Prophylactic mesh use during primary stoma formation to prevent parastomal hernia

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ABSTRACT

INTRODUCTION Parastomal hernia (PSH) is a common problem following stoma formation. The optimal technique for stoma formation is unknown although recent studies have focused on whether placement of prophylactic mesh at stoma formation can reduce PSH rates. The aim of this study was to systematically review use of prophylactic mesh versus no mesh with regard to occurrence of PSH and peristomal complications.

METHODS A systematic search was performed using PubMed, Embase™ and the Cochrane Library to identify randomised controlled trials that analysed placement of prophylactic mesh versus no mesh at time of initial surgery. Meta-analysis was performed using random effects methods.

RESULTS A total of 506 studies were identified by our search strategy. Of these, 8 studies were included, involving 430 patients (217 mesh vs 213 no mesh). Prophylactic mesh placement resulted in a significantly lower rate of PSH formation (42/217 [19.4%] vs 92/213 [43.2%]) with a combined risk ratio of 0.40 (95% confidence interval [CI]: 0.21–0.75, $p=0.004$). Placement of prophylactic mesh did not result in increased peristomal complications (15/218 [6.9%] vs 16/227 [7.0%]) with a combined risk ratio of 1.0 (95% CI: 0.49–2.01, $p=0.990$).

CONCLUSIONS Prophylactic placement of mesh at primary stoma formation may reduce the incidence of PSH, 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.

KEYWORDS

Parastomal hernia – Prevention – Mesh – Systematic review

Accepted 16 April 2016

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A parastomal hernia (PSH) is an incisional hernia immediately adjacent and related to the stoma.¹ The true incidence of PSH is difficult to assess and varies widely depending on the length of follow-up, the type of stoma and use of radiological imaging (computed tomography [CT] or ultrasonography) in diagnosis.

A study from 2015 evaluating quality of life in stoma patients demonstrated a prevalence of PSH of 57% as well as a statistically significant decrease in physical functioning and general health in patients with PSH, who suffer from more pain and are ashamed of their scar.² Pain (35%) and problems with stoma bag fixation resulting in leakage (28%) and consequent peristomal skin irritation are the most frequent problems associated with PSH.⁵ Strangulation, obstruction and perforation are rare but serious complications.⁴ Up to 30% of patients with a PSH may require surgical intervention but the outcomes from various techniques used for repair of PSH are less than impressive.^{5,6} Consequently, there has recently been a renewed effort to look at prevention of PSH.

As with any incisional hernia, efforts to minimise patient risk factors for PSH formation (such as smoking, obesity,

diabetes, malnutrition and immunosuppression) may be made to improve tissue healing and abdominal wall strength but can be challenging to modify in the short period from diagnosis to surgery in emergency situations or even in expedited cancer treatment pathways. Many aspects of the surgical technique specific to stoma creation have been purported to minimise the chance of PSH formation, including the size, shape and location of the trephine in the abdominal wall, route of placement of the bowel and stoma conformation.⁷ Nevertheless, the only technique that has been examined in detail in prospective randomised controlled trials (RCTs) is the use of prophylactic mesh at the time of stoma formation.

Previous systematic reviews have suggested significant reductions of PSH formation with the use of prophylactic mesh.^{8–10} In all of these reviews, the included studies were derived from single institutions, limited by small sample sizes and had variable follow-up techniques as well as a wide range of follow-up periods.^{11–13} Owing to use in a contaminated field, concerns have also persisted regarding the impact of synthetic meshes on peristomal complications such as infection, erosion, fistulation, seromas, stenosis and necrosis.

Furthermore, the long-term efficacy of biological meshes as an alternative in contaminated fields has not been established conclusively.¹⁴

These limitations may in part be why prophylactic mesh has still not been widely adopted. However, several new, large, multicentre RCTs have been published recently. The aim of this study was therefore to perform a systematic review and meta-analysis of RCTs comparing the use of prophylactic mesh versus no mesh at stoma formation in terms of occurrence of PSH and peristomal complications.

