Systematic review of the stage of innovation of biological mesh for complex or contaminated abdominal wall closure

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Background: Achieving stable closure of complex or contaminated abdominal wall incisions remains challenging. This study aimed to characterize the stage of innovation for biological mesh devices used during complex abdominal wall reconstruction and to evaluate the quality of current evidence.

Methods: A systematic review was performed of published and ongoing studies between January 2000 and September 2017. Eligible studies were those where a biological mesh was used to support fascial closure, either prophylactically after midline laparotomy, or for reinforcement after repair of incisional hernia with midline incision. The primary outcome measure was the IDEAL framework stage of innovation. The key secondary outcome measure was the GRADE criteria for study quality.

Results: Thirty-five studies including 2681 patients were included. Four studies considered mesh prophylaxis, 23 considered hernia repair, and eight reported on both. There was one published randomized trial (IDEAL stage 3), none of which was of high quality; the others were non-randomized studies (IDEAL stage 2a). A detailed description of surgical technique was provided in most studies (27 of 35); however, no study reported outcomes according to the European Hernia Society consensus statement and only two described quality control of surgical technique during the study. From 21 ongoing randomized trials and observational studies, 11 considered repair of incisional hernia and 10 considered prophylaxis (seven in elective settings).

Conclusion: The evidence base for biological mesh is limited, and better reporting and quality control of surgical techniques are needed. Although results of ongoing trials over the next decade will improve the evidence base, further study is required in the emergency and contaminated settings.

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Introduction

Incisional hernias carry a significant burden for both patients and the health service1–4. They prevent return to normal activities and can be painful. Elective repair can be challenging, and emergency repair carries significant clinical risks. Incisional hernia is common, occurring in up to 50 per cent of patients after laparotomy5,6, and with the growing number of emergency laparotomies performed in the UK, the number of affected patients is likely to increase7.

To limit the number of incisional hernias there has been a focus on the use of prophylactic mesh reinforcement. The cost of mesh is far less than that of major reoperations and emergency admissions3,8–10. Although synthetic meshes are accepted in many cases, they are not used in complex and contaminated settings owing to the risk of infection (as high as 50–90 per cent), pain, fistulation and need for explantation11–14. Biological mesh has evolved to fill this gap, with expected reduced rates of infection leading to safer prophylaxis. Current guidelines, including the Ventral Hernia Working Group expert consensus, and several systematic reviews recommend against the use of synthetic mesh when the risk of wound complications is high, such as in the presence of gross contamination; instead they advocate the use of a biological absorbable mesh15–17.
Biological mesh has entered widespread clinical practice, but the quality and scope of the evidence base for use in complex and contaminated abdominal wounds are unclear. This review aimed to determine the quality and stage of innovation of the evidence supporting biological mesh placement during abdominal wall reconstruction with primary fascial closure. The hypothesis was that the evidence base supporting biological mesh use is currently too limited to support routine clinical use outside clinical trials.

**Methods**

**Search strategy**

A systematic search of PubMed, EMBASE and the Cochrane Library between 1 January 2000 and 27 September 2017 was performed by two independent investigators. The ClinicalTrials.gov database was also queried for ongoing studies. The search terms used were ‘laparotomy’, ‘mesh’, ‘biologic material’, ‘abdominal wall’, ‘hernia’, and ‘complications’, ‘contamination’, ‘infection’ or ‘surgical site infection’, individually or in combination. The ‘related articles’ function was used to broaden the search, and all citations were considered for relevance. A manual search of reference lists in recent reviews and eligible studies was also undertaken. This paper is reported according to the PRISMA guidelines.

**Inclusion and exclusion criteria**

Studies were included according to the following criteria: evaluation of the use of a xenograft biological mesh to support primary fascial closure of midline abdominal wounds or repair of incisional hernia with midline incision; study design was an RCT, prospective observational study, retrospective cohort study or case series; study included only patients aged 16 years or more.

The following exclusion criteria were employed: study design was a systematic review, meta-analysis, letter, review, comment or conference abstract; fewer than five patients were included in the study; only synthetic mesh or composite meshes were evaluated; allograft or autograft meshes, including human-derived acellular dermal matrix, were used (availability in Europe across the selected inclusion dates was low until recently, so reporting is likely to be incomplete); study reported bridging repairs (fascial closure not achieved), including studies where outcomes for fascial closure were not reported separately from bridging repair.

**Study outcome measures**

The primary outcome measure was the stage of innovation, according to the IDEAL framework. The level of evidence in the IDEAL staging system were 1 (case series with high risk of bias), 2a (cohort study), 2b (feasibility RCT), 3 (RCT) and 4 (high-quality prospective registry with long-term monitoring and low risk of bias). All assessments in the present study were carried out independently by two authors; disagreement was resolved by re-examining the relevant article until consensus was achieved.

