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REVIEW

What is the evidence for the use of biologic or biosynthetic meshes in abdominal wall reconstruction?

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Abstract

Introduction Although many surgeons have adopted the use of biologic and biosynthetic meshes in complex abdominal wall hernia repair, others have questioned the use of these products. Criticism is addressed in several review articles on the poor standard of studies reporting on the use of biologic meshes for different abdominal wall repairs. The aim of this consensus review is to conduct an evidence-based analysis of the efficacy of biologic and biosynthetic meshes in predefined clinical situations.

Methods A European working group, "BioMesh Study Group", composed of invited surgeons with a special interest in surgical meshes, formulated key questions, and forwarded them for processing in subgroups. In January 2016, a workshop was held in Berlin where the findings were presented, discussed, and voted on for consensus. Findings were set out in writing by the subgroups followed by consensus being reached. For the review, 114 studies and background analyses were used.

Results The cumulative data regarding biologic mesh under contaminated conditions do not support the claim that it is better than synthetic mesh. Biologic mesh use should be avoided when bridging is needed. In inguinal hernia repair biologic and biosynthetic meshes do not have a clear advantage over the synthetic meshes. For prevention of incisional or parastomal hernias, there is no evidence to support the use of biologic/biosynthetic meshes. In complex abdominal wall hernia repairs (incarcerated hernia, parastomal hernia, infected mesh, open abdomen, enterocutaneous fistula, and component separation technique), biologic and biosynthetic meshes do not provide a superior alternative to synthetic meshes.

Conclusion The routine use of biologic and biosynthetic meshes cannot be recommended.

Keywords Biologic meshes · Biosynthetic meshes · Complex ventral hernias · Contaminated surgical field · Bridging

Introduction

There is a rising demand for materials to replace or augment a patient's native tissue when it has been compromised [1]. These products are divided into two groups: synthetic and biologic meshes [1]. Synthetic meshes can be either permanent or absorbable [1]. The development of absorbable and biologic meshes was triggered by the complications of using permanent meshes [1]. Contamination of the surgical field poses a dilemma as the use of permanent synthetic material is historically considered contraindicated given the risk of postoperative infective complications and need for mesh removal [2]. The introduction of biologic or absorbable synthetic meshes has provided an alternative [2]. Derived from biologic (human, bovine, or porcine) sources or absorbable synthetic material, these meshes theoretically incorporate into native tissue and possess the ability to resist infection [2]. Although none of the biologic meshes have US Food and Drug Administration approval for use in an infected field and even though there is a paucity of controlled data, they have become the method of choice in many institutions across Europe and the United States over the past several years [3]. Because the outcomes of biologic meshes are perceived to

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be better than those for synthetic non-absorbable meshes, the use of biologic meshes increased exponentially without clear evidence of efficacy [4]. Although many surgeons have adopted the use of biologic meshes in complex situations, others have questioned the use of these products [3]. Criticism is addressed in several review articles on the poor standard of studies reporting on the use of biologic meshes for different abdominal wall repairs [5–21]. In view of this controversial debate about the benefits of biologic meshes, in an invited commentary in the journal, "Hernia" Agneta Montgomery refers to "The battle between biologic and synthetic meshes in ventral hernia repair" [22]. This controversial debate on what mesh to use in which patient in any specific situation became even more complex with the introduction of the biosynthetic meshes in addition to the already existing synthetic and biologic meshes. Biosynthetic meshes were developed as a possible cost-effective alternative to the biologic meshes.

The aim of a group of hernia experts (BioMesh Study Group) was to conduct an evidence-based review of the efficacy of biologic and biosynthetic meshes in predefined clinical situations. The scope of this analysis was focused on guidelines, meta-analyses, systematic reviews, and prospective randomized trials, but also lower level of evidence was accepted when data were missing on specific tasks.

Methods

In the early 2015, a European working group, "BioMesh Study Group", composed of invited surgeons with a special interest in surgical meshes met to analyze the available evidence on the use of biologic and biosynthetic meshes. Key questions were formulated by the BioMesh Study Group and forwarded for processing in subgroups. In January 2016, a workshop was held in Berlin where the findings were presented, discussed, and voted on for consensus. Findings were set out in writing by the subgroups followed by consensus being reached within the BioMesh Study Group. For the review, 114 studies and background analyses were used. The conclusion at the end of each set of questions reflects the consensus reached by the members. At the end of the conclusions, the level of evidence according to the Grade system [23] is given for the studies included in the reviews to answers the key questions.

Characteristics of biologic and absorbable synthetic (biosynthetic) meshes

Biologic meshes derived from the collagen-rich tissues of human, porcine, or bovine sources [24]. The tissues are decellularized with sodium deoxycholate or a similar solvent, which yields a matrix of collagen, elastin, and laminin that serves as supporting scaffold for cellular repopulation and neovascularization. These acellular scaffolds may also be additionally cross-linked, which inhibits collagen degradation by blocking collagenase-binding sites, thereby allowing the mesh to maintain its structure for a longer period with slower incorporation into the adjacent tissue [24].

Although the basic composition of each biologic mesh is the same (i.e., a collagen matrix), the meshes vary in tensile strength, rate of incorporation, and resistance to infection [24]. The more commonly used biologic meshes (Table 1) are human acellular dermal matrix, porcine small intestine submucosa, porcine dermis, and bovine pericardium [24].

The most important step is the biologic mesh integration followed by remodeling new collagen deposition and tissue regeneration [8]. During this process, the implanted mesh is often reabsorbed by the host. Unfortunately, this process is poorly understood and is often difficult to determine and quantify/measure [8].

The absorbable synthetic mesh Bio-A (Gore) is a copolymer of polyglycolic acid and trimethylene carbonate in a three-dimensional matrix, which completely degrades in approximately 6 months [25]. Phasix (Bard/Davol) is a macroporous, fully absorbable synthetic mesh that consists of co-knitted absorbable poly-4-hydroxybutyrate and Phasix ST (Bard/Davol) is a composite mesh with additional polyglycolic acid fibers coated with a chemically modified sodium hyaluronate, carboxymethylcellulose, and polyethylene glycol-based hydrogel on the visceral surface [26]. It has a complete resorption time of 12–18 months [25].

