Surgical Treatment of Parastomal Hernias

Birgitta Hansson

Colofon

Design and layout
Dolf Heebing

Printing
Enk druck & media gmbh

Financial support of this thesis was generously provided by
Arseus/Medicor, ConvaTec, Covidien, Hodes Medische Speciaalzaken, Johnson&Johnson, Nycomed/Takeda, Olympus Nederland B.V., Stöpler/Karl Storz, Stryker, UMCN Afdeling Heelkunde, Wetenschapsfonds Maatschap Heelkunde CWZ, W.L. Gore & Associates.

Surgical Treatment of Parastomal Hernias

Proefschrift

ter verkrijging van de graad van doctor aan de Radboud Universiteit Nijmegen
op gezag van de rector magnificus, prof. mr. S.C.J.J. Kortmann,
volgens besluit van het college van decanen
in het openbaar te verdedigen op donderdag 13 december 2012 om 13.00 uur precies

door

Birgitta Maria Elisabeth Hansson
Geboren op 30 november 1968
te Schoten, België

Promotor
Prof. dr. R.P. Bleichrodt

Copromotor
Dr. I.H.J.T. de Hingh

Manuscriptcommissie
Prof. dr. W.F.J. Feitz (voorzitter)
Prof. dr. J.F. Lange (Erasmus Medisch Centrum Rotterdam)
Dr. F.M. Nagengast

Surgical Treatment of Parastomal Hernias

Doctoral Thesis

to obtain the degree of doctor from Radboud University Nijmegen
on the authority of the Rector Magnificus prof. dr. S.C.J.J. Kortmann,
according to the decision of the Council of Deans
to be defended in public on Thursday December 13, 2012 at 13.00 hours

by

Birgitta Maria Elisabeth Hansson
Born on Novenber 30, 1968
in Schoten, Belgium

Supervisor
Prof. dr. R.P. Bleichrodt

Co-supervisor
Dr. I.H.J.T. de Hingh

Doctoral Thesis Committee
Prof. dr. W.F.J. Feitz
Prof. dr. J.F. Lange (Erasmus Medical Center Rotterdam)
Dr. F.M. Nagengast

Table of Contents

Chapter 1	Introduction and outline of the thesis	**8**
Chapter 2	Promising new technique in the repair of parastomal hernia	**18**
Chapter 3	Laparoscopic parastomal hernia repair is feasible and safe: early results of a prospective clinical study including 55 consecutive patients	**26**
Chapter 4	Laparoscopic parastomal hernia repair using the Keyhole technique results in a high recurrence rate	**40**
Chapter 5	Surgical techniques for parastomal hernia repair: a systematic review of the literature	**50**
Chapter 6	Repair of parastomal hernias with biological grafts: a systematic review of the literature	**78**
Chapter 7	The laparoscopic modified Sugarbaker technique is safe and has a low recurrence rate: a multicenter cohort study	**94**
Chapter 8	Prevention of parastomal hernia with a prosthetic mesh; the Prevent-trial: a multicenter randomized controlled trial	**110**
Chapter 9	Summary and general discussion	**122**
Chapter 10	Samenvatting en algemene discussie	**132**
	List of publications	**142**
	Dankwoord (acknowledgements in Dutch)	**146**
	Curriculum vitae	**150**

Birgitta Hansson

Chapter 1 Introduction and outline of the thesis

Birgitta Hansson

A parastomal hernia is characterized by herniation of the abdominal contents through the trephine, the opening where the bowel passes the abdominal wall. Tangential forces, in combination with increased intra-abdominal pressures are the predominant factors that cause widening of the trephine. Parastomal herniation is the most frequent complication after stoma formation; fifty percent of all patients with a stoma develop a symptomatic parastomal hernia over time [1-3]. Parastomal hernias are observed in patients with all kinds of stomas. However, patients with a colostomy are most likely to develop a parastomal hernia [4,5]. Predisposing factors include an aperture size of more than 35mm, aging (over 70 years of age), disseminated malignancy, BMI over 25 kg/m2, diabetes mellitus and/or chronic elevation of intra-abdominal pressure [4,5].

A considerable number of patients experience a significant reduction in the quality of life following the development of a parastomal hernia. Symptoms may range from mild abdominal discomfort to severe abdominal pain due to stretching of the abdominal wall, and/or a poor fit of the stoma appliances, which result in leakage of the bowel contents and subsequent skin problems. Moreover, life-threatening complications may occur in case of obstruction or strangulation of the intestine. Bulging around the stoma may also cause cosmetic problems and patients may experience difficulty finding properly fitting apparel.

A physical examination often suffices to arrive at the diagnosis, especially when the patient is in an upright position during a Valsalva manoeuvre (figure 1). In supine position the hernia is generally reduced, which allows for palpation of the fascial edges of the trephine [2]. Sometimes however, the diagnosis can only be made by means of ultrasonography, CT- or MRI scanning (figure 2 a-b).

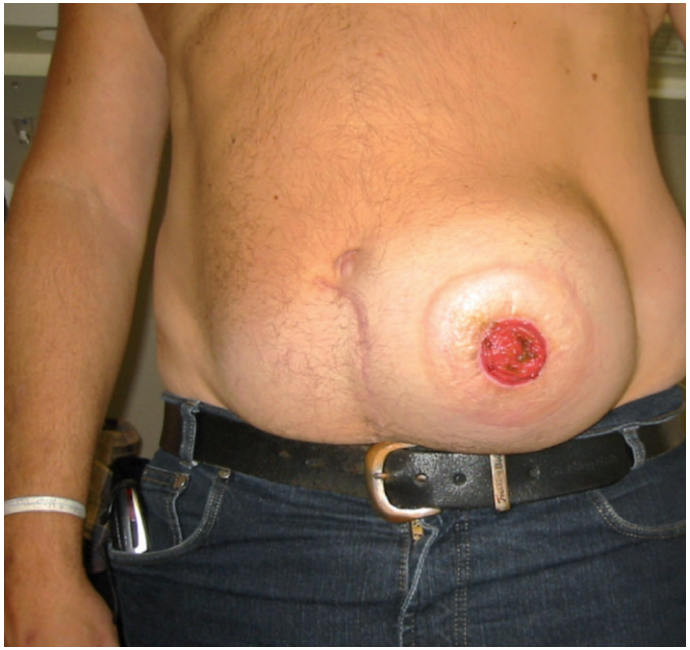

Figure 1 ***Patient with a symptomatic parastomal hernia***

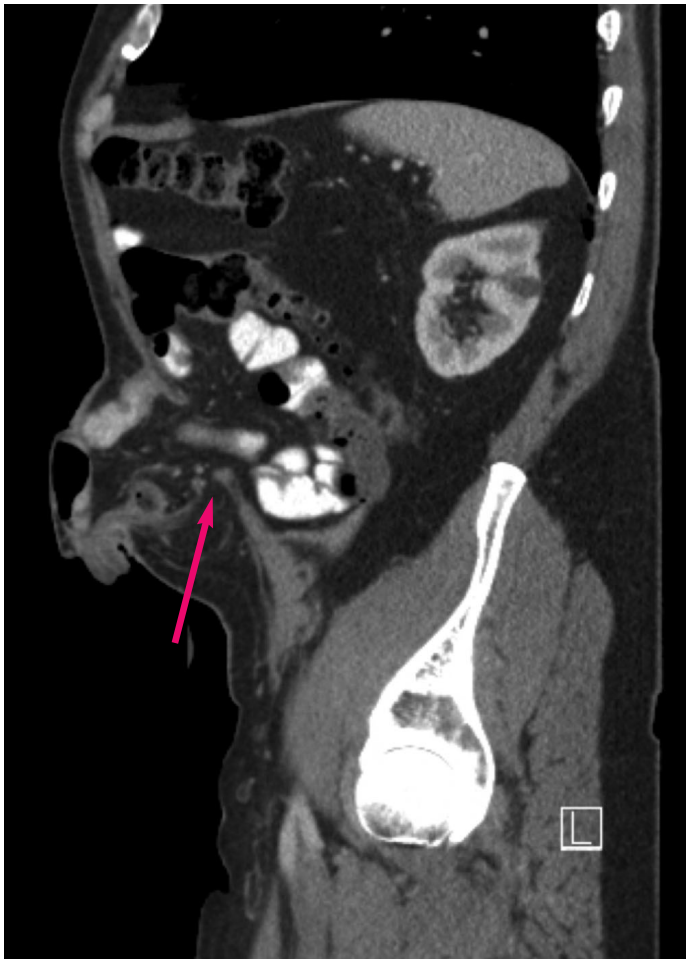

Figure 2a ***Abdominal CT scan (Sagittal plane)*** *Arrow shows parastomal hernia*

The repair of parastomal hernias is notoriously difficult. Several techniques have been advised during the last few decades. During the seventies of the previous century, local suture repair was the technique of choice [6]. This technique however, has been abandoned due to the unacceptably high recurrence rates, exceeding 70% [6,7]. Relocation of the stoma used to be another frequently applied method. This often required extensive surgical intervention with high recurrence rates of approximately 30%. Moreover, incisional hernias at the old ostomy site as well as at the midline laparotomy scar were frequent, occurring in 20-30% of cases [7]. Therefore, both techniques are now considered obsolete.

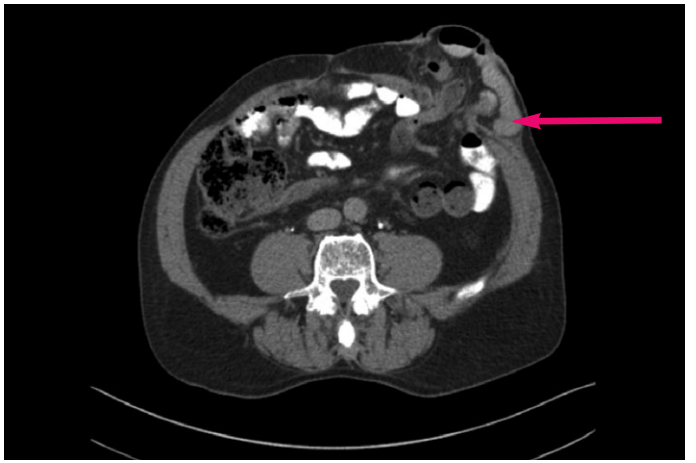

Figure 2b ***Abdominal CT scan (Transverse plane)*** *Arrow shows parastomal hernia*

Klinge and Schumpelick were the first to show that a collagen synthesis disorder may play a role in the development of incisional hernias. They showed that a decreased type I/type III collagen ratio predisposes hernia formation due to an impaired quality of the collagen matrix [8]. As a consequence, repair with a non-resorbable synthetic prosthesis has become the gold standard of hernia repair. Reinforcement of the stoma site with a prosthetic mesh is thought to be a logical and effective method, although it also is accompanied by potential risks such as infection, erosion and eventually perforation of the intestine [9,10].

Several techniques have been developed for open parastomal hernia repair. Prosthetic repair resulted in a considerable reduction of the reherniation rate, but none of the techniques to apply the mesh have been proven to be superior to others. The risk of mesh infection remains a general concern (Chapter 5).

During the last decade laparoscopic incisional hernia repair has gained popularity, especially as the risk of infection appears to be considerably reduced. Leblanc, who introduced the laparoscopic repair in 1993, published excellent results using an e-PTFE prosthesis [11]. These prosthesis are attractive because they are soft and pliable, which results in less severe adhesions to the bowel when compared to polypropylene and polyester meshes [12]. To date, perforations of e-PTFE prostheses into the bowel have not been reported [11,13]. The low infection rates in laparoscopic repair, in combination with the attractive mechanical and physical properties however, make e-PTFE an attractive prosthetic material for laparoscopic parastomal hernia repair.

In 2002, we started laparoscopic parastomal hernia repair using the Keyhole technique with e-PTFE prosthesis at our institution (figure 3). A pilot study with favourable results, presented in **chapter 2** was point of departure for our investigation geared towards improved surgical treatment for patients suffering a parastomal hernia. At that time, a review of literature revealed only case reports and small retrospective studies that left us unconvinced as to which technique was best.

After the pilot study, a prospective multicenter cohort study was initiated. Fifty-five consecutive, symptomatic patients were operated on using the Keyhole technique. **Chapter 3** reveals the short-term results of this study with a specific focus on morbidity.

In **chapter 4**, we present the long-term results including a two-year follow-up. Unfortunately, the recurrence rate was much higher than expected, which prompted us to add a thorough analysis in this chapter. These disappointing long-term results motivated us to perform a systematic review in

order to determine which technique is best suited to repair parastomal hernias. Results of this systematic review are presented in **chapter 5**.

Simultaneously, based upon the assertion that biological prosthesis are replaced by the patient's own tissue, thus reducing the risk of infection, biological prosthesis have become popular in hernia surgery, especially in contaminated areas. A review of the available literature on biological meshes is presented in **chapter 6**.

One of the conclusions of our systematic review is that the laparoscopic Sugarbaker technique is to be favoured over the Keyhole technique.

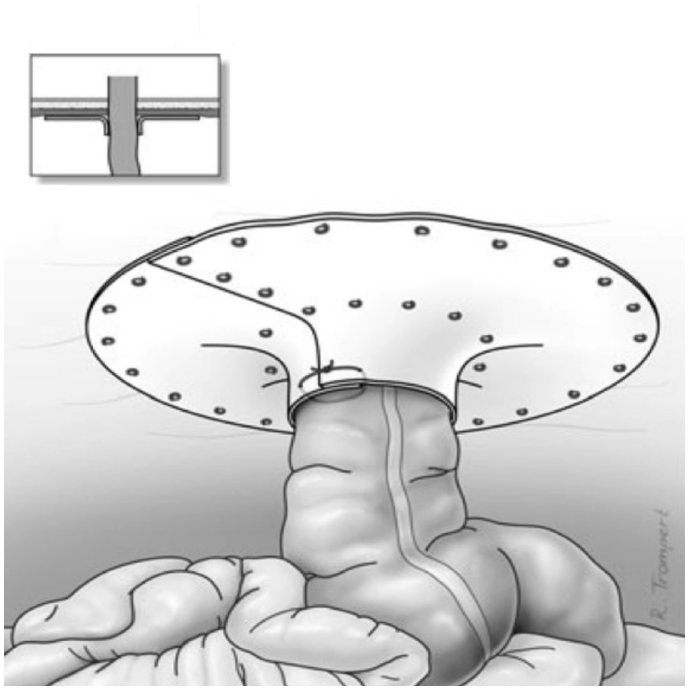

Figure 3 ***Keyhole technique***

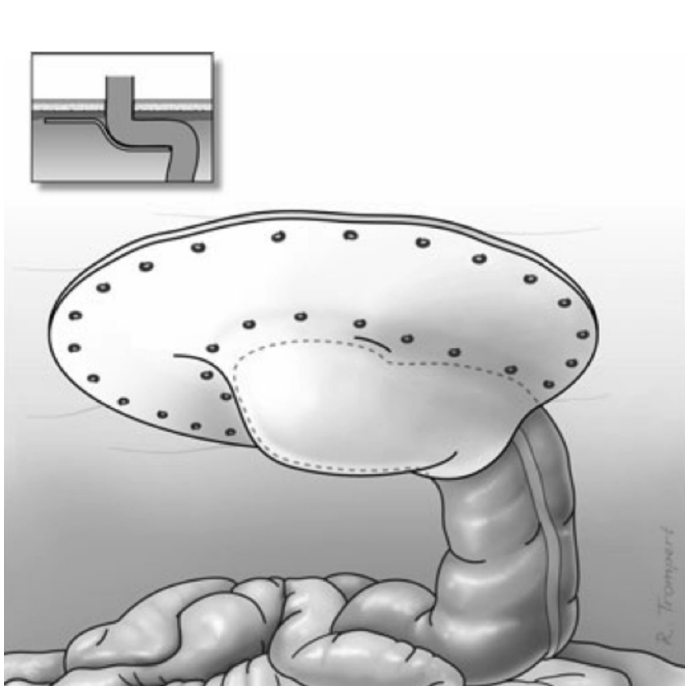

Figure 4 ***Sugarbaker technique***

As a consequence, we analyzed the results of four European Centers that applied the laparoscopic Sugarbaker technique using an e-PTFE patch (figure 3). The results of this retrospective study are presented in **chapter 7**.

Chapter 8 focuses on the prevention of parastomal hernias. In this chapter, the Prevent-trial, a prospective randomized trial with regard to the prevention of parastomal hernias with or without mesh reinforcement, is presented.

Finally, the main findings of this thesis are summarized in **chapter 9** followed by a general discussion.

Chapter 10 provides a Dutch version of the summary.

References

1 *Pearl RK. Parastomal hernias. World J Surg 1989;13:569-572.*

2 *Cingi A, Tebessum Carik, Sever A, Aktan AO. Enterostomy site hernias: a clinical and computerized tomographic evaluation. Dis colon Rectum 2006;49:1559-1563*

3 *Moreno-Matias J, Serra-Aracil X, Darnell-Martin A, Bonbardo-Junca J, Mora-Lopez L, Alcantara-Moral M, Ayguavives-Garnica I, Navarro-Soto S. The prevalence of parastomal hernia after formation of an end colostomy. Colorectal disease 2009;11:173-177*

4 *Pilgrim CHC, McIntyre R, Bailey M. Prospective audit of parastomal hernia: Prevalence and Associates comorbidities. Dis Colon Rectum 2010;53:71-76*

5 *Nastro P, Knowles CH, McGrath A, Porrett TRC, Lunniss PJ. Complications of intestinal stomas. Br J Surg 2010;97:1885-1889*

6 *Horgan K, Hughes LE. Para-ileostomy hernia: failure of local repair technique. Br J Surg 1986;73:439-440*

7 *Rubin MS, Schoetz DJ, Matthews JB. Parastomal hernia; Is stoma-relocation superior to fascial repair? Arch Surg 1994;129:413-419*

8 *Klinge U, Si Yu, Zheng H, Schumpelick V, Bhardway RS, Klosterhalfen B. Abnormal collagen I to III distribution in the skin of patients with incisional hernia. Eur Surg Res 2000;32:43-48*

9 *Rosin JD, Bonardi RA. Para-colostomy hernia with Marlex mesh. Dis Colon Rectum 1977;20:299-302*

10 *Aldridge AJ, Simson JN. Erosion and perforation of colon by synthetic mesh in a recurrent paracolostomy hernia. Hernia 2005; 9:140-144*

11 *Leblanc KA. The critical technical aspects of laparoscopic repair of ventral and incisional hernias. Am Surg 2001;67:809-812*

12 *Simmermacher RK, Schakenraad JM, Bleichrodt RP. Reherniation after repair of the abdominal wall with expanded polytetrafluoroethylene. J Am Coll Surg 1994;178:613-616*

13 *Forbes SS, Eskicioglu C, McLeod RS, Okrainec A. Meta-analysis of randomized controlled trials comparing open and laparoscopic ventral and incisional hernia repair with mesh. Br J Surg 2009; 96:851-858*

Birgitta Hansson

Chapter 2 Promising new technique in the repair of parastomal hernia

B.M.E. Hansson, E.J. van Nieuwenhoven, R.P. Bleichrodt Surg Endosc (2003) 17:1789-1791

Birgitta Hansson

Abstract

Parastomal hernia is a common complication after stoma formation. Although not all hernias require surgical repair, a variety of surgical techniques exist. Facial repair, relocation of the stoma, and the local use of a nonabsorbable mesh are the three major approaches. Despite this variety of techniques, recurrence rate and complications are high. We therefore invented a laparoscopic technique where we close the hernia and reinforce it with a hand-made ”funnel-shaped” Gore-Tex Dual Mesh. This technique has all advantages of laparoscopy (less pain, short hospitalization) combined with local mesh repair (no stoma replacement necessary, low recurrence rate). The risk of infection is also minimised. The shape of the Gore-Tex Mesh reduces hernia recurrence even more, prevents prolaps and allows easy colonoscopy and stoma irrigation.

Introduction

Parastomal herniation is a common complication after stoma formation. The incidence varies from 7 to 48% for paracolostomal hernia vs 11-28% for paraileostomy hernia and increases with time [3]. Most herniation occurs within the first 2 years after stoma formation [7]. Once herniation has occurred, constant enlargement of the trephine opening is guaranteed according to the Law of Laplace which states that forces working on the edge of the trephine opening are related to the radius of the opening [1].

Surgical intervention is indicated in case of pain, poor fitting of the appliance, associated prolaps or stenosis, obstruction, strangulation and incarceration. The surgical techniques may be categorised into stoma relocation, fascial repair and repair with prosthetic mesh.

There are no randomized trials on which method to use. Local fascia repair gives a recurrence rate of 47-76% [6]. Stoma relocation involves laparotomy and closing of the old ostomy site. This can result in an incisional hernia at the ostomy site (30%) or at the laparotomy site (20%). Reported recurrence rate of 33 % [6]. Using a nonabsorbable mesh results in a lower recurrence rate (7.4%) and a relatively low infection rate (9.2%) [3].

With our technique, we combine the advantages of a mesh repair with the advantages of minimal invasive surgery. The operative technique and initial results are described here in.

Materials and methods

Between July 2001 and October 2002 we performed this new laparoscopic technique in four patients suffering from symptomatic parastomal hernia. One patient was operated as an emergency due to obstruction and incarceration. One patient had a huge hernia with cosmetic problems and skin problems due to leakage. All patients had severe pain.

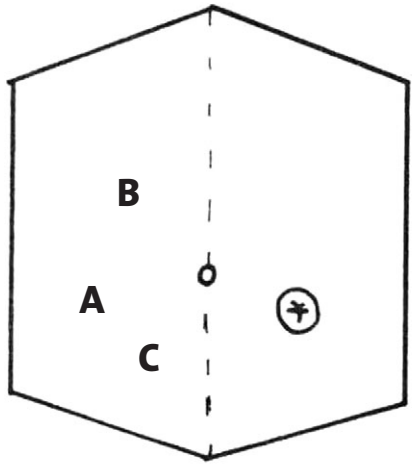

Figure 1 ***Positioning of the trocars***
A: 12mm trocar for laparoscope, B: 5mm trocar, C: 10 mm trocar

Operative technique

The patient is placed under general anaesthesia with endotracheal and nasogastric intubation. Intravenous prophylactic antibiotics are given. The patient is placed in a supine position.Surgeon and assistant stand contralateral to the stoma site. The stoma is covered with a sterile finger condom intraluminal and draped with an Opsite drape at skin level. This to inspect the vascularisation of the stoma and to mobilize the stomaloop during surgery.

The Hasson cannula technique is used to create the pneumoperitoneum to a pressure of 12 mmHg. A 30° laparoscope is inserted and two working ports are placed under direct vision creating a triangle with the stoma (figure 1).

After careful adhesiolysis, hernia contents are reduced, bowel and mesentery identified, and fascial edges freed. The hernia is closed with two Vycril 1 sutures. A 15x19 cm Gore-Tex dual mesh is fashioned with a central keyhole of 2 cm and two radial incisions of 5 mm (figure 2). This makes it possible to give it an intra-abdominal funnel-like shape (figure 3).

Then the mesh is inserted,unrolled and tacked to the abdominal wall with titanium tacks (ProTack) placed at 1-cm interval around the circumference of the patch and in the central part around the central hole. The cylindrical part of the mesh forms a collar covering the stoma loop and is stitched to the bowel wall with two seromusculair U-stitches (Prolene 3-0).

While tacking and suturing, one finger is inserted in the stoma to prevent iatrogenic bowel lesion. This technique comes close to hand-assisted laparoscopic surgery.

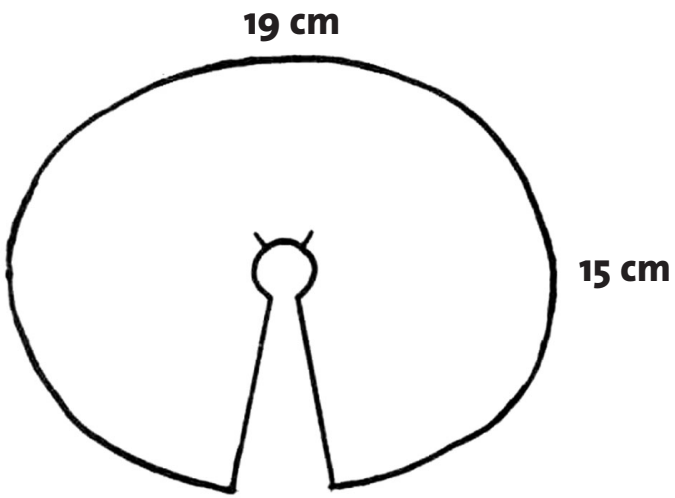

Figure 2 *15x19 cm Gore-Tex dual mesh with central keyhole defect of 2 cm and 2 radial incisions of 5 mm*

Results

All patients survived the operative intervention and there were no procedure-related complications. Laparoscopic reduction of the hernia contents and reinforcement with a Gore-Tex dual mesh was possible in all cases.

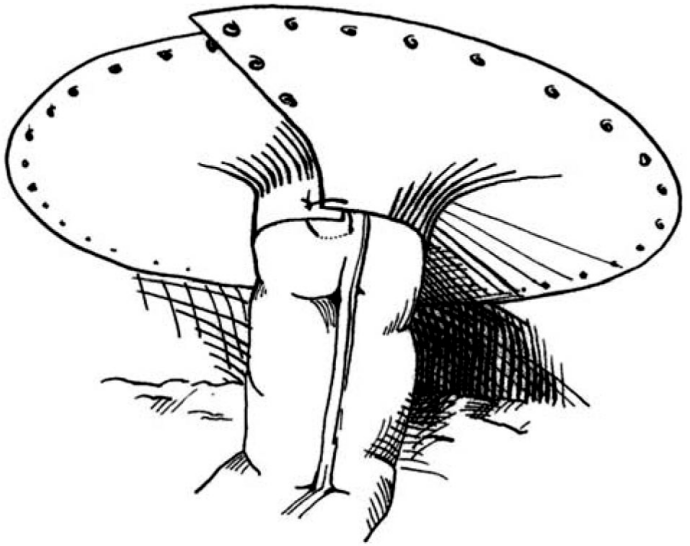

Figure 3 ***Intra-abdominal funnel-shaped mesh tacked to the ventral abdominal wall Fixation of the collar with U-stitches***

No bowel injury occurred. The mean hospital stay was 5 days. At time of writing all patients are asymptomatic with no sign of recurrence.

Discussion

Because of the poor results of conventional surgical techniques, alternative methods are discovered. Relying on the world literature and on our own experience with laparoscopic incisional hernia repair, we invented a promising new laparoscopic technique for the repair of parastomal hernia.

Reviewing the literature, only 3 cases of laparoscopic parastomal hernia are reported [2,5,8]. Porcheron et al. reported a technique where the orifice of the hernia was closed with stitches, and this suture was reinforced with an e-PTFE mesh [4].

Kazlowski et al. reported a technique where the hernia is simply covered with a Gore-Tex dual mesh with an overlap of 2-3 cm, nearly similar to the technique described by Voitk [2,8].

We believe that in both techniques the potential risk of recurrence is still too high. Simply covering the hernia with a mesh can give rise to kinking of the bowel and thus angulation of the intestinal lumen. This may lead to difficult evacuation and obstruction.

In our technique the hernia is closed with stitches and then reinforced by a Gore-Tex mesh of 15x19 cm. This mesh has a central keyhole of 2cm to allow protrusion of the bowel. The cylindrical part of the mesh forms a collar of 5mm and is sutured to the bowel loop with Prolene 3-0.

We believe that this shape will result in fewer recurrences and will prevent prolaps. Kinking of the bowel and thus angulation of the intestinal lumen is avoided and stoma irrigation and colonoscopy remains easy.

By covering the stoma with a sterile finger condom intra-luminal and an Opsite at skin level, the stoma loop can be touched and moved during surgery which can facilitate dissection. This makes is a save laparoscopic procedure nearly hand-assisted!

In addition, this technique avoids laparotomy and stoma relocation and has all routine advantages of minimal invasive surgery; shorter hospitalization, less postoperative pain, faster recovery and less wound and mesh infection [4].

References

1 *Köhler. Parastomale hernie-Technik und Ergebnisse Zentralbl Chir. 1997;122:889-892*

2 *Sjödahl R, Anderberg B, Bolin T. Parastomal hernia in relation to site of the abdominal stoma. Br J Surg 1988;75:339-341*

3 *De Ruiter P, Bijnen AB. Successful local repair of paracolostomy hernia with a newly developed prosthetic device. Int J Colorect Dis 1992;7:132-134*

4 *Rubin MS, Schoetz DJ, Mattthews JB. Parastomal hernia. Arch Surg 1994;129:413-419*

5 *Porcheron J, Payan B, Balique JG. Mesh repair of paracolostomal hernia by laparoscopy. Surg Endosc 1998;12:1281*

6 *Kazlowski PM, Wang PC, Winfield HN. Laparoscopic repair of incisional and parastomal hernias after major genitourinary or abdominal surgery. J Endourology 2001;15:175-179*

7 *Voitk A. Simple technique for laparoscopic paracolostomy hernia repair. Dis colon Rectum 2000;43:1451-1453*

8 *Ramshaw BJ, Esartia P, Schwab J, Manson EM. et al Comparison of laparoscopic and open ventral herniorrhaphy. Am Surg 1999;65: 827-831*

Birgitta Hansson

Chapter 3 Laparoscopic parastomal hernia repair is feasible and safe: early results of a prospective clinical study including 55 consecutive patients

B.M.E. Hansson, I.H.J.T. de Hingh, R.P. Bleichrodt Surg Endosc (2007) 21:989-993

Birgitta Hansson

Abstract

Background

Parastomal herniation is a common complication, and its operative treatment is notoriously difficult. Recently, the authors have described a laparoscopic technique for closure and reinforcement of the hernia with a hand-made "funnel-shaped" Gore-Tex Dual Mesh. Potentially this technique combines the advantages of a mesh repair with those of minimal invasive surgery.

Methods

In 2002, a multicenter trial of this new technique was started in The Netherlands. To date, 55 consecutive patients (27 men; median age, 63 years) with a symptomatic primary (n = 45) or recurrent (n = 10) parastomal hernia have undergone elective surgery using this technique. The demographic, perioperative, and early follow-up data prospectively collected for these patients are presented in this report.

Results

Of the 55 procedures, 47 (85.5%) could be completed laparoscopically (median operation time, 120 min). Conversion to laparotomy was indicated because of dense adhesions prohibiting safe dissection (n = 4) or bowel injury (n = 4). No in-hospital mortality occurred. Postoperative recovery was uneventful for 47 patients (85%), who had a median hospital stay of 4 days. Surgical and nonsurgical complications occurred, respectively, for four patients each (7.2%). Full-thickness enterotomy appeared to be the most troublesome complication. After 6 weeks, when all the patients were reexamined, one recurrence was noted.

Conclusion

Maximal efforts should be undertaken to prevent perioperative full-thickness enterotomy. Because this was achieved for the vast majority of patients, it is concluded that laparoscopic parastomal hernia repair is feasible and safe. Although a longer follow-up period is needed for definitive conclusions to be drawn regarding the recurrence rate, early follow-up evaluation shows very promising results.

Introduction

Parastomal herniation is a common complication of stoma formation. Its incidence varies significantly, but may be as high as 48% for colostomies and 28% for ileostomies [3]. Many operative techniques have been proposed for correction of parastomal hernias, but to date, none has been able to provide satisfactory results, especially in the long term [3, 5].

There is growing evidence that herniation in general results from an intrinsic defect in collagen metabolism and wound repair [9, 16], and that this together with mechanical factors and a high wound complication rate probably explains the high recurrence rates obtained with techniques relying on primary hernia repair alone [1, 4, 5]. This has resulted in the introduction of prosthetic meshes to correct fascial defects, and randomized clinical studies have indeed proven the superiority of prosthetic meshes in the repair of inguinal [7] and incisional [2, 12] hernias, making their usage almost obligatory in these cases.

It seems logical to assume that prosthetic meshes may be of similar value in parastomal hernia repair. However, various authors have published contradictory results on this issue [6, 11, 14, 15, 18]. This may be explained partly by the differing operative techniques (open or laparoscopic), types of mesh (polypropylene, PTFE, or a combination), and positions of the mesh (intraperitoneal, preperitoneal, or onlay) used [3].

