a recurrence after the sandwich technique. The only conversion was necessary because no free abdominal cavity existed and the pneumoperitoneum could not be established. The main problem of the sandwich technique, however, is the possibility of producing a stenosis of the stoma loop. Both cases of our series had in common a subcutaneous prolapse with a siphon-like elongation of the stoma loop to the flank, so the passage through the fascia and both meshes leads to a sharp angulation and stenosis at the fascial level. Both patients underwent a local revision and shortening of the subcutaneous part of the bowel, which abolished the described angulation and restored passage. In one patient, the bowel was digitally perforated intraabdominally. A formal laparotomy was necessary for repair. The patient developed a deep wound

Table 3 Main results—parastomal hernias

Recurrences: 1/47 = 2%
Two revisions because of a stenosis of the stoma with a consecutive wound infection in one patient
One local revision because of an abscess in the hernia sac after the puncture of a seroma
One conversion = 2%
No death
No enterotomy
No hemorrhage
No further delayed defecation
One patient with severe pain and delayed relief, but no surgical revision was necessary because of pain

infection around the stoma, as well as in the midline incision. After consequent VAC therapy, the infection healed and the obviously infected meshes could be preserved. In another patient, we observed an abscess in the parastomal hernia sac which occurred after a puncture. Again VAC therapy led to a final cure with preservation of the mesh.

One patient complained of severe pain and needed regular oral analgetics for 18 months. Afterwards, the pain completely disappeared.

Discussion

As outlined in the introductory section, the laparoscopic repair of incisional hernias is generally accepted. However, the use of meshes preventing adhesions to the visceral organs is mandatory for laparoscopic techniques, which rely on the intraperitoneal onlay placement of meshes. Therefore, the main issue is whether meshes available today are really able to prevent adhesion formation and induce adequate tissue ingrowth for strong incorporation. Up to now, most patients reported in the literature are treated with ePTFE-derived meshes [8]. The visceral side is as smooth as possible and the parietal side is rough or covered with polypropylene to induce strong adhesions to the abdominal wall. Using meshes made by polypropylene or polyester covered with an antiadhesive barrier on the visceral side represents another approach [9, 13, 14]. Inert material which does not adhere to the bowel may be more effective because a real mesh structure can be used, which is a precondition for incorporation and tissue integration. Furthermore, this kind of material can be trimmed to the ideal size, which is not possible when covered meshes are used. Also, overlapping two meshes is sometimes necessary for the ideal repair. Scar tissue cannot pass through ePTFE foils. Also, so far, no data exists as to whether covered meshes can be used overlapping each other.

PVDF is an inert material which has been used as a suture material for a long time. The long-term stability is even better than that of polypropylene [15]. Furthermore, it was shown that PVDF induces only a slight inflammation process on a cellular level and low amounts of fibrotic tissue compared to ePTFE and covered polypropylene meshes [11, 15]. The anti-adhesive properties seem to be comparable to covered polypropylene and much better than ePTFE or polypropylene alone. A further important point about meshes is their tendency to shrink. Shrinkage was found to be most pronounced in ePTFE-derived meshes, which lost about 50% of their original size [11, 16, 17]. PVDF-derived meshes lost only 19% of their original size, which was in the same order of magnitude as covered polypropylene meshes, or even better [11, 16, 17]. So, the experimental data clearly support the view that PVDF-based meshes may be clinically useful.

The present study demonstrates clinical results obtained in 297 patients with incisional hernias and 47 patients with parastomal hernias. Dynamesh IPOM® was implanted in all patients. The recurrence rate, which is the main outcome parameter of hernia repair, is astonishingly low. Compared with the literature, the mesh size is much higher in our series [8, 18, 19]. Also, in our previous series using ePTFE, the mesh size was smaller [20]. Since no other parameter has changed over the years, particularly the fixation technique, the increased mesh size may be the only explanation.

One patient developed a recurrent hernia after removal of the mesh. The second patient had a recurrence at the lower border of the mesh after the repair of an upper midline incisional hernia. The only explanation could be a suture-associated hernia, which has not been described in the literature. Only tack-associated hernias have been observed [21].

Concerning parastomal hernias, the sandwich technique has been recently shown to be superior to the Sugarbaker technique [10], despite other previous promising results with the Sugarbaker technique [22, 23]. The keyhole technique also revealed promising results after an observation period of only 6 weeks [24], which could not be confirmed in other studies [22, 25, 26]. The availability of a mesh material allowing an overlap of two or more meshes was the precondition of the sandwich technique, which clearly exhibits the best results. The only recurrent hernia was the consequence of a surgical correction of a subcutaneous prolapse which had not been reduced during the primary repair. The stoma loop was pulled through the sandwich meshes with an adherent loop of small bowel, producing immediate pain after eating.

A further important property of PVDF-based meshes is the resistance against infections. Four patients developed a deep wound infection after puncture or early surgical revision. In all cases, the mesh could be preserved. Recently, we published a series of 25 patients after prophylactic implantation of a PVDF-based mesh to prevent parastomal hernias [27]. No primary mesh infection was observed in this series. One patient underwent an early relaparotomy and daily revisions because of an enterotomy with stercal peritonitis. After 5 days, the abdominal wall was closed, leaving the mesh in situ. The healing process was uneventful, with no hint of mesh infection underlining the resistance properties against infections.

In our study, one patient developed a secondary enterotomy which was not recognized during the primary procedure. After open treatment of the abscess in the hernia sac and fistulization through the mesh, the defect healed completely. Unrecognized enterotomies, the most serious complication after laparoscopic incisional hernia repair, are reported to occur at a rate of about 2% [18, 28].

According to our present knowledge, nothing is known about the fate of infected meshes with an antiadhesive barrier. Infected ePTFE-based meshes were usually removed [20, 29, 30].

Seroma or hematoma occurred very frequently, as described in the literature [8, 18, 31]. We performed a routine ultrasound after 3–5 days and found a seroma in 100% of the cases. In four patients, a puncture was necessary due to complaints. In three further patients, the hernia sac was excised because of a persistent seroma. All patients with a complicated seroma formation had a small fascial defect <30 cm^2 and a major hernia sac. Therefore, we now use suction drains in these special cases.

Further complications proved to be very rare and were within or below the range as described in the literature [8, 18]. One trocar hernia, which is also described in the literature as a rare event, was repaired by an open sublay procedure. A bladder laceration occurred in a patient with difficult mobilization of the bladder and needed 3 weeks of transurethral drainage. One hemorrhage could not be controlled laparoscopically, needing relaparotomy. The overall rate of complications was very low, supporting the view that the laparoscopic repair of incisional and parastomal hernias with modern meshes such as Dynamesh IPOM® seems to be superior to open techniques [8, 18, 32, 33]. No mesh-related complications occurred.

In conclusion, Dynamesh IPOM® was proved to be a safe and effective mesh for the laparoscopic repair of incisional and parastomal hernias. It provides the possibility to use two or more meshes to achieve ideal overlap in all situations. The material was resistant against bacterial infections and it exhibited promising experimental results with regards to adhesion formation and shrinkage. The surgical technique described for the repair of incisional hernias seems to be effective and provides satisfying medium-term results. According to our knowledge, the repair of parastomal hernias using the sandwich technique reveals astonishingly good results which have not been achieved by other approaches.

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