The American Journal of Surgery (2013) 205, 85–101

The American Journal of Surgery®

Review Article

Repair of incisional hernias with biological prosthesis: a systematic review of current evidence

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KEYWORDS:
Bioprosthetic;
Systematic review;
Incisional hernia

Abstract

BACKGROUND: No consensus has been reached on the use of bioprosthetics to repair abdominal wall defects. The purpose of this systematic review was to summarize the outcomes from studies describing this use of various bioprosthetics for incisional hernia repair.

METHODS: Studies published by October 2011 were identified through literature searches using EMBASE, MEDLINE, and the Cochrane Central Register of Controlled Trials.

RESULTS: A total of 491 articles were scanned, 60 met eligibility criteria. Most studies were retrospective case studies. The studies ranged considerably in methodologic quality, with a modified Methodological Index of Nonrandomized Studies score from 5 to 12. Many repairs were performed in contaminated surgical sites (47.9%). At least one complication was seen in 87% of repairs. Major complications noted were wound infections (16.9%) and seroma (12.0%). With a mean follow-up period of 13.6 months the hernia recurrence rate was 15.2%.

CONCLUSIONS: There is an insufficient level of high-quality evidence in the literature on the value of bioprosthetics for incisional hernia repair. Randomized controlled trials that use standardized reporting comparing bioprosthetics with synthetic mesh for incisional hernia repair are needed.

Despite advances in surgical technique and prosthetic technologies, repair of complex anterior abdominal wall defects, particularly when bacterial contamination is present or the risk of infection is high, remains a complex and challenging surgical undertaking. Although permanent prosthetic mesh is considered the gold standard for minimizing hernia recurrence, their nonabsorbable characteristics may cause potential problems, resulting in erosion into the abdominal viscera, bowel fistulae, and chronic pain, which can lead to more complex and costly surgery.[1,2] Moreover, placement of synthetic mesh is sometimes imprudent, especially in high-risk contaminated wounds. Consequently, within the past decade, several bioprosthetic materials have been developed to support tissue reconstruction while minimizing the potential complications that come from foreign material reactions of synthetic mesh and their potential to act as a nidus for infection.

Biological mesh was introduced in clinical surgery more than a decade ago as an alternative to synthetic mesh for abdominal incisional hernia repair. In general, biological prostheses possess the physical and mechanical characteristics of a clinically acceptable synthetic mesh in that they promote tissue in-growth and have

The authors report no potential conflicts of interest or financial interest.

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Manuscript received November 19, 2011; revised manuscript February 6, 2012

0002-9610/$ - see front matter © 2013 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.amjsurg.2012.02.019

sufficient mechanical strength to withstand the physiological and anatomic stresses of the human abdominal wall while providing a biological scaffold to support tissue regeneration. Biological prostheses have been designed to perform as permanent surgical prosthesis for soft-tissue repair while minimizing mesh-related complications and thus broaden the indications for mesh reinforcement in high-risk incisional hernia cases, especially in contaminated surgical fields.

Recent advances in tissue engineering have resulted in a dramatic increase in the number of commercially available bioprosthetic products for abdominal hernia repair. To date, the Food and Drug Administration has approved 15 different bioprosthetic materials, harvested from 5 types of tissue: bovine pericardium, human cadaveric dermis, porcine small intestine submucosa, porcine dermal collagen, and bovine dermal collagen. These materials are processed to remove hair, cells, and cell components, as well as other antigens present in the tissue, leaving only a highly organized collagen architecture with the surrounding extracellular ground tissue.[3] The inherent source variation (tissue, species, and age) from which these biomaterials are procured is compounded by the diverse tissue harvesting, de-cellularization, disinfection, and sterilization methods used during the manufacturing process, some of which may include the use of chemical cross-linking agents, harsh detergents, broad-spectrum antibiotics, or extremes in pH that can strip the extracellular matrix component of these materials.[4] Because the manufacturing process influences the characteristics of a final bioprosthetic product, the postimplantation biological response in human beings is expected to differ between products. Postimplantation biological responses range from foreign body encapsulation to implant degradation and resorption, to site-specific remodeled tissue in which the implanted material is repopulated by local fibroblasts and a new vasculature that together support the generation of a new, metabolically active, strong tissue at the site of the hernia repair. However, if the process of biological tissue engraftment is inadequate the surgical site will weaken and the hernia likely will recur.

Initial case series with short-term follow-up evaluation ($<$1 y) reported favorable clinical outcomes with biological tissue grafts for hernia repairs.[5,6] However, with longer and more detailed follow-up evaluation it is apparent that there is high morbidity and high incidence of recurrent hernia in patients with complex abdominal hernias repaired with bioprostheses. Given the high costs of biological grafts for hernia repair, stronger evidence of beneficial outcomes are paramount to justify their health care value and continued use.[7] In addition, there is currently no consensus on when or how to optimally use biological prosthesis for incisional hernia repair, and long-term data regarding their clinical efficacy are sparse. Therefore, this systematic review was performed with the purpose to evaluate the clinical effectiveness of these acellular collagen-based scaffolds for the repair of incisional hernias.

Methods

Literature search and study selection

We searched 3 electronic databases: EMBASE (from 1980 onward), MEDLINE (from 1963 onward), and the Cochrane Register of Controlled Trials. The search included literature published as of October 31, 2011. Our search strategy combined text words and subject headings identifying reports relating only to incisional/ventral hernia repairs and biological prosthesis. Search terms used were as follows: "small intestinal submucosa," "acellular human dermis," "cross-linked porcine dermis," "cross-linked bovine pericardium," "multi-layered porcine intestinal," xenograft, allograft, biologic tissue graft, urinary bladder matrix, Surgisis," "Tutomesh," "Veritas," "Alloderm," "FlexHD," "Allomax," "CollaMend," "Permacol," "Strattice," "Fortagen," "A-Cell," "DermaMatrix," "XenMatrix," "SurgiMend," and "hernia" in all possible combinations. The search was limited to English language studies and excluded congenital abdominal wall defects, and femoral, hiatal, diaphragmatic, parastomal, sacral, or inguinal hernias. Studies that combined data from ventral/incisional repair and other hernia types were included in the full article review. The literature search was supplemented with hand searching of relevant journals and reviewing of the bibliographies of identified articles. Retrospective study designs, case reports, case series, commentaries, letters to the editor, and expert opinions were included in this review. Nonpublished studies from experts in the field also were evaluated for inclusion.[8]

Specific inclusion and exclusion criteria were used in considering which articles were appropriate for this systematic review. Eligible studies had to investigate the use of biological prosthesis in patients diagnosed with an incisional/ventral hernia. We defined the following criteria for the inclusion of studies into our review: studies of patients with incisional/ventral hernia repaired with commercially available biological prosthesis; the outcomes evaluated were reported separately for each type of hernia repair; and the patients were adult (age, $\geq$18 y) subjects and follow-up data were available. English-language original articles were included as well as all types of clinical studies (ie, randomized, nonrandomized controlled clinical trials, cohort studies, case–control studies, retrospective patient series, and case reports). Articles were excluded from our systematic review if they were animal studies, reviews, and articles that investigated the application of biological prosthesis for transverse rectus abdominis myocutaneous flap repairs or open abdomens from trauma patients.

