NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia

A stoma is an opening on the front of the abdomen, made to allow faeces or urine to be collected in a bag on the outside of the body. A parastomal hernia happens when part of the intestine bulges around the stoma. This can cause discomfort, difficulties fitting the stoma bag and it can block the stoma. This procedure involves inserting a piece of synthetic or biological mesh close to the stoma when it is created. The aim is to strengthen the abdominal wall and prevent a hernia.

Contents

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in September 2018 and updated in April 2019.

Procedure name

- Reinforcement of a permanent stoma with synthetic or biological mesh to prevent a parastomal hernia

Specialist societies

- Royal College of Surgeons of England
- Royal College of Surgeons of Edinburgh
- Royal College of Physicians and Surgeons of Glasgow
- Association of Coloproctology of Great Britain and Ireland
- British Association of Urological Surgeons
- British hernia society (Speciality association of the Association of Surgeons of Great Britain & Ireland).

Description of the procedure

Indications and current treatment

Stomas are created surgically to divert the contents of the urinary or digestive tract through an opening in the abdominal wall. A parastomal hernia allows

protrusion of abdominal contents through the abdominal-wall defect created by the stoma. They are relatively common, usually developing gradually and increasing in size over time. A parastomal hernia may remain asymptomatic, but can cause problems such as unacceptable physical appearance, poorly-fitting stoma device, bowel obstruction, and bowel ischaemia and strangulation.

A parastomal hernia can be repaired surgically, using an open or laparoscopic approach. Surgical repair is associated with its own morbidity and there is a high risk of recurrence.

What the procedure involves

This procedure is done using general anaesthesia, at the same time as the creation of the stoma. A space is formed between the rectus abdominus muscle and the rectus sheath of the abdominal wall, and a piece of synthetic or biological mesh is inserted into the space. The bowel or ureter is passed through the mesh and then through the abdominal wall. The mesh and the bowel or ureter are stitched to the abdominal wall. The aim is to strengthen the abdominal wall and prevent parastomal herniation.

Efficacy summary

Incidence of parastomal hernia (PH)

In a systematic review and meta-analysis of 844 patients from 10 randomised controlled trials (RCTs) of prophylactic mesh reinforcement compared with no mesh placement at the index procedure, there were statistically significantly fewer parastomal hernias (PHs) in the prophylactic mesh group (22% [84/387]) compared with the non-mesh group (41% [156/384]) at 6-month to 24-month follow-up: risk ratio (RR) 0.53, 95% confidence interval (CI) 0.43 to 0.66; 10 studies, 771 participants; I^2=69%; low-quality evidence. In the same study, the incidence of PH at 12 months was also statistically significantly less in the mesh group compared with the non-mesh group (25% [75/297] compared with 45% [133/295]; RR 0.47, 95% CI 0.29 to 0.78; 7 studies, 592 participants; I^2=74%; low-quality evidence).[1]

In a systematic review and meta-analysis of 500 patients (382 patients who had a synthetic mesh from 13 studies, compared with 118 patients who had a biological mesh from 5 studies) the rate of PH was statistically significantly less in the prophylactic mesh group (synthetic or biological) compared with the non-mesh group (meta-analysis of 7 RCTs [174 mesh compared with 181 non-mesh]): weighted-pooled proportion 14.9% (95% CI 6.1 to 26.6) compared with 46.8%, 95% CI 24.7 to 69.7; odds ratio (OR) 0.20; 95% CI 0.08 to 0.50; p = 0.0006. In the same study, the rate of PH was not statistically significantly different between

the prophylactic mesh group and the non-mesh group in a meta-analysis of all 18 studies. There was also no statistically significant difference between the prophylactic biological mesh group and the prophylactic synthetic mesh group for the rate of PH in a meta-analysis of 7 RCTs.[2]

In an RCT of 232 patients (114 patients who had a synthetic mesh, compared with 118 who had no mesh at colostomy creation) the PH rate 1 year after the procedure was not statistically significantly different between groups.[3]

In an RCT of 133 patients (67 patients who had a synthetic mesh, compared with 66 patients who had no mesh during end-colostomy formation) the PH rate at a median follow-up of 372 days was statistically significantly less in the mesh group (4% [3/67]) compared with the non-mesh group (24% [16/66]), p=0.0011.[4]

In an RCT of 113 patients (55 patients who had a biological mesh, compared with 58 patients who had no mesh during the construction of a permanent stoma) the PH rate at 2-year follow-up was not statistically significantly different between groups.[5]

In a non-randomised study of 206 patients with rectal cancer (71 patients who had mesh, compared with 135 patients who had no mesh during abdominoperineal excision or Hartmann's procedure) the rate of PH was not statistically significantly different between groups 1 year after the procedure.[6]

In a non-randomised comparative study of 226 patients (109 patients who had a mesh, compared with 117 patients who had no mesh during an emergency surgery with formation of a stoma) the rate of PH 1 year after the procedure was not statistically significantly different between groups.[8]

Re-intervention rate

In the systematic review and meta-analysis of 844 patients, there was no statistically significant difference between the mesh group and the non-mesh group for the re-intervention rate at 6-month to 12-month follow-up.[1]

In the RCT of 232 patients, the re-intervention rate within 30 days was not statistically significantly different between the mesh group and the non-mesh group. The reasons for re-intervention were as follows: small bowel obstruction needing adhesiolysis (1 in each group), conversion to transverse colostomy (1 in the mesh group), revision of the enterostomy (2 in the mesh group and 3 in the non-mesh group), bleeding (2 in the mesh group), superficial or deep infection (1 in each group) and wound rupture (1 in the non-mesh group). A further 4 patients in the mesh group and 2 patients in the non-mesh group were reoperated within the first postoperative year. At 1-year follow up, 12 patients in the mesh group and 8 patients in the non-mesh group had been reoperated.[3]

In the RCT of 133 patients, there was no statistically significant difference between the mesh group and the non-mesh group for the re-intervention rate during the initial hospital stay. None of the reoperations were attributable to complications of the mesh. The indications for reoperation were perineal infection (2 in the mesh group and 6 in the non-mesh group), burst abdomen (2 in the mesh group), colonic ischaemia (1 in the mesh group), negative laparotomy (1 in each group) and bowel obstruction (1 in each group).[4]

In the RCT of 113 patients, the PH repair rate was not statistically significantly different between groups.[5]

In the non-randomised comparative study of 206 patients, the rate of re-operation for PH was not statistically significantly different in the mesh group compared with the non-mesh group.[6]

In a retrospective case series of 114 patients, there was no surgical revision due to stoma stenosis, mesh infection or mesh migration.[7]

Length of hospital stay after the procedure

In the systematic review and meta-analysis of 844 patients, there was no statistically significant difference between the mesh group and the non-mesh group for the length of hospital stay after the procedure.[1]

In the RCT of 113 patients, there was no statistically significant difference between the mesh group and the non-mesh group for the length of hospital stay after the procedure.[5]

In the non-randomised comparative study of 226 patients, there was no statistically significant difference between groups for the median length of hospital stay.[8]

Quality of life

In the RCT of 133 patients, there was no statistically significant difference in quality of life (measured with the 36-item Short Form) between the mesh group and the non-mesh group at a median 372-day follow-up.[4]

In the RCT of 113 patients, the stoma-QOL score at 2-year follow-up was not statistically significantly different between groups.[5]

Safety summary

Overall complications

The overall complications rate in the mesh group and in the non-mesh group was not statistically significantly different between groups in a randomised controlled trial (RCT) of 232 patients (114 patients who had a synthetic mesh, compared with 118 who had no mesh at colostomy creation).[3]

Adverse events were reported in 98% (54/55) of patients in the mesh group compared with 95% (55/58) of patients in the non-mesh group within 24-month follow-up in an RCT of 113 patients (55 patients who had a biological mesh, compared with 58 patients who had no mesh during the construction of a permanent stoma); this is not statistically significant. Severe adverse events were reported in 38% (21/55) of patients in the mesh group compared with 52% (30/58) of patients in the non-mesh group.[5]

Complications after the procedure were reported in 42% (30/71) of patients in the mesh group compared with 49% (66/135) of patients in the non-mesh group in a non-randomised comparative study of 206 patients with rectal cancer (71 patients who had a mesh, compared with 135 patients who had no mesh during abdominoperineal excision or Hartmann's procedure); this is not statistically significant. There were no mesh-related complications that needed mesh removal.[6]

Surgical complications

The surgical-complications rate was not statistically significantly different between the mesh group (27% [30/110]) and the non-mesh group (28% [31/112]) in the RCT of 232 patients.[3]

Surgical complications after the procedure were reported in 32% (23/71) of patients in the mesh group compared with 36% (48/135) of patients in the non-mesh group in the non-randomised comparative study of 206 patients; this is not statistically significant.[6]

Mortality

The overall mortality for patients who had mesh placement during stoma creation was 2.5% (21 deaths, weighted pooled proportion in 18 studies, 95% CI 1.3 to 4.2, no time period reported) in a systematic review and meta-analysis of 500 patients (382 patients who had a synthetic mesh from 13 studies, compared with 118 patients who had a biological mesh from 5 studies). None of the deaths were related to the mesh placement. Two postoperative deaths were caused by progressive metastatic disease, 1 was caused by a pulmonary thromboembolism, and 2 were caused by cardiopulmonary complications. Jänes et al. reported 5 deaths due to septic or cardiovascular complications. Fleshman et al. reported 11 deaths, none of which were related to the device or treatment.[2]

The mortality rate was 9% (5/55) in the mesh group compared with 11% (6/58) in the non-mesh group in the RCT of 113 patients over a 24-month follow-up; none of these deaths were related to the device or treatment.[5]

The in-hospital mortality rate was not statistically significantly different between the mesh group (3% [2/71] compared with the non-mesh group (1 patient) in the non-randomised comparative study of 206 patients.[6]

The death rate 1 year after the procedure was not statistically significantly different between the mesh group (42% [46/109]) and the non-mesh group (40% [47/117]) in a non-randomised comparative study of 226 patients (109 patients who had mesh, compared with 117 patients who had no mesh during emergency surgery with formation of a stoma). Mortality within 30 days of the procedure was also not statistically significantly different between groups (15% [16/109] compared with 16% [19/117]). In the mesh group, deaths within 30 days of the procedure were caused by sepsis (14) or malignancy (1), and 1 cause of death was not reported. In the non-mesh group, deaths were caused by sepsis (13), respiratory complications (4), stroke (1) and malignancy (1).[8]

Local (wound) infection

The rate of stoma-related infections was not statistically significantly different between groups at 6-month to 24-month follow-up in a systematic review and meta-analysis of 844 patients from 10 RCTs comparing mesh reinforcement with no mesh placement at the index procedure.[1]

The rate of wound infections (weighted pooled proportion) in the 7 RCTs included in the systematic review and meta-analysis of 500 patients was not statistically significantly different between the mesh group and the non-mesh group. In a total 18 studies (7 of which were included in the meta-analysis), the weighted pooled proportion of wound infections was 6.9% (95% CI 3.6 to 11.1) in the mesh group compared with 9.3% (95% CI 4.8 to 15.1) in the non-mesh group (no further details provided). Six studies reported treatment of a wound infection: 16 infections were treated conservatively, 7 were treated by surgical drainage, and 2 were treated with systemic antibiotics. In the 18 studies there were no infections reported as caused by the mesh, and intra-abdominal or pelvic infection was reported in 2% of patients.[2]

The rate of wound infections was not statistically significantly different between the mesh group (15% [17/110]) and the non-mesh group (14% [16/112]) in the RCT of 232 patients. In the same study, the rate of deep infections was also not statistically significantly different between groups (6% [7/110] compared with 8% [9/112]).[3]