Table 1 Biological meshes currently on the market

Name	Manufacturer	Cross-linked	Source
Alloderm	Life cell	No	Human dermis
Strattice	Life cell	No	Porcine dermis
Permacol	Covidien	Yes	Porcine dermis
Veritas	Baxter	No	Bovine pericardium
Collamend	BARD	Yes	Porcine dermis
Allomax	BARD	No	Human dermis
Xen matrix	BARD	No	Porcine dermis
Surgimend	TEI biosciences	No	Bovine dermis
XCM Biologic	J & J	No	Porcine dermis
Flex HD	J & J	No	Human dermis
Tutomesh	RTI surgical	No	Bovine pericardium
FortaGen	Organogenesis	No	Porcine intestine
Fortiva	RTI surgical	No	Porcine dermis
Cortiva	RTI surgical	No	Human dermis
Biodesign/surgisis	Cook medical	No	Porcine intestine
Epiflex	DIZG	No	Human dermis
Cellis	Mecellis biotech	No	Porcine dermis

The macroporous multifilament absorbable synthetic mesh TIGR Matrix Surgical mesh (Novus Scientific) has also been recently introduced on to the market. It consists of two types of fibers (fast and slow-resorbing fiber) and is a copolymer of lactide and trimethylene carbonate and completely resorbs in 3 years [26].

Are biologic and biosynthetic meshes more resistant to infection than synthetics?

One of the main marketed described advantages of biologic meshes is its ability to be used in contaminated fields without the fear of infection and need for explantation [27]. In theory, the vascular ingrowth that occurs with a biologic mesh allows the host immune system to fight infection, as opposed to synthetic meshes where no true ingrowth occurs [27]. In a critical review of biologic meshes used in ventral hernia repairs under contaminated conditions, Primus et al. pointed out that all reviews on biologic meshes supported biologic mesh use, especially in the setting of contaminated fields [18]. Yet, the primary literature included in reviews consisted entirely of low level of evidence (case series and case reports). The conclusion was that cumulative data regarding biologic mesh use in ventral hernia repair under contaminated conditions do not support the claim that it is better than synthetic mesh used under the same conditions.

Data from the National Surgical Quality Improvement Program (NSQIP) of 33,832 patients with ventral hernia repair using mesh in clean-contaminated and contaminated surgical fields compared to clean cases showed a significantly higher odds ratio (OR) of having one or more postoperative occurrences with 3.56 [3.25–3.89] and 5.05 [1.78–12.41], respectively [28]. There was a significantly increased OR of superficial surgical site infections (SSI) (OR 2.53), deep SSI (OR 3.09) and wound disruption (OR 4.41) for clean-contaminated cases compared to clean cases [28].

A systematic review on synthetic and biologic meshes for abdominal wall reinforcement in contaminated fields found a total of 32 studies that met inclusion criteria. Mean sample size was 41.4 (range 10–190) [29]. Overall study quality was low. Pooled wound infection rate was 31.6% (95% CI 14.5–48.7) with biologic and 6.4% (95% CI 3.4–9.4) with synthetic non-absorbable meshes in clean-contaminated patients. In contaminated and/or dirty fields, wound infection rates were similar, but pooled hernia recurrence rates were 27.2% (95% CI 9.5–44.9) with biologic and 3.2% (95% CI 0.0–11.0) with synthetic non-absorbable. The authors concluded that the available evidence is limited, but does not support the superiority of biologic over synthetic non-absorbable meshes in contaminated fields [29].

In another systematic review by Darehzereshki et al. [30] only including case series with the use of biologic meshes in clean surgical fields, they found significantly fewer infectious wound complications ($p < 0.00001$) for biologic in comparison to synthetic meshes.

The systematic review by Atema et al. [2] showed no benefit of biologic over synthetic mesh for repair of potentially contaminated hernias with comparable surgical site complication rates. Overall surgical complication rate was 50% and mesh removal rate was 1% [2]. The systematic review by Cross et al. [3] comprised 16 studies with 554 patients with contaminated surgical fields. The overall infection rate was 25%. The authors concluded that caution should be used when using biologic mesh products in infected fields, because there is a paucity of controlled data and none have US Food and Drug Administration approval for use in infected fields [3].

A retrospective analysis of a prospective database reviewed 761 ventral hernia repairs with suture, synthetic, or biological mesh in contaminated surgical fields [31]. The unadjusted outcome for surgical site infections (15.1%, 17.8%, 21.0%; $p = 0.280$) was not statistically different between groups [31]. A matched pair analysis of 40 ventral hernia repairs with biological mesh compared to 40 patients having synthetic mesh repair in complicated situations showed no significant differences in surgical site infection (20% vs. 35%; $p = 0.29$) [32].

In a retrospective study comparing 34 contaminated abdominal wall repairs with biological mesh with 24 with synthetic mesh found an overall infection rate of 50% vs. 29.2% ($p = 0.18$) [33].

In a multicenter, retrospective review of patients undergoing open ventral hernia repair in clean-contaminated/contaminated fields (69 biologic and 57 synthetic meshes), there were 13 (22.8%) surgical site events in the synthetic cohort compared to 29 (42.0%) in the biologic cohort ($p = 0.024$) [34]. Similarly, surgical site infections were less frequent in the synthetic group, with 7 (12.3%) versus 22 (31.9%); $p = 0.01$. The authors concluded that overall the findings not only support suitability of synthetic mesh in contaminated settings but also challenge the purported advantage of biologics in clean-contaminated/contaminated ventral hernia repairs [34].

Ko et al. [35] analyzed separately results in patients without contamination (Alloderm $n = 13$; PP $n = 23$). Major complications were comparable (15% vs. 17%), but minor wound complications were lower in the biologic mesh group (8% vs. 17%). Recurrence was seen in 38.5% of Alloderm and only in 4% of PP repaired patients.

El-Gazzaz [36] performed a retrospective study of 25 patients with ventral hernia and concomitant bowel surgery comparing biologic mesh with intraabdominal PP or polytetrafluoroethylene. Wound complications and mesh infection/excision rates did not show advantage of biologic mesh.

Nockolds et al. [37] evaluated retrospectively 23 patients with complex hernias (width 8–17 cm, VHWG III/IV) with 7 patients having an enterocutaneous fistula. A total of 17 had biologic mesh (Biodesign $n = 14$; cross-linked porcine dermis $n = 3$) and 6 had a synthetic (PP). Around 60% had an onlay mesh and 60% had an anterior CST achieving midline closure in 87%. 10, 15, and 10%, respectively, in the biologic mesh group developed wound dehiscence, infection or a recurrence. The numbers in the synthetic mesh group were 17% for each of the outcome parameters.

