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REVIEW

Outcomes after abdominal wall reconstruction using acellular dermal matrix: A systematic review

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Abdominal wall reconstruction;
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Summary *Background:* Complex abdominal wall defects can present a significant challenge to the reconstructive surgeon. In 2003, acellular dermal matrix (ADM) was introduced as an alternative to synthetic materials with suggestions that it has improved capacity to integrate with surrounding tissues with less inclination towards infection, erosion, extrusion, adhesion formation and rejection compared with synthetic materials. This systematic review was conducted to evaluate the existing literature describing the use of ADM for abdominal wall reconstruction in an attempt to identify factors that may affect outcomes.
Methods: A review of the MEDLINE database using the search terms 'dermal matrix' and 'abdomen' or 'hernia' for prospective and retrospective human studies in English was performed. Exclusion criteria were animal studies, case reports, reviews and articles that dealt only with ADM for repair of congenital abdominal wall defects, hiatal, parastomal or inguinal hernias and enterocutaneous fistulae. Two independent reviewers performed the systematic review with the same *a priori* criteria, with discrepancies reconciled by the senior author.
Results: In October 2010, 3394 articles were identified as potentially inclusive based on the search term 'dermal matrix'. When filtered for 'abdomen' or 'hernia', 83 articles were found. Ultimately, 30 articles met criteria. No other systematic reviews, meta-analyses or randomised controlled trials were identified in the existing literature.
Conclusions: At this current time, there is a paucity of high-level evidence comparing ADM with other methods interfering with the ability of physicians to make data-driven

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recommendations on clinical indications, surgical techniques and outcomes following ADM-assisted abdominal wall reconstruction.

Background

Acquired abdominal wall defects result from trauma, previous surgery, infection and tumour resection.[1] The goals of abdominal wall reconstruction are to protect the abdominal contents and restore functional support.[1] Abdominal wall defects can be challenging due to the loss of abdominal wall structures, loss of domain, possible gastrointestinal tract violations and resultant contamination, and the lack of techniques to both restore structural integrity and withstand long-term stresses to the dynamic myofascial abdominal wall. Multiple strategies have been described to address this challenging reconstructive problem, including the use of synthetic and biologic materials, components' separation using autologous tissue, and pedicled and free flap reconstructions.[1] Synthetic materials have been commonly used in abdominal wall reconstruction and can allow for hernia reduction and abdominal wall repair. However, these materials are associated with significant complications, including surgical site infections, delayed wound healing, skin breakdown, seroma collections and fistula formation.[1,2,3,4,5,6,7] In 2003, acellular dermal matrix (ADM) was introduced as an alternative to synthetic materials for abdominal wall reconstruction,[7] with suggestions that it has improved capacity to integrate with surrounding tissues with less inclination towards infection, erosion, extrusion, adhesion formation and rejection compared with synthetic materials.[8] In addition, there are reports of successful reconstructions of large, complex abdominal wall defects even when placed directly over viscera and when the operative field is irradiated and/or contaminated with bacteria.[9,10]

This systematic review was conducted to evaluate the existing literature describing the use of ADM for abdominal wall reconstruction, to categorise the levels of evidence[11] for its use (Table 1) and identify factors that may affect outcomes, including hernia recurrence, abdominal wall laxity and other complications.

Patients and methods

This systematic review examined patients undergoing abdominal wall reconstruction specifically with ADMs. Outcomes including hernia recurrence, abdominal wall laxity and other complications such as delayed wound healing, infection and seroma were studied in an attempt to identify factors. These factors may affect the outcomes.

Search strategy

The study design included a review of the MEDLINE database as of 31 October 2010 using the search terms 'dermal matrix' and 'abdomen' or 'hernia' for prospective and retrospective human studies in the English language. Exclusion criteria were animal studies, case reports, reviews and articles that dealt only with ADM for repair of congenital abdominal wall defects, hiatal, parastomal or inguinal hernias and enterocutaneous fistulae. The references of the included studies were screened to identify potential citations not captured by the MEDLINE search.

Validation of the search results was conducted by two separate reviewers (T.Z. and J.A.) (Figure 1). Any discrepancy was reconciled by a third reviewer (S.O.P.H.). After the group of abstracts was agreed upon, these articles were reviewed in their entirety and selection of articles to include in this systematic review was made based on each article meeting the *a priori* criteria previously listed.

