Parastomal Hernia Repair With 3-D Mesh Implants After Radical Cystectomy and Ileal Conduit Urinary Diversion - A Single-center Experience Using a Purpose Made Alloplastic Mesh Implant

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OBJECTIVE To report and evaluate our open surgical technique for the treatment of parastomal hernias (PSH) after ileal conduit urinary diversion and results using a specifically designed, three-dimensional intraperitoneal onlay mesh aiming to minimize PSH recurrence and perioperative complications.

METHODS We retrospectively evaluated all patients who developed a PSH after ileal conduit urinary diversion and were treated with the 3-dimensional alloplastic IPST mesh at the Marien Hospital Herne, Ruhr-University Bochum, Germany between 01/2009 and 12/2015. As a surgical approach, we used a small, open incision in order to reduce the hernia sac and place the mesh. Subsequently, we performed a voluntary follow-up of the surviving patients to evaluate long-term recurrence and complication rates. In addition, we conducted a reassessment of the cross-sectional imaging available.

RESULTS Between January 2009 and December 2015, 40 patients underwent hernia repair due to a clinically significant hernia. Out of those patients, 1 suffered from a postoperative wound infection. In total 27 patients participated in a voluntary follow-up with a median follow-up period of 29 months (IQR 16, 63 months). Follow-up examination revealed 2 cases of recurrent PSH (7, .4%), 2 patients who developed stoma stenosis (7.4%) and 5 patients who suffered from minor complications (18.5%).

CONCLUSION Our localized open surgical approach using a 3-dimensional mesh implant presents an effective method of treating a PSH with a low complication and recurrence rate. UROLOGY 131: 245–249, 2019.
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The gold standard treatment of muscle-invasive bladder cancer (MIBC) is radical cystectomy (RC) with consecutive urinary diversion. Besides MIBC, RC represents a treatment option for high-risk non-MIBC, infiltration of other malignancies into the bladder, end-stage neurogenic bladder disease, intestinal or vaginal fistula to the bladder, or extensive traumatic damage with bladder involvement.

The development of a parastomal hernia (PSH) is the most frequent long-term complication after RC with ileal conduit (IC) urinary diversion [1]. Cross-sectional imaging is performed in patients after RC for MIBC on a regular basis, radiographic evidence of PSH can be found in up to 50% of patients after a 2-year follow up (Fig. 1 A-B).[2] Known risk factors for the development of a PSH are an increased body-mass index, female gender, prior exploratory laparotomy, and low preoperative albumin.[1,2]

Problems caused by PSH range from esthetic impairment and poorly fitting stoma appliances, to discomfort and pain, as well as a protrusion, obstruction, and incarceration of herniated bowel. Up to 30% of all stoma patients develop a symptomatic or growing PSH and need surgical intervention.[3]

Before the development of alloplastic implants, direct suture repair with narrowing of the hernia, or a relocation of the stoma were performed. With the development and improvement of alloplastic material, various mesh

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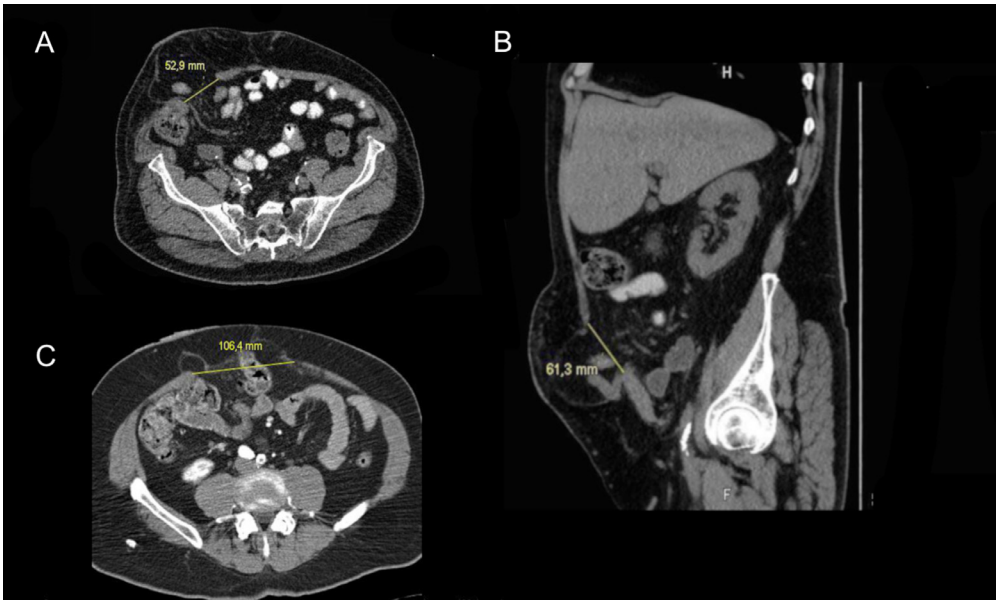