**Secondary outcome measures**

The main secondary outcome measure was the quality of evidence assessed using the GRADE system. In the GRADE approach, studies are categorized as of high (randomized trials or double-upgraded observational studies), moderate (downgraded randomized trials or upgraded observational studies), low (double-downgraded randomized trials or observational studies) and very low (triple-downgraded randomized trials, downgraded observational studies or case series/case reports) quality. The other secondary outcome measures of interest were the numbers of studies reporting: outcomes according to the European Hernia Society consensus statement, incidence of incisional hernia, surgical-site infection (SSI) rate, and seroma.

**Data extraction**

Data extracted included patient demographics, indications and type of biological mesh used. Studies were grouped into those examining prophylactic placement in primary closure of laparotomy only (prophylaxis), repair of incisional hernia only (reinforcement), or both (mixed). Descriptions of procedures performed were collected, including surgical technique, number of procedures previously performed by the surgeon, and monitoring of technique. Degree of contamination (clean-contaminated, contaminated or dirty surgery) was defined according to the US Centers for Disease Control and Prevention (CDC) surgical wounds classification, and the location of biological mesh placement was also evaluated, as either intraperitoneal (intraperitoneal, intraperitoneal onlay mesh, underlay, intra-abdominal) or extraperitoneal (sublay, onlay, inlay, retromuscular, retrorectus, prefascial).

**Statistical analysis**

Analysis was intended to be primarily descriptive in nature, with no need for modelling or multivariable analyses. Event
Biological mesh devices for abdominal wall reconstruction

Records identified through database searching \( n = 1230 \)

Additional records identified through other sources \( n = 74 \)

Records screened after duplicates removed \( n = 1189 \)

Records excluded \( n = 1091 \)

Full-text articles assessed for eligibility \( n = 98 \)

Studies included in qualitative synthesis \( n = 35 \)
  
  Prophylaxis \( n = 4 \)
  Reinforcement \( n = 23 \)
  Mixed \( n = 8 \)

Full-text articles excluded \( n = 63 \)
  
  Synthetic mesh used \( n = 25 \)
  Composite mesh \( n = 5 \)
  Type of mesh not mentioned \( n = 7 \)
  Mesh type not stratified by outcomes \( n = 21 \)
  Bridged repair \( n = 5 \)

Eligibility

Included

Records excluded \( n = 1091 \)

Fig. 1 PRISMA diagram for the study

rates are reported as percentages. Continuous variables were tested for normality.

Results

Of 1304 studies shortlisted, 35 full-text articles\(^{24–58}\) met the inclusion criteria (Fig. 1). Of these, four examined biological mesh for prophylaxis, 23 reported on reinforcement after incisional hernia repair, and eight reported both prophylaxis and incisional hernia repair. Studies of biological mesh for prophylaxis included a total of 85 patients with a median follow-up of 12 (i.q.r. 2–31) months; those used for reinforcement included 1744 patients with a median follow-up of 16 (12–24) months, and those for mixed indications included 852 patients with a median follow-up of 24 (17–48) months.

Mesh characteristics

Tables 1 and 2 summarize characteristics of the included studies. Strattice\textsuperscript{TM} (KCI Medical, Dublin, Ireland) \( (2 \) studies), Surgisis\textsuperscript{®} (Cook Biotech, West Lafayette, Indiana, USA) \( (1 \) study) and bovine pericardium \( (1 \) study) were used for prophylaxis in abdominal wound reconstruction. For reinforcement, Permacol\textsuperscript{TM} (Tissue Science Laboratories, Andover, Massachusetts, USA) \( (9 \) studies) was the most commonly used mesh, followed by Strattice\textsuperscript{TM} \( (4 \) studies) and Surgisis\textsuperscript{®} \( (3 \) studies); a further seven studies each used different meshes. In papers reporting mixed indications, Permacol\textsuperscript{TM} \( (5 \) studies) was the most commonly reported, followed by XenMatrix\textsuperscript{TM} (Brennen Medical, St Paul, Minnesota, USA; Davol, Warwick, Rhode Island, USA) \( (1 \) study), Strattice\textsuperscript{TM} \( (1 \) study) and SurgiMend\textsuperscript{TM} (TEI Biosciences, Boston, Massachusetts, USA) \( (1 \) study).

IDEAL stage of innovation and GRADE quality of evidence

Distribution of IDEAL stage and GRADE quality of included studies are presented in Tables 3 and 4 respectively. Of the four prophylaxis studies, two\(^{24,25}\) evaluated biological mesh at the time of stoma closure, one\(^{26}\) following midline laparotomy after abdominal aortic aneurysm (AAA) repair, and one\(^{27}\) after cytoreduction and hyperthermic intraperitoneal chemotherapy. All four studies included only elective patients and the degrees of contamination were clean-contaminated \( (2 \) studies) and contaminated \( (2 \) studies). Strattice was used in two studies\(^{24,25}\) with an intraperitoneal placement; the others used bovine pericardium in an extraperitoneal position \( (1 \) study) or Surgisis\textsuperscript{®} in an intraperitoneal position \( (1 \) study). One study\(^{24}\) was IDEAL stage 2\(a\) (low quality) and the other\(^{26}\) was IDEAL stage 3 (moderate quality). Two studies\(^{25,27}\) reported only outcomes of patients with biological mesh; both studies were IDEAL stage 2\(a\) (very low quality).