Data extraction

Two investigators (A.S. and J.M.) independently reviewed all titles and abstracts to identify potentially relevant articles and then compared them for reliability. Full text articles were retrieved for studies considered relevant. In addition, for those articles with titles and abstracts that contained insufficient information to allow judgment of relevance, these also were retrieved and evaluated by 2 independent reviewers to determine eligibility for inclusion in this review. Any differences were resolved by mutual consensus with a third independent reviewer (C.F.B.).

After final selection of the articles, information was extracted by 2 authors (A.S. and J.M.) from the full texts using a data extraction form and compared. A third reviewer was consulted (C.F.B.) if consensus was not reached. If 2 or more studies presented the same data from a single patient population, we included these data only once in the review. All reports on repair of incisional/ventral hernias using a bioprosthetic as the sole material to reinforce or bridge the defect were included. All other types of repair were excluded. We contacted primary investigators when necessary for clarification of data in different articles. For the purposes of this systematic review the following data were extracted: study population (eg, sample size, type and size of the defect, type of material used), study design (prospective/retrospective/case series), intervention, and outcomes (eg, duration of follow-up evaluation, recurrence, infection, seroma).

Assessment of study quality. One of the limitations in reviewing the available literature was that most studies on incisional hernia repair using biological prosthesis are observational and nonrandomized. Two review authors (A.S. and J.M.) independently thoroughly reviewed and rated the strength of evidence and the methodologic quality of the included studies based on the type of data included therein. Disagreements were resolved in a consensus meeting and a third review author (C.F.B.) was consulted when necessary. We used a standardized instrument called the Levels of Evidence Rating Scale for Therapeutic Studies[9] using 5 levels of evidence and a modified version of the Methodological Index of Nonrandomized Studies (MINORS).[7] The MINORS is a 6-item, validated checklist that assesses the reporting quality of nonrandomized studies. The MINORS method scores may range from 0 to 12. The quality of each article was not used as an exclusion from our analysis. However, a study having a total score less than 9, or no score on items 2, 5, or 6 on the modified MINORS, was defined as having poor methodologic quality.

Ventral Hernia Working Group grading system. Because the well-established Centers for Disease Control and Prevention wound classification system was not reported in 83.3% of the articles included in this review and because classifying each repair site into clean, clean-contaminated, contaminated, and dirty/infected based on available information from the article was not possible, the Ventral Hernia Working Group (VHWG) grading system was used to stratify each patient's likelihood for surgical-site occurrence such as infection. This system consists of 4 grades, ranging from low surgical site risk (grade 1) to high risk (grade 4), and is based on risk factor characteristics of the patient and the wound for surgical site occurrence (SSO). Although the VHWG grading system[10] was reported directly in only 5.0% of our included articles, we were able to classify all repairs using this grading scale independently based on the patient information presented in the articles and/or correspondence with the authors. All incisional hernia repairs were graded by 2 investigators, with any discrepancies in grading between the initial reviewers reconciled by discussion with the entire research team.

Data analysis

To assess the effectiveness of hernia repair with biological mesh, the results of outcome measures were extracted from the original studies. The outcome data of some studies were recalculated because the authors of the original articles did not account for drop-outs, and/or patients lost to follow-up evaluation adequately. In addition, because all authors did not use the VHWG grading system, we calculated the grading based on the information in the original article. When the results were not clear the primary author was contacted. If a study reported several follow-up intervals, the outcome of the longest follow-up period was used. Because studies were heterogeneous regarding study populations, repair techniques, outcome measures, and follow-up moments, statistical pooling was not performed. However, another calculation, the variance weighted approach, was used with the assumption that the relative risks across studies were equal and the rates were not assumed to be identical across studies.[11] Therefore, to determine the study quality in respect to the number of included studies, a weighted average score for the level of evidence and MINORS criteria were calculated from the following equation: weighted average $= (x_1\ w_1 + x_2\ w_2 \ldots + x_n\ w_n)/(w_1 + w_2 \ldots + w_n)$, where x = sample mean and w = number of repairs.

Follow-up time was calculated as an average of all the mean and median times to provide an overall mean with the assumption that the distributions are symmetric. The average weighted recurrence rate was calculated using the inverse of the variance, r (1-r)/n, where r = recurrence rate and n = number of repairs, as the weight. For studies with a recurrence of 0, the variance was estimated as .5/n.[12] To account for the recurrence rate in regard to follow-up period, the variance for the weighted average was calculated as described earlier with n = average follow-up period. Weighted averages were not calculated for Surgisis because it was the single variable in the subgroup, but its value was used in the calculation of

total weighted averages. Data are presented in a descriptive way. Biological prosthesis material performances were reported individually and combined in groups according to material source to facilitate comparisons.

Results

A total of 491 unique citations were identified in our review. After screening titles and abstracts to discard duplicate records and obviously irrelevant citations, 69 potentially eligible studies were identified and were reviewed in-depth for inclusion in this systematic review. An additional 25 articles were identified through reference review, hand search, and expert consultation. Among these articles, 60 publications[13–72] meeting all inclusion criteria were identified (Table 1). Figure 1 contains a flow diagram of the study selection process. A total of 34 studies[5,6,73–104] did not meet the inclusion criteria and were excluded from this review (Supplementary Table 1). The main reasons for exclusion were as follows: (1) data could not be separated by mesh type, (2) data could not be separated by hernia type, and (3) data could not be separated from trauma patients.

Forty-three percent of corresponding authors were contacted via e-mail to obtain additional information to resolve any conflicting data, with a response rate of 76.9%. In the end, 1,241 repairs with biological prosthesis were identified and included, but 29 repairs were lost to follow-up evaluation. Thus, 1,212 repairs with follow-up data were available for analysis. After careful review of all available studies, it was determined that a pooled analysis could not be performed on the basis of Simpson's paradox.[105]

Included studies

The interval from 2009 to 2010 appears to have been the peak period for publication on incisional hernia repair with biological prosthesis. There were no randomized trials identified for analysis. However, multiple other types of clinical studies were identified describing the use of bioprosthetics for incisional hernia repair. The most common type of study was case series (56.7%) and 75% of these reports included fewer than 30 patients. Because most of the included studies were case series there is a potential risk of publication bias. Moreover, because only a few of the included studies reported the consecutive recruitment of participants or the blinding of patients or clinicians and researchers, the risk of selection and information bias is also high.