Methods

A search strategy was developed in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.¹⁵ An electronic search of several databases (PubMed, Embase™, Cochrane Library) was conducted independently by two authors (JBC and SP), covering the time period from 1 January 1980 to 20 December 2015. The search strategy included the text terms and Medical Subject Headings 'parastomal hernia', 'mesh' and 'prevention and/or prophylaxis'. Bibliographies of relevant studies were used to identify additional studies. All citations and abstracts identified were reviewed thoroughly by independent investigators (JBC and SP). The last date for this search was 31 December 2015.

Inclusion and exclusion criteria

Included studies compared the effect of prophylactic mesh placement at the time of stoma formation versus no mesh. Only RCTs were considered for inclusion. The studies were evaluated carefully for duplication and overlapping of data. No language restrictions were applied. Animal studies, case reports, reviews, conference abstracts, letters and editorials were excluded from analysis.

Outcome measures

Data were extracted on both the primary (occurrence of PSH) and secondary (peristomal complications) outcome measures. PSH diagnosis could be on clinical or radiological (CT or ultrasonography) as well as intraoperative examination. Peristomal complications were defined as infection, cellulitis or a seroma adjacent to the stoma, erosion of the mesh into the stoma, fistulation from the loop of bowel forming the stoma to the skin and stomal stenosis or necrosis. Data were also extracted for follow-up duration, type of stoma, type of prosthetic mesh used, occurrence of PSH based on reported patient symptoms, clinical findings, CT or ultrasonography findings, and perioperative morbidity and mortality.

Study selection

Two authors (JBC and SP) independently performed the search strategy. Both the authors reviewed the abstracts identified by the search to exclude those that did not meet our inclusion criteria. When no abstract was available or the abstract details were inadequate, the full article was reviewed. Differences between the two authors in selection of the studies were resolved by consensus with the senior author

(NJS). If the selection of the study was still not resolved by consensus between the three authors, the senior author's decision was considered final.

Data extraction

Extraction of data was done independently by the two authors (JBC and SP) using a standardised form. Any disagreement was resolved by consensus with the senior author (NJS). The following demographic and clinical parameters were recorded: study characteristics (first author, year of publication), population characteristics and outcomes of interest.

Statistical analysis

RevMan version 5 (Nordic Cochrane Centre, Copenhagen, Denmark) was used for data handling and statistical analysis. Data were pooled and rate differences as well as weighted mean differences with their 95% confidence intervals (CIs) were calculated. The random effects model was used as the effects were expected to be heterogeneous owing to the variety of study populations and study designs included in the analysis.¹⁶ Heterogeneity was tested using I^2 .

Quality assessment

RCTs were assessed using the Cochrane risk of bias tool by two authors (JBC and SP).

Results

The search terms yielded a total of 507 articles (Fig 1). Of these, 152 were duplicates. After title screening, a further 296 articles were excluded, leaving 59 potentially significant papers. Following abstract review, 13 of these were thought to be relevant and the full texts were obtained. Five studies were subsequently excluded as they did not meet the inclusion criteria. The remaining eight papers were included in our meta-analysis.

Study characteristics

There were 430 patients randomised in 8 trials with studies ranging from 20 to 102 participants.^{11–15,17–21} A total of 217 patients received the intervention (prophylactic mesh) while 215 patients were controls (no mesh). Only two of the eight trials were considered to be at low risk of bias.^{19,20} Assessment of randomisation in all studies showed no significant difference between most patient characteristics. Four trials blinded patients from their intervention and five trials reported blinded observers for assessment (Table 1).

Seven studies reported patient demographics (Table 2). In the control group, the mean age was 62.6 years (range: 50–71 years) and the mean body mass index was 26.6 kg/m² (range: 25.4–27.5 kg/m²). In the intervention (mesh) group, the mean age was 62.8 years (range: 42–72 years) and the mean body mass index was 26.1 kg/m² (range: 24.6–26.5 kg/m²). Six studies recruited only patients undergoing permanent end colostomy for rectal cancer or faecal incontinence^{12,15,17,18,20,21} and one recruited only those having temporary stomas (not specified whether colostomy or ileostomy) for a heterogeneous group of conditions.¹¹ Only one study included four patients undergoing emergency surgery.¹²

Surgical technique for stoma construction and mesh placement was described in detail in all studies (Table 3). The prophylactic mesh was placed in the retrorectus plane in all studies except two, which placed the mesh in the intraperitoneal position.^{17,21} Each study investigated a different mesh; six were synthetic^{12,13,17,18,20,21} and two were biological.^{11,19} All studies compared prophylactic mesh with no mesh and there were no studies that compared different mesh types directly.