Additionally, studies are mostly retrospective in design with only a small number of patients. Therefore, it is currently impossible to draw definitive conclusions on important issues such as perioperative morbidity and mortality and long-term recurrence rates after parastomal hernia mesh repair.

One of the issues raised is the relatively high perioperative complication and mortality rates reaching 65% and 8%, respectively [11, 13, 15, 18]. Recently, we have developed and described a laparoscopic technique for repairing parastomal hernias with a prosthetic mesh [8]. To provide insight into the feasibility and safety of this procedure, a prospective clinical study was started in 2002. The perioperative details and early results for the first 55 consecutive patients included in the study are presented in this report.

Patients and methods

Between 2002 and 2006, all patients electively referred to the Radboud University Medical Center or the Canisius-Wilhelmina Hospital, both in Nijmegen, The Netherlands, with a symptomatic parastomal hernia (severe pain, recurrent obstruction, poor fitting of appliance, cosmetic problems) were asked to participate in this prospective study. Adult patients (ages, 18-80 years) who gave written informed consent were included in the study. The exclusion criteria specified pregnancy, cardiopulmonary contraindications for

laparoscopy, or life expectancy shorter than 2 years. Demographic data, indications for enterostomy, comorbidity (chronic obstructive pulmonary disease, cardiovascular disease, and diabetes), American Society of Anesthesiology (ASA) classification, body mass index, size of the hernia, operative details, operation time, perioperative and postoperative complications, time to mobilization, food intake, stoma production, hospital stay, and 6-week follow-up data were recorded on a standard form. The study protocol was reviewed and approved by the institutional ethics commission of the participating hospitals.

Operative procedure

All procedures were performed or supervised by an experienced laparoscopic surgeon (B.H.), as previously described [8]. For the procedure, the patient is placed under general anesthesia with endotracheal and nasogastric intubation. Intravenous prophylactic antibiotics are given. The patient is placed in a supine position. The surgeon and assistant stand contralateral to the stoma site. The stoma is covered with a sterile finger condom intraluminally and draped with an Opsite drape at skin level for inspection of stoma vascularization and mobilization of the stomaloop during surgery. The Hasson cannula technique is used to create the pneumoperitoneum to a pressure of 12 mmHg. A 30° laparoscope is inserted, and two working ports are placed under direct vision, creating a triangle with the stoma.

After careful adhesiolysis, hernia contents are reduced, bowel and mesentery are identified, and fascial edges are freed. The hernia opening is narrowed with two Mersilene 0 sutures (Ethicon, Somerville, NJ, USA). A 15 x 19-cm expanded polytetrafluoroethylene patch (Gore-Tex Dual Mesh Biomaterial, WL Gore & Associates, Flagstaff, AZ, USA) is fashioned with a central keyhole of 2 cm and two radial incisions of 5 mm. This makes it possible to give it an intraabdominal funnel-like shape. The mesh is then inserted, unrolled, and tacked to the abdominal wall with titanium tacks (ProTack, Autosuture, Tyco, Norwalk, CT, USA) placed at 1-cm intervals around the circumference of the patch and in the central part around the central hole. The cylindrical part of the mesh forms a collar covering the stoma loop and stitched to the bowel wall with two seromuscular U-stitches using Prolene 3.0 (Ethicon), as shown in figure 1.

In this study, serosal bowel lesions were repaired laparoscopically, but in the case of an inadvertent full-thickness enterotomy or when safe dissection was deemed impossible because of dense adhesions, the procedure was converted to an open repair using the same mesh.

Postoperative period

All the patients were examined on a daily basis by the first author. The wound and stoma sites were inspected for signs of infection, formation of seroma, hernia recurrence, or other

complications. Unrestricted mobilization and a normal diet were allowed as soon as possible. Patients were discharged when normal mobilization, diet, and stoma production were achieved. All patients were reexamined in the outpatient clinic 6 weeks after the operative procedure.

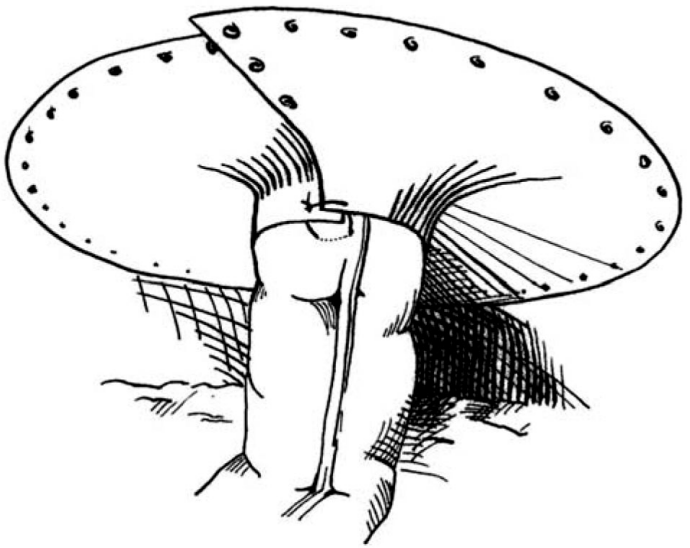

Figure 1 ***Operative result for the funnel-shaped Gore-Tex Dual Mesh tacked to the ventral abdominal wall and fixation of the collar with U-stitches***

Results

Patients

A total of 55 consecutive patients with a primary (n = 45) or recurrent (n = 10) parastomal hernia were included in this prospective study. Demographics, ASA classification, and body mass index (BMI) are shown in table 1. The stomas were initially constructed for the treatment of colorectal cancer (n = 31), fecal incontinence (n = 10), inflammatory bowel disease (n = 8), congenital anomaly (n = 2), acute diverticulitis (n = 1), slow-transit constipation (n = 1), and perineal trauma (n = 1).

Operative procedure

In all situations, the hernia could be repaired using the Gore-Tex Dual Mesh. Of the 55 procedures, 47 (85.5%) were completed laparoscopically. Conversion to laparotomy was performed for eight patients (14.5%). The reasons for conversion were multiple dense adhesions prohibiting safe dissection (n = 4) and full-thickness injury to the bowel with contamination (n = 4). In three additional cases, serosal bowel damage was noted and repaired laparoscopically.

The median operation time was 120 min (range, 40-315 min), and the median blood loss was 20 ml (range, 0-500 ml). No significant difference in operation time or blood loss was noted between primary and recurrent hernias (table 2). Higher incidences of conversion, intestinal damage, and

	Total	Primary hernia	Recurrent hernia
n (%)	55 (100)	45 (81,8)	10 (18,2)
Male/female: n (%)	27 49.1)/28 (50.9)	24 (53.3)/21(46.7)	3 (30) / 7 (70)
Age (years): n (%)	63 (27-87)	62 (27-78)	68 (56-87)
ASA-1: n (%)	8 (14,5)	7 (15,6)	1 (10)
ASA-2: n (%)	44 (80)	36 (80)	8 (80)
ASA-3: n (%)	3 (5.5)	2 (4.4)	1 (10)
BMI (kg/m2): n (range)	27 (19-57)	28 (19-57)	25 (19-36)
Colostomy: n (%)	47 (85.4)	38 (84.4)	9 (90)
Ileostomy: n (%)	5 (9.1)	5 (11.1)	0
Urostomy: n (%)	3 (3.6)	2 (4.4)	1 (10)
Diameter hernia sack (cm): n (range)	10 (4-20)	10 (4-20)	8 (4-15)
Trephine diameter (cm): n (range)	5 (3-10)	5 (3-10)	4,5 (4-7)
Not reponible: n (%)	43 (76.3)	39 (84,4)	4 (40)

Table 1 ***Patient demographics and stoma details*** *ASA, American Society of Anesthesiology; BMI, Body Mass Index*

	Total	Primary hernia	Recurrent hernia
OR-Time (min)	120 (40-315)	120 (40-315)	120 (60-180)
Blood loss (ml)	20 (0-500)	20 (0-500)	25 (20-250)
Conversion (%)	8 (14.5)	5 (11.1)	3 (30)
Intestinal damage (%)	6 (10.9)	4 (8.8)	2 (20)
Reoperation (%)	4 (7.3)	2 (4.4)	2 (20)
Pulmonary complication (%)	2 (3.6)	2 (4.4)	0
Ileus (%)	2 (3.6)	2 (4.4)	0
Mesh infection (%)	2 (3.6)	1 (2.2)	1 (10)
Mortality	0	0	0

Table 2 ***Operative details and early postoperative complications*** *OR-time = length of the procedure. OR-time and blood loss are given as median values with range*

reoperation were diagnosed in the recurrent hernia group, but the number of patients was too small for the results to reach statistical significance.

Early postoperative course

Typically, patients were able to consume a normal diet on day 1 (range, 1-3 days), had stoma production on day 2 (range, 1-13 days), and could be released from the hospital on postoperative day 4 (range, 2-20 days). No statistically significant differences were observed in these parameters between laparoscopic repairs and converted procedures.

Postoperative complications occurred for eight patients (14.4%), with four patients (7.2%) requiring a reoperation. One patient underwent reoperation almost immediately after the first operation for correction of bleeding from the epigastric artery. This patients further recovery was uneventful.

Signs of peritonitis developed in two patients. In one patient, a previously unrecognized full-thickness colonic lesion with fecal contamination of the abdomen was diagnosed during laparotomy on postoperative day 9. This resulted in removal of the mesh and primary closure of the hernia. In the other patient, a small bowel injury was noted during relaparotomy. After closure of the lesion and mechanical cleaning of the abdomen, the abdomen was closed with the mesh left in place. Both patients received intravenous antibiotics and could be released from hospital, respectively, 14 and 16 days after the initial procedure without signs of infection.

For one patient, the mesh had to be removed on postoperative day 12 because of local abscess formation. Interestingly, this was one of four patients whom required conversion to the open technique because of fullthickness bowel damage.

Nonsurgical complications developed in another four patients (7.2%). Respiratory insufficiency developed in one patient immediately after surgery, requiring temporary admission to the intensive care unit. Pneumonia developed in another patient, for which treatment with antibiotics was started. Prolonged ileus (>7 days) was noted in two patients. All these patients were treated successfully with conservative measures. No inhospital mortality occurred.

Early wound complications were relatively common but mild. A hematoma was seen at the trocar site in five patients. At the former hernia site, seroma (n = 15) and erythema (n = 3) were noted, but no signs of infection.

Follow-up evaluation at 6 weeks

All the patients (100% follow-up rate) were examined at the outpatient clinic 6 weeks after the initial operation. The majority of the patients (n = 50) had an uneventful recovery and were free of symptoms. Four patients reported pain at the site of the mesh. Ulnaropathy of the right arm was diagnosed for one patient.

At the physical examination, one recurrent parastomal hernia was diagnosed in one of the patients for whom conversion to laparotomy was performed because of a full-thickness bowel injury. The hernia was small and did not cause symptoms. Most wound complications had resolved. Only one residual hematoma was noted, and persisting seroma at the site of the hernia was diagnosed for three patients (table 3).

	At discharge	After 6 weeks
Trocar-site hematoma	5	1
Trocar-site infection	0	0
Stoma-site seroma	15	3
Stoma-site erythema	3	0
Stoma-site infection	0	0

Table 3 ***Number of wound complications at discharge and after 6 weeks***

Discussion

Parastomal hernia is a common but mostly asymptomatic complication after stoma formation. Mild symptoms include parastomal discomfort, local pain, and obstruction, but these may progress gradually to more severe and even life-threatening complications such as strangulation and perforation. Besides this, parastomal hernias tend to increase in size over time and may result in large disfiguring hernias causing cosmetic problems and poor fitting of the appliance. Fortunately, conservative measures yield satisfactory results for most patients, but surgical repair of the parastomal hernia clearly is indicated for patients with severe complaints.

Many techniques for the repair of parastomal hernias have been described in recent decades. Generally, the techniques fall into one of three categories: local tissue repair, stoma relocation, or repair with prosthetic material [3]. Although clinical trials to compare one technique with the others have never been performed, it is now commonsense to regard techniques using local tissue repair as outdated because of the high recurrence rates in most studies [1, 4, 5].

Stoma relocation may seem to be an attractive alternative, but it has some major drawbacks such as the risk for the development of a parastomal hernia at the new stoma site and an incisional hernia at the old stoma site [5, 17]. In addition,

this technique requires a formal relaparotomy, causing further damage to the abdominal wall, thereby introducing the risk of an incisional hernia at this particular site. Taking into consideration the recent findings that hernias are, at least in part, caused by underlying defects in wound healing and collagen metabolism [9, 16], we consider this technique to be too traumatic for the abdominal wall. Instead, an operative procedure for correction of a parastomal hernia should aim to reinforce the abdominal wall and cause as little additional damage to it as possible. To meet these goals, we previously presented a novel technique in which the parastomal hernia is repaired laparoscopically using a prosthetic mesh.

Meshes for parastomal hernia repair were introduced already 30 years ago, but this has not revolutionized the treatment of parastomal hernias as it has, for instance, changed the treatment of inguinal hernias. This is explained by the concern that, in contrast to inguinal hernia repair, the mesh must be situated in close proximity to the bowel, putting it at risk for adhesive, erosive, and eventually infectious complications. Various authors have indeed reported such problems [14, 19]. However, the choice of the type of mesh seems to be of paramount importance in this respect. Polypropylene meshes were popular in the early days of parastomal mesh repair, but they currently are known to cause dense adhesions and even erosion of the bowel wall. Their usage for parastomal repair is therefore discouraged currently [14, 19].

Despite the abundance of meshes currently available, the 'ideal mesh' that should combine rapid ingrowth in the abdominal wall, offer high resistance to infections, and completely lack adhesion to the intestine is not yet available. Meshes made of expanded polytetrafluoroethylene (ePTFE) cause only few adhesions, are soft and pliable, and anchor to the abdominal fascia when fixed with sutures or tacks [10]. Therefore, these meshes are currently deemed most suitable for parastomal hernia repair and were used in the current study.

The practice of performing laparoscopic instead of open repair may be advantageous in terms of surgical damage to the abdominal wall, but it could be argued that it may increase the risk of iatrogenic intestinal laceration because parastomal hernia repair is by definition a reoperation, making disturbed anatomy and multiple dense adhesions very common. Indeed, in the current study, accidental full-thickness enterotomy occurred in six patients (11%) despite the presence of an experienced laparoscopic surgeon. However, this still compares favorably with the 19% rate for inadvertent enterotomies during 270 relaparotomies in open surgery, as reported by van der Krabben et al. [20]. The laparoscopic technique in itself should thus not be regarded as a risk factor for iatrogenic bowel injury. A risk factor may be the presence of a recurrent hernia because the percentage of inadvertent intestinal damage and reoperation is higher for these patients than for those with primary hernias. This may

be explained by the disturbed anatomy and fibrosis caused by the previous operations, but it must be realized that the number of patients studied is too small for definitive conclusions to be drawn.

Four of the six bowel perforations were recognized during the initial procedure, which resulted in conversion to an open procedure. In two of these patients, further complications developed in the early postoperative period: an abscess on the mesh requiring its removal on the postoperative day 12 and an early recurrence. In two patients, full-thickness enterotomy was recognized only at the time of relaparotomy for signs of peritonitis, and although the patients eventually recovered completely, the hospital stay was prolonged and one mesh had to be removed because of infection. Full-thickness enterotomy should thus be regarded as a very serious perioperative event because it has resulted in considerable postoperative morbidity in affected patients. On the basis of the observations in this study, it might even be argued that mesh repair should be postponed in the event of a recognized enterotomy.

Fortunately, the vast majority of laparoscopic procedures were completed without bowel injury, and the data show that in these cases, the perioperative morbidity rate was very low and postoperative recovery was fast. Wound problems usually were mild and self-limiting. It is not likely that the successful results of the current study are attributable to a favorable patient selection because the patients in this study generally were obese (median BMI, 27 kg/m2), their hernias were large (median hernial sack diameter, 10 cm) and mostly not reponible (76% of cases), and 10 patients with a recurrent hernia were included.

Current knowledge concerning important issues of laparoscopic parastomal hernia repair such as feasibility of the procedure, perioperative morbidity and mortality, the number of mesh infections, and the recurrence rate is sparse and ambiguous. Some authors report low complication and recurrence rates, whereas others are much less optimistic. However, it must be realized that these results are based mainly on case reports and small retrospective series with insufficient follow-up evaluation and quality for definitive conclusions to be drawn on these important issues. The only prospective study addressing the topic of perioperative complication rates reports on only 12 patients, and although the low recurrence rate of only 8% is promising as compared with other techniques, the perioperative complication rate of 25% and one fatality may deter others from adopting this technique [11]. Therefore, the current study was undertaken to determine the feasibility and safety of laparoscopic parastomal hernia repair specifically and prospectively.

On the basis of the results from the current study, which represents by far the largest patient series available to date, it is concluded that laparoscopic parastomal hernia repair is feasible, even in cases of recurrent parastomal hernia. However, every possible precaution should be taken to prevent perioperative full-thickness enterotomy because this puts the patient at risk for serious infectious complications in the early postoperative period. In search of answers to other important issues regarding parastomal hernia repair such as infection and recurrence rates in the long term, this group of patients will be closely monitored and results will be reported in the near future.

References

1 *Allen-Mersh TG, Thomson JP. Surgical treatment of colostomy complications. Br J Surg 1988;75: 416-418*

2 *Burger JW, Luijendijk RW, Hop WC, Halm JA, Verdaasdonk EG, Jeekel J. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg 2004;240: 578-583*

3 *Carne PW, Robertson GM, Frizelle FA. Parastomal hernia. Br J Surg 2003;90:784-793*

4 *Cassar K, Munro A. Surgical treatment of incisional hernia. Br J Surg 2002;89:534-545*

5 *Cheung MT, Chia NH, Chiu WY. Surgical treatment of parastomal hernia complicating sigmoid colostomies. Dis Colon Rectum 2001;44:266-270*

6 *de Ruiter P, Bijnen AB. Successful local repair of paracolostomy hernia with a newly developed prosthetic device. Int J Colorectal Dis 1992;7:132-134*

7 *Grant AM. Open mesh versus nonmesh repair of groin hernia: meta-analysis of randomized trials based on individual patient data. Hernia 2002;6:130-136*

8 *Hansson BM, van Nieuwenhoven EJ, Bleichrodt RP. Promising new technique in the repair of parastomal hernia. Surg Endosc 2003;17:1789-1791*

9 *Junge K, Klinge U, Rosch R, Mertens PR, Kirch J, Klosterhalfen B, Lynen P, Schumpelick V. Decreased collagen type I/III ratio in patients with recurring hernia after implantation of alloplastic prostheses. Langenbecks Arch Surg 2004;389:17-22*

10 *Koehler RH, Begos D, Berger D, Carey S, LeBlanc K, Park A, Ramshaw B, Smoot R, Voeller G. Minimal adhesions to ePTFE mesh after laparoscopic ventral incisional hernia repair: reoperative findings in 65 cases. JSLS 2003;7:335-340*

11 *LeBlanc KA, Bellanger DE, Whitaker JM, Hausmann MG. Laparoscopic parastomal hernia repair. Hernia 2005;9:140-144*

12 *Luijendijk RW, Hop WC, van den Tol MP, de Lange DC, Braaksma MM, IJzermans JN, Boelhouwer RU, de Vries BC, Salu MK, Wereldsma JC, Bruijninckx CM, Jeekel J. A comparison of suture repair with mesh repair for incisional hernia. N Engl J Med 2000;343: 392-398*

13 *Mancini GJ, Ramshaw BJ, Heniford BT, Novitsky YM, LeBlanc KA, Elieson MJ, Park AE, Kavic SM, Voeller GR, Goldenberg BA. Laparoscopic parastomal hernia repair using a non-slit mesh technique. Surg Endosc 2007;21:1487-1491*

14 *Morris-Stiff G, Hughes LE. The continuing challenge of parastomal hernia: failure of a novel polypropylene mesh repair. Ann R Coll Surg Engl 1998;80:184-187*

15 *Rieger N, Moore J, Hewett P, Lee S, Stephens J. Parastomal hernia repair. Colorectal Dis 2004;6:203-205*

16 *Rosch R, Junge K, Knops M, Lynen P, Klinge U, Schumpelick V. Analysis of collagen-interacting proteins in patients with incisional hernias. Langenbecks Arch.Surg 2003;387:427-432*

17 *Rubin MS, Schoetz DJ Jr., Matthews JB. Parastomal hernia: is stoma relocation superior to fascial repair? Arch Surg 1994;129:413-418*

18 *Safadi B. Laparoscopic repair of parastomal hernias: early results. Surg Endosc 2004;18:676-680*

19 *Steele SR, Lee P, Martin MJ, Mullenix PS, Sullivan ES. Is parastomal hernia repair with polypropylene mesh safe? Am J Surg 2003;185: 436-440*

20 *Van Der Krabben AA, Dijkstra FR, Nieuwenhuijzen M, Reijnen MM, Schaapveld M, Van Goor H. Morbidity and mortality of inadvertent enterotomy during adhesiotomy. Br J Surg 2000;87:467- 471*

Birgitta Hansson

Chapter 4 Laparoscopic parastomal hernia repair using the Keyhole technique results in a high recurrence rate

B.M.E. Hansson, R.P. Bleichrodt, I.H.J.T. de Hingh Surg Endosc (2009) 23:1456-1459

Birgitta Hansson

Abstract

Background

Parastomal herniation is a common complication of stoma formation, and its operative treatment is notoriously difficult. Recently we have reported the promising short-term results of a keyhole technique in which a Gore-Tex Dual Mesh with a central keyhole is laparoscopically fashioned around the bowel to close the hernia. In the long-term, recurrence is one of the major issues in hernia repair, therefore, this aspect was prospectively investigated.

Methods

Since 2002, a total of 55 consecutive patients (27 men; median age, 63 years) with a symptomatic primary (n = 45) or recurrent parastomal hernia (n = 10) were electively operated using this technique. Patients were invited to the outpatient clinic on a regular basis and were examined for the occurrence of a recurrent hernia. At the last visit, all patients were asked to complete a short questionnaire.

Results

Median follow-up (98%) was 36 (range, 12-72) months. During follow-up a recurrent parastomal hernia was diagnosed in 20 patients (37%). Three recurrences were asymptomatic and were treated conservatively. The other 17 patients (85%) developed mild-to-severe symptoms necessitating redo-surgery in 9 (45%) patients. Surprisingly, satisfaction with the procedure was high among patients (89%), even in the presence of a recurrence. Patients who reported unsatisfactory results belonged mainly to the group in whom the initial laparoscopic approach had to be converted to an open procedure.

Conclusions

Based on the results from the present study, which represents one of the largest patient series with the longest follow-up available to date, it is concluded that laparoscopic parastomal hernia repair using a keyhole technique has an intolerably high recurrence rate with the currently available meshes. A new mesh with a less pliable central part and without the tendency to shrink is awaited.

Introduction

Parastomal herniation is a common complication of stoma formation. The incidence varies significantly and may be as high as 48% for colostomies and 28% for ileostomies [3]. Fortunately, most parastomal hernias can be managed conservatively but nevertheless they may cause annoying symptoms, such as pain, leakage of stomal contents, and cosmetic disfigurement. A small but substantial number of patients develop more severe complications, such as obstruction or incarceration, which may become lifethreatening if left untreated. To correct symptomatic parastomal hernias, many operative techniques have been proposed but so far none has been able to provide satisfactory results, especially in the long-term [3,4].

Previously, we have described a new method for parastomal hernia repair [5]. This method was designed to correct the parastomal hernia by applying an ePTFE patch against the abdominal wall, using a laparoscopic approach. A central keyhole is fashioned in the patch to allow the bowel to pass through the abdominal wall. Therefore, this technique often is referred to as the 'Keyhole technique' as opposed to the 'Sugarbaker technique' in which a non-slit covering mesh is used to correct the hernia [15].

Our early results in 55 consecutive patients treated with this method have been published previously and with a conversion rate and a complication rate of 14% each, this technique seemed to be both feasible and safe [6]. However, one of the major issues in parastomal hernia repair is the recurrence rate in the long-term because parastomal hernia repair has a high recurrence rate after open surgical repair [3, 4, 10]. We hypothesized that the laparoscopic approach for parastomal hernia repair would result in lower recurrence rates. This was mainly based on the assumption that this approach would offer a superior view of the abdominal wall, including the edges of the hernia, facilitating adequate placement and fixation of the mesh in a sublay position. Furthermore, the laparoscopic approach results in only minimal additional trauma to the abdominal wall.

To prove this hypothesis, all 55 treated patients were invited to the outpatient clinic on a regular basis and were examined for the occurrence of a recurrent parastomal hernia. At the last visit, all patients were asked to complete a short questionnaire about their satisfaction with the operation.

Patients and methods

Between 2002 and 2006, a total of 55 consecutive patients who were electively referred to the Radboud University Medical Center and the Canisius-Wilhelmina Hospital, both in Nijmegen, the Netherlands, with a symptomatic para-

stomal hernia (severe pain, recurrent obstruction, poor fitting of appliance, cosmetic problems) were asked to participate in this prospective study. Adult patients (18-80 years) who gave written informed consent were included in the study. Exclusion criteria were: pregnancy, cardiopulmonary contraindications for laparoscopy or life expectancy shorter than 2 years. Demographic data, indications for enterostomy, comorbidity (COPD, cardiovascular disease, and diabetes), ASA classification, body mass index, size of the hernia, operative details, operation time, peroperative and postoperative complications, time to mobilization, food intake, stoma production, hospital stay and 6-week follow-up data were recorded on a standard form and were previously published [6]. The study protocol was reviewed and approved by the institutional ethics commission of the participating hospitals.

Operative procedure

All procedures were performed or supervised by an experienced laparoscopic surgeon (BH). The patient is placed under general anesthesia with endotracheal and nasogastric intubation. Intravenous prophylactic antibiotics are given. The patient is placed in a supine position. Surgeon and assistant stand contralateral to the stoma site. The stoma is covered with a sterile finger condom intraluminal and draped with an Opsite drape at skin level to inspect the vascularization of the stoma and to mobilize the stoma loop during surgery. The Hasson cannula technique is used to create the pneumoperitoneum to a pressure of 12 mmHg. A 30° laparoscope is inserted and two working ports are placed under direct vision creating a triangle with the stoma.

After careful adhesiolyis, hernia contents are reduced, bowel and mesentery identified, and fascial edges freed. The hernia opening is narrowed with two Mersilene 0 sutures (Ethicon, Somerville, NJ, USA). A 15 x 19-cm expanded polytetrafluoroethylene patch (Gore-Tex Dual Mesh Biomaterial®, WL Gore & Associates, Flagstaff, AZ, USA) is fashioned with a central keyhole of 2 cm and two radial incisions of 5 mm, thus creating a funnel-like shape for fixation to the bowel. Then the mesh is inserted, unrolled, and tacked to the abdominal wall with titanium tacks (ProTack™, Autosuture/Tyco, Norwalk, CT, USA) placed at 1-cm interval around the circumference of the patch and in the central part around the central hole. The cylindrical part of the mesh forms a collar covering the stoma loop and is stitched to the bowel wall with two seromuscular U-stitches using Prolene 3.0 (Ethicon).

Serosal bowel lesions were repaired laparoscopically. The parastomal hernia could be repaired in all patients. In eight cases the procedure was converted to an open procedure because of dense adhesions (n = 4) or full-thickness bowel injury (n = 4).

Follow-up was performed in the outpatient clinic. The stoma was investigated for signs of recurrence at every visit. In case of doubt radiological examinations were performed. During their last visit patients were asked to complete a short, anonymous questionnaire. Patients were asked whether they were satisfied with the final result of the repair (yes or no) and about their self-perceived quality of life after the operation (improved, unchanged, or worsened).

Results

Follow-up

One patient died of metastasized colorectal cancer and was lost to follow-up, resulting in a follow-up rate of 98%. The median follow-up was 3 (range, 1-6) years.

Recurrence rate

In total 20 of 54 patients (37%) developed a recurrent parastomal hernia. In two patients this was caused by infection and subsequent removal of the mesh during the early postoperative period. Another eight recurrences developed within 1 year after surgery, whereas ten patients developed a recurrence thereafter. Three of the 20 patients with a recurrence had no complaints and were treated conservatively. The other 17 patients (85%) developed mild-to-severe symptoms, which necessitated redo-surgery in 9 (45%) of these patients. Unfortunately, this again resulted in a recurrent hernia in seven of these patients.

Satisfaction

When asked about their overall satisfaction with the procedure, 48 patients (89%) confirmed that they were satisfied. Surprisingly, this also included 18 of the 20 patients with a recurrent hernia. This was confirmed by the fact that 18 of these patients (90%) reported an improved quality of life (13 patients) or an unchanged quality of life (5 patients) after the operation despite the presence of a recurrence. In total six patients (11%) were unsatisfied and five patients (9%) reported that their quality of life had worsened after the operation. Interestingly, the latter group included only two patients with a recurrent hernia and all the patients in this last category belonged to the group of patients in whom the laparoscopic procedure was converted to an open procedure because of complications during surgery.

Discussion

Previously we have reported the short-term results of a laparoscopic technique in which the parastomal hernia is repaired by using a keyhole technique. With a conversion rate of less than 15%, a median hospital stay of only 4 days, a complication rate of 14% with no mortality, and an early (within 6 weeks) recurrence rate of only one patient, we considered this technique both feasible and safe [6].

Previous studies after parastomal hernia repair have shown that recurrence rates tend to increase over time and therefore any given technique should only be considered successful after reaching adequate follow-up [3, 4, 10]. Therefore, the patients included in this study were regularly investigated for the occurrence of a recurrent herniation in the outpatient clinic. It was anticipated that the laparoscopic technique would perform better than the previously reported open techniques; however, at a median follow-up of 36 months the recurrence rate in our study-population reached an unsatisfying 37%. Despite the fact that a reintervention was only required in nine patients, this result is clearly disappointing.

Fortunately most patients included in the study remained satisfied even in the case of a recurrence. This is probably explained by the fact that the parastomal hernias with which they initially presented were generally large (median hernia sack diameter of 10 cm) and mostly irreducible (76% of cases) [6]. Recurrences were generally smaller and caused fewer symptoms as illustrated by the fact that 65% of the patients with a recurrence still reported an improvement in their quality of life. Patients in whom the laparoscopic procedure was converted to an open procedure due to complications were generally not satisfied, including three patients in whom the hernia repair appeared to be successful.

There are probably multiple reasons for the high failure rate as found in the present study. First, most patients with hernias are probably affected by underlying defects in wound healing and collagen metabolism [7, 11]. This explains why the narrowing of the stoma opening with the Mersilene as performed in our technique will only have a temporary effect, as has already indicated by the failure rate of up to 100% when relying on tissue repair alone [1, 3, 4]. Therefore, the repair of the hernia depends completely on the presence of an adequate positioned mesh. Ideally, such mesh should achieve rapid ingrowth in the abdominal wall while being inert to the bowel. Furthermore, the mesh should be highly resistant to bacterial infections. Expanded polytetrafluoroethylene (ePTFE) was chosen because it is a very inert, soft, and pliable material that does not adhere to the bowel [8]. However, a major disadvantage of this mesh was its tendency to shrink, as observed in almost all patients who were reoperated for a recurrent parastomal hernia in our study. This shrinkage is thought to be the result of the small pore size of ePTFE, which does not allow ingrowth of anchoring fibrocollagenous tissue into the patch, together with contraction of the capsula that envelopes the mesh postoperatively [12-14]. At reoperation, the mesh appeared smaller, the central opening wider, and the funnel-shaped part everted probably due to the intra-abdominal pressure and disrupture of the Mersilene sutures. This results in a widening of the central keyhole and this is held responsible for the recurrence because the intra-abdominal pressure and the

tangential forces working on the abdominal wall will result in ongoing widening of the defect according to Laplace's law (T = P x R/2).

Based on the high recurrence rate, one may conclude that ePTFE is not suitable for repairing parastomal hernias with the keyhole technique, and because there is currently no real alternative for ePTFE, the usage of the keyhole technique as a whole should be reconsidered awaiting better meshes.