Figure 1. Measurement of a parastomal hernia using cross-sectional imaging in the (**A**) axial and (**B**) sagittal plane with (**C**) concomitant incisional hernia. (Color version available online.)

implants were developed and used on a regular basis. Recurrence and complication rates of nonmesh and flat mesh techniques range from 33%-76% and 50%-88%, respectively.[4] In order to address those problems, 3-dimensional alloplastic mesh implants were developed. The IPST mesh by Dynamesh (FEG Textiltechnik, Aachen, Germany) is a 2-component mesh with a 3-dimensional, central funnel (Fig. 2a) purpose made for PSH repair. The IPST-implant is a monofilament, open pore mesh consisting of polyvinylidene fluoride (PVDF) (88%) and polypropylene (PP) (12%).

The literature on surgical PSH treatment in a urological setting is scarce and hardly ever describes larger cohorts.

This study aims to describe our standardized open surgical technique, as well as complication and recurrence rates for the treatment of PSH using the IPST funnel-mesh.

SUBJECTS AND METHODS

Between January 2009 and December 2015, 563 patients underwent cystectomy at our institution. IC urinary diversion with consecutive end-stoma was chosen in 374 cases (66.4%). The standard protocol for cystectomy at our institution has been described before.[5] Within the same interval, all patients with clinically significant PSH after RC were treated using the 3-dimensional funnel mesh. PSH was defined as clinically significant if it became symptomatic (pain or discomfort), grew in size, or caused other side effects, such as peristomal dermatitis or hydronephrosis. The disease characteristics and demographic data of these patients, their body-mass index, American Society of Anesthesiologists physical status classification and Eastern Cooperative Oncology Group performance status, as well as the initial indication for RC, Charlson comorbidity status, and smoking history were documented. Continuous variables were presented as median and interquartile range (IQR).

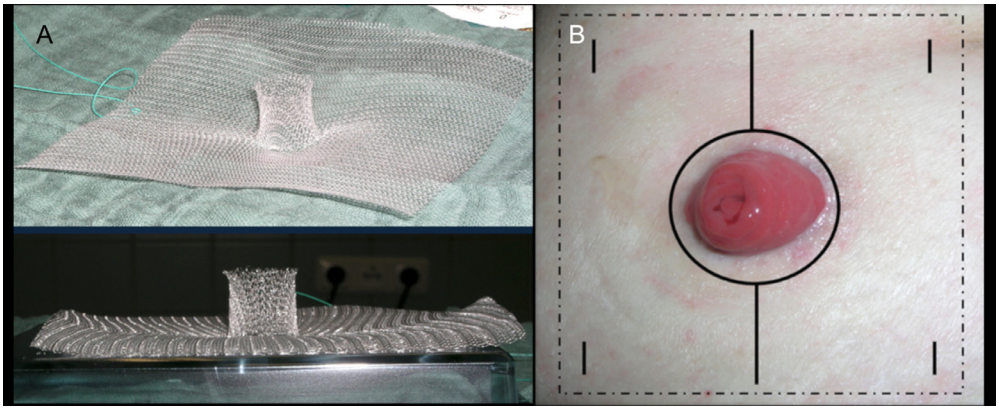

Figure 2. (**A**) Three-dimensional mesh implant with central funnel (Measurements 15 × 15 cm with an internal funnel diameter of 2 cm) (**B**) Schematic drawing showing the localized incisions for mesh placement and mesh fixation (solid lines), as well as the position of the 3-dimensional funnel. (Color version available online.)