The follow-up duration ranged from 30 days to 85 months. Two studies followed patients for twelve months only.^{11,21} In six studies, follow-up was by a combination of clinical examination and radiological imaging (CT and ultrasonography),^{13,14,17,18,20,21} and in one study, it was by clinical examination alone.¹² Intraoperative findings at temporary stoma closure were used as the follow-up method in the remaining study.¹¹ Patients lost to follow-up were included

in the final analysis in all studies except one, which reported per protocol analysis at 24 months of follow-up.¹⁹

Parastomal hernia occurrence

The meta-analysis of the eight studies demonstrated that prophylactic mesh placement resulted in a significantly lower rate of PSH formation than no mesh (42/217 [19.4%] vs 92/213 [43.2%]). The combined risk ratio was 0.40 (95% CI: 0.21–0.75, $p=0.004$) (Fig 2).

If the different types of mesh are considered separately when compared with controls, synthetic mesh results in a significantly lower occurrence of PSH (37/158 [23.4%] vs 82/150 [54.7%]). The combined risk ratio was 0.36 (95% CI: 0.17–0.77, $p=0.008$) (Fig 3). Conversely, prophylactic biological mesh does not give a statistically significant reduction in PSH occurrence (6/59 [10.2%] vs 10/63 [15.9%]). The combined risk ratio was 0.58 (95% CI: 0.11–2.95, $p=0.510$) (Fig 4).

When the clinical diagnosis of PSH is compared with CT detected PSH, a statistically significant reduction in the occurrence of PSH is still demonstrable. The combined risk ratio for clinical diagnosis was 0.23 (95% CI: 0.13–0.43, $p<0.00001$) (Fig 5). For CT detected PSH, the combined risk ratio was 0.68 (95% CI: 0.52–0.90, $p=0.006$) (Fig 6).

Peristomal complications

The meta-analysis of the eight studies comparing any prophylactic mesh placement at stoma formation with no mesh demonstrated that prophylactic mesh placement did not show a statistically significant higher incidence of peristomal complications related to the mesh (15/218 [6.9%] vs 16/227 [7.0%]). The combined risk ratio was 1.0 (95% CI: 0.49–2.01, $p=0.990$) (Fig 7).

Discussion

This meta-analysis shows a statistically significant reduction in formation of PSH after prophylactic placement of any mesh without an increased risk of peristomal complications. Previous systematic reviews of fewer RCTs have drawn similar conclusions.^{8–10} Indeed, some authors have contended that the benefits of prophylactic mesh use during stoma formation were so overwhelming that further trials were unnecessary and even unethical.¹² Despite the enthusiasm of some surgeons, the routine placement of prophylactic mesh at the time of primary stoma formation has not been widely adopted and the prevalence of the technique is unknown.

One possible reason for the failure to adopt the use of prophylactic mesh into routine practice may be concerns regarding safety. This is related to but not synonymous with complications. Complications tend to relate to short-term outcomes (within 30 days postoperatively [eg infection]) whereas safety may relate to outcomes in the longer term (in the range of years to decades [eg mesh erosion]). Medium to long-term safety concerns regarding mesh placement adjacent to bowel (particularly mesh erosion) are not uncommon in the fields of hernia surgery in general^{22–24} or pelvic organ prolapse^{25–27} but there is a relative paucity of

Table 1 Risk of bias for the included studies

	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting
Hammond, 2008 ¹¹	?	-	+	+	+	-	-
Jänes, 2009 ¹²	?	-	+	+	-	+	-
Serra-Aracil, 2009 ¹³	?	-	-	+	-	-	-
López-Cano, 2012 ¹⁷	-	-	+	+	-	-	-
Târcoveanu, 2014 ¹⁸	+	+	+	+	+	+	-
Fleshman, 2014 ¹⁹	-	-	-	+	-	-	-
Lambrecht, 2015 ²⁰	-	-	-	+	-	-	-
Vierima, 2015 ²¹	-	-	-	+	+	-	-