Gurrado et al. [38] evaluated retrospectively a group of 76 patients with midline defects (mean defect size 150 cm^2) and fascial closure (± relaxing incisions). Clean contamination was differentiated from contaminated/dirty settings. Sixteen percent of the patients in the synthetic and 61% in the biologic mesh group were contaminated/dirty. Synthetic meshes were PP or polyester and biologic mesh was bovine pericardium. Onlay mesh was used in about 2/3 and retromuscular mesh in the remainder, equally divided between both groups. Wound infection rates were 53% versus 3% in the synthetic versus biologic group, seroma incidence 34% versus none, and recurrence rate at 1-year follow-up 16% versus none. Complications in the synthetic mesh group were almost exclusively seen in the onlay group.

In a study by Sahoo et al. [39], a total of 438 patients with clean-contaminated and contaminated wounds were considered for comparative analysis of 30-day outcomes. Within this cohort, 58 (13.2%) patients underwent ventral hernia repair with biosynthetic mesh (Phasix, Bio-A) and 380 (86.8%) with polypropylene mesh. Propensity-matched-analysis showed no significant difference between biosynthetic and polypropylene mesh groups for 30-day surgical site occurrence (20.7% vs. 16.7%; $p = 0.49$) or unplanned readmission (13.8% vs. 9.8%; $p = 0.4$). However, surgical site infections (22.4% vs. 10.9%; $p = 0.03$), surgical site occurrences requiring procedural intervention (24.1% vs. 13.2%; $p = 0.049$) and reoperation rates (13.8% vs. 4.0%; $p = 0.009$) were significantly higher in the biosynthetic group.

In a retrospective case series by Madani et al. [40], 46 hernias were repaired with biologic mesh in clean-contaminated ($n = 16$; 35%), contaminated ($n = 11$; 24%), and dirty ($n = 19$; 41%) fields. Incidences of surgical site events and surgical site infection were 43% ($n = 20$) for contaminated and 56% ($n = 25$) for dirty fields.

In a study by Sbitany et al. [41], a prospectively maintained database was reviewed for all patients undergoing repair with component separation technique with biologic mesh in potentially contaminated or infected ventral hernias. The overall postoperative wound infection rate was 15%. No mesh was removed due to perioperative infection [41].

A retrospective case series with 140 patients with biologic mesh repair of complex abdominal wall hernias showed a wound complication rate of 30.7% and a mesh removal rate of 10% [42].

In a retrospective study with 80 patients with contaminated field and major complex abdominal wall repair using biological mesh, 36 patients (45%) developed a wound infection [43]. None required mesh removal. The authors concluded that repair of challenging and contaminated abdominal wall defects can be done effectively with biologic mesh and component separation technique without the need for mesh removal despite wound infections [43].

In a retrospective, comparative study of the use of Phasix versus biologic mesh in complex abdominal wall reconstruction, the postoperative infection rates were 31% versus 12.9% ($p = 0.073$) [44].

In a study by Rosen et al. [45] with contaminated ventral hernia repair using Bio-A, the surgical site infection rate was 18.3%. The authors concluded that biosynthetic absorbable meshes offer an alternative to biologic and permanent synthetic meshes in these complex situations.

In an expert consensus guided by systematic review on ventral hernia management, a statement is made that biological meshes have been safely utilized in abdominal wall reconstruction with few mesh explantations [46]. However, their role still needs to be defined. No data exist on the safety, efficacy, or effectiveness of bioabsorbable synthetic meshes [46].

Conclusion

The cumulative data regarding biologic and biosynthetic mesh use in ventral hernia repair under contaminated conditions do not support the claim that it is better than synthetic mesh used under the same conditions [18]. The available evidence is limited in quantity and quality, but it does not support the superiority of biologic over synthetic non-absorbable meshes in contaminated fields [29] (level of evidence according to the GRADE system [LoE GRADE]: moderate).

Can biologic or biosynthetic meshes be used for bridging in ventral hernia repairs?

Mesh implantation during abdominal wall reconstruction decreases ventral hernia recurrence rate substantially and has become the recommended method for repair [47]. The onlay position or bridging the gap is less favorable mesh locations and results in the highest recurrence rates [47]. In a meta-analysis, component separation with primary fascial closure and mesh reinforcement was associated with a lower risk of surgical site occurrence and recurrence compared with bridged repairs [48]. When considering a biologic mesh repair, the position of the mesh has also a major impact on recurrence rate. When biologic

mesh is sewn to the edge of the fascia and used as a bridge, recurrence rates are as high as 80% [1]. When the fascia can be reapproximated and the mesh used to reinforce the repair, the recurrence rate drops to approximately 20% [1].

The systematic review by Albino et al. [47] summarizes the main findings from each of the individual studies including 1181 patients having a ventral hernia repair using biologic mesh. A bridging position of a biologic mesh resulted in the highest rate of hernia recurrences (56%) compared to onlay (20%), underlay (16%), and retrorectus position (8%) ($p = 0.03$) [47].

In another systematic review, component separation followed by primary fascial closure was compared to a bridged repair for ventral hernia [48]. Four studies were identified. The pooled recurrence rate was 49.0% (range 20.5–72.7%; $n = 102$) for bridged repair and 11.1% (range 7.7–18.2%; $n = 341$) for primary fascial closure [48].

In the systematic review by Atema et al. [2] including three studies with bridged repair in 47–100% of cases, a hernia recurrence rate of 24% was found.

The LAPSIS trial was a four-armed randomized-controlled European multicenter study comparing open retromuscular (mesh augmentation technique) versus laparoscopic repair (mesh bridging technique) [49]. A non-cross-linked biologic mesh versus classical synthetic mesh for clean primary ventral and incisional hernia with a diameter of 4–10 cm was used in both groups. Inclusion of patients was prematurely stopped. The Independent Data Monitoring Committee of the trial recommended this action because of a higher recurrence rate in the biological mesh compared with the synthetic mesh group at interim analysis. Based on the "as-treated" population of 257 patients, the exploratory analysis (median follow-up 1 year) showed that implantation of a biologic mesh resulted in a higher rate of early recurrence in each of the study arms: 19% recurrence for biologic mesh versus 5% for synthetic after laparoscopic repair, and 11% versus 3% after open repair. The authors concluded that care should be taken and bridging of hernia defects with biologic mesh should be avoided.

In a retrospective study, Basta et al. [50] reported on 37 patients undergoing complex ventral hernia repair using a biologic mesh for bridging. With an average of 8.2-month follow-up, the recurrence rate was 18.9% [50].