The proportion of surgical site infections was 21% (15/72) in the mesh group compared with 25% (19/76) in the non-mesh group in an RCT of 133 patients (67 patients who had a mesh, compared with 66 patients who had no mesh during end-colostomy formation); no p value reported. There were 9 perineal wound infections and 1 parastomal infection in the mesh group compared with 11 perineal wound infections and 3 parastomal infections in the non-mesh group. Most wound infections were treated conservatively. No mesh-related infections were identified and no mesh had to be removed.[4]

The rate of infections within 24-month follow-up was not statistically significantly different in the mesh group compared with the non-mesh group in the RCT of 113 patients.[5]

Wound infection in the midline incision was reported in 5% (3/57) of patients within a mean 35-month follow-up in a retrospective case series of 114 patients. In the same study, infection adjacent to the stoma was reported in 2% (1/57) of patients.[7]

Intra-abdominal abscess needing reoperation within 30 days of the procedure was reported in 2% (2/109) of patients in the mesh group compared with 3% (3/117) of patients in the non-mesh group, in the non-randomised comparative study of 226 patients. In the same study, sepsis was reported statistically significantly more in the mesh group (43% [47/109]) compared with the non-mesh group (29% [34/117]), p=0.03. Surgical site infection was reported in 21% (23/109) of patients in the mesh group compared with 15% (18/117) of patients in the non-mesh group. Superficial stoma infection was reported in 3% (3/109) of patients with mesh compared with 1% (1/117) of patients without mesh.[8]

Stoma necrosis

Stoma necrosis was reported in 12% of patients in the systematic review and meta-analysis of 500 patients.[2]

The rate of stoma necrosis was not statistically significantly different between the mesh group (4% [5/110]) and the non-mesh group (7% [8/112]) in the RCT of 232 patients.[3]

Stoma-related problems

Problems related to the stoma including pain, leakage and secondary skin problems were reported in 9% (6/67) of patients in the mesh group compared with 21% (14/66) of patients in the non-mesh group, after 1-year follow-up in the RCT of 133 patients (p=0.09). In the same study, 10% (7/67) of patients needed modification of their stoma appliances after 1 year in the mesh group compared with 24% (16/66) of patients in the non-mesh group (p=0.06).[4]

Stoma-related events were reported in 24% (13/55) of patients within 30 days of the procedure and in 56% (31/55) of patients from 30 days after the procedure in the mesh group, compared with 52% (29/58) of patients within 30 days and 66% (38/58) of patients more than 30 days after the procedure in the non-mesh group, in the RCT of 113 patients. In the mesh group, the stoma-related events reported within 30 days of the procedure were gastrointestinal complication (7%, [4/55]), stoma site pain (4% [2/55]), stenosis of a gastrointestinal stoma (5% [3/55]), stoma site irritation (1 patient), stoma site infection (1 patient), intestinal stoma leak (1 patient) and intestinal stoma obstruction (1 patient). The stoma-related events reported more than 30 days after the procedure were stoma site irritation (22% [12/55]), gastrointestinal stoma complication (13% [7/55]), stomal hernia (11% [6/55]), prolapse of intestinal stoma (1 patient), stoma site infection (4% [2/55]), abdominal pain (1 patient), stoma site pain (1 patient) and enterocutaneous fistula (1 patient). In the non-mesh group, the stoma-related events reported within 30 days of the procedure were gastrointestinal complication (19%, [11/58]), stoma site pain (3% [2/58]), stoma site irritation (3% [2/58]), cellulitis (3% [2/58]), stoma site infection (1 patient), incision site pruritus (1 patient) and stoma site bleeding (1 patient). The stoma-related events reported more than 30 days after the procedure were stoma site irritation (21% [12/58]), gastrointestinal stoma complication (12% [7/58]), stomal hernia (12% [7/58]), prolapse of intestinal stoma (3% [2/58]), stoma site infection (1 patient), abdominal pain (1 patient), stoma site candida (3% [2/58]), stoma site pain (1 patient), cellulitis (1 patient), intestinal stoma leak (1 patient), stomal ulcer (1 patient), stoma site bleeding (1 patient) and stoma site inflammation (1 patient). There was no statistically significant difference between groups for all comparisons.[5]

Stoma-related complications that needed reoperation were reported in 6% (6/109) of patients in the mesh group compared with 6% (7/117) of patients in the non-mesh group within 30 days of the procedure, in the non-randomised comparative study of 226 patients (no p value reported). In the mesh group, the stoma-related complications were necrosis of ostomy bowel (2 patients), intra-abdominal abscess (1 patient), stoma obstruction (1 patient) and stoma subcutaneous perforation (2 patients). In the non-mesh group, the complications were necrosis of ostomy bowel (5 patients), prolapsed stoma (1 patient) and stoma obstruction (1 patient). There were also 3% (3/109) of patients in the mesh group and 1 patient in the non-mesh group who had a superficial infection of the stoma without reoperation within 30 days. Within 1 to 12 months after the procedure, 1 patient in the mesh group compared with none in the non-mesh group had a superficial infection without reoperation and 1 patient compared with 3% (3/117) of patients had a complication needing reoperation. The complications were iatrogenic perforation of stoma bowel in the mesh group and stoma dysfunction in the non-mesh group.[8]

Cutaneous/fascial dehiscence

Cutaneous or fascial dehiscence was reported in 4% of patients in the systematic review and meta-analysis of 500 patients.[2]

Pneumonia or other respiratory/thoracic/mediastinal events

The rate of pneumonia was not statistically significantly different between the mesh group (2% [2/110]) and the non-mesh group (1 patient) in the RCT of 232 patients.

The rate of respiratory, thoracic or mediastinal events was not statistically significantly different in the mesh group (4%) compared with the non-mesh group (3%) within 24-month follow-up, in the RCT of 113 patients.[5]

Respiratory complications were reported in 24% (26/109) of patients in the mesh group compared with 19% (22/117) of patients in the non-mesh group within 30 days of the procedure in the non-randomised comparative study of 226 patients.[8]

Cardiovascular complications

Cardiopulmonary events were reported in 5% of patients in the systematic review and meta-analysis of 500 patients (no further details provided).[2]

Acute myocardial infarction was reported in 2 patients in each group in the RCT of 232 patients.[3]

Cardiovascular complications were reported in 8% (9/109) of patients in the mesh group compared with 9% (10/117) of patients in the non-mesh group within 30 days of the procedure in the non-randomised comparative study of 226 patients (no p value reported).[8]

Blood loss

Blood loss needing a blood transfusion was reported in 13% (7/55) of patients in the mesh group compared with 10% (6/58) of patients in the non-mesh group in the RCT of 113 patients; not statistically significantly different. The median estimated blood loss was 100 ml in the mesh group compared with 150 ml in the non-mesh group.[5]

Gastrointestinal bleeding was reported in 4% (4/109) of patients with mesh compared with none of the patients without a mesh within 30 days of the procedure, in the non-randomised comparative study of 226 patients.[8]

Seroma

Seromas were reported in 7% of patients who had a mesh placement (either synthetic or biological) in the systematic review and meta-analysis of 500 patients, and they were all treated by surgical drainage.[2]

Intestinal complications

The rate of intestinal obstruction was not statistically significantly different between the mesh group (2% [2/110]) and the non-mesh group (1 patient) in the RCT of 232 patients.[3]

Bowel obstruction needing reoperation was reported in 5% (5/109) of patients in the mesh group compared with 3% (4/117) of patients in the non-mesh group within 30 days of the procedure, in the non-randomised comparative study of 226 patients. In the mesh group, 1 patient had a re-intervention at 10 days for intestinal obstruction caused by adhesions between the small bowel and mesh that partly protruded intraperitoneally. The adhesions were released and the peritoneum was adapted to cover the mesh left in situ, and the patient experienced no further complications.[8]

The rate of gastrointestinal events such as nausea, vomiting or pain was 24% in the mesh group compared with 30% in the non-mesh group within 24-month follow-up in the RCT of 113 patients (not statistically significantly different).[5]

Burst abdomen

Burst abdomen was reported in 6% (6/109) of patients in the mesh group compared with 9% (10/117) of patients in the non-mesh group within 30 days of the procedure, in the non-randomised comparative study of 226 patients. The patients had reoperations.[8]

Bowel perforation or necrosis

Bowel perforation or necrosis needing reoperation was reported in 6% (6/109) of patients in the mesh group compared with 2% (2/117) of patients in the non-mesh group within 30 days of the procedure, in the non-randomised comparative study of 226 patients.[8]

Gastric ulcer perforation

Gastric ulcer perforation needing reoperation was reported in 1 patient in the mesh group compared with none of the patients in the non-mesh group within 30 days of the procedure in the non-randomised comparative study of 226 patients.[8]

Anastomotic leakage

Anastomotic leakage needing reoperation was reported in none of the patients in the mesh group compared with 1 patient in the non-mesh group within 30 days of the procedure, in the non-randomised comparative study of 226 patients.[8]

Short bowel syndrome

Short bowel syndrome was reported in 3% (3/109) of patients in the mesh group compared with 2% (2/117) of patients in the non-mesh group within 30 days of the procedure, in the non-randomised comparative study of 226 patients.[8]

Thrombosis

Thrombosis was reported in 2% (2/110) of patients in the mesh group compared with none of the patients in the non-mesh group in the RCT of 232 patients; not statistically significantly different. [3]

Blood or lymphatic events

The rate of blood or lymphatic events was 6% in the mesh group compared with 4% in the non-mesh group within 24-month follow-up, in the RCT of 113 patients (p value not reported).[5]

Incisional hernia

Incisional hernia was reported in 10% (7/67) of patients who had a mesh compared with 12% (8/66) of patients who had no mesh after 1-year follow-up, in the RCT of 133 patients (not statistically significantly different).[4]

A midline incisional hernia was reported in 4% (2/57) of patients within a mean 35-month follow-up in the retrospective case series of 114 patients.[7]

Neoplasm

The rate of neoplasm events was 3% in the mesh group compared with 1% in the non-mesh group within 24-month follow-up, in the RCT of 113 patients (p value not reported).[5]

Urogenital complications

Urogenital complications were reported in 7% (8/109) of patients in the mesh group compared with 5% (6/117) of patients in the non-mesh group within 30 days of the procedure, in the non-randomised comparative study of 226 patients.[8]

Urinary tract infection was reported in 5% of patients in the systematic review and meta-analysis of 500 patients.[2]

Urinary tract infection was reported in 4% (5/110) of patients in the mesh group compared with 1 patient in the non-mesh group in the RCT of 232 patients; not statistically significantly different.[3]

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, specialist advisers listed the following anecdotal adverse event: adhesions causing bowel obstruction. They consider that the following are theoretical adverse events: delaying rather than preventing PH formation and, when hernia does occur, the bowel being stuck to the mesh making the stoma much more difficult to repair.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia. The following databases were searched, covering the period from their start to 4 March 2019: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with a need for a permanent stoma construction.
Intervention/test	Reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 1,521 patients from 2 systematic reviews and meta-analyses[1,2], 3 randomised controlled trials[3-5], 2 non-randomised comparative studies[6, 8] and 1 case series[7].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in the appendix.

Table 2 Summary of key efficacy and safety findings on reinforcement of a permanent stoma with mesh to prevent a parastomal hernia

Study 1 Jones HG (2018)

Details

Study type	**Cochrane systematic review and meta-analysis of RCTs**
Country	Systematic review and meta-analysis: UK Included studies: not reported
Recruitment period	Literature search up until 11/01/2018
Study population and number	n= **844 (mesh versus no mesh)** patients having stoma creation from 10 RCTs
Age and sex	Not reported
Patient selection criteria	Only RCTs were included. Inclusion criteria: All individuals of any age receiving a permanent or temporary abdominal wall stoma for colorectal (ileostomy or colostomy) operations in the elective and emergency setting, regardless of the underlying indication for surgery. Patients with intraoperative faecal contamination were also included.
Technique	Any form of mesh reinforcement of the stoma site at the index operation, regardless of type of mesh, type of stoma, anatomical plane of placement, and experience of the operating surgeon were included. Approaches were laparoscopic or open.
Follow-up	**9 of the studies had a minimum of 1 year-follow-up**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: A minimum follow-up period of 6 months from the time of the index operation was necessary to assess the presence of a PH. Data on the incidence of PH at 12 months was usually used, otherwise data on the longest follow-up period reported was used.

