PARASTOMAL HERNIA
Clinical Studies on
Definitions and Prevention

Arthur Jänes

Department of Surgical and Perioperative Sciences
Umeå University
901 87 Umeå
Sweden
www.surgery.umu.se
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Tutor..................................Leif A Israelsson
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Inget är så dåligt att det inte kan bli sämre av en operation
Lars Wikström, Hudiksvall

To Joel, Jakob, Simon and Elin
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ABSTRACT

Parastomal hernia is a frequent complication after stoma formation occurring in up to 80% after five years. In previous studies, no consistent definition of parastomal hernia has been used at clinical examination or at CT-scan.

Aims of the studies
To evaluate the short and long term effects of prophylactic prosthetic mesh placed in a sublay position at the index operation on the development of parastomal hernia and stoma complications. The purpose was also to validate a definition of parastomal hernia at clinical examination and a method and a definition of parastomal hernia at CT-scan.

Patients and Methods

A. 27 patients were randomized to a conventional stoma and 27 patients to the addition of a prophylactic low weight, large pore mesh in a sublay position. Follow up was after one month, one year and five years.

B. In routine surgery 93 consecutive patients were provided with a sigmoidostomy with the intention of receiving a prophylactic mesh in a sublay position. Follow-up was after one year.

C. 27 patients with stomas were examined by three surgeons and parastomal hernia was defined as any protrusion in the vicinity of the stoma. CT-scans were assessed by three radiologists with patients examined in the supine and prone positions. Herniation was defined as any intra abdominal content protruding beyond peritoneum or the presence of a hernia sac.

Results

A. Without a prophylactic mesh parastomal hernia was present after one year in 13 of 26 patients (50%) and after five years in 17 of 21 (80%). With a mesh parastomal hernia was present after one year in 1 of 21 patients (5%) and after five years in 2 of 15 (14%). There were no mesh related complications.
B. A prophylactic mesh was used in 75 of 93 patients. In 9 a mesh could not be utilized due to scarring after previous surgery. In 9 a mesh was omitted because of the surgeons' decision. A mesh was used in 19 severely contaminated wounds. Wound infection occurred in 6 of 73 (8%) patients with a mesh and in 4 of 15 (27%) where no mesh was used. Parastomal hernia was present in 8 of 61 (13%) patients with a mesh and in 8 of 12 (67%) where no mesh was used.

C. 27 patients were assessed by three surgeons and three radiologists. Kappa was 0.85 for the surgeons and 0.85 for the radiologists, with CT-scan in the prone position. Kappa was 0.80 for surgeons and radiologists collectively, with CT-scan in the prone position. Four parastomal hernias detected with CT-scan in the prone position could not be detected in the supine position. A clinically diagnosed parastomal hernia was always detected with CT-scan in the prone position.

Conclusions

A prophylactic mesh placed in a sublay position at the index operation reduces the rate of parastomal hernia without increasing stoma complications. A mesh can be placed in severely contaminated wounds. Parastomal hernia should at clinical examination be defined as any protrusion in the vicinity of the stoma with the patient straining in a supine and an erect position. At CT-scan, with the patient examined in the prone position, herniation should be defined as any intra abdominal content protruding beyond peritoneum or the presence of a hernia sac.

Key words: Parastomal hernia, stoma complications, prosthetic mesh, mesh complications, sigmoid stoma, ileostomy, laparoscopic stoma, CT-scan
This picture shows a large parastomal hernia.
**ARTICLES INCLUDED**

This thesis is based on the following articles

I. Arthur Jänes, Yucel Cengiz, Leif A Israelsson  
Preventing parastomal hernia with a prosthetic mesh  
*Archives of Surgery* 2004; 139 (12): 1356 - 1358

II. Arthur Jänes, Yucel Cengiz, Leif A Israelsson  
Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study  

III. Arthur Jänes, Yucel Cengiz, Leif A Israelsson  
Experiences with a prophylactic mesh in 93 consecutive ostomies  
*World Journal of Surgery* 2010; 34: 1637 - 1640

IV. Arthur Jänes, Lena Weisby, Leif A Israelsson  
Parastomal hernia: Clinical and Radiological Definitions  
Submitted
INTRODUCTION AND BACKGROUND

There are historic reports of stomas occurring spontaneously after trauma or incarcerated hernias developing spontaneous fistulas. The latter seems sometimes to have saved the patient’s life for a period of time - but most certainly with a very much diminished quality of life. One such instance was Ms. Margreth White treated in 1740 by Mr. Cheselden for a spontaneous ostomy from an incarcerated umbilical hernia. Surgeons also surgically opened incarcerated groin hernias with subsequent ileostomies developing. In such instances spontaneous closure sometimes seems to have occurred. Olof Acrel, in 1752 surgeon at Serafimerlasarettet, Stockholm, Sweden, presents such a case in his surgical memoirs “Chirurgiske Händelser” (Inspärradt tarmbråck i högra ljumsken, upbrutet af tilslagen brand och läkt utan fistel). In 1710 Littré suggested colostomy as a surgically useful procedure. In 1779 Pillore performed the first caecostomy and in 1793 a colostomy was performed by Duret on an infant with anal atresia. The first successful colostomy with long term survival may have been performed by Pring in 1819.

Ms. Margreth White was in 1740 treated by Mr. Cheselden for an incarcerated umbilical hernia that formed a spontaneous ostomy.
Today creating ostomies surgically is a common procedure in both emergent and elective surgery. It is a procedure employed in infants with congenital anomalies as well as in adolescents and elderly with acquired maladies or functional disorders. An ostomy may be intended to be permanent but is also used solving emergent situations, as protection of an intestinal anastomosis or as preparatory of definitive surgery with the aim of restoring bowel continuity at a later stage. An ostomy can be created during open as well as laparoscopic surgery. If bowel is resected or cut the bowel end is brought out as an end ostomy. Especially in emergent situations or in situations when the ostomy is not judged to be needed for a long period of time the full bowel is exteriorized and a loop stoma is created. The development of ostomies as a frequent procedure has been enabled not only by the progress in methods of anesthesia and surgery but also by the development of modern stoma bandages. The terms ostomy and stoma (Greek: mouth) are often used interchangeably but have somewhat different meanings. An ostomy refers to any surgically created opening in the body for the discharge of body wastes. A stoma is the actual end of a hollow viscus that protrudes through the abdominal wall. In the present context focus is on ostomies consisting of ileum or colon brought out through the abdominal wall by a surgical procedure.