In a retrospective study by Giordano et al. [51], a total of 484 (90%) patients underwent mesh-reinforced abdominal wall reconstruction without bridging and 51 (10%) underwent a bridging repair. A cellular dermal matrix was used in 98% of the bridged repairs and in 96% of the reconstructions without bridging. Bridged repairs had a greater hernia recurrence rate of 33.3% versus 6.2% without bridging ($p < 0.001$) [51].

Conclusion

Biologic mesh use should be avoided when bridging is needed in ventral hernia repairs due to the very high risk of a recurrence (LoE GRADE: moderate).

Biologic and biosynthetic meshes for inguinal hernia repair

In the European Hernia Society guidelines on the treatment of inguinal hernia in adult patients the use of a tension-free, synthetic non-absorbable flat mesh technique is recommended on the evidence-level grade A [52]. "Material reduced" meshes have some advantages with respect to chronic pain and foreign body sensation in the first year(s) after open inguinal hernia repair. There is, however, no difference in the incidence of severe chronic pain [53]. This advantage has not been shown in endoscopic repair [53]. In the guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia of the International Endohernia Society, a statement is given that lighter meshes with larger pores do not lead in the long-term comparison to improvements of the quality of life or a reduction of discomfort of statistical significance [54, 55]. According to the European Association of Endoscopic Surgeons Consensus Development Conference repair of incarcerated, non-reducible groin hernias have to be done urgently and can be performed with an endoscopic technique [56]. Mesh placement during surgery for strangulated groin hernia is possible in clean-contaminated situations (i.e., in case of a bowel resection) [56].

Biologic or biosynthetic meshes are a potential alternative to the synthetic meshes with the aim to avoid complications [57]. In a systematic review and meta-analysis, Nie et al. [58] compared three randomized-controlled trials (RCTs) encompassing 200 patients with porcine small intestinal submucosa (SIS) versus polypropylene in open inguinal hernia repair. There was no significant difference in recurrence (OR 2.03; 95% CI 0.37–11.23; $p = 0.4$), hematomas (OR 3.55; 95% CI 0.95–13.22; $p = 0.06$), postoperative pain within 30 days (OR 0.63; 95% CI 0.19–2.06; $p = 0.45$), or postoperative pain after 1 year (OR 0.32; 95% CI 0.07–1.36; $p = 0.12$) between the two groups. The incidence of discomfort was significantly lower (OR 0.09; 95% CI 0.02–0.36; $p = 0.0006$) in the SIS group. However, the SIS group experienced a significantly higher incidence of seroma (OR 3.96; 95% CI 1.16–13.50; $p = 0.03$) [57].

Fang et al. [59] compared in a meta-analysis with a total of 382 patients in 5 RCTs biologic versus synthetic mesh in open inguinal hernia repair. The two groups did not significantly differ in chronic pain (OR 0.54; 95% CI 0.29–1.02; $p = 0.06$) or recurrence (OR 2.15; 95% CI 3.39–11.74; $p = 0.38$). The incidence of seroma

trended higher in biologic mesh group (OR 2.67; 95% CI 1.12–6.35; $p = 0.03$). Operating time was significantly longer with biologic mesh (Mean difference = 6.27; 95% CI 0.57–11.97; $p = 0.03$). There was no significant difference in hematomas (OR 1.62; 95% CI 0.73–3.62; $p = 0.23$).

In a systematic review of the literature including 7 RCTs no difference in the recurrence rate was found, but differences in the postsurgical pain incidence in favor of the biologic mesh [57]. The biologic mesh was used successfully in a potentially contaminated setting [57].

The systematic review and meta-analysis of RCTs and non-RCTs by Öberg et al. [60] showed no difference in recurrence rate with a median follow-up of 18 months and chronic pain rates (1-year follow-up) between absorbable biologic/synthetic and permanent synthetic meshes.

Conclusion

Biologic and biosynthetic meshes do not have a clear advantage over the synthetic meshes and can, therefore, not be recommended for routine use in elective groin hernia repair. They can be considered in situations with contaminated and dirty surgical fields (LoE GRADE: moderate).

Prevention of incisional hernias with biologic or biosynthetic meshes

The use of primary mesh augmentation for abdominal wall closure is associated with significant lower incidence of incisional hernia compared to primary suture [61]. In a large multicenter RCT, a significant reduction in incidence of incisional hernia was achieved with onlay mesh reinforcement compared with sublay mesh reinforcement and primary suture only without increase of surgical site infection [62, 63]. In the EHS guidelines on the closure of abdominal wall incisions, prophylactic mesh augmentation for an elective midline laparotomy in a high-risk patient to reduce the risk of incisional hernia is suggested [64]. No recommendation on the type of mesh for prophylactic mesh augmentation can be given due to lack of data [64].

In a systematic review on prevention of incisional hernias with biologic mesh, only two RCTs, two case–control studies, and two case series were identified [65]. The studies were very heterogeneous. After qualitative assessment, the conclusion was that the level of evidence on the efficacy and safety of biologic meshes for prevention of incisional hernias is very low. No comparative studies were found comparing biologic mesh with permanent synthetic meshes for the prevention of incisional hernia [65].

Conclusion

There is no evidence supporting the use of biologic or biosynthetic meshes for the prevention of incisional hernia when closing a laparotomy in high-risk patients or in stoma reversal wounds. There is no evidence to support the use of biosynthetic meshes in preference to permanent synthetic meshes in clean or clean-contaminated surgery (LoE GRADE: low).

Prevention of parastomal hernias by biological or biosynthetic mesh reinforcement

On reviewing four meta-analyses, it was found that mesh placed prophylactically at the time of stoma creation reduced the rate of parastomal hernias without an increase in mesh-related complications [66–69]. In the majority of included studies, permanent synthetic meshes have been used for prophylaxis of a parastomal hernia.

In a systematic review on prevention of a parastomal hernia focusing on biological mesh reinforcement, only two randomized-controlled trials (RCT) and two case-controlled studies were found [70]. In one RCT and two case-controlled studies, respectively, there was a significant smaller incidence of parastomal herniation as well as a similar complication rate compared to the control group [70]. Only in one RCT, no significant difference regarding the incidence of parastomal hernia was reported with comparable complication rates [70].

Conclusion

The quality of data does not support a significant risk reduction of parastomal hernia development by biologic mesh reinforcement of a permanent stoma at the primary operation. The use of biologic meshes for prophylaxis of a parastomal hernia should not be performed outside clinical studies (LoE GRADE: low).

