



# Mesh fracture as a cause for recurrence in laparoscopic Sugarbaker parastomal hernia repair: a case series

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**Background:** Parastomal hernia is common and bothersome for patients. Parastomal hernia repair has become increasingly common, and although several different approaches exist, they all carry high risk of postoperative complications. Mesh fracture is a known, but rare complication in other types of hernia repair. We describe seven cases of mesh fracture as reason for recurrence in patients undergoing laparoscopic Sugarbaker parastomal hernia repair.

**Methods:** This retrospective case series present seven patients with intraoperatively verified mesh fracture. All patients underwent primary laparoscopic Sugarbaker parastomal hernia repair between October 2014 and May 2016, using a monofilamentous composite polyester mesh (Parietex<sup>TM</sup> Composite Parastomal Mesh). All patients were diagnosed with hernia recurrence, and mesh fracture was confirmed during the surgical procedure for recurrence. Data on demography, perioperative findings and length of stay were presented.

**Results:** During the inclusion period, a total of 41 patients underwent laparoscopic parastomal hernia repair in our department. Seven patients (17%) subsequently developed hernia recurrence requiring surgical intervention. Diagnosis of hernia recurrence occurred median 29 months (range, 20–36 months) after primary hernia surgery. Recurrence hernia surgery occurred median 32 months (range, 20–67 months) after primary hernia surgery. Three of these patients were emergencies due to hernia-related acute bowel obstruction. In all patients re-herniation was due to a fracture in the central part of the mesh. None of the patients with mesh fracture experienced postoperative complications at either primary or recurrence surgeries. Length of stay was median 7 days (3–8 days) after primary surgery and 4 days (3–9 days) after recurrence surgery.

**Conclusions:** We describe seven cases of mesh fracture as reason for recurrence in patients undergoing primary laparoscopic parastomal Sugarbaker hernia repair. Our findings underline the importance of post-marketing surveillance of medical devices, and consideration should be given to centralization of these complicated procedures.

**Keywords:** Parastomal hernia; mesh fracture; mesh repair; hernia recurrence; surgical complication

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## Introduction

Parastomal hernia is common, with a reported incidence of up to 44% (1). Patients with parastomal hernia are often bothered by pain, intestinal obstruction, poor cosmesis or leakage due to difficult fitting of the stoma appliance. Consequently, operative repair of parastomal hernia is requested by a substantial part of the patients (2,3).

Independent of surgical technique, parastomal hernia repair carries a high risk of postoperative complications, including risk of bowel perforation, surgical site infection, bowel obstruction and chronic pain (4-6).

Several operative techniques have been described for parastomal hernia repair, including laparoscopic repair using the Sugarbaker technique, in which an intraperitoneal onlay mesh causes a lateral position of the bowel adherent to the abdominal wall (7). Mesh repair of ventral abdominal wall hernias—including parastomal hernias—is advantageous, as the incidence of hernia recurrence is significantly decreased compared to suture repair (7-11). Thus, mesh repair has become routine in parastomal hernia repair. This presents the surgeon with the dilemma of balancing the advantages in mesh repair with the substantial risk of complications.

Mesh fracture is a rare cause of recurrence after ventral abdominal wall hernia repair, and this adverse event has not previously been reported on following parastomal hernia repair (12-14).

In the current study, we report seven cases of mesh fracture in patients undergoing laparoscopic Sugarbaker parastomal hernia repair using an identical specific synthetic composite mesh. We present the following article in accordance with the AME Case Series Checklist (available at <http://dx.doi.org/10.21037/ls-20-116>).

## Methods

This was a retrospective case series aiming at reporting on patients with intraoperative verification of mesh fracture after previous laparoscopic parastomal hernia repair in our institution. Patients included in the study underwent primary laparoscopic surgery with the Sugarbaker technique for a parastomal hernia at the Digestive Disease Center at Bispebjerg Hospital, University of Copenhagen, Denmark between October 2014 and May 2016. This center has regional function for treatment of parastomal hernias serving a background population of 1.8 million. Patients undergoing a keyhole mesh repair were excluded.

All patients were operated on using a modified

laparoscopic Sugarbaker technique with a 20 cm Parietex™ Composite Parastomal Mesh (Medtronic, MN, USA) designed for the Sugarbaker technique. This mesh is composed of a 3D monofilament polyester textile with a central band of translucent 2D monofilament polyester textile, which is intended to cover the bowel forming the stoma. The visceral side of the mesh is covered with an absorbable, hydrophilic film made of collagen and glycerol, designed to limit the formation of adhesions to the mesh. On the parietal side, only the 2D band is covered with the collagen film, whereas the rest of the surface is polyester to enhance tissue integration. The mesh was fixated with permanent Bard CapSure™ tackers (Bard Davol, RI, USA) and non-absorbable subcutaneous transfascial sutures. Suture closure of the defect was not conducted.