Study design issues:

- The primary objective was to evaluate whether mesh reinforcement during stoma formation reduces the incidence of parastomal herniation.
- It was not possible to analyse mesh-related infections, quality of life, and rehospitalisation rate due to sparse data or because the outcome was not reported in the included studies.
- The authors judged the risk of bias across all domains to be low in 6 trials. They judged 4 trials to have an overall high risk of bias.

Study population issues: All ten included studies excluded patients having emergency surgery or patients with intraoperative contamination.

Key efficacy and safety findings

Efficacy
Number of patients analysed: **844 (mesh versus no mesh)** **Overall incidence of PH (follow-up: 6 to 24 months)**: 22% (84/387) versus 41% (156/384); RR 0.53, 95% CI 0.43 to 0.66; 10 studies, 771 participants; I^2 = 69%; low-quality evidence - statistically significant reduction in the risk of PH between the experimental and control groups **Incidence of PH at 12 months**: 25%* (75/297) versus 45% (133/295); RR 0.47, 95% CI 0.29 to 0.78; 7 studies, 592 participants; I^2 = 74%; low-quality evidence – statistically significant benefit in using prophylactic mesh **In the paper, it is written 21%.* **Reoperation rate (follow-up: 6 to 12 months)**: 5% versus 5%; RR 0.90, 95% CI 0.50 to 1.64; 9 studies, 757 participants; I^2 = 0%; low-quality evidence – no statistically significant difference between groups **Post-operative length of hospital stay**: MD -0.95 days, 95% CI -2.03 to 0.70, 4 studies, 500 participants; moderate-quality evidence - no statistically significant difference between groups
Safety
Stoma-related infections (follow-up: 6 to 24 months): 3% versus 3%; RR 0.89, 95% CI 0.32 to 2.50; 6 studies, 472 participants; I^2 = 0%; low-quality evidence - no statistically significant difference between groups
Abbreviations used: CI, confidence interval; MD, mean differences; PH, parastomal hernias; RR, risk ratio.

Study 2 Knaapen L (2017)

Details

Study type	**Systematic review and meta-analysis**
Country	Systematic review and meta-analysis: The Netherlands Included studies: not reported
Recruitment period	Literature search up to 19/04/2016
Study population and number	n= **500 (382 synthetic mesh [13 studies] versus 118 biological mesh [5 studies])** patients having stoma creation
Age and sex	Not reported
Patient selection criteria	Randomised and non-randomised studies were included. When multiple studies describing the same population were published, the most complete report was used. Inclusion criteria for the included studies: participants (human adults, minimum of 18 years of age), intervention (prophylactic placement of mesh), and sufficient data available (10 or more patients). Exclusion criteria: Stoma relocation, primary suture repair, and unspecified surgical technique. Studies published only as abstracts.
Technique	Prophylactic mesh placement with synthetic or biological mesh at the time of stoma creation.
Follow-up	**Range 7 to 65 months**
Conflict of interest/source of funding	None

Analysis

Study design issues:

- The systematic review was performed in accordance with PRISMA.
- The primary aim was to compare biological and synthetic mesh use for the treatment and prevention of parastomal hernia.
- The surgical techniques used for prophylactic mesh placement were as follows: open reinforcement in 12 studies, laparoscopic reinforcement in 3 studies, combined open and laparoscopic reinforcement in 2 studies and combined onlay and sublay techniques in 1 study.

Study population issues: 7 RCTs out of 18 studies were included in this systematic review and meta-analysis. 6 of these were included in the Cochrane systematic review and meta-analysis. The Tarcoveanu (2014) study was not included in the Cochrane systematic review and meta-analysis.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **382 synthetic mesh versus 118 biological mesh**

Prophylactic mesh versus no prophylactic mesh

- **Incidence of PH *(meta-analysis of 7 RCTs [174 mesh compared with 181 non-mesh])***: weighted-pooled proportion 14.9%; 95%CI: 6.1 to 26.6 versus 46.8%; 95%CI: 24.7 to 69.7) (OR = 0.20; 95% CI: 0.08 to 0.50; **p = 0.0006**) – Parastomal hernia occurred statistically significantly less in the prophylactic group compared with the conventional group.
- **Incidence of PH (18 studies):** weighted-pooled proportion 11.5% (95%CI: 7.1 to 16.8) versus 51.5%; 95% CI: 33.7 to 69.1) OR = 0.79 (95% CI 0.40 to 1.55; p= 0.49)

  There was no statistically significant difference between groups.

Prophylactic biological mesh placement versus prophylactic synthetic mesh placement

- ***Meta-analysis of the 7 RCTs***

  Incidence of PH: OR = 0.48; 95%CI: 0.18 to 1.25; p= 0.13

  There was no statistically significant difference between groups.

Safety

Overall mortality for prophylactic mesh placement *(weighted pooled %, in 18 studies):* 2.5% (21 deaths, weighted pooled proportion, 95% CI: 1.3 to 4.2). None of the deaths were related to the mesh placement.

Two postoperative deaths were due to progressive metastatic disease, one was due to a pulmonary thromboembolism, and two were due to cardiopulmonary complications. Jänes et al reported five deaths due to septic or cardiovascular complications not further specified. Fleshman et al described eleven deaths, none of which were related to the device or treatment not further specified.

Prophylactic mesh versus no prophylactic mesh (weighted pooled %)

- **Wound infection rate (7 RCTs):** 7.8% (95% CI 1.8 to 17.5) versus 8.2% (95% CI 4.2 to 13.4); OR = 1.04 (95%CI 0.53 to 2.02; p = 0.91).
- **Wound infection rate (18 studies):** 6.9% (95% CI 3.6 to 11.1) versus 9.3% (95% CI 4.8 to 15.1)

Six studies reported treatment of a wound infection. Sixteen patients were treated conservatively, 7 patients were treated by surgical drainage, and 2 patients were treated with systemic antibiotics.

Mesh infection (weighted pooled %, 18 studies): 0% (95% CI 0 to 2.0)

Other complications reported in the 18 studies:

Seroma: 7%. All nine reported seromas were treated by surgical drainage.

Cardiopulmonary event: 4.7%

Urinary tract infection: 5.4%

Cutaneous/fascial dehiscence: 3.9%

Stoma necrosis: 12.4%

Intra-abdominal/ pelvic infection: 1.6%

Stoma-related problems: 1.6%

Miscellaneous: 20.9%

Severe events not further specified: 39.5%

Abbreviations used: CI, confidence interval; OR, odds ratio; PH, parastomal hernia

Study 3 Odensten C (2017) – *The Stomamesh study*

Details

Study type	**Double-blinded RCT (8 centres)**
Country	Sweden
Recruitment period	2007-15
Study population and number	n= **232 (114 prophylactic mesh versus 118 no mesh)** patients having creation of a permanent end colostomy
Age and sex	Mean 70 years Mesh group: 65% (74/114) male; Non mesh group: 52% (62/118) male
Patient selection criteria	Inclusion criteria: patients scheduled for permanent colostomy with no previous stoma, older than 18 years, and with informed consent. Exclusion criteria: expected survival less than 3 years, faecal peritonitis, previous stoma, and no informed consent.
Technique	In the mesh group, a lightweight polypropylene mesh was placed around the colostomy in the sublay position via open surgery Surgery was done by an experienced colorectal surgeon with an annual volume of at least 100 major surgical procedures. Postoperative mobilisation was according to each hospital's routine.
Follow-up	**1 year**
Conflict of interest/source of funding	Financial support was received from the Swedish Research Council and the Department of Research and Development, Region Norrbotten. The authors reported no conflicts of interest.

Analysis
Follow-up issues:
- Follow-up was done after 1 month and 1 year. Computerised tomography and clinical examination were used to detect PH at the 1-year follow-up.
- After 1 year, 91% (211/232) of patients had a clinical examination and 85% (198/232) had radiologic assessments.
- Reasons for being lost to follow-up were: incomplete follow up because of surgical complication (3 patients); progression of disease (1); development of dementia (1); refusal of patient to participate further in the study (9); and death (7).
- Early complications were evaluated at 1 month, and late complications and possible recurrence of PH were assessed at a 1-year follow up.
- 240 patients were first included in the study but 8 had to be excluded because of a change in surgical approach during the procedure.

Study design issues:
- The aim of the study was to determine if PH rate can be reduced by using synthetic mesh in the sublay position when constructing permanent end colostomy.
- Data were analysed on an intention-to-treat basis.
- Randomisation was done using sealed envelopes, stratified per hospital in blocks of 4, to ensure balance between the 2 arms.
- Postoperative assessment was made by a surgeon not involved in the primary procedure.
- If randomisation of a patient was performed incorrectly, the patient was replaced by 3 new patients to ensure maintenance of power.
- The trial reached a *de facto* power of 91%.
- The study was blinded to patients and surgeons assessing the patient after the procedure.

Study population issues: Only 1 patient had an emergency surgery in the study population.
Other issues: This RCT was included in the Cochrane systematic review and meta-analysis included in Table 2.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **232 (114 prophylactic mesh versus 118 no mesh)**

PH rate at 1 year

	Mesh Group (n= 104)	Non-mesh Group (n=107)	p
Hernia (judged clinically)	29% (30)	30% (32)	0.866
Bulge, no hernia (judged clinically)	14% (15)	17% (18)	0.631
Hernia classified 2 and 3 on CT	24% (25)	26% (28)	0.748
Hernia classified 1, 2, and 3 on CT	32% (33)	34% (36)	0.765

CT-scan was done on 99 patients in each group and the findings were classified according to the model by Moreno-Matias.

Bulge was defined as a protrusion around the stoma judged not to be a hernia.

Safety

Complications at 1 month

	Mesh Group (n= 110)	Non-mesh Group (n=112)	p
Overall complications	34% (38)	32% (36)	0.668
Surgical complications	27% (30)	28% (31)	0.947
Wound infection	15% (17)	14% (16)	0.785
Deep infection	6% (7)	8% (9)	0.644
Intestinal obstruction	2% (2)	1% (1)	0.618*
Stoma necrosis	4% (5)	7% (8)	0.570*
Reoperation within 30 days	6% (7)	5% (6)	0.783*
Other complications			
Acute myocardial infarction	2% (2)	2% (2)	1.000*
Pneumonia	2% (2)	1% (1)	0.618*
Thrombosis	2% (2)	0	0.242*
Urinary tract infection	4% (5)	1% (1)	0.116*

*The assumption for the X^2 test was not fulfilled in these comparisons and Fischer exact test was used.

Reasons for reoperations:

-small bowel obstruction needing adhesiolysis (1 in each group)

-conversion to transverse colostomy (1 in the mesh group)

-revision of the enterostomy (2 in the mesh group and 3 in the non-mesh group)

-bleeding (2 in the mesh group)

-superficial/deep infection (1 in each group)

-wound rupture (1 in the non-mesh group).

A further 2 patients in the non-mesh group and 4 patients in the mesh group were reoperated within the first postoperative year. At the 1-year follow up, a total of 8 patients in the non-mesh and 12 in the mesh group had been reoperated.