Biologic and biosynthetic meshes for complex abdominal wall hernia repair

A clear definition of "complex abdominal wall hernia (CAWH)" is missing, though the term is often used [71]. Three consensus meetings were convened by surgeons with expertise in complex abdominal wall hernias, aimed at laying down criteria that can be used to define "complex hernia" patients, and to divide patients in severity classes [71]. Emergency operations with bowel resection, open abdomen, parastomal hernias, current mesh infections, enterocutaneous fistulas, wound environment with surgical wound class

III (contaminated) or IV (dirty), and large-sized abdominal wall hernias ≥ 10 cm in width beside others fulfil the criteria of a "complex abdominal wall hernia" [71].

The role of biologic and biosynthetic meshes for these indications will now be explored in greater depth below. The basic problems encountered when using biologic or biosynthetic meshes in the setting of an infected abdominal wall and for bridging have already been discussed above. The various clinical situations will now be addressed in detail below.

Open and laparo-endoscopic repair of incarcerated abdominal wall hernias by the use of biologic and biosynthetic meshes

In the new international guidelines of the HerniaSurge group, it is recommended not to use mesh during emergent groin hernia repair in a contaminated or dirty surgical field [72]. Little evidence exists comparing the implantation of mesh of various types in non-clean surgical fields. Large-pore monofilament polypropylene, and biologic and biodegradable meshes have unknown effects on mesh infection risks [72]. As surgical field contamination status worsens, it is recommended that mesh use be ever more conscientiously considered. If mesh is used, the risk/benefit ratio must be carefully contemplated [72].

There are limited data on emergency ventral hernia repair [46]. Short-term and long-term outcomes are worse compared with elective repair [46]. Factors that are important in deciding which type of repair to perform include patient stability, patient comorbidities, the degree of contamination, and the presence of bowel obstruction or edema [46]. Surgeons should be cautious and use discretion in creating flaps or performing other complex procedures such as component separation in this setting [46].

In a systematic review of the use of biologic and biosynthetic meshes in incarcerated abdominal wall hernia repair, only five retrospective cohort studies, two case-controlled studies, and six case series could be found [73]. The limited evidence demonstrated a very low incidence of infection and recurrence of porcine intestine submucosa in laparoscopic IPOM with defect closure in infected fields [73] and acellular dermal matrix by open approach [73]. Both studies achieved acceptable outcome in a follow-up of at least 3.5 years compared to the use of synthetic mesh in this high-risk population [73].

In the guidelines of the World Society of Emergency Surgery concerning emergency surgery of complicated abdominal wall hernias with potentially contaminated surgical field caused by intestinal strangulation and/or concurrent bowel resection, direct suture is recommended when the hernia defect is small [74]. Synthetic mesh repair may be performed, but with caution. Biologic meshes may be a valid option but merit detailed cost–benefit analysis [74].

According to the guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias of the International Endohernia Society [75–77], laparoscopic repair of incisional and ventral hernias with non-cross-linked biologic meshes in an infected or potentially contaminated surgical field may be a viable option if the hernia defect is closed primarily.

Conclusion Up to now, there is lack of studies comparing the use of biologic or biosynthetic versus synthetic meshes in contaminated or dirty surgical fields of incarcerated and/or strangulated abdominal wall hernia repair. The use of biologic and biosynthetic meshes is an option in contaminated or dirty fields of incarcerated and/or strangulated abdominal wall hernia repair when defect closure is possible (LoE GRADE: very low).

Repair of parastomal hernias with biologic or biosynthetic meshes

Suture repair of parastomal hernias should be abandoned because of increased recurrence rates [78]. The use of mesh in parastomal hernia repair significantly reduces recurrence rates and is safe with a low overall rate of mesh infection [78]. In laparoscopic repair, the Sugarbaker technique is superior over the key-hole technique showing fewer recurrences [78, 79]. In open techniques for parastomal hernia repair, there is insufficient evidence to determine which mesh technique (onlay, sublay, and underlay) is most successful in terms of recurrence rates and morbidity [80]. Four retrospective studies with a combined enrolment of 57 patients were included in a systematic review of biologic mesh use in parastomal hernia repair. Recurrence occurred in 15.7% of patients and wound-related complications in 26.2% [81]. No mortality or mesh infection was reported [81]. The authors concluded that the use of reinforcing or bridging biologic meshes during parastomal hernia repair results in acceptable rates of recurrence and complications. However, given the similar rates of recurrence and complications achieved using synthetic meshes in this scenario, the evidence does not support use of biologic meshes.

Conclusion Biologic meshes do not provide a superior alternative to synthetic meshes for parastomal hernia repair, while at the same time being less cost-effective for this indication. Biologic meshes cannot be considered an alternative to synthetic meshes for elective parastomal hernia repair (LoE GRADE: very low).

Replacement of an infected synthetic by a biologic or biosynthetic mesh

A systematic review identified three different options to treat an infected synthetic mesh: removal of the synthetic mesh alone, replacement with either a new synthetic, or a new biologic mesh [82]. Removal of the mesh alone is an option limited to inguinal hernias [82]. In ventral/incisional hernias, the use of a biological mesh for replacement resulted in a very high recurrence rate if bridging was required [82]. Either a synthetic (onlay) or a biologic mesh seems to work as a replacement when fascial closure can be achieved [82]. Reports on replacement with a biologic mesh are few and of low quality. Only 90 patients were identified. The overall wound infection rate was 39% and the recurrence rate 27% with a median follow-up of 2 years. The wound complications will resolve on local treatment with no report on mesh removal of median 2-year follow-up. Either an onlay or retromuscular position seems to work [82].

In another systematic review, a hernia recurrence rate of 21.4% was achieved when the mesh was placed in a retrorectus or underlay position [83]. Bridged repairs were highly prone to recurrence (88.9%; $p = 0.001$) [83].

Conclusion It is recommended not to use a biologic mesh for bridging in replacement of an infected synthetic mesh due to the high risk of recurrence. Either a synthetic (onlay) or biologic mesh seems to work as a replacement of an infected synthetic mesh if the fascia defect can be closed in ventral and incisional hernia (LoE GRADE: very low).