Preoperative data on patient demography included age, gender, body mass index (BMI), comorbidities, American Society of Anesthesiologists (ASA) score, indication for index surgery and type of stoma. We also collected data regarding primary hernia surgery including hernia defect size, postoperative complications, length of stay, time from primary hernia surgery to diagnosis of recurrence and time to recurrence surgery.

The current paper specifically describes those patients who subsequently were operated on for parastomal hernia recurrence and had verification of a mesh fracture at laparoscopy. End of follow-up was August 2020.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). According to Danish law, no informed consent is required from patients anonymously reported on, and thus, individual consent was waived for the present study. The Danish Data Protection Agency (ref. BFH-2016-071) and the Danish Patient Safety Authority (ref. 3-3013-1848/1) approved the study.

## Results

A total of 41 patients underwent laparoscopic modified Sugarbaker repair of a parastomal hernia during the inclusion period.

Of these, seven (17%) patients (four females) were diagnosed with hernia recurrence median 29 months (range, 20–63 months) after the primary hernia surgery. The recurrence repair occurred median 32 months (range, 20–67 months) after primary hernia surgery. None of these seven patients had complications during the postoperative stay after their primary hernia surgery, however three of the patients were operated on as an emergency case due

**Table 1** Demographic data for patients with mesh fracture after parastomal hernia repair

Gender	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m <sup>2</sup> )	Indication for stoma	Comorbidities	ASA
Female	38	178	136	46	Benign	Asthma	2
Male	84	170	75	26	Malignant	Hypertension, ischemic heart disease, pulmonary insufficiency following lobectomy	3
Male	76	172	91	31	Malignant	Hypertension	2
Female	57	169	109	37	Benign	Hypertension	2
Female	68	169	92	34	Benign	Hypertension	2
Male	70	182	104	31	Benign	Alcohol abuse	2
Female	77	178	84	27	Malignant	Hypertension, recurrent pulmonary embolism	2

ASA, American Society of Anesthesiologists score.

**Figure 1** Three cases of central mesh fracture diagnosed during surgery for recurrence of parastomal hernia.

to bowel obstruction through the fractured mesh, though there was no need for bowel resection.

All patients with diagnosed hernia recurrence had a colostomy due to previous colorectal malignancy (n=3) or benign disease (n=4). Demographic data are given in *Table 1*.

In all seven patients, the mesh fracture occurred in the transition zone between the 2D and 3D zones of the mesh. The mesh fracture defect sizes varied between 2.0 cm × 2.0 cm and 4.0 cm × 4.0 cm. *Figure 1* demonstrates the intraoperative presentation of the mesh fracture in three of the cases.

During surgery for recurrence, the following findings were made in each case:

- (I) Herniation of small bowel through a circular central fracture of the mesh. The herniated bowel was vital and easily repositioned. Additional fracture along the bowel forming the stoma.
- (II) Central 4 cm × 4 cm mesh fracture. Adhesions

between omentum and mesh.

- (III) Central 3 cm × 3 cm mesh fracture at the site, where the stoma forming intestine passed through the fascia. Adhesions between omentum and mesh.
- (IV) Central 4 cm × 4 cm mesh fracture with herniation of small bowel and omentum. Adhesions between omentum and mesh.
- (V) Central 2 cm × 2 cm mesh fracture causing herniation of small bowel.
- (VI) Mesh fracture with herniation of mesentery. Severe adhesions between omentum and mesh.
- (VII) Central 3 cm × 5 cm mesh fracture causing small bowel herniation. Several adhesions between small bowel, omentum and mesh.

All seven patients operated on for hernia recurrence had an uneventful recovery and were discharged 3 to 9 days after recurrent repair (*Table 2*).

**Table 2** Primary and recurrence surgery data

Defect size (cm)	Primary hernia surgery, LOS (days)	Time from primary surgery to diagnosis of hernia recurrence (months)	Time from primary surgery to repair of hernia recurrence (months)	Surgery for hernia recurrence	
				Priority	LOS (days)
5.0×4.5	8	34	37	Elective	6
4.5×5.0	7	20	20	Emergency	9
4.0×5.0	3	32	32	Emergency	4
4.0×6.5	7	21	22	Elective	3
4.5×6.5	4	20	26	Elective	4
2.5×6.3	4	29	37	Elective	4
5.0×5.0	9	63	67	Emergency	4

LOS, Length of stay.

## Discussion

We report seven cases of mesh fracture after laparoscopic parastomal modified Sugarbaker mesh repair, in which all patients developed recurrence within 36 months after the primary stoma construction.

