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Review

A systematic review of complications in prepectoral breast reconstruction☆

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Summary The use of implants for breast reconstruction began over four decades ago, with implants initially placed in the prepectoral space. Concerns arose regarding the high incidence of capsular contracture and complication rates. With the introduction of acellular dermal matrix (ADM), plastic surgeons are again considering the advantages of prepectoral implant placement. A systematic review was conducted to examine complication profiles in prepectoral breast reconstruction alone versus prepectoral with ADM or mesh.
A systematic review of the PubMed database was performed from inception to March 2017 to identify literature on postmastectomy patients undergoing prepectoral breast reconstruction with and without ADM or mesh. Study characteristics, complication rates, and outcomes were extracted for analysis. Study quality was assessed using the Newcastle–Ottawa Scale, and complication profiles were analyzed using the random-effects model.
Twenty-seven studies met criteria for inclusion out of 550 identified for review. For 1881 total breasts, the complication rate with ADM was 23.4%, while the rate without an additional implant material was 27.5%. The difference in the capsular contracture rate with and without ADM was 2.3% and 12.4%, respectively.
The use of ADM in prepectoral breast reconstruction correlated with lower capsular contracture and overall complications rates; however, rates of implant loss, infection, and mastectomy flap

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necrosis were higher with the use of ADM. Results were variable across studies, and in general, the quality of evidence reported was low. Because the methodology for outcome assessment was inconsistent, there is a need for further investigation with comparative studies and standardized outcome reporting.

Contents

Introduction

The use of implants for reconstruction after mastectomy began over four decades ago when Snyderman and Guthrie first used the Cronin silicone implant for these procedures.[1] Initially, implants were placed prepectorally, and only small sizes could be used to avoid excessive tension on the skin with the potential for skin necrosis or implant extrusion. In the decades following, there were numerous published reports of high complication rates with prepectoral placement of tissue expanders and implants, as well as high rates of capsular contracture.[2-5] These findings contributed to a paradigm shift away from prepectoral and toward submuscular implant placement.

Advantages of submuscular implant placement stem from the added layer of tissue between the implant and the mastectomy flap. These include additional protection against implant exposure in cases of wound breakdown, a decrease in visible rippling particularly with saline implants, and a proposed decreased rate of capsular contracture.[2,6] Drawbacks of the submuscular technique include deficiencies in upper pole contour, animation deformity, and increased postoperative pain and length of recovery secondary to muscle dissection.[7-9]

The introduction of acellular dermal matrix (ADM) in breast reconstruction in 2005 led to several improvements in submuscular reconstruction, including improved definition of the inframammary fold, decreased capsular contracture rates, prevention of implant migration, and decreased tension on mastectomy skin flaps leading to increased initial expansion volumes.[10-14] However, the use of ADM did not address postoperative pain, recovery time, or animation deformity and may be associated with increased rates of infection and seroma.[15,16] Synthetic mesh products have also proven to be safe and effective in implant-based breast reconstruction to address the same problems as those with ADM but are used less frequently in the United States.[17]

Along with the use of ADM for implant coverage, many refinements in the techniques for oncologic resection and subsequent reconstruction have occurred since the first attempts at prepectoral reconstruction. In light of these advancements, prepectoral implant-based breast reconstruction has re-emerged as a viable surgical technique after skin or nipple-sparing mastectomy. Supporters posit that these procedures carry less morbidity and provide more natural-looking results. In addition, animation deformity is no longer an issue with prepectoral placement. According to the ASPS Plastic Surgery Statistics Report in 2015, over 106,000 breast reconstruction procedures were performed in the United States. Implant-based reconstructions were the most common procedures, and ADM was used in 53% of the surgeries.[18] Despite this impressive scale, the current literature on prepectoral breast reconstruction with ADM is limited.

Systematic reviews on prepectoral breast reconstruction by Salibian et al. and Chatterjee et al. found relatively low pooled complication rates; however, follow-up times and complication rates across studies were inconsistent.[19,20] These reviews mainly included reconstructions incorporating the use of ADM or mesh; outcomes with and without additional implant material have not yet been reviewed. A systematic review was conducted to examine outcomes in postmastectomy patients undergoing breast reconstruction using prepectoral placement of TEs and implants, and then, the complication profiles with and without the use of ADM or synthetic mesh were compared.