Table 1. Classification of parastomal hernias by the European Hernia Society (Roman Numerals) and frequency (percentage) of patients diagnosed with the respective degree of herniation.

EHS Classification of PSH		Small ≤ 5 cm	Large > 5 cm
Concurrent incisional hernia	No	I 5 (17.2%)	III 13 (45.8%)
	Yes	II 4 (13.8%)	IV 7 (24.2%)

Postoperative complications were evaluated according to the classification of surgical complications by Dindo et al.[6,7] Preoperative cross-sectional imaging, using computed tomography or magnetic resonance imaging, was reassessed, and hernias were classified according to the European Hernia Society (EHS) criteria. This classification uses the largest diameter of the hernia with a cut-off of 5 cm, as well as a concurrent incisional hernia (Fig. 1 c). This system results in 4 different subgroups (Table 1).

Ensuing, we re-examined 27 surviving patients during a collective follow-up between March and April 2016. These remaining patients underwent clinical and ultrasound examination. In addition, a descriptive data analysis was performed. Institutional review board approval was obtained. The study protocol followed the Declaration of Helsinki guidelines.

Diagnosis and Classification

A PSH is defined as a bulging of peristomal skin indicating the passage of 1 or more loops of bowel through a fascial defect around the stoma and into the subcutaneous tissues, caused by the formation of a stomath.[8,9] Clinical signs of a PSH mainly include a peristomal protrusion of the abdominal wall or prolapse of the intestine next to the IC. These symptoms can be provoked by abdominal thrust or Valsalva maneuvers. Cross-sectional imaging, physical, ultrasound, and radiological examination are the primary tools for performing an adequate diagnosis of a PSH.

Surgical Technique

A localized open surgical approach was chosen and standardized. Preoperative imaging was performed to plan surgery and to provide the urologist with the EHS classification.

Initially, the IC is digitally examined to precisely evaluate the location and extent of the hernia. Afterward, an 18 French gauge catheter is inserted into the IC and inflated with 10-mL saline solution. The stoma is then being excised circularly with additional straight incisions at the 12 and 6 o'clock position (Fig. 2B). In a subsequent step, the IC is carefully dissected, while the hernia and the fascial edges of the defect are exposed. The hernia sac is then excised, and the abdominal contents are repositioned. Thereupon, the IC is led through the funnel of the 3-dimensional funnel mesh with the "chimney" directed to the abdominal cave, while the mesh plane faces the abdominal wall (Fig. 3). The implant is positioned as an intraperitoneal onlay mesh (Fig. 3). After tension free placement, the mesh is fixated with nonabsorbable 2/0 prolene sutures (Fig. 2b). The PVDF side now faces the intestine and prevents intestinal adhesions to the mesh. The PP on the other side supports the postoperative stability by promoting adhesions to the abdominal wall.[10] The fascia is then closed over the mesh. The subcutaneous tissue and the skin are closed without constricting the IC. The stoma is then placed at its former location and fixated to the abdominal skin.

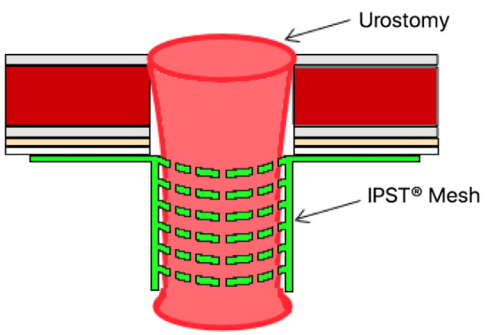

Figure 3. Postoperative position of the IPST mesh as an intraperitoneal onlay mesh. (Color version available online.)