Results

As of 31 October 2010, 3394 articles were identified as potentially inclusive based on the search term 'dermal matrix'. When this group of articles was filtered using the search terms 'abdomen' or 'hernia', a total of 83 articles was found. A search of the titles of this subset to further eliminate

Table 1 Levels of Evidence Rating Scale for Therapeutic Studies.[a]

Level of Evidence	Qualifying Studies
I	High-quality, multicentered or single-center, randomized controlled trial with adequate power; or systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies
III	Retrospective comparative study; case-control study; or systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

[a] From the American Society of Plastic Surgeons. Evidence-based clinical practice guidelines. Available at: http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Evidence-based_GuidelinesPractice_Parameters/Description_and_Development_of_Evidence-based_Practice_Guidelines/ASPS_Evidence_Rating_Scales.html. Accessed December 19, 2010.

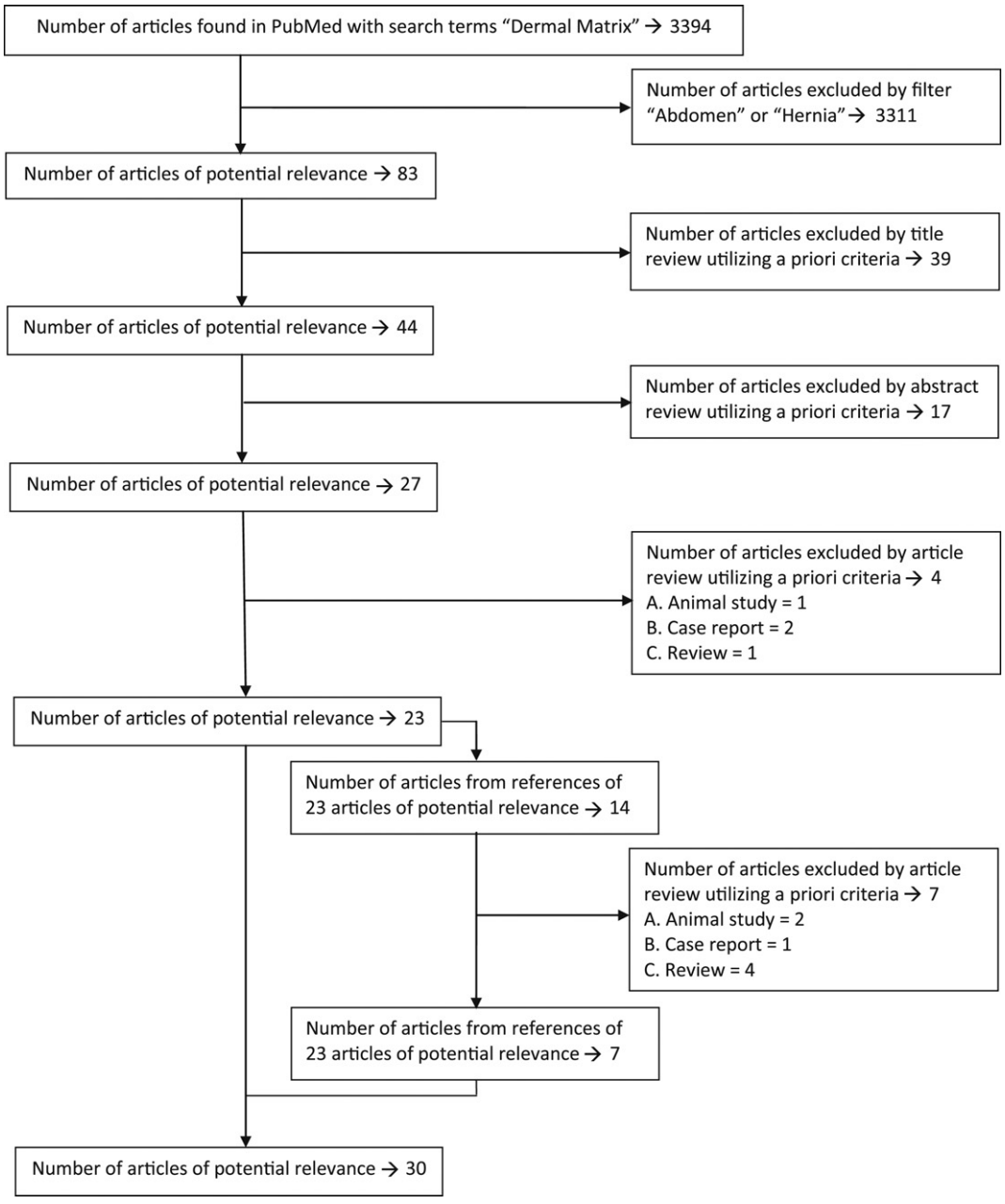

Figure 1 Article selection process.