Management of the open abdomen for definitive closure using a biologic or biosynthetic mesh

An open abdomen is a widely performed practice in patients with severe sepsis or trauma [84]. A temporary abdominal closure is indispensable to reduce the incidence of complications [84]. The ultimate goal of temporary abdominal closure is to achieve definitive fascial closure [84]. To improve survival rates, the early fascial closure is routinely preferred to achieve a permanent abdominal closure [84]. Early fascial closure is defined as a reapproximated closure of abdominal fascia within the window of 2–3 weeks after an open abdomen [84]. The early fascial closure rate ranged from 29 to 85% [84]. Vacuum-assisted fascial closure was described in 85% [84]. The mean duration to a definitive abdominal closure ranged from 2.2 to 14.6 days in early fascial closure rate [84].

Fascial traction reduces the need of a mesh for definitive closure. Cocollini et al. also reported on definitive fascial closure to be achievable in up to 90% [85]. Early closure seems to be a key point for success. Closure exceeding 8 days seems to result in a progressively increasing complication rate. When definitive closure cannot be achieved by suturing, a mesh to bridge the gap is needed. Either a synthetic or a biologic mesh has been used and reported on.

An updated version of the World Society of Abdominal Compartment Syndrome (WSACS) guidelines was published in 2015, including consensus definitions and recommendations for clinical practice using the GRADE methodology [86]. Twelve clinical relevant questions were raised out of which one (with subquestions) was on the use of biologic meshes for definitive closure. The question was: "How should we avoid abdominal compartment syndrome or how should we deal with the open abdomen? Does early closure with biologic meshes improve patient outcomes compared to strategies that do not use biologic meshes which thus accept skin graft closures and delayed reconstruction in critically ill adults with open abdomen in critical care units?"

Recommendations/suggestions made by the World Society of Abdominal Compartment Syndrome were as follows [85]:

- "We recommend that among ICU patients with open abdominal wounds, conscious and/or protocolized efforts be made to obtain an early or at least the same hospital stay abdominal fascial closure [GRADE 1D]."
- "We suggest that biologic meshes should not be routinely used in the early closure of the open abdomen compared to alternative strategies [GRADE 2D]."

Montori et al. reported on a prospective case series of patients who had abdominal wall reconstruction using a dermal non-cross-linked swine collagen prostheses [87]. A total of 17 out of 30 were treated with open abdomen for various reasons. One mesh out of 17 was removed. Fascial closure was achieved in nine patients. The mesh was put in a sublay position in nine, intraperitoneally in five, in an onlay position in two and in an inlay position in one patient. Time to definitive closure was median 6 days. Four patients had a stoma. ICU stay was median 24 days, and the following ward stay was 28 days. A total of 10 of 17 patients (59%) had some sort of complication; five patients died (two for aortic rupture, two for septic shock, one for respiratory insufficiency and septic shock), one mesh was removed due to a duodenal fistula with wound infection. Follow-up was completed at 3 (nine patients) and 6 (six patients) months; two recurrences were reported.

Burlew et al. reported on 100 consecutive patients that underwent damage control where 49 attained fascial closure at second laparotomy [88]. The remaining 51 required open abdomen and fascial closure could not be attained in 10 (20%). Two patients had skin closure only. The remaining eight patients had an acellular human skin graft. Two patients had their mesh removed due to infection and a

split-thickness skin graft was applied. No long-term results were reported.

Taixiera et al. reported on open abdomen in trauma patients [89]. A total of 93/900 (10%) laparotomies were left open and 85 of these 93 (91%) survived and fascial closure was achieved in 72 (85%) between 1 and 21 days. Out of the remaining 13, seven were successfully closed using a biologic mesh, five by skin graft, and one by skin closure. No long-term data were available.

Sutton et al. reported on using a biosynthetic mesh (Gore Bio-A®) in management of the open abdomen after operation for a strangulated perforated intrathoracic hiatal hernia [90]. Early closure was achieved using an onlay mesh after managing the septic situation. Defect size was not defined by the authors. The skin could be closed in all cases. A good cosmetic result and no hernia after 4 months were observed.

Caviggioli et al. reported on a patient with a complicated history of peritonitis. An enterocutaneous fistula was created due to enteric leakage [91]. A large defect of the abdominal wall was reconstructed using a porcine cross-linked mesh. Negative pressure wound therapy was applied on top of the mesh to promote formation of granulation tissue on top of the mesh. The mesh was used as a scaffold before a split-thickness skin graft was applied successfully on a small remaining central part. Wound healing was achieved after 55 days. No hernia was reported until 6 months.

Primary closure does not seem to be possible in around 10% of patients after open abdomen treatment. All together, 34 patients have been reported on having a definitive closure using a biologic or biosynthetic mesh. Wound infection rate was 24 and 11% of meshes were removed. Two (7.4%) recurrences were reported at short time follow-up. Bridging was not reported on separately. The overall mortality in patients closed with a biologic mesh was 20%, but probably not related to the mesh per se.

The literature does not give any evidence for or against the use of biologic or biosynthetic meshes for definitive closure of the open abdomen if bridging is avoided. A note of caution is that biologic meshes degrade over time and their use is not recommended when bridging is required or when an upper GI leakage is present.

Conclusion International guidelines do not recommend routine use of biologic or biosynthetic meshes in early closure of the open abdomen. Alternative strategies are recommended. Concerning short-term outcome, it seems safe to use either a biologic or biosynthetic or synthetic mesh, if fascial closure can be achieved. Negative wound pressure treatment can be recommended to reduce wound morbidity and shorten wound healing (LoE GRADE: very low).

Treatment of abdominal wall defects with enteric fistulas by the use of biologic or biosynthetic meshes

Patients with enteric fistulas and an abdominal wall defect present an extreme challenge to surgeons and have been associated with significant morbidity and mortality [92]. Key steps in managing patients with enterocutaneous fistulation and an abdominal wall defect include dealing effectively with abdominal sepsis and providing safe and effective nutritional support and skin care, then assessing intestinal and abdominal anatomy, before undertaking reconstructive surgery [93]. Incomplete sterility with contamination from enteric organisms implicates the more prominent role of biologic hernia implants and autologous reconstructive methods, such as component separation [94].

Connolly et al. [95] used inlay mesh (Permacol $n = 12$, Vicryl $n = 12$, Vypro $n = 3$) when suture repair was not possible. Incisional hernia rates were expectedly high at 29 months of follow-up (42% for Permacol, 92% for Vicryl and 0% for Vypro), but also the refistulisation rate was extremely high (42% vs. 12% for Vicryl/Vypro; $p = ns$). All Permacol patients who developed a refistulisation had a recurrence later on.