Of the 23 studies\(^{28–50}\) using biological mesh for reinforcement, all reported only elective patients undergoing
Table 1 Patient characteristics (arranged alphabetically by timing of surgery)

| Reference | No. of patients | Median age (years) | Mean BMI (kg/m²) | Timing of surgery* | Indication for surgery |
|-----------|-----------------|--------------------|------------------|--------------------|------------------------|
| Bali et al. | 26              | 40                 | 75               | Elective AAA repair |
| Bhangu et al. | 7               | 9                  | n.a.             | Elective Stoma closure |
| Boulos et al. | 45              | 57                 | 33               | Elective Incisional hernia repair |
| Bourtos et al. | 8               | 60                 | n.a.             | Elective AWR after HIPEC |
| Chamieh et al. | 58              | n.a.               | n.a.             | Elective Incisional hernia repair |
| Chavarriga et al. | 18             | 49                 | n.a.             | Elective Incisional hernia repair |
| Cheng et al. | 270             | 60                 | 32               | Elective Incisional hernia repair |
| Cox et al. | 6               | 49                 | 25               | Elective Incisional hernia repair |
| Faezizadeh et al. | 77             | 56                 | 35               | Elective Incisional hernia repair |
| Garvey et al. | 191             | 58                 | 31               | Elective AWR, incisional hernia repair |
| Giordano et al. | 109             | 64                 | 30               | Elective Incisional hernia repair |
| Giordano et al. | 484             | 59                 | 31               | Data not available |
| Gnaneswaran et al. | 12          | 51                 | 32               | Elective Incisional hernia repair |
| Hicks et al. | 60              | 59                 | 36               | Elective Incisional hernia repair |
| Høyrup et al. | 10              | 66                 | n.a.             | Elective Incisional hernia repair, stoma closure, left hemicolectomy, anterior resection, bowel obstruction |
| Hsu et al. | 28              | 55                 | 34               | Elective Incisional hernia repair |
| Itani et al. | 80              | 57                 | n.a.             | Elective Incisional hernia repair |
| Limpert et al. | 26              | 54                 | n.a.             | Elective Incisional hernia repair |
| Madani et al. | 46              | 58                 | 28               | Elective Incisional hernia repair |
| Maggiori et al. | 30             | 61                 | 26               | Elective Stoma closure |
| Majumder et al. | 126            | 59                 | 37               | Elective Incisional hernia repair |
| Nockolds et al. | 23             | 57                 | n.a.             | Elective Incisional hernia repair |
| O’Halloran et al. | 85            | 56                 | 33               | Elective Incisional hernia repair |
| Patel et al. | 41              | 42                 | 20               | Elective Incisional hernia repair |
| Rosen et al. | 128             | 58                 | 34               | Elective Incisional hernia repair |
| Sbitany et al. | 41              | 66                 | 25               | Elective Incisional hernia repair |
| Shah et al. | 58              | 57                 | 34               | Elective Incisional hernia repair |
| Shaikh et al. | 20              | 51                 | n.a.             | Elective Incisional hernia repair, re-exploration laparotomy, multiple stab wounds, desmoid tumour resection |
| Ueno et al. | 20              | 60                 | n.a.             | Elective Incisional hernia repair |
| Warwick et al. | 57              | 64                 | 30               | Elective Incisional hernia repair |
| Zerbst et al. | 14              | 60                 | 35               | Elective Incisional hernia repair |
| Abdelfatah et al. | 65            | 55                 | 35               | Mixed |
| Byrnes et al. | 57              | 49                 | 32               | Incisional hernia repair, trauma laparotomy |
| Parker et al. | 9               | 58                 | n.a.             | Incisional hernia repair, AWR for abdominal wall tumour |
| Pomahac and Aflaki | 16             | 59                 | 28               | Mixed |

*Mixed indicates both elective and emergency surgery. AAA, abdominal aortic aneurysm; AWR, abdominal wall reconstruction; HIPEC, hyperthermic intraperitoneal chemotherapy.
Table 2 Summary of surgery and mesh characteristics (arranged chronologically by indication)