+ = high risk of bias; - = low risk of bias; ? = unclear risk of bias

data specific to PSH and it pertains to repair rather than prophylaxis.²⁸

In our meta-analysis, safety was not an outcome on its own, largely because most of the studies reported only short to medium-term follow-up with insufficient time for safety concerns such as mesh erosion to manifest. However, the data regarding short-term complications were favourable, with few numbers reported and morbidity being generally minor. Other issues surrounding technology adoption by the surgical community are well documented and in the case of prophylactic mesh placement at stoma formation, these may reflect concerns regarding the methodological limitations of the trials.²⁹

Most of the individual studies included in this meta-analysis had significant methodological limitations, resulting in at least moderate risk of bias (Table 1), with five of the eight trials being single institution studies limited by small sample sizes. This has been confounded further by variable follow-up techniques (both clinical and radiological), with large differences in follow-up duration (1–84 months). The heterogeneity of indications for surgery, type of stoma formed, mesh used, location of mesh placement and surgical access (open vs laparoscopic) has added to the uncertainty of the applicability of the findings (of both the individual studies and previous meta-analyses) to everyday practice.

Poor quality in the control arm of surgical RCTs is increasingly recognised as a significant methodological problem.³⁰ In this context, the technique used for stoma formation in the control arm was not standardised either within or between most of the studies, possibly leading to an overestimation of the effect size of mesh placement. The evidence that supports the assertion of a potential overestimate of effect size for prophylactic mesh lies in the range of PSH incidence in the control arms (13–94%). This sevenfold difference in PSH incidence is far greater than the relative risk reduction of 60% from prophylactic mesh use.

Several technical factors have been purported to influence PSH formation, including: emergency surgery; trephine size, shape and location; route of the loop of bowel that

forms the stoma (transperitoneal or extraperitoneal); portion of bowel that forms the stoma (colostomy or ileostomy); and the stoma conformation (loop or end).^{5,4} Although individual technical factors that predispose to PSH formation have been identified, there is no consensus on the optimal technique for stoma formation.

Some of the quality limitations of previous studies of prophylactic mesh placement were addressed in one of the multicentre RCTs, which had a low risk of bias and standardised the stoma formation technique for both arms of the trial.¹⁹ Interestingly, this trial demonstrated no difference in the rates of PSH formation between patients with prophylactic biological mesh and controls. The overall incidence of PSH in the trial was 11.5% (based on the intention-to-treat figures) at two years of clinical and CT follow-up. This is substantially lower than the anticipated 30%, which had been used in the power calculations, and markedly lower than the incidence reported in the other RCTs (Table 2). However, in this study, there was a significant proportion of patients who were lost to follow-up (attrition bias) and the study was reported using per protocol analysis rather than basing analysis on intention to treat.

This raises the question as to whether (despite the apparent benefit of prophylactic mesh in this meta-analysis) comparable outcomes may be achievable if stoma formation techniques are optimised. Single institution retrospective studies have observed remarkably low rates of PSH using the extraperitoneal rather than the transperitoneal route for colostomy formation^{31,32} or circular stomal trephines in the abdominal wall fascia^{33,34} and a prospective RCT is ongoing.³⁵ Furthermore, there are now series that have reported outcomes from institutions that have adopted prophylactic mesh more routinely into their practice and the reported outcomes have not demonstrated any benefit in terms of reduction of PSH incidence from prophylactic mesh.^{36,37}

The type of mesh used and location of mesh placement differed between all studies. The impressive reduction of PSH formation that occurred with prophylactic synthetic mesh was not observed with biological mesh. Whether this