Abbreviations used: CT, computerised tomography; PH, parastomal hernia

Study 4 Brandsma H-T (2017) – *The Prevent-trial*

Details

Study type	**Single-blinded RCT**
Country	The Netherlands (14 centres)
Recruitment period	2010-12
Study population and number	**n= 133 (67 mesh versus 66 non-mesh)** patients having formation of a permanent end-colostomy during elective colorectal surgery
Age and sex	Mesh group: Mean 64 years; 60% (43/72) male Non-mesh group: Mean 63 years; 62% (48/78) male
Patient selection criteria	Inclusion criteria: formation of a permanent end colostomy, age between 18 and 85 years, signed informed consent and ability to understand the study questionnaires. Exclusion criteria: expected survival <12 months, stoma formation in an emergency setting, formation of an ileostomy and correction of a previous constructed colostomy.
Technique	In the mesh group, patients received a lightweight polypropylene mesh (Parietene Light (Covidien) surrounding the stoma, which was placed retromuscular, on the posterior fascia of the rectus abdominis muscle. In the control group, a conventional stoma was created without augmentation of the abdominal wall. In both groups, pre-operative antibiotic prophylaxis was given according to local protocol. Bowel preparation was done when considered necessary by the local surgeon.
Follow-up	**Median 372 days**
Conflict of interest/source of funding	None

Analysis
Follow-up issues:
- Outpatient follow-up was scheduled at 3 weeks, 3 months, and 1 year after surgery. Future follow-up will be done at 2 and 5 years after the procedure.
- The incidence of a PH, morbidity, mortality, quality of life, and cost-effectiveness were measured after 1 year of follow-up.
- From 150 patients initially recruited, 2 patients died postoperatively during their index admission due to non-mesh-related complications, and 4 patients died during the first year of follow-up due to progressive disease. Five patients withdrew their consent, 1 due to undefined personal reasons and 4 patients had progressive disease with subsequent chemotherapy. One patient was accidently randomised despite exclusion criteria and was withdrawn at the time of discovery. A further 4 patients were lost to follow-up, 3 patients because they were referred to a non-participating hospital before or shortly after surgery, and 1 patient was randomised for conventional treatment but did not receive a colostomy and did not attend clinical follow-up afterwards. The intention-to-treat analysis was therefore done with a total of 133 patients, with 66 in the non-mesh group and 67 in the mesh group.

Study design issues:
- The aim of this study was to investigate the incidence of PH after end-colostomy formation using a polypropylene mesh.
- All patients were blinded as to their method of stoma formation.
- Patients were randomly allocated in the recruiting hospital by telephone using an interactive computer voice response system. The intervention was stratified into blocks of 6 allocations per hospital and the trial was closed when 150 patients were included.
- The power calculation estimated that 67 patients were needed in each arm of the trial.
- CT imaging was only done in patients suspected for a PH at clinical examination.

Other issues: This RCT was included in the Cochrane systematic review and meta-analysis included in Table 2.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **133 (67 mesh versus 66 non-mesh)**

PH

	Mesh (n=67)	Non-mesh (n=66)	p
PH rate	4% (3/67)	24% (16/66)	**0.0011**
Patients needing surgical intervention due to pain, obstruction or incarceration	1	4	

Quality of life (SF-36)

	Mesh	Non-mesh	p
General Health	61.8±3.2	63.1±3.7	0.7905
Physical Pain	77.5±3.1	77.2±4.5	0.9454
Vitality	62.7±3.2	61.8±3.4	0.8383
Mental Health	77.2±2.4	74.9±3.0	0.5467
Role Emotional	78.5±5.2	71.4±6.3	0.3863
Role Physical	58.9±6.1	58.9±6.9	0.9935
Social Functioning	76±3.8	77.7±4.1	0.7694
Physical Functioning	64.6±3.2	66.3±3.7	0.7287

There was no statistically significant difference in quality of life (SF-36) between both study groups.

Severity of chronic pain (Von Korff Score)

	Mesh	Non-mesh	p
Moment	5.9±1.7	7.1±2.7	0.6995
Maximum	10.4±3.1	12.6±3.4	0.6428
Average	7.9±2.3	9.5±2.8	0.6594
Disability	1.1±0.1	1.2±0.1	0.3942
Activity	5.5±1.8	7.1±2.7	0.6236
Social	8.3±3	7.6±2.8	0.8694
Work	7.2±2.3	8.5±3	0.7152

Safety

Indication for reoperation during the initial hospital stay

	Mesh (n=72)	Non-mesh (n=76)	p
Total	10% (7/72)	11% (8/76)	NS
Perineal infection	2	6	NS
Burst abdomen	2	0	NS
Ischaemia colon	1	0	NS
Negative laparotomy	1	1	NS
Bowel obstruction	1	1	NS

None of the reoperations was attributable to complications of the mesh.

Infection

	Mesh (n=72)	Non-mesh (n=76)
Surgical site infection	21% (15/72)	25% (19/76)
Perineal wound infection	9	11
Parastomal infection	1	3

Most wound infections were treated with conservative management. No mesh-related infections were identified and no mesh had to be removed.

Incisional hernia: 10% (7/67) versus 12% (8/66), p=NS

Morbidity after 1 year

	Mesh	Non-mesh	p
Patient complaints relating to stoma including pain, leakage and secondary skin problems	9% (6/67)	21% (14/66)	0.09
Patients needing modification of their stoma appliances	10% (7/67)	24% (16/66)	0.06

There was 1 stricture of the stoma in the non-mesh group.

Abbreviations used: NS, not statistically significant; PH, parastomal hernia; SF-36, 36-Item Short Form;

Study 5 Fleshman J W (2014)

Details

Study type	**Patient- and third-party assessor-blind RCT**
Country	USA (multicentre)
Recruitment period	2010-12
Study population and number	n= **113 (55 stoma reinforcement versus 58 controls)** patients having construction of a permanent stoma
Age and sex	Mean 60 years; 52% (59/113) male
Patient selection criteria	Inclusion criteria: Adult patients who needed a single permanent ileostomy or colostomy. Exclusion criteria: abdominal hernia (or history of abdominal hernia) in the quadrant selected for stoma placement, surgical mesh present in the area of the stoma, temporary stoma, BMI >34 kg/m^2, life expectancy <24 months, American society of anaesthesiologists class ≥4, substance use, need for chronic psychotropic medication for a significant psychiatric disorder, emergent treatment preventing preoperative stoma site marking, confinement to a bed or non-ambulatory status, and any conditions that could adversely affect the patient's safety.
Technique	Patients were prospectively randomly assigned to have standard end-stoma construction with or without porcine-derived acellular dermal matrix reinforcement (Strattice reconstructive tissue Matrix, Lifecell Corporation). Both open and laparoscopic techniques were used.
Follow-up	**2 years**
Conflict of interest/source of funding	This work was funded by LifeCell Corporation, Branchburg, NJ. Three of the authors received honoraria, grants or research funding from LifeCell Corporation,

Analysis
Follow-up issues:

- Patients were monitored daily in the hospital for complications related to the study intervention, surgical procedure, or disease process. At each postoperative time point (days 1–7 and 30, 6 months, 12 months, and 24 months), patients were evaluated for stoma complications, hernia formation, and adverse events by a blinded assessor. If there was clinical suspicion that a hernia was present, an abdominal CT scan was done.
- A validated stoma quality-of-life questionnaire (Stoma-QOL) was filled out on days 7 and 30 after surgery, and months 3, 6, and 12. The questionnaire comprises 20 questions covering 4 domains – sleep, sexual activity, relations to family and close friends, and social relations outside family and close friends – with a scale of 0 to 100 (with higher scores indicating better quality of life).
- 75 patients (40 reinforcement versus 35 control) completed the 24-month follow-up.

Study design issues:

- The main objective of the study was to assess the safety and efficacy of stoma reinforcement with sublay placement of noncross-linked porcine-derived acellular dermal matrix at the time of stoma construction.
- The incidence of parastomal hernia, safety, and stoma-related quality of life were assessed.
- Randomisation was conducted centrally by using 160 equally weighted blocks of 2 treatments with a blocking factor of 4. Patients and staff members who did the assessments were blinded as to assignment. Non-blinded investigators and staff members were responsible for enrolling and assigning patients, managing the study product, and handling the blinded data.
- The power calculation estimated that 55 patients were needed in each arm of the trial for 80% power, assuming 10% would be lost to follow-up.
- An intention-to-treat analysis was used.

Study population issues: There was no significant difference between the groups in terms of baseline characteristics with the exception of ethnicity (p = 0.045).

IP overview: Reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia

Other issues: This RCT was included in the Cochrane and in the Knaapen (2017) systematic review and meta-analyses included in Table 2.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **113 (55 stoma reinforcement versus 58 controls)**

Hospital length of stay (mean): 9.45 days versus 8.83 (p=NS)

PH at 2-year follow-up

	Stoma reinforcement group	Control group	RR
PH rate per-protocol analysis	10% (5/49)	13% (7/53)	0.85 (95% CI 0.42 to 1.72)
PH rate ITT analysis	-	-	0.94 95% CI 0.51 to 1.75

Of the 13 hernias that occurred (ITT analysis), 11 were confirmed by CT scan and 2 were confirmed operatively.

Repair for PH within 2-year follow-up

	Stoma reinforcement group	Control group	RR
PH repair rate per-protocol analysis	4% (2/49)	11% (6/53)	0.50 (95 % CI 0.15 to 1.69)
PH repair rate ITT analysis	5% (3/55)	10% (6/58)	0.67 (95 % CI 0.26 to 1.71)

QoL

Stoma-QOL score at 24 months (mean±SD): 65.5±19.4 versus 70.8±21.8 (p=0.22)

Safety

Intraoperative findings (ITT population)

Variable	Stoma reinforcement group	Control group	p
Adhesions	36% (20/55)	45% (26/58)	0.44
Iatrogenic injury	2% (1/55)	2% (1/58)	1.0
Intra-abdominal contamination	5% (3/55)	3% (2/58)	0.67
Blood transfusion	13% (7/55)	10% (6/58)	1.0
Estimated blood loss, ml (median)	100	150	0.65

Overall safety over 24 months

Event	Stoma reinforcement group (n=55)	Control group (n=58)	p
Total adverse events	98% (54) patients	95% (55) patients	0.62
Gastrointestinal events (nausea, vomiting, pain)	24% (171) events	30% (216) events	
Blood/lymphatic events	6% events	4% events	
Infections/ infestations	14% events	9% of events	
Respiratory/thoracic/mediastinal events	4% of events	3% of events	
Neoplasms	3% of events	1% of events	
Severe events	38% (21/55) of patients	52% (30/58)	
Deaths (none were related to the device or treatment)	9% (5/55)	11% (6/58)	

Stoma-related events ≤30 and >30 days after surgery

Event	Stoma reinforcement group (n=55)	Control group (n=58)
Number of patients with early (≤30 days after surgery) events	24% (13)	52% (29)
GI stoma complication*	7% (4)	19% (11)
Stoma site pain	4% (2)	3% (2)
Stenosis of GI stoma[a]	5% (3)	0
Stoma site irritation	2% (1)	3% (2)

	Cellulitis	0	3% (2)
	Stoma site infection	2% (1)	2% (1)
	Incision site pruritus	0	2% (1)
	Stoma site bleeding	0	2% (1)
	Intestinal stoma leak	2% (1)	0
	Intestinal stoma obstruction	2% (1)	0
	Number of patients with late (>30 days after surgery) events	56% (31)	66% (38)
	Stoma site irritation	22% (12)	21% (12)
	GI stoma complication**	13% (7)	12% (7)
	Stomal hernia	11% (6)	12% (7)
	Prolapse of intestinal stoma	2% (1)	3% (2)
	Stoma site infection	4% (2)	2% (1)
	Abdominal pain	2% (1)	2% (1)
	Stoma site candida	0	3% (2)
	Stoma site pain	2% (1)	2% (1)
	Cellulitis	0	2% (1)
	Enterocutaneous fistula	2% (1)	0
	Intestinal stoma leak	0	2% (1)
	Stomal ulcer	0	2% (1)
	Stoma site bleeding	0	2% (1)
	Stoma site inflammation	0	2% (1)

p = NS for all between-group comparisons

*In the control group, this included stoma oedema, superficial stoma ischemia, stoma retraction, and mucocutaneous separation of stoma. In the stoma reinforcement group, this included stoma oedema, superficial stoma ischemia, and stoma retraction

**In the control group, this included stoma/other skin related problems, parastomal bulge, and abdominal bulge. In the stoma reinforcement group, this included stoma/other skin-related problems and parastomal bulge.