| Reference          | Year | Country | Indication | Type of mesh | Median follow-up (months) |
|--------------------|------|---------|------------|--------------|---------------------------|
| Boutros et al.     | 2010 | USA     | Prophylaxis | Surgisis®    | 6                         |
| Bhangu et al.      | 2014 | UK      | Prophylaxis | Strattice™   | 1                         |
| Bali et al.        | 2015 | Greece  | Prophylaxis | Bovine pericardium | 36                       |
| Maggiori et al.    | 2015 | France  | Prophylaxis | Strattice™   | 17                        |
| Lieno et al.       | 2004 | USA     | Reinforcement | Surgisis®     | 16                        |
| Limpert et al.     | 2009 | USA     | Reinforcement | Bovine pericardium | 22                       |
| Hsu et al.         | 2009 | USA     | Reinforcement | Permacol™    | 16                        |
| Chavarriaga et al. | 2010 | USA     | Reinforcement | Permacol™    | 7                         |
| Cox et al.         | 2010 | USA     | Reinforcement | Surgisis®    | 10                        |
| Shah et al.        | 2011 | USA     | Reinforcement | XenMatrix™   | 12                        |
| Patel et al.       | 2012 | USA     | Reinforcement | Strattice™   | 16                        |
| Itani et al.       | 2012 | USA     | Reinforcement | Strattice™   | 24                        |
| Rosen et al.       | 2013 | USA     | Reinforcement | Strattice™   | 22                        |
| Nockolds et al.    | 2014 | UK      | Reinforcement | Permacol™    | 17                        |
| Cheng et al.       | 2014 | USA     | Reinforcement | Permacol™/Strattice™ | 25                       |
| O’Halloran et al.  | 2014 | USA     | Reinforcement | Unknown      | 14                        |
| Zerib et al.       | 2015 | France  | Reinforcement | Permacol™    | 13                        |
| Giordano et al.    | 2015 | UK      | Reinforcement | Permacol™    | 24                        |
| Sbitany et al.     | 2015 | USA     | Reinforcement | Strattice™   | 5                         |
| Ganesanwaran et al.| 2016 | Australia | Reinforcement | BioDesign®     | 14                        |
| Fayezizadeh et al.| 2016 | USA     | Reinforcement | Permacol™    | 28                        |
| Majumder et al.    | 2016 | USA     | Reinforcement | Permacol™    | 22                        |
| Hicks et al.       | 2016 | USA     | Reinforcement | SurgiMend™   | 12                        |
| Warwick et al.     | 2017 | UK      | Reinforcement | Permacol™    | 18                        |
| Madani et al.      | 2017 | Canada  | Reinforcement | Surgisis®    | 47                        |
| Champine et al.    | 2017 | USA     | Reinforcement | Mixed        | 11                        |
| Boules et al.      | 2018 | USA     | Reinforcement | Permacol™    | 72                        |
| Parker et al.      | 2006 | USA     | Mixed       | Permacol™    | 18                        |
| Shaikh et al.      | 2007 | Ireland | Mixed       | Permacol™    | 18                        |
| Ponnahac and Aflaki| 2010 | USA     | Mixed       | Permacol™    | 17                        |
| Byrnes et al.      | 2011 | USA     | Mixed       | XenMatrix™   | 31                        |
| Heyrup et al.      | 2012 | Denmark | Mixed       | Permacol™    | 8                         |
| Abdelsattah et al.| 2015 | USA     | Mixed       | Permacol™    | 60                        |
| Garvey et al.      | 2017 | USA     | Mixed       | Strattice™   | 53                        |
| Giordano et al.    | 2017 | USA     | Mixed       | SurgiMend™   | 31                        |

Table 3 Distribution of IDEAL stage of innovation, by indication

| IDEAL stage | Total (n = 35) | Prophylaxis (n = 4) | Reinforcement (n = 23) | Mixed (n = 8) |
|-------------|----------------|---------------------|------------------------|--------------|
| 1 (case report) | 0              | 0                   | 0                      | 0            |
| 2a (cohort study) | 34             | 3                   | 23                     | 8            |
| 2b (feasibility RCT) | 0              | 0                   | 0                      | 0            |
| 3 (RCT) | 0              | 0                   | 0                      | 0            |
| 4 (registry) | 0              | 0                   | 0                      | 0            |

Table 4 Distribution of GRADE study quality, by indication

| GRADE quality | Total (n = 35) | Prophylaxis (n = 4) | Reinforcement (n = 23) | Mixed (n = 8) |
|---------------|----------------|---------------------|------------------------|--------------|
| High          | 0              | 0                   | 0                      | 0            |
| Moderate      | 5              | 1                   | 14                     | 3            |
| Low           | 18             | 2                   | 7                      | 3            |
| Very low      | 12             | 2                   | 4                      | 3            |

elective and emergency operations. The eight studies involved a mixture of procedures, with degree of contamination ranging from clean-contaminated to dirty. Mesh placement was intraperitoneal in six studies, extraperitoneal in one study, and a combination in one study. All were IDEAL stage 2a (cohort studies). Evidence was of very low quality in three studies, low quality in three, and moderate quality in two. The evidence in one study of abdominal wall reconstruction with porcine acellular dermal matrix (Permacol™) was of moderate quality owing to reporting of long-term outcomes of at least 5 years.

Outcome reporting

None of the studies in this review reported outcomes according to the European Hernia Society consensus statement, and none reported 'free from hernia' survival times. All four studies in the prophylaxis group
reported a definition for detection of incisional hernia, which included a combination of clinical examination and radiological assessment. In the reinforcement group, 12, 29, 30, 31, 32, 33, 35, 36, 38, 39, 41, 44, 47 of the 23 studies gave a definition for recurrence of hernia (6 clinical, 7 radiological, none patient-reported). SSI rates were reported in one of the four studies in the prophylaxis group, and in 21 of the 23 studies in the reinforcement group. The incidence of seroma was reported in three prophylaxis and 19 reinforcement studies.

