A Meta-Analysis of Outcomes Using Acellular Dermal Matrix in Breast and Abdominal Wall Reconstructions

Event Rates and Risk Factors Predictive of Complications

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Background: The use of acellular dermal matrix (ADM) has gained acceptance in breast and abdominal wall reconstructions. Despite its extensive use, there is currently a wide variation of reported outcomes in the literature. This study definitively elucidates the outcome rates associated with ADM use in breast and abdominal wall surgeries and identifies risk factors predisposing to the development of complications.

Methods: A literature search was conducted using the Medline database (PubMed, US National Library of Medicine) and the Cochrane Library. A total of 464 articles were identified, of which 53 were eligible for meta-analysis. The endpoints of interest were the incidences of seroma, cellulitis, infection, wound dehiscence, implant failure, and hernia. The effects of various risk factors such as smoking, radiation, chemotherapy, and diabetes on the development of complications were also evaluated.

Results: A majority of the studies were retrospective (68.6%) with a mean follow-up of 16.8 months (SD ± 10.1 months) in the breast group and 14.2 months (SD ± 7.8 months) in the abdominal wall reconstructive group. The overall risks and complications were as follows: cellulitis, 5.1%; implant failure, 5.9%; seroma formation, 8%; wound dehiscence, 8.1%; wound infection, 16.1%; hernia, 27.6%; and abdominal bulging, 28.1%. Complication rates were further stratified separately for the breast and abdominal cohorts, and the data were reported. This provides additional information on the associated abdominal wall morbidity in patients undergoing autologous breast reconstruction in which mesh reinforcement was considered as closure of the abdominal wall donor site. Radiation resulted in a significant increase in the rates of cellulitis ($P = 0.021$), and chemotherapy was associated with a higher incidence of seroma ($P = 0.014$).

Conclusion: This study evaluates the overall complication rates associated with ADM use by conducting a meta-analysis of published data. This will offer physicians a single comprehensive source of information during informed consent discussions as well as an awareness of the risk factors predictive of complications.

Key Words: acellular dermal matrix, AlloDerm, meta-analysis, complications, breast reconstruction, abdominal wall reconstruction

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The use of acellular dermal matrix (ADM) is widespread in breast and abdominal wall reconstructions. One of the most commonly used matrices is the human ADM, commonly referred to as AlloDerm (LifeCell Corp, Branchburg, NJ). Currently, ADM has an established role in expander-based breast reconstruction, which is currently the most common form of postmastectomy reconstruction.[1] Its use has been described in the single-stage reconstruction as an inferolateral breast hammock, as well as in 2-stage prosthetic reconstructions.[2–6] It provides capsular reinforcement, reduces rippling, and decreases the incidence of inadequate scar capsule that can contribute to implant bottoming out and undesirable cosmetic results.[7,8] The most common use of ADM in breast reconstruction is to provide coverage of the exposed inferolateral pole of the breast prosthesis.[1,9–13] Several studies have reported on certain outcomes associated with and without the use of ADM. The overall rate of infection in tissue expander and implant-based reconstructions is estimated at 1% to 6%,[14–16] whereas the incidence of infection with ADM use is 0% to 8.3%.[3,10,11,13] Although several factors predispose to infection, the only variable with a significant association reported to date is radiation.[14,16]

ADM use is also used in abdominal wall reconstruction. It is desirable to synthetic mesh alternatives because of the lower risk of adhesions, better incorporation into the surrounding tissues, and decreased risk of infection. Radiation and fecal contamination have been shown to increase the risk of prosthetic mesh complications such as infections, fistula formation, and hernia development.[17–20] Furthermore, AlloDerm use in abdominal wall surgeries has become prevalent over the years because of the minimal adhesion formation, increased resistance to infection, and its ability to integrate and revascularize within host tissues.[21–25] In autologous breast reconstructions, AlloDerm is often incorporated during closure of the abdominal wall to reinforce the abdominal donor site following flap harvest. In a critical review of 300 patients, Hartrampf and Bennett reported the incidence of hernia and abdominal wall laxity at 0.3% and 0.6%, respectively, following transverse rectus abdominis myocutaneous flap reconstruction without mesh use.[26] However, other authors have reported rates of hernias and abdominal wall laxity as high as 44% when primary closure was used.[27] For these reasons, many surgeons have switched from primary closure to ADM use in closure of the abdominal wall donor sites during transverse rectus abdominis myocutaneous reconstruction. In additional, several plastic and general surgeons managing complex abdominal wall hernias routinely incorporate ADM in their reconstructions.