Table 2 Summary of study characteristics												
Study	Mesh						No mesh					
	Number of patients	Mean age in years	Male-to-female ratio	Mean BMI in kg/m ²	Emergency surgery	PSH complications	Number of patients	Mean age in years	Male-to-female ratio	Mean BMI in kg/m ²	Emergency surgery	PSH complications
Hammond, 2008 ¹¹	10	42.6	3:7	26.3	Elective	0	10	50	4:6	26.3	Elective	3
Jánes, 2009 ¹²	27	70	15:12	26	1	2	27	71	16:11	27	4	20
Serra-Aracil, 2009 ¹³	27	67.5	19:8	25.6	Elective	6	27	67.2	16:11	27.3	Elective	11
López-Cano, 2012 ¹⁷	19	72.2	11:8	26.3	Elective	9	17	65.9	7:10	27.5	Elective	15
Târcoveanu, 2014 ¹⁸	20	Not stated	Not stated	Not stated	Elective	0	22	Not stated	Not stated	Not stated	Elective	6
Fleishman, 2014 ¹⁹	55	60.2	30:25	26.2	Elective	6	58	59.1	29:29	24.7	Elective	7
Lambrecht, 2015 ²⁰	32	64	22:10	24.6	Elective	2	26	63	21:5	25.5	Elective	12
Vierima, 2015 ²¹	35	67.1	18:17	26.2	Elective	5	35	65.1	19:16	25.4	Elective	12
BMI = body mass index; PSH = parastomal hernia												

Table 3 Summary of surgical techniques used in each study

Study	Surgery	Notable exclusions	Stoma site	Mesh	Mesh trephine	Position	n	Colostomy	Ileostomy	Follow-up duration	Definition of PSH	Incidence of PSH in 'mesh' group	Incidence of PSH in 'no mesh' group
Hammond, 2008 ¹¹	Not stated	End stomas	Through rectus muscle	Permacol™	Circular	Retrorectus	20	Not stated	Not stated	6.5 mths median	Intraoperative	0/10	3/10
Jänes, 2009 ¹²	Open	None	Through rectus muscle	Vypro®	Cruciate	Retrorectus	54	54	0	65 mths mean	Clinical exam by blinded assessor	2/27	20/27 with dead included
Serra-Aracil, 2009 ¹³	Not stated	BMI >35kg/m ²	Through rectus muscle	Ultrapro®	Not available	Retrorectus	54	54	0	29 mths median	Clinical exam by blinded assessor and CT with Moreno-Matias grade by blinded radiologist	Clinical: 4/27 CT: 6/27	Clinical: 11/27 CT: 12/27
López-Cano, 2012 ¹⁷	Laparoscopic	None	Stoma therapist marked	Proceed®	Cruciate	Intraperitoneal	36	36	0	12 mths	CT by blinded radiologist	9/18	15/16
Târcoveanu, 2014 ¹⁸	Open	None	Through rectus muscle	Polypropylene	Not available	Retrorectus	42	42	0	24 mths	Clinical exam and ultrasonography, not blinded	0/20	6/22
Fleshman, 2014 ¹⁹	Open and laparoscopic	BMI >35kg/m ²	Through rectus muscle	Strattice™	Cruciate	Retrorectus	113	71	42	24 mths	Clinical exam by blinded assessor with CT confirmation	6/49	7/53
Lambreht, 2015 ²⁰	Open	None	Through rectus muscle	ProLite™ / Parietene™ Light	Cruciate	Retrorectus	58	58	0	40 mths median	Clinical exam and CT	Clinical: 2/32 CT: 8/32	Clinical: 12/26 CT: 11/26
Vierima, 2015 ²¹	Laparoscopic	None	Through rectus muscle	DynaMesh®	Cruciate	Intraperitoneal	70	70	0	12 mths	Clinical exam and CT	Clinical: 5/35 CT: 18/34	Clinical: 12/32 CT: 17/32
PSH = parastomal hernia; BMI = body mass index; CT = computed tomography

Figure 2 Forest plot of the risk of parastomal herniation following stoma formation with prophylactic mesh placement versus no mesh

Figure 3 Forest plot of the risk of parastomal herniation following stoma formation with prophylactic synthetic mesh placement versus no mesh

Figure 4 Forest plot of the risk of parastomal herniation following stoma formation with prophylactic biological mesh placement versus no mesh

Figure 5 Forest plot of the risk of clinically diagnosed parastomal herniation following stoma formation with prophylactic mesh placement versus no mesh

is because of the methodological issues related to study design described above or problems inherent with the mesh type is unclear as there are no direct comparisons between mesh types. The role of biological mesh therefore remains

uncertain¹¹ but the low rates of peristomal complications reported with prophylactic synthetic mesh suggest that the additional cost of biological prostheses is unwarranted in this situation.