**Reporting of surgical technique**

Of the 35 studies, 27 provided details of surgical procedures; all four studies in the prophylaxis group, 16 in the reinforcement group, and seven in the mixed group (Table 5). Only one paper reported the minimum number of procedures performed by the operating surgeons as a requirement.

**Ongoing studies**

Twenty-one ongoing studies were identified from ClinicalTrials.gov, of which ten were for prophylaxis and 11 for reinforcement. In the prophylaxis group, all were RCTs; four had completed data collection, five were still recruiting, and one had terminated early. Patient groups being studied included emergency midline laparotomy (1 study), elective patients for AAA repair (1), midline laparotomy (1), contaminated abdominal wall defect (1, terminated), abdominoperineal resection (1) and stoma closure (5). Of these ten, the majority studied Strattice (4), followed by Permacol (1) and Surgisis® (1). The type of biological mesh was not mentioned in the remaining four studies. In the 11 ongoing trials of reinforcement, nine were RCTs and two were cohort studies. Two studies (1 cohort study of Permacol and 1 RCT of XenMatrix) were in follow-up phase; the remainder were still recruiting patients.

**Discussion**

This review identified that the evidence base for biological mesh in complex and contaminated settings is still evolving, and highlighted areas for improvement. At present, the quality of the evidence base is generally low, with a few exceptions. The majority of studies included in this review were IDEAL stage 1 or 2 (case series or cohort studies) with a low or very low GRADE quality of evidence, indicating that biological meshes remain in the early stages of evaluation and adoption. This is compounded by a wide variation in mesh types and mesh placement, with little control for surgical technique, making synthesis of evidence ineffective.

There are two key recommendations from the present study. First, the evidence base needs to be improved by testing the efficacy of biological mesh in randomized trials. This should include standardization of techniques and reporting, and inclusion of more emergency cases to establish the limits of indication. Second, future studies should allow consistent reporting of mesh type and exact placement to enable high-quality recommendations to help standardize practice. Until such data are available, use in selected higher-risk patients (such as prophylaxis during abdominal wall closure in contaminated cases at high risk of incisional hernia) should be supported by data capture within controlled trials or registries. Routine clinical use in low-risk patients is not yet justified.

Surgeons and patients will benefit from knowing about mesh performance based on the specific type of mesh, the position it is placed in, and the expected long-term outcome. The present study identified variation in outcome reporting for recurrence rates, SSI and seroma. This variation precludes reliable assessment of outcomes and formation of recommendations. Recently, Blencowe and
colleagues\textsuperscript{59} proposed a standard approach for the description, standardization and monitoring of the intervention to enable reliable assessment of outcome from this type of study and, importantly, reproducibility of an intervention by surgeons in their clinical practice. In this review, only one study\textsuperscript{60} had monitoring of technique by a senior surgeon to allow consistency of mesh placement.

It is plausible that different biological meshes may have varying failure rates, degrees of immunogenicity, biocompatibility and risk profiles\textsuperscript{60}. In a rat study\textsuperscript{61} of 85 laparoscopic ventral hernia repairs, Strattice\textsuperscript{TM} and Parietex\textsuperscript{TM} (Covidien Surgical, Dublin, Ireland) were seen to grow a new mesothelial layer on their visceral side, whereas microscopic degradation and new collagen formation were seen in the Surgisis\textsuperscript{TM} group. In a mouse model of 135 mice with peritonitis, XCM BIOLOGIC\textsuperscript{TM} (LifeCell, KCI, Branchburg, New Jersey, USA) and Permacol\textsuperscript{TM} showed better incorporation than Strattice\textsuperscript{TM}, whereas Strattice\textsuperscript{TM} had fewer strong adhesions\textsuperscript{62}. More accurate information from human studies may allow improved selection of mesh for patients in future clinical practice.

The direct advantages of biological mesh remain unproven in widespread practice. First, the long-term durability of biological grafts used for complex abdominal wall reconstruction has been disappointing\textsuperscript{16,43}. Rosen and co-workers\textsuperscript{43} reported the overall hernia recurrence rate as 31 per cent over a mean follow-up of 21.7 (range 1–74) months, and estimated the 3-year recurrence-free survival rate to be 51 per cent. Second, implementation and use of biological mesh in clinical practice depend on the cost, as biological meshes can be up to ten times more expensive than synthetic ones\textsuperscript{17,61}. Totten et al.\textsuperscript{64} demonstrated that use of biological mesh for hernia repair can cost $21 000 (€17 100; exchange rate 20 April 2018) in comparison with synthetic mesh, which costs $7100 (€5780) for minimal cost savings to health services. Nevertheless, this scoring system is used widely for assessing strength of evidence in the literature\textsuperscript{20}. Biosynthetic resorbable meshes and patients undergoing bridged repairs were not included in the study, as they represent a clinically separate group and are likely to have a different stage of innovation due to timing of introduction.