In 1989 Pearl regarded parastomal hernia as an incisional hernia related to a abdominal wall stoma [1]. Parastomal hernia is a common complication and Goligher even considered some degree of parastomal hernia to be an almost inevitable complication of colostomy formation [2]. Several attempts have been made with different surgical techniques when creating an ostomy in order to lessen the rate of parastomal hernias developing but with discouraging results [3]. Once a parastomal hernia has developed it is very difficult to repair and an abundance of methods have
been tried. Such repair has often been associated with poor outcome and high recurrence rates [3-4]. A parastomal hernia often causes the patient discomfort and problems with stoma bandages including leakage. In 2008 Kald showed that patients with parastomal hernia, defined as bulging at the stoma site, had a significantly impaired quality of life [5]. On the other hand a well functioning ostomy without herniation may allow a very good quality of life [5-9].

**Definition of Parastomal Hernia**

Currently the generally accepted definition of an inguinal hernia is a protrusion in the groin when the patient is straining in the supine and the erect position [10]. Similarly an incisional hernia is defined as any protrusion in the vicinity of the incision when the patient is straining in the supine and the erect position [11]. There has, however, not been any generally accepted definition of parastomal hernia. A parastomal hernia may be regarded as an incisional hernia related to an abdominal wall stoma [1]. Parastomal hernia has been classified into four subtypes: the subcutaneous type with a subcutaneous hernia sac, the interstitial type with a hernia sac within the muscle / aponeurotic layers of the abdomen, the perstomal type with the bowel prolapsing through a circumferential hernia sac enclosing the stoma, and the intrastomal type in ileostomies with a hernia sac between the intestinal wall and the everted intestinal layer [12]. In clinical examination it is difficult to distinguish between these four subtypes of parastomal hernia so it has not been used in clinical studies.

In surgical reports over the years there has not been any uniform definition of parastomal hernia used at follow-up examination [3-4]. The lack of a uniform definition is a major problem when assessing and trying to compare rates of parastomal hernia presented in different clinical reports or
trials. Until 2003 the definition of parastomal hernia used at follow-up was actually given in only one report. Then herniation was defined as a palpable cough impulse at the ostomy site [13]. In all other clinical reports before 2004 no definition of parastomal hernia was given at all [4]. In the years following 2004 several authors have defined parastomal hernia as a palpable defect or bulge adjacent to the stoma [5, 14-21]. In two studies a CT-scan was added to the clinical examination and the radiological definition of a parastomal hernia was any abdominal content protruding along the ostomy [14, 22]. The correlation between parastomal hernia detected at clinical examination by several examiners has not been very good [23]. The correlation between herniation detected at clinical examination and at CT-scan has been rather poor. Herniation present at clinical examination may not be detected at CT-scan and vice versa [22-24]. This is a problem that needs to be solved and a consistent definition at clinical examination that correlates to findings at CT-scan should be sought. Agreement between assessments is often analysed by calculating the Kappa value. Kappa has a maximum of 1.0 when agreement is perfect. A value of zero indicates no agreement better than chance and negative values indicates agreement worse than chance. The strength of agreement is often interpreted as Kappa 0.6-0.8 as good and 0.8 or higher as very good.

Some authors have differentiated between parastomal hernia and stoma prolapse [25-31]. In these reports neither the definition of parastomal hernia or stoma prolapse was given so it is unclear how they differentiated between these conditions at clinical examination. In a Cochrane report in 2007 on loop stomas a difference was made between stoma prolapse and parastomal hernia [32]. Prolapse was defined as an eversion of the stoma through the abdominal wall and parastomal hernia as a hernia beside the stoma. The authors did not give any guidelines on how to differentiate
between these two conditions at clinical examination. Many authors may have considered both entities as a parastomal hernia.

The lack of a uniform definition and the almost total lack of any definition presented in reports before 2004 makes it difficult to compare the rates of parastomal hernia between different studies. It is generally agreed that follow-up should be no less than 12 months after the index operation in order to detect a ventral incisional hernia and this seems to be applicable for parastomal hernias also [33]. However, the rate of parastomal hernia increases with time and the rate seem to increase for 8 to 10 years after surgery [21, 34].

An incisional hernia is defined as abdominal contents protruding through a defect in the abdominal wall. An ostomy is a bowel brought out through a surgically created opening in the abdominal wall. Thus, it can be argued that a surgeon creating a stoma per definition also creates an incisional hernia. In view of this it is perhaps not surprising that a high proportion of patients with an ostomy over time develop a parastomal hernia.

**Incidence of Parastomal Hernia**

The lack of a uniform definition of parastomal hernia used at follow-up makes it difficult to estimate the true rate of herniation. It is very hard to make a true estimate as in several reports the authors have not presented how parastomal hernia was defined at follow-up examination [13-14, 17-18, 20-22, 26-28, 31, 34-53]. The incidence reported varies greatly and this is probably very much related to different definition of parastomal hernia used at follow-up examination. With a CT-scan the incidence of parastomal hernia has sometimes been higher than at clinical examination. This has been attributed to small parastomal hernias not noticed at clinical examination being detected with a CT-scan [13-14, 22, 24]
Follow-up time varies considerably in clinical reports on parastomal hernia and in only a few studies follow-up examination has been after a year or more [17, 20-22, 26-27, 38-39, 50, 54]. The rate of parastomal hernia reported varies from 5% up to 80% [13-14, 22, 24-28, 31, 34-37, 39-48]. Experiences gained in studies on incisional hernia indicate that the highest hernia rates reported are the most accurate [11]. Considering that no uniform definition of parastomal hernia has been used in available reports and the variability of time to follow-up, the true rate of parastomal hernia is very difficult to estimate but is it probably between 30% and 50% in general surgical practice.

The rate of parastomal hernia has been suggested to be lower after an ileostomy than after a colostomy [39, 44, 55-56]. There are reports that did not detect any difference in herniation rates between ileostomies and colostomies, so the matter is not definitely settled [13, 26, 57]. The rate of herniation with loop ileostomies and loop colostomies cannot easily be compared with end stomas. Loop stomas are often intended to be temporary and bowel continuity is then often restored after a short period of time. Loop stomas are also often used as a palliative means in patients with short expected survival. Thus, time to follow-up is often very different between loop stomas and end stomas [3-4, 32, 58-59].