Figure 6 Forest plot of the risk of computed tomography detected parastomal herniation following stoma formation with prophylactic mesh placement versus no mesh

Figure 7 Forest plot of the risk of peristomal complications (infection, necrosis, stenosis) following stoma formation with prophylactic mesh placement versus no mesh

There are also no direct comparisons regarding the location of prophylactic mesh at stoma formation. Only two RCTs used the intraperitoneal approach,^{17,21} with the others favouring the retrorectus position. For incisional hernia repair, the lowest rates of recurrence have been observed with mesh placed in the retrorectus plane⁵⁸ and no studies have directly compared location of prophylactic mesh when closing abdominal incisions.

All of the studies on prophylactic mesh used incidence of PSH as the primary outcome measure, which (although logical superficially) from a surgical perspective would be better reported as free from hernia by Kaplan–Meier analysis, as recommended by European Hernia Society guidelines.⁵⁹ Moreover, these outcome measures may not be the most appropriate from the patient perspective. Quality of life or other patient reported outcome measures are reported sparsely and variable questionnaire use limits comparisons. Patient centred core outcome set reporting would facilitate data synthesis.⁴⁰

The economic impact of PSH is poorly understood although it is recognised that symptomatic stoma patients are more likely to have increased rates of consultation with community healthcare teams.⁴¹ This results in increased direct costs related to stoma bags and associated products such as belts, adhesives, sprays, wipes and barrier creams. In 2012–2013 the cost of stoma bags and associated products was over £250 million in England alone, and costs have risen over 30% in the past five years.⁴² Skin irritation (one of the

most common problems associated with PSHs) is estimated to cost an additional 50 Euro per patient over a 7-week treatment period.⁴³ The cost of stoma bags and accessories for a patient managing his or her stoma effectively varies between £780 and £1,800 a year. In situations such as PSH where there are difficulties managing the stoma, this can rise to £6,000.⁴⁴ None of the estimated costs incorporate the expense and/or time of dedicated stoma care nurses.

Prophylactic mesh has been analysed from a health economic perspective, using models based on North American healthcare systems, and extrapolation to publically funded healthcare systems found in Europe may not be appropriate. The use of biological meshes as prophylaxis at initial stoma construction has been estimated to be cost effective if the risk of subsequent surgery for PSH repair is in excess of 39%.⁴⁵ In patients at highest risk of PSH formation (permanent end colostomy for rectal cancer), prophylactic synthetic mesh use was associated with significantly lower costs and more quality adjusted life years than no mesh for patients with cancer stages I–III whereas the benefit in stage IV rectal cancer was marginal.⁴⁶

In the UK, the National Institute for Health Research has recognised the importance of PSH and has funded the CIPHER study (Cohort study to Investigate the prevention of Parastomal HERnia). This non-randomised prospective observational study will include the development of a measure for symptoms associated with PSH as well as describing the key components of stoma formation. It will investigate

which factors lead to PSH formation in contemporary surgical practice and should hopefully inform the optimal design of a trial evaluating interventions to prevent PSH.

Conclusions

Prophylactic placement of mesh at primary stoma formation may reduce the incidence of PSH, without an increase in peristomal complications. However, the overall quality of RCTs 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. The optimal type of mesh, location for mesh placement and cost effectiveness still needs to be defined.

Conflict of interest

IRD and NJS have received honoraria from Covidien for lecturing on hernia surgery.