Methods

Literature search

A broad search of the literature was performed using the PubMed database from inception to March 2017. The database was queried using the following search terms: “breast” and “implant” and “subcutaneous” or “sub-cutaneous” or “prepectoral” or “pre-pectoral.” In addition, the references of relevant studies were reviewed for potential inclusion.

Study selection and data extraction

Studies were considered eligible if they reported on outcomes and complications of breast reconstruction with prepectoral implant or tissue expander placement in post-mastectomy patients. Two authors independently evaluated each eligible study, and selection was determined based on two levels of screening. Titles and abstracts were first reviewed for the following exclusion criteria: papers that solely discussed surgical techniques, individual case reports, systematic reviews with studies already included in our review, studies with patients already included in our review, and languages other than English. The studies were then read in full and further selected using the predetermined exclusion criteria. Information from the articles that passed both levels of screening was extracted for analysis using a standardized data collection sheet (see Tables 1 and 2). Studies were also reviewed for study design, patient selection, comparability, and outcome of interest.

Quality assessment

Study quality was assessed using the Newcastle–Ottawa Scale (NOS). Again, two authors independently evaluated each study for selection, comparability, and outcome of interest using the established star-based system. When the two quality scores were not in concordance, a joint re-evaluation of the original article was conducted. Length of follow-up was not part of the established exclusion criteria; rather it was used as part of the study quality assessment. Adequate patient follow-up was established as greater than 90%, and adequate follow-up period was established for greater than one year. The evaluation of bias is incorporated into the NOS, and this scale was used to indirectly assess the risk of bias at the study level.

Analysis

A meta-analysis of patients who underwent breast reconstruction with prepectoral implant placement was conducted separately for groups with ADM and synthetic mesh, ADM alone, and no additional material. The pooled complication rates and confidence intervals were calculated based on the random-effects model. Heterogeneity was evaluated using the Cochran Q and I^2 tests. Funnel plots were used to access the publication bias. The analyses were performed using the meta for package for R version 3.3.1. *P*-values less than 0.05 were considered statistically significant.

Results

Study characteristics

A total of 550 articles were identified using our search terms and inclusion criteria. After two levels of screening, 27 articles were identified for analysis in our systematic review (see Figure 1). The 27 studies included a total of 1881 breasts or procedures. The majority of articles reported complications according to the number of breasts, as we did in this review. When examining material for implant or tissue expander coverage, there were 893 breasts with ADM, 18 breasts with Vicryl mesh, and 64 breasts with titanium-coated polypropylene mesh (TCPM). Six studies reported on complications with both tissue expanders and implants during staged reconstruction, while two studies reported solely on TE-based complications (see Table 1).

Follow-up time was reported as a mean when possible, but because of the heterogeneity of the articles, this was also recorded as a median or range when mean was unavailable. There were eight studies with follow-up times of less than one year and one study for which follow-up time was not stated (see Table 2). Complications extracted from each study included capsular contracture, infection, seroma, hematoma, implant loss/reconstructive failure, mastectomy flap necrosis, and nipple-areola complex necrosis (see Table 1). Not all studies specifically commented on each of these complications. Complications not extracted but included in the overall complication rate included iatrogenic TE puncture with deflation, implant rupture, severe rash, and silicone granuloma requiring excision. Rippling and recurrence requiring repeat operation were not considered complications in this review.

Study quality

Content, quality, and inter-rater reliability were assessed using the Newcastle–Ottawa Scale. On average, studies received 4.8 stars. Zhu et al., Bernini et al., and Gruber et al. received the highest ratings at seven stars.[2,6,21] Reitsamer and Peintinger and Hartley et al. received three stars as a result of weak patient selection, lack of controlled variables, and inadequate follow-up (see Table 2).[22,23] In general, studies were weakest with regard to comparability, with only three studies receiving stars in that category.

Complications

The overall complication rate in breast reconstruction with TEs and implants placed in the subcutaneous plane was 25.5% based on 1881 breasts or patients. The complication rate with the use of ADM was 23.4% and without the use of any additional material for coverage was 27.5%. Kobraei et al. used Vicryl mesh in all cases with the addition of ADM in three cases, while Zhu et al. used ADM in 30% of cases; however, they did not stratify their complications by material

Table 1 Study characteristics and complications.