When creating an ileostomy after a Bricker diversion the rate of parastomal hernia has been reported within the same range as with other ostomies i.e. 5% to 65% [54, 57, 60-64]

**Surgical Technique When Forming a Stoma**
Throughout the history of surgical stoma formation there have been a great variety of methods used to bring out a stoma [1]. There are no randomized trials available comparing different ways to bring out a stoma and there are
only retrospective reports at hand. For certain you should never bring out a stoma through the laparotomy wound since it causes disastrous result in terms of wound infection, wound dehiscence and herniation [2, 65-67]. An extra-peritoneal route has in two retrospective studies been associated with a lower rate of parastomal hernia than reported with a conventional straight route but there is no randomized trial available and the definition of parastomal hernia used at follow up was not presented [38, 68]. The extra-peritoneal technique has on these grounds been advocated by some but it has also been challenged by others and is today probably not widely used [69-70].

In the Scandinavian countries it is probably quite common to bring out the stoma through the rectus abdominis muscle. This practice is based on one Swedish and one Danish retrospective non-randomized report of a lower rate of parastomal hernia with the stoma brought out through the rectus muscle than lateral to the rectus muscle [36, 44]. Four other retrospective studies did not detect any difference in the rate of herniation with these methods [13, 37-38, 71] and in one recent report a lower herniation rate was found if the stoma was brought out lateral to the rectus muscle [72]. The definition of parastomal hernia at follow-up is not given in these clinical reports and there is no randomized trial comparing the methods. The indications of superior results with the stoma through the rectus muscle available, that this places the stoma close to the midline - appreciated by patients and stoma therapists at it facilitates stoma care - and that there is no obvious disadvantage associated with this stoma placement, has probably enhanced it acceptance among Scandinavian surgeons.

Making a too large opening in the abdominal wall for the stoma is often claimed to be the cause of parastomal hernias developing [2, 27, 43, 67, 70, 73]. There is no clinical evidence available as of what is to be
regarded as a too large opening but a suggestion of not exceeding a
diameter of 2.5 cm has been made. In surgical practice it has to be
recognized that the opening in the abdominal wall must always be large
enough to let the bowel through and in case the bowel is very wide and
embedded in fat the opening must be sized accordingly. There is no evidence
that fixating the mesentery or suturing the bowel to the aponeurosis diminish
the rate of parastomal hernia [3, 26, 38-39]. There are some patient and
operative factors suggested to be associated with the development of
parastomal hernia. Thus, the risk for parastomal hernia has been proposed to
increase with old age, wound infection, obesity, corticosteroid use, chronic
respiratory disorders, malnutrition and increased waist circumference [2, 12,
71, 74-75].

With an ostomy created with a laparoscopic technique the parastomal
hernia rate has been reported to be between none and 12%. However,
follow-up was in these reports less than 12 months and there was no
definition of parastomal hernia given [76-77]. In a recent publication a
laparoscopic extra-peritoneal route was utilized when creating the stoma but
there was no follow-up of patients presented [78]. There are no randomized
trials comparing results with an open versus a laparoscopic formation of
 stomas. In two clinical series with less than 25 patients included in each
report a trephine device was tried for the formation of stomas [79-80]

Surgical Treatment of Parastomal Hernia
Surgical repair has in retrospective reports been called for in 11% to 70% of
patients with a parastomal hernia [13, 21, 25, 27, 44, 54]. Once again the
lack of a uniform definition of parastomal hernia makes it difficult to deal with
this figure. Available reports within this field have not presented the definition
of parastomal hernia used. With a wide definition of parastomal hernia and a
consequent high rate of herniation many hernias may be small and a small proportion might demand repair. With a narrow definition fewer but larger hernias may be detected and a higher proportion might require repair. There are no randomized studies comparing results with different surgical treatments of parastomal hernias and only small series with a particular technique from single centres are available [4].

There are four strategies when repairing parastomal hernias: local repair, relocation of the stoma, mesh repair and relocation of the stoma with a prophylactic mesh at the new stoma site. Local aponeurotic repair is today an obsolete method since it has produced an unacceptably high recurrence rate, reported in the range of 10% to 76% [2-3, 12, 81-85]. After relocation of the stoma the risk of developing a new parastomal hernia is at least as high as after the first operation and recurrence rate of 24% to 86% have been reported [12, 81-82, 84, 86-87]. If the stoma is relocated a second time recurrence rates are reported to be even higher [81]. If a stoma is relocated it should be relocated to the other side of the midline since recurrence rates have been reported to be very high if relocation is to the same side of the midline [84].

The lowest recurrence rates have been reported with prosthetic mesh repairs, although there is no randomized trial available comparing mesh repair with local repair or relocation of the stoma. The strategy of repairing parastomal hernias with a mesh is based on the experiences with mesh repair of incisional hernias [88]. Mesh repair is a common and well established technique for the repair of incisional hernias [89-90]. The mesh can be placed in an onlay, an inlay, a sublay or an intra peritoneal onlay position (IPOM) [73-74, 88, 91]. The IPOM technique can be used in both open and laparoscopic repairs.
There are several types of meshes available: non absorbable, absorbable [88], partly absorbable [88] and acellular collagen matrix [92] meshes, all of which have been used for parastomal hernia repair. Several types of meshes can be placed in a contaminated environment without major complications [17, 93]. There are though potential dangers associated with the use of meshes, such as fistula formation, adhesions, septic complications and seroma formation [29, 94-95]. Meshes that induce an inflammatory tissue response cannot be placed in contact with abdominal contents without a risk of fistula formation, adhesions and septic complications [96]. With the IPOM technique a mesh constructed of two layers is therefore usually used. The mesh surface facing the abdominal wall is usually of a non absorbable material inducing tissue response allowing integration of the mesh to the abdominal wall. The mesh surface facing abdominal contents is a non reactive material causing a low or negligible inflammatory response so that adhesions are not formed.

Relocation of the stoma to the other side of the midline with a prophylactic mesh at the new stoma site and a mesh repair at the old stoma site has been reported in one small series with few complications and no recurrence detected after 12 months [97].