References

- Pearl RK. Parastomal hernias. *World J Surg* 1989; **13**: 569–572.
- van Dijk SM, Timmermans L, Deerenberg EB *et al*. Parastomal hernia: impact on quality of life? *World J Surg* 2015; **39**: 2,595–2,601.
- Ripoche J, Basurko C, Fabbro-Perray P, Prudhomme M. Parastomal hernia. A study of the French federation of ostomy patients. *J Visc Surg* 2011; **148**: e435–e441.
- Shabbir J, Britton DC. Stoma complications: a literature overview. *Colorectal Dis* 2010; **12**: 958–964.
- Hansson BM, Slater NJ, van der Velden AS *et al*. Surgical techniques for parastomal hernia repair: a systematic review of the literature. *Ann Surg* 2012; **255**: 685–695.
- Hotouras A, Murphy J, Thaha M, Chan CL. The persistent challenge of parastomal herniation: a review of the literature and future developments. *Colorectal Dis* 2013; **15**: e202–e214.
- Carne PW, Robertson GM, Frizelle FA. Parastomal hernia. *Br J Surg* 2003; **90**: 784–793.
- Tam KW, Wei PL, Kuo LJ, Wu CH. Systematic review of the use of a mesh to prevent parastomal hernia. *World J Surg* 2010; **34**: 2,723–2,729.
- Wijeyekoon SP, Gurusamy K, El-Gendy K, Chan CL. Prevention of parastomal herniation with biologic/composite prosthetic mesh: a systematic review and meta-analysis of randomized controlled trials. *J Am Coll Surg* 2010; **211**: 637–645.
- Shabbir J, Chaudhary BN, Dawson R. A systematic review on the use of prophylactic mesh during primary stoma formation to prevent parastomal hernia formation. *Colorectal Dis* 2012; **14**: 931–936.
- Hammond TM, Huang AM, Prosser K *et al*. Parastomal hernia prevention using a novel collagen implant: a randomised controlled phase 1 study. *Hernia* 2008; **12**: 475–481.
- Jänes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study. *World J Surg* 2009; **33**: 118–121.
- Serra-Aracil X, Bombardo-Junca J, Moreno-Matias *et al*. Randomized, controlled, prospective trial of the use of a mesh to prevent parastomal hernia. *Ann Surg* 2009; **249**: 583–587.
- Smart NJ, Bryan N, Hunt JA, Daniels IR. Porcine dermis implants in soft-tissue reconstruction: current status. *Biologics* 2014; **8**: 83–90.
- Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred Reporting Items for Systematic reviews and Meta-Analyses: the PRISMA Statement. *Ann Intern Med* 2009; **151**: 264–269.
- DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials* 1986; **7**: 177–188.
- López-Cano M, Lozoya-Trujillo R, Quiroga S *et al*. Use of a prosthetic mesh to prevent parastomal hernia during laparoscopic abdominoperineal resection: a randomized controlled trial. *Hernia* 2012; **16**: 661–667.
- Tărcoveanu E, Vasilescu A, Cotea E *et al*. Parastomal hernias – clinical study of therapeutic strategies. *Chirurgia* 2014; **109**: 179–184.
- Fleshman JW, Beck DE, Hyman N *et al*. 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. *Dis Colon Rectum* 2014; **57**: 623–631.
- Lambrech JR, Larsen SG, Reiertsen O *et al*. Prophylactic mesh at end-colostomy construction reduces parastomal hernia rate: a randomized trial. *Colorectal Dis* 2015; **17**: O191–O197.
- Vierimaa M, Klintrup K, Biancari F *et al*. Prospective, randomised study on the use of a prosthetic mesh for prevention of parastomal hernia of permanent colostomy. *Dis Colon Rectum* 2015; **58**: 943–949.
- Muysoms FE, Bontinck J, Pletinckx P. Complications of mesh devices for intraperitoneal umbilical hernia repair: a word of caution. *Hernia* 2011; **15**: 463–468.
- Fortelny RH, Petter-Puchner AH, Glaser KS *et al*. Adverse effects of polyvinylidene fluoride-coated polypropylene mesh used for laparoscopic intraperitoneal onlay repair of incisional hernia. *Br J Surg* 2010; **97**: 1,140–1,145.