The average level of evidence for each mesh material is presented in Table 2. Of note, only 4 studies were level 3,[29,34,43,62] with a weighted mean of 4.5 (range, 3–5). The highest number of case reports was found for porcine dermis (44.0%). When studies were combined into groups according to the material source, the weighted average level of evidence was similar for all biomaterials.

The methodologic quality of the included studies was generally poor. For the modified MINORS index the average weighted score was 9.7 (range, 5–12). A total score less than 9, or no score on items 2, 5, or 6 on the modified MINORS index, was calculated for 24 of the 60 articles (40%). Only 4 of 60 (6.7%) studies had a maximum score of 12.[36,37,52,62] Overall, common reporting weaknesses included the following: lack of reporting wound classification, lack of a control group, failure to provide information on surgical technique and outcomes, failure to report which patients were lost to follow-up evaluation, and failure to provide biological mesh-specific information on hernia recurrence. There was no observed trend between study quality scores and year of publication.

In our review we found that many studies had missing or incomplete data. For example, 29 of 60 studies (48.3%) did not report defect size, 4 studies (6.7%) reported using more than one biological prosthetic, 17 studies (28.8%) reported more than one surgical technique, and 83% of the studies did not report the Centers for Disease Control and Prevention wound classification. Eight studies (13.3%) did not report any complications after graft implantation. Seven articles (11.7%) reported recurrence as the only end point. However, the surgical technique (98.3%) and reason for biological prosthetic use generally were well reported in the studies included in the review.

Study results

The overall mortality from reviewed and included studies was 4.0% (n = 48/1,212). The duration of the follow-up period varied considerably between studies, ranging from 5 days to 60 months, with an overall mean of 13.6 months (Fig. 2). The weighted average follow-up period for each type of biological prosthetic by source is listed in Table 3. The most frequently described major complication of the repairs with biological mesh was recurrence. The reported frequency of recurrence varied from 0% to 100%, with an overall weighted recurrence rate of 15.2%. The weighted average hernia recurrence rate for each type of bioprosthetic by source is listed in Table 3.

The amount of surgical experience by an individual surgeon or hospital often is associated with better clinical outcomes. One possible surrogate measure of experience that was available in this review was the number of procedures performed per report. When this variable was plotted against recurrence there was no obvious correlation between recurrence and procedure number (Fig. 3). Another possible measure of experience that was available was the article publication year. Plotting the publication year against the recurrence rate showed no obvious correlation between hernia recurrence and publication year (Fig. 4).

The relationship of the VHWG grading system and use of biological prosthesis was explored. This grading system is based on risk factors for surgical site occurrences. As shown in Table 3, each material with follow-up data was stratified by the VHWG grading system. Although most

Table 1 Studies included in the systematic review

Study	Level of evidence	Modified MINORS index	Biological mesh	Repairs	Lost to follow-up evaluation, N (%)	Follow-up period, mo (range)	Defect size (range)	Types of repair	Recurrence, N (%)
Adedeji et al,[13] 2002	V	5	Permacol	1	0	12	NR	Onlay	0
Alaedeen et al,[14] 2007	IV	10	Alloderm	8	1 (29.1)	Mean, 14 (2–68)	NR	Midline reapproximated with CST plus reinforced-onlay, underlay, sandwich	0
Alaedeen et al,[14] 2007	IV	10	Alloderm	2	0	Mean, 7 (5–8)	NR	Bridged	2 (100)
Asham et al,[15] 2006	V	5	Alloderm	1	0	24	84 cm^2	Inlay	0
Awad et al,[16] 2010	IV	11	Strattice	80	9 (11.3)	Mean, 12	236 cm^2	Retrorectus, underlay, onlay; midline reapproximated with/without CST plus reinforced-retrorectus, underlay, onlay	15 (21.1)
Bachman et al,[17] 2009	IV	11	Surgisis	2	0	Median, 6 (.25–9)	NR	Midline reapproximated with CST plus reinforced-underlay	0
Bachman et al,[17] 2009	IV	11	FlexHD	2	0	Median, 6 (.25–9)	NR	Midline reapproximated with CST plus reinforced-underlay	0
Baillie et al,[18] 2007	IV	5	Permacol	1	0	5	600 cm^2	Bridged	0
Baillie et al,[18] 2007	IV	5	Alloderm	1	0	5	300 cm^2	Bridged	0
Bluebond-Langner et al,[19] 2008	IV	10	Alloderm	5	0	Mean, 12	628 cm^2 (220–900 cm^2)	Midline reapproximated with CST plus reinforced-onlay interposition	0
Boutros et al,[20] 2010	IV	10	Surgisis	3	0	Mean, 6.3	NR	Underlay; midline reapproximated plus reinforced-underlay	0*
Brewer et al,[21] 2011	IV	10	Alloderm	34	0	Mean, 26	NR	Overlay, underlay, interposition	8 (23.5)
Butler and Campbell,[22] 2011	IV	11	Strattice	38	0	Mean, 12.4	494 cm^2	Bridged-inlay; midline reapproximated with CST plus reinforced-inlay	1 (2.6)
Canda and Karaca,[23] 2009	V	7	Collamend	1	0	3	NR	Inlay	0
Candage et al,[24] 2008	IV	11	Alloderm	46	0	Mean, 12.1 (1–39)	NR	Bridged-underlay midline reapproximated with/without CST plus reinforced-onlay, underlay, sandwich	14 (30.4)