Reference (author, year)	Prosthesis	Additional Implant Material	Complication Rate (%)	Capsular Contracture (%)	Infection (%)	Seroma (%)	Hematoma (%)	Implant Loss (%)	Mastectomy Flap Necrosis (%)	NAC Necrosis (%)
Salibian et al., 2017	Implant, TE	None	18.8	7.6	2.4	NS	2.0	3.6	3.6	3.2
Sigalove et al., 2017	Implant	ADM, human (all)	9.1	0	4.5	2.0	NS	NS	2.5	NS
Woo et al., 2017	Implant, TE	ADM, human (all)	9.6	NS	2.2	1.5	2.2	2.2	1.5	NS
Caputo et al., 2016	Implant	ADM, porcine (all)	7.4*	NS	0	NS	NS	0	7.4	NS
Downs and Hedges, 2016	Implant	ADM, human (all)	81.0	10.1	10.1	15.2	NS	17.7	27.8	NS
Kobraei et al., 2016	Implant	Vicryl mesh (+ADM, 3 cases)	38.5*	0	7.7	23.1	7.7	7.7	0	NS
Schnarrs et al., 2016	Implant, TE	ADM, human (all)	19.7*	NS	NS	NS	NS	NS	NS	NS
Zhu et al., 2016	TE	ADM, human (30%); None (70%)	16.0	NS	2.0	10.0	NS	0	4.0	NS
Becker et al., 2015	Implant	ADM, human (84%); Vicryl (16%)	29.0*	6.4	3.2	3.2	3.2	6.4	6.4	NS
Bernini et al., 2015	Implant	TCPM (all)	12.8	0	0	0	2.6	7.7	2.6	0
Casella et al., 2015	Implant, TE	TCPM (all)	24.0	NS	16.0	0	4.0	0	4.0	NS
Hammond et al., 2015	Implant	None	26.3	21.1	0	5.3	NS	0	NS	NS
Reitsamer and Peintinger, 2015	Implant	ADM, porcine (all)	13.6	0	NS	NS	4.5	NS	NS	15.4
Berna et al., 2014	Implant	ADM, porcine (all)	20.0	0	4.0	16.0	NS	12.0	0	NS
Engel et al., 2013	TE	None	8.7	0	0	4.3	4.3	4.3	0	NS
Bayram et al., 2010	Implant	None	15.4	NS	NS	NS	NS	0	NS	15.4
Benediktsson and Perbeck, 2006	Implant	None	20.6	20.6	NS	NS	NS	5.6	NS	NS
Artz et al., 1991	Implant, TE	None	35.9*	5.1	2.6	12.8	5.1	0	7.7°	NS
Pennisi, 1990	Implant	None	32.3	21.7	0.9	NS	0.9	0	6.1	NS
Vandamme, 1985	Implant	None	27.8	11.1	0	NS	5.6	0	11.1	NS
Schatten, 1984	Implant	None	0*	0	0	NS	NS	0	0	NS
Ward and Edwars, 1983	Implant	None	70.5*	11.4	0	NS	27.3	22.7	31.8	NS
Radovan, 1982	Implant, TE	None	29.4*	11.8	7.4	NS	4.4	4.4	2.9	1.5
Gruber et al., 1981	Implant	None	46.7	40.0	6.7	NS	NS	6.7	NS	NS
Burnand et al., 1980	Implant	None	8.5	5.1	NS	NS	NS	3.4	3.4°	NS
Khalil, 1977	Implant	None	38.8*	24.1	NS	NS	NS	7.4	11.1°	NS
Hartley et al., 1975	Implant	None	50.0*	NS	NS	NS	NS	NS	20.0°	30.0

ADM, acellular dermal matrix; NS, not stated; TCPM, titanium-coated polypropylene mesh; TE, tissue expander.
* Complication rates based on number of patients or procedures.
° Noted as implant exposure or dehiscence.

Table 2 Study quality based on Newcastle-Ottawa Scale.