articles that did not meet the *a priori* criteria resulted in 44 remaining articles. A review of these 44 abstracts resulted in 27 articles that were examined in detail to yield a final total of 23 articles that met the *a priori* criteria. A review of these 23 articles and their references generated an additional 14 articles, of which seven articles met the *a priori* criteria. This brought the total number of articles to include in this systematic review to 30. Cohen's kappa for level of agreement between the two reviewers was 1.0.

Studies that met the *a priori* criteria

A total of 30 articles was identified that met *a priori* criteria (Table 2). No level I or II studies were identified. There were four level III[12–17] and 26 level IV[7–10,16–37] studies. Data were collected prospectively in three articles[20,27,35] and retrospectively in 27 articles.[7–10,12–19,21–26,28–34,36,37] Human (H) ADM was studied in 26 articles,[7–10,13–18,20–30,32–35,37] whereas porcine (P)[12,19,31] and bovine (B)[36] ADMs were studied in three articles and one article, respectively.

Indications for use of ADM

The indications for use of ADM varied greatly amongst the articles. Generalised, ill-defined terms (e.g., abdominal wall reconstruction, high-risk/recurrent/complex/large ventral hernia and high-risk/contaminated wound) were used to broadly describe the patient populations in the reviewed studies. Specific indications found in the article set are listed in Table 3.

Table 2 Summary of Studies Included in Systematic Review.

Reference	Level of Evidence	Type of ADM	Number of Patients	Etiology	Types of Repair	Follow-up	Primary/ Recurrent hernia
Cobb and Shaffer 2005[12]	III	Porcine	ADM 55 Composite mesh 84	Ventral/incisional and recurrent hernia	Laparoscopic ventral hernia repair	14 m 31 m	6% 1%
Gupta et al. 2006[13]	III	Human	ADM 33 Porcine small intestinal submucosal mesh 11	Ventral hernia repair	Interposition Overlay Underlay	18 m 29 m	24% 0%
Espinosa-de-los- Monteros et al. 2007[14]	III	Human	ADM 37 Polypropylene mesh 39	Abdominal wall reconstruction	CS + overlay Overlay + Polypropylene mesh	15 m 13 m	5% 20%
Jin et al. 2007[15]	III	Human	ADM bridged 11 ADM reinforced CS 26	Abdominal wall reconstruction	Bridged (interposition/ underlay) Reinforced CS (onlay/ underlay/sandwich)	24m(18m-37 m) 13m(6-31 m)	80% 20%
Guy et al. 2003[8]	IV	Human	9	Abdominal compartment syndrome	Interposition	20m(11m-30 m)	11%
Buinewicz and Rosen 2004[7]	IV	Human	44	Incisional hernia/TRAM flap donor site repair	Overlay Multilayer interposition	20m(8m-32 m)	5%
Butler et al. 2005[9]	IV	Human	12	Tumor resection, high risk wound	Inlay	6m(2m-13 m)	0%
Nemeth and Butler 2009[10]	IV	Human	12	Tumor resection, high risk wound	Inlay	43m(41m-53 m)	8%
Kolker et al. 2005[16]	IV	Human	16	Incisional and recurrent hernia	Multilayer with underlay, overlay, CS	16m(9m-23 m)	0%
Diaz et al. 2006[17]	IV	Human	75	Ventral hernia repair	Inlay Interposition Onlay CS	9m(no range)	16%
Kim et al. 2006[18]	IV	Human	29	High risk/recurrent hernia repair	Underlay + CS	6m(0m-16 m)	10%
Parker et al. 2006[19]	IV	Porcine	9	Complicated fascial defects	Underlay	18m(no range)	11%
Schuster et al. 2006[20]	IV	Human	18	Contaminated abdominal wall fascial defects	Interposition	9m(5m-27 m)	50%
Scott et al. 2006[21]	IV	Human	27	Open abdomen	Underlay	Unreported	0%
Bellows et al. 2007[22]	IV	Human	20	Abdominal wall reconstruction	Underlay	9m(2m-16 m)	30%
Patton et al. 2007[23]	IV	Human	67	Contaminated abdominal wall reconstruction	Inlay Interposition Onlay	10m(0m-38 m)	17%