Table 1 Continued

Study	Level of evidence	Modified MINORS index	Biological mesh	Repairs	Lost to follow-up evaluation, N (%)	Follow-up period, mo (range)	Defect size (range)	Types of repair	Recurrence, N (%)
Catena et al,[25] 2007	IV	11	Permacol	7	0	Mean, 11.1 (7–18)	145 cm^2 (110–182 cm^2)	Bridged-onlay, underlay	0
Cavallaro et al,[26] 2010	IV	7	Tutomesh	2	0	Mean, 54 (48–60)	NR	Retrorectus	0
Chavarriaga et al,[27] 2010	IV	10	Collamend	18	0	Mean, 7.3 (2–14)	NR	Midline reapproximated with/without CST plus reinforced-inlay, overlay, interposition	8 (44.4)
Chuo and Thomas,[28] 2008	V	6	Permacol	1	0	15	375 cm^2	Bridged-underlay	0
Cobb and Shaffer,[29] 2005	III	11	Permacol	55	0	Mean, 14	NR	Bridged-underlay	4 (7.3)
Coyle et al,[30] 2010	V	7	Permacol	1	0	1.4	NR	Underlay	0
Dorafshar et al,[31] 2009	V	5	Alloderm	1	0	24	24 cm^2	Onlay	0
Edelman and Bellows,[32] 2010	IV	11	Surgisis	16	0	Mean, 12	3–6 cm^2*	Midline reapproximated plus reinforced-underlay	1 (6.3)
Eid et al,[33] 2004	IV	11	Surgisis	12	0	Mean, 13 (7–18)	17.7 cm^2 (9–50 cm^2)	Bridged-underlay	0
Espinosa-de-los-Monteros et al,[34] 2007	III	11	Alloderm	32	0	Median, 15	155 cm^2	Midline reapproximatedwith CST plus reinforced-overlay	0
Gentile et al,[35] 2011	V	7	Permacol	1	0	12	NR	Bridged	0
Gupta et al,[36] 2006	IV	12	Surgisis	41	0	Mean, 29	NR	Overlayunderlay interposition	0
Gupta et al,[36] 2006	IV	12	Alloderm	33	0	Mean, 18	NR	Overlay, underlay, interposition	8 (24.2)
Helton et al,[37] 2005	IV	12	Surgisis	53	0	Median, 14 (2–29)	202 cm^2	Bridged-inlay; midline reapproximated with/without CST plus reinforced-inlay, underlay	9 (17.0)
Hirsch,[38] 2004	V	7	Alloderm	1	0	9	180 cm^2	Interposition	0
Holton et al,[39] 2005	IV	10	Alloderm	43	0	Mean, 6.1 (.6–30.6)	NR	Onlay, underlay, sandwich interposition	4 (9.3)

Table 1 Continued

Study	Level of evidence	Modified MINORS index	Biological mesh	Repairs	Lost to follow-up evaluation, N (%)	Follow-up period, mo (range)	Defect size (range)	Types of repair	Recurrence, N (%)
Hsu et al,[40] 2009	IV	10	Permacol	28	0	Mean, 16 (10–23)	150 cm^2 (10–600 cm^2)	Bridged-underlay	3 (10.7)
Jin et al,[41] 2007	IV	9	Alloderm	37	4 (10.8)	Mean, 21.4 (15–36)	NR	Bridged-interposition; midline reapproximated with/without CST plus reinforced-onlay, underlay, sandwich	12 (36.4)
Kim et al,[42] 2006	IV	10	Alloderm	29	0	Mean, 6.1 (.3–16.4)	NR	Midline reapproximated with CST plus reinforced-inlay	2 (6.9)
Ko et al,[43] 2009	III	10	Alloderm	26	0	Mean, 17.3(3–36.3)	12.6 cm (6–19.7 cm)	Midline reapproximated with CST plus reinforced-underlay	12 (46.1)
Kolker et al,[44] 2005	IV	10	Alloderm	16	0	Mean, 16 (9–23)	NR	Midline reapproximated with CST plus reinforced-sandwich	0
Lee et al,[45] 2009	IV	11	Alloderm	68	15 (22.1)	Mean, 15.4	NR	Underlay	21 (39.6)
Limpert et al,[46] 2009	IV	11	Veritas	30	0	Mean, 22 (4–37)	111 cm^2 (20–600 cm^2)	Inlay, onlay; midline reapproximated with CST plus reinforced-onlay	5 (16.7)
Lin et al,[47] 2009	IV	11	Alloderm	144	0	Mean, 5.4 (0–23.3)	>25 cm^2	Overlay, underlay, interposition, unknown	39 (27.1)
Lipman et al,[48] 2007	IV	10	Alloderm	8	0	Mean, 10 (2–29)	535 cm^2 (300–884 cm^2)	Midline reapproximated with CST plus reinforced-underlay $\pm$ onlay	1 (12.5)
Liyanage et al,[49] 2006	V	7	Permacol	1	0	12	600 cm^2	Underlay	0
Martins et al,[50] 2010	V	7	Alloderm	1	0	6	2 cm	Underlay	0
McDonald and Weiss,[51] 2005	IV	9	Alloderm	5	0	Mean, 1.9 (.2–8)	242 cm^2 (48–400 cm^2)	Interposition retrorectus	3 (60)
Misra et al,[52] 2008	IV	12	Alloderm	70	0	Mean, 12	(10–25 cm)	Onlay underlay interposition	14 (20)
Morrison et al,[53] 2009	V	7	Alloderm	1	0	60	NR	Inlay	1 (100)*
Nemeth and Butler,[54] 2009	IV	9	Alloderm	11	0	Mean, 23.1 (5–53.1)	468.1 cm^2 (150–1045 cm^2)	Bridged-inlay,underlay	1 (9.1)
O'Brien et al,[55] 2011	V	7	Permacol	1	0	24	NR	Onlay	0
Parker et al,[56] 2006	IV	10	Permacol	9	0	Mean, 18.2	NR	Underlay	1 (11.1)

Table 1 Continued

Study	Level of evidence	Modified MINORS index	Biological mesh	Repairs	Lost to follow-up evaluation, N (%)	Follow-up period, mo (range)	Defect size (range)	Types of repair	Recurrence, N (%)
Parra et al,[57] 2010	IV	8	Strattice	3	0	Mean, 6	70.5 cm^2 (20–113 cm^2)	Underlay	0
Paton et al,[58] 2007	IV	9	Surgisis	2	0	Mean, 36	NR	NR	0
Pomahac and Aflaki,[59] 2010	IV	11	XenMatrix	16	0	Mean, 16.5	440 cm^2 (100–750 cm^2)	Underlay ± interposition; midline reapproximated with/without CST plus reinforced-underlay	1 (6.3)
Saettele et al,[60] 2006	V	7	Permacol	1	0	4	NR	Midline reapproximated+ reinforced-retrorectus	0
Sailes et al,[61] 2011	IV	10	Alloderm	100	0	Mean, 6*	NR	Midline reapproximated with CST plus reinforced-onlay	19 (19.0)
Sailes et al,[61] 2011	IV	10	Permacol	13	0	Mean, 6*	NR	Midline reapproximated with CST plus reinforced-onlay	1 (7.7)
Satterwhite et al,[62] 2011	III	12	Permacol	19	0	Mean, 11 (1–33)	321 cm^2	Midline reapproximated with/without CST plus reinforced-sandwich	0
Schuster et al,[63] 2006	IV	9	Alloderm	18	0	Mean, 9.1 (5–27)	NR	Underlay	9 (50)
Shaikh et al,[64] 2007	IV	11	Permacol	18	0	Median, 18 (6–36)	180 cm^2 (96–850 cm^2)	Midline closed plus reinforced-underlay	2 (11.1)
Shaikh et al,[65] 2011	V	7	Permacol	1	0	6	120 cm^2	Onlay	1 (100)
Singh et al,[66] 2008	IV	10	Alloderm	10	0	Mean, 10.3 (.1–24)	NR	Inlay	0
Tong et al,[67] 2011	IV	6	Surgisis	1	0	12	4 cm	Onlay	0
Treviño et al,[68] 2006	IV	11	Surgisis	5	0	Median 10 (3–12)	NR	Midline reapproximated plus reinforced-sandwich	0*
Tung et al,[69] 2006	V	7	Alloderm	1	0	12	60 cm^2	Underlay	0
Walker et al,[70] 2009	V	6	Permacol	1	0	3	NR	Bridged	0
Wietfeldt et al,[71] 2009	IV	11	SurgiMend	4	0	Median, 10 (9–17)	100 cm^2 (50–150 cm^2)	Inlay	0
Wotton and Akoh,[72] 2009	V	7	Permacol	1	0	4	NR	Bridged	0