Because of its extensive use, most surgeons consider the discussion of AlloDerm use as a routine part of the informed consent process. However, there is variation in the literature regarding complication rates and outcomes associated with its use. The goal of this study was several-fold: (1) conduct a systematic literature review by performing a meta-analysis of, specifically AlloDerm, in breast and abdominal wall reconstructions; (2) elucidate the complication rates associated with its use. These complications of interest were seroma, cellulitis, wound infection, hernia rates, and

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implant failure; (3) compare the complication rates between AlloDerm and non-AlloDerm reconstructions; (4) compare initial tissue expander fill volumes intraoperatively, and mean time to completion of tissue expansion with AlloDerm use versus total submuscular coverage; (5) evaluate the effect of several risk factors in the development of complications. These risk factors include age, body mass index, smoking, diabetes, chemotherapy, and radiation; (6) synthesize the above data in a single comprehensive source that can be referenced by both physicians and patients during the informed consent process.

METHODS

Literature Search and Study Selection

A thorough literature search was conducted using the Medline database (PubMed, US National Library of Medicine) and the Cochrane Library for publications involving the use of AlloDerm. The search was intentionally kept broad, using all permutations and combinations of the following words to generate an exhaustive list of references: AlloDerm, seroma, acellular dermis, cadaveric dermis, decellularized human cadaveric dermis, decellularized human dermis, AlloDerm regenerative tissue matrix, breast, abdomen, abdominoplasty, panniculectomy, metaanalysis, mastectomy, hernia, abdominal wall reconstruction, and breast reconstruction. Search terms used were "AlloDerm and seroma," "acellular dermis and seroma," "cadaveric dermis and seroma," "decellularized human cadaveric dermis," "AlloDerm regenerative tissue matrix and seroma," "AlloDerm regenerative tissue matrix," "AlloDerm and breast," "acellular dermis and breast," "AlloDerm and meta-analysis," "AlloDerm and abdomen," "AlloDerm and abdominoplasty," "AlloDerm and panniculectomy," "acellular dermis and panniculectomy," "acellular dermis and meta-analysis," "cadaveric dermis and breast," "acellular dermis and breast," "acellular dermis and abdomen," "acellular dermis and abdominoplasty," "acellular dermis and panniculectomy," and "acellular dermis and mastectomy," "acellular dermis and hernia," "cadaveric dermis and seroma and hernia," "cadaveric dermis and seroma and breast," and "acellular dermis and seroma and breast." Whenever search terms generated overlapping articles, the duplicates were discarded. This initial search generated a total of 464 articles.

Inclusion and Exclusion Criteria

Studies considered eligible for inclusion were breast and abdominal wall reconstructive cases in which AlloDerm was used in human subjects only. The 464 articles generated were closely reviewed, and the inclusion and exclusion criteria were applied. On this initial perusal, nonhuman studies and studies involving the use of porcine or other noncadaveric dermal matrices were excluded. Studies including the use of AlloDerm in the following areas were identified and excluded: head and neck, urologic, neurosurgical, cardiothoracic, gastroesophageal, burn, and pediatric, and surgeries, leaving 68 eligible articles.[1–3,5–7,9–11,13,16,21,22,28–82] Of these, a few additional articles were identified that were ineligible for analysis. These were discussion articles, letters to editors, case reports, and narrative articles without statistical data. This resulted in a final total of 53 articles eligible for analysis.[1–3,5,6,9–11,13,16,21,28,29,31,33–37,40–45,47–50,55–74,77–79,81]

Study Endpoints, and Measured Outcomes

The endpoints of interest were the incidence of seroma formation, wound dehiscence, cellulitis, wound infection, implant failure, and hernia rates. Implant failure was defined as unplanned explantation of a tissue expander or implant, or removal of previously placed AlloDerm. Several risk factors including smoking, diabetes, radiation, and chemotherapy were evaluated to elucidate any potential associations with the development of complications.