**Prevention of Parastomal Hernia**

Since parastomal hernia is a common complication that is difficult to treat, several prophylactic measures have been tried. Placing a prosthetic mesh at the time of the initial stoma formation was first suggested by Rosin and Bornardi in 1977 [98]. In view of the similarities between incisional hernias and ostomies, using a prophylactic mesh may appear rational when creating a stoma. Incisional hernia is defined as intra abdominal contents protruding
through a defect in the abdominal wall. Constructing an ostomy the surgeon creates a defect in the abdominal wall for the bowel to pass through. As this per definition is a hernia the high rates of parastomal hernia encountered are perhaps not surprising. If stomies are regarded as intentionally created hernias it seems logical that parastomal hernias be prevented in the same way as incisional hernias are repaired i.e. with a mesh. Bayer published the first clinical series with a prophylactic prosthetic mesh in 1986 [99]. In that study, 36 patients received a polypropylene ring with four cross wise prolongations fashioned as a fascia onlay and no herniation was reported after 4 years. Local infection developed in three patients but this did not prompt removal of the mesh. After 8 months one patient developed a stricture and the mesh had to be removed. Light described a technique for intra peritoneal mesh placement at the time of the colostomy formation but provided no data on the rate of complications [100].

New prosthetic meshes have been developed with a large pore size of about 5 millimetres. Such low weight, large pore meshes are associated with a low degree of inflammatory response in the vicinity of the mesh [101]. This probably reduces the risk for the mesh eroding into the bowel [88]. Low weight, large pore meshes that are constructed out of equal proportions of non-absorbable and absorbable materials are also available. The rational for this construction is that the mesh is initially heavy enough to induce tissue response for adequate tissue integration but is still strong enough to achieve its purpose when the absorbable part of the mesh has vanished.
Types of Meshes

A high weight, small pore mesh is dense and induces a considerable tissue response.

A low weight, small pore mesh is not as dense as a high weight mesh but the pore size is small. The mesh induces less tissue response than a high weight mesh.

A low weight, large pore mesh is as dense as a light weight mesh but is constructed with large pores. The tissue response is similar to a low weight mesh but there is minimal tissue response within the open pores.
Aims of the Studies

The aims of the studies are

1. to evaluate the short and long term effects of a prophylactic prosthetic mesh placed in a sublay position at the index operation on the development of parastomal hernia

2. to evaluate the short and long term effects a prophylactic mesh on surgical site infection, stoma stenosis and enteric fistula formation

3. to validate a definition of parastomal hernia at clinical examination

4. to validate a method and a definition of parastomal hernia at CT-scan examination
Patients and Methods

Articles I and II

Between January 2001 and April 2003 patients scheduled for an ostomy were randomised to either a conventional stoma through the rectus abdominis muscle or to the same procedure with the addition of a prosthetic mesh. Randomisation was by opening consecutively numbered sealed envelopes, arranged into batches of four. The mesh was placed in a sublay position between the rectus abdominis muscle and the posterior rectus sheath (Figure 1). A Vypro® (Ethicon, Norderstedt, Germany) mesh was cut to 10 by 10 centimetres, and the bowel was brought out through a cross 2 by 2 centimetres cut in its centre. The mesh was anchored to the posterior rectus sheath with absorbable stitches placed in the lateral corners. Closing the midline incision the running suture included the medial part of the mesh together with peritoneum to prevent the mesh coming into contact with abdominal contents. Patient age, sex and body mass index (BMI = weight / length²) were recorded. The indication for surgery and if surgery was emergent were noted. In elective surgery prophylactic antibiotics were a single oral dose of tetracyklin and metronidazol. In emergent surgery intravenous antibiotics were administered dependant on the clinical situation.

Patients were examined after 1 month, 12 months and 5 years. Patients were examined relaxed and straining in an erect position and relaxed and with lifted legs in a supine position. Any protrusion in the vicinity of the stoma was considered a parastomal hernia. Wound infection, mesh infection, fistula formation, stricture formation, reoperation and parastomal hernia repair were recorded. An independent observer (Inga-Lena Nilsson, MD, PhD) had the power to terminate the trial if the annually analysed complication rates proved unacceptably high.
The study was approved by the regional ethics committee. The SPSS™ 18.0 (SPSS Inc, Chicago, Illinois, USA) software was used for statistical analysis. Fisher’s exact test and Mann-Whitney U test were used for the analysis as appropriate. ClinicalTrials.gov ID: NCT00509054.

**Article III**

Between April 2003 and November 2006 a prophylactic mesh was intended in all patients with an end ostomy created at open surgery. The abdomen was accessed through the midline. A partially absorbable low-weight mesh was placed in a sublay position between the rectus abdominis muscle and the posterior rectus sheath (Figure 1). The bowel was brought out through a cross cut in the centre of a 10 by 10 centimetres Ultrapro ® mesh (Ethicon, Norderstedt, Germany). The cross was cut just large enough to let the bowel through. The mesh was anchored to the posterior rectus sheath with absorbable stitches placed in its lateral corners. The running suture closing the midline included the medial part of the mesh together with peritoneum to prevent the mesh coming in contact with abdominal contents. In elective surgery prophylactic antibiotics were a single oral dose of tetracyklin and metronidazol. In emergent surgery intravenous antibiotics were administered dependant on the clinical situation.

Patient age, sex and body mass index (BMI = weight / length$^2$) were recorded. The indication for surgery and if surgery was emergent were noted. Wound contamination was registered and wounds were regarded dirty if there was pus or faecal contents in the abdominal cavity. Surgical site infection was recorded ten days after surgery, defined according to the definition of the US Centre for Disease Control. One year after surgery patients were examined by one surgeon (AJ). Surgical site infection,
parastomal hernia, fistula formation, stenosis of the stoma and if the mesh had been removed were recorded. A protrusion in the vicinity of the stoma with the patient straining in a supine and an erect position was regarded as a parastomal hernia.

The SPSS™ 18.0 (SPSS Inc, Chicago, Illinois, USA) software was used for the statistical analysis. Mean and 95% confidence intervals (CI) were calculated.

**Article IV**

Patients with a sigmoidostomy included in the routine follow-up program for colorectal cancer used at the department were first assessed by one of the surgeons (AJ) for presence of parastomal hernia. Inclusion in the study aimed at achieving an even distribution between parastomal hernias and intact stomas. Patients were then clinically examined by another senior and one young surgeon. All three raters were at clinical examination unaware of any previous judgment of the presence of parastomal hernia or of the use of a prophylactic mesh. The definition of parastomal hernia used at clinical examination was thoroughly discussed among the raters prior to patient examination.