Recently both Mancini and Berger have published series on laparoscopic parastomal hernia repair and both have used a modified Sugarbaker technique [2, 9]. Mancini et al. describe a technique in which the bowel is lateralized covering the hernia with a non-slit ePTFE mesh [9]. After a median follow-up of 19 months, only 1 of 25 patients has experienced a recurrence. No bowel obstruction has occurred. Although one might question the quality of this study (retrospective design, only 25 patients included 5 years in six different institutes), these results seem very promising. Berger and Bientzle initially used a similar technique and mesh but experienced a 20% recurrence rate after 24 months [2]. Unsatisfied with these results, the technique was modified to a 'Sandwich-technique' using two polyvinylidenefluoride meshes. Since then no recurrence occurred but two patients required reoperation due to stoma obstruction, a well-known complication of this technique.

Moreover, the median follow up of 12 months is too short to make definitive conclusions regarding the recurrence rate, as demonstrated in our present study with the majority of recurrences appearing 1 year after the initial repair. Nevertheless, it is entirely conceivable that the Sugarbaker technique is less vulnerable in the case of mesh-shrinkage compared with the keyhole technique.

Conclusions

The ideal technique for laparoscopic parastomal hernia repair is still under debate and longer follow-up of published series has to be awaited. Based on the results from this study, which represents one of the largest patient series with the longest follow-up available to date, it is concluded that laparoscopic parastomal hernia repair using a keyhole technique may be feasible, safe, and well tolerated by patients but it has a high recurrence rate with the currently available meshes. A new ePTFEmesh with a less pliable central part and without the tendency to shrink is awaited.

References

1 *Allen-Mersh TG, Thomson JP.Surgical treatment of colostomy complications. Br J Surg 1988;75:416-418*

2 *Berger D, Bientzle M.Laparoscopic repair of parastomal hernias: a single surgeon's experience in 66 patients. Dis Colon Rectum 2007;50:1668-1673*

3 *Carne PW, Robertson GM, Frizelle FA. Parastomal hernia. Br J Surg 2003:90:784-793*

4 *Cheung MT, Chia NH, Chiu WY. Surgical treatment of parastomal hernia complicating sigmoid colostomies. Dis Colon Rectum 2001; 44:266-270*

5 *Hansson BM, van Nieuwenhoven EJ, Bleichrodt RP. Promising new technique in the repair of parastomal hernia. Surg Endosc 2003; 17:1789-1791*

6 *Hansson BM, de Hingh IH, Bleichrodt RP. Laparoscopic parastomal hernia repair is feasible and safe: early results of a prospective clinical study including 55 consecutive patients. Surg Endosc 2007; 21:989-993*

7 *Junge K, Klinge U, Rosch R, Mertens PR, Kirch J, Klosterhalfen B, Lynen P, Schumpelick V. Decreased collagen type I/III ratio in patients with recurring hernia after implantation of alloplastic prostheses. Langenbecks Arch Surg 2004;389:17-22*

8 *Koehler RH, Begos D, Berger D, Carey S, LeBlanc K, Park A, Ramshaw B, Smoot R, Voeller G.Minimal adhesions to ePTFE mesh after laparoscopic ventral incisional hernia repair: reoperative findings in 65 cases. JSLS 2003;7:335-340*

9 *Mancini GJ, McClusky DA III, Khaitan L, Goldenberg EA, Heniford BT, Novitsky YW, Park AE, Kavic S, LeBlanc KA, Elieson MJ, Voeller GR, Ramshaw BJ. Laparoscopic parastomal hernia repair using a non-slit mesh technique. Surg Endosc 2007;21:1487-1491*

10 *Rieger N, Moore J, Hewett P, Lee S, Stephens J. Parastomal hernia repair. Colorectal Dis 2004;6:203-205*

11 *Rosch R, Junge K, Knops M, Lynen P, Klinge U, Schumpelick V. Analysis of collagen-interacting proteins in patients with incisional hernias. Langenbecks Arch Surg 2003;387:427-432*

12 *Simmermacher RKJ, van der Lei B, Schakenraad JM, Bleichrodt RP. Improved tissue ingrowth and anchorage of expanded polytetrafluoroethylene by perforation: an experimental study in the rat. Biomaterials 1991;12:22-24*

13 *Simmermacher RKJ, Bleichrodt RP, Schakenraad JM. Review: biomaterials for abdominal wall reconstruction. Cells Mater 1992; 4:281-290*

14 *Simmermacher RKJ, Schakenraad JM, Bleichrodt RP. Reherniation after repair of the abdominal wall with polytetrafluoroethylene. JACS 1994;178:613-616*

15 *Sugarbaker PH. Peritoneal approach to prosthetic mesh repair of paraostomy hernias. Ann Surg 1985;201:344-346*

Birgitta Hansson

Chapter 5 Surgical techniques for parastomal hernia repair: a systematic review of the literature

B.M.E. Hansson, N.J. Slater, A. Schouten van der Velden, H.M.M. Groenewoud, O.R. Buyne, I.H.J.T. de Hingh, R.P. Bleichrodt Ann Surg (2012) 255:685-695

Birgitta Hansson

Abstract

Background

Parastomal hernias are a frequent complication of enterostomies that require surgical treatment in approximately half of patients. This systematic review aimed to evaluate and compare the safety and effectiveness of the surgical techniques available for parastomal hernia repair.

Methods

Systematic review was performed in accordance with PRISMA. Assessment of methodological quality and selection of studies of parastomal hernia repair was done with a modified MINORS. Subgroups were formed for each surgical technique. Primary outcome was recurrence after at least 1-year follow-up. Secondary outcomes were mortality and postoperative morbidity. Outcomes were analyzed using weighted pooled proportions and logistic regression.

Results

Thirty studies were included with the majority retrospective. Suture repair resulted in a significantly increased recurrence rate when compared with mesh repair (odds ratio [OR] 8.9, 95% confidence interval [CI] 5.2-15.1; $P < 0.0001$). Recurrence rates for mesh repair ranged from 6.9% to 17% and did not differ significantly. In the laparoscopic repair group, the Sugarbaker technique had less recurrences than the keyhole technique (OR 2.3, 95% CI 1.2-4.6; $P = 0.016$).Morbidity did not differ between techniques. The overall rate of mesh infections was low (3%, 95% CI 2-5) and comparable for each type of mesh repair.

Conclusions

Suture repair of parastomal hernia should be abandoned because of increased recurrence rates. The use of mesh in parastomal hernia repair significantly reduces recurrence rates and is safe with a low overall rate of mesh infection. In laparoscopic repair, the Sugarbaker technique is superior over the keyhole technique showing fewer recurrences.

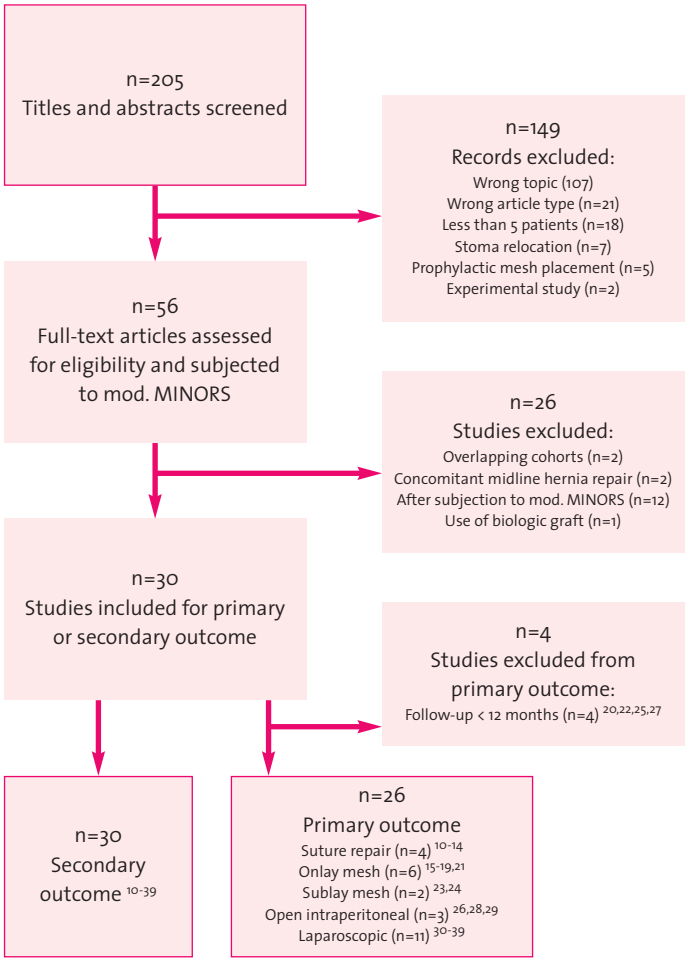

Figure 1 ***Search flow-chart following PRISMA***

Introduction

A parastomal hernia is an incisional hernia related to the presence of an enterostomy [1]. It is a common complication of stoma formation, and the reported incidence varies and depends on the type of stoma [1,2]. For colostomies, the incidence ranges from 3% to 39%, whereas for loop ileostomy, its incidence is reported between 0% and 6% [2]. The majority of parastomal hernias develop in the first years after stoma formation [3]. Most of the parastomal hernias are asymptomatic and therefore can be treated conservatively. Indications for surgery are ill-fitting appliances causing leakage, pain, discomfort, and cosmetic complaints. Treatment is mandatory when incarceration or strangulation of hernia content occurs. Surgical treatment options are relocation of the stoma or repair with or without the use of prosthetic material, either by an open or by a laparoscopic approach. This review focuses on recurrence rates and postoperative morbidity of suture and prosthetic repair of parastomal hernias either by open or laparoscopic approach. Stoma relocation is not taken into account [4].

Methods

Search Strategy

A flowchart of the search strategy is shown in figure 1. Articles for this review were identified by search of PubMed, EMBASE,

and Medline (January 1950-November 2010). The keywords used were paracolostomy, paraileostomy, parastomal, colostomy, ileostomy, hernia, defect, closure, repair, reconstruction, and combinations hereof. Furthermore, reference lists of selected articles were cross-searched for additional literature. There was no date limit set, and papers published in English, French, Spanish, and German were included. Papers discussing treatment of parastomal hernia by relocation or prevention of parastomal hernia were excluded. In cases of overlapping patient cohorts between reports from the same authors, the most recent report with the longest follow-up was chosen.

Critical Appraisal

All selected papers were evaluated for methodological quality using a modified Methodological Index of Nonrandomized Studies (modified MINORS, table 1) [5]. The MINORS tool has

Item	Criteria	Option	Score
1	A clearly stated aim	Not reported	0
		Partially reported, no clear aim	1
		Clear aim	2
2	Minimum of 5 included patients	No	0
		Yes	2
3	Inclusion of consecutive patients	Not reported	0
		Patients in a certain time period	1
		Consecutive patients + characteristics	2
4	Type of stoma specified	Not reported	0
		Reported	2
5	Surgical technique reported	Not reported	0
		Incomplete	1
		Reported clearly, appropriate to aim	2
6	Report of end points	Not reported	0
		Recurrences only	1
		Recurrences and postoperative complications	2
	Maximum score		**12**

Table 1 ***Modified Methodological Index of Nonrandomized Studies (MINORS)***

been shown a consistent and reliable instrument to assess methodological quality and potential bias in nonrandomized studies [5]. The modification consists of leaving out points that concern mainly prospective trials (prospective collection of data, blinded assessment of end-points, and prospective study size calculation), and the addition of points needed for proper subgroup formation employed in the current study (stoma type and surgical technique). Three authors (A.S.V.D.V., B.M.E.H., and N.J.S.) produced the modified MINORS score for all selected publications. Papers with a score "zero" on either item were considered ineligible and the minimum score for a study to be included was set at 9 points. Any disagreement was resolved by consensus with a fourth reviewer (R.P.B.). For determination of weighted pooled recurrence rates, only studies with a follow-up of at least 12 months were included in analysis.

Primary and Secondary Outcome

The primary outcome measure was recurrence rate of parastomal hernia. Secondary outcomes were in-hospital mortality, wound infection, mesh infection, other complications (medical and surgical), and overall morbidity. Primary and secondary outcomes were as defined by the individual investigators. Overall morbidity was calculated by counting wound infection, mesh infection, and other complications.

Data Extraction and Analysis

All reports were thoroughly reviewed, and data for primary and secondary outcome were extracted. Study design, year of publication, number of patients included and evaluated, surgical technique (open or laparoscopic, anatomical mesh position, keyhole, or Sugarbaker mesh technique), reinterventions, and duration of follow-up were also noted.

Subgroups were formed for every surgical technique: suture repair, onlay mesh repair, sublay mesh repair, open intraperitoneal mesh repair, and laparoscopic intraperitoneal mesh repair. Within the open and laparoscopic intraperitoneal repair groups, keyhole, and Sugarbaker repairs were grouped separately. Patients in the reports that underwent parastomal hernia repair with a certain technique were grouped accordingly.

Statistical Analysis

Rates of wound infection, mesh infection, other complications, and mortality are provided for every subgroup with their "exact" 95% confidence intervals (CI) following Clopper and Pearson [6]. The heterogeneity of every subgroup concerning the outcome recurrence and overall morbidity was determined with the Cochran's Q test statistic and quantified using I^2 [7]. Weighted pooled proportions were calculated for the outcome recurrence and overall morbidity using StatsDirect statistical software [8]. In cases of a positive Cochran's

Q test (P<0.05) and a high I^2 (>50%), a random-effects model was chosen for the weighted pooled proportion. Otherwise, a fixed-effects model was chosen. Comparison of subgroups was undertaken using a logistic regression analysis with laparoscopic repair as explanatory variable and presented as odds ratios (ORs) and their 95% CIs. Logistic regression analysis was done with SAS/STAT software [9] and a P value of less than 0.05 was considered statistically significant.

Results

The search yielded a total of 205 titles and abstracts (figure 1). After screening, 55 full-text articles were retrieved for assessment of eligibility and were further subjected to the modified MINORS tool. A further 25 studies were excluded, which left 30 studies to be included in systematic review. Five studies provided information on 106 suture repairs (table 2, figure 2) [10-14], 7 studies on 157 onlay mesh repairs (table 3, figure 3) [15-21], 3 studies on 42 sublay mesh repairs (table 4, figure 4) [22-24], 5 studies on 65 open intraperitoneal mesh repairs (table 5, figure 5) [25-29], and 11 studies on 363 laparoscopic mesh repairs (table 6, figures 6 and 7) [14,30-39].

Suture Repair

With suture repair of a parastomal hernia, a laparotomy is avoided. After a parastomal incision and reduction of the hernia sac, the fascial opening is narrowed with absorbable or nonabsorbable sutures. Five retrospective studies including 106 patients were eligible for review (table 2) [10-14]. Four patients died in the postoperative period [11,12]. The cause of death in these patients is not mentioned, though in 3 the parastomal hernia repair was performed as an emergency operation. Overall morbidity was 22.6% (95% CI 14.6-32.4): surgical site infection developed in 11.8% (95% CI 6.1-20.2), whereas other complications were reported in 10.8% (95% CI 5.3-18.9) of patients. Follow-up was adequate in 4 series including a total of 92 patients, of whom 69.4% (95% CI 59.7-78.3) had a recurrent parastomal hernia [10,11,13,14]. In the series of Rubin and colleagues [10] a second suture repair in seven of 29 recurrences was undertaken. All these patients developed a recurrent hernia during follow-up.

Prosthetic repair

Surgical Technique

The promising results of mesh repair for other types of hernias have encouraged its use for parastomal hernia repair. Prosthetic material can be used to reinforce suture repair or to bridge the fascial gap. Meshes can be placed in different anatomic positions (figure 8). With an onlay repair, the mesh is subcutaneously placed and fixed onto the fascia of anterior rectus sheath and the aponeurosis of the external oblique abdominal muscle. A retromuscular technique indicates that

the prosthesis is placed dorsally to the rectus muscle and anteriorly to the posterior rectus sheath.With an intraperitoneal position, the mesh is placed intra-abdominally onto the peritoneum. The inlay technique, in which mesh is placed within the fascial defect and sutured to the fascial edges, is nowadays abandoned in incisional hernia repair because of high recurrence rates [40]. Potential drawbacks of prosthetic repair are mesh infection, erosion causing perforation, fistulas, and adhesions [41]. Polypropylene mesh (PPM) and expanded-polytetrafluorethylene (e-PTFE) patch are the prosthetic materials most often used.

Onlay mesh repair

In 1977, Rosin and Bonardi [42] were the first to report the technique of a paracolostomy hernia repair with onlay PPM. Seven retrospective series reporting on a total of 157 repairs were included (table 3). In the majority of these repairs, the prefascial plane was entered through a lateral parastomal incision [15,18-21]. After reduction of the hernia sac, the fascial opening was narrowed with sutures and a PPM was placed to reinforce the suture repair. Three different techniques for mesh positioning are described. The majority used the

Reference	Time Period	Mod. MINORS Index	No. Repairs	Type of Stoma	Type of Sutures	No. Complications (%)		Mortality	Recurrence (%)*	Follow-Up**
						Infection	Other			
Rubin et al.[10]	1983-1991	10	36	EC, LC, EI	>85% nonabsorbable	5	2	0	29 (80.6)	31
Cheung et al.[11]	1990-1999	11	16	EC, LC	Nonabsorbable	0	5	3	6 (46.2)	38
Rieger et al.[12]	1990-2002	10	14	EC, EI, LI, LC	NS	4	3	1	7 (53.8)	7**
Riansuwan et al.[13]	1999-2005	11	27	10 C, 17 IC	Nonabsorbable	2	0	0	20 (74.1)	23
Pastor et al.[14]	1999-2006	11	13	9 C, 4 IC	91% nonabsorbable	NS	NS	0	7 (53.8)	14
Weighted pooled % (95% CI)	-		106	-	-	11.8% (6.1-20.2)	10.8% (5.3-18.9)	3.8% (1.0-9.4)	69.4%*** (59.7-78.3)	Median**** 27

Table 2 ***Study Characteristics and Outcomes of Suture Repair of Parastomal Hernia*** **Excluding in-hospital deaths. **Values are mean months follow-up unless otherwise stated. ***Weighted pooled proportion (fixed effects model) using only studies with ≥12 months mean follow-up. ****Median of reported follow-up of studies with ≥12 months follow-up. C: colostomy, EC: end colostomy, EI: end ileostomy, IC: ileal conduit, LC: loop colostomy, LI: loop ileostomy, NS: not specified*

keyhole technique in which the prosthesis is placed around the stoma after creating a slit and a central hole in the prosthesis (figure 9) [15,18-21]. In both other techniques, the bowel is pulled through a hole in the prosthesis, requiring full mobilization of the bowel. Two series described the use of a PPM with a reinforced solid polypropylene ring to allow passage of bowel through the prosthesis [16,19]. Data from the patients who underwent this procedure in the study by Lüning and Spillenaar-Bilgen (n = 2) could not be extracted from the rest of the patients. In the other series, de Ruiter and Bijnen [16] present 46 paracolostomy hernia repairs with the use of a reinforced solid polypropylene ring. Infection occurred in 2 patients postoperatively requiring prosthesis removal in one. Another patient presented with a late infection after a follow-up of 23 months, who also had the prosthesis removed. After a mean follow-up of 51 months, 7 (15%) paracolostomy hernias recurred. Overall, the prosthesis was removed in 12 (26%) of the 46 patients: in 2 after mesh infection, in 5 because of a recurrent hernia, and in another 5 during reoperations for other reasons. Steele and colleagues [17] described the so-called "stove pipe hat" technique, in which a PPM is placed overlying the fascial repair (figure 10). The stoma is pulled through the center of the mesh, thereby creating a 360-degree repair. An additional piece of mesh is then fixed to both the bowel circumferentially and onto the onlay mesh. Steele and coworkers repaired 58 parastomal hernias using the "stove pipe hat" technique [17]. In selected cases, an additional mesh was placed beneath the fascia to provide additional support. Surgical site infections were seen in 2 patients (3.4%) and mesh erosion in 1 patient (1.7%). Other complications were reported in 9 patients (15.5%). No patients required removal of the mesh. After a mean follow-up of 51 months, 15 parastomal hernias recurred (25.9%).

All 157 patients undergoing onlay mesh repair, irrespective of technique, were pooled. There were no deaths reported. Postoperatively, the use of short-term (<24-48 hours) suction

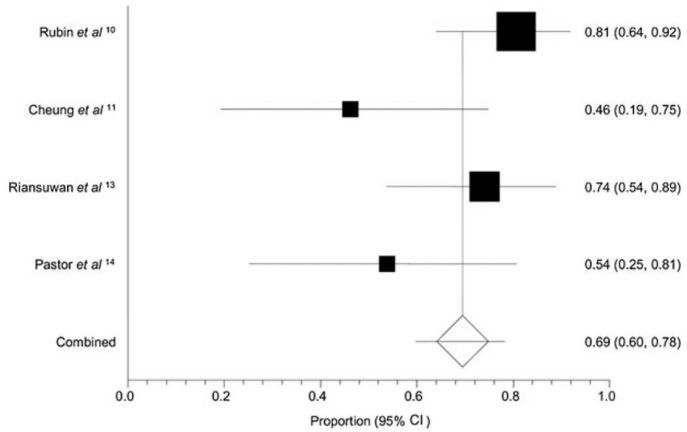

Figure 2 ***Meta-analysis (fixed-effects model; $I^2 = 56.5\%$; $\chi^2 = 6.9$, $P = 0.0752$) of proportion of recurrences of suture repair of parastomal hernia. The square size represents the weight of the study, and the horizontal line through the square represents the CI of the effect estimate***

drainage was noted in all but 2 of the 7 series [16,21]. Preoperative administration of antibiotics was reported in 5 series [15,16,18-21]. Overall morbidity was 12.7% (95% CI 8.0-19.0). Surgical site infection occurred in 3 patients (1.9% [95% CI 0.4-5.5]), mesh infection in 4 patients (2.6% [95% CI 0.7-6.4]), and other complications in 13 patients (8.2% [95% CI 4.5-13.7]). In 3 of the 4 patients with mesh infection, the prosthesis was removed. In 6 series reporting on 149 patients, a follow-up of at least 12 months was noted [15-19,21]; 27 patients (18.6% [95% CI 12.8-25.1]) had a recurrent hernia.

						No. Complications (%)					
Reference	Time Period	Mod. MINORS Index	No. Repairs	Type of Stoma	Material; Technique	Wound Infection	Mesh Infection	Other	Mortality	Recurrence (%)	Follow-Up*
Ho and Fawcett[15]	1982-2001	11	15	IC	PPM; KH	0	0	2	0	1 (6.7)	15
De Ruiter and Bijnen[16]	1988-2002	11	46	C	CRE-PPM	0	3	1	0	7 (15.2)	51
Steele et al.[17]	1988-2002	11	58	31 EC, 24 EI, 3 LI	PPM; 'Stove pipe hat'	2	0	9	0	15 (25.9)	51
Venditti et al.[18]	1993-1996	9	8	EC	PPM, KH	1	0	0	0	0 (0)	38
Lüning and Spillenaar-Bilgen[19]	1997-2006	11	16	12C, 3 IC	PPM (7), PE (6), Vicryl (1), KH (14), CRE-PPM (2)	0	1	1	NS	3 (18.8)	33
Amin et al.[20]	1999	9	9	1 C, 8 EI	PPM, KH	0	0	0	0	0 (0)	7
Kald et al.[21]	1999-2000	10	5	4 C, 1 EI	PPM, KH	0	0	0	0	1 (20.0)	12
Weighted pooled% (95% CI)	-		157	-	-	1.9% (0.4-5.5)	2.6% (0.7-6.4)	8.3% (4.5-13.7)	0% (0.0-2.3)	17.2%** (11.9-23.4)	Median*** 36

Table 3 ***Study Characteristics and Outcomes of Onlay Mesh Repair of Parastomal Hernia*** **Values are mean months follow-up unless otherwise stated. **Weighted pooled proportion (fixed effects model) using only studies with ≥12 months mean follow-up. ***Median of reported follow-up of studies with ≥12 months follow-up. C: colostomy, CRE-PPM: central ring enforced polypropylene mesh, EC: end colostomy, EI: end ileostomy, IC: ileal conduit, LC: loop colostomy, LI: loop ileostomy, NS: not specified*

Retromuscular mesh repair

With the retromuscular technique, the mesh is placed posterior to the rectus abdominis muscle onto the posterior rectus sheath. The mesh is placed either via a laparotomy or a parastomal incision. Three studies including a total number of 49 patients were included [22-24]. All authors used the keyhole technique. Two reports mentioned the use of pre-operative antibiotics [22,23]. None of the patients died. Besides 4.8% (95% CI 0.6-16.2) wound infections, no mesh infections or other complications were reported. Follow-up was adequate in 2 series including 35 patients [23,24]. The overall recurrence rate was 6.9% (95% CI 1.1-17.2).

Open intraperitoneal mesh repair

Basically, 2 techniques are used to repair parastomal hernias with an intraperitoneally placed prosthesis: the "Sugarbaker" technique and the keyhole technique. In 1985, Sugarbaker described a new technique for parastomal hernia repair [43]. Via a laparotomy, the trephine opening is covered with an intraperitoneally placed prosthetic mesh which is sutured to the fascial edge (figure 11). The bowel is lateralized passing from the hernia sac between the abdominal wall and the prosthesis into the peritoneal cavity. Six recurrent and 1 primary parastomal hernia were repaired, and no recurrences were reported after a mean follow-up of 5 years [43]. This study was not included in the analysis because it did not meet the inclusion criteria.

One retrospective study presenting the results of an open Sugarbaker repair in 20 paracolostomy hernias fulfilled the inclusion criteria [29]. In this report by Stelzner and colleagues, repair was done using a large e-PTFE prosthesis covering the trephine opening with an overlap of at least 5 cm. One intraoperative complication (urinary bladder lesion) and 2 major postoperative complications (bowel obstruction secondary to dense adhesions unrelated to the mesh and a

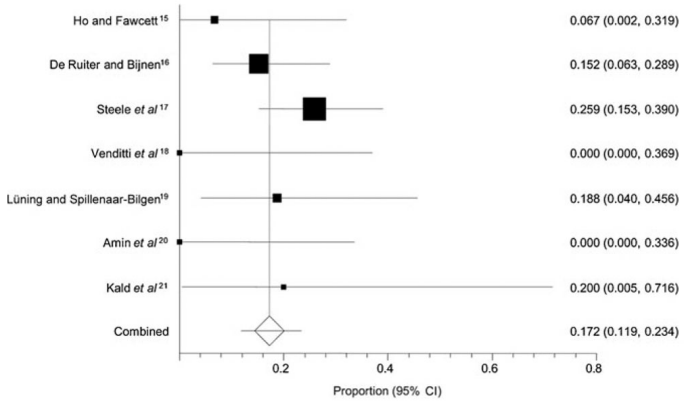

Figure 3 ***Meta-analysis (fixed-effects model; $I^2 = 36.3\%$; $\chi^2 = 9.4$, $P = 0.1513$) of proportion of recurrences of onlay mesh repair of parastomal hernia. The square size represents the weight of the study, and the horizontal line through the square represents the CI of the effect estimate***

pulmonary embolism) were reported. One surgical site infection was reported without infection of the prosthesis. Minor complications were seroma formation, bowel paralysis, and pain at the site of the transfascial sutures. Three recurrences (15.0%) after a mean followup of 42 (range 3-48) months were found. All these recurrences were asymptomatic and treated conservatively.

In 4 studies [25-28], the keyhole technique was used including 65 intraperitoneal parastomal hernia repairs (table 5). The use of perioperative antibiotics was mentioned in 2 reports [21,24]. Both a single wound infection and a mesh infection were reported (2.2% [95% CI 0.0-11.8]). Overall morbidity was 22.2% (95% CI 11.2-37.1).

Morris-Stiff and Hughes [26], who used an intraperitoneal PPM in 7 repairs, reported complications related to dense adhesions in 4 patients (57.1%). Hofstetter et al. reported migration of the e-PTFE prosthesis resulting in angulation of the stoma in 2 of 13 patients, which were still asymptomatic at the time of writing. Two patients underwent a re-laparotomy for unrelated reasons; the prosthesis was found to be fixed

						No. Complications (%)					
Reference	Time Period	Mod. MINORS Index	No. Repairs	Type of Stoma	Material; Technique	Wound Infection	Mesh Infection	Other	Mortality	Recurrence (%)*	Follow-Up**
Kasperk[22]	1996-2000	11	7	4 C, 3 EI	PPM; KH	0	0	0	0	2 (28.6)	NS
Longman and Thompson[23]	2000-2004	11	10	7 EC, 2 EI, 1 LI	PPM; KH	0	0	1	0	0 (0)	30 (median)
Guzman-Valdivia[24]	2008	11	25	C	PPM; KH	2	0	2	0	2 (8.0)	12
Weighted pooled % (95% CI)	-		42	-	-	4.8% (0.6-16.2)	(0.0-8.4)	7.1% (1.5-19.5)	(0.0-8.4)	6.9%* (1.1-17.2)	Median*** 12

Table 4 ***Study Characteristics and Outcomes of Retromuscular Mesh Repair of Parastomal Hernia*** **Weighted pooled proportion (fixed effects model) using only studies with ≥12 months mean follow- up. **Values are mean months follow-up unless otherwise stated. ***Median of reported follow-up of studies with ≥12 months follow-up. C: colostomy, EC: end colostomy, EI: end ileostomy, LI: loop ileostomy, NS: not specified*

to the adjacent fascia and the colon by ingrowth of fibro-colleagenous tissue [27].

Follow-up was adequate in 3 of the 4 series using the keyhole technique [25,26,28]. Recurrent hernia was found in 3 of 32 patients (9.4% [95% CI 2.0-25.0]).

Laparoscopic intraperitoneal mesh repair

The laparoscopic approach involves minimally invasive access to the abdominal cavity and intraperitoneal placement of prosthetic material with or without narrowing the trephine opening. Generally, 3 to 4 trocars are used for access. Adhesiolysis, reduction of the hernia sac content, and placement and fixation of the prosthesis are the key steps of the procedure. Similarly to the open intraperitoneal mesh repair, both the Sugarbaker, the keyhole and a combination of both (i.e., sandwich), are used. The keyhole technique was used in 165 patients in 8 studies, the Sugarbaker technique was used in 124 patients in 7 studies and the sandwich technique was used in 47 patients in 1 study (table 5). In another report a sandwich technique was used in a proportion of patients [33] but these patients were excluded because of overlapping cohorts with a more recent report by the same authors (confirmed by personal communication) [39]. For the outcome measures other than recurrence, the data of all laparoscopic techniques were pooled because in most articles these outcomes were reported together and not extractable per technique. For the outcome recurrence, data divided per technique (Sugarbaker vs keyhole) were extractable from all but 1 study [32].

In total, 11 series including 363 repairs are included for review of laparoscopic parastomal hernia repair (table 6) [14-30-39]. All but 2 series used an ePTFE mesh, in 1 series a polytetrafluoroethylene-polypropylene mesh (PTFE-PPM) was used [34] and in another a polyvinylidenefluoride-polypropylene mesh

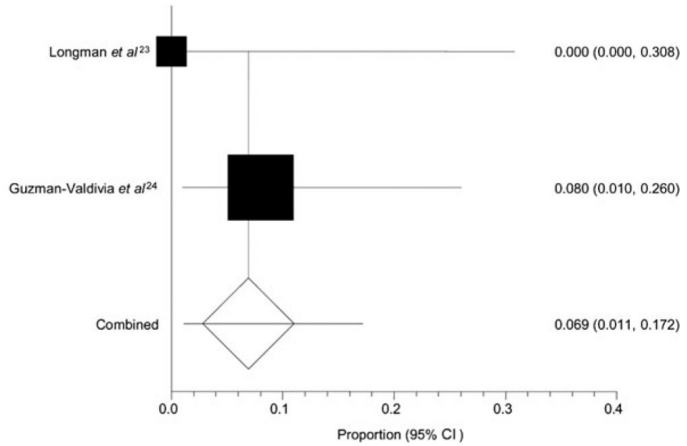

Figure 4 ***Meta-analysis (fixed-effects model; $\chi^2 = 0.8$, $P = 0.3716$) of proportion of recurrences of retro-muscular mesh repair of parastomal hernia. The square size represents the weight of the study, and the horizontal line through the square represents the CI of the effect estimate***

(PVDF-PPM) was used (table 6) [39]. Use of antibiotic prophylaxis was mentioned in 5 series [31,35-38], and 1 series mentioned not using perioperative antibiotics [34]. Conversion to open repair occurred in 13 of the 363 repairs (3.6%). Reasons for conversion were multiple dense adhesions in 6 [34,37] and intraoperative full-thickness bowel injury in another 6 procedures [14,34,37], and an inaccessible abdomen in 1 patient [33].