CST = component separation technique; NR = not reported; sandwich = biological onlay plus biological underlay.

*Additional information obtained from author.

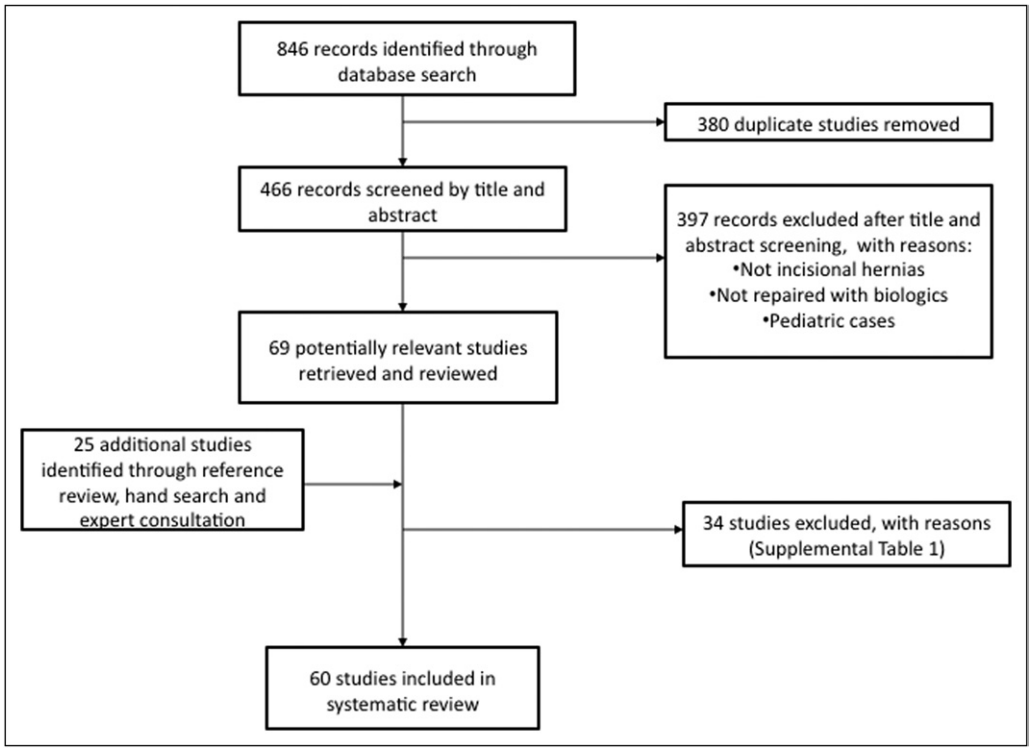

Figure 1 Flow chart of literature search results and inclusion/exclusions.

repairs were performed in patients considered grade 2 (comorbid) compared with those in grades 3/4 (potentially contaminated/infected), exceptions were noted for a few materials. For example, for Strattice there was more cumulative experience for patients considered grades 3/4 (90%).

Other than listing hernia recurrences, there was little consistency in the way investigators reported complications. In fact, outcomes other than hernia recurrence could be extracted cleanly for only 930 of the 1,212 repairs (76%). In those articles, 491 of 930 repairs (52.8%) reported a SSO.

Table 2 Average level of evidence and methodologic index by material type

Mesh	Earliest study published for incisional hernia repair	Number of publications	Average level of evidence	Average modified MINORS index
Human cadaveric dermis				
Alloderm (LifeCell, Branchburg, NJ)	2004	27	4.1	9.2
FlexHD (Ethicon, Cornelia, GA)	2009	1	4.0	11.0
Weighted average			4.1	9.2
Porcine small intestinal submucosa				
Surgisis (Cook Surgical, Bloomington, IN)	2004	9	4.0	10.3
Xenogenic dermis (porcine and bovine)				
Permacol (Covidien, Mansfield, MA)	2002	18	4.4	8.1
Strattice (LifeCell, Branchburg, NJ)	2009	3	4.0	10.0
XenMatrix (Davol, Warwick, RI)	2010	1	4.0	11.0
Collamend (Davol, Warwick, RI)	2009	2	4.5	8.5
SurgiMend (TEI Biosciences, Boston, MA)	2009	1	4.0	11.0
Weighted average			4.3	8.6
Xenogenic pericardium (bovine)				
Tutomesh (RTI Biologics, Alachua, FL)	2010	1	4.0	7.0
Veritas (Synovis Surgical, St. Paul, MN)	2007	1	4.0	11.0
Weighted average			4.0	9.0
Total		64*		

*Four publications contained data on 2 different biological meshes.[17,18,36,61]