[a]By day 30 evaluation, 1 patient in the stoma reinforcement group was reported to have stoma stenosis and partial bowel obstruction at the stoma. The patient was successfully treated conservatively, without stomal revision. Two other patients in this group had stoma stenosis before day 30; one was considered a serious adverse event, the other was not. No surgical intervention was needed in either patient. No other events of stenosis or obstruction were reported.

Abbreviations used: BMI, body mass index; CI, confidence interval; CT, computerised tomography; GI, gastrointestinal; ITT, intention-to-treat; NS, not statistically significant; PH, parastomal hernia; QOL, quality of life; RR, relative risk; SD, standard deviation.

Study 6 Nikberg M (2015)

Details

Study type	**Non-randomised comparative study**
Country	Sweden
Recruitment period	1996-2012
Study population and number	n= **206 (71 mesh versus 135 non-mesh)** rectal cancer patients having an abdominoperineal excision or Hartmann's procedure
Age and sex	Mesh group: median 70 years; 61% (43/71) male Non-mesh group: median 72 years; 62% (84/135) male
Patient selection criteria	All patients having a Hartmann's procedure and abdominoperineal excision between 1996 and 2012 at the Colorectal Unit, Västmanland's Hospital Västerås, with a catchment area of 260,000, were included. From 2007, a prophylactic stoma mesh was used in all rectal cancer patients operated electively.
Technique	In patients who received a prophylactic stoma mesh, the mesh was placed between the rectus abdominis muscle and the posterior rectus sheath. Two different meshes were used, the Vipro (Ethicon) mesh cut to 10×10 cm from 2007 until 2009 and the Parietex ProGrip™ (TYCO Healthcare) mesh 15×9 cm from 2010 onwards.
Follow-up	**Median 31 months**
Conflict of interest/source of funding	This study was supported by a research grant from the County of Västmanland, Sweden. The authors declare no conflict of interest.

Analysis

Follow-up issues:

- All patients were monitored by clinical examinations and radiology according to the follow-up routine, and the data were registered prospectively in the registry. Since 2001, CT was done at 1- and 3-year post-operative visits. Clinical examination of the abdomen and perineum was done annually until 5 years had elapsed.
- 91% (187/206) of patients were alive 1 year after the procedure and CT scans were available in 75% (141/187) of patients.
- All patients alive more than 1 year after the procedure were assessed by either clinical examination or CT, and no patient was lost to follow-up.

Study design issues:

- The aim of the study was to evaluate the rate of parastomal hernias in a population-based cohort of patients, operated with and without a prophylactic mesh at 2 different time periods.
- This study is a retrospective analysis if prospectively collected data.
- A radiologist blinded to the presence of a stoma mesh re-evaluated all available CT scans to detect parastomal hernias. One- and 3-year postoperative scans were used, and in addition, the last available CT scan was also assessed.
- All procedures were done by a limited number of experienced colorectal surgeons, and one surgeon did or supervised 95 % of the procedures.

Study population issues:

- There was a statistically significant difference between groups at baseline for the World Health Organisation performance scale with fitter patients in the mesh group (p=0.008).
- Patients with a prophylactic mesh were more often treated with postoperative chemotherapy (34% versus 25%, p=0.048).

IP overview: Reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia

Key efficacy and safety findings

Efficacy

Number of patients analysed: **206 (71 mesh versus 135 non-mesh)**

Parastomal hernia in patients alive 1 year after the procedure and available for the analysis

	Mesh group	Control group	p
Clinically verified parastomal hernia	25% (16/63)	25% (31/124)	0.953
CT-verified parastomal hernia	53% (32/60)	53% (43/81)	0.176
CT- and clinically verified parastomal hernia	52% (34/66)	43% (49/115)	0.247
Follow-up (months, median [range])	24 (12–89)	36 (12–202)	-
Re-operation due to parastomal hernia	1% (1)	2% (3)	-

There was no difference in the parastomal hernia rate between the 2 time periods 2007–2009 (Vipro mesh, n=45) and 2010–2011 (ProGripmesh, n=26; p=0.647).

In a Cox multivariate analysis, a high BMI was the only independent risk factor for parastomal hernia formation (HR 1.11, 95% CI 1.04 to 1.18, p=0.001).

In another Cox regression analysis, risk factors for parastomal hernia formation at only clinical presentation were smoking (adjusted HR 3.11, 95 % CI 1.22 to 7.94) and BMI (HR=1.09, 95 % CI 1.00 to 1.18).

Safety

Safety events

Event	Mesh group (n=71)	Control group (n=135)	p
Postoperative complication	42% (30)	49% (66)	0.359
Postoperative surgical complications	32% (23)	36% (48)	0.194
Re-laparotomy	4% (3)	1% (2)	0.343
In-hospital mortality	3% (2)	1% (1)	0.276

There were no mesh-related complications necessitating mesh removal.

Abbreviations used: BMI, body mass index; CI, confidence interval; CT, computerised tomography; HR, hazard ratio.

Study 7 Styrke J (2015)

Details

Study type	**Retrospective case series**
Country	Sweden (single centre)
Recruitment period	2003-12
Study population and number	n= **114** consecutive patients having an ileal conduit
Age and sex	Patients with follow-up examinations (n=58): mean 69 years; 59% (34/58) male
Patient selection criteria	All consecutive patients who had cystectomies with the construction of an ileal conduit between 2003 and 2012.
Technique	The ileoureteral anastomosis was constructed using the Wallace I technique. A lightweight, large-pore mesh (Ultrapro, Ethicon) was used and placed in a sublay position. All stomas were positioned through the rectus abdominis muscle, and the mesh was placed posterior to the rectus muscle and anterior to the dorsal rectus sheet.
Follow-up	**Mean 35 months**
Conflict of interest/source of funding	None

Analysis
Follow-up issues:

- The patients were invited to follow-up in 2008 or 2013, 12 months or longer after the surgery.
- A search of the patients' medical records was conducted to detect any stoma stenosis, mesh infection or mesh migration into the ileal conduit or other bowel segments. Patients were also asked at follow-up examination whether they could recall having had any postoperative wound infections in the midline incision or surrounding the stoma, in case this had not been documented in the department's medical records.
- In total, 117 cystectomies with a construction of an ileal conduit were done but a prophylactic mesh was used in 114 of these patients. Forty-three patients died prior to follow-up. Three declined to participate. One patient had his ileal conduit surgically removed before the follow-up because of cancer recurrence. In 9 patients less than 1 year had passed since the cystectomy. The remaining 58 patients were subjected to follow-up.

Study design issues:

- The primary objective of this study was to determine the prevalence of PH.
- Seven urological surgeons performed cystectomies with the construction of an ileal conduit with a prophylactic mesh.

Study population issues: Bladder cancer was the most common cause for surgery (83% [48/58]).

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>Number of patients analysed: 114

PH at mean 35-month follow-up: 14% (8/58)
There were 5 EHS class 1 (≤ 5 cm without cIH), 2 class 3 (> 5 cm without cIH) and 1 class 4 (> 5 cm with cIH) PHs.</td><td>No surgical revision due to stoma stenosis, mesh infection or mesh migration was performed on any of the 114 patients who had a mesh until the end of 2013.

Complications at mean 35-month follow-up
<table>
<tr><th>Complication</th><th>% patients</th></tr>
<tr><td>Postoperative wound infection in the midline incision</td><td>5% (3/57)</td></tr>
<tr><td>Infection adjacent to the stoma</td><td>2% (1/57)</td></tr>
<tr><td>Midline incisional hernia</td><td>4% (2/57)</td></tr>
</table></td></tr>
<tr><td colspan="2">Abbreviations used: cIH, concomitant incisional hernia; EHS, European hernia society; PH, parastomal hernia</td></tr>
</table>

Study 8 Lykke A (2017)

Details

Study type	**Non-randomised comparative study**
Country	Denmark
Recruitment period	Mesh group: 2012-14 Reference group: 2010-12
Study population and number	n= **226 (109 Mesh versus 117 No mesh)** patients having emergency surgery with formation of a stoma
Age and sex	Median 72 years; 46% (103/226) male
Patient selection criteria	Patients who had an emergency surgery with formation of an ileostomy or colostomy were candidates for the study. Emergency surgery was defined as surgery commenced within 6 hours after the booking procedure. The mesh group included patients who had an emergency stoma from 1 July 2012 to 1 April 2014.The reference group included patients who had emergency formation of a stoma without a prophylactic mesh from 1 July 2010 to 30 June 2012.
Technique	In the mesh group, patients were treated with a slowly resorbable synthetic light weight 7 × 10-cm mesh (TIGR® Matrix Surgical Mesh, Novus Scientific). The mesh was placed on the anterior surface of posterior rectus sheath dorsal to the rectus muscle to reduce the risk of bacterial contamination.
Follow-up	**1 year**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: 26 patients were excluded from insertion of a prophylactic mesh without documented reasons.

Study design issues:

The main objective of the study is to assess the safety and efficacy associated with hernia prophylaxis using a retromuscular slowly resorbable synthetic mesh for stoma reinforcement.

Study population issues: The operative field was contaminated or dirty in 48% of the procedures.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **226 (109 Mesh versus 117 No mesh)**

Hospital length of stay (median): 14 days versus 12 days (p=0.76)

Cumulative numbers of events within 1 year after the procedure

	Mesh group	Reference group (n = 117)	p

Safety

Cumulative numbers of events within 1 year after the procedure

	Mesh group (n = 109)	Reference group (n = 117)	p
Death	42% (46)	40% (47)	0.79

No clinical mesh infections were reported and no patients in the mesh group had the mesh removed surgically.

IP overview: Reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia

	(n = 109)		
Parastomal hernia, verified by CT	7% (8)	8% (9)	0.42
Peristomal bulging	18	16	0.58
Emigration	1	5	0.21
Relocation of stoma	4	2	0.43
Reversal of stoma	16	23	0.38

Cumulative rates of 30-day events

	Mesh group (n = 109)	Reference group (n = 117)	p
Complications requiring reoperation[a]	23% (25)	21% (24)	0.66
Burst abdomen	6% (6)	9% (10)	
Stoma related	6% (6)	6% (7)	
Bowel obstruction	5% (5)	3% (4)	
Intra-abdominal abscess	2% (2)	3% (3)	
Bowel perforation/necrosis	6% (6)	2% (2)	
Gastric ulcer perforation	1% (1)	0	
Anastomotic leakage	0	1% (1)	
Other complications[a]	66% (72)	58% (68)	0.22
Sepsis	43% (47)	29% (34)	**0.03**
Respiratory	24% (26)	19% (22)	
Surgical site infection	21% (23)	15% (18)	
Cardiovascular	8% (9)	9% (10)	
Urogenital	7% (8)	5% (6)	
Stroke (cerebral)	1% (1)	3% (4)	
Short bowel syndrome	3% (3)	2% (2)	
Superficial stoma infection	3% (3)	1% (1)	
Gastrointestinal bleeding	4% (4)	0	
Other	6% (6)	4% (5)	
Clavien-Dindo classification			0.13
1	24% (26)	28% (33)	
2	15% (16)	19% (22)	
3	7% (8)	13% (15)	
4	39% (43)	24% (28)	
5	15% (16)	16% (19)	

Mortality	15% (16)	16% (19)	0.75
Sepsis	13% (14)	11% (13)	
Respiratory	-	3% (4)	
Stroke (cerebral)	-	1% (1)	
Malignancy	1% (1)	1% (1)	
Missing	1% (1)	-	

[a] Number of patients with at least one complication.