Iatrogenic, intraoperative bowel lesions were reported in 15 patients (4.1%). Five injuries were repaired laparoscopically [30,34,35,39]; in 1 of these, hernia repair was postponed for 4 days after which repair was successful [30]. Six bowel injuries were repaired after conversion to a laparotomy [14,34,37]. Four small-bowel injuries went undetected during operation; 3 lead to a peritonitis necessitating a reoperation [34,37], and 1 resulted in multiple organ failure and death [34]. Overall morbidity was 17.2% (95% CI 13.4-21.3): wound infection occurred in 11

						No. Complications (%)					
Reference	Time Period	Mod. MINORS Index	No. Repairs	Type of Stoma	Material; Technique	Wound Infection	Mesh Infection	Other	Mortality	Recurrence (%)	Follow-Up*
Byers et al.[25]	1982-1989	11	9	6 C, 3 EI	PPM; KH	1	0	0	0	0 (0)	13
Morris-Stiff and Hughes[26]	1990-1992	11	7	2 EC, 5 EI	PPM; KH	0	1	3	0	2 (28.6)	78
Hofstetter et al.[27]	1998	10	13	C	PTFE; KH	0	0	0	0	0 (0)	NS
Van Sprundel and Gerritsen van der Hoop[28]	2000-2003	11	16	8 EC, 5 EI, 4 IC	e-PTFE; KH	0	0	5	0	1 (6.3)	28
Weighted pooled %; (95% CI)	-	-	45	-	-	2.2% (0.0-11.8)	2.2% (0.0-11.8)	17.8% (8.0-32.1)	0.0% (0.0-7.9)	7.2%** (1.7-16.0)	Median*** 28
Stelzner et al.[29]	1994-2002	10	20	C	e-PTFE; SB	1	0	2	0	3 (15.0)	42

Table 5 ***Study Characteristics and Outcomes of "Open" Intraperitoneal Mesh Repair of Parastomal Hernia*** **Values are mean months follow-up unless otherwise stated. **Weighted pooled proportion (fixed effects model) using only studies with ≥12 months mean follow-up. ***Median of reported follow-up of studies with ≥12 months follow-up. C: colostomy, EC: end colostomy, EI: end ileostomy, IC: ileal conduit, LC: loop colostomy, LI: loop ileostomy, KH: keyhole, (e-) PTFE: (expanded-) polytetrafluoroethylene, NS: not specified, SB: Sugarbaker*

patients (3.3% [95% CI 1.6-5.7]), mesh infection in 9 patients (2.7% [95% CI 1.2-5.0]) and other complications in 43 patients (12.7% [95% CI 9.4-16.8]).

Meta-analyses of the pooled patient data for recurrence associated with the keyhole and Sugarbaker techniques are shown in figures 6 and 7, respectively. In 6 studies reporting on 110 Sugarbaker repairs [10,26,29,31,32,34], a recurrent hernia was reported in 13 patients (11.6% [95% CI 6.4-18.0]). In 7 studies reporting on 160 repairs using the keyhole technique [10,26,27,30,32-34], recurrence was reported in 38 patients (20.8% [95% CI 15.0-27.3]). All studies had a follow-up period of at least 12 months.

Five studies included both the Sugarbaker and the keyhole techniques. In 4 studies, the recurrence rate was lower in the Sugarbaker group [14,30,36,38], whereas in 1 study, no separate data were available [32]. Muysoms noted a recurrence in 8 of 11 (73%) patients after keyhole repair and 2 of 13 (15%) patients after Sugarbaker repair [36]. Craft and coworkers [38] reported a recurrence in 1 of 5 repairs done with the keyhole technique and none using the Sugarbaker technique, and Pastor et al. reported a reherniation in 2 of 3 patients after keyhole repair and in 2 of 7 (28.6%) patients after Sugarbaker repair [14].

Berger and coworkers [39] report on the use of a sandwich technique, which combines the Sugarbaker and the keyhole techniques [39]. A PVDF-PPM was used throughout. After a median follow-up of 20 (range 6-48) months, one of 47 (2.1%) patients had a recurrent hernia.

Comparison of techniques

The results of pooled data for the different techniques of parastomal hernia repair are summarized in table 7. Logistic regression analyses were performed with the outcomes recurrence, wound infection, mesh infection, and overall complications.

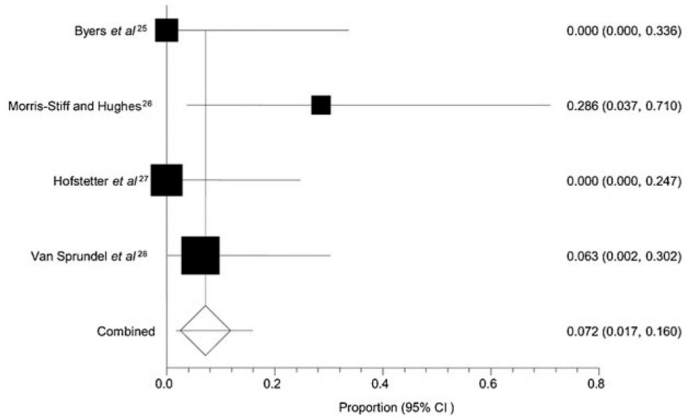

Figure 5 ***Meta-analysis (fixed-effects model; I^2 = 38.1%; χ^2 = 4.8, P = 0.1833) of proportion of recurrences of open intraperitoneal mesh repair of parastomal hernia. The square size represents the weight of the study, and the horizontal line through the square represents the CI of the effect estimate***

Reference	Time Period	Mod. MINORS Index	No. Repairs	Type of Stoma	Material; Technique	No. Complications (%)			Mortality	Recurrence (%)*	Follow-Up**
						Wound Infection	Mesh Infection	Other			
LeBlanc et al.[30]	N/S	10	12	8 EC, 2 EI, 2 IC	e-PTFE; 7 SB, 5 KH	0	0	2	1	1 (8.3)	20
Safadi[31]	1998-2001	10	9	5 IC, 2 EI, 2 EC	e-PTFE; KH	0	0	1	0	4 (44.4)	24
McLemore et al.[32]	1999-2006	11	19	9 IC, 5 EI, 5 EC	e-PTFE; 14 SB, 5 KH	0	2	5	0	2 (10.5)	20
Berger and Bientzle[33]	1999-2006	9	41	EI, IC, EC	e-PTFE; SB	1	2	5	0	8 (19.5)	24 (median)
Wara and Andersen[34]	1997-2008	12	72	48 C, 24 I	e-PTFE-PP; KH	4	0	17	2	2 (2.8)	36 (median)
Pastor et al.[14]	1999-2006	11	12	6 I, 6 C	e-PTFE; 7 mod. SB, 3 KH, 1 lateral slit	2	0	2	0	4 (33.3)	13.9
Mancini et al.[35]	2001-2005	11	26	15 EC, 5 EI, 6 IC	e-PTFE; SB	2	1	1	1	1 (3.8)	19 (median)
Muysoms[36]	2001-2007	10	24	20 C, 2 IC, 2 I	Various; 11 KH, 13 SB	0	0	0	0	10 (41.7)	22
Hansson et al.[37]	2002-2006	12	55	47 EC, 5 EI, 3 IC	e-PTFE; KH	0	2	4	0	20 (36.4)	36 (median)
Craft et al.[38]	2004-2006	11	21	5 C, 7 EI, 9 IC	e-PTFE; 16 SB, 5 KH	1	2	5	0	1 (4.8)	14
Berger and Bientzle[39]	2004-2008	10	47	NS	PVDF-PP; "Sandwich"	1	0	1	0	1 (2.1)	20 (median)
Weighted pooled % (95% CI)	-	-	338	-	-	3.3% (1.6-5.7)	2.7% (1.2-5.0)	12.7% (9.4-16.8)	1.2% (0.3-3.0)	***	-

Table 6 ***Study Characteristics and Outcomes of Laparoscopic Repair of Parastomal Hernia*** **Median of reported follow-up of studies with ≥12 months follow-up; excluding in-hospital deaths. **Values are mean months follow-up unless otherwise stated. ***Recurrences rates of laparoscopic repair divided by technique (Sugarbaker vs keyhole) are presented in table 7. C: colostomy, EC: end colostomy, EI: end ileostomy, e-PTFE-PP: expanded polytetrafluorethylene-polypropylene, IC: ileal conduit, LC: loop colostomy, LI: loop ileostomy, NS: not specified, PVDF-PP: polyvinylidene fluoride-polypropylene*

Suture repair resulted in an increased recurrence rate compared to other techniques (P<0.0001). The recurrence OR for suture repair versus laparoscopic repair equaled 8.88 (95% CI 5.2-15.1). The other techniques did not differ significantly from laparoscopic, although both open intraperitoneal (P = 0.07) and sublay (P = 0.07) techniques approached significance in favor of these techniques. Within the laparoscopic procedures, the Sugarbaker technique resulted in a significantly lower recurrence rate compared with the keyhole technique (OR 2.3, 95% CI 1.2-4.6; P = 0.016).

The risk of mesh infection did not differ between mesh techniques (P = 0.99) with an overall rate of 2.3% (95% CI 1.3-3.9). Similarly, other postoperative morbidity (P = 0.43) and overall postoperative morbidity (P = 0.38) did not differ between all surgical techniques. Wound infection was higher in suture repair than in the other techniques (OR 4.0, 95% CI 1.7-9.5; P = 0.02).

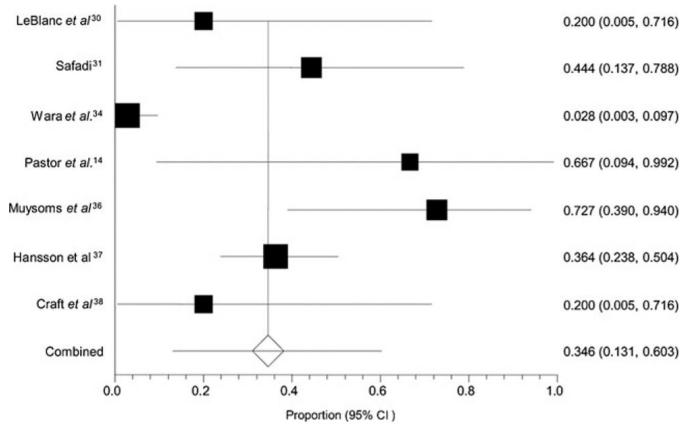

Figure 6 Meta-analysis (random-effects model; I^2 = 88.1%; χ^2 = 50.6, P < 0.0001) of proportion of recurrences of laparoscopic mesh repair of parastomal hernia using the keyhole technique. The square size represents the weight of the study, and the horizontal line through the square represents the CI of the effect estimate

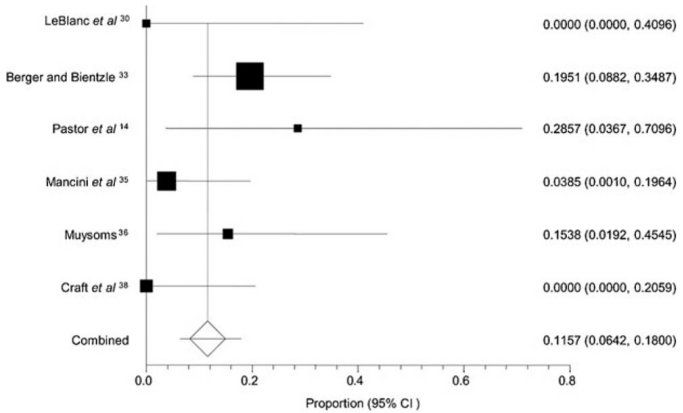

Figure 7 Meta-analysis (fixed-effects model; I^2 = 52%; χ^2 = 10.4, P = 0.0644) of proportion of recurrences of laparoscopic mesh repair of parastomal hernia using the Sugarbaker technique. The square size represents the weight of the study, and the horizontal line through the square represents the CI of the effect estimate

Discussion

Despite the abundance of literature on parastomal hernia repair, it is not possible to draw firm conclusions about the preferred technique. Suture repair should be abandoned because in this technique recurrence rate is significantly higher than in any other technique. The results of open and laparoscopic techniques are similar. Laparoscopic repair using the Sugarbaker technique results in significantly less recurrences than with the keyhole technique.

The majority of the literature about treatment of parastomal hernia consists of retrospective studies and case series with only small numbers of patients. There have been no randomized clinical trials published to date. The study populations are diverse with different types of stomas and some series also include rerepairs. The outcome parameters are ill defined, and the method of follow-up to detect postoperative complications or recurrent hernias differs between series. Also, proper definitions of surgical site infection and mesh infection are lacking. Therefore, the results of the present review

			Complications (95% CI)			
Technique	No. Studies	No. Repairs	Wound Infection	Mesh Infection	Other	Recurrence, %* (95% CI)
Suture repair	5	106	11.8% (6.1-20.2)	-	10.8% (5.3-18.9)	69.4% (59.7-78.3)
Onlay mesh	8	176	1.9% (0.4-5.5)	2.6% (0.7-6.4)	8.3% (4.5-13.7)	17.2% (11.9-23.4)
Sublay mesh	3	42	4.8% (0.6-16.2)	0% (0.0-8.4)	7.1% (1.5-19.5)	6.9% (1.1-17.2)
Open intraperitoneal mesh	5	65	- -	- -		
• Sugarbaker	1	20	5.0% (0.1-24.9)	0 (0.0-16.8)	10.0% (1.2-31.7)	15.0% (3.2-37.9)
• Keyhole	4	45	2.2% (0.0-11.8)	2.2% (0.0-11.8)	17.8% (8.0-32.1)	7.2% (1.7-16.0)
All laparoscopic mesh	12	338	3.3% (1.6-5.7)	2.7% (1.2-5.0)	12.7% (10.2-17.5)	14.2% (10.7-18.0)
• Sugarbaker	6	110	-	-	-	11.6% (6.4-18.0)
• Keyhole	7	160	-	-	-	34.6% (13.1-60.3)
• Sandwich	1	47	2.1%	0	2.1%	2.1%

Table 7 ***Summary of Pooled Proportions of Outcome Measures Per Surgical Technique for Parastomal Hernia Repair*** **Weighted pooled proportion using only studies with 12 months mean follow-up*

should be interpreted with care. The quality of evidence is level C/D following Lebwohl et al. [44].

Suture repair is attractive because it is a simple technique and it avoids a laparotomy. However, suture repair should be regarded as outdated because of the unacceptable high recurrence rate of 69.4%. Similarly, to suture repair for incisional hernia, the high recurrence rate may be explained by an intrinsic defect in wound repair and collagen metabolism,which is not corrected for by merely suturing the defect [45]. In addition, the unfavorable biomechanics in suture repair, which make a tension-free repair impossible, may also be responsible for the poor results.

Synthetic mesh repair gives significantly better results than suture repair with respect to wound infection and recurrence rate. Depending on technique and placement, recurrence rates after mesh repair vary between 6.9% and 17.8%. Nevertheless, surgeons are reluctant to use synthetic meshes because tight adhesions between the mesh and the bowel may develop and meshes may even erode into the bowel. Moreover, implantation of a foreign body increases the risk of seroma formation and infection [17,24,41]. These prejudices are not supported by the available literature. The overall mesh infection rate is 2.4% and wound infection rate is even lower in mesh repair (4.1%) than in suture repair (11.7%). These results are similar to the use of synthetic meshes in a

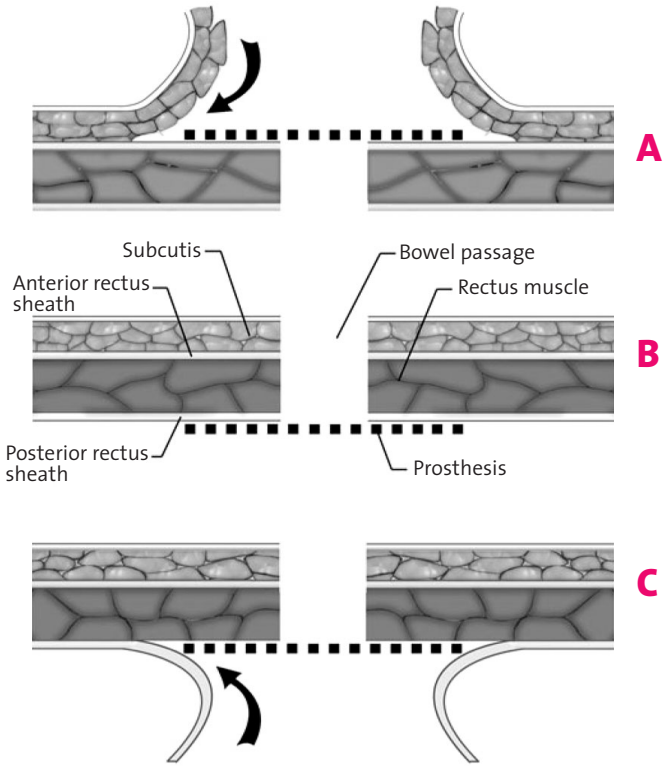

Figure 8 ***Schematic illustrations of the anatomic positions of prostheses placement in parastomal hernia repair. Arrows indicate direction of dissection.*** *A: Onlay mesh is subcutaneously placed and fixed onto the fascia of the anterior rectus sheath. B: Intraperitoneal (underlay) mesh is placed intra-abdominally onto the peritoneum. C: Sublay (retromuscular)mesh is placed dorsally to the rectus abdominis muscle and anterior to the posterior rectus sheath. Inlay mesh (not shown) is placed within the fascial defect and sutured directly to the fascial edges; this technique is now largely abandoned due to high recurrence rate*[40]

contaminated field for hernia repair, which further supports that application of meshes for parastomal hernia repair is safe [46,47]. It is therefore concluded that synthetic mesh repair is favored over suture repair.

Meshes can be implanted in an onlay, sublay, or intraperitoneal position. The rates of wound and mesh infection did not differ between the various techniques of mesh repair. Although not statistically significant, the onlay technique had the highest recurrence rate and the sublay (preperitoneal) technique the lowest. The sublay and intraperitoneal mesh techniques are biomechanically more attractive because the intra-abdominal pressure supports the fixation of the prosthesis against the fascia. The sublay position has the additional benefit that the mesh is enveloped in well-vascularized tissue and that the fascia and peritoneum form a natural barrier between the prosthesis and the abdominal organs.

When performing intraperitoneal repair, the choice can be made between the keyhole and Sugarbaker repair. The recurrence rate is significantly lower with laparoscopic repair using the Sugarbaker compared to the keyhole technique. There is as yet insufficient evidence to show whether this holds true for open intraperitoneal repair of parastomal hernias. With the keyhole technique, it is difficult to estimate the size of the hole to "snugly" accommodate passage of the colon. Also, shrinkage of the mesh may result in enlargement of the central hole, which is often noted as the site of reherniation [36,37]. One laparoscopic study reported on a sandwich repair using PVDF-PPM prostheses combining both the Sugarbaker and keyhole techniques resulting in the lowest recurrence rate [39].

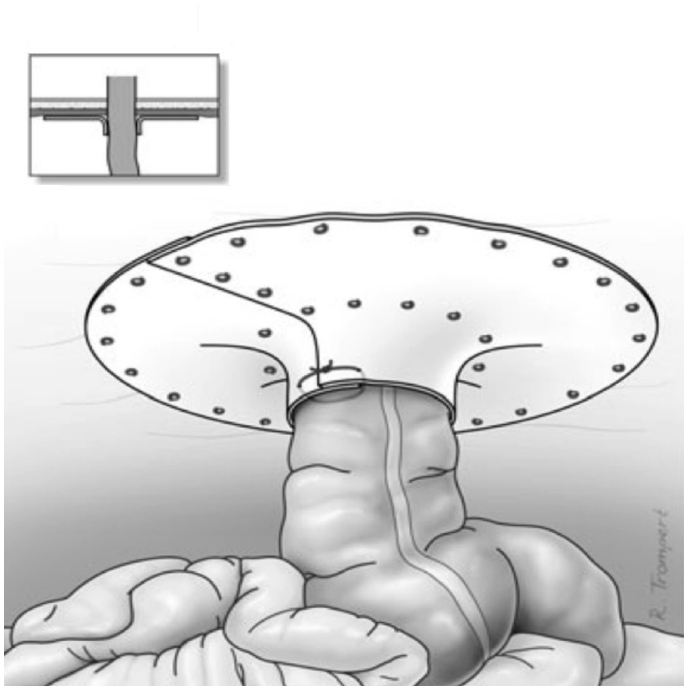

Figure 9 *"Keyhole" mesh technique of parastomal hernia repair*

Overall, laparoscopic repair had no advantage over open repair with respect to morbidity and mortality. There are insufficient data available to compare both techniques on other aspects such as operative time, postoperative pain, return to work, and development of incisional hernia. Only 1 study compared laparoscopic and open repair in a nonrandomized retrospective study [14]. No statistically significant differences were found with respect to morbidity, recurrence, and duration of operation. Still, length of stay was nearly significant (3 days [laparoscopic] versus 5 days [open]) in a small population (P=0.05). In the current review, inadvertent enterotomy during laparoscopic repair was observed in 4%

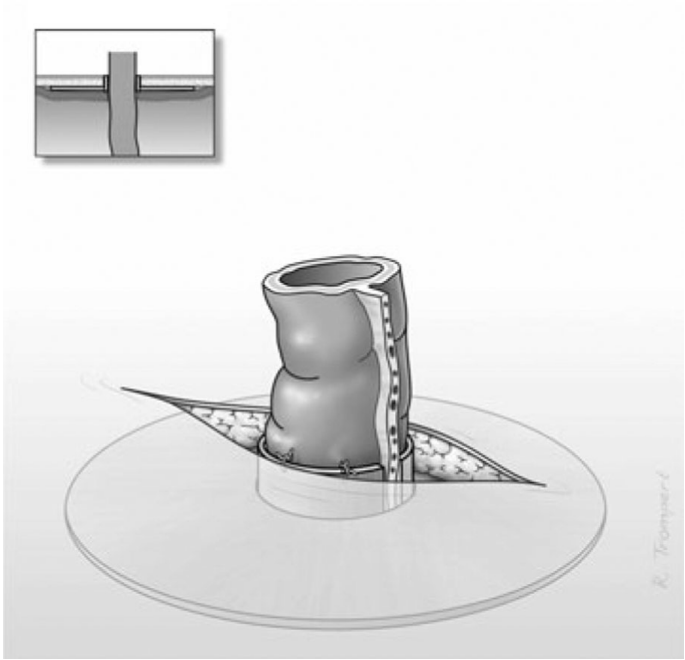

Figure 10 *"Stove pipe hat" mesh technique of parastomal hernia repair*

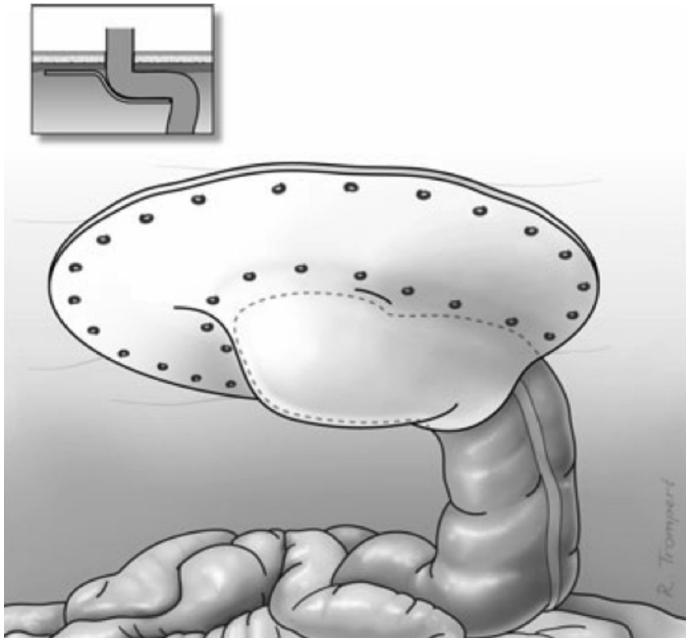

Figure 11 *Sugarbaker mesh technique of parastomal hernia repair*

of cases. Although this complication was not mentioned in the open repair studies, inadvertent enterotomy is reported in 4.7% to 20% of patients undergoing a relaparotomy [48-50].

Polypropylene and e-PTFE are the most frequently used prosthetic materials for parastomal hernia repair. Polypropylene anchors well to the adjacent fascia by ingrowth of fibrocollagenous tissue. However, the open mesh structure causes dense adhesions between the mesh and the adjacent organs. Moreover, the sharp edges and the formation of sharp folds due to shrinkage of the mesh may cause erosion of the mesh into adjacent organs [4,25]. To prevent erosion into the bowel, De Ruiter and Bijnen [51] developed a polypropylene mesh with a central polypropylene ring sized appropriately for passage of the bowel. Although mesh erosion was prevented, the results were disappointing with a 39% reoperation rate for complications or recurrences. It is well-recognized that implantation of PPM into the peritoneal cavity is potentially hazardous [26,52], and further studies and greater follow-up are mandatory before meshes including polypropylene can be liberally applied in this manner.

e-PTFE meshes have a microporous structure not allowing tissue ingrowth into the prosthesis [53-55]. The anchorage of these meshes solely depends on the sutures and the envelop of fibrocollagenous tissue that surrounds the prosthesis, thus increasing the risk of reherniation [53,54]. The softness of the material and the low tendency for developing adhesions are major advantages. To combine the advantageous properties of both materials, several composite prostheses of PPM combined with either e-PTFE or PVDF have been made. Berger and Bientzle [39] used intraperitoneally placed PVDF-PPM in 47 patients using the sandwich technique resulting in a single recurrence (2%). Only 1 patient developed a wound infection and 3 patients underwent a revision; 2 because of stenosis and 1 due to an abscess. No other mesh-related complications were reported. Wara and Andersen [34] laparoscopically placed e-PTFE-PPM in a keyhole fashion, which also resulted in a low recurrence rate (3%), but mesh-related complications required reoperation in 7% of patients. Infection is another major concern with the application of mesh. Because of its hydrophobicity and the microporous structure, e-PTFE is more susceptible to infections than PPM [53], although no differences in wound and mesh infections were found in this review. Therefore, on the basis of the present review no recommendations can be made about the preferred prosthetic material. More recently, biologic grafts have been used in parastomal hernia repair as an alternative, but they are very expensive and results do not differ from synthetic mesh repair [56].

In summary, the quality of evidence for the various surgical techniques for parastomal hernia repair is low and precludes firm conclusions. Randomized controlled trials would be ideal

to compare the various techniques of parastomal hernia repair, but none could be identified in the literature. Also, additional prospective comparative trials would be more able to delineate preferred techniques than the currently available literature. According to the available evidence, suture repair should be abandoned in preference for mesh repair because of much lower recurrence rates and a low mesh infection rate found with mesh repair. No anatomic position of mesh is convincingly preferred above another, although onlay repair seems to coincide with a higher recurrence rate. When performing laparoscopic repair with an e-PTFE prosthesis, the Sugarbaker technique is preferred to the keyhole technique. New composite prostheses including a PPM component are now available, but careful consideration should be taken besides rigorous long-term follow-up when placing these prostheses in the abdominal cavity.