Reference (author, year)	Study Quality (no. of stars)	Selection/ Comparability/ Outcome	IRB Approval	Funding	Number of Patients	Number of Breasts	Duration of Follow-up (mo.)	Patient Satisfaction Assessment
Salibian et al., 2017	6	3/0/3	Y	N	155	250	55.5	NS
Sigalove et al., 2017	4	3/0/1	NS	N	207	353	6-26	NS
Woo et al., 2017	4	2/0/2	Y	N	79	135	10	NS
Caputo et al., 2016	4	2/0/2	Y*	N	27	33	14.7	NS
Downs and Hedges, 2016	6	3/0/3	Y*	Y	45	79	22	NS
Kobraei et al., 2016	4	3/0/1	Y	N	13	23	10	NS
Schnarrs et al., 2016	4	3/0/1	Y	Y	NS	188	>3	NS
Zhu et al., 2016	7	3/2/2	Y	N	29	50	2.6	NS
Becker et al., 2015	6	3/0/3	Y*	Y	31	62	24	NS
Bernini et al., 2015	7	3/1/3	Y*	N	34	39	25	Y, BREAST-Q
Casella et al., 2015	5	2/0/3	Y	N	25	25	14	Y, BREAST-Q
Hammond et al., 2015	5	2/0/3	Y	N	10	19	13.8	Y, statement
Reitsamer and Peintinger, 2015	3	2/0/1	N	N	13	22	6	NS
Berna et al., 2014	6	3/0/3	Y	NS	19	25	14	NS
Engel et al., 2013	4	3/0/1	NS	N	22	23	6	NS
Bayram et al., 2010	5	3/0/2	NS	NS	15	26	12	NS
Benediktsson and Perbeck, 2006	4	2/0/2	Y	NS	107	107	60	NS
Artz et al., 1991	4	2/0/2	NS	NS	39	44	32.7	NS
Pennisi, 1990	4	3/0/1	NS	NS	NS	115	72	NS
Vandamme, 1985	5	3/0/2	NS	NS	18	18	40	Y, statement
Schatten, 1984	4	2/0/2	NS	NS	32	NS	6-60	NS
Ward and Edwars, 1983	5	3/0/2	NS	NS	44	46	25.3	Y, survey
Radovan, 1982	4	2/0/2	NS	NS	68	77	<6-36	NS
Gruber et al., 1981	7	3/1/3	NS	NS	NS	30	12-60	NS
Burnand et al., 1980	5	3/0/2	NS	NS	32	59	36	Y, statement
Khalil, 1977	4	2/0/2	NS	NS	54	NS	6-84	Y, statement
Hartley et al., 1975	3	2/0/1	NS	NS	10	NS	NS	NS

IRB, institutional review board; N, no; NS, not stated; Y, yes.
* Conformed to the declaration of Helsinki.

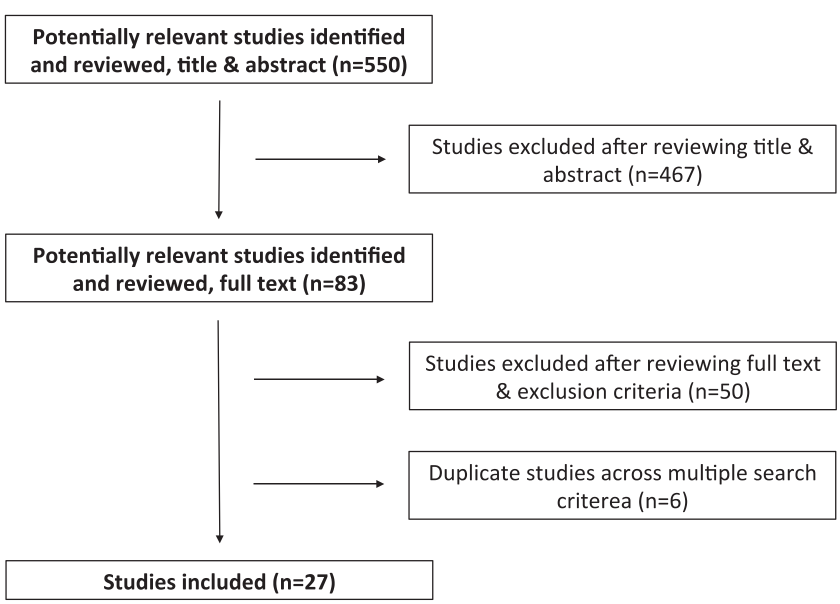

Fig. 1 Schematic for the literature search strategy.

Table 3 Capsular contracture with and without ADM.

Material	Number of Studies	Number of Contractures	Rate (CI)	Heterogeneity	
				P	I^2
ADM	5	8	2.3% (0.0-5.3)	0.043	58%
ADM and/or Mesh*	7	10	2.4% (0.0-4.9)	0.056	54%
None	13	115	12.4% (7.2-17.7)	<0.001	86%

ADM, acellular dermal matrix; CI, confidence interval.
* Mesh included Vicryl and TCPM.

used in reconstruction and were therefore excluded from the above statistic.[6,24] When ADM, Vicryl mesh, and TCPM were combined into a single category, the overall complication rate was largely similar at 23.7%.