Data Abstraction

To maintain consistency, the primary author (O.A.A.) performed the literature search and subsequently reviewed full text articles and abstracts to determine studies fulfilling the eligibility criteria. Following this, team members including the statistical staff met to discuss sample articles, study goals, and data abstraction before data entry. Data were subsequently abstracted by the first 2 authors (O.A.A. and S.E.S.) and recorded in excel format. It is important to note that no interpretations or assumptions regarding

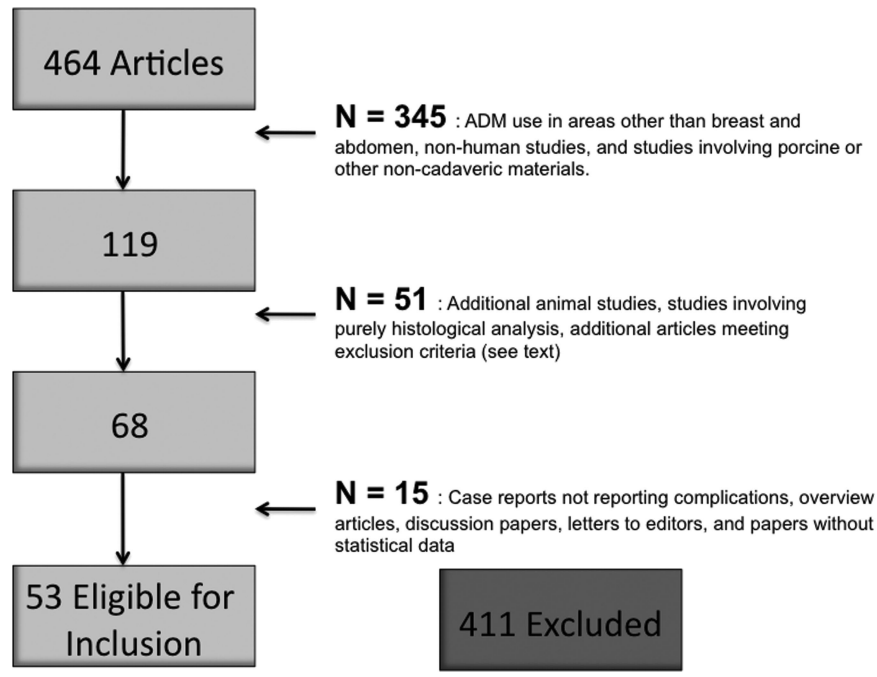

FIGURE 1. Article selection by application of inclusion and exclusion criteria.

the data were made. If the authors failed to report a particular complication, the lack of reporting was not interpreted as the absence of such complication, but rather was noted as not reported for data analysis purposes. Regarding abdominal wall donor site complications, some articles reported this end point as "abdominal bulging" while others reported it as "hernia." To preserve data integrity, we maintained these endpoints as 2 distinct outcomes as well. In articles comparing AlloDerm with other matrices, the data specific to AlloDerm was abstracted and included in the statistical analysis to ensure all data points were captured for analysis.

TABLE 1. Overall Outcome Rates Associated With ADM Use

Complications	Overall Incidence (%)
Seroma	8
Cellulitis	5.1
Wound dehiscence	8.1
Wound Infection	16.1
Implant failure	5.9
Hernia	27.6
Bulging	28.1

Complication	Breast (%)	Abdomen (%)	P-value
Seroma	4.1	11.8	0.000
Bulging	N/A	28.1	N/A
Cellulitis	4.4	17	0.017
Wound dehiscence	2	10.9	0.113
Wound infection	5.1	24.6	0.000
Implant failure	6.1	3.4	0.461
Hernia	N/A	27.6	N/A

FIGURE 2. Complications by group (breast vs. abdominal wall reconstruction).

RESULTS

Figure 1 shows the data mining process that resulted in the eligible articles included in this study. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 18. Most of studies were retrospective (68.6%). The mean follow-up in the breast group was 16.8 months (SD ± 13.2 months) and in the abdominal wall reconstruction cohort was 14.2 months (SD ± 7.8 months).

The overall outcomes are summarized in Table 1. The highest complication rates were noted with bulging and hernia. Bulging occurred with a frequency of 28.1%, and the rate of hernia development was 27.6%. Complications were further classified by breast versus abdominal wall reconstructive cases (Fig. 2). There was a statistically significant difference in the rates of seroma formation ($P < 0.0001$), wound infection ($P < 0.0001$), and cellulitis ($P = 0.017$) between the 2 groups. Although the overall risk of wound infection was 16.4%, there was a significant difference in occurrence between the breast (5.1%) cohort when compared with the abdominal group (24.6%). Sample forest plots with associated 95% confident intervals (CIs) are also illustrated for the complications reported (Figs. 3–7). Inherent to meta-analysis is the concept of publication bias. To investigate the effect of publication bias and the degree to which this bias exists, funnel plots were generated for the complications reported. When interpreting funnel plots, it is critical to evaluate the dispersion of all data points with respect to the inverted V shape like a funnel (hence the name of the plot). The presence of data points beneath the inverted V indicates cohesion among the data points, and hence the presence of minimal publication bias. Conversely, the presence of data points outside the inverted V of the funnel plot indicates the presence of significant publication bias. As illustrated in the funnel plots (Figs. 8–12), most of the data points fall beneath the inverted V of the funnel, giving the true appearance of an inverted funnel. These nearly symmetrical plots indicate that publication bias is minimum, and thus, the reported complication rates are likely a true reflection of actual expected outcome rates without significant effect from publication bias.