Blatnik et al. 2008[24]	IV	Human	11	Abdominal wall reconstruction	Interposition	24m(18m-37 m)	80%
Bluebond-Langer et al. 2008[25]	IV	Human	27	Large ventral hernia with loss of domain	Interposition Onlay Interposition + polypropylene mesh	Unreported	Unreported
Candage et al. 2008[26]	IV	Human	46	Abdominal wall hernia	Bridged (underlay) Reinforced (onlay/ Underlay/sandwich)	12m(1m-39 m)	13%
de Moya et al. 2008[27]	IV	Human	10	Open abdomen	Underlay	12m(1m-12 m)	17%
Gu et al. 2008[28]	IV	Human	3	Abdominal wall reconstruction	Underlay + omental flap	3m(1m-11 m)	0%
Singh et al. 2008[29]	IV	Human	10	Abdominal wall reconstruction after liver transplantation	Interposition	10m(0m-24 m)	0%
Diaz et al. 2009[30]	IV	Human	240	Complex ventral hernia repair	Inlay Onlay CS Interposition	9m(0m-38 m)	17%
Hsu et al. 2009[31]	IV	Porcine	28	Abdominal wall reconstruction	Underlay	16m(10m-23 m)	10%
Lee et al. 2009[32]	IV	Human	68	Abdominal wall reconstruction	Underlay	15m(no range)	27%
Lin et al. 2009[33]	IV	Human	144	Abdominal wall reconstruction	Underlay Interposition Overlay	5m(0m-23 m)	27%
Maurice and Skeete 2009[34]	IV	Human	63	Abdominal wall reconstruction	Underlay Interposition Overlay	7m(0m-24 m)	41%
Tang et al. 2009[35]	IV	Human	ADM 6 Other techniques 21	Abdominal wall reconstruction after tumor resection	Interposition Interposition + TFL Interposition + omental flap	4m(3m-21 m)	0%
Weitfeldt et al. 2009[36]	IV	Bovine	5	Abdominal wall reconstruction	Interposition	10m(9m-17 m)	20%
Shinall et al. 2010[37]	IV	Human	5	Open abdomen pediatric patients	Interposition	13m(3m-21 m)	0%

ADM, acellular dermal matrix; CS, component separation; TFL, tensor fascia lata flap; m, months.

Table 3 Indications for Use of Acellular Dermal Matrix for Abdominal Wall Reconstruction.

Abdominal hernia[7]
Strangulated/incarcerated hernia[19,22,23,26]
Ventral hernia[7,12,13,24–26,30]
Incisional hernia[12,16,19,22,26,30]
Recurrent hernia[12,14,26,33]
Umbilical hernia[7]
Parastomal hernia[26,34,36]
Parasternal hernia[7]
Loss of abdominal domain[25]
Intraabdominal catastrophe/trauma[23]
Open abdomen[8,21,27,31,37]
Evisceration[20,34]
Wound/fascial dehiscence[20,22,23]
Nonhealing wound[15,24]
Tenuous skin coverage[18]
Bowel resection[15,20,24,26]
Anastomotic leak[20]
Ostomy takedown[15,19,22,30]
Fistula takedown[15,16,18,22–24,26,30,34]
Enterotomy[26]
Prosthetic mesh exposure/infection/ removal[15,16,18–20,22–24,26,30,34]
Bacterial contamination[9,10]
Necrotizing infection[22,26,34]
Feculent peritonitis[26]
Intraabdominal abscess[26]
High risk for postoperative infection[18,24]
Preoperative radiation[9,10]
Immunocompromised patient[15]
Tumor resection[7,19,22,28,34]
TRAM flap donor site[7]

Incidence of postoperative/recurrent hernia and abdominal Wall laxity following ADM Reconstruction