RESULTS

Patients

Overall, 40 patients underwent hernia repair as described above at our institution due to clinically significant PSH. Initial RC of 32 patients was performed at our institution. The remaining 8 patients underwent primary surgery in 7 other hospitals. The cohort consisted of 15 female and 25 male patients. Additionally, 15 of 40 (37.5%) patients showed 1 or more: 12 of 40 (30%) patients showed a stenosis of the stoma on the skin or fascia level, 3 of 40 (7.5%) patients developed a clinically significant obstruction resulting in an expanded renal pelvis or hydronephrosis, and 6 of 40 (15%) patients presented with an additional peristomal dermatitis caused by ill-fitting stoma appliances. The median time between RC and PSH repair surgery was 33.5 months (IQR 15, 82). The exact point of time of PSH development could not be evaluated.

Each PSH was classified according to EHS criteria, resulting in the distribution depicted in Table 1. Preoperative imaging was available for 31 of 40 (77.5%) patients. Overall, 29 of 31 (94%) patients showed a PSH without signs of incarceration of the herniated intestines, while 2 of 31 (6%) patients presented with a significant obstruction by a long, protruding IC, resulting in a siphon-like configuration of the IC. Additional incisional hernias were found in 11 of 31 (35.5%). These patients underwent an additional abdominal midline incision in order to repair the defect with a flat mesh implant.

Postoperatively, 39 of 40 patients recovered well without any complications within 90 days. One patient developed a postoperative wound infection, which could be treated conservatively with extensive wound care and intravenous antibiotics. It was not necessary to remove the mesh implant. Due to extensive surgical wound care, this event was classified as a grade IIIa complication as defined by the classification for surgical complications by Dindo et al.

Follow-up

Complete follow-up data was available for 27 of 40 (68%) patients. Two patients refused to participate. Eight patients had died of metastatic bladder cancer. Three patients were lost to follow-up.

The median follow-up interval for the remaining 27 patients was 29 months (IQR 16, 63 months), ranging from 4 to 80 months.

Overall, 2 patients developed a recurrent PSH due to mesh dislocation, which were confirmed by cross-sectional imaging. The first patient developed a recurrence 64 months after IPST implantation. There was concomitant stenosis of the stoma with extensive obstruction of urine flow. The patient was treated by amputating the whole IC and performing a left-to-right ureteroureteral anastomosis with percutaneous nephrostomy of the right kidney. This intervention correlates to a CDC grade III b complication. The second patient showed no signs of impairment. The recurrence developed on the right cranial edge of the stoma 28 months postoperatively. The patient remained under urological surveillance.

Out of the 27 available patients, 1 suffered from complete stenosis of the IC due to peritoneal carcinomatosis. There was no impairment caused by the mesh implant.

At last follow-up, 5 patients presented with peristomal dermatitis due to poorly fitting stoma appliances. These cases could be treated conservatively by adjusting ostomy care and thus, correlate to CDC grade II complications. There were no cases of mesh erosion into the intestine. Out of the subgroup of patients with concomitant incisional hernias, 5 of 11 (45.5%) patients were available for follow-up. There were no mesh related complications or recurrences in this subgroup.

Taken together, our cohort presented with an overall of 2 of 27 (7.4%) major mesh-related complications (≥ CDC grade III) and 5 of 27 (18.5%) minor mesh-related complications (≤ CDC grade II). The recurrence rate at follow-up was 2 of 27 (7.4%).

DISCUSSION

Development of a PSH can cause many different problems, ranging from esthetic strain to life-endangering obstruction and incarceration of the intestine. Many past and present techniques for treating PSH have shown high complication and recurrence rates of up to 33% and 52%, respectively.[4,11] Most treatment options derive from treating PSH in colostomy or ileostomy patients.[12-14] Only very few studies specifically address the problem of PSH after cystectomy and IC urinary diversion, even though patients with IC urinary diversion have a significantly higher risk of suffering from a PSH.[10] Most recent techniques involve the use of alloplastic mesh implants.[3,14-16]

Several ready available implants have been modified to serve the particular demands of PSH surgery.[17] In contrast to improvised modifications, the purpose made IPST mesh provides a flexible guard against a recurrent protrusion without a predetermined breaking point.[9] Additionally, the combination of PVDF and PP helps to strengthen the defect in the abdominal wall around the urostomy without leading to extensive obstructions or erosions of the bowel or the IC.