The hernia repair was done using a Parietex™ Composite Parastomal Mesh for Sugarbaker repair, which is a monofilament polyester mesh. A previous study of 36 patients undergoing open incisional hernia repair using a monofilament lightweight polyester mesh reported a 22%-recurrence rate, and seven of these eight recurrences (88%) were due to mesh fracture (13). The incidence of mesh fracture in that study was not reported. In the present series, suture repair was not performed before placement of the mesh. Using the modified Sugarbaker technique thus creates a bridged repair at the fascial defect of the stoma, which is not supported by anterior aponeurotic tissue. This is in parallel with the description of Žuvela *et al.* that incomplete closure of the anterior fascial layer was associated with fracture of a polypropylene mesh in three patients having previously undergone retromuscular mesh repair of a ventral hernia (14). Hypothetically, closure of the defect may have reduced the forces of tension on the mesh, however if mesh fracture was avoidable with defect closure remains unknown. In addition, the current findings suggest a relative weakness of the Parietex™ Composite Parastomal Mesh for Sugarbaker repair at the junction between the 2D and 3D zones, which may cause fracture years after the primary hernia repair.

Previous studies have found similarly high recurrence rates after parastomal hernia repair, even with different

types of meshes. In a recent study including 38 patients undergoing recurrent parastomal hernia repair, a biological mesh had been used in 50% of the patients, and a collagen mesh in the remaining 50% (15). Similarly, a study including 50 consecutive patients undergoing open keyhole surgery using a polypropylene mesh showed a 26% recurrence rate (16). This underlines the difficult nature of parastomal hernia repair regardless of technique and mesh type.

The intraoperative findings did not offer a clear explanation as to why the mesh fracture happened. In addition to the bridged repair of the hernia defect, most patients were obese, which has previously been associated with mesh fracture after incisional hernia repair (14). The intraperitoneal placement of the mesh might play a role as well, seeing that the mesh is unprotected in the abdominal cavity, and as such possibly subject to more wear and tear by intraabdominal organs and the tack fixation.

The same type of mesh was used in all patients that had mesh fracture, indicating that this mesh type may be unsuitable for parastomal hernia repair. Previous data from our center showed initial promising results using this mesh, but the observation was limited by a relatively short median follow-up of 12 months (0–59 months) (17). In the present study, recurrence was diagnosed between 20 and 63 months after primary hernia surgery, indicating that a degenerative process in the mesh may play a role in mesh fracture, and warranting a very long follow-up in patients undergoing laparoscopic parastomal hernia repair.

As stated above, several factors may contribute to mesh fracture. It is unclear whether the fracture was due to failure of the polyester material, or a failure in the design. Considering that all fractures occurred in the same area of

the mesh (i.e., the junction between the 2D and 3D zones), it seems likely to be a failure due to design rather than material.

As a consequence of our findings, the Parietex™ Composite Parastomal Mesh for laparoscopic Sugarbaker parastomal hernia repair was withdrawn from the world market.

Only patients with verified mesh fracture in the study period was included, and not the entire population of patients undergoing parastomal hernia repair in the same period, which limits the study. However, since no diagnostic tool other than laparoscopy can accurately verify mesh fracture, the true incidence of mesh fracture would most likely be understated. Preoperative CT scan in a specialized hernia protocol was performed on all patients included in this study, and did not reveal any mesh fractures. Thus, to accurately assess the full scope of the problem, all patients with recurrent parastomal hernia after previous mesh repair would have to undergo laparoscopic surgery, which was not feasible.

The current study underlines the importance of post-marketing surveillance after introduction of new mesh products on the international market. Most notably, in 2016 the manufacturer Ethicon withdrew the Physiomesh®, which was a large-pore lightweight polypropylene mesh intended for laparoscopic incisional hernia repair. This action was taken following data from a Polish randomized study that was terminated at interim analysis, and unpublished data from both the German and the Danish Hernia databases. These registry studies suggested significantly higher risks of recurrence following the use of Physiomesh® compared to other available mesh types (18). Data from the respective databases were later published confirming the preliminary results (19,20).

Surgeons worldwide play a crucial role in detecting unreliable or even unsafe medical devices. In Denmark, surgical treatment of parastomal hernia has been centralized to five centers. Patients are treated and operated on by a dedicated team of hernia surgeons, all specializing in parastomal hernia repair. This ensures a relatively high volume of procedures performed by few surgeons. Centralization also ensures that all patients undergoing surgery at our center are re-referred when complications including hernia recurrence are suspected. These factors—in combination with a national prospective hernia registry (19)—are of paramount importance, when it comes to post-marketing surveillance of medical devices. In light of this, we believe our findings warrant further investigation into

mesh fracture as a reason for recurrence in parastomal hernia repair.

In conclusion, we report seven cases of mesh fracture as reason for recurrence after laparoscopic parastomal hernia repair, using a monofilamentous composite polyester mesh. Consideration should be given to prioritizing centralization of these surgical procedures and close long-term monitoring on a national level of surgical techniques and implants in a constant effort to optimize safety and quality after parastomal hernia repair.

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