The evidence base for biological mesh in this clinical context is limited and evolving. Better reporting and quality control of surgical techniques is needed and, although new trial results over the next decade will improve the evidence base, more trials in emergency and contaminated settings are required.

Disclosure

The authors declare no conflict of interest.

References

1 Deerenberg EB, Harlaar JJ, Steyerberg EW, Lont HE, van Doorn HC, Heisterkamp J et al. Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet 2015; 386: 1254–1260.
2 Bosanquet DC, Ansell J, Abdelrahman T, Cornish J, Harries R, Stimpson A et al. Systematic review and meta-regression of factors affecting midline incisional hernia rates: analysis of 14 618 patients. PLoS One 2015; 10: e0138745.
3 Fischer JP, Basta MN, Mirzabeigi MN, Bauder AR, Fox JP, Drehin JA et al. A risk model and cost analysis of incisional hernia after elective, abdominal surgery based upon 12 373 cases: the case for targeted prophylactic intervention. Ann Surg 2016; 263: 1010–1017.
4 van Ramshorst GH, Eker HH, Hop WC, Jeekel J, Lange JF. Impact of incisional hernia on health-related quality of

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life and body image: a prospective cohort study. *Am J Surg* 2012; **204**: 144–150.

5 Chand B, Indeck M, Needleman B, Finnegan M, Van Sickle KR, Ystgaard B et al. A retrospective study evaluating the use of Permacol™ surgical implant in incisional and ventral hernia repair. *Int J Surg* 2014; **12**: 296–303.

6 Iacco A, Adeyemo A, Riggs T, Janczyk R. Single institutional experience using biological mesh for abdominal wall reconstruction. *Am J Surg* 2014; **208**: 480–484.

7 Saunders DI, Murray D, Pichel AC, Varley S, Peden CJ. UK Emergency Laparotomy Network. Variations in mortality after emergency laparotomy: the first report of the UK Emergency Laparotomy Network. *Br J Anaesth* 2012; **109**: 368–375.

8 Burger JW, Luijendijk RW, Hop WC, Halm JA, Verdaasdonk EG, Jeekel J. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. *Ann Surg* 2004; **239**: 578–583.

9 Luijendijk RW, Hop WC, van den Tol MP, de Lange DC, Braaksm Ma, IJzermans JN et al. A comparison of suture repair with mesh repair for incisional hernia. *N Engl J Med* 2000; **343**: 392–398.

10 Bhangu A, Fitzgerald JE, Singh P, Battersby N, Marriott P, Pinkney T. Systematic review and meta-analysis of prophylactic mesh placement for prevention of incisional hernia following midline laparotomy. *Hernia* 2013; **17**: 445–455.

11 Cevasco M, Itani KM. Ventral hernia repair with synthetic, composite, and biologic mesh: characteristics, indications, and infection profile. *Surg Infect (Larchmt)* 2012; **13**: 209–215.

12 Pérez-Köhler B, Bayon Y, Bellón JM. Mesh infection and hernia repair: a review. *Surg Infect (Larchmt)* 2016; **17**: 124–137.

13 Jones JW, Jurkovich GJ. Polypropylene mesh closure of infected abdominal wounds. *Am Surg* 1989; **55**: 73–76.

14 Voyles CR, Richardson JD, Bland KI, Tohin GR, Flint LM, Polk HC Jr. Emergency abdominal wall reconstruction with polypropylene mesh: short-term benefits versus long-term complications. *Ann Surg* 1981; **194**: 219–223.

15 Ventral Hernia Working Group, Breuing K, Butler CE, Ferzoo S, Franz M, Hultman CS, Kilbridge JF et al. Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. *Surgery* 2010; **148**: 544–558.

16 Shankaran V, Weber DJ, Reed RL. 2nd, Luchette FA. A review of available prosthetics for ventral hernia repair. *Ann Surg* 2011; **253**: 16–26.

17 Bachman S, Ramshaw B. Prosthetic material in ventral hernia repair: how do I choose? *Surg Clin North Am* 2008; **88**: 101–112, ix.

18 Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. *BMJ* 2009; **339**: b2700.

19 McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC et al. No surgical innovation without evaluation: the IDEAL recommendations. *Lancet* 2009; **374**: 1105–1112.

20 Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S et al.; GRADE Working Group. Grading quality of evidence and strength of recommendations. *BMJ* 2004; **328**: 1490.

21 Muysoms FE, Deerenberg EB, Peeters E, Agresta F, Berrevoet F, Campanelli G et al. Recommendations for reporting outcome results in abdominal wall repair: results of a Consensus meeting in Palermo, Italy, 28–30 June 2012. *Hernia* 2013; **17**: 423–433.

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

23 Muysoms F, Jacob B. International Hernia Collaboration consensus on nomenclature of abdominal wall hernia repair. *World J Surg* 2018; **42**: 302–304.