- Wiegand A, Schlegel N, Isbert C *et al*. Lessons and challenges during a 5-year follow-up of 21 Composix Kugel implantations. *Hernia* 2013; **17**: 435–443.
- Badrek-Al Amoudi AH, Greenslade GL, Dixon AR. How to deal with complications after laparoscopic ventral mesh rectopexy: lessons learnt from a tertiary referral centre. *Colorectal Dis* 2013; **15**: 707–712.
- Consten EC, van Iersel JJ, Verheijen PM *et al*. Long-term outcome after laparoscopic ventral mesh rectopexy: an observational study of 919 consecutive patients. *Ann Surg* 2015; **262**: 742–747.
- Evans C, Stevenson AR, Sileri P *et al*. A multicenter collaboration to assess the safety of laparoscopic ventral rectopexy. *Dis Colon Rectum* 2015; **58**: 799–807.
- Steele SR, Lee P, Martin MJ *et al*. Is parastomal hernia repair with polypropylene mesh safe? *Am J Surg* 2003; **185**: 436–440.
- Wilson CB. Adoption of new surgical technology. *BMJ* 2006; **332**: 112–114.
- Strobel O, Büchler MW. The problem of the poor control arm in surgical randomized controlled trials. *Br J Surg* 2013; **100**: 172–173.
- Hamada M, Ozaki K, Muraoka G *et al*. Permanent end-sigmoid colostomy through the extraperitoneal route prevents parastomal hernia after laparoscopic abdominoperineal resection. *Dis Colon Rectum* 2012; **55**: 963–969.
- Leroy J, Diana M, Callari C *et al*. Laparoscopic extraperitoneal colostomy in elective abdominoperineal resection for cancer: a single surgeon experience. *Colorectal Dis* 2012; **14**: e618–e622.
- Resnick S. New method of bowel stoma formation. *Am J Surg* 1986; **152**: 545–548.
- Koltun L, Benyamin N, Sayfan J. Abdominal stoma fashioned by a used circular stapler. *Dig Surg* 2000; **17**: 118–119.
- Correa Martinez A, Erestam S, Haglund E *et al*. Stoma-Const – the technical aspects of stoma construction: study protocol for a randomised controlled trial. *Trials* 2014; **15**: 254.
- Nikberg N, Sverrisson I, Tsimogiannis K *et al*. Prophylactic stoma mesh did not prevent parastomal hernias. *Int J Colorectal Dis* 2015; **30**: 1,217–1,222.
- Marinez AC, González E, Holm K *et al*. Stoma-related symptoms in patients operated for rectal cancer with abdominoperineal excision. *Int J Colorectal Dis* 2016; **31**: 635–641.
- Helgstrand F, Rosenberg J, Kehlet H *et al*. Nationwide prospective study of outcomes after elective incisional hernia repair. *J Am Coll Surg* 2013; **216**: 217–228.
- Muysoms FE, Deerenberg EB, Peeters E *et al*. Recommendations for reporting outcome results in abdominal wall repair. *Hernia* 2013; **17**: 423–433.
- Gargon E, Gurung B, Medley N *et al*. Choosing important health outcomes for comparative effectiveness research: a systematic review. *PLoS One* 2014; **9**: e99111.
- Burch J. Stoma complications: an overview. *Br J Community Nurs* 2013; **18**: 375–378.

-
42. HC Deb 7 November 2013 c326W.
 43. Meisner S, Lehur PA, Moran B *et al.* Peristomal skin complications are common, expensive, and difficult to manage: a population based cost modeling study. *PLoS One* 2012; **7**: e37813.
 44. Oxenham J. Reviewing prescription spending and accessory usage. *Br J Nurs* 2014; **23**: S4, S6, S8 passim.
 45. Figel NA, Rostas JW, Ellis CN. Outcomes using a bioprosthetic mesh at the time of permanent stoma creation in preventing a parastomal hernia: a value analysis. *Am J Surg* 2012; **203**: 323–326.
 46. Lee L, Saleem A, Landry T *et al.* Cost effectiveness of mesh prophylaxis to prevent parastomal hernia in patients undergoing permanent colostomy for rectal cancer. *J Am Coll Surg* 2014; **218**: 82–91.