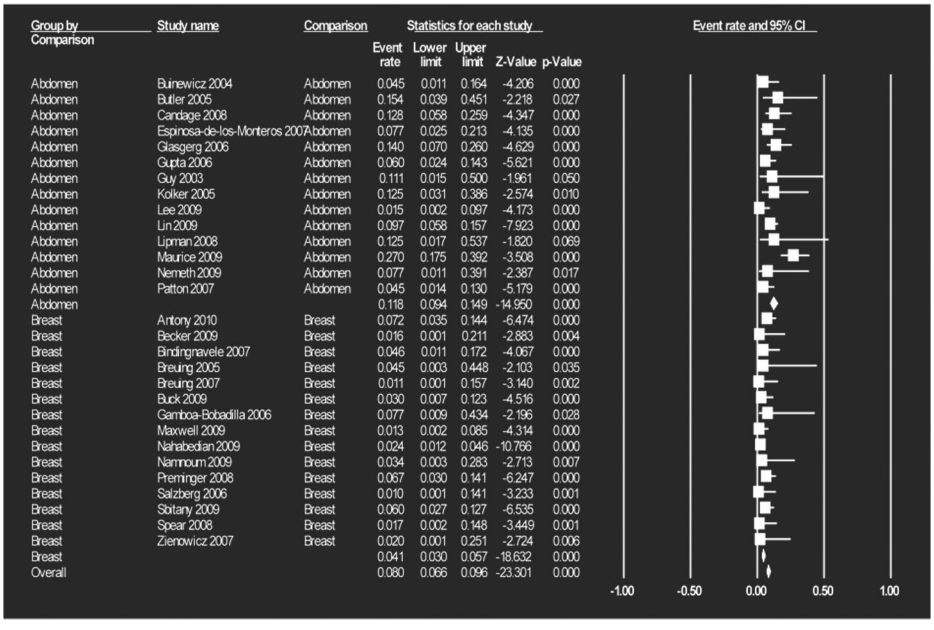

FIGURE 3. Forest plot showing rates of seroma with 95% confidence intervals.

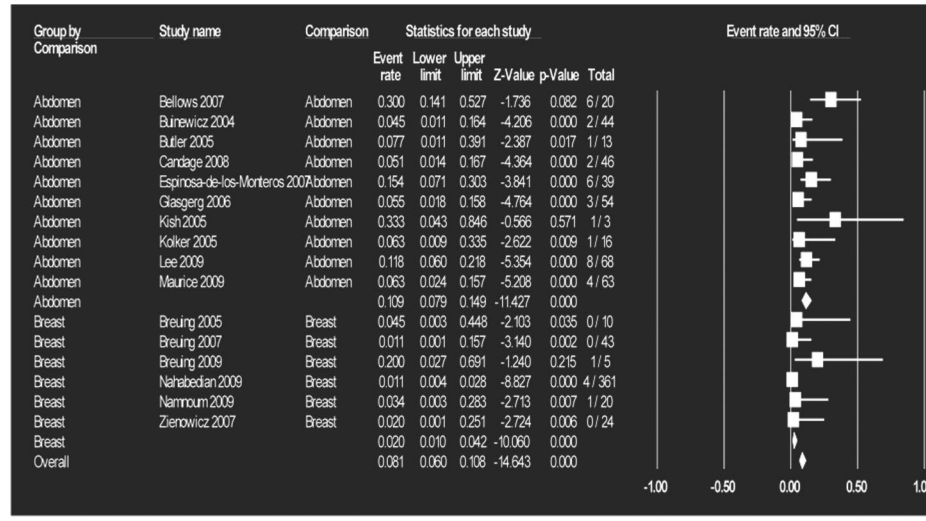

FIGURE 4. Forest plot showing rates of wound dehiscence complications with 95% confidence intervals.