The incidence of postoperative/recurrent hernia ranged widely from 0%[16,21,28,29,35,37] to 80%[15,24] when ADM was used for abdominal wall reconstruction. Gupta et al.[13] compared their experience with Human acellular dermal matrix (HADM) (33 patients) and porcine small intestinal submucosa material (PSISM) (41 patients) for ventral hernia repair. Both materials were used as interposition, overlay and underlay repairs using permanent sutures. They reported that HADM had a high rate of hernia recurrence (24%) and laxity (45%), with recurrence occurring between 10 and 90 days postoperative and laxity becoming evident as late as 18 months postoperatively. Recurrence typically occurred at the ADM—fascia or ADM—ADM interface; it was most frequently found following its use as an interposition material. Although recurrence and laxity were not observed when PSISM was used, the PSISM used initially was not perforated and resulted in a high incidence of seroma (91%). The incidence of seroma decreased dramatically when they switched to using perforated PSISM (23%). This study was performed retrospectively and there was no statistical analysis.

Espinosa-de-los-Monteros et al.[14] retrospectively compared outcomes following abdominal wall reconstruction in two groups: HADM used as overlay (37 patients and 39 procedures) was compared with randomly selected cases without any HADM (39 patients and 39 procedures). In the HADM group, medium-sized hernias were repaired with components' separation and direct fascial approximation with HADM overlay (82%), and large-sized hernias were reconstructed with polypropylene mesh as an underlay when fascial closure was not possible, followed by HADM overlay (18%). The randomly selected control group underwent similar repairs without the use of HADM (medium-sized hernias 74% and large-sized hernias 26%). The hernia recurrence in the HADM group was 5% compared with 20% hernia recurrence in the control group; this was statistically significant. When analyzed by size of defect, hernia recurrence was significantly lower when HADM was used as an overlay in medium-sized hernias, compared to similar repairs without HADM (0% compared with 13%). For large-sized hernias, addition of HADM did not make a significant difference to hernia recurrence (29% compared with 30%). The incidence of laxity was unreported.

Cobb and Shaffer[12] retrospectively compared complications following laparoscopic ventral hernia repair of ventral/incisional and recurrent hernias using Porcine acellular dermal matrix (PADM) (55 patients) or composite polypropylene and expanded polytetrafluoroethylene mesh (CPEPM) (84 patients). Both materials were used as an underlay. They did not find a statistically significant difference between the two materials with respect to recurrence (6.6% PADM compared with 1.2% composite mesh). Laxity was unreported.

Jin et al.[15] reported their experience with HADM used as a bridged repair (interposition or underlay) (11 patients) compared with a reinforced repair (onlay, underlay or sandwiched) combined with components separation (26 patients). Hernia recurrence was 80% in the bridged repair group compared with 20% in the reinforced repair combined with components separation group, which was statistically significant. Recurrence occurred at a mean of 1 year following surgery but was seen up to 31 months after.

The two studies with the highest incidence of postoperative/recurrent hernia were by Jin et al.[15] and Blatnik et al.[24] at 80%. Jin et al.[15] found a statistically significant difference in incidence of postoperative hernia when HADM was used as a bridged repair (8 of 11 patients) compared with a reinforced repair (4 of 26 patients) when direct fascial reapproximation was obtained. Blatnik et al.[24] also reported an 80% (8 of 11 patients) incidence of postoperative hernia when HADM was used as an interposition repair. Seven studies[16,21,28,29,35,37] reported a 0% incidence of postoperative/recurrent hernia using HADM. All were level IV evidence and included between three and 27 patients with a mean follow-up ranging between 3 and 16 months; the study with 27 patients did not report the length of follow-up.[21]

The incidence of abdominal wall laxity was largely unreported. In the 10 articles[10,13,16,22,25–27,32,33] that reported on laxity, the incidence ranged from 0%[10,13] to 83%.[27] Bluebond-Langner et al.[27] reported that laxity occurred more frequently in large abdominal wall defects or following surgical site infections. Gupta et al.[13] reported that development of laxity was observed until the end of their follow-up period of 18 months.