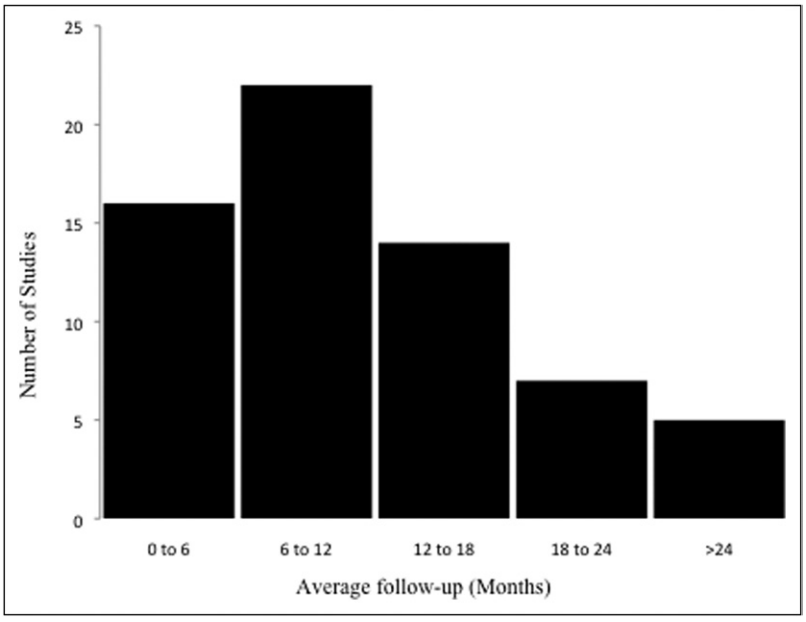

Figure 2 Histogram of articles sorted by average length of follow-up period. For example, there were 5 articles with more than 24 months of follow-up evaluation.

As shown in Table 4, the most common SSO was a postoperative infection and this was reported to occur in 157 (16.9%) repairs. Seroma/hematoma was the second most common complication reported and occurred in 12% of patients (112 patients). Most seromas resolved without intervention, but 24 of 112 (21.4%) required a bedside or outpatient intervention and 16 of 112 (14.2%) required surgical interventions. Hence, 36% of all patients with a seroma required some type of intervention. Mesh disintegration (.6%) and flap necrosis (.3%) were the least commonly reported outcomes. Twenty-five of 1,212 implanted devices were reported to have been explanted (2%), with the most common reason cited being infection or poor mesh incorporation (64%). The overall incidence of an SSO, after combining mesh product by source, ranged from 6.3% to 82.6% (human dermis, 48.3%; porcine small intestinal sub-

Table 3 Hernia recurrence rates, mean follow-up period in months, and Ventral Hernia Working Group grading by material

Material	Repairs with follow-up evaluation, n*	Recurrences, N (%)	Average follow-up period, mo	Grade 2: comorbid, N (%)†	Grades 3/4: potentially contaminated/infected, N (%)
Cadaveric dermis					
Alloderm	732	170 (23.2)	14.6	417 (57.0)	315 (43.0)
FlexHD	2	0	6.0	1 (50.0)	1 (50.0)
Porcine small intestinal submucosa					
Surgisis	135	10 (7.4)	15.4	76 (56.3)	59 (43.7)
Xenogenic dermis (porcine and bovine)					
Permacol	160	12 (7.5)	10.7	104 (65.0)	56 (35.0)
Strattice	112	16 (14.3)	10.1	12 (10.7)	100 (89.3)
XenMatrix	16	1 (6.3)	16.5	8 (50.0)	8 (50.0)
Collamend	19	8 (42.1)	5.2	8 (42.1)	11 (57.9)
SurgiMend	4	0	10.0	0	4 (100)
Xenogenic pericardium (bovine)					
Tutomesh	2	0	54.0	0	2 (100)
Veritas	30	5 (16.7)	22.0	5 (16.7)	25 (83.3)
Overall totals	1,212			631 (52.1)	581 (47.9)

*Reported number of hernia repairs; some patients had more than one repair.
†No repairs were performed in patients considered grade 1 (low risk).

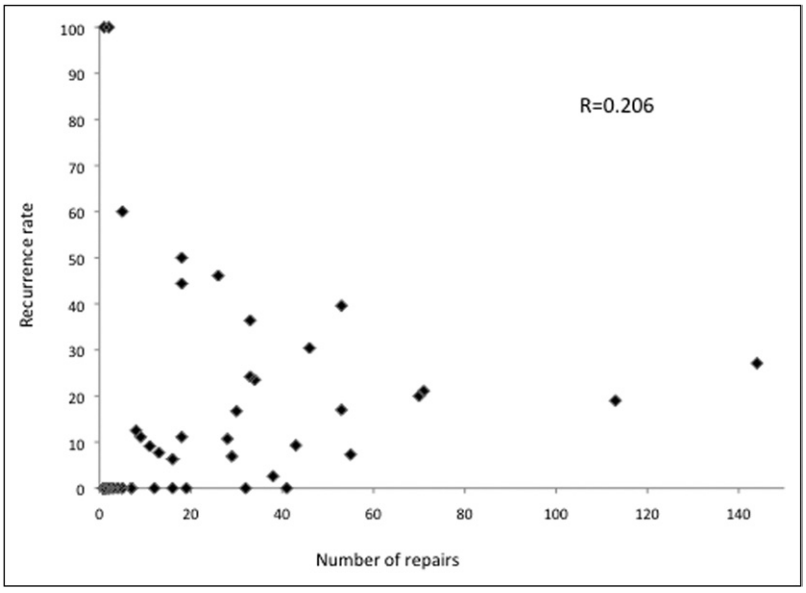

Figure 3 Scattergram of recurrence rates versus procedure number (ie, the denominator from which the rate was calculated). Each diamond represents the rate from one study. Data are summarized in Table 3. R = correlation coefficient for a linear curve fit.

mucosa, 82.6%; xenogenic dermis, 50.7%; and xenogenic pericardium, 6.3%). The SSO according to the VHWG grading system could not be evaluated accurately because of inadequate study details of several reports.

Because the level of collagen cross-linking can define whether a mesh acts more like biologic or prosthetic we combined the data for all porcine cross-linked mesh and compared these data with the porcine non–cross-linked mesh for both infection and recurrence. Interestingly, these data showed that the recurrence rate for the porcine cross-linked mesh (Permacol, Collamend) was 11.2% (20 of 179) and 10.1% (27 of 267) for the porcine non–cross-linked mesh (Surgisis, Strattice, XenMatrix, and Surgimend). Infection rates for the porcine cross-linked and non–cross-linked mesh were 9.1% and 18.6%, respectively.