References

1 *Pearl RK. Parastomal hernias. World J Surg. 1989;13:569-572*

2 *Carne PWG, Robertson GM, Frizelle FA. Parastomal hernia. Br J Surg 2003;90:784-793*

3 *Londono-Schimmer EE, Leong APK, Phillips RKS. Life table analysis of stomal complications following colostomy. Dis Colon Rectum 1994;37:916-920*

4 *Israelsson LA. Parastomal hernias. Surg Clin North Am 2008;88: 113-125*

5 *Slim K, Nini E, Forestier D, et al. Methodological index for non-randomized studies (MINORS): development and validation of a new instrument. ANZ J Surg 2003;73:712-761*

6 *Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 1934;26:404-413*

7 *Mahid SS, Hornung CA,Minor KS, et al. Systematic reviews and meta-analysis for the surgeon scientist. Br J Surg 2006;93:1315-1324*

8 *StatsDirect statistical software [computer program]. Version 2.7.8. England: StatsDirect Ltd; 2008*

9 *SAS/STAT software [computer program]. Version 9. Cary, NC: SAS Institute Inc; 2010*

10 *Rubin MS, Schoetz DJ, Matthews JB. Parastomal hernia. Is stoma relocation superior to fascial repair? Arch Surg 1994;129:413-419*

11 *Cheung M-T, Chia N-H, Chiu W-Y. Surgical treatment of parastomal hernia complicating sigmoid colostomies. Dis Colon Rectum 2001;44:266-270*

12 *Rieger N, Moore J, Hewett P, et al. Parastomal hernia repair. Colorectal Dis 2004;6:203-205*

13 *Riansuwan W, Hull TL, Millan MM, et al. Surgery of recurrent parastomal hernia: direct repair or relocation? Colorectal Dis 2010; 12:681-686*

14 *Pastor DM, Pauli EM, Koltun WA, et al. Parastomal hernia repair: a single center experience. JSLS 2009;13:170-175*

15 *Ho KMT, Fawcett DP. Parastomal hernia repair using the lateral approach. BJU Int 2004;94:598-602*

16 *De Ruiter P, Bijnen AB. Ring-reinforced prosthesis for paracolostomy hernia. Dig Surg 2005;22:152-156*

17 *Steele SR, Lee P, Martin MJ, et al. Is parastomal hernia repair with polypropylene mesh safe? Am J Surg 2003;185:436-440*

18 *Venditti D, Gargiani M, Milito G. Parastomal hernia surgery: personal experience with use of polypropylene mesh. Tech Coloproctol 2001;5:85-88*

19 *Luning TH, Spillenaar-Bilgen EJ. Parastomal hernia: complications of extraperitoneal onlay mesh placement. Hernia 2009;13:487-490*

20 *Amin SN, Armitage NC, Abercrombie JF, et al. Lateral repair of parastomal hernia. Ann R Coll Surg Engl 2001;83:206-208*

21 *Kald A, Landin S, Masreliez C, et al. Mesh repair of parastomal hernias: new aspects of the onlay technique. Tech Coloproctol 2001;5:169-171*

22 *Kasperk R, Klinge U, Schumpelick V. The repair of large parastomal hernias using a midline approach and a prosthetic mesh in the sublay position. Am J Surg 2000;179:186-188*

23 *Longman RJ, Thompson WH. Mesh repair of parastomal hernias-a safety modification. Colorectal Dis 2005;7:292-294*

24 *Guzman-Valdivia G, Guerrero TS, Laurrabaquio HV. Parastomal hernia repair using mesh and an open technique. World J Surg 2008;32:465-470*

25 *Byers JM, Steinberg JB, Postier RG. Repair of parastomal hernias using polypropylene mesh. Arch Surg 1992;127:1246-1247*

26 *Morris-Stiff G, Hughes LE. The continuing challenge of parastomal hernia: failure of a novel polypropylene mesh repair. Ann R Coll Surg Engl 1998;80:184-187*

27 *HofstetterWL, Vukasin P, Ortega AE, et al. New technique for mesh repair of paracolostomy hernias. Dis Colon Rectum 1998;41:1054-1055*

28 *Van Sprundel TC, Gerritsen van der Hoop A. Modified technique for parastomal hernia repair in patientswith intractable stoma care problems. Colorectal Dis 2005;7:445-449*

29 *Stelzner S, Hellmich G, Ludwig K. Repair of paracolostomy hernias with a prosthetic mesh in the intraperitoneal onlay position: modified Sugarbaker technique. Dis Colon Rectum 2004;47:185-191*

30 *LeBlanc KA, Bellanger DE, Whitaker JM, et al. Laparoscopic parastomal hernia repair. Hernia 2005;9:140-144*

31 *Safadi B. Laparoscopic repair of parastomal hernias. Early results. Surg Endosc 2004;18:676-680*

32 *McLemore EC, Harold KL, Efron JE, et al. Parastomal hernia: short-term outcome after laparoscopic and conventional repairs. Surg Innov 2007;14:199-204*

33 *Berger D, Bientzle M. Laparoscopic repair of parastomal hernias: a single surgeon's experience in 66 patients. Dis Colon Rectum 2007;50:1668-1673*

34 *Wara P, Andersen LM. Long-term follow-up of laparoscopic repair of parastomal hernia using a bilayer mesh with a slit. Surg Endosc 2010;25:526-530*

35 *Mancini GJ, McClusky DA, Khaitan L, et al. Laparoscopic parastomal hernia repair using a nonslit mesh technique. Surg Endosc 2007;21:1487-1491*

36 *Muysoms F. Laparoscopic repair of parastomal hernias with a modified Sugarbaker technique. Acta Chir Belg 2007;107:476-480*

37 *Hansson BME, Bleichrodt RP, De Hingh IHJT. Laparoscopic parastomal hernia repair using a keyhole technique results in a high recurrence rate. Surg Endosc 2009;23:1456-1459*

38 *Craft RO, Huguet KL, McLemore EC, et al. Laparoscopic parastomal hernia repair. Hernia 2008;12:137-140*

39 *Berger D, Bientzle M. Polyvinylidene fluoride: a suitable mesh material for laparoscopic incisional and parastomal hernia repair! A prospective, observational study with 344 patients. Hernia 2009;13:167-172*

40 *De Vries Reilingh TS, Van Geldere D, Langenhorst B, et al. Repair of large midline incisional hernias with polypropylene mesh: comparison of three operative techniques. Hernia 2004;8:56-59*

41 *Aldridge AJ, Simson JNL. Erosion and perforation of colon by synthetic mesh in a recurrent paracolostomy hernia. Hernia 2001;5:110-112*

42 *Rosin JD, Bonardi RA. Paracolostomy hernia repair with Marlex mesh: a new technique. Dis Colon Rectum 1977;20:299-302*

43 *Sugarbaker PH. Peritoneal approach to prosthetic mesh repair of paraostomy hernias. Ann Surg 1985;201:344-346*

44 *Lebwohl M, Heymann WR, Berth-Jones J, et al. Treatment of Skin Disease: Comprehensive Therapeutic Strategies. 3rd ed. New York, NY: Saunders-Elsevier; 2010*

45 *Rosch R, Binnebösel M, Junge K, et al. Analysis of c-myc, PAI-1 and uPAR in patients with incisional hernias. Hernia 2008;12:285-288*

46 *Kelly ME, Behrman SW. The safety and efficacy of prosthetic hernia repair in clean-contaminated wounds. Am Surg 2002;68:524-529*

47 *Geisler DJ, Reilly JC, Vaughan SG, et al. Safety and outcome of use of nonabsorbable mesh for repair of fascial defects in the presence of open bowel. Dis Colon Rectum 2003;46:1118-1123*

48 *Van der Krabben A, Dijkstra FR, Nieuwenhuizen M, et al. Morbidity and mortality of inadvertent enterotomy during adhesiolysis. Br J Surg 2000;87: 467-471*

49 *Fevang BT, Fevang J, Lie SA, et al. Long-term prognosis after operation for adhesive small bowel obstruction. Ann Surg 2004; 240:193-201*

50 *Fazio VW, Cohen Z, Fleshman JW, et al. Reduction in adhesive small bowel obstruction by Seprafilm adhesion barrier after intestinal resection. Dis Colon Rectum 2006;49:1-11*

51 *De Ruiter P, Bijnen AB. Successful local repair of paracolostomy hernia with a newly developed prothetic device. Int J Colorectal Dis 1992;7:132-134*

52 *Halm JA, de Wall LL, Steyerberg EW, et al. Intraperitoneal polypropylene mesh hernia repair complicates subsequent abdominal surgery. World J Surg 2007;31:423-429*

53 *Bleichrodt RP, Simmermacher RK, van der Lei B, et al. Expanded polytetrafluoroethylene patch versus polypropylene mesh for the repair of contaminated defects of the abdominal wall. Surg Gynecol Obstet 1993;176:18-24*

54 *Simmermacher RK, Schakenraad JM, Bleichrodt RP. Reherniation after repair of the abdominal wall with expanded polytetrafluoroethylene. J Am Coll Surg 1994;178:613-616*

55 *Van der Lei B, Bleichrodt RP, Simmermacher RK, et al. Expanded polytetrafluoroethylene patch for the repair of large abdominal wall defects. Br J Surg 1989;76:803-805*

56 *Slater NJ, Hansson BME, Buyne OR, et al. Repair of parastomal hernias with biologic grafts: a systematic review. J Gastrointest Surg 2011;15:1252-1258*

Birgitta Hansson

Chapter 6 Repair of parastomal hernias with biological grafts: a systematic review of the literature

N.J. Slater, B.M.E. Hansson, O.R. Buyne, T. Hendriks, R.P. Bleichrodt J Gastrointest Surg (2011) 15:1252-1258

Birgitta Hansson

Abstract

Background

Biologic grafts are increasingly used instead of synthetic mesh for parastomal hernia repair due to concerns of synthetic mesh-related complications. This systematic review was designed to evaluate the use of these collagen-based scaffolds for the repair of parastomal hernias.

Methods

Studies were retrieved after searching the electronic databases MEDLINE, EMBASE and Cochrane CENTRAL. The search terms 'paracolostomy', 'paraileostomy', 'parastomal', 'colostomy', 'ileostomy', 'hernia', 'defect', 'closure', 'repair' and 'reconstruction' were used. Selection of studies and assessment of methodological quality were performed with a modified MINORS index. All reports on repair of parastomal hernias using a collagen-based biologic scaffold to reinforce or bridge the defect were included. Outcomes were recurrence rate, mortality and morbidity.

Results

Four retrospective studies with a combined enrolment of 57 patients were included. Recurrence occurred in 15.7% (95% confidence interval [CI] 7.8–25.9) of patients and wound-related complications in 26.2% (95% CI 14.7–39.5). No mortality or graft infections were reported.

Conclusions

The use of reinforcing or bridging biologic grafts during parastomal hernia repair results in acceptable rates of recurrence and complications. However, given the similar rates of recurrence and complications achieved using synthetic mesh in this scenario, the evidence does not support use of biologic grafts.

Introduction

Parastomal herniation is a common complication following creation of an ileostomy or colostomy, with observed rates of up to 28% and 48%, respectively [1]. Besides risk of incarceration and stenosis of the bowel, parastomal herniation can cause pain, discomfort and an ill-fitting pouching system that in turn may cause leakage and skin excoriation. Needless to say, body image is adversely affected in patients that might already be experiencing social problems associated with the presence of a stoma [2]. Surgical treatment modalities available are relocation of the stoma and repair of the defect using either direct suture repair, or bridging or reinforcement with prostheses. Relocation of the stoma does not address tissue weakness secondary to systemic risk factors and, just like direct suture repair, often results in high recurrence rates [3,4]. Since the introduction of synthetic mesh to reinforce or bridge the defect, this procedure has been regarded as the best possible care for parastomal herniation, showing lower recurrence rates [1,5]. Its prophylactic use at the time of initial stoma creation is now often propagated to prevent future herniation [5,6]. At the same time, reservations have arisen with respect to the implantation of synthetic mesh in close proximity to bowel and stoma due to risk of erosion and fistula formation [7]. Also, dense adhesions may complicate future abdominal surgery [8]. Besides these concerns, there is the universal fear of infection when implanting foreign body material, especially in contaminated fields.

Collagen-based biologic grafts have been produced since the 1980's [9]. These prostheses consist of an acellular collagen matrix that is slowly degraded and replaced by fibrocollagenous tissue of the host. Their properties depend on the species and type of tissue that the material is extracted from, the processing methods (including decellularisation and sterilisation), and whether or not they are intentionally crosslinked. Biologic grafts used for incisional hernia repair are derived from either human dermis, porcine dermis, porcine small intestinal submucosa, or bovine pericardium. During processing, the materials are made functionally acellular to prevent a foreign body response, while still maintaining their extracellular collagenous structure that allows for the host tissue ingrowth. Sterilisation of the materials by ethylene oxide gas or irradiation aims at making the final product pathogen free. Some products receive additional cross-linking of the collagen matrix to control or reduce the enzymatic degradation of the graft. This should give the host more time to deposit fibro-collagenous tissue and remodel the prosthesis into strong native tissue. Due to their bio-compatibility resulting in rapid vascularisation and migration of host (immune) cells, it is thought that biologic prostheses are less prone to infection than synthetic grafts. Moreover,

they are soft and pliable which potentially decreases the risk of discomfort and erosion into the bowel. However, given the high financial costs of biologic grafts, proper evidence of more beneficial outcomes or cost savings in the long run are paramount to support their use. This systematic review aims to evaluate the use of these acellular collagen-based scaffolds for the repair of parastomal hernias, focusing on recurrence and complication rates.

Methods

Search Methods for Study Identification

Studies were identified using the electronic databases MEDLINE (including in-process and other non-indexed citations, 1950-present), EMBASE (1980-present) and the Cochrane Central Register of Controlled Trials. Search terms used were: 'parastomal', 'paracolostomy', 'paraileostomy', 'stoma', 'hernia',

Item	Criteria	Option	Score
1	A clearly stated aim	Not reported	0
		Partially reported, no clear aim	1
		Clear aim	2
2	Minimum of 5 included patients	No	0
		Yes	2
3	Inclusion of consecutive patients	Not reported	0
		Patients in a certain time period	1
		Consecutive patients+characteristics	2
4	Type of stoma specified	Not reported	0
		Reported	2
5	Surgical technique reported	Not reported	0
		Incomplete	1
		Reported clearly, appropriate to aim	2
6	Report of end points	Not reported	0
		Recurrences only	1
		Recurrences and postoperative complications	2
	Maximum score		**12**

Table 1 ***Modified Methodological Index of Non-Randomized Studies (MINORS)***

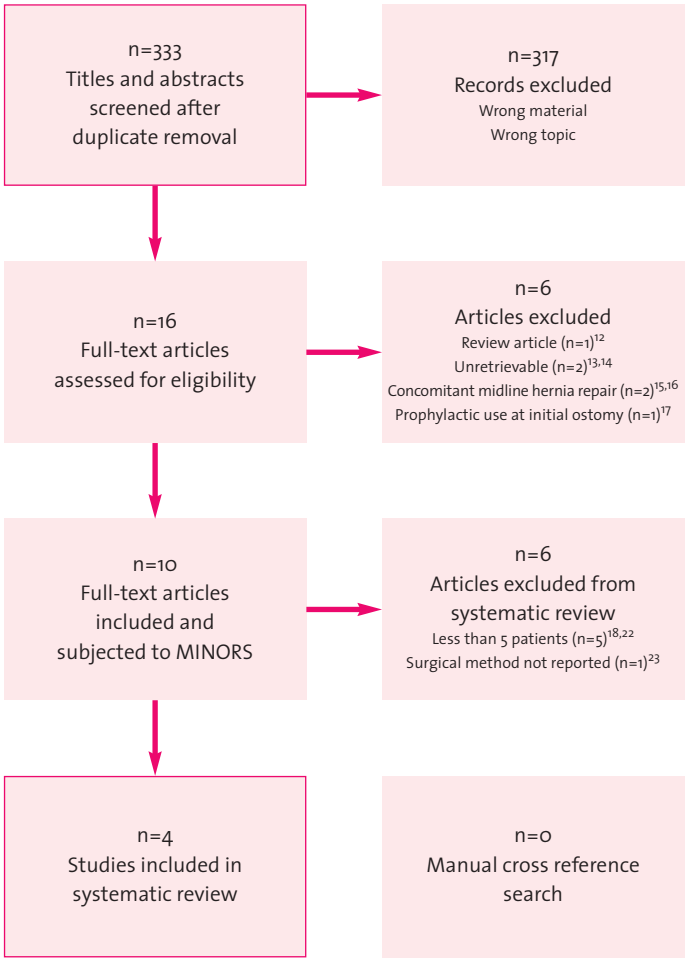

Figure 1 ***Flowchart of search strategy***

'defect' and 'repair'. Terms were searched for as free text and where applicable were also mapped to MeSH terms. Full-text articles retrieved for evaluation were scanned for other relevant references. No limits were set on language or publication status. Titles and abstracts were screened for eligibility and full-text articles were retrieved. The last search was performed on 13 September 2010. All reports on repair of parastomal hernias using a acellular collagen-based biologic scaffold as sole material to reinforce or bridge the defect were included. All other types of repair were excluded.

Assessment of Study Quality

All studies selected were subjected to a modified version of the Methodological Index for Non-Randomized Studies (MINORS) tool to evaluate their methodological quality (table 1). This instrument was constructed and validated for appraisal of non-randomized trials in surgery [10]. Studies were scored independently by two authors (NJS, RPB). This modified version contains six items with a maximum score of two on each, yielding a maximum index of 12. Studies with a total score less than nine, or no score on item 2, 5 or 6 were excluded from systematic review. Disagreement was resolved by discussion and consensus between authors. Also, the diagnostic modality for the primary outcome was determined for every study.

Data Extraction

The primary outcome was the rate of parastomal hernia recurrence observed, as defined by the respective authors. Study characteristics (year of publication, no. of patients, surgical technique, follow-up), perioperative (30 days) mortality and rates and type of wound-related complications were also noted. Total amount of wound-related complications were calculated by adding up all relevant complications, including only the studies with adequate reporting. Weighted pooled proportions with their respective 95% confidence intervals (CI) following the fixed-effects (inverse variance) model were determined for recurrences and wound-related complications using StatsDirect® statistical software [11].

Results

A flowchart overview of the search is depicted in figure 1. The search strategy yielded 333 titles and abstracts. After screening, 317 records were excluded leaving 16 articles to be retrieved and assessed for eligibility. Six of these were excluded after assessment [12-17] leaving a total of 10 articles that reported on the repair of parastomal hernias with biologic prostheses. After subjecting these to the modified MINORS tool, another six were excluded due to too small sample sizes [18-22] and inadequate reporting on surgical technique [23]. This left four studies to be included in the systematic review [24-27].

Findings of Systematic Review

All included studies were retrospective with a combined enrolment of 57 patients (range 11-20). The definition of a recurrence was not given by any author. Follow-up ranged from 8.1 to 50.2 months, and was done by clinical examination in three [25-27] and also by CT imaging in one [26]. One study was unclear as to how follow-up was performed [24]. No mortality was reported. Study characteristics and outcomes including weighted pooled rates of recurrence and wound-related complications are shown in table 2. The weighted pooled proportion of recurrences was 15.7% (95% CI 7.8-25.9; figure 2).

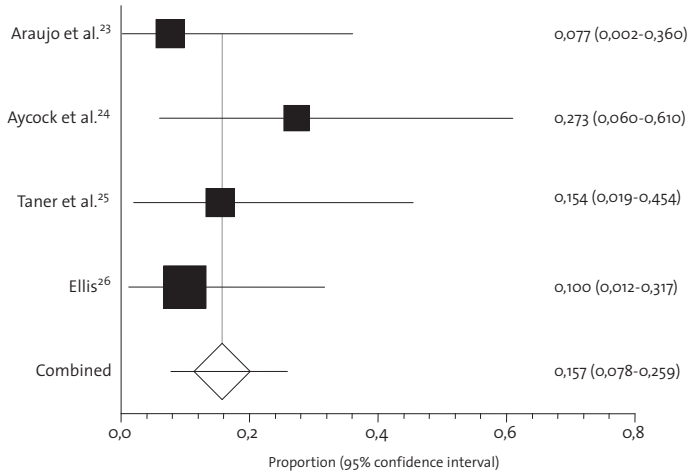

Figure 2 ***Weighted pooled proportion (fixed-effects model; Cochran's Q=1.917, p=0.5899) of recurrences after parastomal hernia repair using biological grafts***

Reference	Year	No. of patients	MINORS index	Material used	Type of repair	No. of wound complications (%)[b]	Recurrence (%)	Months follow-up (range)
Araujo et al.[24]	2005	13	10	Peri-Guard	Onlay	n/a	1 (7.7)	50.2 (n/a)[a]
Aycock et al.[25]	2007	11	9	Alloderm	Inlay (n=8) and onlay (n=3)	2 (18.2)	3 (27.3)	8.1 (1-21)
Taner et al.[26]	2009	13	9	Alloderm	Under+onlay sandwich	5 (38.5)	2 (15)	9 (4-16)
Ellis[27]	2010	20	12	Surgisis	Intraperitoneal underlay (Sugarbaker)	4 (20.0)	2 (10)	18 (6-38)
Weighted pooled %[c] (95% CI)	-	-	-	-	-	26.2% (14.7-39.5)	15.7% (7.8-25.9)	-

Table 2 ***Study characteristics and recurrence rates of studies included in systematic review*** *[a] This follow-up is that of a larger group of which these patients were part of [b] Complications: wound infection (3),[5,26] seroma formation (6),[26,27] incisional separation (2)[26], [c] Using a fixed-effects (inverse variance) model*

Material	Source	Additional cross-linking	Preparation	Costs per cm²[a]
Alloderm	Human dermis	None	Refrigeration, rehydration	$ 35.31
Permacol	Porcine dermis	Yes; HMDI	None	$ 18.97
Surgisis	Porcine SIS	None	Rehydration	$ 20.00
Collamend	Porcine dermis	Yes; EDC	Rehydration	$ 18.88
Peri-guard	Bovine pericardium	Yes; gluteraldehyde	Rehydration	$ 3.91
Veritas	Bovine pericardium	None	None	$ 22.02
	Polypropylene/e-PTFE/Composite	-	None	$ 3.65

Table 3 ***Characteristics and costs of biologic and synthetic prostheses used for parastomal hernia repair*** *[a] Based on sheet sizes sufficient for parastomal hernia repair, excluding account discount. Manufacturers and distributors were contacted directly via telephone.* ***SIS*** *small intestinal submucosa;* ***HMDI*** *hexamethylene diisocyanate;* ***EDC*** *1-ethyl-(3-dimethylaminopropyl) carbodiimide hydrochloride;* ***Alloderm*** *LifeCell Corp., Branchburg, NJ, USA;* ***Permacol*** *Tissue Science Laboratories, Aldershot, UK;* ***Surgisis*** *Cook Surgical, Bloomington, IN, USA;* ***Collamend*** *Bard Inc., Warwick, RI, USA;* ***Xenmatrix*** *Brennen Medical Inc., St. Paul, MN, USA;* ***Veritas, Peri-Guard*** *Synovis Surgical Innovations, St. Paul, MN, USA*

No cases of infected grafts were reported. Araujo et al. only reported on infection (which was absent) and therefore their data were not included in the calculation of wound-related complications. Various surgical techniques were used, including onlay, inlay, and underlay (pre- and intraperitoneal) placement of the biologic graft. Both open and laparoscopic procedures were performed. Biologic grafts used were products derived from human acellular dermis (Alloderm®), bovine pericardium (Peri-Guard®) and porcine small intestinal submucosa (Surgisis®). Characteristics of the biologic grafts used in the included and excluded studies are given in table 3.

Studies Excluded From Systematic Review

Six reports on the use of biologic grafts for the repair of parastomal hernias were excluded after subjecting them to the modified MINORS tool, including retrospective studies, [20,23] case reports [19,21] and case series [18,22] (table 4). Two case reports and two case series described the use of biologic grafts for the repair of parastomal hernia. Greenstein and Aldoroty [19] reported on a patient with a history of ulcerative colitis and four ileostomy revisions that presented with unremitting obstructive symptoms. An incarcerated parastomal hernia confirmed by CT was repaired using cross-linked porcine dermis (Collamend®) in a retromuscular fashion. Patient regained ileostomy function within a few days and when seen at 18 months was pain free with no evidence of graft infection, hernia recurrence, ileostomy malfunction or obstruction. Lo Menzo et al. [21] reported on a patient with a history of abdominoperineal resection for rectal cancer that presented with a three-time recurrent parastomal hernia, for which an expanded polytetrafluoroethylene mesh was used for the last repair using the keyhole technique. The Sugarbaker technique [28] was employed using bovine pericardium (Veritas®). Postoperatively, a seroma developed which resolved spontaneously; and at 17-month follow-up, there was no evidence of recurrence, the patient was pain free and satisfied with cosmetic results. In a case series of three patients, Kish et al. [22] reported on the primary repair of parastomal hernia using human acellular dermis (Alloderm) as onlay reinforcement. Two patients were followed for 6 months and 1 year, respectively, and remained hernia free. One patient presented 8 months later with symptoms of intestinal obstruction treated conservatively. The patient subsequently returned 3 months later with intestinal obstruction and recurrent parastomal hernia that necessitated an operation for relocation of the stoma and repeat hernia repair. Inan et al. [18] reported on two patients, one with a history of proctectomy after severe radiation proctitis presenting with discomfort and obstructive episodes, the other presenting with symptomatic hernia 18 years after abdominoperineal resection. Both were repaired laparoscopically using cross-linked porcine dermis (Permacol®), and at 9 and 3 months postoperatively there was no evidence of recurrence or mesh-related complications.

Two retrospective studies on the use of cross-linked porcine dermis (Permacol) for various types of hernia repair in complex, infected or potentially contaminated settings, included six patients undergoing parastomal hernia repair. Of the total of 133 procedures, Franklin et al. [23] repaired parastomal hernia using intraperitoneal onlay mesh in two patients, showing no recurrences [20]. Follow-up ranged 1-78 months using clinical examination. Loganathan et al. [23] reported on repair of four parastomal hernias, one of which underwent reversal of the colostomy at the time of the hernia repair. Of the other three patients, one that had six previous attempts at hernia repair experienced a recurrence. This patient developed an ischaemic end ileostomy which subsequently developed a localised perforation which manifested as a fistula formation. Another patient also developed a fistula. Cross-linked porcine dermis (Permacol) was placed as inlay or onlay. Median follow-up of the complete series was 377 days (range 85-1,905 days) performed by clinical examination.

Discussion

The current systematic review evaluated the use of biologic grafts for parastomal hernia repair, which results in acceptable rates of recurrence, with a pooled rate of 15.7% (95% CI

Reference	Year	No. of patients	Material used	Type of repair	No. of wound complications (%)[b]	Recurrence (%)	Months follow-up (range)
Kish et al.[22]	2005	3	Alloderm	Onlay	n/a	1 (33.3)	(6-12)
Inan[18]	2007	2	Permacol	Laparoscopic (method not specified)	n/a	0 (0)	6 (3-9)
Greenstein & Aldoroty[19]	2008	1	Collamend	Retromuscular/sublay	0 (0)	0 (0)	18
Franklin et al.[20]	2008	2	Surgisis	Intraperitoneal onlay mesh (Laparoscopic)	n/a	0 (0)	n/a
Lo Menzo et al.[21]	2008	1	Veritas	Intraperitoneal (Laparoscopic Sugarbaker)	1 (100)	0 (0)	17
Loganathan et al.[23]	2010	3	Permacol	n/a	2 (66)	1 (33)	12 (3-62)[a]

Table 4 ***Study characteristics and recurrence rates of studies excluded from systematic review*** *[a] This follow-up is that of a larger group of which these patients were part of*
[b] Complications: seroma formation (1),[21] ischaemic ileostomy and subsequent fistula (1),[23] fistula (1)[23]

7.8-25.9). Wound-related complications were reported in 26.2% (95% CI 14.7-39.5). Given the current evidence, biologic grafts do not provide a superior alternative to other surgical options.

In their review on parastomal hernia from 2003, Carne et al. [1] shed some light on the outcomes of different techniques of parastomal hernia repair. In studies using synthetic meshes (intraperitoneal, preperitoneal and fascial onlay), the overall recurrence rate was 6/77 (7.8%). Infection is uncommon and only infrequently requires removal of the mesh. A search of the literature published since reveals reherniation occurring in 62/371 (16.7%) patients [29-42]. As found by Carne et al., complications were low, with mesh infection reported in 15/460 (3%) of the patients. In the current systematic review of parastomal hernia repair using biologic grafts, rates of recurrence ranged from 7.7% to 27.3%, with a weighted pooled average of 15.7% (95% CI 7.8-25.9). Graft infection was zero, and other woundrelated complications including wound infection were 26.2% (95% CI 14.7-39.5). Thus, these rates are very similar to those found for synthetic mesh. Notably, even the risk of mesh infection appears to be low when a synthetic graft is implanted. Given the current evidence, it cannot be concluded that biologic prostheses are more preferable than synthetic mesh to reduce the rates of immediate or long-term complications. Moreover, biologic grafts are very expensive compared to synthetic mesh (table 3), which further refutes their superiority over synthetic mesh to provide not only effective but also efficient and cost-effective healthcare. With limited financial resources, careful consideration must be taken whilst choosing the types of materials to use.

It is well established that parastomal hernias can occur after great periods of time. Also, on the long run, risk of infection may remain higher for non-absorbable synthetic meshes compared to degradable biologic grafts due to a prolonged presence of foreign body material. Studies with longer follow-up are therefore imperative to yield more reliable rates of recurrence and late complications for both these treatment modalities. The results of this systematic review were troubled by typical issues of potential bias, including the lack of uniformity between studies in definition and reporting of outcomes and patient characteristics.

Given the scarcity of relevant studies, combined with the variety of biologic grafts used, it is impossible to make a direct comparison between the different products or types of material. The same goes for the surgical technique used (i.e. the type of prosthetic placement), which is also of relevance for outcome. With synthetic meshes, average rates of recurrence after sublay mesh (5.7%) [34,39] and intraperitoneal mesh (11.1%) [32,33] are lower than after onlay mesh (22.8%) [29-31] or laparoscopically placed intraperitoneal mesh (16.6%) [35-38,40-42]. Onlay placement requires extensive dissection of subcu-

taneous tissue which predisposes for hematoma and seroma formation and may disrupt skin vascularisation leading to impaired wound healing. Moreover, due to its anatomical position, intra-abdominal pressure may lead to lateral detachment of the graft resulting in its higher recurrence rates. On the other hand, sublay and underlay techniques theoretically benefit from the intra-abdominal pressures which may help to keep the graft in place. Concerning complications, the sublay placement again theoretically seems the most advantageous of the techniques, resulting in the least contact between mesh and bowel.

Besides its use for the repair of parastomal hernia, there has been much debate as to the effectiveness of the prophylactic placement of a reinforcing prosthesis at the time of initial stoma formation. In a recent systematic review of the use of a mesh to prevent parastomal hernia, Tam et al. [6] made a strong case for the use of prophylactic mesh at the time of initial stoma formation, showing an overall recurrence rate of 15.4%, compared to 55.2% in patients who received a conventional stoma. Their meta-analysis performed on three randomized controlled trials yielded similar results. Complications were very low and did not differ between the two groups. To date, only one study can be identified that used a biologic graft for this purpose [17]. Hammond et al. compared the prophylactic use of cross-linked porcine dermis (Permacol) to conventional stoma formation. After a median follow-up of only 6.5 months, the conventional group had a recurrence rate of 33.3%, while the prophylactic group showed no recurrences. No complications were observed. Given the very low rate of complications associated with prophylactic synthetic mesh placement, there is as yet no support for the use of biologic grafts instead of synthetic ones in this surgical scenario.

As mentioned earlier, when studying rates of hernia recurrence, next to an appropriate follow-up a properly defined outcome measure is deemed essential to create uniform and comparable findings. None of the studies in the current review provided a proper definition of a recurrence. Most studies used clinical examination to detect hernias, and one study also used CT imaging in all patients [26]. Here, the two patients that had radiologic evidence of a recurrence continued to be asymptomatic at 385 and 509 days follow-up, respectively, requiring no revision of their repair. Another study, which was excluded from this review due to the prophylactic placement of a biologic graft, also used CT imaging in all patients to determine hernia occurrence [16]. Similarly, the only two occurrences were found on CT scan and were small asymptomatic hernias. If these studies had used only clinical examination, it is conceivable that these asymptomatic patients might not have been found to have a recurrence. Most recently, Gurmu et al. examined the inter-observer reliability of clinical examination of parastomal

hernia in three hospitals [43]. This appeared to be low, with kappa values ranging between 0.29 and 0.73. The correlation between CT and patient-reported complaints using a colostomy questionnaire was also low, revealing a kappa of 0.45. Even though the underestimation of rates of (minor) parastomal hernias may well be very common, its clinical relevance in asymptomatic and satisfied patients is only manifest in an increased risk of complications due to the hernia, such as incarceration and stenosis of bowel. It is hard to estimate these risks in patients with asymptomatic or small hernias, but given the marginal amount of recurrences and long-term complications in the studies discussed in this review and in the literature, they do not seem to give cause for concern.