24 Maggioli L, Mozskowicz D, Zappa M, Mongin G, Panis Y. Bioprosthetic mesh reinforcement during temporary stoma closure decreases the rate of incisional hernia: a blinded, case–matched study in 94 patients with rectal cancer. *Surgery* 2015; **158**: 1651–1657.

25 Bhangu A, Futaha K, Patel A, Pinkney T, Morton D. Reinforcement of closure of stoma site using a biological mesh. *Tech Coloproctol* 2014; **18**: 305–308.

26 Bali C, Papakostas J, Georgiou G, Kouvelos G, Avgos S, Arnaoutoglou E et al. A comparative study of sutured versus bovine pericardium mesh abdominal closure after open abdominal aortic aneurysm repair. *Hernia* 2015; **19**: 267–271.

27 Boutros C, Somasundar P, Espat NJ. Early results on the use of biomaterials as adjuvant to abdominal wall closure following cytoreduction and hyperthermic intraperitoneal chemotherapy. *World J Surg Oncol* 2010; **8**: 72.

28 Cheng AW, Abbas MA, Tejirian T. Outcome of abdominal wall hernia repair with biologic mesh: Permacol™ versus Strattice™. *Ann Surg* 2014; **80**: 999–1002.

29 Ueno T, Pickett LC, de la Fuente SG, Lawson DC, Pappas TN. Clinical application of porcine small intestinal submucosa in the management of infected or potentially contaminated abdominal defects. *J Gastrointest Surg* 2004; **8**: 109–112.

30 Warwick AM, Smart NJ, Daniels IR. Retro-rectus repair of complex incisional hernia leads to low recurrence rate. *ANZ J Surg* 2017; **87**: 591–594.

31 Chamieh J, Tan WH, Ramirez R, Nohra E, Apakama C, Symons W. Synthetic versus biologic mesh in single-stage repair of complex abdominal wall defects in a contaminated field. *Surg Infect (Larchmt)* 2017; **18**: 112–118.

32 Chavarriaga LF, Lin E, Losken A, Cook MW, Jeansonne LO, White BC et al. Management of complex abdominal...
wall defects using acellular porcine dermal collagen. Am Surg 2010; 76: 96–100.

33 Fayezizadeh M, Majumder A, Belyansky I, Novitsky YW. Outcomes of retromuscular porcine biologic mesh repairs using transversus abdominis release reconstruction. J Am Coll Surg 2016; 223: 461–468.

34 Hicks CW, Poruk KE, Baltodano PA, Soares KC, Azoury SC, Cooney CM et al. Long-term outcomes of sandwich ventral hernia repair paired with hybrid vacuum-assisted closure. J Surg Res 2016; 204: 282–287.

35 Hsu PW, Salgado CJ, Kent K, Finnegan M, Pello M, Simons R et al. Evaluation of porcine dermal collagen (Permocoll) used in abdominal wall reconstruction. J Plast Reconstr Aesthet Surg 2009; 62: 1484–1489.

36 Itani KM, Rosen M, Vargo D, Awad SS, Denoto G III, Butler CE; RICH Study Group. Prospective study of single-stage repair of contaminated hernias using a biologic porcine tissue matrix: the RICH Study. Surgery 2012; 152: 498–505.

37 Limper JN, Desai AR, Kumpf AL, Fallucco MA, Aridge DL.. Repair of abdominal wall defects with bovine pericardium. Am J Surg 2009; 198: e60–e65.

38 Madani A, Niculiseanu P, Marini W, Kaneva PA, Mappin-Kasirer B, Vassiliou MC et al. Biologic mesh for repair of ventral hernias in contaminated fields: long-term clinical and patient-reported outcomes. Surg Endosc 2017; 31: 861–871.

39 Majumder A, Winder JS, Wen Y, Pauli EM, Belyansky I, Novitsky G. Comparative analysis of biologic versus synthetic mesh outcomes in contaminated hernia repairs. Surgery 2016; 160: 828–838.

40 Nockolds CL, Hodde JP, Rooney PS. Abdominal wall reconstruction with components separation and mesh reinforcement in complex hernia repair. BMC Surg 2014; 14: 25.

41 O’Halloran EB, Barwegen CJ, Dombrowski JM, Vandevelde DK, Luchette FA. Can’t have one without the other: component separation plus mesh for repairing difficult incisional hernias. Surgery 2014; 156: 894–899.

42 Patel KM, Nahabedian MY, Gatti M, Bhanot P. Indications and outcomes following complex abdominal reconstruction with component separation combined with porcine acellular dermal matrix reinforcement. Ann Plast Surg 2012; 69: 394–398.

43 Rosen MJ, Krpata DM, Ermlich B, Blatnik JA. A 5-year clinical experience with single-stage repairs of infected and contaminated abdominal wall defects utilizing biologic mesh. Ann Surg 2013; 257: 991–996.

44 Sbitany H, Kwon E, Chern H, Finlayson E, Varma MG, Hansen SL. Outcomes analysis of biologic mesh use for abdominal wall reconstruction in clean-contaminated and contaminated ventral hernia repair. Ann Plast Surg 2015; 75: 201–204.