Cumulative rates of stoma-related complications (no p value reported)

	Mesh group (n = 109)	Reference group (n = 117)
Superficial infection without reoperation within 30 days	3% (3)	1% (1)
Complications requiring reoperation within 30 days	6% (6)	6% (7)
Necrosis of ostomy bowel	2% (2)	5% (5)
Intra-abdominal abscess	1% (1)	-
Stoma prolapsed	-	1% (1)
Stoma obstruction	1% (1)	1% (1)
Stoma subcutaneous perforation	2% (2)	-
Superficial infection without reoperation within 1–12 months	1% (1)	-
Complications requiring reoperation within 1–12 months	1% (1)	3% (3)
Stoma dysfunction	-	3% (3)
Iatrogenic perforation of stoma bowel	1% (1)	-

In the mesh group, one patient had a re-intervention on day 10 for intestinal obstruction due to adhesions between the small bowel and a part of the mesh that partly protruded intraperitoneally. After release of the adhesions, the peritoneum was adapted to cover the mesh that was left in situ, and the patient experienced no further complications

Abbreviations used: CT, computerised tomography

Validity and generalisability of the studies

- 2 systematic reviews[1,2] and meta-analyses have been included in table 2 but many others have been published and are included in the appendix.
- There are several techniques for prophylactic mesh placement and different types of meshes are available.
- Most of the randomised controlled trials have small patient populations.
- Some studies excluded patients having an emergency procedure but others did not. Study 8 only includes patients having emergency surgery.[8]
- The patient populations differed between studies (particularly the indications for stoma creation).
- There is more evidence for colostomy than for ileostomy.

Existing assessments of this procedure

- The Association of Coloproctology of Great Britain and Ireland (ACPGBI) published a position statement on prevention and treatment of parastomal hernia in 2018[9]. It says:

  "Statement

  The use of non-absorbable synthetic mesh may reduce the incidence of PSH in patients who have permanent end colostomy formation for cancer only during elective surgery.

  There is insufficient evidence regarding

  1 optimal mesh position within the abdominal wall (retromuscular vs intraperitoneal on-lay mesh)

  2 use of biologic meshes

  3 prophylactic mesh in emergency surgery

  4 prophylactic mesh use for ileostomy/urostomy

  5 indications for stoma other than cancer (e.g. inflammatory bowel disease/ functional)

6 cost effectiveness

7 long-term data, although this is in progress. Results are expected in the next few years.

Recommendation

Prophylactic synthetic non-absorbable mesh may be used when constructing an elective permanent end colostomy for cancer only to reduce the risk of PSH development.

Quality of evidence

Moderate

Strength of recommendation

Weak''

- The European Hernia Society published guidelines on prevention and treatment of parastomal hernias in 2018[10]. They say:

'' *Statements*: High quality evidence supports the use of a prophylactic mesh during construction of a permanent end colostomy in elective surgery in reducing the incidence of parastomal hernia development.

Recommendation: It is recommended to use a prophylactic synthetic non-absorbable mesh when constructing an elective permanent end colostomy to reduce the parastomal hernia rate.

Quality of evidence: 4/4

Strength of recommendation: Strong

Recommendation: No recommendation to use a prophylactic mesh can be made for ileostomies or ileal conduit stomas, nor for the use of synthetic absorbable or biological meshes.

Quality of evidence: 2/4

Strength of recommendation: No''

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Transanal total mesorectal excision of the rectum. NICE interventional procedures guidance 514 (2015). Available from http://www.nice.org.uk/guidance/IPG514
- Laparoscopic cystectomy. NICE interventional procedures guidance 287 (2009). Available from http://www.nice.org.uk/guidance/IPG287
- Percutaneous endoscopic colostomy. NICE interventional procedures guidance 161 (2006). Available from http://www.nice.org.uk/guidance/IPG161

NICE guidelines

- Colorectal cancer: diagnosis and management. NICE clinical guideline 131 (2014). Available from http://www.nice.org.uk/guidance/CG131
- Faecal incontinence in adults: management. NICE clinical guideline 49 (2007). Available from http://www.nice.org.uk/guidance/cg49

Additional information considered by IPAC

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. One

Specialist Advisor Questionnaire for reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia was submitted and can be found on the NICE website.

Patient commentators' opinions

NICE received 10 completed questionnaires. The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

Company engagement

A structured information request was sent to 4 companies who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

Ongoing studies:

- ISRCTN94943190 Stapled mesh stoma reinforcement technique (SMART) to prevent parastomal herniation. RCT. Ongoing. Trial end date: 30/09/2020. N=116. Germany, Spain, United Kingdom.

- NCT02703662 Performance of Biologic Mesh Materials in Abdominal Wall Reconstruction. RCT. Estimated study completion date: October 2020. Canada. Recruiting. Estimated enrolment: 90.

- NCT02387333 Role of Mesh Stoma Reinforcement Technique (MSRT) in Prevention of Parastomal Hernia After Ileal Conduit Urinary Diversion. RCT. Recruiting. Estimated study completion date: February 2019. Egypt. Estimated enrolment: 40.

- NCT02121743 Use of a Biological Mesh (StratticeTM) for the Prevention of Parastomal Hernia After Colorectal Surgery With Colostomy

(PROBIOCOL). RCT. Recruiting. Estimated study completion date: December 2018. France. Estimated enrolment: 108.

- NCT02908061 A Study to Determine if Mesh Placement During Bladder Surgery Can Reduce the Chances of Developing a Hernia. RCT. Recruiting. Estimated study completion date: August 2019. USA. Estimated enrolment: 160.

- NCT02238964 Reinforcement of Closure of Stoma Site (ROCSS). RCT. Active, not recruiting. Study completed. Denmark, Netherlands, United Kingdom. Actual enrolment: 790**.** No results posted yet.

- NIHR study: UK Cohort study to Investigate the prevention of Parastomal Hernia (CIPHER). Started: October 2016. Status: Research in progress

- NCT01694238 A Randomized Trial on the Technical Aspects of Stoma Construction (Stoma-Const). RCT. Recruiting. Sweden. Estimated study completion date: October 2018. Estimated enrolment: 240.

References

1. Jones H G, Rees M, Aboumarzouk O M et al. (2018) Prosthetic mesh placement for the prevention of parastomal herniation. Cochrane Database of Systematic Reviews 7, CD008905
2. Knaapen L, Buyne O, van Goor H et al. (2017) Synthetic vs biologic mesh for the repair and prevention of parastomal hernia. World Journal of Meta-Analysis; 5(6): 150-166
3. Odensten C, Strigard K, Rutegard J et al. (2017) Use of Prophylactic Mesh When Creating a Colostomy Does Not Prevent Parastomal Hernia: A Randomized Controlled Trial-STOMAMESH. Annals of Surgery 23, 23
4. Brandsma H T, Hansson B M, Aufenacker T J et al. (2017) Prophylactic Mesh Placement During Formation of an End-colostomy Reduces the Rate of Parastomal Hernia: Short-term Results of the Dutch PREVENT-trial. Annals of Surgery 265(4), 663-669
5. Fleshman J W, Beck D E, Hyman N et al. (2014) A prospective, multicenter, randomized, controlled study of non-cross-linked porcine acellular dermal matrix fascial sublay for parastomal reinforcement in patients undergoing surgery for permanent abdominal wall ostomies. Diseases of the Colon and Rectum 57(5), 623-631
6. Nikberg M, Sverrisson I, Tsimogiannis K et al. (2015) Prophylactic stoma mesh did not prevent parastomal hernias. International Journal of Colorectal Disease; 30(9):1217-22
7. Styrke J, Johansson M, Granasen G et al. (2015) Parastomal hernia after ileal conduit with a prophylactic mesh: a 10 year consecutive case series. Scandinavian Journal of Urology 49(4), 308-12
8. Lykke A, Andersen J F. B, Jorgensen L N et al. (2017) Prevention of parastomal hernia in the emergency setting. Langenbecks Archives of Surgery 402(6), 949-955
9. Group ACPGBI Parastomal Hernia (2018) Prevention and treatment of parastomal hernia: a position statement on behalf of the Association of Coloproctology of Great Britain and Ireland. Colorectal Disease 20 Suppl 2, 5-19
10. Antoniou S A, Agresta F, Garcia Alamino et al. (2018) European Hernia Society guidelines on prevention and treatment of parastomal hernias. Hernia 22(1), 183-198

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	04/03/2019	Issue 3 of 12, March 2019
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	04/03/2019	Issue 3 of 12, March 2019
HTA database (CRD website)	04/03/2019	n/a
MEDLINE (Ovid)	04/03/2019	1946 to March 01, 2019
MEDLINE In-Process (Ovid) & MEDLINE Epubs ahead of print (Ovid)	04/03/2019	1946 to March 01, 2019 and March 01, 2019
EMBASE (Ovid)	04/03/2019	1974 to 2019 Week 09

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

MEDLINE search strategy

1 hernia, abdominal/ or hernia, ventral/

2 HERNIA/ or INCISIONAL HERNIA/

3 ((parastomal or postoperat* or incision* or abdominal* or abdomen or ventral*) adj4 hernia*).tw.

4 herniorrhaphy/

5 (herniorrhaph* or (hernia* adj4 (repair* or prevent*))).tw.

6 or/1-5

7 Surgical Stomas/ or Ileostomy/ or Colostomy/ or Enterostomy/ or Urostomy/

8 (stoma or stomas or ileostom* or colostom* or enterostom* or urostom*).tw.

9 7 or 8

10 Surgical Mesh/

11 (mesh* or patch* or ((woven or weave) adj4 material*)).tw.

12 (permacol or vypro or ultrapro or physiomesh or strattice or dynamesh).tw.

13 or/10-12

14 6 and 9 and 13

15 Animals/ not Humans/

16 14 not 15

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Bayer I, Kyzer S, and Chaimoff C (1986) A new approach to primary strengthening of colostomy with Marlex mesh to prevent paracolostomy hernia. Surgery, and Gynecology & Obstetrics 163(6), 579-80	Case series n=36 FU= maximum 48 months	Four years after operation, no hernia or prolapse has occurred in the patients who underwent this procedure.	Studies with more patients or longer follow-up are included.
Berger D (2008) Prevention of parastomal hernias by prophylactic use of a specially designed intraperitoneal onlay mesh (Dynamesh IPST). Hernia 12(3), 243-6	Case series n=22 Median FU= 11 months	The prophylactic use of Dynamesh IPST is a safe and effective procedure preventing stoma complications such as hernia formation or prolapse, at least in the short run.	Studies with more patients or longer follow-up are included.
Biswas A, Marimuthu K, and Mathew G (2015) Prevention of Parastomal Hernia Using Pre-peritoneal Mesh - Long Term Outcome of a Prospective Study. Acta Chirurgica Belgica 115(1), 15-9	Case series n=42 Median FU= 60 months	Putting a pre-peritoneal polypropylene mesh is an easy, quick and inexpensive method, and easy to learn. The outcome is better than creating stomas without mesh, but further studies are needed to explore potential benefits of different types of mesh and their methods of positioning and anchoring.	Studies with more patients or longer follow-up are included.
Brandsma H T, Hansson B M, Aufenacker T J et al. (2016) Prophylactic mesh placement to prevent parastomal hernia, early results of a prospective multicentre randomized trial. Hernia 20(4), 535-41	RCT n=150 (72 versus 78) FU= 3 months	During open and elective formation of an end-colostomy, primary placement of a retromuscular light-weight polypropylene mesh for prevention of a parastomal hernia is a safe and feasible procedure.	The study population is the same as in the Brandsma (2017) RCT which is included in Table 2 but the follow-up is shorter.
Canda A E, Terzi C, Agalar C et al. (2018) Preventing parastomal hernia with modified stapled mesh stoma reinforcement technique (SMART) in patients who underwent surgery for rectal cancer: a case-	Prospective non-randomised controlled study n=67 (29 versus 38)	SMART is easy to use, safe and effective for paracolostomy hernia prophylaxis.	Studies with more patients or longer follow-up are included.