Complications associated with the use of ADM

Both the type and frequency of complications varied between studies. Delayed wound healing occurred in up to 64% of patients.[26] Infection-related complications including surgical site infections, cellulitis and deep/intra-abdominal abscesses were as high as 40%.[30] Diaz et al.[17] reported that wound infections occurred in 33% of patients with clean-contaminated wounds compared with 36% in patients with contaminated-dirty wounds. Bellows et al.[22] found that the proportion of patients with perioperative complications was significantly higher in those with dirty/contaminated wounds compared with those patients with clean-contaminated/clean wounds. Several studies reported successful management of ADM-related infections using antibiotics and local wound care.[12,17,22,27] In a small number of patients, ADM required removal due to recalcitrant infection.[12,17,23] Seroma was commonly reported and occurred in 27% of patients with HADM abdominal wall reconstructions.[34]

Outcomes related to type of ADM

Three studies reported experience with PADM: one level III[12] and two level IV[19,31] studies. The only level III study was by Cobb and Shaffer[12] comparing PADM with CPEPM in laparoscopic ventral hernia repair. A level IV study by Parker et al.[19] reviewed nine patients who underwent abdominal wall reconstruction with PADM as an underlay. The average follow-up was 18 months postoperatively, with 11% incidence of hernia and 22% incidence of wound-healing complications. The other level IV study by Hsu et al.[31] reported experience with 28 patients that had PADM as an underlay. There was 10% recurrence, occurring a mean of 10 months postoperatively and a 32% overall complication rate.

Only one study[31] reported experience with BADM. Wietfeldt et al.[36] reviewed five patients that underwent abdominal wall reconstruction with Bovine acellular dermal matrix (BADM) as an interposition. The average follow-up was 10 months postoperatively, with 20% incidence of hernia and 60% incidence of wound-healing complications.

Outcomes related to technique

Several technical considerations related to the use of ADM for abdominal wall reconstruction that may affect outcomes include: location of ADM, type of fascial repair and type of suture used (Table 4).

Table 4 Technical Aspects of Acellular Dermal Matrix for Abdominal Wall Reconstruction.

Location of ADM
Underlay/inlay
Interposition
Overlay/onlay
Sandwiched (underlay and overlay)
Type of Fascial Repair
Bridged (no re-approximation of fascia)
Reinforced (re-approximation of fascia)
Type of Suture Used
Absorbable
Permanent

ADM, acellular dermal matrix.

Location of ADM

In the articles identified, ADM was used as underlay/inlay, interposition, overlay/onlay and sandwiched (underlay and overlay) repairs. Gupta et al.[13] reported that HADM used as an interposition material had a higher incidence of recurrence (37%) compared with underlay (25%) and overlay (0%); they did not test for statistical significance. Diaz et al.[17] found that HADM used as an underlay had the lowest incidence of recurrence (7%) compared with that used as an onlay (13%), component separation with HADM reinforcement (20%) and interposition (30%). This trend was also observed by Lin et al.,[33] although it did not reach statistical significance. Postoperative/recurrent hernia ranged from 0%[21,28] to 30%[22] when ADM was used as an underlay/inlay. As an interposition, it ranged from 0%[29,37] to 80%[24]. As an overlay/onlay, it was between 0%[13] and 14%.[30] Patton et al.[23] reported that there was a statistically significant correlation between HADM used as an interposition or onlay with recurrence. Maurice and Skeete[34] reported a statistically significant recurrence in patients with ADM used as an interposition.

Type of fascial repair

Aside from the location of ADM, type of fascial repair (bridged vs. reinforced) was observed to be important in determining strength of the reconstruction. In cases where fascial re-approximation was achieved, HADM used in a reinforced repair with fascial re-approximation was significantly better than that used in a bridged repair without fascial re-approximation.[15]

Type of suture used

Fifteen studies reported using permanent sutures. Diaz et al.[17] reported a 25% hernia recurrence rate when absorbable suture was used compared with a 10% rate when permanent suture was used; however, this was not statistically significant. In a later multi-institutional study by Diaz et al.,[30] they reported 16% recurrence rate when absorbable suture was used compared with 20% when permanent suture was used; this was again not statistically significant.