References

1 *Carne PW, Robertson GM, Frizelle FA. Parastomal hernia. Br J Surg. 2003;90:784-793*

2 *Cheung MT. Complications of an abdominal stoma: an analysis of 322 stomas. Aust N Z J Surg. 1995;65:808-811*

3 *Rubin MS, Schoetz DJ Jr, Matthews JB. Parastomal hernia. Is stoma relocation superior to fascial repair? Arch Surg. 1994;129:413-418.*

4 *Riansuwan W, Hull TL, Millan MM, Hammel JP. Surgery of recurrent parastomal hernia: direct repair or relocation? Colorectal Dis. 2010;12:681-6*

5 *Israelsson LA. Preventing and treating parastomal hernia. World J Surg. 2005;29:1086-1089*

6 *Tam KW, Wei PL, Kuo LJ, Wu CH. Systematic review of the use of a mesh to prevent parastomal hernia. World J Surg. 2010;34:2723-2729*

7 *Aldridge AJ, Simson JNL. Erosion and perforation of colon by synthetic mesh in a recurrent paracolostomy hernia. Hernia. 2001;5:110-112*

8 *Morris-Stiff G, Hughes LE. The continuing challenge of parastomal hernia: failure of a novel polypropylene mesh repair. Ann R Coll Surg Engl. 1998;80:184-187*

9 *Decurtins M, Buchmann P. Bovine pericardium - a new graft material for hernial repair. Res Exp Med (Berl.) 1982;180:11-14*

10 *Slim K, Nini E, Forestier D, Kwiatkowski F, Panis Y, Chipponi J. Methodological index for non-randomized studies (MINORS): development and validation of a new instrument. ANZ J Surg. 2003;73: 712-761*

11 *StatsDirect statistical software [computer program]. Version 2.7.8. England: StatsDirect Ltd; 2008*

12 *Hiles M, Record Ritchie RD, Altizer AM. Are biologic grafts effective for hernia repair? A systematic review of the literature. Surg Innov. 2009;16:26-37*

13 *Wietfeldt ED, Hassan I, Rakinic J. Utilization of bovine acellular dermal matrix for abdominal wall reconstruction: a retrospective case series. Ostomy Wound Manage. 2009;55: 52-56*

14 *Pullan R., Defriend D. Colorectal Dis 2009 Sep;11 Suppl 2:1-57. Abstracts of the Fourth Annual Meeting of the European Society of Coloproctology. September 23-26, 2009. Prague, Czech Republic.*

15 *Liyanage SH, Purohit GS, Frye JN, Giordano P. Anterior abdominal wall reconstruction with a Permacol implant. J Plast Reconstr Aesthet Surg. 2006;59:553-555*

16 *Rosen MJ, Reynolds HL, Champagne B, Delaney CP. A novel approach for the simultaneous repair of large midline incisional and parastomal hernias with biological mesh and retrorectus reconstruction. Am J Surg. 2010;199:416-420*

17 *Hammond TM, Huang A, Prosser K, Frye JN, Williams NS. Parastomal hernia prevention using a novel collagen implant: a randomized controlled phase 1 study. Hernia. 2008;12:475-481*

18 *Inan I, Gervaz P, Hagen M, Morel P. Multimedia article. Laparoscopic repair of parastomal hernia using a porcine dermal collagen (Permacol) implant. Dis Colon Rectum. 2007;50:1465*

19 *Greenstein AJ, Aldoroty RA. Parastomal hernia repair using cross-linked porcine dermis: report of a case. Surg Today. 2008;38:1048-1051*

20 *Franklin ME Jr, Treviño JM, Portillo G, Vela I, Glass JL, González JJ. The use of porcine small intestinal submucosa as a prosthetic material for laparoscopic hernia repair in infected and potentially contaminated fields: long-term follow-up. Surg Endosc. 2008;22: 1941-1946*

21 *Lo Menzo E, Martinez JM, Spector SA, Iglesias A, Degennaro V, Cappellani A. Use of biologic mesh for a complicated paracolostomy hernia. Am J Surg. 2008;196:715-719*

22 *Kish KJ, Buinewicz BR, Morris JB. Acellular dermal matrix (AlloDerm): new material in the repair of stoma site hernias. Am Surg. 2005;71:1047-1050*

23 *Loganathan A, Ainslie WG, Wedgwood KR. Initial evaluation of Permacol bioprosthesis for the repair of complex incisional and parastomal hernias. Surgeon. 2010;8:202-205*

24 *Araujo SE, Habr-Gama A, Teixeira MG, Caravatto PP, Kiss DR, Gama-Rodrigues J. Role of biological mesh in surgical treatment of paracolostomy hernias. Clinics (Sao Paulo). 2005;60:271-276*

25 *Aycock J, Fichera A, Colwell JC, Song DH. Parastomal hernia repair with acellular dermal matrix. J Wound Ostomy Continence Nurs. 2007;34: 521-523*

26 *Taner T, Cima RR, LarsonDW,Dozois EJ, Pemberton JH,Wolff BG. The use of human acellular dermal matrix for parastomal hernia repair in patients with inflammatory bowel disease: a novel technique to repair fascial defects. Dis Colon Rectum. 2009;52:349-354*

27 *Ellis CN. Short-term outcomes with the use of bioprosthetics for the management of parastomal hernias. Dis Colon Rectum. 2010;53:279-283*

28 *Sugarbaker PH. Prosthetic mesh repair of large hernias at the site of colonic stomas. Surg Gynecol Obstet. 1980;150:576-578*

29 *Steele SR, Lee P, Martin MJ, Mullenix PS, Sullivan ES. Is parastomal hernia repair with polypropylene mesh safe? Am J Surg. 2003;185: 436-440*

30 *Ho KMT, Fawcett DP. Parastomal hernia repair using the lateral approach. BJU Int. 2004;94:598-602*

31 *Rieger N, Moore J, Hewett P, Lee S, Stephens J. Parastomal hernia repair. Colorectal Dis. 2004;6:203-205*

32 *Stelzner S, Hellmich G, Ludwig K. Repair of paracolostomy hernias with a prosthetic mesh in the intraperitoneal onlay position: modified Sugarbaker technique. Dis Colon Rectum. 2004;47:185-191*

33 *Van Sprundel TC, Gerritsen van der Hoop A. Modified technique for parastomal hernia repair in patients with intractable stoma care problems. Colorectal Dis. 2005;7:445-449*

34 *Longman RJ, Thompson WH. Mesh repair of parastomal hernias, a safety modification. Colorectal Dis. 2005;7:292-294*

35 *LeBlanc KA, Bellanger DE, Whitaker JM, Hausman MG. Laparoscopic parastomal hernia repair. Hernia. 2005;9:140-144*

36 *McLemore EC, Harold KL, Efron JE, Laxa BU, Young-Fadok TM, Heppell JP. Parastomal hernia: short-term outcome after laparoscopic and conventional repairs. Surg Innov. 2007;14:199-204*

37 *Mancini GJ, McClusky DA, Khaitan L et al. Laparoscopic parastomal hernia repair using a nonslit mesh technique. Surg Endosc. 2007; 21:1487-1491*

38 *Berger D, Bientzle M. Laparoscopic repair of parastomal hernias: a single surgeon's experience in 66 patients. Dis Colon Rectum. 2007;50:1668-1673*

39 *Guzman-Valdivia G, Guerrero TS, Laurrabaquio HV. Parastomal hernia repair using mesh and an open technique. World J Surg. 2008;32:465-470*

40 *Craft RO, Huguet KL, McLemore EC, Harold KL. Laparoscopic parastomal hernia repair. Hernia. 2008;12:137-140*

41 *Hansson BME, Bleichrodt RP, De Hingh IHJT. Laparoscopic parastomal hernia repair using a keyhole technique results in a high recurrence rate. Surg Endosc. 2009;23:1456-1459*

42 *Pastor DM, Pauli EM, Koltun WA, Haluck RS, Shope TR, Poritz LS. Parastomal hernia repair: a single center experience. JSLS. 2009; 13:170-175*

43 *Gurmu A, Matthiessen P, Nilsson S, Påhlman L, Rutegård J, Gunnarsson U. The inter-observer reliability is very low at clinical examination of parastomal hernia. Int J Colorectal Dis. 2010; 26:89-95*

Birgitta Hansson

Chapter 7 Laparoscopic modified Sugarbaker technique is safe and has a low recurrence rate: a multicenter cohort study

B.M.E. Hansson, S. Morales-Conde, T. Mussack, J. Valdes, F.E. Muysoms, R.P. Bleichrodt Accepted Surg Endosc

Birgitta Hansson

Abstract

Background

Parastomal hernia is a frequent complication of intestinal stomata. Mesh repair gives the best results, either inserted via laparotomy or laparoscopically. It was the aim of this retrospective multicenter study to determine the early and late results of the laparoscopically performed, modified Sugarbaker technique with an ePTFE mesh.

Patients and Methods

From 2005-2010, 61 consecutive patients with a symptomatic parastomal hernia, mean age 61, underwent a laparoscopic repair using the modified Sugarbaker technique with an ePTFE mesh. Fitfty-five patients had a colostomy, 4 patients an ileostomy and 2 an urostomy according to Bricker. The records of the patients were reviewed with respect to patient characteristics, post-operative morbidity and mortality. All patient underwent physical examination to detect a recurrent hernia, after a follow-up of at least 1 year.

Morbidity was 19%, including woundinfection (n=1), ileus (n=2), trocar site bleeding (n=2), reintervention (n=2), pneumonia (n=1). One patient died in the postoperative period due to metastasis of a lungcarcinoma causing bowel obstruction.

Concomitant incisional hernias were detected in 25 out of 61 patients (41%) and could be repaired at the same time in all cases. A recurrent hernia was found in 3 patients at physical examination and in 1 patient an asymptomatic recurrence was found on CT-scan. The overall recurrence rate was 6.6% after a mean follow-up of 26 months.

Conclusion

The laparoscopic Sugarbaker technique is a safe procedure to repair parastomal hernias. Overall morbidity is 19% and recurrence rate 6.6% after a mean follow-up of 26 months. Moreover, the laparoscopic approach revealed concomitant hernias in 41% of the patients, that could be repaired successfully at the same time.

Introduction

A parastomal hernia is an incisional hernia related to the presence of an enterostomy [1]. It is a common complication of stoma formation and the reported incidence varies from 3 to 39% for colostomies and 0-6% for ileostomies [2]. Most of the parastomal hernias are asymptomatic and therefore can be treated conservatively. Indications for surgery are ill-fitting appliances causing leakage, pain, discomfort, and cosmetic complaints [3]. Urgent treatment is indicated when incarceration or strangulation of hernia content occurs.

Surgical treatment options are relocation of the stoma or repair with or without the use of prosthetic material, either by an open or laparoscopic approach. Recently, a systematic review on surgical repair of parastomal hernias was published by Hansson et al [4]. It was concluded that, suture repair should be regarded as outdated because of the high recurrence rate of 69.4%. Synthetic mesh repair had significantly better results with respect to wound infection and recurrence rate. Depending on technique and placement, recurrence rates after mesh repair varied between 6.9% and 17.8%. The overall mesh infection rate was 2.4%. Recurrence rate was similar in patients in whom the mesh was implanted on the fascia (onlay), preperitoneally behind the rectus muscle or intraperitoneally, although the onlay position tended to have a higher recurrence rate.

The preperitoneal- retromuscular or intraperitoneal positions of meshes are biomechanically more attractive and therefore favored by most surgeons. In the review of Hansson et al. it was found that the modified Sugarbaker technique had the best results with regard to recurrence rate [4]. In 1985, Sugarbaker described his technique for parastomal hernia

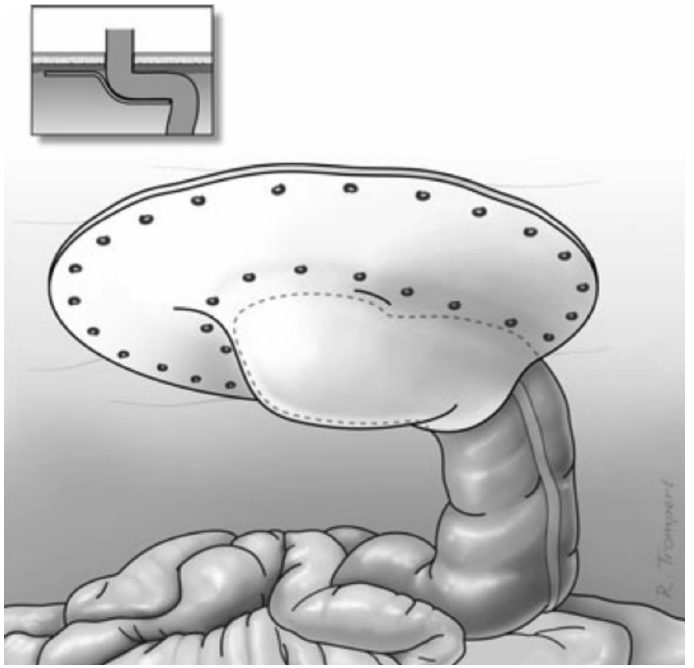

Figure 1 ***Laparoscopic Sugarbaker Technique***

repair [5]. Via a laparotomy the trephine opening is covered with an intraperitoneally placed prosthetic mesh which is sutured to the fascial edge. The bowel is lateralized passing from the hernia sac between the abdominal wall and the prosthesis into the peritoneal cavity. As we have learned from incisional hernia repair, an overlap of 3-5 cm between the mesh and the adjacent fascia is mandatory to prevent recurrent hernias [6]. Therefore the Sugarbaker technique was modified guaranteeing an adequate overlap between the mesh and the fascia, around the trephine opening (figure 1,2).

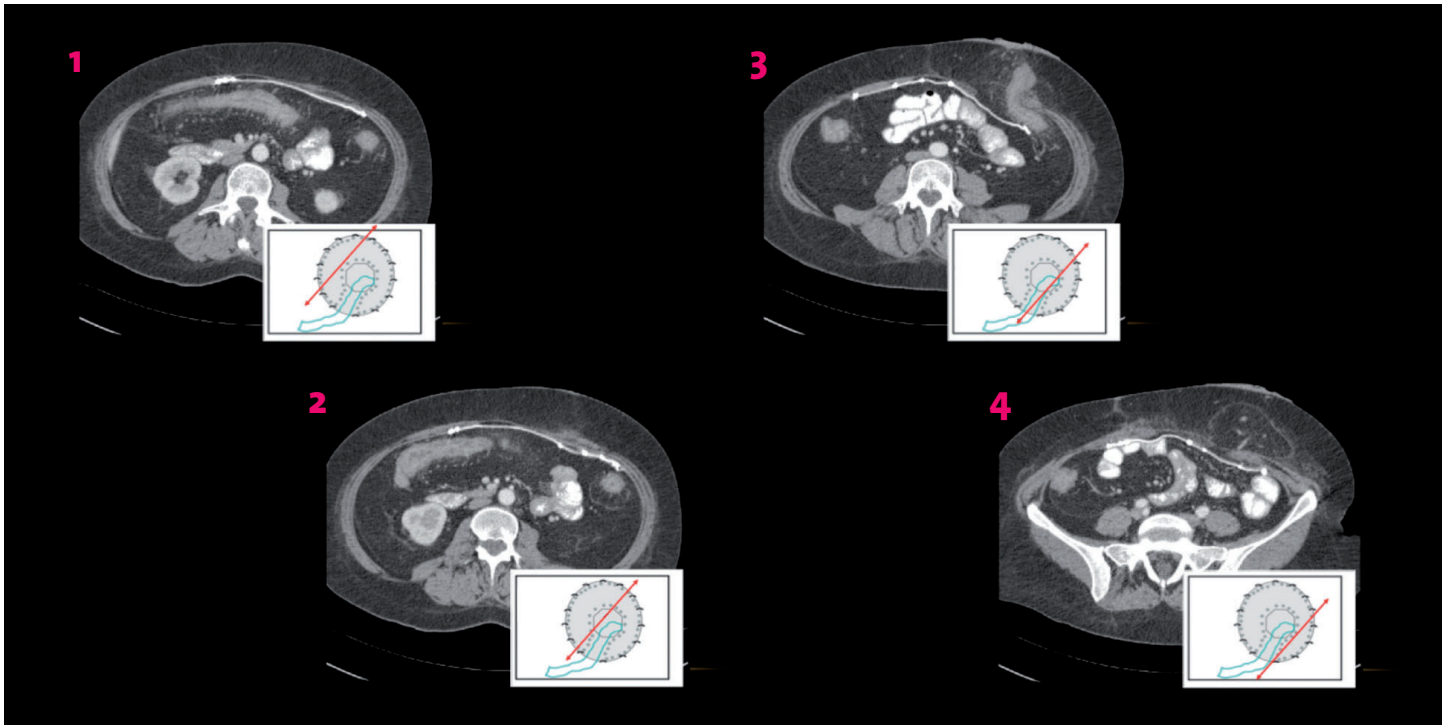

Figure 2 ***Postoperative multislice CT scan after laparoscopic Sugarbaker repair***

Laparoscopic repair of incisional hernia is favored by many surgeons because of a low infection rate of 0.7% [7]. Meta-analysis of all RCT performed by Forbes and co-workers showed a significant lower wound and mesh infection rate in the laparoscopic group [8]. Another potential advantage of the laparoscopic approach is that concomitant incisional hernias can be detected and repaired at the same time. In a recent meta-analysis, recurrence rate of the laparoscopic Sugarbaker repair was found to be 11.6% (95%-CI 6.4-18.0) in a group of 110 patients from 6 studies [4]. Berger and co-workers report on the use of a sandwich technique which combines the Sugarbaker and the keyhole technique [9]. After a median follow-up of 20 (range 6-48) months, one out of 47 (2.1%) patients had a recurrent hernia. Recently, Mizrahi and co-workers published similar data on the keyhole technique as Hansson et al. published previously. Recurrences up to 46.4% were reported by his group[10].

The aim of the present study was to determine the results of the laparoscopically performed Sugarbaker technique for the repair of parastomal hernias in 4 European Centers having extensive experience in laparoscopy and laparoscopic hernia repair.

Patients and methods

A retrospective, multicenter study was performed to determine the results of laparoscopic repair of parastomal hernias with a modified Sugarbaker technique. All consecutive patients that were operated on in four participating centers between May 2005 and June 2010, were included in the study. The following data were extracted from the records: Age, BMI, size of defect, co-morbidities, ASA-score, indication for surgery, technical details of the operation (adhesion score, size of the trephine opening , calculated as the area of an ellipse with the formula; π x (0.5 x length) x (0.5 x width), intraoperative complications, duration of operation), post-operative mortality and morbidity, duration of follow-up and the presence of a recurrent hernia. Adhesions were scored following Zühlke [11]: Grade 1: filmy adhesion, easy to separate by blunt dissection. Grade 2: stronger adhesion, blunt dissection possible, partly sharp dissection necessary. Grade 3: strong adhesions, lysis possible by sharp dissection only. Grade 4: very strong adhesions, lysis possible by sharp dissection only, organs strongly attached with severe adhesions, damage of organs hardly preventable.

Surgical technique

The patient is operated in supine position with both arms placed along the body. The surgeon and the assistant stand at the contralateral site of the stoma. After application of

pneumoperitoneum, one (or two) 10 mm trocar and two (or one) 5 mm trocars are introduced, as described by Muysoms [12]. A careful adhesiolysis is performed.

After freeing the adhesions, the stoma loop is completely dissected free from the fascia and the peritoneum around the trephine opening is freed from adhesions, to allow an overlap between the abdominal wall and the prosthesis of at least 4 cm, around the hernia defect.

The trephine opening is covered with an intraperitoneally placed ePTFE patch (Gore-Tex Dual Mesh Biomaterial®, WL Gore Associates, Newark DE, USA). The bowel is lateralized passing from the hernia sac between the abdominal wall and the prosthesis into the peritoneal cavity. In this way a tunnel is created between the abdominal wall and the prosthesis (figure 1). It is of utmost importance to prevent narrowing of the bowel in the tunnel and to prevent angulation of the bowel when entering the abdominal cavity. The prosthesis is fixed to the abdominal wall using the Double Crown Technique, as described by Morales-Conde [13]. After removal of the trocars, the 10mm trocar opening is closed in layers.

Follow-up

All patients were seen in the outpatient department and underwent physical examination. A recurrent hernia was defined as a recurrent or persistant bulge in standing position during Valsalva manoevre or palpation of the fascial defect in supine position [14]. When in doubt a CT or MRI were performed. In our study 27 patients underwent additional CT or MRI.

Results

From May 1st, 2005 to June 1st, 2010, 61 consecutive patients, 40 women and 21 man, mean age 63 years (range 36-83 years) were treated for a symptomatic parastomal hernia. The demographic details are listed in table 1. All but two of the procedures were performed in an elective setting. Two procedures were done as an emergency procedure for an incarcerated hernia. A concomitant incisional hernia was present in 25 (41%) of the patients.

Of the 61 patients, 55 had a colostomy, and 4 an ileostomy and 2 an urostomy according to Bricker. Enterostomies were created for colorectal and anal malignancies in 43 patients, bladder cancer in 2 patients, inflammatory bowel disease in 6 patients, diverticulitis in 6 patients, incontinence in 3 patients and benign rectal stenosis in 1 patient.

A first repair was performed in 50 patients, 47 patients with a colostomy, 2 with an ileostomy and 1 with an urostomy. Eleven patients, 8 with a colostomy, 2 with an ileostomy and

1 with an urostomy, were treated for a recurrent parastomal hernia after having an open mesh repair (n=7), a laparoscopic keyhole repair (n=3) or a suture repair (n=1).
The indications for elective repair were stoma care problems in 10 patients, intermittent bowel obstruction in 18 patients, pain in 31 patients, problems with bowel irrigation in two patients, and esthetic problems in 26 patients. The indication for emergency surgery was an incarcerated hernia with bowel obstruction in 2 patients.

Surgery

In all patients a laparoscopic Sugarbaker repair was performed. All patients had antibiotic prophylaxis with a Cephalosporin. In one out of 61 patients the operation was converted to an open procedure because of an inadvertent enterotomy. The mean duration of the operative procedure was 111.9 min (range 55-295 min). The mean size of the trephine opening was 31.92 cm^2 (range 6-169 cm^2).

Age	Mean 63 years (36-83)
Gender	M 40 (65,6%) - F 21 (34,4%)
BMI	30,9 (18,6-51)
ASA	I 5 (8,2%) - II 34 (55,7%) - III 20 (32,8%) - IV 2 (3.3%)
Comorbidity	9 Coronary Disease - 1 Diabetes - 5 COPD - 2 IBD
Stoma type	55 colostomy - 4 ileostomy - 2 urostomy
Indication for stoma	43 colorectal and anal malignancy - 2 bladdercarcinoma - 6 IBD (4 CU - 2 Crohns disease) 6 diverticulitis - 3 incontinence - 1 benign rectal stenosis
Previous PSH repair	7 Open mesh repair - 1 Primary suture repair - 3 Laparoscopic keyhole technique
Symptoms	10 stomacare problems - 18 intermittent bowel obstruction - 31 pain 2 problems with bowel irrigation - 26 cosmetic complaints - 2 incarceration

Table 1 ***Demographic data***

Adhesions were present in 54 patients: Grade 1 adhesions in 22 patients, Grade 2 in 15 and Grade 3 in 17 patients. No severe hemorrhages were reported. In 25 patients a concomitant incisional hernia was found during laparoscopy. In all cases this hernia could be repaired at the same time just by using a larger mesh or by using an additional mesh in 4 patients. The mean size of the mesh used was 331.54 cm^2 (range 225-884 cm^2). The mesh was fixed to the abdominal wall with spiral tacks (Protack®, Covidien, Mansfield, MA, USA) in all 61 patients. In 27 patients cardinal sutures and in 16 patients fibrin glue was used as well, to fix the prosthesis.

One patient had a small bowel obstruction due to a metastasized lung carcinoma, and died one month after operation. Overall morbidity was 19% (12 patients). Surgical complications occurred in 11 patients (18%): wound infection (n=1), postoperative ileus needing insertion of a nasogastric tube (n=6) and trocar site bleeding (n=2). In two patients a reintervention was done. One patient had a mesh infection and the mesh was removed via a laparotomy. One patient had a postoperative pneumonia. No other medical complications occurred. The mean hospital stay was 5 days (range 1-21 days).

Follow-up

During follow-up the mesh was removed in one patient undergoing total colectomy and ileostomy. At the time of operation, no recurrence was detected. All patients were seen in the outpatient clinic for clinical evaluation of their stoma. The mean follow-up time was 26 months. Seroma formation occurred in 12 patients (20%) and was treated conservatively in all patients. Recurrent symptomatic hernias were found in 3 out of 60 patients (5%), including one as a result of mesh removal for infection. Recurrences occurred after 6,10 and 20 months, respectively.

In 27 of the 60 patients a CT or MRI scan was made after a mean follow-up of 20.4 months (range 12-64 months). In one of the participating centers a CT or MRI was made routinely, after one or two years. One of these 19 patients had an asymptomatic hernia. The other 8 CT scans were made on indication. None of these patients had a recurrent hernia. Overall, a recurrent hernia was found in 4 out of 61 patients (6.6%).

Discussion

The laparoscopic Sugarbaker technique is a safe procedure to repair parastomal hernias. Overall morbidity is 19% and recurrence rate 6,6%, after a mean follow-up of 26 months.

The present study is a retrospective multicenter study. Therefore, the perioperative complication rate may be underreported. Recurrence rate was determined during follow-up for stoma evaluation, at least after one year. All patients

underwent physical examination without performing imaging routinely. Therefore, it is reasonable to assume that overall recurrence rate might be higher than reported.

Laparoscopic parastomal hernia repair is a safe and feasible procedure [15]. Conversion to open repair is rare. In a recent review of Hansson and co-workers, a conversion to open repair was reported in 3.6% of 363 laparoscopic repairs [4]. Reasons for conversion were multiple dense adhesions in six patients, intra-operative full-thickness bowel injury in another six procedures and an inaccessible abdomen in one patient. Iatrogenic, intra-operative bowel lesions were reported in 4.1%. Conversion rate (1.6%) and inadvertent enterotomy rate (1.6%) were less frequent is our study, probably because all procedures were done by experienced laparoscopic surgeons.

Overall morbidity in this study was 19% which is similar to the morbidity rate of 17.2% (95%-CI 13.4-21.3) of laparoscopic parastomal hernias in a recent meta-analysis [4]. Also, the kind of complications were similar: Wound infection in 3.3% (95%-CI 1.6-5.7), mesh infection in 2.7% (95%-CI 1.2-5.0) and other complications in 12.7% (95%-CI 9.4-16.8). Most complications resolve without further consequences, however, mesh infection often results mesh removal and a recurrent hernia.

In our present study, all repairs were done, using an e-PTFE patch. At this moment, e-PTFE is the most frequently used prosthetic material for parastomal hernia repair. It is soft and pliable and gives less severe adhesions to the viscera, compared to polypropylene meshes [16]. If adhesions occur, the bowel can be easily dissected free from the prosthesis [17].

The hydrofobicity of e-PTFE and the lack of ingrowth of fibrocollagenous tissue into the prosthesis makes it vulnerable for infection [18]. Microorganisms can easily settle into the micropores of the prosthetic material which makes them unreachable for granulocytes and macrophages. Therefore infection of an e-PTFE prosthesis results almost always in removal of the prosthesis. Laparoscopic (parastomal) hernia repair is considered to be a clean operation because contact between prosthesis and bowel contents is avoided. In the only prospective series reporting on the laparoscopic repair of 55 parastomal hernias with an e-PTFE patch, prosthetic infection was found in 3.6 % [19]. These results are in corroboration with those of several other studies as reviewed by Hansson et al [4]. Although the use of an e-PTFE prosthesis is safe, the authors advise to be reluctant in using these prosthesis in a contaminated field, for example after inadvertent large bowel enterotomy.

The lack of ingrowth of fibrocollagenous tissue into this microporous structured mesh, and its tendency to shrink due to intense inflammatory reaction of the host may increase the risk of reherniation [16,20]. Initiallly, anchorage of the patch

to the adjacent fascia solely depends on sutures and tacks. Later a fibrocollagenous envelop develops around the prosthesis, which will anchor the prosthesis to the fascia. In experimental studies, it was found that the patches shrink due to retraction of the enveloping tissue. Therefore, an overlap of at least 4 cm between the fascia and the prosthesis is advocated. In clinical practice the problem may be less outspoken. Rakic et al. reported that shrinkage of ePTFE in 656 patients undergoing laparoscopic hernia repair was only 7.5% when measured by CT [21]. This was recently confirmed by Leblanc and co-workers who reported a mean shrinkage rate of 6.7% confirming that ePTFE has minimal contraction in the human clinical situation [22].

Overall recurrence rate in our series was 6.6%. In literature, recurrence rates of the laparoscopic Sugarbaker technique are somewhat higher. In a recent meta-analysis reporting on 6 studies on 110 Sugarbaker repairs, a recurrent hernia was reported in 13 patients (11.6% (95%-CI 6.4-18.0)) [9,23,26,27,28,30]. Recurrence rate of the keyhole technique tended to be higher than the Sugarbaker technique. In seven studies reporting on 160 repairs using the keyhole technique [19,23,24,25,26,27,28], recurrences were reported in 38 patients (34.6% (95%-CI 15.0-27.3)). All studies had a follow-up of at least 12 months [4]. In four series repairs were done with either the Sugarbaker or the keyhole technique. In all studies the recurrence rate was lower in the Sugarbaker group. Muysoms et al. noted a recurrence in 2 out of 13 (15%) patients after Sugarbaker repair and 8 out of 11 (73%) patients after keyhole repair [28]. Craft and colleagues reported no recurrences using the Sugarbaker technique and 1 out of 5 repairs done with the keyhole technique [27]. Pastor et al. reported a reherniation in 2 out of 7 (28.6%) patients after Sugarbaker repair and 2 out of 3 patients after keyhole repair [26].

Recurrence rates may be further reduced by using a polypropylene prosthesis that is fully incorporated into native tissue. Most surgeons are reluctant to implant polypropylene meshes into the abdomen because its tendency to cause severe adhesions and even visceral damage which may have serious complications and huge consequences during reoperations [30]. Berger et al. used intraperitoneally placed PVDF-PP meshes (Dynamesh®) in 47 patients using a combination of the Sugarbaker and keyhole technique, better known as the Sandwich technique. Only one patient developed a wound infection and three patients underwent revision; two because of stenosis and one due to an abscess. Recurrence rate of 2% was reported [31]. Although a recurrence rate of 6.6% in our study is very promising, we must keep in mind that the incidence of reherniation of incisional hernias will always increase over time, as stated by Jeekel and coworkers [32]. For this reason, Flum reinforced the importance of a follow-up of at least 5 years in comparing new techniques in hernia repair [33].

Reviewing the literature, no report on parastomal hernia repair meets this criterium. Therefor the authors of this paper intend to report long-term results on these patients after 5 and 10 years.

Final Conclusion

Laparoscopic parastomal hernia repair using the Sugarbaker technique with an e-PTFE mesh is safe and feasible in experienced hands.

Our study shows an overall morbidity of 19 % and a recurrence rate of 6,6 % after a mean follow-up of 2 years.

Laparoscopic approach reveals a concomitant incisional hernia in 41% of the patients that could be repaired at the same time in all cases.

Besides that, laparoscopy is minimally invasive to the patients abdominal wall which is already at risk for herniation.

References

1 *Pearl RK. Parastomal hernias. World J Surg 1989;13:569-572*

2 *Carne PWG, Robertson GM, Frizelle FA. Parastomal hernia. Br J Surg 2003;90:784-793*

3 *Israelsson LA. Parastomal hernias. Surg Clin North Am 2008; 88:113-125*

4 *BME Hansson, NJ Slater, AP Schouten van der Velden, HMM Groenewoud, OR Buyne, IHJT de Hingh, RP Bleichrodt. Surgical techniques for parastomal hernia repair: a systematic review of the literature. Ann Surg 2012;255:685-695*

5 *Sugarbaker PH. Peritoneal approach to prosthetic mesh repair of paraostomy hernias. Ann Surg 1985;201:344-346*

6 *de Vries Reilingh TS, van Geldere D, Langenhorst B, de Jong D, van der Wilt GJ, van Goor H, Bleichrodt RP. Repair of large midline incisional hernias with polypropylene mesh: comparison of three operative techniques. Hernia 2004;8:56-59*

7 *Heniford BT, Park A, Ramshaw B, Voeller G. Laparoscopic repair of ventral hernias. Nine years' experience with 850 consecutive hernias. Ann Surg 2003;238:391-400*

8 *Forbes SS, Eskicioglu C, McLeod RS, Okrainec A. Meta-analysis of randomized controled trials comparing open and laparoscopic ventral and incisional hernia repair with mesh. Br J Surg 2009; 96:851-858*

9 *Berger D, Bientzle M. Polyvinylidene fluoride: a suitable mesh material for laparoscopic incisional and parastomal hernia repair! A prospective, observational study with 344 patients. Hernia 2009;13:167-172*

10 *Mizrahi H, Bhattacharya P, Parker MC. Laparoscopic slit mesh repair of parastomal hernia using a designated mesh: long-term results. Surg Endosc 2012;26:267-270*

11 *Zülke HV, Lorenz EM, Straub EM, Sawas V. Pathophysiology and classification of adhesions. Langenbecks Arch Chir Suppl II Verh Dtsch Ges Chir 1990;1009-1016. German*

12 *Muysoms F.E. Laparoscopic repair of parastomal hernias with a modified Sugarbaker technique. Acta Chir Belg 2007;107:476-480*

13 *Morales-Conde S, Cadet H, Cano A, Bustos M, Martin J, Morales-Mendez S. Laparoscopic ventral hernia repair without sutures-Double Crown Technique: our experience after 140 cases with a mean follow-up of 40 months. Int Surg 2005;90:56-62*

14 *Cingi A, Tebessum Carik, Sever A, Aktan AO. Enteroteomy site hernias: a clinical and computerized tomographic evaluation. Dis Colon Rectum 2006;49:1559-1563*

15 *Hansson BME, de Hingh IHJT, Bleichrodt RP. Laparoscopic parastomal hernia repair is feasible and safe: early results of a prospective clinical study including 55 consecutive patients. Surg Endosc 2007;21:989-993*

16 *Simmermacher RK, Schakenraad JM, Bleichrodt RP. Reherniation after repair of the abdominal wall with expanded polytetrafluoroethylene. J Am Coll Surg. 1994;178:613-616*

17 *Wassenaar EB, Schoenmaeckers EJP, Raymakers JFTJ, Rakic S. Subsequent abdominal surgery after laparoscopic ventral and incisional hernia repair. Hernia 2010;14:137-142*

18 *Bleichrodt RP, Simmermacher RK, van der Lei B, et al. Expanded polytetrafluoroethylene patch versus polypropylene mesh for the repair of contaminated defects of the abdominal wall. Surg Gynecol Obstet. 1993;176:18-24*

19 *Hansson BME, Bleichrodt RP, De Hingh IHJT. Laparoscopic parastomal hernia repair using a keyhole technique results in a high recurrence rate. Surg Endosc 2009;23:1456-1459*

20 *Van der Lei B, Bleichrodt RP, Simmermacher RK, et al. Expanded polytetrafluoroethylene patch for the repair of large abdominal wall defects. Br J Surg 1989;76:803-805*

21 *Schoenmaeckers EJP, van der Valk SBA, van den Hout HW, Raymakers JFTJ, Rakic S. Computed tomographic measurements of mesh shrinkage after laparoscopic ventral and incisional hernia repair with an expanded polytetrafluoroethylene mesh. Surg Endosc 2009;23:1620-1623*

22 *Carter PR, Leblanc KA, Hausmann MG, Whitaker JM, Rhynes VK, Kleinpeter KP, Allain BW. Does expanded polytetrafluoroethylene mesh really shrink after laparoscopic ventral hernia repair? Hernia 2012;16:321-325*

23 *LeBlanc KA, Bellanger DE, Whitaker JM, et al. Laparoscopic parastomal hernia repair. Hernia 2005;9:140-144*

24 *Safadi B. Laparoscopic repair of parastomal hernias. Early results. Surg Endosc 2004;18:676-680*

25 *Wara P, Andersen LM. Long-term follow-up of laparoscopic repair of parastomal hernia using a bilayer mesh with a slit. Surg Endosc 2011;25:526-530*

26 *Pastor DM, Pauli EM, Koltun WA, et al. Parastomal hernia repair: a single center experience. JSLS 2009;13:170-175.*

27 *Craft RO, Huguet KL, McLemore EC, et al. Laparoscopic parastomal hernia repair. Hernia 2008;12:137-140.*

28 *Muysoms FE, Hauters PhJ, Van Nieuwenhove Y, Huten N, Claeys DA Laparoscopic repair of parastomal hernias: a Multicenter retrospective review and shift in technique. Acta Chir Belg 2008; 108:400-404*

29 *Mancini GJ, McClusky DA, Khaitan L, et al. Laparoscopic parastomal hernia repair using a nonslit mesh technique. Surg Endosc 2007; 21:1487-1491*

30 *Halm JA, de Wall LL, Steyerberg EW, Jeekel J, Lange JF. Intraperitoneal polypropylene mesh hernia repair complicates subsequent abdominal surgery. World J Surg 2007;31:423-429*

31 *Berger D, Bientzle M. Laparoscopic repair of parastomal hernias: a single surgeon's experience in 66 patients. Dis Colon Rectum 2007;50:1668-1673*

32 *Burger JW, Luijendijk RW, Hop WC, Halm JA, Verdaasdonk EG, Jeekel J. Long-term follow-up of a randomized controlled trial of suture repair versus mesh repair of incisional hernia. Ann Surg 2004;240:578-578*

33 *Flum DR, Horvath K, Koepsell T. Have outcomes of incisional hernia repair improved with time? Ann Surg 2003;237:129-135*

Birgitta Hansson

Chapter 8 Prevention of parastomal hernia with a prosthetic mesh The PREVENT-TRIAL: a multicenter randomized controlled trial

H.T. Brandsma, B.M.E. Hansson, H van Haaren-de Haan, T.J. Aufenacker, C. Rosman, R.P. Bleichrodt Submitted Trials

Birgitta Hansson

Abstract

Background

Parastomal hernia is a common complication of a colostomy. Ultimately, one third of patients with a parastomal hernia will need surgical correction due to frequent leakage or life-threatening bowel obstruction or strangulation. However, treatment remains a challenge resulting in high recurrence rates. Two single center trials demonstrated that the frequency of parastomal hernias decreases by prophylactic placement of a mesh around the stoma at the time of creation. Unfortunately, both studies were underpowered which was the reason to initiate a prospective randomized multicenter trial to determine if a retromuscular, preperitoneal mesh at the place of the stoma prevents parastomal hernia.