control study. Hernia 22(2), 379-384	Median FU=27 months		
Chapman SJ, Wood B, Drake TM et al. (2017) Systematic review and meta-analysis of prophylactic mesh during primary stoma formation to prevent parastomal hernia. Diseases of the Colon and Rectum, 60 (1). pp. 107-115. ISSN 0012-3706 https://doi.org/10.1097/DCR.0000000000000670	Systematic review and meta-analysis n=432 patients from 7 RCTs Literature search up until 25/03/2016	Mesh prophylaxis at the time of stoma formation appears safe and effective in preventing parastomal hernia, however limitations of the primary evidence justify larger, more rigorous RCTs.	More recent systematic reviews and meta-analyses are already included in Table 2.
Conde-Muino R, Diez J L, Martinez A et al. (2017) Preventing parastomal hernias with systematic intraperitoneal specifically designed mesh. BMC Surgery 17(1), 41	Prospective case series n=31 Median FU=17.5 months	Prophylactic parastomal mesh placement might be a safe and effective procedure with a potential to reduce the risk of parastomal hernia. Routine use of this technique should be further analysed.	Studies with more patients or longer follow-up are included.
Cornille J B, Pathak S, Daniels I R et al. (2017) Prophylactic mesh use during primary stoma formation to prevent parastomal hernia. Annals of the Royal College of Surgeons of England 99(1), 2-11	Systematic review and meta-analysis n=430 patients from 8 RCTs Literature search up until 31/12/2015	Prophylactic placement of mesh at primary stoma formation may reduce the incidence of PH, without an increase in peristomal complications. However, the overall quality of the randomised controlled trials included in the meta-analysis was poor, and should prompt caution regarding the applicability of the findings of the individual studies and the meta-analysis to everyday practice.	More recent systematic reviews and meta-analyses are already included in Table 2.
Cross A J, Buchwald P L, Frizelle F A et al. (2017) Meta-analysis of prophylactic mesh to prevent parastomal hernia. British Journal of Surgery 104(3), 179-186	Systematic review and meta-analysis n=649 patients from 10 RCTs Literature search up until May 2016	Mesh placed prophylactically at the time of stoma creation reduced the rate of parastomal hernia, without an increase in mesh-related complications.	A more recent systematic review and meta-analysis is already included in Table 2.
Donahue T F, Cha E K, and Bochner B H (2016) Rationale and Early Experience with Prophylactic Placement of Mesh to Prevent Parastomal Hernia Formation after Ileal Conduit Urinary Diversion and Cystectomy for Bladder Cancer. Current Urology Reports 17(2), 9	Review and case series n=40 Median FU=297 days	What is notable in this short period of follow-up is the discrepancy between the radiographic and clinical rates of hernias in the cohorts. Six (18%) patients in the prophylactic mesh arm developped radiographic PH, only 1 of which was clinically apparent. Longer follow-up is needed to assess the efficacy of this approach in these high-risk patients.	Studies with more patients or longer follow-up are included.

Figel N A, Rostas J W, and Ellis C N (2012) Outcomes using a bioprosthetic mesh at the time of permanent stoma creation in preventing a parastomal hernia: a value analysis. American Journal of Surgery 203(3), 323-6; discussion 326	Case series n=16 Median FU=38 months	These data show the safety and efficacy of using a bioprosthetic at the time of permanent stoma creation in preventing a parastomal hernia and defines the parameters for this approach to be cost-effective.	Studies with more patients or longer follow-up are included.
Findlay J M, Wood C P. J, and Cunningham C (2018) Prophylactic mesh reinforcement of stomas: a cost-effectiveness meta-analysis of randomised controlled trials. Techniques in Coloproctology 07, 07	Systematic review and meta-analysis n=907 patients from 11 RCTs Literature search up until 09/02/2018	Reinforcing elective stomas with mesh (primarily synthetic) reduces subsequent PSH rates, complications, repairs and saves money. We recommend that future RCTs compare mesh subtypes, techniques, and applicability to emergency stomas.	A systematic review and meta-analysis which is as recent as this one is already included in Table 2. The main goal of this study was to inform a cost-effectiveness analysis.
Gogenur I, Mortensen J, Harvald T, Rosenberg J et al. (2006) Prevention of parastomal hernia by placement of a polypropylene mesh at the primary operation. Diseases of the Colon & Rectum 49(8), 1131-5	Prospective case series n=25 Median FU=1 year	Placement of a polypropylene mesh in an onlay position at the primary operation is a safe procedure and probably results in a low risk of parastomal hernia occurrence.	Studies with more patients or longer follow-up are included.
Hammond T M, Huang A, Prosser K, Frye J N et al. (2008) Parastomal hernia prevention using a novel collagen implant: a randomised controlled phase 1 study. Hernia 12(5), 475-81	RCT n=20 (10 versus 10) Median FU=6.5 months	In this study, in contrast to published data relating to the use of conventional synthetic mesh, there were no complications related to infection or the implant's proximity to the bowel. This trial demonstrates that the implant is safe, feasible to use and has the potential to prevent parastomal herniation.	This RCT is included in both meta-analyses included in Table 2.
Hauters P, Cardin J L, Lepere M et al. (2016) Long-term assessment of parastomal hernia prevention by intra-peritoneal mesh reinforcement according to the modified Sugarbaker technique. Surgical Endoscopy 30(12), 5372-5379	Prospective case series n=29 Median FU=48 months	In this series, the incidence of PSH was 7 % and no specific mesh-related complication was noted. Prophylactic mesh reinforcement according to the modified Sugarbaker is an effective technique that addresses the issues related to the occurrence of PSH.	This study is a longer follow-up of the Hauters (2012) study that is included in Table 2.
Hauters P, Cardin J L, Lepere M et al. (2012) Prevention of parastomal hernia by intraperitoneal onlay mesh	Case series n=20	With 95 % of excellent results, intraperitoneal onlay mesh reinforcement at the time of end colostomy formation in selected patients is a very promising	This small study was included in the Knaapen systematic review and meta-analysis

reinforcement at the time of stoma formation. Hernia 16(6), 655-60	Median FU=24 months	procedure. A drawback of this technique is the possibility of developing a stoma loop hernia due to sliding of the exiting colon between the covering mesh and the abdominal wall. However, this risk is low, and no adverse clinical consequence for the patient was noted in our series.	included in Table 2.
Israelsson L A (2005) Preventing and treating parastomal hernia. World Journal of Surgery 29(8), 1086-9	RCT n=54 (27 mesh versus 27 non-mesh) FU=1 year	The only method that has reduced the rate of parastomal hernia in a randomised trial is the use of a prophylactic prosthetic mesh. A large-pore low-weight mesh with reduced polypropylene content and a high proportion of absorbable material placed in a sublay position at the primary operation significantly reduces the rate of parastomal hernia.	These patients are included in the Janes (2009) RCT which is included in both systematic reviews and meta-analyses included in Table 2.
Janes A, Cengiz Y, and Israelsson L A (2010) Experiences with a prophylactic mesh in 93 consecutive ostomies. World Journal of Surgery 34(7), 1637-40	Case series n=75 FU=1 year minimum	Creating a stoma in routine open surgery a prophylactic mesh can be placed in most patients. A mesh does not increase the rate of complications and can be used in severely contaminated wounds.	Studies with more patients or longer follow-up are included.
Janes A, Cengiz Y, and Israelsson L A (2009) Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study. World Journal of Surgery 33(1), 118-21; discussion 122-3	RCT n=54 (27 versus 27) FU=5 years	After 5 years, 21 patients with a conventional stoma were alive and parastomal herniation was recorded in 17 patients, of whom repair had been demanded in 5. In 15 patients operated on with the addition of a mesh herniation, that did not require repair, was present in 2 ($p<0.001$). No fistulas or strictures developed. No mesh infection was noted and no mesh was removed during the study period.	This study is included in both systematic reviews and meta-analyses included in Table 2.
Janes A, Cengiz Y, and Israelsson L A (2004) Preventing parastomal hernia with a prosthetic mesh: A randomized study. Archives of Surgery 139(12), 1356-1358	RCT n=54 (27 versus 27) FU=1 year	No infection, fistula formation, or pain occurred (observation time, 12-38 months). At the 12-month follow-up, parastomal hernia was present in 13 of 26 patients without a mesh and in 1 of 21 patients in whom the mesh was used.	These patients are included in the Janes (2009) RCT which is included in both systematic reviews and meta-analyses included in Table 2.
Jano Z, and Nagy A (2014) Results of 3-dimensional mesh implantations at the time of Miles operation to prevent parastomal	Non-randomised comparative study	Our experiences confirm the literature data that placing a mesh at the time of definitive stoma formation is preferable. The devices used by us unite the advantages of strengthening	Studies with more patients or longer follow-up are included.

hernia. European Surgery - Acta Chirurgica Austriaca 46(1), 25-31	n=34 (17 mesh versus 17 non-mesh) FU=5 years	both sheets of the rectus abdominis muscle. In addition, changing the operative strategy to a laparoscopic approach gives an extra advantage to this procedure.	
Janson A R, Janes A, and Israelsson L A (2010) Laparoscopic stoma formation with a prophylactic prosthetic mesh. Hernia 14(5), 495-8	Case series n=25 FU=mean 19 months	In laparoscopic stoma formation, a prophylactic large-pore, low-weight mesh in a sublay position is an easy and safe procedure associated with a low rate of parastomal hernia.	Studies with more patients or longer follow-up are included.
Kohler G, Hofmann A, Lechner MCase et al. (2016) Prevention of parastomal hernias with 3D funnel meshes in intraperitoneal onlay position by placement during initial stoma formation. Hernia 20(1), 151-9	Retrospective case series n=80 FU=median 21 months	PH developed in 3 patients (3.75%). No mesh-related complications were encountered and none of the implants had to be removed. Ostomy-related complications had to be noted in 7 (8.75%) patients. No manifestation of ostomy prolapse occurred.	Studies with more patients or longer follow-up are included.
Kohler G, Wundsam H, Pallwein-Prettner L et al. (2015) Magnetic resonance visible 3-D funnel meshes for laparoscopic parastomal hernia prevention and treatment. European Surgery - Acta Chirurgica Austriaca 47(3), 127-132	Prospective case series n=5 FU=1 year	The pilot use of a new method of MR investigation using a mesh with enhanced signal through the addition of iron particles into the polyvinylidene fluoride base material provides detailed mesh depiction. Furthermore, funnel mesh implantation seems to offer a safe and promising surgical alternative for both PSH prevention and treatment.	Studies with more patients or longer follow-up are included.
Lambrecht J R, Larsen S G, Reiertsen O et al. (2015) Prophylactic mesh at end-colostomy construction reduces parastomal hernia rate: a randomized trial. Colorectal Disease 17(10), O191-7	RCT N=58 (32 mesh versus 26 non-mesh) FU=median 40 months	The retromuscular insertion of synthetic mesh at the time of formation of an end-colostomy reduced the risk of PH.	This study is included in the Cochrane systematic review and meta-analysis included in table 2.
Lopez-Cano M, Brandsma H T, Bury K et al. (2017) Prophylactic mesh to prevent parastomal hernia after end colostomy: a meta-analysis and trial sequential analysis. Hernia 21(2), 177-189	Systematic review and meta-analysis n=451 patients from 7 RCTs Literature search up until 31/10/2015	PSH prevention with mesh when creating an end colostomy reduces the incidence of PSH, the risk for subsequent PSH repair and does not increase wound infections. Trial sequential analysis shows that the required information size is reached for the primary outcome. Additional RCTs in the previous context are not needed.	More recent systematic reviews and meta-analyses are already included in Table 2.
Lopez-Cano M, Serra-Aracil X, Mora L et al.	RCT	Placement of a prosthetic mesh by the laparoscopic approach	This study is included in the