Comments

This systematic review summarizes the published results on the use of biological prosthesis for incisional hernia repair. Unfortunately, there are no data establishing superiority or even equivalency to permanent synthetic meshes in

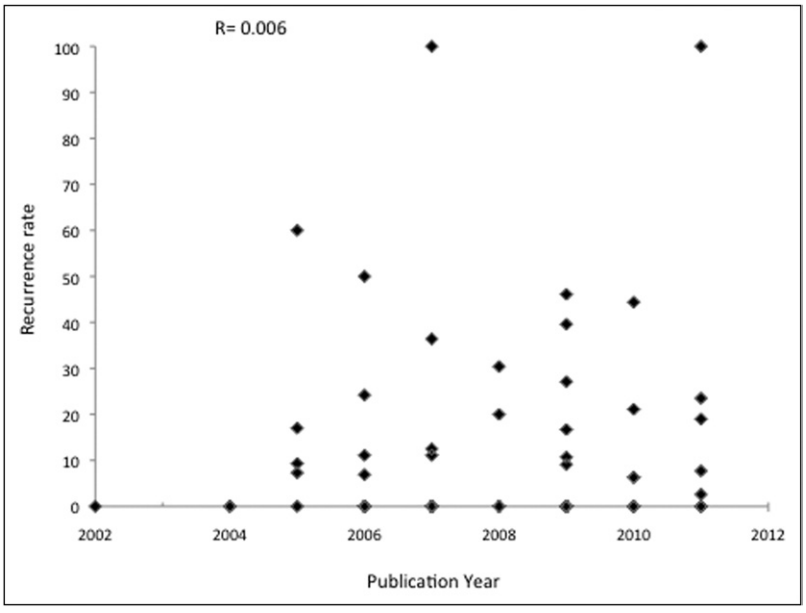

Figure 4 Scattergram of recurrence rate versus year of publication. R = correlation coefficient for a linear curve fit.

Table 4 Surgical site occurrences

Surgical site occurrences	Number reported (%)
Postoperative infection	157 (16.9)
Hematoma/seroma	112 (12.0)
Pain	44 (4.7)
Bulging/abdominal wall laxity	39 (4.2)
Superficial dehiscence	35 (3.8)
Fistula	30 (3.2)
Acute mechanical failure/evisceration	19 (2.0)
Skin necrosis	8 (.9)
Mesh reaction/rejection	8 (.9)
Poor mesh integration	8 (.9)
Mesh disintegration	5 (.5)
Flap necrosis	3 (.3)
Other	23 (2.5)
Total	491 (52.8)

patents with incisional hernia repairs owing to the absence of comparative clinical trials. In addition, our review found no robust evidence to suggest that any biological prosthetic is superior over others. This review was limited, however, by the type and quality of the studies reported to date in the public domain. We found only cohort studies, case reports, and descriptive case series with poor methodology and research designs and no case-matched studies, or prospective randomized control trials. These findings have important implications because research design and methodologic differences can result in studies reaching different conclusions about treatment efficacy and can even interfere with the detection of true treatment effects. Consequently, we were not able to perform a proper statistical meta-analysis to determine the relative value of biological prosthesis in patients with incisional hernia repairs as it relates to a reduction in risk of hernia recurrence.

The increase in the number of articles published using biological mesh for abdominal incisional hernia repair highlights a dramatic change in the field of hernia surgery. We found 60 articles and more than 1,200 repairs published using the search terms used and most of these were published within the past 5 years. Interestingly, only a few of the biological graft materials in use have hundreds of cumulative patient-years of published experience (eg, AlloDerm), and some (eg, Allomax, Davol, Mansfield, MA; FortaGen, Organogenesis, Canton, MA; DermaMatrix, Synthes, West Chester, PA, and A-cell, Columbia, MD) have no preclinical or clinical peer-reviewed published human data about their use for incisional hernia repair. Hence, a preponderance of publications has been on a limited number of materials that have been in use for the longest period. Indeed, the experience with these biologics is limited and results are still very mixed. Careful review of the literature reveals that most publications on this topic described the use of AlloDerm in the repair of incisional hernias. AlloDerm is known to contain more elastin and less collagen. It is possible, although unproven, that the amount of elastin results in the stretching and laxity reported with AlloDerm. Interestingly, several case reports and series have indicated efficacy, but our data show a high recurrence rate compared with other biological prosthesis so the reports must be viewed cautiously.

Across all the biological grafts, there were slightly more hernia repairs performed in patients considered to have grade 2 as opposed to grades 3 or 4 hernias (potentially contaminated or infected). This observation is similar to the previous findings of Hiles et al,[106] who found that the published experience for biological mesh was much greater in clean field cases (75%) than in infected fields. According to the VHWG, grade 2 represents a broad range of patients who have comorbidities that might increase the risk for developing an SSO such as infection, but have no evidence of wound contamination or active infection. Therefore, there may be a potential advantage to some biological repair materials for hernia repairs in patients considered grade 2. In our review, we were unable to separate the SSO by the VHWG grading system and thus were not able to make any data-driven recommendations regarding this recommendation regarding the use of biological prosthetics for patients with specific hernia grades.

Similar to a previous review on biological prosthesis,[106] the lowest recurrence rates were seen with porcine small intestinal submucosa, but with less than a 2-year follow-up period it is difficult to know whether this material will continue to have the lowest reported failure rates among biological meshes. The highest recurrence rates were seen with acellular dermal matrix. This material also had the highest number of publications, and patients treated.

As the study and use of biological prosthetics has increased with time, one would hope and expect that the quality of published studies would increase over time. Our review surprisingly did not find this to be the case. Only 4 studies were considered high quality, scoring the maximum of 12 points on the modified MINORS criteria (1 AlloDerm study, 1 Surgisis study, 1 Permacol study, and 1 both Alloderm and Surgisis study). It is astonishing that despite the substantial increased cost for biological mesh products that there has yet to be any published, well-controlled, clinical trials, let alone any prospective randomized control trials justifying their expense. Until there are data from well-controlled clinical trials showing the short- and/or long-term value of biological mesh in incisional hernia repair, the surgical community should not expect or be surprised if third-party payers do not fully or even partially reimburse their high costs.

Inconsistencies in duration of study, reporting methods, and short patient follow-up periods likely skew published data toward higher success rates than are truly the case. In our review, only 19 repairs (2% of all reported patients reviewed) were reported to have a mechanical failure of the biological product and 5 of all patients reviewed (.5%) were reported to have prosthetic disintegration. If this low incidence of mesh failure is indeed true, then biological meshes differ from permanent prosthetics because most of them,

once infected, have to be removed. It should be noted, however, that this low explant rate is in contrast to a recent review of complications reported to the Food and Drug Administration manufacturer and user facility device experience (MAUDE) database by practitioners and patients who have used or undergone hernia repair with biological mesh devices.[107] In this article, the most common complications were acute mechanical failure (42%), and mesh disintegration (32%). However, because the denominator of infected meshes nationwide is unknown, one cannot know for certain what the real percentage is of infected meshes requiring surgical removal. Nevertheless, the discrepancy between the anonymous voluntary reporting system used for MAUDE and the peer-review medical literature raises concerns regarding publication bias in this field about the true incidence of complications in patients undergoing hernia repair with biological mesh.