Discussion

Between 1 December 2003 and 31 October 2010, 30 articles have been published that met our *a priori* inclusion and exclusion criteria. No level I or II evidence was identified. No systematic review of this topic was identified. Only four of the identified studies were level III evidence: two studies compared HADM with other materials including PSISM[13] and polypropylene mesh[14]; one study compared PADM with CPEPM[12] and one study compared HADM used as a bridged repair versus a reinforced repair combined with components separation.[15]

The large number of indications for the use of ADM in abdominal wall reconstruction identified in this systematic

review makes it difficult to produce clear indications for the use of this material based on high level evidence. Based on the articles included in this systematic review, the most common indications for the use of ADM were abdominal wall reconstruction in a surgical field at high risk for infection (i.e., contaminated, dirty wounds) and complex or recurrent abdominal hernias.[6]

The key technical considerations related to the use of ADM for abdominal wall reconstruction that may affect outcomes include: type of ADM, location of ADM, type of fascial repair and type of suture. In terms of the type of ADM, three studies reported experience with PADM: one level III[12] and two level IV[19,31] studies. Only one study[36] reported experience with BADM. With very few studies describing outcomes with PADM or BADM, it is difficult to draw any evidence-based conclusions on the sparse data available. In addition, reports of abdominal wall laxity following reconstruction with HADM have made the use of PADM more popular. However, limited number of studies have reported outcomes following PADM for abdominal wall reconstruction, although more reports are emerging.[38,39] Recently, the preliminary results of a level IV, prospective observational, multicenter trial of PADM for the repair of infected or contaminated abdominal incisional hernias in 80 patients were reported.[40] There was 19% hernia recurrence at an average of 1-year follow-up with a 27% rate of seroma and 29% with surgical site infections. Furthermore, the method in which these newer biologic materials are manufactured (e.g., hydrated/non-hydrated, cross-linked/non-cross-linked, etc.) and the impact of these processing strategies on outcomes have yet to be discerned.[38,41,42]

The location of ADM is the most contentious and variable aspect of the technical description of ADM-assisted abdominal wall repair in the literature. ADM location has been described as an underlay/inlay, overlay/onlay, interposition or sandwiched (underlay and overlay). 'Underlay', also referred to as inlay, describes the material being positioned deep to the fascial layer with underlap of the edges. 'Overlay', also referred to as onlay, describes the material being positioned superficial to the fascial layer with overlap of the edges. 'Interposition' involves imbrications of the material directly to the fascial edge. While some authors found the highest incidence of recurrence when ADM was used as an interposition material,[13,23,34] and lowest incidence of recurrence when it was used as an overlay,[13,23] others report the lowest rate of recurrence when ADM was used an underlay/inlay.[17,33] Material positioning as an underlay/inlay, rather than interposition or overlay/onlay, is hypothesised to result in a stronger abdominal wall repair due, in part, to continuous positive intra-abdominal pressure causing the implant to buttress the undersurface of the myofascial abdominal wall[43]; however, the evidence is unclear.

Furthermore, in some studies, it is unclear whether the material was used as a 'reinforced' repair, with direct approximation of the fascial layer, or as a 'bridged' repair, without approximation of the fascial layer. This distinction needs to be clearly made as fascial continuity has important implications in the likelihood of postoperative hernia formation.[15] ADM used in a reinforced repair with direct fascial approximation is preferable to a bridged repair without fascial approximation.[15] While adequate fascial underlay of ADM has been felt to be important to strengthen the AFM-fascial repair, the amount of critical overlap has been cited to be from 1 to 5 cm.[9,15,18,19,21–23,25–28,30–32] Finally, there are inconsistent findings regarding the ideal suture material for ADM-assisted abdominal reconstruction to prevent future hernia formation. In conclusion, recommendations on the ideal technique of ADM-assisted abdominal wall repair cannot be made due to the heterogeneous description of surgical techniques, including type of ADM, location of ADM, type of fascial repair and type of suture in the literature.