Methods

One hundred and fifty patients undergoing elective formation of a permanent end-colostomy will be randomized into two groups. In the intervention group a colostomy is created with placement of a preperitioneal, retromuscular lightweight monofilament polypropylene mesh, and compared to a group with a traditional stoma without mesh. Patients will be recruited from 14 teaching hospitals in the Netherlands during a two year period. Primary endpoint is the incidence of parastomal hernia. Secondary endpoints are stoma complications, cost-effectiveness and quality of life and pains scores. Follow-up will be performed at three weeks, three months and at , one-, two- and five years. To find a difference of 20% with a power of 90%, a total number of 134 patients must be included. All results will be reported according to the CONSORT 2010 statement.

Discussion

The Prevent-trial is a multicenter randomized controlled trial powered to determine whether prophylactic placement of a polypropylene mesh decreases the incidence of a parastomal hernia versus the traditional stoma formation without a mesh.

Trial registration

The Prevent-trial is registered at: www.trialregister.nl/trialreg/admin/rctview.asp?TC=2018

Introduction

Colorectal cancer is, together with breast cancer, the most common malignancy in the Netherlands. The incidence of colorectal cancer was over 12000 in the year 2009. About 28000 patients have an enterostomy, of which roughly 60%-70% have a colostomy [1]. About half of the patients with a colostomy develops a parastomal hernia over time [2].

Probably, the true incidence is underestimated because many of these hernias are asymptomatic. Cingi et al. showed that 52% of their patients with a colostomy had a parastomal hernia at clinical examination, while additional computed tomography yielded an incidence of 78% [3].

Symptoms include pain due to stretching of the abdominal wall, leakage due to poor fitting appliances, skin problems and cosmetic complaints. Moreover, bowel obstruction and strangulation of the hernia contents may be life-threatening. Despite evolution of surgical techniques, incidence rates have not declined the past 20 years [4]. Ultimately, one third of the patients with a PSH needs surgical correction [5,6].

Parastomal hernia repair is challenging and results vary markedly between techniques. Suture repair, narrowing the opening in the fascia, is considered an obsolete procedure because the recurrence rates are over 70%. Relocation of the stoma is associated with a recurrence rate of 33% with an additional risk of developing an incisional hernia in the midline or at the old ostomy site of 20% [2,7,8,9]. Nowadays, prosthetic repair is the gold standard of parastomal hernia repair. Several techniques have been developed having similar results with respect to morbidity and recurrence rate [10]. In the last decade, laparoscopic repair of PSH was developed. Basically two techniques are used, the modified Sugarbaker technique and the keyhole technique, of which the last seems to have a significantly higher risk of recurrence.

Because of the high incidence, inconsistent results of available data on parastomal repair and lack of sufficient treatment options, surgeons started focussing on prevention of the hernia with local reinforcement of the abdominal wall using a prosthetic mesh. At time of writing the Prevent-trial protocol in 2009, only a few reports on this topic were published (table 1). Two recent reviews showed that parastomal hernias can be prevented by implantation of a preperitoneal, retromuscular mesh around the stoma [11,12]. Randomized trials from Jänes and Serra-Aracil, both using a light-weight polypropylene mesh in a preperitoneal retromuscular position, found significantly more parastomal hernias in the group with a conventional stoma (53.7%) as compared to the mesh group (14,8%; p <0,001). Mesh related complications are rare. Serra-Aracil reported on three woundinfections, one peristomal infection and one necrosis of the stoma in both

groups. Jänes reported no mesh-related complications (table 1). The percentage of patients who required surgical intervention decreased in the mesh group in comparison with the non-mesh group. Seven out of 54 patients in the non-mesh group required surgical repair versus none in the mesh group [13,14].

Unfortunately the trials were small, 27 patients per group, although a meta-analysis offers compensation for this flaw, sample size still be too small for detecting a difference when events occur infrequent. Furthermore the risk of bias increases due to a variability of clinical factors and non-uniform reporting of clinical parameters such as stoma site, patient characteristics and type of surgery all contributed to the heterogeneity. Due to these shortcomings there is need for more methodologically sound trials.

Methods

Study objectives

The aim of this single blind, multicenter randomized controlled trial is to determine if parastomal herniation is prevented by the prophylactic placement of a polypropylene mesh around a colostomy during open surgery. Patients are randomized into two groups. In one group a preperitoneal, retromuscular positioned polypropylene mesh is placed around the stoma. In the control group a conventional stoma is created. It was hypothesized that mesh placement will reduce the incidence of parastomal hernia by 20%.

	Follow-up Months	Repair	n	PSH n (%)	Complications n (%)
Jänes et al.[13]	65 (57-83)	Polypropylene Mesh (Vypro®)	27	2 (13%)	None
		Non-Mesh	27	17 (81%)	None
Serra-Aracil et al.[14]	29 (13-49)	Polypropylene Mesh (Ultrapro®)	27	6 (22%)	Woundinfection 3 (11%), Peristomal infection 1 (3,7%), Stoma necrosis 1 (3,7%)
		Non-Mesh	27	12 (44%)	Woundinfection 3 (11%), Peristomal infection 1 (3,7%), Stoma necrosis 1 (3,7%)

Table 1 ***Data from all randomized controlled trials regarding prevention of parastomal hernias (PSH) with a peristomal retromuscular mesh***

Primary endpoint
The primary endpoint is the incidence of parastomal hernia, either symptomatic or asymptomatic.

Secondary endpoints
Secondary endpoints are perioperative morbidity and mortality, pain and cost effectiveness.

Patient sample size
Based on available literature it is hypothesized that 30% of patients will develop a parastomal hernia, the majority in the first few years. Based on published data it is assumed that parastomal hernia will occur in 10% in the study group receiving the prophylactic mesh. This study is powered to reveal significant differences between the two study groups. With a two-sided log-rank test with an Alpha error of 5% and a power of 90%, 67 patients need to be included in each arm of the trial. We decided to include a total of 150 patients which are randomly allocated in both groups. Analyses of recorded Prismant data estimate that 600 colostomies are constructed each year in the Netherlands. It is expected that the inclusion period will take two years and 15 hospitals are required to participate.

Setting
Patients receiving a permanent end-colostomy in an elective setting will be recruited from the following centers: Canisius-Wilhelmina Hospital, Nijmegen; Radboud University Nijmegen Medical Center, Nijmegen; Rijnstate Hospital, Arnhem; Maxima Medisch Centrum, Veldhoven; St Antonius Hospital, Nieuwegein; Catharina Hospital, Eindhoven; AMC Amsterdam, Amsterdam; OLVG, Amsterdam; University Medical Center Utrecht; Utrecht; Isala Clinics, Zwolle; Erasmus Medical Center, Rotterdam; Slingeland Hospital, Doetinchem; Medisch Spectrum Twente, Enschede; Albert Schweitzer Hospital, Dordrecht, The Netherlands

The total trial period is estimated to be 7 years; the recruitment period will be 2 years, followed by a 5 year follow-up period.

Inclusion criteria
- Patients undergoing formation of an end-colostomy in an elective setting
- Age between 18 and 85 years
- Signed Informed Consent
- Able to understand the study questionnaires

Exclusion criteria
- Expected survival less than 12 months
- Correction of a previous constructed colostomy
- Previous surgery at the colostomy site

Ethical Considerations
This trial is conducted in accordance with the Declaration of Helsinki and "Good Clinical Practice Guidelines". It is approved by the Medical Ethics Committee of Nijmegen (CMO-ABR 22695). All local Medical Ethics Committees approved the final protocol. Patients willing to participate in the trial will be provided with a patient information sheet and a reconsideration period. They will be included after written informed consent is obtained.

The Prevent-trial is registered at
www.trialregister.nl/trialreg/admin/rctview.asp?TC=2018

Reporting
All results will be reported according to the CONSORT 2010 statement.

Randomization
Randomization will be performed by telephone using an interactive voice response system. Patients are randomized by computer, treatment will be stratified and blocked by center to ensure each center has similar numbers of patients allocated to one of the two treatment groups.

Safety and Quality control
The trial coordinator will monitor all centers in order to identify non-compliance to protocol and Serious Adverse Events. SAE's are defined as any event leading to major complications and/or prolonged hospital stay due to the placement of the mesh. SAE's will be reported to the Data Safety Monitoring Board and to the accredited Medical Ethical Board (METC). A Data Safety Monitoring Board will perform interim safety analyses and make recommendations regarding the conduct of the study to the accredited METC and the trial committee. When the mesh related complication rate is higher than 15%, the trial will be terminated.

Preoperative work-up
In an outpatient setting all participants receive information and guidance by a stomal therapy nurse. Stoma site marking is performed by a stomal therapy nurse prior to surgery. Colonic lavage will be performed if necessary. In both groups pre-operative antibiotic prophylaxis will be given according to the local agreements.

Surgical Techniques
A light- weight monofilament polypropylene mesh, Parietene Light™ (Covidien®) is used throughout the study. This mesh is chosen because there is level 2b evidence that shrinkage of the mesh, postoperative foreign body sensation and pain are less than after implantation of traditional polypropylene mesh [15,16].

According to the technique of Jänes and Israëlsson, the intended bowel for the colostomy is closed with a stapling device, thus minimizing the chance of contamination. The trephine is created by excision of the skin-oval at the pre-operatively marked ostomy site. No subcutaneous tissue is excised. After exposing the anterior rectus sheath, a cross-shaped incision is made in the fascia. The rectus abdominus muscle is split in the direction of the fibers. In the mesh group a retromuscular space is created and dissected to the lateral border via the median laparotomy. The posterior fascia/peritoneum is left undisturbed. A 10x10cm Parietene Light™ mesh, with a cross-shaped incision in the center of the prosthesis to allow passage of the colon loop, is placed on the posterior rectus sheath (figure 1). The lateral corners of the mesh are fixed with two absorbable monofilament sutures. Then the posterior fascia is opened over the trephine in the mesh and the bowel is gradually passed through. Closing the midline incision, the running suture includes the medial border of the mesh and the peritoneum, thus preventing contact between the mesh and the viscera (figure 2).

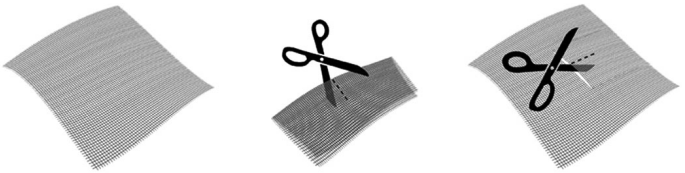

Figure 1 *10 x 10 cm mesh with cross-shaped incision*

The stoma prominates 1 cm and is fixed with everting resorbable sutures to the skin [13].

Follow-up and Definitions of complications

Outpatient follow-up is scheduled at 3 weeks, 3 months, 1, 2 and 5 years post-operatively. Post-operative complications, such as peristomal infections, degree of stomal ingrowth and leakage are recorded.

- Parastomal hernia is defined as a symptomatic hernia or a hernia present at physical examination.
- Prolapse is scored if significant prolabation of bowel occurred causing the stoma to increase in length.
- Wound infection was defined in deep, superficial or peristomal infections using the C.D.C criteria for surgical site infection [17].
- Stomal dehiscence was defined as separation of the bowel mucosa from the skin, measured in millimetres.
- Stenosis is defined as narrowing of the stoma trephine leading to stomal obstruction.
- Leakage is present if stomal material has to be replaced more than once every two days.

If there is a clinical or physical suspicion of a hernia a CT scan will be performed. Quality of Life is determined using validated health scores preoperatively and during all moments of follow-up after the index operation.

Health status scores

- The SF-36 is a validated multi-purpose, short-form health survey. It yields an 8-scale profile of functional health and well-being scores as well as physical and mental health summary measures and a preference-based health utility index [18,19]. Completed preoperatively, 1 year and 5 years after index operation
- Questionnaire of von Korff for Grading the Severity of Chronic Pain will be completed at 3 months and one year after the index operation [20].

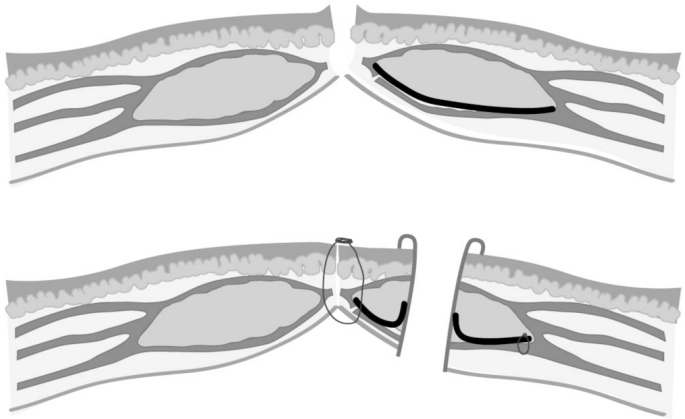

Figure 2 ***Positioning of the mesh after closure of the abdomen***

- EuroQoL-5D is an instrument which calculates an index which gives a societal-based quantification of the patients health status combined with a visual analogue scale [21]. This so-called health-related quality of life (HRQoL) instrument will be completed during every moment of follow-up. This index gives a societal-based global quantification of the patient's health status.

Cost analysis

The cost analysis exists of two main parts. First, on patient level, volumes of care will be measured prospectively using case record forms. Per arm (intervention and control) full cost-prices will be determined using activity based costing. Productivity losses for patients (sick leave) will be estimated by using the case record forms (CRF's). The friction cost-method will be applied following the Dutch guidelines [22].

The second part of the cost analysis consists of determining the cost prices for each volume of consumption in order to use these for multiplying the volumes registered for each participating patient. The Dutch guidelines for cost analyses will be used. For units of care/resources where no guideline or standard prices are available real cost prices will be determined.

Data collection

All data will be collected in personal CRF's, which will be stored in the patient's own hospital. Copies of the completed

forms will be sent to our coordinating center (Canisius-Wilhelmina Hospital, Nijmegen). All data will be stored in a double-entry database (SAS). Independent monitoring visits will be performed throughout the entire duration of the trial. When patients are not treated according to their allocation, for any reason, they will stay in the trial following the Intention-to-Treat-principle.

Trial status

The Prevent-trial is currently open for recruitment. We expect to reach our powered number of included patients in the coming months.

List of abbreviations

PSH: parastomal hernia
CRF: Case record form
RCT: Randomized Controlled trial

Acknowledgements and funding

The Prevent-trial is an investigator-initiated study supported in part by Covidien® without scientific influence.
It is sponsored by ZonMW, The Netherlands Organization for Health Research and Development. Projectnumber 170991011

References

1 *Data retrieved from the Dutch Cancer Registry and the Dutch Stoma Association.*
2 *Cheung MT, Chia NH, Chiu WY. Surgical treatment of parastomal hernia complicating sigmoid colostomies. Dis Colon Rectum 2001; 44:266-270*
3 *Cingi A, Cakir T, Sever A, Aktan AO. Enterostomy site hernias: a clinical and computerized tomographic evaluation. Dis Colon Rectum 2006;49:1559-1563*
4 *Sjodahl R, Anderberg B, Bolin T. Parastomal hernia in relation to site of the abdominal stoma. Br J Surg 1988;75:339-341*
5 *Burns FJ. Complications of colostomy. Dis Colon Rectum 1970; 13:448-450*
6 *Shellito PC. Complications of abdominal stoma surgery. Dis Colon Rectum 1998;41:1562-1572*
7 *Pastor DM, Pauli EM, Koltun WA, Haluck RS, Shope TR, Poritz LS. Parastomal hernia repair: a single center experience. JSLS 2009; 13:170-175*
8 *Riansuwan W, Hull TL, Millan MM, Hammel JP. Surgery of recurrent parastomal hernia: direct repair or relocation? Colorectal Dis 2010;12:681-686*
9 *Rubin MS, Schoetz DJ, Jr., Matthews JB. Parastomal hernia. Is stoma relocation superior to fascial repair? Arch Surg 1994;129:413-418; discussion 418-419*

10 *Hansson BME, Slater NJ, Schouten van der Velden AP, Groenewoud HMM, Buyne OR, de Hingh IJT, Bleichrodt RP. Surgical techniques for parastomal hernia repair: a systematic review of the literature. Ann Surg 2012;255(4):685-695*

11 *Tam KW, Wei PL, Kuo LJ, Wu CH. Systematic review of the use of a mesh to prevent parastomal hernia. World J Surg 2010;34:2723-2729*

12 *Wijeyekoon SP, Gurusamy K, El-Gendy K, Chan CL. Prevention of parastomal herniation with biologic/composite prosthetic mesh: a systematic review and meta-analysis of randomized controlled trials. J Am Coll Surg 2010;211:637-645*

13 *Jänes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study. World J Surg 2009;33:118-121; discussion 122-113*

14 *Serra-Aracil X, Bombardo-Junca J, Moreno-Matias J, Darnell A, Mora-Lopez L, Alcantara-Moral M, Ayguavives-Garnica I, Navarro-Soto S. Randomized, controlled, prospective trial of the use of a mesh to prevent parastomal hernia. Ann Surg 2009;249:583-587.*

15 *Agarwal BB, Agarwal KA, Sahu T, Mahajan KC. Traditional polypropylene and lightweight meshes in totally extraperitoneal inguinal herniorrhaphy. Int J Surg 2010;8: 44-47*

16 *Chui LB, Ng WT, Sze YS, Yuen KS, Wong YT, Kong CK. Prospective, randomized, controlled trial comparing lightweight versus heavyweight mesh in chronic pain incidence after TEP repair of bilateral inguinal hernia. Surg Endosc 2010;24:2735-2738*

17 *Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. Am J Infect Control 1999;27:97-132; quiz 133-134; discussion 196*

18 *McHorney CA, Ware JE, Jr, Lu JF, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. Med Care 1994;32:40-66*

19 *Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-483*

20 *Von Korff M, Dworkin SF, Le Resche L. Graded chronic pain status: an epidemiologic evaluation. Pain 1990;40:279-291*

21 *Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med 2001;33:337-343*

22 *Oostenbrink JB, Koopmanschap MA, Rutten FF. Standardisation of costs: the Dutch Manual for Costing in economic evaluations. Pharmacoeconomics 2002;20:443-454*

Birgitta Hansson

Chapter 9 Summary and general discussion

Birgitta Hansson

Summary

The aim of the investigations described in this thesis is to improve surgical treatment of patients with a parastomal hernia, with a focus on laparoscopic techniques.

In **chapter 2** we describe the so-called Keyhole technique, a new laparoscopic technique to repair parastomal hernias. This technique combines suture repair with mesh repair. The trephine opening is narrowed with non-resorbable sutures, and subsequently, the suture line and part of the trephine opening are covered with an expanded-PTFE prosthesis (Gore-Tex Dual Mesh®). The mesh, which has a central keyhole defect, is draped around the stoma loop and fixed to both the peritoneum and the underlying fascia by means of staples. The central, cylindrical part of the mesh is fixed to the bowel loop with non-resorbable sutures. We used this technique in four patients with a parastomal hernia and found that it proved to be a safe technique with good short-term results.

The pilot study was followed by a prospective multicenter cohort study that included 55 consecutive patients. In **chapter 3** we present the short-term results after a six weeks follow-up. Of the 55 procedures, 47 (85.5%) were completed laparoscopically. Conversion to laparotomy was indicated in a total of eight patients (14.5%), in four patients this was due to dense adhesions prohibiting safe dissection; and due to inadvertent bowel injury in another four patients. No in-hospital mortality occurred. Post-operative recovery was uneventful in 47 patients (85%); all patients had a median hospital stay of four days. Surgical (n=4) and nonsurgical (n=4) complications occurred in eight patients (14.5%). Inadvertent full-thickness enterotomy (n=6) appeared to be the most troublesome complication. We re-examined all patients six weeks post-operatively; only one recurrence was diagnosed at that time. We concluded that laparoscopic parastomal hernia repair with the Keyhole technique is both a safe and feasible surgical method with good short-term results.

In order to evaluate the long-term results, patients were seen at regular intervals postoperatively, over a period of two years. In **chapter 4** we present the results of this follow-up period. Recurrent parastomal hernias were diagnosed in 20 patients (37%). Three recurrences were asymptomatic. The other 17 patients (85%) developed mild to severe symptoms that led to reoperation in nine patients. Surprisingly, satisfaction with the procedure was high among patients (89%), even in the presence of a recurrence. Patients who reported unsatisfactory results mainly belonged to the group of patients for whom the procedure had to be converted to an open procedure. In conclusion, the laparoscopic parastomal hernia repair using the Keyhole technique with an e-PTFE

mesh resulted in an unacceptable high recurrence rate in the long-term.

These rather disappointing results warranted a systematic review of the literature on parastomal hernia repair, the results of which are presented in **chapter 5**. Thirty studies on the subject of open and laparoscopic repair of parastomal hernias met our inclusion criteria. The majority of these studies were retrospective. Clearly, suture repair resulted in a significantly higher recurrence rate than mesh repair. Recurrence rates for mesh repair ranged from 6.9% to 17%. We found no significant differences in outcome between the various techniques that were used. Laparoscopic repair can be performed by means of a Keyhole technique but also using the modified Sugarbaker technique. Hereby, a prosthetic mesh without a hole is used. After lateralization of the stoma loop, the trephine opening is completely covered with a mesh. Using a laparoscopic repair, the modified Sugarbaker technique showed fewer recurrences than the Keyhole technique (OR 2.3, 95% CI 1.2-4.6; p=0.016), while morbidity was similar in both the open and in the laparoscopic group. The overall rate of mesh infections, in both open and laparoscopic repair, was low (3%) and comparable for each type of mesh repair. We conclude that suture repair of parastomal hernias can no longer be considered a satisfactory technique due to the unacceptable high recurrence rate. The use of a mesh prosthesis in parastomal hernia repair significantly reduces recurrence rates. Furthermore, the use of mesh is judged to be safe with a low overall rate of mesh infection. Comparison of laparoscopic repair methods shows that the modified Sugarbaker technique appears to be superior to the Keyhole technique, as it results in fewer recurrences.

Biological prosthesis currently gains popularity in hernia surgery. The theoretical advantage is that one can avoid the placement of synthetic material in a contaminated area. A review of the available literature is presented in **chapter 6**. We included four retrospective studies with a total number of 57 patients. The use of biological grafts during parastomal hernia repair had an overall complication rate of 26.2%(14.7-39.5). No mortalities were reported. Wound infection occurred in three patients, but none of them involved the graft and all grafts were left in situ. Recurrence rate after a follow-up ranging from 8 to 50 months was 15.7% (95% CI 7.8-25.9). One can conclude that repair with biologic or synthetic prosthesis provides similar results. The possibility to leave the prosthesis in situ in case of an infection might be an advantage of biological over synthetic prostheses.

As we already have concluded in our systematic review, the laparoscopic modified Sugarbaker technique shows fewer recurrences than the Keyhole technique. Since the patient series were rather small and heterogeneity between the

studies large, we have decided to perform an international multicenter retrospective cohort study to evaluate the results of the modified Sugarbaker technique. The results of this study are presented in **chapter 7**. In total, 61 patients underwent laparoscopic parastomal hernia repair by means of the modified Sugarbaker technique using an e-PTFE prosthesis (Gore-Tex Dual Mesh®). All operations were performed laparoscopically. No inadvertent enterotomies occurred. The overall morbidity was 19%, including wound infection (n=1), ileus (n=2), trocar site bleeding (n=2), reintervention (n=2) and pneumonia (n=1). One patient died during the postoperative phase due to bowel obstruction that was caused by a metastasis of a lung carcinoma. Concomitant incisional hernias were detected in 25 out of 61 patients (41%). The overall recurrence rate was 6.6% after a mean follow-up of 26 months (range 12-64 months). We concluded that the laparoscopic modified Sugarbaker technique with an e-PTFE mesh is both safe and feasible, and shows a low recurrence rate. Moreover, the laparoscopic approach revealed concomitant hernias in 41% of the patients that could be repaired successfully at the same time.

In **chapter 8** we present a multicenter prospective randomized trial, the Prevent-trial, that compares two groups of patients for whom a colostomy is created during laparotomy, either with or without a retromuscular, preperitoneal mesh in order to prevent parastomal hernias.

General discussion

The treatment of parastomal hernias remains a challenging task for surgeons. A significant increase in the number of parastomal hernias is to be expected in the future. This is due to the increasing numbers of surviving cancer patients with an enterostomy and due to the fact that obesity is rapidly becoming a problem of endemic proportions. As obesity increases intra-abdominal pressure and stretches the abdominal wall, it may enlarge the trephine and subsequently promote herniation.

The systemic review in chapter 5 leads to the conclusion that suture repair is an obsolete technique, as recurrent parastomal hernias occurred in more than 70% of patients and wound infections were found in 12%. Stoma relocation shows an unacceptably high recurrence rate of 30% as well. However, if preventive mesh placement proves to be valuable, stoma relocation may regain its place as an optional treatment. At this moment, mesh repair remains the gold standard for parastomal hernia repair. Several techniques have been propagated such as the onlay mesh repair (e.g. Stovepipe), the Keyhole and the Sugarbaker technique. Although recurrence rates after open surgery were similar for all techniques, the modified Sugarbaker appears to be the best laparoscopic technique. Still, as few prospective or randomized controlled studies are available, one must be careful with interpreting

the results. Moreover, the heterogeneity between the available studies was significant.

In the first part of this thesis we present the early and long-term results of the laparoscopic Keyhole technique. Post-operative morbidity was rather high (29%). Inadvertent enterotomy occurred in 14.5% of patients and caused considerable morbidity. Nowadays, inadvertent enterostomy rates are much lower, as was demonstrated in our series of Sugarbaker repairs. With increasing awareness and experience, this complication will more than likely become an exception. Yet, the long-term results show a relatively high recurrence rate of 36%. The high recurrence rate of the Keyhole technique is explained by progressive widening of the central opening after stretching of the prosthesis as a result of (increased) intra-abdominal pressure.

In 1985 Sugarbaker developed a new open technique to repair parastomal hernias [1]. He fixed the prosthesis with sutures to the fascial edge of the trephine, without creating an overlap between the fascia and the prosthesis. Although his initial results were reported as excellent, the technique evolved over time. Nowadays, an overlap of at least 5 cm is created between the adjacent fascia and the prosthesis, in order to prevent re-herniation: the modified Sugarbaker technique. The prosthesis covers the widened trephine and counteracts the intra-abdominal pressure. Thus the prosthesis prevents widening of the trephine. In literature recurrence rates of 15% are reported after open Sugarbaker repair [2]. Not until 2005 studies have been published on laparoscopic parastomal hernia repair [3].

A recent meta-analysis reporting on 110 laparoscopic modified Sugarbaker repairs shows a recurrence rate of 11.6% (95%-CI 6.4-18.0). This is somewhat higher than the results from our multicenter cohort study in chapter 7, revealing a recurrence rate of only 6.6% after a median follow-up of 26 months (12-64 months). Albeit mainly based on retrospective non-randomised studies, these data suggest that the laparoscopic Sugarbaker repair results in a lower recurrence rate as compared to the open Sugarbaker repair. An additional advantage of the laparoscopic over the open approach is the detection of concomitant incisional hernias in 41% of patients that can be repaired simultaneously. Furthermore, laparoscopy is a minimally invasive technique, hereby sparing the abdominal wall of the patient and therefore decreasing the risk of future procedure related incisional hernias.

Taking these arguments in account, we conclude that the modified Sugarbaker technique is the method of choice to repair parastomal hernias, preferably by the laparoscopic approach. However, prospective studies with long-term follow-up must be performed to determine if our conclusion is justified.

Since the number of patients with an enterostomy will undoubtedly increase, prevention of parastomal hernias is of the utmost importance. Preventive efforts must be focussed on an adequate surgical technique, but also on prevention and treatment of diseases that cause increased intra-abdominal pressure, such as obesity and chronic cough. Recently, Israelsson et al. advocated the application of synthetic meshes around the stoma to prevent parastomal hernia [4]. In a recent meta-analysis from Wijeyekoon et al. it was found that placement of meshes around the enterostomy, at the level of the abdominal fascia, may considerably reduce the incidence of parastomal hernias [5]. Unfortunately, all studies that were included in this meta-analysis were underpowered. Therefore, we already have initiated a prospective randomized trial in order to determine if the application of a mesh can indeed prevent parastomal hernias in open surgery (Prevent-trial).

Apart from clinical studies, gathering more information about the incidence of parastomal hernias, the promoting factors and the results of surgical treatment could lead to further improvements. Recently, the EuraHS database (European registry of abdominal wall hernias) was launched. This database will provide us with an international online platform that allows for the registration of abdominal wall surgery, including the measurement of the various outcomes. This ambitious project is an initiative of the EuraHS working group formed under auspices of the European Hernia Society [6]. It is expected that the EuraHS database will become an important tool to collect important information with regard to parastomal hernias and that it will contribute to a decrease of this dreadful disease.

At the present time, we can conclude that laparoscopic parastomal hernia repair using the Sugarbaker technique is to be preferred.

Looking to the future, the on-going Prevent-trial may give further reduction of parastomal hernias after open surgery. With respect to the growing group of patients in whom a laparoscopic colostomy is created, we have decided to enrol a new trial, the Prevent-trial II. The goal of this new study is to place preventively a mesh in order to further decrease the unbearable consequences of a parastomal hernia.