45 Shah BC, Tiwari MM, Goede MR, Eichler MJ, Hollins RR, McBride CL et al. Not all biologies are equal! Hernia 2011; 15: 165–171.

46 Zerbib P, Caiazzo R, Piesen G, Rogosnitzky M, Séquier C, Koriche D et al. Outcome in porcine acellular dermal matrix reinforcement of infected abdominal wall defects: a prospective study. Hernia 2015; 19: 253–257.

47 Giordano P, Pullan RD, Ystgaard B, Gossetti F, Bradburn M, McKinley AJ et al. The use of an acellular porcine dermal collagen implant in the repair of complex abdominal wall defects: a European multicentre retrospective study. Tech Coloproctol 2015; 19: 411–417.

48 Cox TC, Pearl JP, Ritter EM. Rives–Stoppa incisional hernia repair combined with laparoscopic separation of abdominal wall components: a novel approach to complex abdominal wall closure. Hernia 2010; 14: 561–567.

49 Boules M, Strong AT, Corcelles R, Hasksins IN, Ilie R, Wathen C et al. Single-center ventral hernia repair with porcine dermis collagen implant. Surg Endosc 2018; 32: 1820–1827.

50 Gnaneswaran N, Perera M, Jenkin A, Lau II, Presley R. Ventral hernia repair with lateral component separation and onlay Biodesign graft. Eur J Plast Surg 2016; 39: 279–286.

51 Byrnes MC, Irwin E, Carlson D, Campeau A, Gipson JC, Beal A et al. Repair of high-risk incisional hernias and traumatic abdominal wall defects with porcine mesh. Am Surg 2011; 77: 144–150.

52 Garvey PB, Giordano SA, Baumann DP, Liu J, Butler CE. Long-term outcomes after abdominal wall reconstruction with acellular dermal matrix. J Am Coll Surg 2017; 224: 341–350.

53 Giordano S, Garvey PB, Baumann DP, Liu J, Butler CE. Primary fascial closure with biologic mesh reinforcement results in lesser complication and recurrence rates than bridged biologic mesh repair for abdominal wall reconstruction: a propensity score analysis. Surgery 2017; 161: 499–508.

54 Parker DM, Armstrong PJ, Frizzi JD, North JH Jr. Porcine dermal collagen (Permocoll) for abdominal wall reconstruction. Curr Surg 2006; 63: 255–258.

55 Pomahac B, Aflaki P. Use of a non-cross-linked porcine dermal collagen implant in the repair of complex abdominal wall defects: a European multicentre retrospective study. Hernia 2015; 19: 253–257.

56 Shaikh FM, Giri SK, Durrani S, Waldron D, Grace PA. Experience with porcine acellular collagen implant in one-stage tension-free reconstruction of acute and chronic abdominal wall defects. World J Surg 2007; 31: 1966–1972.

57 Hoyrup S, Bruun J, Bertelsen CA. Use of biological mesh in facilitation of early closure in potentially infected abdominal wall defects. Dan Med J 2012; 59: A4389.

58 Abdelfatah MM, Rostambeigi N, Podgaetz E, Sarr MG. Long-term outcomes (> 5-year follow-up) with porcine acellular dermal matrix (Permacoll) in incisional hernias at risk for infection. Hernia 2015; 19: 135–140.

59 Blencowe NS, Mills N, Cook JA, Donovan JL, Rogers CA, Whiting P et al. Standardizing and monitoring the delivery of surgical interventions in randomized clinical trials. Br J Surg 2016; 103: 1377–1384.
60 Hammond TM, Chin-Aleong J, Navsaria H, Williams NS. Human in vivo cellular response to a cross-linked acellular collagen implant. Br J Surg 2008; 95: 438–446.

61 Ditzel M, Deerenberg EB, Grotenhuis N, Harlaar JJ, Monkhorst K, Bastiaansen-Jenniskens YM et al. Biologic meshes are not superior to synthetic meshes in ventral hernia repair: an experimental study with long-term follow-up evaluation. Surg Endosc 2013; 27: 3654–3662.

62 Kaufmann R, Jairam AP, Mulder IM, Wu Z, Verhelst J, Vennix S et al. Characteristics of different mesh types for abdominal wall repair in an experimental model of peritonitis. Br J Surg 2017; 104: 1884–1893.

63 Primus FE, Harris HW. A critical review of biologic mesh use in ventral hernia repairs under contaminated conditions. Hernia 2013; 17: 21–30.

64 Totten CF, Davenport DL, Ward ND, Roth JS. Cost of ventral hernia repair using biologic or synthetic mesh. J Surg Res 2016; 203: 459–465.

65 Rosen MJ, Bauer JJ, Harmaty M, Carbonell AM, Cobb WS, Matthews B et al. Multicenter, prospective, longitudinal study of the recurrence, surgical site infection, and quality of life after contaminated ventral hernia repair using biosynthetic absorbable mesh: the COBRA study. Ann Surg 2017; 265: 205–211.