The most common complication was capsular contracture with a rate of 8.8% and 20 out of 27 studies reporting on it. Only Baker grade III/IV contracture was considered a complication in this review. When stratified, the rate of capsular contracture with the use of ADM was 2.3%, which is less than the rate without additional implant coverage at 12.4%. Both of these values demonstrated significant heterogeneity with Cochran's *Q* test *p*-values less than 0.05. Of the six studies utilizing ADM and commenting on capsular contracture, only one study reported contracture as a complication; however, this study did not distinguish between contracture grades (see Table 3).[25]

The overall infection rate was 2.6%, seroma 5.1%, hematoma 2.4%, implant loss 3.3%, mastectomy flap necrosis 5.4%, and NAC necrosis 2.7%. Pooled seroma rates were higher in patients with no additional material than in those that used ADM or mesh, with rates of 6.9% and 4.1%, respectively. The rates of implant loss (7.2%) and mastectomy flap necrosis (7.4%) with ADM were higher than in patients without additional implant coverage (3.0% and 4.2%, respectively). When examining the heterogeneity among studies using the Cochran's *Q* test, only capsular contracture, seroma, and mastectomy flap necrosis were statistically significant with a *p*-value less than 0.05 and an I^2 value greater that 50%.

Discussion

After initial attempts at prepectoral placement of implants and TEs, there have been many developments that have led surgeons to re-examine prepectoral implant placement as a reconstructive option. These advancements include improved design of implants and TEs, intraoperative perfusion assessment technologies, and fat grafting to augment soft tissue between the skin flap and implant.[26-31] Form-stable silicone implants have been shown to be associated with lower rates of capsular contracture and minimize the risk of rippling.[32,33] Harless et al. utilized LA-ICGA in 269 consecutive patients to assess perfusion intra-operatively and reported a 86% decrease in the rate of mastectomy skin flap necrosis.[26,34] In addition, breast surgeons have a clearer understanding of mastectomy planes, with thickness varying between patients, leaving mastectomy flaps with improved vascularity. Adequate mastectomy flap perfusion is critical with prepectoral techniques, as the implant applies more direct pressure to the skin and can potentially cause ischemia to flaps with questionable perfusion. Furthermore, there is no muscular coverage; hence, necrosis can lead to implant exposure.[12,22,26,27,35]

Arguably, the most influential development in prepectoral breast reconstruction was the introduction of acellular dermal matrix, which, in this review, was associated with a decreased rate of capsular contracture at 2.3% in reconstruction that used ADM compared to 12.4% in reconstructions that did not use ADM or mesh. Prior studies on the use of ADM in submuscular implant placement also reported lower rates of contracture when ADM was used.[36] However, other factors have been noted to correlate with the development of a contracture, including implant material, implant size, and preoperative radiation.[30,37-39] The length of follow-up in the studies could have also affected capsular contracture rates. One study on long-term capsular contracture rates in implant-based breast reconstruction found that all contractures developed within the first 2 years postsurgery.[30] While some of the reviewed studies had long-term follow-up of at least two years, others did not.

Rates of seroma and infection have been shown to be significantly higher in submuscular reconstruction with the use ADM in several meta-analysis.[16,40,41] One explanation suggests that before revascularization, ADM acts as an additional foreign body contributing to the inflammatory response, which can lead infection or seroma.[16] In our analysis, pooled seroma rates were higher in patients with no implant coverage material than in those that used ADM or mesh, with rates of 6.9% and 4.1%, respectively. These results could have been influenced by the use of drains, which was not specifically recorded. It is also notable that only three studies that did not use ADM reported seroma rates. Infection rates, however, were lower in studies with no additional coverage material, which was consistent with the previous meta-analysis (Tables 4 and 5).