The available published evidence suggests that, as a whole, the clinical results of biological mesh application in repair of abdominal wall defects were satisfactory in terms of recurrence (18.3%) and seroma formation (12.0%) in complex hernia repairs. These results are not dissimilar with the outcomes after repair of complex incisional hernia repairs with permanent synthetic mesh.[108] However, the wound infection rate in our review was higher than in most series using synthetic mesh.[109,110] This is most likely because about half of the hernia repairs in our review were performed in potentially contaminated or contaminated surgical fields and the others were performed in patients considered at risk for infection owing to comorbidities.

The use of this review is limited for a number of reasons. First, there was tremendous heterogeneity of the published literature. The selection of patients, severity of hernia, medical comorbidities, surgical technique, type of material used, and manner in which the material was implanted were all widely variable and therefore interpretation of specific covariates on their individual impact on outcomes is difficult and probably not feasible. Other limitations of this review were that only articles in English were included and therefore additional outcomes available in the gray literature or published in other languages was excluded. Another limitation of the review was that most studies did not risk-stratify patients and their outcomes. Despite this weakness, we still were able to classify repairs by the VHWG grading system.

Another limitation of our systematic review may be related to the high degree of publication bias in this field. The number of publications on the use of biological materials probably underestimates the actual use of these materials throughout the world. Although published studies have increased our understanding of some types of complications related to the use of biological mesh for hernia repair, it is possible that the utility and limitations of biological mesh when used for abdominal wall hernia repairs are underreported. The public also needs to appreciate that it is likely that only positive results are being published because publication bias prevents adverse outcomes from being reported. This is particularly true when the results of industry-sponsored large prospective clinical trials are never presented or published because of adverse effects, or less than expected favorable outcomes are observed. One clinical trial that bears mentioning is the Laparoscopic Surgisis (LAPSIS) trial.[111] This randomized controlled multicenter European study compared open retromuscular (mesh augmentation technique) versus laparoscopic repair (mesh bridging technique) and the use of a non–cross-linked biological mesh (Surgisis Gold) versus permanent synthetic mesh for clean primary ventral and incisional hernia with a diameter of 4 to 10 cm, in a 2-factorial design. The primary outcome was major complication rate (hernia recurrence, prosthetic infection, or reoperation associated with previous hernia surgery) within 3 years after surgery. Because of serious concerns with a low rate of patient recruitment, incompleteness of the study data, and a higher preliminary recurrence rate in the biological mesh group compared with the synthetic mesh group, the trial was stopped prematurely. Because the trial was terminated and the clinical outcomes of enrollees was not reported, the potential value of defining the limits and benefits of the particular mesh product being studied (Surgisis Gold) are lost to the surgical community. Such publication bias may result in an overestimation of technical and clinical success rates, and an underestimation of complications and length of hospital stay.

Despite the presence of publication bias that appears to exist in this field, there are a number of high-quality clinical trials registered at http://clinicaltrials.gov that appear to be of sufficient design and statistical power to address many of the shortcomings in the current literature regarding the use of biological mesh for incisional hernia repairs (Table 5). Many of these studies already have accrued large numbers of patients and will have several years of follow-up evaluation at completion. Public disclosure of the results generated from these clinical trials is essential to advance current understanding of the use of biological meshes for incisional hernia repair. Hence, it is sincerely hoped that the results of these trials, whether positive or negative, will be published, or at least presented publicly. A Food and Drug Administration or third-party payer-sponsored mandatory clinical outcomes database, in which long-term risk-adjusted outcomes are reported, also could overcome publication bias. Such a data repository dramatically could enhance current understanding of the limits, benefits, and health care value of biological mesh for incisional hernia repairs.

Conclusions

This systematic review shows that a paucity of high-quality evidence exists in the peer-reviewed medical literature on the use of biological tissue grafts for incisional hernia repair. Although the rationale for using biological prosthesis for complex and contaminated incisional hernias

Table 5 Ongoing clinical trials

NCT number	Product	Trial	Study design	Sponsor	Enrollment/ number of sites	Status	Results expected
01268514	Permacol	Prospective evaluation of Permacol in the repair of complex abdominal wall cases	Prospective	Covidien	200/30	Recruiting	December 2015
892333	SurgiMend	Repair of large abdominal hernia with SurgiMend 3.0	Prospective case-only	TEI	100/5	Recruiting	April 2012
01295125	XenMatrix	Comparative study of biological mesh vs repair with component separation	Randomized	Davol	40/1	Recruiting	February 2014
01426477	Veritas	Veritas in nonbridging ventral hernia repair	Prospective cohort	Synovis	100/1	Recruiting	August 2017
01305486	XenMatrix	A study of complex ventral hernia repair using the XenMatrix surgical graft with component separation	Prospective cohort	Davol	120/1	Terminated	June 2011
01214252	Permacol	A retrospective study evaluating the use of Permacol surgical implant in the repair of abdominal wall defects	Retrospective	Covidien	427/1	Ongoing	January 2012
01205399	AlloMax	A retrospective study with prospective follow-up evaluation of complex ventral hernia repair using the AlloMax surgical graft	Retrospective, cross-sectional	Davol	150/1	Recruiting	December 2010
01083472	Strattice	Repair of significant abdominal midline fascial dehiscence: Strattice in abdominal wall repair	Randomized	LifeCell	200/29	Recruiting	April 2013
01073072	Tutomesh	Study comparing Tutomesh repair with conventional surgical techniques in potentially contaminated hernia repair and abdominal wall reconstruction	Randomized	Centre Hospitalier Regional Universitaire, Montpellier	136/15	Recruiting	September 2011
00930787	Strattice	Hernia repair in multiply morbid patients	Randomized	LifeCell	100/13	Terminated	May 2012
01355939	Multiple meshes*	Comparative effectiveness multicenter trial for adhesion characteristics of ventral hernia repair mesh	Prospective cohort	Washington University School of Medicine	360/7	Recruiting	May 2016

*Alloderm, Allomax, FlexHD, Biodesign Surgisis, Strattice, XenMatrix, Veritas, SurgiMend, Peri-Guard, Permacol, and Collamend.

is related to surgeons' concerns regarding the potential dire consequences of using permanent mesh in contaminated fields, there are yet to be any published prospective clinical trials justifying their preference over conventional mesh materials. Until such evidence is forthcoming, the use of biological prosthetics in complex incisional hernia repairs should proceed with caution. There may very well be a solid place for the use of these materials, but for them to add true value to complex hernia repair, better-designed and reported studies are necessary to help guide clinical practice.

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Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.amjsurg.2012.02.019.