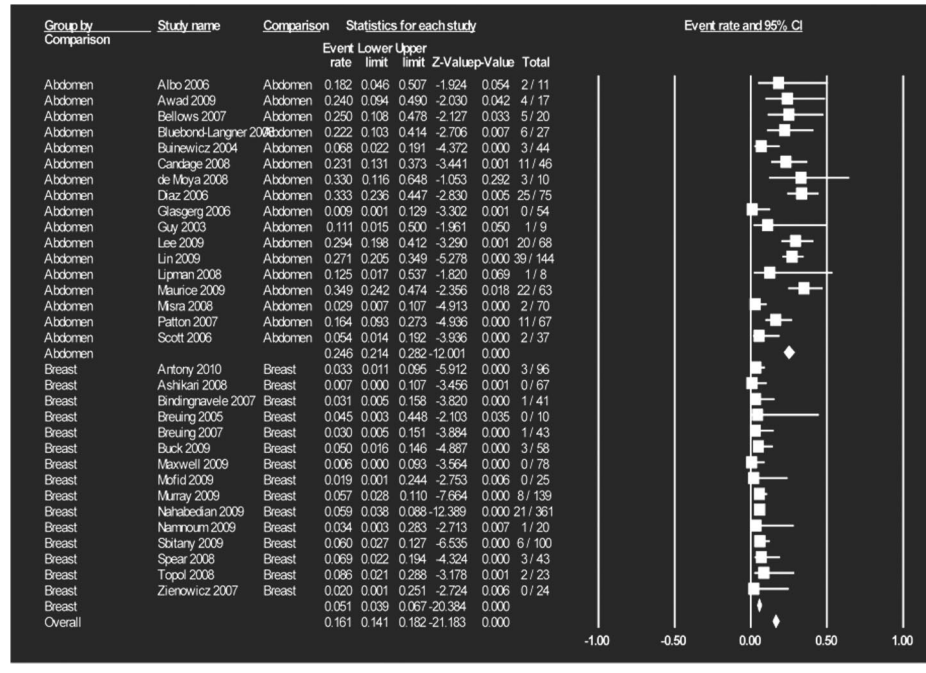

FIGURE 5. Forest plot showing rates of wound infection with 95% confidence intervals.

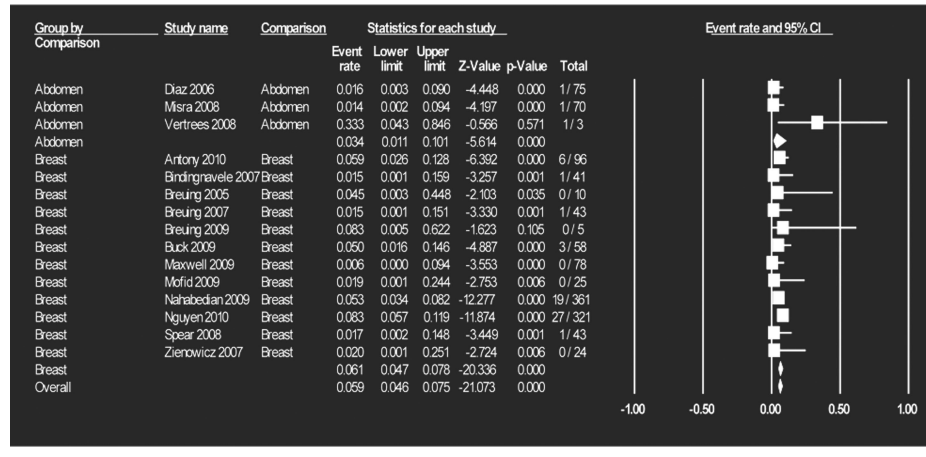

FIGURE 6. Forest plot showing rates of implant failure with 95% confidence intervals.