Rates of both mastectomy flap necrosis and reconstructive failure were higher when ADM or mesh was used (Table 5). Again, when looking at the data with ADM and submuscular reconstruction in three meta-analysis, Lee and Mun also saw an increased risk of mastectomy flap necrosis, Kim et al. observed an increased risk of reconstructive failure, and Ho et al. reported a higher likelihood of reconstructive failure.[16,40,41] Possibly contributing to the higher rates of reconstructive failure and implant loss are the higher rates of infection and higher intraoperative fill volumes with the use of ADM. Although not specifically examined in this review, higher intraoperative fill volumes have been shown to correlate with higher rates of mastectomy flap necrosis.[16,42] ADM is thought to support higher initial fill volumes

Table 4 Pooled complication rates.

Complication	Number of Papers	Number of Complications	Rate (CI)	Heterogeneity	
				P	I^2
Capsular Contracture	20	125	8.8% (5.1-12.4)	<0.001	91%
Infection	20	20	2.6% (1.6-3.5)	0.340	14%
Seroma	12	41	5.1% (2.2-8.0)	0.007	74%
Hematoma	13	33	2.4% (1.2-3.6)	0.074	10%
Implant Loss (recon failure)	23	63	3.3% (2.0-4.6)	0.002	42%
Mastectomy Flap Necrosis	21	88	5.4% (3.1-7.6)	<0.001	77%
NAC Necrosis	6	19	2.7% (1.1-4.2)	0.060	0.01%

NAC, nipple areolar complex; CI, confidence interval.

Table 5 Complications stratified by implant coverage material.

Complication	ADM		ADM and/or Mesh		None	
	Rate	95% CI	Rate	95% CI	Rate	95% CI
Capsular Contracture	2.3%	0.0-5.3	2.4%	0.0-4.9	12.4%	7.2-17.7
Infection	3.8%	2.0-5.5	3.5%	1.9-5.1	1.8%	0.8-2.9
Seroma	5.9%	0.3-11.5	4.1%	0.9-7.4	6.9%	1.5-12.4
Hematoma	2.5%	0.3-4.8	2.7%	0.8-4.7	4.5%	0.9-8.0
Implant Loss (recon failure)	7.2%	1.0-13.4	5.9%	1.9-9.8	3.0%	1.6-4.5
Mastectomy Flap Necrosis	7.4%	0.0-14.8	5.6%	1.0-10.1	4.2%	2.8-5.7

ADM, acellular dermal matrix; CI, confidence interval.

by relieving tension from the mastectomy skin flaps. Results could also have been influenced if ADM was preferentially used with thinner mastectomy skin flaps or in a higher proportion of direct to implant vs. staged reconstruction, factors that should be examined in future analysis. As the precise etiology of these critical complications is not fully understood, surgeons should practice careful patient selection and meticulous intraoperative flap assessment when pursuing prepectoral reconstructive techniques. Ideal candidates are nonsmoking patients with BMI $< 35\,\mathrm{kg/m^2}$, with mild-to-moderate breast volumes who want to maintain their current size, and with grade 1 or 2 ptosis.[31,43]

This systematic review was primarily limited by the heterogeneity in study design, outcome reporting, and operative technique between studies. Follow-up time was variable and long-term complications such as capsular contracture could have been underestimated in newer studies. Not all studies commented on each complication, and the definition of a complication often differed among studies. There were a variety of ADM products utilized from both porcine and human sources that could have different complication profiles. Additionally, some surgeons incorporated the ADM into a sling for partial implant coverage, while others completely wrapped the implants.[43] These differences in technique and type of product used would make analysis of cost-effectiveness in prepectoral reconstruction challenging. The use of ADM in two-stage implant-based reconstruction was shown to be cost-effective in a cost utility analysis by Krishnan et al. Although these conclusions should not be applied to prepectoral reconstruction, they demonstrate that the clinical benefit can outweigh the high cost of ADM, one of the major drawbacks of ADM.[20,44] Prepectoral breast reconstruction with ADM would likely have a higher cost because of the additional quantity of ADM utilized for implant coverage, but further analysis would be necessary to determine whether improved outcomes and patient satisfaction offset the costs.[33]

In conclusion, the use of ADM in prepectoral breast reconstruction correlated to lower capsular contracture and overall complications rates; however, implant loss, infection, and mastectomy flap necrosis were higher with the use of ADM. The results of this systematic review provide evidence to support the use of ADM in prepectoral breast reconstruction and provide data for those considering this technique. It should be taken into consideration that in general, the quality of evidence reported was low and the methodology for outcome assessment was inconsistent. There is a need for further investigation with comparative studies and standardized outcome reporting.

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Conflict of interest

None.

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