The definition of parastomal hernia at CT-scan was discussed and decided upon by the three authors (AJ, LW, LAI) prior to the assessment of CT-scans. The senior radiologist (LW) thoroughly informed and discussed the definition to be used with the other two radiological raters prior to their ratings. All radiological raters were at examination unaware of any previous clinical judgment of the presence of parastomal hernia. All three radiologists examined CT-scans independently of each other.
The maximum distance between aponeurotic edges at the stoma site was measured in the vertical and the horizontal planes. The area of the stoma opening was calculated as measurements being diagonals of a rhomb (height x width / 2).

Parastomal hernia was at clinical examination defined as any protrusion in the vicinity of the stoma with the patient straining in a supine and an erect position. At CT-scan parastomal hernia was defined as any intra abdominal content protruding beyond the peritoneum or the presence of a hernia sac. The conventional CT-scan was performed with the patients supine. With the new CT-scan method patients were in the prone position with the stoma positioned in the centre of an inflatable plastic ring approximately 10 centimeters high. Adding the novel CT-scan examining patients in prone position was approved by the local Radiation committee. This examination was voluntary to the patients and they all agreed.

The SPSS™ 18.0 (SPSS Inc, Chicago, Illinois, USA) was used for the analysis. Fleiss Kappa for multiple raters was used utilizing a macro developed for SPSS [102-103].
Figure 1. A prophylactic prosthetic mesh is placed in a sublay position, posterior to the rectus abdominis muscle and anterior to the dorsal rectus sheath.
Results

Article I and II

Fifty-four patients were included in the randomised study. 27 were allocated to receive a conventional stoma, and 27 to the addition of a prophylactic mesh (Table 1). In the group with a conventional stoma one patient died before 12-month follow-up and parastomal hernia was present in 13 of the 26 remaining. In the group with a prophylactic mesh six patients died before 12-month follow-up and parastomal hernia was present in 1 of the 21 remaining (Table 2). With these results available the independent observer stopped the randomized trial as it was judged to be unethical to continue the study when it became evident that use of the mesh involved a dramatically lower rate of parastomal hernia. It was the observer’s view that it was unethical to subject patients not receiving a mesh to the very high rate of parastomal hernia.

Five year follow up was after 57 to 83 months (mean 65.2), similar for both groups. After 5 years another 5 patients with a conventional stoma had died. In the 21 remaining parastomal hernia was found in 12 and 5 had been subjected to parastomal hernia repair. In the group receiving a prophylactic mesh another six patients had died and in the 15 remaining parastomal hernia was present in 2, which had not demanded hernia repair (p<0.001). (Table 2)

No fistula formation or stoma stricture was found in the two groups after one and five years. No mesh infection was noted and no mesh was removed during the study period.
Table 1. Patient and operative characteristics related to enterostoma with or without a prosthetic mesh

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<th>No mesh n=27</th>
<th>Mesh n=27</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean years (95% CI)</td>
<td>71 (67-76)</td>
<td>70 (64-75)</td>
<td>0.80 §</td>
</tr>
<tr>
<td>Women, No.</td>
<td>11</td>
<td>12</td>
<td>1.0 *</td>
</tr>
<tr>
<td>Body Mass Index, mean (95% CI)</td>
<td>27 (25-29)</td>
<td>26 (24-28)</td>
<td>0.56 §</td>
</tr>
<tr>
<td>Emergency laparotomy</td>
<td>4</td>
<td>1</td>
<td>0.35 *</td>
</tr>
<tr>
<td>Reason for operation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malignant tumour</td>
<td>22</td>
<td>25</td>
<td>0.42 *</td>
</tr>
<tr>
<td>Diverticulitis</td>
<td>3</td>
<td>1</td>
<td>0.61 *</td>
</tr>
<tr>
<td>Inflammatory bowel disease</td>
<td>1</td>
<td>1</td>
<td>1.0 *</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0</td>
<td>1.0 *</td>
</tr>
</tbody>
</table>

* Fisher’s exact test, § Mann Whitney U-test
Table 2. Parastomal hernia at 1- and 5-year follow-up

<table>
<thead>
<tr>
<th></th>
<th>No mesh n=27</th>
<th>Mesh n=27</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Died before 1-year follow up</td>
<td>1</td>
<td>6</td>
<td>0.10 *</td>
</tr>
<tr>
<td>Parastomal hernia after 1 year</td>
<td>13 of 26</td>
<td>1 of 21</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Died between 1-year and 5-year follow up</td>
<td>5</td>
<td>6</td>
<td>0.51*</td>
</tr>
<tr>
<td>Mean follow up (months)</td>
<td>64.5</td>
<td>66.0</td>
<td>0.80 §</td>
</tr>
<tr>
<td>Parastomal hernia after 5 years</td>
<td>17 of 21</td>
<td>2 of 15</td>
<td>&lt;0.01 *</td>
</tr>
<tr>
<td>Fistula, n</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Stenosis, n</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Mesh removed, n</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

* Fisher’s exact test, § Mann Whitney U-test
An end ostomy was constructed in 93 patients. The most common indication for surgery was malignant disease. In 8 patients other indications were for example anal incontinence, rectal fistula, perineal trauma and obstetric complications. (Table 3 - 4)

A prophylactic mesh was used in 75 patients and was omitted in 18. A mesh was omitted in 8 of 68 patients (12%) operated on by four surgeons that performed at least 10 operation during the study period. A mesh was omitted in 10 of 25 patients (40%) by 8 surgeons performing less than 10 operations. In 9 patients a mesh could not be placed at the planned stoma site due to severe scarring of peritoneum and the abdominal wall after previous surgery. The surgeon omitted a prophylactic mesh in 5 patients because of limited life expectancy and in 4 patients because of planned early stoma closure.

A prophylactic mesh was used in 19 of 28 (68%) emergent operations and in 56 of 65 (86%) elective. A prophylactic mesh was used in 19 of 29 (65%) dirty wounds and in 56 of 64 (87%) contaminated. In patients receiving a mesh mean age was 65 (95% CI 62, 68) years and 57 (95% CI 47, 68) without a mesh.

Within 10 days of surgery 5 patients died of septic or cardiovascular complications not related to the use of a mesh. Surgical site infection was present in 10 of the 88 (11%) remaining. (Table 4) Infections were in the laparotomy wound and no mesh was infected. Infection was more common when a mesh was omitted. The rate of the infection was similar for surgeons performing less than 10 operations and those creating more stomas (10% vs. 12%). Most infections were minor, not requiring treatment. In two patients a
There were no late infections or persistent infections during the observation period.