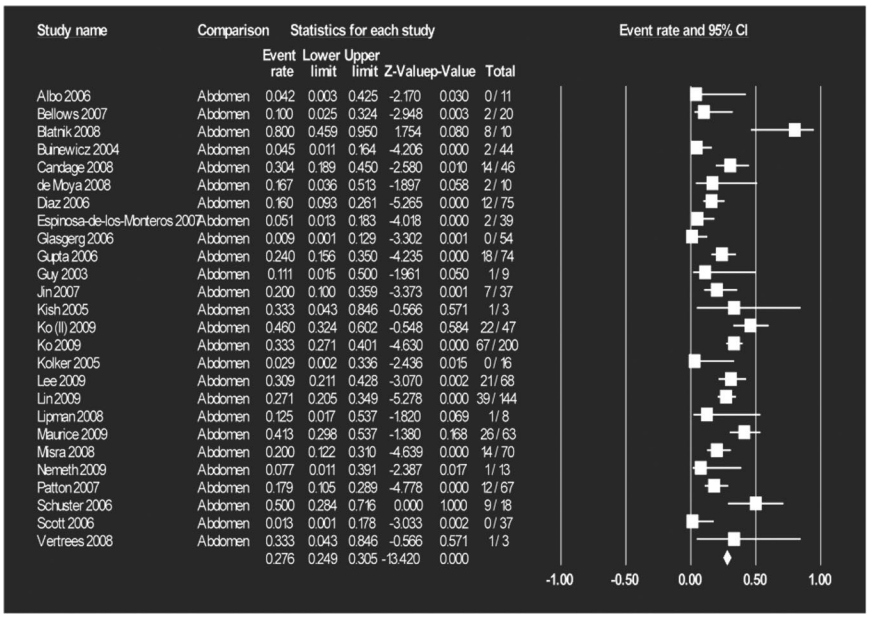

FIGURE 7. Forest plot showing rates of hernia formation with 95% confidence intervals.

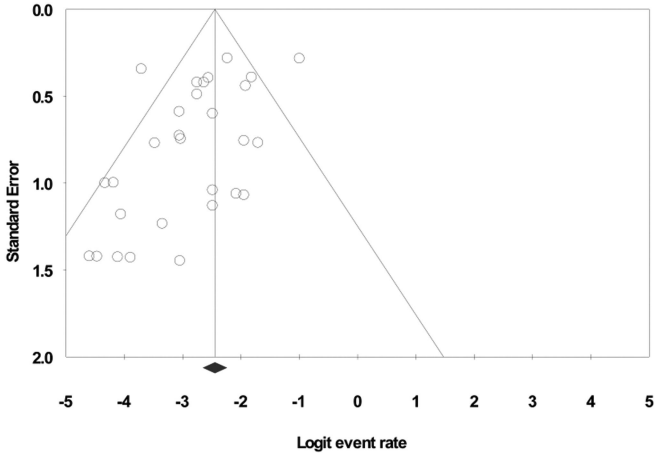

FIGURE 8. Funnel plot to evaluate the effect of publication bias on rates of seroma.

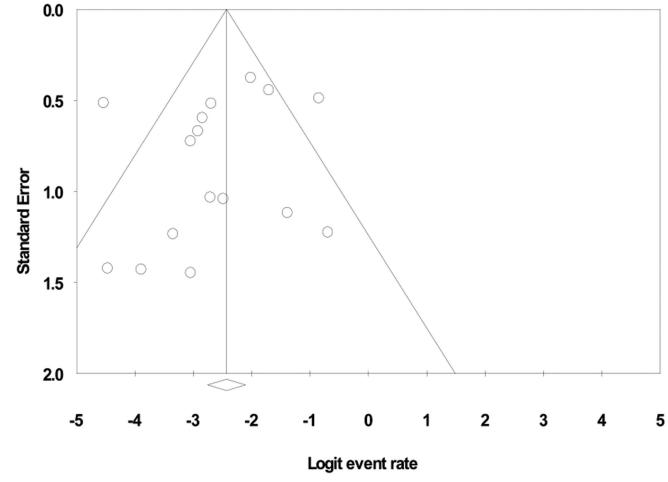

FIGURE 9. Funnel plot to evaluate the effect of publication bias on rates of dehiscence.

Several risk factors were studied to evaluate which factors, if any, correlated with the development of complications. Independent sample *t* tests were used in analysis, and *P* values and CIs are reported. A $P < 0.05$ was considered statistically significant. Radiation was found to be significantly associated with the development of cellulitis ($P = 0.021$ with 95% CI = 0.035, 0.206), and chemotherapy was associated with the development of seroma ($P = 0.014$, 95% CI = 0.018, 0.119). There was a trend toward increased rates of wound infection in patients treated with chemotherapy, but this was not statistically significant ($P = 0.068$). These results are summarized in Table 2. No significant correlations were noted with the remaining risk factors.