Krpata et al. [96] described a group of 37 patients with fistula closure and abdominal wall reconstruction (mean defect area 426 cm^2), using retrorectus or IPOM biologic non-cross-linked mesh. Mesh bridging was required in 11% of patients. Overall postoperative wound morbidity was 65%. About one-third of these patients needed surgical debridement, without mesh explantation. Five patients developed an anastomotic leak/recurrent fistula; four of them had their mesh placed intraabdominally. With a mean follow-up of 20 months, 1/3 of the patients developed a recurrence.

Conclusion In case of enterocutaneous fistula, the use of biologic mesh allows a one-stage repair, if possible without bridging, with acceptable outcomes. A high wound morbidity, risk for refistulisation, and recurrence rate have to be expected (LoE grade: very low).

Component separation technique with biologic or biosynthetic mesh

Abdominal wall reconstruction remains a challenging surgery. Difficulty obtaining primary fascial closure can compromise the success of the operation [97]. Techniques such as component separation have facilitated our ability to achieve primary fascial closure [97]. In patients with a moderate loss of abdominal domain, component separation may allow for primary midline fascial closure without the use of a mesh [97]. However, despite abdominal wall continuity, recurrence and bulging can remain an issue [97]. In an effort to minimize the risk of recurrence, the use

Table 2 CST and biologic mesh

References	Year	Journal	*n*	Follow-up	Complications	Recurrence Rate	Type of mesh	specifics	Conclusions
Diaz [98]	2006	Am Surg	10 CST/75	275 ± 209 days	Overall wound infection rate 33.3% (25/75), (14/75) with surgical reintervention	Overall 16% CST/HADM 10%	HADM	Wound infection rate CST 50%	Analysis demonstrates the value of HADM in the repair of ventral hernia in a compromised surgical field. The relatively low rate of surgical wound infection and recurrence coupled with infrequent necessitiy for mesh removal favors its use over synthetic mesh for contaminated ventral hernia closure
Kim [99]	2006	Am J Surg	29	182 days	Wound compl. 45%	10%	ADM		The use of ADM allowed for successful primary closure in 90% of patients. A postoperative wound occurrence rate of 45% shows the use of this material in resisting infection. ADM can be used in VHR in high-risk wounds with a high degree of success
Espinosa-de-los-Monteros [100]	2007	Ann Plast Surg	37 82% with CST	15	Local complications 26%	5%	HADM (overlay)		Improved results with HADM are obtained by achieving tension-free repairs
Diaz [101]	2009	Arch Surg	31 CST	317 days	Wound dehiscence 8.8% (21/240)	6.5% in CST patients	ADM	240 patients with compromised surgical field	ADM is a suitable alternative for complex VHR in a compromised surgical field

Table 2 (continued)

References	Year	Journal	*n*	Follow-up	Complications	Recurrence Rate	Type of mesh	specifics	Conclusions
Nasajpour [102]	2011	Ann Plast Surg	18	14 (4–24) months	Infection 33% Seroma 33% Infection requiring surgical intervention 39%	0%	PADM		New synth. and biol. meshes revolutionized the management of complicated hernias. However, these products carry a higher RR. We have found that these meshes, used in conjunction with CST, have had no recurrence to date, but are prone to complications
Patel [97]	2012	Ann Plast Surg	41 CST and PADM	474 (194–1017) days	24.4%	0%	PADM/Strattice	80% Grade II 10% Grade III 10% Grade IV BMI 35.8 kg/m2 Hernia defect 14.3 cm Perforator preservation 83%	Strattice is an effective adjunct and appears to add durability to midline reconstructions with no recurrences during the follow-up period
Clemens [103]	2013	Plast Reconstr Surg	106/120 CST	21 ± 9.9 months	36.6% overall (44.9% PADM vs. 25.5% BADM), surgical complications 29.2%/21.6%	2.9%/3.9%	69/120 PADM (98.6% CST) 51/120 BADM (74.5% CST)		Both BADM and PADM are associated with similar rates of postoperative surgical complications and appear to result in similar outcomes. PADM may be prone to intraoperative device failure

Table 2 (continued)

References	Year	Journal	*n*	Follow-up	Complications	Recurrence Rate	Type of mesh	specifics	Conclusions
Henry [104]	2013	Ann Plast Surg	66 (62% CST)	24 months	nr	Overall 16% Inlay mesh 9% Underlay/onlay 12% Without mesh 22% Biologic mesh interposition 40%	16% no mesh 11% HADM 81% PADM		RR are decreased with primary fascial repair; further reduction occurs when biologic mesh reinforcement is used. The lowest RR were seen in the group with CST and PADM
Hood [105]	2013	Am J Surg	68	20 months	Wound infection and/or breakdown 32% Seroma 9%	1.5%	AlloMax	BMI 36 kg/m^2 Hernia defect 20 cm	Large complex VH can be reliably repaired using the CST. The short-term RR is significantly reduced in this case series using a biologic mesh onlay
Patel [106]	2013	Int Surg	29 CST/41	445 (176–648) days	Wound compl. 4.9% Seroma 7.3% Reoperation rate 7.3%	0%	Strattice	BMI 35.5 kg/m2	Patients with multiple comorbidities at intermediate risk of postoperative complications can achieve successful, safe abdominal wall reconstruction with Strattice
Alicuben [107]	2014	Hernia	16/22	7 (2–14) months	Seroma 28.6% 18.2% wound infection	4.8%	PADM (XenMatrix)	BMI 26 (24–35) 16/22 Grade III	XenMatrix overlay has excellent short-term results in patients at risk for mesh infection. No patient required mesh removal
Chand [108]	2014	Int J Surg	89/343 CST 197/343 mod. Stoppa 17/343 Rives-Stoppa	36 months	Overall: Seroma 19% Wound infection 15%	5.8% (1 year) 16.6% (2 year) 31% (3 year) Kaplan–Meier analysis	Permacol		Permacol surgical implant was shown to be safe with relatively low rates of hernia recurrence

Table 2 (continued)