(2016) Preventing Parastomal Hernia Using a Modified Sugarbaker Technique With Composite Mesh During Laparoscopic Abdominoperineal Resection: A Randomized Controlled Trial. Annals of Surgery 264(6), 923-928	n=52 (24 mesh versus 28 non-mesh) FU= median 26 months	following the modified Sugarbaker technique is safe and effective in the prevention of PH, reducing significantly the incidence of PH.	Cochrane systematic review and meta-analysis included in table 2.
Lopez-Cano M, Lozoya-Trujillo R, Quiroga S et al. (2012) Use of a prosthetic mesh to prevent parastomal hernia during laparoscopic abdominoperineal resection: a randomized controlled trial. Hernia 16(6), 661-7	RCT N=36 (19 mesh versus 17 non-mesh) FU=1 year	Use of prophylactic large-pore lightweight mesh in the intraperitoneal/onlay position by a purely laparoscopic approach reduced the incidence of parastomal hernia formation. Subcutaneous fat thickness ≥23 mm measured by CT was an independent predictor of parastomal hernia.	This study is included in both systematic reviews and meta-analyses included in Table 2.
Macina S, Mandolfino F, Frascio M et al. (2016) Stapled Mesh Reinforcement Technique (SMART) to Prevent Parastomal Hernias: Our Initial Experience and Review of the Literature. Surgical Technology International 28, 153-7	Case series n=6 FU=not reported	Our cases show that the procedure is rapid, cost effective, and safe (in our experience, there are no post-surgical complications that are procedure-related). A long term follow-up and a higher number of patients will give us confirmation of the initial hopeful results.	Studies with more patients or longer follow-up are included.
Marimuthu K, Vijayasekar C, Ghosh D et al (2006) Prevention of parastomal hernia using preperitoneal mesh: a prospective observational study. Colorectal Disease 8(8), 672-5	Case series n=18 FU= 6 to 28 months	The early results, in this group of patients, show that prophylactic polypropylene mesh insertion at the time of permanent stoma formation is encouraging and long-term results are awaited.	Studies with more patients or longer follow-up are included.
Ng Z Q, Tan P, and Theophilus M (2017) Stapled Mesh stomA Reinforcement Technique (SMART) in the prevention of parastomal hernia: a single-centre experience. Hernia 21(3), 469-475	Case series n=14 FU=median 24 months	Our medium-term experience has demonstrated the efficacy of SMART in the reduction of parastomal hernia occurrence. With appropriate learning curve, parastomal hernia can be prevented.	Studies with more patients or longer follow-up are included.
Patel S V, Zhang L, Chadi S A et al. (2017) Prophylactic mesh to prevent parastomal hernia: a meta-analysis of randomized controlled studies. Techniques in	Systematic review and meta-analysis n=569 patients from 9 RCTs	Prophylactic mesh is associated with decreased odds of parastomal hernia formation and the need for surgical repair. There is no evidence that mesh placement increases the odds of complications.	A more recent systematic review and meta-analysis is already included in Table 2.

Coloproctology 21(1), 5-13	Literature search up until 23/08/2016		
Pianka F, Probst P, Keller A V et al. (2017) Prophylactic mesh placement for the PREvention of paraSTOmal hernias: The PRESTO systematic review and meta-analysis. PLoS ONE [Electronic Resource] 12(2), e0171548	Systematic review and meta-analysis n=755 patients from 8 RCTs (included 1 conference abstract report) and 3 non-randomised controlled trials Literature search up until April 2016	Prophylactic mesh placement is safe and reduces PH rate. A recommendation for prophylactic non-absorbable meshes in a sublay position can be made for patients undergoing open colorectal operations with end-ostomies. Further research endeavours should focus on patient-oriented outcomes, not only PH rate, with respect to tailored treatment in specific patient populations.	2 more recent systematic reviews and meta-analyses are already included in Table 2. Furthermore, a conference abstract report is included in the analysis.
Sajid M S, Kalra L, Hutson K et al. (2012) Parastomal hernia as a consequence of colorectal cancer resections can prophylactically be controlled by mesh insertion at the time of primary surgery: a literature based systematic review of published trials. Minerva Chirurgica 67(4), 289-96	Systematic review and meta-analysis n=128 patients from 3 RCTs Literature search up until September 2011	The incidence of PH can be reduced by the insertion of mesh at stoma site at the time of primary stoma construction. A major multicentre RCT recruiting higher number of patients and longer follow up is needed before recommending the routine use of mesh for PSH prevention.	2 more recent systematic reviews and meta-analyses are already included in Table 2.
Serra-Aracil X, Bombardo-Junca J, Moreno-Matias J et al. (2009) Randomized, controlled, prospective trial of the use of a mesh to prevent parastomal hernia. Annals of Surgery 249(4), 583-7	RCT n=54 (27 mesh versus 27 non-mesh) FU=median 29 months	Parastomal placement of a mesh reduces the appearance of PH. The technique is safe, well-tolerated, and does not increase morbidity rates.	This study is included in both systematic reviews and meta-analyses included in Table 2.
Shabbir J, Chaudhary B N, and Dawson R (2012) A systematic review on the use of prophylactic mesh during primary stoma formation to prevent parastomal hernia formation. Colorectal Disease 14(8), 931-6	Systematic review and meta-analysis n=128 patients from 3 RCTs Literature search up until January 2010	Although only 3 trials with 128 patients fulfilled the criteria for this systematic review, the data suggest that the use of prophylactic prosthetic mesh at the time of primary stoma formation reduces the incidence of parastomal hernia.	More recent systematic reviews and meta-analyses are already included in Table 2.
Tam K W, Wei P L, Kuo L J et al. (2010) Systematic review of the use of a mesh to prevent parastomal hernia. World Journal of Surgery 34(11), 2723-9	Systematic review and meta-analysis n=7 studies Literature search up until February 2010	Prophylactic use of mesh at the time of stoma formation is a safe procedure and reduces the risk of parastomal hernia. For more detailed evaluation, additional large, double-blinded, randomized controlled trials with long-term follow-up are necessary.	More recent systematic reviews and meta-analyses are already included in Table 2.

Tarcoveanu E, Vasilescu A, Cotea E et al. (2014) Parastomal hernias -- clinical study of therapeutic strategies. Chirurgia (Bucuresti) 109(2), 179-84	RCT n=42 (20 mesh versus 22 non-mesh) FU=median 20 months	Parastomal hernia is a relatively rare disease compared to the number of incisional hernias. With increasing life expectancy stands we noted increased incidence of parastomal hernia as well. Prophylactic use of mesh during the primary operation is a safe procedure and reduces the risk of parastomal hernia.	This study is included in the Knaapen (2017) systematic review and meta-analysis included in table 2.
Valdes-Hernandez J, Diaz Milanes, J A, Capitan Morales et al. J (2015) Prevention of parastomal hernia with a preperitoneal polypropelene mesh. Cirugia Espanola 93(7), 455-9	Case series n=45 Median FU=22 months	The use of a prophylactic polypropylene mesh placed in a sublay position at the stoma site is a safe and feasible technique. It lowers the incidence of parastomal hernias with no increased morbidity.	Studies with more patients or longer follow-up are included.
Ventham N T, Brady R R, Stewart R G et al. (2012) Prophylactic mesh placement of permanent stomas at index operation for colorectal cancer. Annals of the Royal College of Surgeons of England 94(8), 569-73	Non-randomised comparative study n=41 (17 versus 24) FU=1 year	Prophylactic mesh placement at the time of the index procedure reduces the diameter of abdominal wall aperture and the incidence of parastomal hernias containing bowel. Future studies should use both objective radiological and clinical endpoints when assessing parastomal hernia development with and without prophylactic mesh.	Studies with more patients or longer follow-up are included.
Vierimaa M, Klintrup K, Biancari F et al. (2015) Prospective, Randomized Study on the Use of a Prosthetic Mesh for Prevention of Parastomal Hernia of Permanent Colostomy. Diseases of the Colon & Rectum 58(10), 943-9	RCT n=70 (35 mesh versus 35 non-mesh) FU= 1 year maximum	Prophylactic laparoscopic placement of intraperitoneal onlay mesh does not significantly reduce the overall risk of radiologically detected parastomal hernia after laparoscopic abdominoperineal resection. However, prophylactic mesh repair was associated with significantly lower risk of clinically detected parastomal hernia.	This study is included in both systematic reviews and meta-analyses included in Table 2.
Vijayasekar C, Marimuthu K, Jadhav V et al. (2008) Parastomal hernia: Is prevention better than cure? Use of preperitoneal polypropylene mesh at the time of stoma formation. Techniques in Coloproctology 12(4), 309-13	Case series n=42 Mean FU=31 months	The results of the 2-year follow-up in this study (incidence of parastomal herniation 9.5%) along with available evidence in the literature (incidence 0-8.3%), compared to the results of repair make a strong case for the use of a mesh at the time of initial surgery for the formation of any permanent stoma to prevent parastomal herniation.	Studies with more patients or longer follow-up are included.
Wang S, Wang W, Zhu B et al. (2016) Efficacy of	Systematic review and meta-analysis	Prophylactic placement of a mesh at the time of a stoma	More recent systematic

Prophylactic Mesh in End-Colostomy Construction: A Systematic Review and Meta-analysis of Randomized Controlled Trials. World Journal of Surgery 40(10), 2528-36	n=309 patients from 6 RCTs Literature search up until September 2015	formation seems to be associated with a significant reduction in the incidence of parastomal hernia and reoperation related to parastomal hernia after surgery for rectal cancer, but not the rate of stoma-related morbidity. However, the results should be interpreted with caution because of the heterogeneity among the studies.	reviews and meta-analyses are already included in Table 2.
Wijeyekoon S P, Gurusamy K, El-Gendy K et al. (2010) Prevention of parastomal herniation with biologic/composite prosthetic mesh: a systematic review and meta-analysis of randomized controlled trials. Journal of the American College of Surgeons 211(5), 637-45	Systematic review and meta-analysis n=129 patients from 3 RCTs Literature search up until October 2009	Composite or biological mesh reinforcement of stomas in the preperitoneal/sublay position is associated with a reduced incidence of parastomal herniation with no excess morbidity. Mesh reinforcement also demonstrates a trend toward a decreased incidence of parastomal herniation requiring surgical repair.	More recent systematic reviews and meta-analyses are already included in Table 2.
Williams N S, Hotouras A, Bhan C et al. (2015) A case-controlled pilot study assessing the safety and efficacy of the Stapled Mesh stomA Reinforcement Technique (SMART) in reducing the incidence of parastomal herniation. Hernia 19(6), 949-54	Case-controlled pilot study n=33 (22 versus 11) Median FU= 21 months	SMART is a new and simple technique of precisely creating a reinforced stoma trephine at both open and laparoscopic surgery. It obviates the technical disadvantages of traditional stoma formation. This pilot study, in a selected group of patients at high risk for parastomal herniation, indicates that the procedure is clinically safe but randomised controlled trials are required to determine its efficacy in reducing parastomal herniation in all patients undergoing elective stoma formation.	Studies with more patients or longer follow-up are included.
Zhou Z, Bilkhu A, and Anwar S (2017) The use of a composite synthetic mesh in the vicinity of bowel - For repair and prophylaxis of parastomal hernias. Does it increase the risk of short term infective complications?. International Journal Of Surgery 45, 67-71	Retrospective case series n=27 prophylactic mesh FU=8 months	The use of a composite synthetic mesh using a laparoscopic IPOM technique for the prophylaxis and treatment of parastomal hernias, even in a clean contaminated surgical field, is safe and feasible.	Studies with more patients or longer follow-up are included.
Zhu J, Pu Y, Yang X et al. (2016) Prophylactic Mesh Application during Colostomy to Prevent Parastomal Hernia: A	Systematic review and meta-analysis	This meta-analysis demonstrated that prophylactic mesh application at the time of primary colostomy formation is a promising method for the	More recent systematic reviews and meta-analyses are

Meta-Analysis. Gastroenterology research & practice 2016, 1694265	n=522 patients from 8 RCTs Literature search up until April 2016	prevention of parastomal herniation.	already included in Table 2.