Certain study objectives were not amenable for analysis. For instance, there was insufficient reporting on age and body mass index across the articles, thus meaningful pooled analysis could not be generated to evaluate the effect of these variables on the development of complications. Similarly, there was insufficient standardized reporting and data comparison across all articles comparing complications rates in AlloDerm versus non-AlloDerm use. We also set out to investigate whether initial tissue expander fill intraoperatively and subsequent mean times to the completion of tissue expansion was significantly different in patients undergoing AlloDerm-based breast reconstruction compared with patients with total submuscular coverage. Again, very few of the articles consistently addressed this end point making it difficult to generate meaningful outcome analysis.

DISCUSSION

The use of AlloDerm in breast and abdominal wall reconstruction has gained popularity because of several desirable properties. It is tolerant to infection and revascularizes quickly,[21,47] and animal models have shown increased collagen deposition and organization, good host cell proliferation, and promising tensile strength and lymphatic development.[46,75,83–85] Because of its viscoelastic nature, it is recommended that ADM should be inset under some tension,[70] but stretching and a decrease in tensile strength have been reported to occur likely due to the elastin contained in the product.[16,36,49,55,86,87] AlloDerm has also been

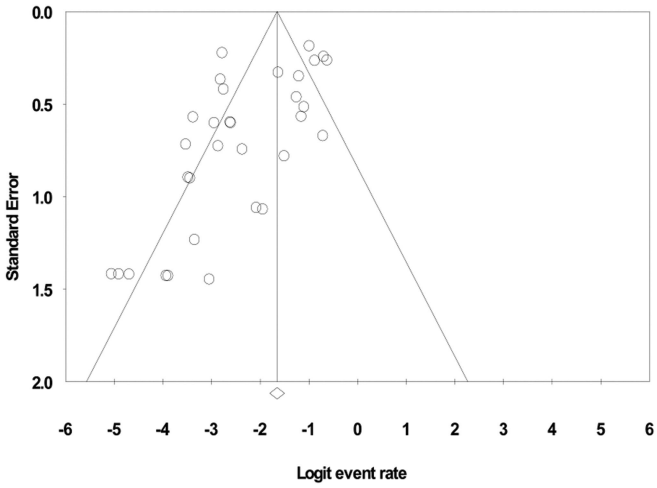

FIGURE 10. Funnel plot to evaluate the effect of publication bias on rates of wound infection.

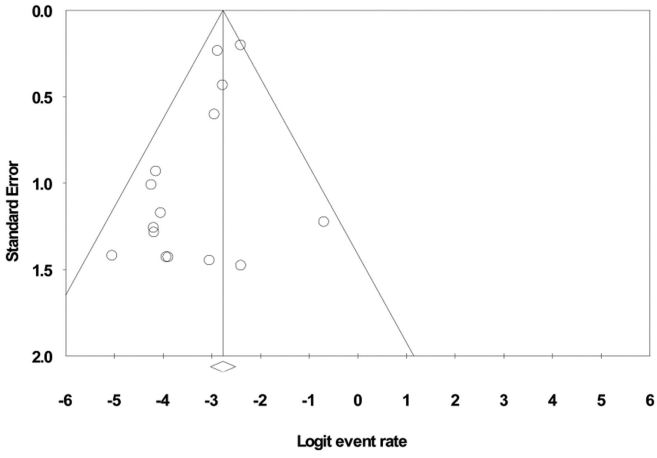

FIGURE 11. Funnel plot to evaluate the effect of publication bias on rates of implant failure.

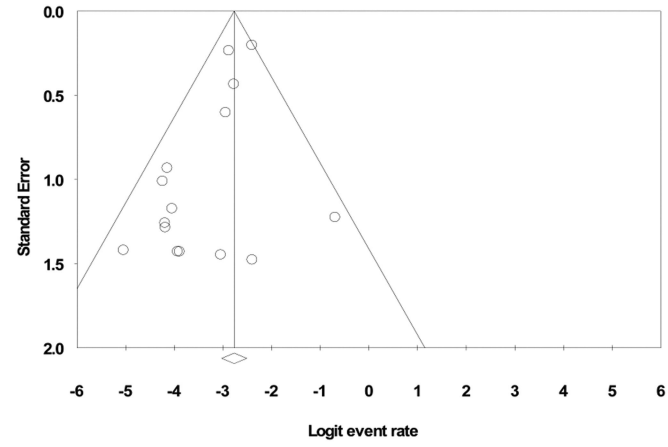

FIGURE 12. Funnel plot to evaluate the effect of publication bias on rates of hernia.