To our knowledge, this study composes the largest cohort of patients after IC urinary diversion and consecutive PSH treated with a 3-dimensional mesh implantation. Our study describes the use of this implant as an intraperitoneal onlay mesh for the treatment of PSH through a local open surgical intervention. The open approach provides an excellent surgical oversight and enables the surgeon to better evaluate the fascial defect, the IC, and the corresponding blood supply. As described by Köhler et al (2014), adhesions caused by the primary operation or potential previous mesh implants can pose a problem, especially during laparoscopic surgery.[11] Our local open approach allows a direct and thus potentially more diligent adhesiolysis. In addition, by limiting the surgical field to the ostomy site, this technique potentially reduces the risk of bowel perforation or laceration.

Another example for alloplastic mesh implants used for the treatment of PSH is the Bard CK PSH Patch by Davol Inc. Lampel and Runkel described their open surgical approach using this 2-dimensional, ovally shaped mesh with a central hole and connecting slot, through which the stoma can be placed. Lampel describes his technique especially with regards to PSH after RC and IC. As several other studies, describing novel techniques for the treatment of PSH,[11,18,19] this paper only contains a small number of patients (n = 3). None of the treated by this method developed a recurrent hernia within a median follow-up of 31 months.[3]

Recent surgical approaches include conventional open surgery, laparoscopic, and even robotic surgery.[3,11,17,20] In 2013, Hansson et al. published a retrospective multi-center study with a series of 61 consecutive patients, who had been operated using the laparoscopic Sugarbaker approach.[13] Their cohort consisted mainly of patients with colostomies (55), but also 4 patients with an ileostomy and 2 patients with a urostomy. With a median follow-up of 26 months, they showed perioperative morbidity of 19%, with 1 patient being in need of mesh removal due to postoperative infection. On the other hand, the study found a promising low recurrence rate of 6.6%.[13] To further promote a minimal-invasive approach to treating PSH, Köhler et al. described a laparoscopic single port approach. Over the course of 5 months (September 2013—January 2014), they treated 9 patients with permanent left-sided colostomies suffering from a PSH by inserting the IPST mesh implant through a single laparoscopic port. This technique, however, relies on an additional open approach in order to safely dissect adhesions and to guide the stoma through the chimney of the mesh implant.[12,15] With a median follow-up of 10.6 weeks, the study showed no recurrences and only 1 postoperative superficial parastomal wound healing defect. This study was updated in 2017 with a retrospective analysis of 56 patients treated for PSH. The cohort mainly consisted of colostomy and ileostomy patients but included an overall of 7 urostomy patients. The patients underwent open or laparoscopic hernia repair using the 3-dimensional mesh implant and additional same side relocation of the stoma.[15] This study found a perioperative complication rate of 8.9% with regards to major complications (CDC grade III b or higher). The overall complication rate was 16.1%. The recurrence rate of the series was 12.5% with a median follow-up of 38 months.[15] Those studies show a rather heterogeneous patient collective and vary regarding

the applied techniques and follow-up. Nevertheless, they show, that hernia repair using an alloplastic 3-dimensional mesh is a safe and effective way to treat PSH. Our study, portraying a homogeneous cohort of 40 patients with IC, is consistent with these results. With a recurrence rate of 7.4% and an overall complication rate of 25.9% (18.5% minor, 7.4% major complications), our results closely resemble the above mentioned.

Our study has several limitations. First, due to the high long-term mortality of MIBC, several patients were lost to follow-up, which may have introduced a selection bias to our study. Second, as there was no standardized approach to treating PSH before the implementation of the technique portrayed in this study, there is no control group to compare outcomes. In combination with the limited number of patients, statistical analysis was limited to a descriptive analysis. Third, widespread use of the purpose made funnel-mesh may be limited by availability and monetary limits. With a price-range of 794€-849€ (equivalent to 891.68-953.45 U.S.), costs for the 3-dimensional mesh surpass commonly used flat mesh implants (473€ /531.25 $ U.S.).[21] Finally, this study shares the limitations associated with all nonrandomized, retrospective studies including unmeasured confounding.

CONCLUSION

The development of a PSH is the most common complication after RC and IC diversion. Our open, standardized technique using a 3-dimensional funnel mesh presents an effective method to repair PSH with low complication and recurrence rates.

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