Table 3. Patient and operative characteristics for 93 patients with an ostomy created

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N 93</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean years (95% CI)</td>
<td>63 (60, 67)</td>
</tr>
<tr>
<td>Male / Female</td>
<td>61 / 32</td>
</tr>
<tr>
<td>Body Mass Index, mean (95% CI)</td>
<td>25 (24, 26)</td>
</tr>
<tr>
<td>Malignant disease</td>
<td>65</td>
</tr>
<tr>
<td>Inflammatory bowel disease</td>
<td>7</td>
</tr>
<tr>
<td>Perforated diverticulitis</td>
<td>10</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
</tr>
<tr>
<td>Emergent surgery</td>
<td>28</td>
</tr>
<tr>
<td>Degree of wound contamination:</td>
<td></td>
</tr>
<tr>
<td>Contaminated</td>
<td>64</td>
</tr>
<tr>
<td>Dirty</td>
<td>29</td>
</tr>
<tr>
<td>Ostomy:</td>
<td></td>
</tr>
<tr>
<td>Colon</td>
<td>79</td>
</tr>
<tr>
<td>Ileum</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>No mesh</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Surgical site infection, n (95% CI)</td>
<td>4 of 15 (27% 1, 52)</td>
</tr>
<tr>
<td>Minor infection, n</td>
<td>3</td>
</tr>
<tr>
<td>Major infection, n</td>
<td>1</td>
</tr>
<tr>
<td>Wound contaminated</td>
<td></td>
</tr>
<tr>
<td>Surgical site infection, n</td>
<td>1 of 7</td>
</tr>
<tr>
<td>Wound dirty</td>
<td></td>
</tr>
<tr>
<td>Surgical site infection, n</td>
<td>3 of 8</td>
</tr>
</tbody>
</table>
Before one year follow-up 13 patients died and in 7 bowel continuity had been restored. Follow up examination was for the 73 remaining after 10 to 45 months (mean 15 months, 95% CI 14, 16). With a prophylactic mesh parastomal hernia was less frequent than without a mesh. (Table 5)

**Table 5.** Complications after one year in 73 patients operated on with an ostomy created

<table>
<thead>
<tr>
<th></th>
<th>No mesh</th>
<th>Mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parastomal hernia, n (95% CI)</td>
<td>8 of 12 (67% 35, 98)</td>
<td>8 of 61 (13% 4, 22)</td>
</tr>
<tr>
<td>Colostomy</td>
<td>7 of 8</td>
<td>7 of 52</td>
</tr>
<tr>
<td>Ileostomy</td>
<td>1 of 4</td>
<td>1 of 9</td>
</tr>
<tr>
<td>Fistula, n</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Stenosis, n</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mesh removed, n</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
In 27 patients the mean area of the stoma opening was 4.3 cm² (Range 0.6 cm² to 11.3 cm²). At CT-scan in the prone position assessments were in total agreement for surgeons and radiologists in 21 patients. They then regarded 11 parastomal hernias to be present and 10 stomas to be intact. In these 21 patients herniation was regarded present in none of 8 patients with a stoma area of less than 3 cm² and in 11 of 13 with a larger opening (p<0.001).

In 6 patients the raters’ assessment was not in total agreement (Table 6). In patient A surgeons regarded the stoma to be intact and radiologists considered a parastomal hernia to be present. In patients B and C (stoma area of 0.9 cm² and 1.9 cm² respectively) only one radiologist regarded a parastomal hernia to be present.

In 4 patients a parastomal hernia was detected at CT-scan with the patient in the prone position but not when supine. Stoma area was in these patients 3.1 cm², 3.5 cm², 4.3 cm² and 8.3 cm² respectively. In 3 out of these there was total agreement on a parastomal hernia being present among the surgeons and radiologists with CT-scan in the prone position (Table 6). In one patient two surgeons did not detect a parastomal hernia.

For the surgeons at clinical examination Kappa was 0.85. For the radiologists Kappa was 0.85 with CT-scan in the prone position and 0.82 in the supine position. For the surgeons and radiologists collectively, Kappa was 0.80 with CT-scan in the prone position. With CT-scan in the supine position Kappa was for the surgeons and radiologists collectively 0.64. With CT-scan in the prone and supine position Kappa was 0.65. The assessments of the two senior surgeons were in total agreement (Kappa 1.0) and together with the two radiologists that differed least between each another (Kappa 0.93) the collective Kappa was 0.90 was for CT-scan in prone position. (p<0.001 for all Kappa values)
Table 6. Raters’ assessment of a parastomal hernia being present in 6 patients where there was not total agreement for all surgeons and radiologists, at CT-scan in prone position.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Surgeon 1</th>
<th>Surgeon 2</th>
<th>Surgeon 3</th>
<th>Radiologist 1</th>
<th>Radiologist 2</th>
<th>Radiologist 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>B</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>C</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>D</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>E</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>F</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
Discussion

Parastomal hernia is a clinical problem that despite several efforts to find surgical techniques to lower the rates continues to be a major problem. An incisional hernia is defined as abdominal contents protruding through a defect in the abdominal wall. This means that the surgeon constructing an ostomy per definition also creates an incisional hernia. Experiences during the last decades clearly show that in order to achieve low recurrence rates incisional hernias should be repaired with a prosthetic mesh. If one regards an ostomy as a deliberately created incisional hernia the very high rates of parastomal hernia are perhaps not surprising. Continuing this line of thought it may also seem logical that the path towards preventing the development of parastomal hernia is similar to the way incisional hernias are repaired i.e. with a prosthetic mesh.

There are several reasons to hesitate in placing a prosthetic mesh at the stoma site. The clinical experience is that a mesh in close contact with bowel may cause adhesions, inflammatory response, strictures, fistulas and severe septic complications. These complications are to some extent related to the properties of the mesh. High density, small pore meshes induce a higher degree of inflammatory response in the tissues and are prone to erode into the bowel and cause severe septic complications. In general hernia surgery these aspects have been considered for many years and there is a distinct trend towards utilizing low weight, large pore meshes. Such meshes induce a lower degree of inflammatory response and therefore probably a lower risk of strictures, adhesions and erosion into the bowel. Integration of the mesh into surrounding tissues seems to be good enough for the stability of the repair, with available low weight meshes. The concept of low weight, large pore meshes is presently not quite clear as there is no uniform
definition or standardisation of mesh properties. There is on the other hand considerable clinical and experimental experience available for a great variety of meshes.