TABLE 2. Complications Based on Risk Factors With Associated *P* Values

	P			
Complications	**Diabetes**	**Smoking**	**Radiation**	**Chemotherapy**
Seroma	0.193	0.594	0.664	0.014*
Cellulitis	0.897	0.873	0.021*	0.734
Wound dehiscence	0.379	0.136	0.216	0.271
Wound infection	0.363	0.389	0.324	0.068
Implant failure	0.868	0.132	0.103	0.346
Hernia	0.251	0.382	N/A	N/A
Bulging	0.193	0.192	N/A	N/A

*Significant *P* value.

shown to reduce the effect of radiation-related inflammation in animal models presumable by retarding the progression of capsular formation, fibrosis, and contraction.[83,84] This study set out to elucidate the rates of outcomes associated with AlloDerm use in breast and abdominal wall reconstructions, specifically regarding seroma formation, infection, wound dehiscence, hernia, and implant failure. The effect of various risk factors on the development of complications is also presented.

Overall complication rates were lower in the breast group. In this cohort, the rate of seroma formation was 4.1%, and incidence of implant failure was 6.1%. The highest complication rates in abdominal wall reconstruction were seen with abdominal bulging (28.1%) and hernia development (27.6%). If one assumes these 2 complications (abdominal bulging and hernia) are on spectrum, the combined incidence for both complications is 55.7%. This represents a rather high risk of abdominal wall sequela, and it will be prudent for physicians to discuss this with patients during informed consent process. This is especially important in patients undergoing autologous breast reconstruction in which the abdominal wall is the proposed donor site. In these cases, mesh reinforcement is usually considered for donor site reinforcement after flap harvest. It is likely that the properties that make AlloDerm a good adjunct in breast reconstruction, specifically its elastic quality, may make it unsuitable for long-term integrity in abdominal wall reconstruction as illustrated by the incidence of hernia and bulging. This meta-analysis also demonstrates a statistically significant association with the development of cellulitis in patients with radiation and seroma formation in chemotherapy patients. There was a trend toward increased wound infection in chemotherapy-treated patients, but this finding did not reach significance.

None of the other variables showed a significant association with development of complications in this meta-analysis. It is possible that there are links between the other risk factors and several complications as reported in individual articles, but collective analysis of the literature at this time does not establish this correlation. Certain study objectives were not finalized for several reasons. One of such objectives was to compare AlloDerm to other nonsynthetic mesh alternatives such as Surgisis (Cook Surgical, Bloomington, Indiana) and DermaMatrix (Synthes, Inc, West Chester, PA). However, the number of publications addressing these comparisons was too limited to generate meaningful pooled analysis. Another study goal was to compare AlloDerm versus total submuscular coverage in breast reconstruction to compare complication rates and time to completion of expander-based reconstruction based on time to completion of expansion. Again, there was insufficient homogenously reported data to allow for strong comparative analysis for these specific endpoints. Although at the present time, readers may need to refer to the individual studies to

address these specific questions, larger studies in the future will be invaluable in delineating some of these objectives.

There are certain potential limitations to this study. First is the inclusion of articles written in the English language. However, abstracts for all the 464 articles were available in English; therefore, we were able to apply our inclusion and exclusion criteria to the possible eligible articles. Although it is not impossible, it is very unlikely that we have excluded an important study in another language. Another probable limitation is the possibility that fugitive literature, such as dissertation theses or government documents, may have been overlooked.[88] In addition, data with positive results are more likely to be submitted and/or accepted for publication compared with studies with negative or null results,[89,90] and thus, it is possible that there is an inherent bias in the published literature used for meta-analysis. A funnel plot provides a helpful adjunct in evaluating the effects of publication bias, and as our results indicate publication bias in this study appeared to be minimal. Despite these possible limitations, this study provides useful information on complication rates associated with AlloDerm use and risk factors predictive of complications. By pooling available data to date, this analysis offers invaluable information in the absence of a randomized controlled trial addressing these questions.

CONCLUSION

This meta-analysis provides a comprehensive overview of the outcome rates associated with AlloDerm use. Radiation and chemotherapy are significantly associated with the development of cellulitis and seroma, respectively. The high rates of abdominal wall bulging and hernia suggest AlloDerm may not be the ideal material for use in abdominal wall reconstructions when donor site morbidity is a concern. Although larger, prospective, randomized studies are needed to make definitive conclusions, this article provides an invaluable reference in the surgeon's armamentarium during preoperative counseling, intraoperative decision-making, and postoperative management of breast and abdominal wall reconstructive patients in which the use of AlloDerm is contemplated.

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