Twenty-six of the 30 studies reported on outcomes using HADM. The most important primary outcome that was considered was the development of postoperative/recurrent abdominal hernia. The incidence of postoperative/recurrent hernia ranged widely from 0%[16,21,28,29,35,37] to 80%.[15,24] The incidence of abdominal wall laxity was largely unreported in the identified studies. In the 10 articles[10,13,16,22,25–27,32,33] that reported on abdominal wall laxity, it occurred from 0%[10,13] to 83%.[27] Follow-up duration in the reviewed studies varied between 0 months[33] and 53 months[10] and was unreported in two studies.[21,25] Since the exact length of follow-up required to accurately assess postoperative/recurrent hernia incidence is unknown, higher rates of observed postoperative hernia or abdominal wall laxity may be related to longer follow-up duration in some studies. Significant predictors of recurrent abdominal hernia formation have been identified to be: enterocutaneous fistula/stoma takedown, mesh removal, surgical site infection, body mass index (BMI) greater than 30 $kg\,m^{-2}$ and female gender.[30,33] Other cited factors included open wounds (open wound 83% vs. closed wound 33%),[20] size of defect,[32] implant size greater than 100 cm^2,[34] and surgical time of 300 min or longer.[34] Review of the data indicates that there is a lack of clearly defined outcome measures as well as a lack of high-level studies comparing the use of ADM with other materials or direct closure. However, with the complex nature of this problem combined with the multitude of variables to consider, including patient characteristics, technical factors and appropriate outcome measures, producing studies with high levels of evidence poses a formidable challenge.

While examining the trends in a systematic review can be a valid method of evaluating the existing literature,[44] the lack of level I or II evidence combined with the heterogeneity of the identified studies with respect to design, data collection, patient population, surgical technique and length of follow-up, however, makes it difficult to perform a meaningful meta-analysis. Indications for the use of ADM varied as previously outlined. Hernia recurrence may significantly differ based on the surgical indication. For example, the incidence of postoperative hernia following abdominal wall reconstruction for defects after an open abdomen or tumour ablation may be very different from that of a recurrent hernia, as there is likely a predisposition to recurrence in this group of patients.[45] While ADM-assisted abdominal wall reconstruction techniques are still relatively new, a myriad of surgical techniques have already been described that differ in the type of ADM used, fascial repair, suture for fixation and location of ADM. Unfortunately, until a more clearly defined system is adopted for describing surgical techniques involving ADM, recommendations on the ideal technique of ADM-assisted

abdominal wall repair cannot be made. Finally, in evaluating the primary outcome of abdominal wall reconstruction, a standardised and clear distinction must be made between hernia and laxity/bulge/eventration as the two entities are distinct outcomes altogether.

Finally, in the current climate of increasing resource restraints and financial responsibilities, cost-effectiveness analysis (CEA) of novel biologic materials needs to be performed before incorporating them into routine practice. Paramount in CEAs is not only considerations of direct and indirect costs of the interventions but also patient perceptions of their health outcome (utility) and complications or morbidity as a consequence of the interventions. Several studies[15,20] reported the total cost of ADM used during surgery. Only Blatnik et al.[24] reported on the cost-effectiveness of HADM and concluded that the cost of HADM for a bridged repair was unjustified because of the high hernia recurrence postoperatively. However, no study identified in this systematic review performed a cost-utility analysis. In addition, CEA of these novel biologic materials should include comparisons with more traditional one- or two-staged reconstructions with synthetic materials for which more data exist.[46,47]

Conclusions

In conclusion, after a systematic review of the existing literature examining outcomes after abdominal wall reconstruction using ADM, there is a deficiency of data derived from high level of evidence studies. The existing studies fail to provide conclusive evidence as to whether or not:

1. ADM may be useful in the contaminated/infected surgical field during abdominal wall reconstruction compared with synthetic materials.
2. Technical details including positioning of ADM, implantation of ADM under tension and the type of suture material used may lead to improved long-term outcomes with lower postoperative/recurrent hernia rates.

In addition, the results of this systematic review suggest the following:

1. More level I, II and III studies conducted in a prospective fashion are needed to appropriately evaluate the efficacy of ADM in abdominal wall reconstruction, particularly in comparison with existing techniques such as the use of synthetic materials, components separation, and pedicled and free flap reconstructions.
2. More studies are required to evaluate the efficacy and safety of PADM and BADM, and compare their outcomes with HADM as well as against synthetic materials.
3. An economic evaluation including a cost-utility analysis of ADM versus existing techniques should be performed.

Disclosures

Dr. Zhong has received funding from Plastic Surgery Educational Foundation for one-stage breast reconstruction using dermal matrix/implant versus two-stage expander/implant procedure (AlloDerm RCT). Dr. Janis serves as a consultant for LifeCell Corporation. Drs. Ahmad and Hofer do not have any financial interest with any of the products, devices, or drugs mentioned in this article.

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