The Vypro® (Ethicon, Norderstedt, Germany) mesh is generally regarded as a low weight, large pore mesh. It is constituted out of equal proportions of monofilament polypropylene and multifilament polyglactin. Succeeding the Vypro® mesh the Ultrapro® (Ethicon, Norderstedt, Germany) mesh was developed, constituted out of equal proportions of monofilament polypropylene and monofilament poliglecaprone. The polypropylene component is non absorbable and after integration of the mesh into surrounding tissues constitutes the long term stability of the mesh. The polyglactin and poliglecaprone components are absorbable materials contributing to the strength of the mesh for two to three weeks and are within a couple of months completely absorbed. The rational for this construction is that the mesh initially has a higher density inducing sufficient inflammatory response for integration of the mesh into surrounding tissues and as this phase is completed only the proportion of the mesh necessary for its supportive function is left in the wound. Generally materials implanted in tissues should be monofilament as they are associated with a lower risk of infection than multifilaments. For this reason the multifilament polyglactin in the Vypro® mesh was in the Ultrapro® mesh replaced by the monofilament poliglecaprone. [104-105]

There is considerable clinical experience with the use of low weight, large pore meshes. It seems to be possible to place such meshes into close contact with bowel without detrimental effects and their supportive effect has been sufficient for inguinal and incisional hernia repair. They appear resistant to infection and if an infection occurs the mesh does not have to be removed as infection subsides with general surgical and antibiotic treatment of surgical
site infection. Searching for a suitable prosthetic mesh to place into close contact with bowel low weight, large pore meshes seemed suitable and were therefore chosen for the present studies.

Although theoretical assumptions and clinical experiences were in favour of placing a low weight, large pore mesh as a prophylactic mesh in close contact with bowel at stoma formation a degree of uncertainty regarding complications still remained. There was a possibility of stricture, mesh eroding into bowel and severe septic complications developing within this setting. To avoid that in our randomized study the trial was continued despite such complications frequently occurring an independent observer annually looked into the number of complications recorded and had the power to close randomization if an unduly high rate occurred. The observer did eventually close randomization. Not because of a high rate of complications with a mesh utilized but because it was considered unethical to subject patients to a very high rate of parastomal hernia when a mesh was not used.

The intention was to include all patients at the department provided with an ostomy into the randomized trial. Surgeons and staff were informed about the trial, inclusion criteria and of the surgical technique when placing a prophylactic prosthetic mesh. The trial was approved by the local ethics committee. Patients were informed and were asked for their consent for inclusion in the trial. Generally all patients asked approved inclusion but in the emergent situation many patients could not be included as the situation and their septic condition was not compatible with obtaining proper informed consent. Randomization was by opening closed envelopes. These were sorted in batches of four as it was regarded important for surgeons’ adherence to the trial that a mesh was utilized on a regular basis. This had the consequence that when multiples of four were randomized an equal
number of mesh / non mesh was included. When an even number, not a multiple of four, were randomized the probability of an equal number of mesh / non mesh was 66%.

Results of the randomized trial after one year and after five years convincingly showed that with a low weight, large pore mesh placed in a sublay position at the index operation substantially reduces the risk of parastomal hernia. This was achieved without any long term complications related to the mesh [16, 21]. These findings are in congruence with two later randomized trials [22, 52] and several clinical reports [19-20, 50, 52-53, 106] with a prophylactic mesh utilized in sublay, onlay or IPOM position. One of the randomized trials was conducted, into detail, similarly to the present trial and results were also very comparable. It is very interesting that a mesh in the present setting could be placed in severely contaminated surroundings with an acceptable rate of wound infection and without infection of the mesh occurring [107]. The sublay position of the mesh may have been important for this outcome as it was then into close contact with a well vascularised rectus abdominis muscle possible enhancing rapid tissue integration of the mesh and prompt cellular response.

After closing the randomized trial a prophylactic mesh was used in all end stomas at the department. A prophylactic mesh utilized in routine surgery with several surgeons involved and in both elective and emergency surgery was evaluated. This study currently represents the largest cohort using a prophylactic mesh when forming a stoma. Findings in this study showed that a prophylactic mesh could be placed in most patients. A mesh had to be omitted in only 10% because of severe scarring of the abdominal wall after previous surgery. It was also obvious that surgeons at the index operation were not able to anticipate the patients’ expected survival or the probability of a permanent stoma. Thus, surgeons tended to omit a prophylactic mesh in
patients that may very well have profited by a prophylactic mesh. This tendency was more pronounced for surgeons inexperienced in colorectal surgery. The rate of parastomal hernia was in routine surgery very similar to those achieved in the randomized trial. It is very interesting that a mesh could also be placed in a large number of patients with severely contaminated wounds, including faecal peritonitis, with an acceptable rate of infection and without infection of the mesh occurring.

The question must be raised of why a prophylactic prosthetic mesh reduces the rate of parastomal hernia. The clue to answering this question may be to recognize that there was a strong correlation between the area of the stoma opening and the presence of herniation at CT-scan. The opening made by cutting a cross in the centre of the mesh probably sets an upper limit for the size of the stoma opening. Thus, a prophylactic mesh may prevent the development of parastomal hernia because it prevents the stoma opening from growing any larger than the size created at the index operation.

The lack of a uniform definition of parastomal hernia at clinical examination and at CT-scan is a major problem when comparing results in different reports. In the five year follow-up of the randomized trial 80% of patients had developed a parastomal hernia when a conventional stoma without a prophylactic mesh was constructed. That almost every patient with a stoma actually develops a parastomal hernia is difficult to accept and may have affected the definition of herniation used at follow-up. In reports with a low rate of parastomal hernia the authors may, reluctant to accept the very high rates otherwise encountered, have regarded small protrusions as a normal condition after stoma formation and regarded only larger protrusions as parastomal hernias. Concerning this no exact knowledge is possible regarding studies reported before 2004 since the definition of herniation used at follow-up was not presented. Beginning in 2004 many authors have used
the same clinical definition as in the present studies and they have reported very similar herniation rates.