References	Year	Journal	*n*	Follow-up	Complications	Recurrence Rate	Type of mesh	specifics	Conclusions
Golla [109]	2014	Int Surg	47	31 months	Wound infection 4% Seroma 6%	6.4%	PADM	Single surgeon study; 25% Grade I 62% Grade II 2% Grade III 11% Grade IV	PADM reinforcement following CST resulted in low rates of postoperative complications and hernia recurrence
Nockolds [37]	2014	BMC Surgery	23	17 (2–48) months	Wound dehiscence 22% (5/23)	13% (3/23)	6 synthetic, 3 porcine dermis, 14 Biodesign Hernia Graft	Classified by the VHWG grading system 13 Grade III 10 Grade IV	CST and reinforcement with biological mesh is a successful technique in the grade III and IV abdomen with acceptable rate of recurrence and complications
Richmond [110]	2014	Am Surg	40 CST/PADM 40 conventional open VHR	33.1 months	Mesh infection 0% vs. 23% Reoperation 17.5% vs. 52.5%	13.2% vs. 37.5%	CST: PADM Conventional: different meshes (26 synth., 14 biologic)		Superior results with CST/PADM (lower RR, overall complication rate and mesh infection)
Skipworth [111]	2014	W J Surg	58	nr	26% SSI	5%	PADM	48% Grade II 33% Grade III 19% Grade IV	Low risk of SSI and RR, no requirements for mesh explantation
Yang [112]	2015	Am Surg	35	36.5 months	Wound dehiscence 4/35 Seroma 5/35 Infection 5/35	0	ACM	Contaminated large hernias, 9/35 fistula resection, 13/35 ostomy takedown	Use of ACM combined with CST is safe and efficient management for repair of contaminated large ventral hernia, in which permanent prosthesis placement is contraindicated

Table 2 (continued)

References	Year	Journal	*n*	Follow-up	Complications	Recurrence Rate	Type of mesh	specifics	Conclusions
Sandvall [113]	2016	Ann Plast Surg	45	13.9 months	Minor complications 17%, Major complications 22%	11%	Human and porcine dermis	VHWG Grade 1 9% Grade 2 29% Grade 3 29% Grade 4 33%	Comparison with synthetics mesh group: Minor complication rates were 26% in synthetic group and 37% in the biologic group and major complications rates 15% in the synthetic group and 22% in the biologic group. There was 1 recurrence (4%) in the synthetic group vs. (11%) in the biologic mesh group. All results were not significant different

Table 2 (continued)

References	Year	Journal	*n*	Follow-up	Complications	Recurrence Rate	Type of mesh	specifics	Conclusions
Ghazi [114]	2011	Ann Plast Surg	165	34 (0.5–90) months	Overall complication rate 23.6%	Overall hernia recurrence rate 20.6%	Mesh repair $n = 133/165$ 81% ADM $n = 103/133$ 77%		Component separation technique in 77 patients (47%). Primary fascial closure was performed in 64% of the cases ($n = 106/165$). Bridging 36% ($n = 59/195$). Average BMI 38 kg/m^2. 44.8% categorized as high risk. The recurrence rate was lower in the synthetic mesh group (17%) compared with the ADM group (22%), but the difference was not statistically different.

ACM acellular dermal matrix, *PADM* porcine acellular dermal matrix

of synthetic mesh to reinforce the component separation has been advocated [97]. Despite the benefits of synthetic mesh, potential drawbacks remain [97]. In patients of high risk for complications, wound dehiscence and/or infection can lead to mesh infections and multiple secondary procedures, oftentimes leading to mesh removal [97]. Biologic meshes are associated with a high salvage rate when faced with infection [13].

To assess the role of biologic meshes for complex abdominal wall reconstructions with component separation, there are several studies, with studies with more or fewer than 40 patients being somewhat evenly balanced (Table 2) [37, 97–112]. Here, too, there is widespread variability in the follow-up times. Often, complication rates of up to 30% and more have been reported. The reported recurrence rates vary between 0 and 40%, but most reports do not exceed 10–15%. A common feature of the majority of studies is that they involve complex or very complex patient collectives with concomitant wound infection or wound contamination and/or patients with high BMI. All studies except two [113, 114] come without the comparison with synthetic meshes to the questionable conclusion that biologic meshes confer "advantages" for these patients undergoing complex abdominal wall reconstruction in combination with a component separation technique. However, certain studies have reported complications in relation to the meshes used [102, 103]. The recurrence rate reported by the majority of studies—while taking account of the difficult baseline conditions—was "relatively low", the proportion of mesh explantations reported was low and in almost all studies was 0%. These studies are all clinical observational studies with poorly controlled baseline and target conditions, although many studies endeavored to implement stratification with regard to wound contamination/infection. Overall, the study conditions were very heterogeneous, in particular in terms of the wound contamination grade, implantation techniques employed and, above all, the differences in the materials used. As such, any form of comparison of these studies is not meaningful.

Conclusion Component separation technique reinforced with biologic meshes has no significantly higher recurrence rate compared with synthetic meshes in clean field operations and patients with higher infection risks. However, the number of major SSO/SSI including need for reoperation does not seem to be decreased substantially by the use of biologic versus synthetic meshes. In the subgroup of patients with contaminated surgical field, there might be a place for the use of biologic mesh due to potentional higher salvage rate in case of mesh infection. Further high-quality comparative studies are needed (LoE GRADE: low).

Summary

Criticism is addressed in several review articles on the poor standard of studies concerning the use of biologic and biosynthetic meshes mainly consisting of retrospective case series without comparison with synthetic meshes. The critical review of the cumulative data regarding biologic and biosynthetic mesh use under contaminated conditions does not support the claim of better results than synthetic meshes. Biologic and biosynthetic mesh should not be used in a bridging situation. There seems to be no clear advantages of biologic and biosynthetic meshes in inguinal hernia repair. There is no evidence for the use of biologic or biosynthetic meshes in the prevention of incisional and parastomal hernias. In complex abdominal wall hernia repairs (incarcerated hernia, parastomal hernia, infected mesh, open abdomen, entero-cutaneous fistula, and component separation technique), biologic and biosynthetic meshes do not provide a superior alternative to synthetic meshes. Concluding these results of the literature review and consensus meeting biologic and biosynthetic meshes cannot be recommended for routine use. There is an urgent need for high standard comparative studies in well-defined patient populations.

Compliance with ethical standards

Conflict of interest NNA, SAA, FF, MMH, FKA, IK, FM, SKN, AP, WR, HS, and BS declare no conflict of interest. NS declares conflict of interest directly related to the submitted work. IRD, RHF, MM, AM, SM, FM, MS, CS, and GW declare conflict of interest not directly related to the submitted work. FK declares conflict of interest directly and not directly related to the submitted work.

Ethical approval This article does not contain any studies with human participants or animals performed by the authors.

Human and animal rights This article does not contain any study with animals performed by any of the authors.

Informed consent For this type of article informed consent is not required.

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