References

1 *Sugarbaker PH. Peritoneal approach to prosthetic mesh repair of paraostomy hernias. Ann Surg 1985;201:344-346*

2 *Stelzner S, Hellmich G, Ludwig K. Repair of paracolostomy hernias with a prosthetic mesh in the intraperitoneal onlay position: modified Sugarbaker technique. Dis Colon Rectum 2004;47:185-191*

3 *Leblanc KA, Bellager DE, Whitaker JM, Hausmann MG. Laparoscopic parastomal hernia repair. Hernia 2005;9:140-144*

4 *Jänes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study. World J Surg 2009;33:118-121*

5 *Wijeyekoon SP, Gurusamy K, El-Gengy K, Chan CL. Prevention of parastomal herniation with biologic/composite prosthetic mesh: a systematic review and meta-analysis of randomized controlled trials. J Am Coll Surg 2010;211:637-645*

6 *Muysoms FE, Campanelli G, Champault GG, DeBaux AC, Dietz UA et al. EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal wall hernia repair. Hernia 2012;16:239-250*

Birgitta Hansson

Chapter 10 Samenvatting en algemene discussie

Birgitta Hansson

Samenvatting

Het doel van het onderzoek beschreven in dit proefschrift is het verbeteren van de chirurgische behandeling van patiënten met een parastomale hernia. Hierbij wordt er specifiek gekeken naar de laparoscopische technieken.

In **hoofdstuk 2** wordt de zogenaamde Keyhole-techniek beschreven, een nieuwe laparoscopische methode om parastomale hernia's te herstellen. Deze techniek combineert het vernauwen van de breukpoort met het plaatsen van een kunststof mat. De stoma opening wordt vernauwd met niet-resorbeerbare hechtingen en vervolgens worden deze hechtingen en een deel van de stoma opening bedekt met een mat (Gore-Tex Dual Mesh ®). De mat wordt voorzien van een centraal sleutelgatvormig defect en wordt rondom de stomalis gedrapeerd en zowel aan het peritoneum als aan de onderliggende fascie bevestigd. Het centrale cilindrische deel van de mat wordt met niet-resorbeerbare hechtingen bevestigd aan de darmlis die het stoma vormt. We pasten deze techniek toe bij vier patiënten met een parastomale hernia en stelden vast dat het een veilige techniek is met goede kortetermijnresultaten.

De pilot studie werd gevolgd door een prospectieve multicentrische cohortstudie waarin 55 opeenvolgende patiënten met een symptomatische parastomale hernia werden geïncludeerd. In **hoofdstuk 3** worden de kortetermijnresultaten na een follow-up van zes weken gepresenteerd. Van de 55 procedures werden er 47 (85,5%) laparoscopisch voltooid. Er was conversie naar een laparotomie noodzakelijk bij acht patiënten (14,5%). Bij de ene helft was dit te wijten aan stugge verklevingen en bij de andere helft kwam dit door een iatrogeen darmletsel. Er was geen mortaliteit. Het postoperatieve herstel was normaal bij 47 patiënten (85%). De mediane opnameduur was vier dagen. Chirurgische (n = 4) en niet-chirurgische (n = 4) complicaties kwamen voor bij acht patiënten (14,5%). Iatrogene perforatie van de darm was de meest problematische complicatie en kwam voor bij zes patiënten. Na zes weken werden alle patiënten opnieuw onderzocht waarbij één recidief van de parastomale hernia werd vastgesteld. We concludeerden dat het laparoscopisch herstel van een parastomale hernia door middel van de Keyhole-techniek een veilige en haalbare operatie is met goede resultaten op de korte termijn.

Om de langetermijnresultaten te evalueren, werden de patiënten na de operatie gedurende twee jaar gevolgd. In **hoofdstuk 4** presenteren we de resultaten van deze follow-up. Een recidief van de parastomale hernia werd gediagnosticeerd bij 20 patiënten (37%). Drie recidieven waren asymptomatisch. De overige 17 patiënten (85%) ontwikkelden lichte tot ernstige symptomen waarvoor bij negen patiënten een nieuwe operatie nodig was. Opmerkelijk

was dat de tevredenheid over de procedure hoog was onder de patiënten (89%), zelfs bij die patiënten die een recidief ontwikkelden. Degenen die niet tevreden waren behoorden vooral tot de groep bij wie de procedure moest worden geconverteerd naar een open procedure. We concludeerden dat het laparoscopisch herstel van een parastomale hernia door middel van de Keyhole-techniek op de lange termijn leidt tot een onaanvaardbaar hoog recidiefpercentage.

Deze teleurstellende resultaten stimuleerden ons om nogmaals de literatuur over de chirurgische behandeling van parastomaal hernia's te bestuderen. De resultaten van deze systematische review worden in **hoofdstuk 5** gepresenteerd. Dertig studies over open en laparoscopisch herstel van parastomale hernia's voldeden aan onze inclusiecriteria. De meerderheid van deze studies was retrospectief. Vernauwen van de breukpoort met hechtingen alleen resulteerde in een significant hogere kans op recidief dan herstel met behulp van een kunststof mat. Recidief percentages van een hersteloperatie met een mat varieerden van 6,9% tot 17%. We vonden geen significante verschillen in uitkomst tussen de verschillende technieken. Bij het laparoscopische herstel bleek de gemodificeerde Sugarbaker-techniek, een techniek waarbij een mat zonder gat gebruikt wordt, minder recidieven te hebben dan de bekende Keyhole-techniek (OR 2,3; 95% BI 1,2-4,6 p = 0,016). Het percentage van mat-infecties, zowel bij een open als een laparoscopisch operatie was laag (3%) en vergelijkbaar voor elk type ingreep. Wij concludeerden dat primair sluiten van parastomale breuken niet meer toegepast zou mogen worden wegens het onaanvaardbaar hoog recidiefpercentage. Het gebruik van een mat bij het herstellen van een parastomale hernia vermindert de kans op een recidief en is veilig zoals blijkt uit het lage infectiepercentage. Het vergelijken van de laparoscopische methoden toont aan dat de gemodificeerde Sugarbaker-techniek waarschijnlijk beter is dan de Keyhole-techniek aangezien deze leidt tot minder recidiefbreuken.

Biologische matten worden steeds populairder in de hernia chirurgie. Het theoretische voordeel is dat in een gecontamineerd milieu geen kunststof materiaal meer geplaatst hoeft te worden. Een overzicht van de beschikbare literatuur wordt gepresenteerd in **hoofdstuk 6**. Er werden vier retrospectieve studies geïncludeerd met een totaal aantal van 57 patiënten. Het gebruik van biologische matten voor het herstel van een parastomale hernia resulteerde in een complicatiepercentage van 26,2%. Er werden geen sterfgevallen gemeld. Wondinfectie trad op bij drie patiënten maar dit leidde niet tot infectie van de mat waardoor deze in situ kon blijven. Het recidiefpercentage na een follow-up van 8 tot 50 maanden was 15,7% (95% BI 7,8-25,9). Geconcludeerd werd dat het herstel met biologische en kunststof matten vergelijkbare resultaten gaf. De mogelijkheid om de mat in situ te laten in geval van infectie, lijkt een voordeel van biologische

ten opzichte van kunststof matten.

Zoals werd beschreven in onze systematische review, toonde de laparoscopische gemodificeerde Sugarbaker-techniek minder recidieven dan de Keyhole-techniek. Aangezien het aantal patiënten per studie vrij klein was en de heterogeniteit tussen de studies groot, hebben we besloten een internationale multicentrische studie op te zetten naar de resultaten van de Sugarbaker-techniek. De resultaten van deze studie worden gepresenteerd in **hoofdstuk 7**. In totaal ondergingen 61 patiënten een laparoscopische parastomale herniaoperatie door middel van de gemodificeerde Sugarbaker-techniek met een kunststof mat (Goretex Dual Mesh ®). Alle operaties werden laparoscopisch uitgevoerd. Geen van de ingrepen werd geconverteerd naar een open procedure en er traden geen iatrogene darmletsels op. De morbiditeit was 19%. Het betrof een wondinfectie (n = 1), een ileus (n = 2), een door een trocar veroorzaakte bloeding (n = 2), een heroperatie (n = 2) en een pneumonie (n = 1). Eén patiënt overleed tijdens de postoperatieve fase als gevolg van een darmobstructie die werd veroorzaakt door een metastase van een bronchuscarcinoom. Littekenbreuken ter hoogte van de mediane laparotomie werden gelijktijdig aangetroffen bij 25 van de 61 patiënten (41%). Het aantal recidieven was 6,6% na een gemiddelde follow-up van 26 maanden (12-64 maanden). Geconcludeerd kan worden dat de laparoscopische gemodificeerde Sugarbaker-techniek met een kunststof mat zowel veilig als haalbaar is met een laag recidiefpercentage. Bovendien leidt de laparoscopische techniek tot het gelijktijdige herkennen en behandelen van littekenbreuken in 41% van de patiënten.

In **hoofdstuk 8** presenteren we de Prevent-trial, een multicentrische prospectief gerandomiseerde studie naar het voorkomen van parastomale hernia's bij patiënten met een eindstandig colostoma. Er wordt gerandomiseerd tussen patiënten die een conventioneel colostoma krijgen en patiënten waarbij er preventief een preperitoneaal en retromusculair, lichtgewicht kunststof matje wordt geplaatst.

Algemene discussie

De behandeling van parastomale hernia's is een uitdaging voor chirurgen. Wij verwachten in de nabije toekomst een significante toename van het aantal parastomale hernia's. Dit komt onder meer door het toenemend aantal in leven blijvende kankerpatiënten met een stoma en daarnaast door het feit dat obesitas een endemisch probleem geworden is. Obesitas verhoogt immers de intra-abdominale druk en rekt de buikwand uit, wat de kans vergroot op het groter worden van de stomaopening en het ontstaan van een hernia.

Het systematische review gepresenteerd in hoofdstuk 5 leidt tot de conclusie dat het vernauwen van de breukpoort door

hechtingen alleen een obsolete techniek is aangezien recidieven in meer dan 70% optreden. Wondinfecties werden bij 12% van de patiënten aangetroffen. Ook het verplaatsen van het stoma naar een andere plaats op de buik geeft onbevredigende resultaten met een recidiefpercentage van 30%. Indien het preventief plaatsen van een kunststof mat effectief blijkt te zijn dan zou deze techniek een goede chirurgische optie kunnen worden. Op dit moment is het herstel van een parastomale hernia met een mat de gouden standaard.

Verschillende technieken worden in de literatuur besproken, zoals de onlay mesh repair (o.a. de Stovepipe-techniek), de Keyhole-techniek en de gemodificeerde Sugarbaker-techniek. Hoewel het recidiefpercentage vergelijkbaar was voor al deze technieken, lijkt de Sugarbaker-techniek de beste laparoscopische methode te zijn. Aangezien er hierover weinig prospectieve of gerandomiseerde studies zijn gepubliceerd, moet men voorzichtig zijn bij het interpreteren van de resultaten. Bovendien is de heterogeniteit tussen de beschikbare studies groot.

In het eerste deel van dit proefschrift presenteren we de korte- en langetermijnresultaten van de laparoscopische Keyhole-techniek. De postoperatieve morbiditeit was relatief hoog (29%). Iatrogeen darmletsel kwam voor bij 14,5% van de patiënten en veroorzaakte een aanzienlijke morbiditeit. Tegenwoordig zijn deze letsels zeldzamer door de toegenomen laparoscopische kennis en kunde. Dit blijkt ook uit onze multicentrische studie naar de resultaten van de laparoscopische Sugarbaker-techniek waarin geen darmletsels meer werden gevonden. Helaas toonde de Keyhole-techniek op lange termijn een hoog recidiefpercentage van 36%. Dit werd verklaard door het progressief groter worden van de centrale opening in de mat als gevolg van een (verhoogde) intra-abdominale druk.

In 1985 ontwikkelde Sugarbaker een nieuwe, open techniek om parastomale hernia's te herstellen [1]. Hij hechtte de mat vast aan de fascierand van de stomaopening, zonder overlap tussen de fascia en de mat. Hoewel er aanvankelijk uitstekende resultaten werden gemeld, werd de techniek gedurende de jaren gewijzigd. Tegenwoordig wordt een overlap van 5 cm genomen tussen de aangrenzende fascia en de mat om een recidief te voorkomen: de gemodificeerde Sugarbaker-techniek. In de literatuur wordt een recidiefpercentage van 15% gemeld na een open Sugarbaker-operatie [2]. Pas sinds 2005 worden er onderzoeken gepubliceerd over laparoscopisch herstel van een parastomale hernia [3].

Een recente meta-analyse van 110 laparoscopische Sugarbaker-operaties toont een recidiefpercentage van 11,6% (95%-BI 6,4-18,0). Dit is iets hoger dan de resultaten van onze multicentrische cohort studie die in hoofdstuk 7 werd beschreven en die een recidief- percentage van slechts 6,6% toonde na

een mediane follow-up van 26 maanden (12-64 maanden). Hoewel de uitkomsten vooral zijn gebaseerd op retrospectieve niet-gerandomiseerde studies, suggereren deze dat de laparoscopische Sugarbaker-operatie resulteert in een lager recidiefpercentage in vergelijking met de open variant.Een bijkomend voordeel van de laparoscopische benadering ten opzichte van de open techniek, is het gelijktijdig opsporen van andere littekenbreuken die meteen kunnen worden hersteld. Bovendien is laparoscopie minimaal invasief waardoor de buikwand van de patiënt gespaard blijft. Het risico op nieuwe littekenbreuken zal hierdoor verminderen.

Rekening houdend met deze argumenten, concluderen we dat de gemodificeerde Sugarbaker-techniek de methode bij uitstek is om een parastomale hernia te herstellen, bij voorkeur door middel van de laparoscopische benadering. Er moeten echter prospectieve studies met langdurige follow-up worden uitgevoerd om te bepalen of onze conclusie gerechtvaardigd is.

Aangezien het aantal patiënten met een stoma in de toekomst zal toenemen, is het voorkómen van parastomale hernia's van groot belang. Preventie moet zowel gericht zijn op een adequate chirurgische techniek als op preventie en behandeling van ziekten die een verhoogde intra-abdominale druk veroorzaken, zoals obesitas en chronische hoest. Israelsson et al. hebben reeds gepleit voor de toepassing van een kunststof mat rond een stoma om een parastomale hernia te voorkómen [4]. In een recente meta-analyse van Wijeyekoon et al. bleek dat plaatsing van een mat de kans op een parastomale hernia aanzienlijk vermindert [5]. Helaas zijn alle studies die geïncludeerd zijn in deze meta-analyse underpowered. Daarom zijn we zelf gestart met een prospectieve gerandomiseerde studie om te bepalen of het plaatsen van een mat ter hoogte van een stoma een parastomale hernia kan voorkomen (Prevent-trial).

Naast het uitvoeren van klinische studies zal het verzamelen van meer informatie over de incidentie van parastomale hernia's, de uitlokkende factoren ervan en de resultaten van chirurgische behandelingen kunnen resulteren in een betere kwaliteit van zorg. Onlangs werd daartoe de EuraHS database (European registry of abdominal wall hernias) gelanceerd. Deze database zorgt voor een internationaal online platform waar alle gegevens over buikwandoperaties kunnen worden geregistreerd. Dit ambitieuze project is een initiatief van de EuraHS-werkgroep die is gevormd onder auspiciën van de Europese Hernia Society [6]. De verwachting is dat de EuraHS-database een belangrijk instrument zal worden om essentiële informatie te verzamelen, onder meer over de parastomale hernia. Wij verwachten dat dit in de toekomst zal bijdragen tot een verlaging van de incidentie van deze ernstige aandoening.

Op dit moment kunnen we dus aanbevelen dat het herstel van een parastomale hernia bij voorkeur gebeurt door een laparoscopische operatie volgens de gemodificeerde Sugarbaker-techniek.

De resultaten van de Prevent-trial zullen in de nabije toekomst laten zien of het preventief plaatsen van een kunststof mat ter hoogte het stoma de incidentie van parastomale hernia's na laparotomie kan verminderen.

Aangezien de laparoscopische colorectale chirurgie een enorme vlucht genomen heeft zullen we weldra starten met een nieuwe trial, de Prevent II-trial, waarbij patiënten met een laparoscopisch aangelegd colostoma gerandomiseerd zullen worden voor al dan niet het preventief plaatsen van een mat rondom het stoma. Het doel van deze studie is de incidentie van parastomale hernia's bij laparoscopisch geopereerde patiënten te bestuderen en te reduceren.

Referenties

1 *Sugarbaker PH. Peritoneal approach to prosthetic mesh repair of paraostomy hernias. Ann Surg 1985;201:344-346*

2 *Stelzner S, Hellmich G, Ludwig K. Repair of paracolostomy hernias with a prosthetic mesh in the intraperitoneal onlay position: modified Sugarbaker technique. Dis Colon Rectum 2004;47:185-191*

3 *Leblanc KA, Bellager DE, Whitaker JM, Hausmann MG. Laparoscopic parastomal hernia repair. Hernia 2005;9:140-144*

4 *Jänes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study. World J Surg 2009;33:118-121*

5 *Wijeyekoon SP, Gurusamy K, El-Gengy K, Chan CL. Prevention of parastomal herniation with biologic/composite prosthetic mesh: a systematic review and meta-analysis of randomized controlled trials. J Am Coll Surg 2010;211:637-645*

6 *Muysoms FE, Campanelli G, Champault GG, DeBaux AC, Dietz UA et al. EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal wall hernia repair. Hernia 2012;16:239-250*

Birgitta Hansson

List of publications regarding this topic

B.M.E. Hansson
Nieuwe techniek in de behandeling van stomabreuken
Vooruitgang 2003;3:36-37

B.M.E. Hansson, E.J. van Nieuwenhoven, R.P. Bleichrodt
Promising new technique in the repair of parastomal hernias
Surgical Endoscopy 2003;17:1789-1791

R.P. Bleichrodt, T.S. de Vries Reilingh, A.W. Malyar, H. vanGoor, B.M.E. Hansson, B. van der Kolk
Component separation technique to repair large hernias
Operative techniques in General Surgery 2004;6:179-188

B.M.E. Hansson, I.H.J.T. de Hingh, R.P. Bleichrodt
Laparoscopic parastomal hernia repair is safe and feasible! Early results of a prospective clinical trial including 55 consecutive patients
Surgical Endoscopy 2007;21:989-993

B.M.E. Hansson
Buikwandbreuken; de andere methode
Vooruitgang 2008;3:13

B.M.E. Hansson, R.P. Bleichrodt, I.H.J.T. de Hingh
Laparoscopic parastomal hernia repair using a Keyhole technique results in a high recurrence rate
Surgical Endoscopy 2009;23:1456-1459

B.M.E. Hansson, I.H.J.T. de Hingh, R.P. Bleichrodt
Laparoscopic parastomal hernia repair: Pitfalls and complications
in HERNIA REPAIR SEQUELLAE by Volker Schumpelinck and Robert J. Fitzgibbons, ISBN 978-3-642-04552-3
Edition 2010 Chapter 58;451-455

N.J. Slater, B.M.E. Hansson, O.R. Buyne, T. Hendriks, R.P. Bleichrodt
Repair of parastomal hernias with biological grafts: a systematic review
Journal of Gastrointestinal Surgery 2011;15:1252-1258

B.M.E. Hansson, N.J. Slater, A.P. Schouten van der velde, H.M.M. Groenewoud, O.R. Buyne, I.H.J.T. de Hingh, R.P. Bleichrodt
Surgical techniques for parastomal hernia repair: a systematic review of the literature
Annals of Surgery 2012;255:685-695

B.M.E. Hansson
A 66-year old obese woman undergoing parastomal hernia repair. Case Report
General Surgery 2012;7:6-7

B.M.E. Hansson, S. Morales-Conde, T. Mussack, J. Valdes, F.E. Muysoms, R.P. Bleichrodt
The laparoscopic modified Sugarbaker technique is safe and has low recurrence rate: a multicenter cohort study
Surgical Endoscopy 2012, In Press

H.T. Brandsma, B.M.E. Hansson, H. van Haaren-de Haan, T.J. Aufenacker, C. Rosman, R.P. Bleichrodt
Prevention of a parastomal hernia with a prosthetic mesh; The Prevent-trial; a multicenter randomized controlled trial
Trials 2012, Submitted

B.M.E. Hansson
Reply to: H.Mizrahi et al. Laparoscopic slit mesh repair of parastomal hernia using a designated mesh: long-term results
Letter to the editor. Surgical Endoscopy 2012, In Press

B.M.E. Hansson
A parastomal hernia as consequence of complicated abdominal surgery; case report and review of the literature
Case 94 in TREATMENT OF MAJOR COMPLICATIONS AFTER DIGESTIVE SURGERY by M.A. Cuesta and H.J. Bonjer
In Press

Birgitta Hansson

Dankwoord

Geachte promotor, beste Rob,
Vele jaren geleden heb je me naar Nijmegen gelokt om in het UMCN de laparoscopie te komen opzetten. Dat heb ik met hart en ziel gedaan en ben je daar, tot op de dag van vandaag, nog steeds erkentelijk voor. Opereren met jou was een lust voor het oog en vitaminen voor het hart.
De academie kan een slangenkuil zijn en in die kuil heb jij mij gemotiveerd om onderzoek te doen. Je hebt me geleerd dat het kicken op een nieuwe laparoscopische techniek ook bestond uit het opschrijven ervan en het opstarten van een landelijke studie. Het kind was geboren. Het tot wasdom brengen was een andere zaak.
Rob, jij bent de witte motor achter dit proefschrift, zonder jou was er vandaag geen promotie, mijn dank is enorm.

Geachte copromotor, beste Ignace,
Ik heb jou vele jaren geleden leren kennen als een jonge, gedreven, handige en enthousiaste assistent. Met jou aan tafel was het altijd feest. Absurd hoe na al die jaren de rollen omgekeerd zijn en jij nu mijn copromotor bent!
Ontzettend trots ben ik op jou en bijzonder blij ben ik met jou als copromotor. Jij hebt een substantiële rol gespeeld in het tot wasdom brengen van dit boekje, waarvoor dank!

Geachte co-auteurs,
Ook zonder jullie, geen boekje! Dank voor de tomeloze inzet van velen.

Geachte leden van de manuscriptcommissie,
Ik dank u hartelijk voor het lezen en goedkeuren van het manuscript.

Maatschapsleden Chirurgie CWZ,
Dank voor jullie steun en voor dat extra duwtje in de rug. Thanks!

Collegae chirurgen, fellows, Chivo's, assistenten, PA's, NP's, Trial-nurses, verpleegkundigen, OK assistenten, doktersassistenten en secretaresses van beide Nijmeegse ziekenhuizen
Bedankt voor de mooie, plezierige en soms hilarische tijd die ik met velen van jullie tot nu toe beleefd heb.
The future looks bright!

Voor al mijn bijzondere vrienden,
Praten, dansen, lachen, drinken, huilen en onnozel doen... dat is onze gemene deler... en daar hou ik jullie aan!

Voor al mijn vrienden en kennissen mét een talenknobbel,
Jullie waren geweldig. Duizend maal dank voor alles!

Mijn paranimfen Barbara en Miranda,
Onze vriendschap ontstond 10 jaar geleden toen we samen op de chirurgie van het Radboud werkten. Vele zeetjes hebben we intussen doorzwommen... Wat is het heerlijk om jullie als boezemvriendinnen te hebben en lief en leed met

elkaar te delen. Dank ook voor jullie fantastische steun tijdens het maken van dit boekje. Ik vind het een hele eer dat jullie vandaag mijn paranimfen willen zijn! *De drie gelaarsde katten gaan ervoor!*

Voor mijn harige kinderen,
Vijf zijn het er nu al, vier die kwispelen en één die hinnikt. Wat een oergeweld als ik elke dag weer thuiskom. Dank voor jullie onvoorwaardelijke liefde, lachwekkende momenten en miljoenen gewilde en ongewilde likjes. Dank ook voor al die verscheurde hondenmanden, bergen was, balen haar, opgegeten mobieltjes, vreugdeplasjes (helaas op de verkeerde plaats) en ga zo maar door... Jullie snappen er toch niets van, ik hou van jullie en ben blij dat ik jullie roedelleider mag zijn.

Voor mijn familie, klein maar fijn,

Mama,
Wat ben ik blij dat je er vandaag bij kan zijn. Ik weet dat je zo fier bent als een gieter, ook al vind je het onderwerp van het boekje niet zo enorm smakelijk en had je misschien liever een hersenchirurg gehad als dochter of een kassière bij de Delhaize in Schoten ;-). Je bent een moeder uit de duizend, altijd was je er voor me, luisterend, raadgevend en relativerend. Maar vooral voor die enorme dosis humor en geestigheid kom ik met plezier naar Schoten gereden. Wat is het er altijd weer een feest, zeker als Eric thuis is!

Eric,
Mijn broertje, allez zeg maar broer! Wij zijn 2 handen op één buik en dat zal tot in de eeuwigheid duren. Ook al verblijf je vaak aan de andere kant van de wereld, in mijn hart ben je altijd bij mij. Ook jou hilarische manier om dingen te vertellen en jou grappige opmerkingen zijn jou absolute troef.
Met ons drietjes hebben we vaak de slappe lach om niets. Ik hoop dat de buren ons dat niet al te kwalijk nemen...

Papa,
Ook jij mag in dit rijtje niet ontbreken alhoewel je helaas wel ontbreekt in levende lijve. Wat zou jou vaderlijke trots vandaag geëxplodeerd zijn! Ook jij hebt bijgedragen aan mijn vorming en zonder dat je het beseft ook aan dit boekje. In de vorm van een Zweedse stelling, wie had dat ooit gedacht...

Tot slot, Robbert, mijn lief
Dat je het met mij en de roedel uithoudt is op zich al een enorme verdienste! Dank dat je zoveel werk uit mijn handen neemt zodat ik me eindelijk kon focussen op het afwerken van dit proefschrift. Het is gelukt! Je bent mijn rots in de branding, op jou kan en wil ik bouwen!
Liefs, Bibi

Alea iacta est

Birgitta Hansson

Curriculum Vitae

Net buiten de bruisende metropoolstad Antwerpen, om precies te zijn te Schoten, België, werd op 30 november 1968 Birgitta Maria Elisabeth Hansson, roepnaam Bibi, geboren. Samen met haar oudere broer Eric, werd ze liefdevol opgevoed door haar Vlaamse moeder en Zweedse vader. Deze gedeeltelijk buitenlandse afkomst zou van grote invloed zijn op haar verdere leven en verklaart vermoedelijk haar passie voor vreemde culturen en verre reizen.

In haar jeugdjaren was ze voornamelijk bezig met paarden, sport en sociale activiteiten. School kwam soms op de tweede plaats, maar in 1986 slaagde ze voor het eindexamen aan het Sint-Cordula Instituut te Schoten, waar ze een Wetenschappelijke richting volgde.

Aansluitend ging ze Geneeskunde studeren aan de Rijksuniversiteit Antwerpen en behaalde het diploma van Doctor in de Genees,-Heel- en Verloskunde in juni 1993 na een turbulent actief studentenleven. Zo maakte ze naast haar studie ook tijd vrij voor de studentenvereniging Aesculapia waar ze met plezier de functie van sport- en cultuurpraeses op zich nam. Door de fascinatie voor het buitenland besloot ze samen met haar vriendinnen coschappen gynaecologie, verloskunde en pediatrie te lopen in het Hospital Apoyo in Huanuco, Peru.

In oktober 1993 startte ze de opleiding Heelkunde aan het Universitair Ziekenhuis Antwerpen (UZA). Eerlijkheid gebied ons te noemen dat ze initieel in opleiding was voor orthopedie. Echter na enkele maanden ontdekte ze haar passie voor de abdominale chirurgie en mocht ze de opleiding omzetten, waarvoor oprechte dank aan professor dr. J. Verstreken en wijlen professor dr. E. Eyskens. Ze behaalde met verve haar eindexamen chirurgie en werd gecertificeerd chirurg op 30 september 1999.

Aansluitend begon ze aan de vervolgopleiding Gastro-Intestinale Chirurgie aan het toenmalige Academisch Ziekenhuis in Groningen, Nederland, tegenwoordig beter bekend onder de naam UMCG. Dr. René Verschueren, landgenoot, trainde haar in de vele facetten van de gastro-intestinale chirurgie op zijn haast legendarische, professionele en humoristische wijze. Verre landen bleven haar aantrekken en gedurende de vakantie- en reductieperiode werkte ze vrijwillig als algemeen chirurg in een Afrikaans ziekenhuis in San, Mali.

In 2001 werd ze door Professor Rob Bleichrodt gecontacteerd om kennis te komen maken in het UMC St-Radboud te Nijmegen, de oudste stad van Nederland. Hoewel dat haar toen nog niet bekend was, was ze meteen gecharmeerd. Op 1 mei 2001 begon ze haar carrière als abdominaal chirurg in bovenvermeld ziekenhuis. Toen werd de basis gelegd aan het promotieonderzoek wat geleid heeft tot dit proefschrift ruim enkele jaren later. Na de introductie van de laparoscopische parastomale hernia chirurgie werd ze verscheidene malen geïnviteerd voor het geven van presentaties en life demonstraties over deze nieuwe techniek in binnen- en buitenland. Zo verzorgde ze life operaties in ondermeer Sevilla en in verschillende steden in China.

In 2004 is ze toegetreden tot de Maatschap Chirurgie van het Canisius-Wilhelmina Ziekenhuis te Nijmegen waar ze tot op heden werkt.

Birgitta Hansson was born on November 30th, 1968 in Schoten, Belgium a small town on the outskirts of the vibrant City of Antwerp. It was here that her Flemish mother and Swedish father lovingly raised both Bibi and her elder brother, Eric. The mixed cultural heritage significantly influenced her life and ignited her passion for different cultures and distant travel.

During her childhood and teen years Bibi's life consisted mostly of horses, sports and social activities. School was at times secondary to all these extra-curricular activities, nevertheless; she did attend the Sint-Cordula Institute in Schoten and graduated in 1986 majoring in Scientific Studies.

She then went on to study Medicine at the University of Antwerp. 'Never a boring moment' seems to be Bibi's credo. So even though her studies had her 'almost' undivided attention, she found sufficient time to enjoy a full, tumultuous and active student life. A fair share of this 'free' time she spent actively involved in the student corps, where her efforts were mainly focussed on the enhancement of sports and culture. At that time, distant horizons beckoned and she decided to complete her residency in Gynaecology, Obstetrics and Paediatrics at the Hospital Apoyo in Huanuco, Peru. In June of 1993 she successfully obtained her degree as a Doctor of Medicine.

In October 1993 she started her surgical training at the Academic Hospital Antwerp (UZA). In all fairness, it should be mentioned that initially she started her training in the field of Orthopaedics. However, a few months into her training she discovered her passion for Abdominal Surgery. Fortunately, she was allowed to make the switch to General Surgery, for which Bibi would like to express her sincere gratitude to Professor dr. J. Verstreken and the late Professor dr. E. Eyskens. She passed her final surgical examinations with flying colours and became a certified surgeon on the 30th of September 1999.

Bibi then pursued further specialization in Gastrointestinal Surgery at the former Academic Hospital in Groningen, the Netherlands, presently known as the UMCG. Dr. René Verschuren, a fellow countryman who was well known for his almost legendary, highly professional and humorous training methods, was responsible for her training in the many facets of Gastrointestinal Surgery.

In 2001 Professor dr. Rob Bleichrodt invited Bibi to visit the UMC St-Radboud in Nijmegen, the oldest city of the Netherlands. She immediately fell in love with this charming city at the banks of the river Waal, where she would start her career as an Abdominal Surgeon on the 1st of May, 2001. It was then that the foundation for her PhD research was laid, research that finally led to the thesis that is now before you. After the introduction of the laparoscopic parastomal hernia surgery Bibi received various invitations to give presentations and live demonstrations both at home and abroad. Since, she has performed live surgeries in Sevilla and a variety of cities in China.

In 2004 she joined the Surgical Partnership at the Canisius-Wilhelmina Hospital in Nijmegen, where she continues to work to this day.