In our studies a very standardized definition of parastomal hernia was used at clinical examination. Any protrusion in the vicinity of the stoma with the patient straining in both supine and erect positions was regarded as a parastomal hernia. With this simple definition there is a minimum of subjectivity when grading of the protrusion. In order to validate this definition three surgeons independently examined patients and achieved a Kappa of 0.85. Kappa 0.60 to 0.79 is generally regarded as a good correlation between raters’ judgment and Kappa 0.80 or higher as a very good correlation. CT-scan is usually done with the patient in the supine position. It is then difficult to ask the patients to strain during the time it takes to perform the CT-scan and it cannot be performed with the patient erect. A new method was therefore developed adding a CT-scan with the patient in the prone position and the stoma placed in the centre of an inflatable ring. In this way a situation with the patient constantly straining was mimicked as all intra abdominal pressure was transmitted to the stoma. Three radiologists independently examined the CT-scans. For radiologists Kappa was 0.85 with CT-scan in the prone position and 0.82 in the supine position. For surgeons and radiologists collectively, Kappa was 0.80 with CT-scan in the prone position and 0.64 in the supine position. When all surgeons agreed that there was a parastomal hernia present at clinical examination all radiologists also detected a hernia at CT-scan. Thus, there was a strong correlation and reproducibility for the clinical and the radiological definitions used. This was very probably related to the simplicity of the definitions and the thorough information and discussion of the definitions used among raters before the assessments were done. The correlation between clinical examination and findings at CT-scan with the patient’s in the prone position was very strong. It was not as strong
with CT-scan in the supine position and it was obvious that several
parastomal hernias that were detected at clinical examination and at CT-scan
in the prone position could not be detected with patients supine.

The strong correlation between clinical examination and CT-scan in
the prone position support the theory that the clinical definition used at follow-
up examination in the present studies is relevant. Kald has previously shown
that patients with a parastomal hernia according to this definition have a
poorer quality of life [5]. In the present study we found a very strong
agreement between the clinical diagnosis and the radiological diagnosis. It
was in fact so strong that a CT-scan as a complement to the clinical
examination hardly seems justified. Thus, the present and other reports that
have used this clinical definition have not only reported very similar rates of
parastomal hernia but have probably also reported a rate very much
reflecting the clinical reality.

It has been claimed that with a CT-scan small parastomal hernias
are detected that cannot be found clinically [13-14, 22]. This was not the case
in the present study when patients were examined in the prone position. It
was also obvious that several hernias detected at clinical examination could
not be detected with a CT-scan with patients supine. There have been
attempts to subtype parastomal hernias according to how they present at CT-
scan but in the present context this did not serve any purpose. The aim of the
present studies was to find and validate clinical and radiological definitions of
parastomal hernia that distinguished between the presence and absence of a
parastomal hernia [3-4, 97, 108-109].

In the present studies a validated definition of parastomal hernia at
clinical examination and with CT-scan was found. A prophylactic prosthetic
mesh reduced the rate of parastomal hernias developing without increasing
the rate of complications. It seems appropriate to conclude that the present
studies show that the path towards reducing the rate of parastomal hernia includes the use of a prophylactic mesh.

**Future perspectives**

We cannot know, however, if the type of mesh used in the present studies is the optimal mesh or if other types of meshes can be used for the same purpose with similar results. Future studies may identify meshes or new meshes may be developed that are even more suitable in this situation. Meshes were placed in a sublay position. This placement was quick and easy to perform and it can also be done by a laparoscopic technique with similar results [110].

Ileostomies are also constructed in urological procedures such as Bricker diversions, probably with similar high parastomal hernia rates as with other ostomies. A major problem with parastomal hernias after Bricker diversion is that the repair of such hernias is technically very difficult and represents a major surgical challenge. The recurrence rate after such repair is not known. At the Department of Urology, Sundsvall hospital, a prophylactic low weight, large pore mesh in a sublay position has also been utilized for preventing the development of parastomal hernia after Bricker diversion. Non published results of 36 ileostomies at Bricker diversions receiving a prophylactic mesh indicate that similar low parastomal hernia rates are achieved as with other ostomies.

Future studies may find that the mesh can be placed in other positions with similar results. The most attractive positioning is then probably an intra abdominal onlay position (IPOM) since it is technically an easy procedure. This demands meshes, however, that provide appropriate tissue integration of the mesh without increasing the risk of adhesions or the development of...
enteric fistulas. Unfortunately long term effects of intra peritoneal meshes are today virtually unknown. There are several meshes available with the mesh surface facing abdominal contents constructed in a fashion that allegedly prevents adhesions and inflammatory response. The problem is that long term follow-up or randomized trials are lacking.

In the present studies a flat mesh with a cross cut in its centre was used. It is very tempting to assume that meshes shaped with a funnel arising, as developed by Berger [53] would further reduce the rate of parastomal hernias developing. This is of course because a parastomal hernia, once the mesh is integrated with surrounding tissues, can only protrude through the space between the bowel and the mesh opening. If the flat portion of the mesh continues into the funnel this weak spot for hernia development might be eliminated. There are, however, several challenges encountered constructing such a mesh. The shape of the funnel is especially crucial, as is the type of mesh used for the funnel. If the funnel part of the mesh causes too much tissue response adhesions, enteric fistulas and stenosis may prove to be a problem. No doubt in the future there will be experiments and clinical studies carried out in this direction.

The use of a prophylactic mesh in Bricker diversions should be further explored and long term results be provided. Permanent stomas are also constructed in children. With an ostomy present for their entire life it is of course essential that no parastomal hernia develops. Although there is no data available on the rate of parastomal hernia in children there is probably no reason to assume the rate to be very much lower than in adults. Thus, children may also benefit by the use of a prophylactic mesh. Generally, one should be cautious about placing a prosthetic mesh in growing persons. This area would therefore present a challenge for future studies.
Conclusions

1. A prophylactic prosthetic large pore, low weight mesh placed in a sublay position at the index operation substantially reduces the rate of parastomal hernia.

2. A prophylactic mesh is not associated with an increased rate of surgical site infection, stoma stenosis or enteric fistulas, even if placed in severely contaminated wounds.

3. Parastomal hernia should at clinical examination be defined as any protrusion in the vicinity of the stoma with the patient straining in a supine and an erect position. With this definition there is a strong correlation between the assessments of clinical raters and CT-scan.

4. At CT-scan parastomal hernia should be defined as any intra abdominal content protruding beyond peritoneum or the presence of a hernia sac with the patient examined supine face down. With this definition there is a strong correlation between the assessments of radiological raters and clinical assessments.
References


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