Review of Outcomes in Prepectoral Prosthetic Breast Reconstruction with and without Surgical Mesh Assistance

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Background: In the past decade, surgeons have increasingly advocated for a return to prepectoral breast reconstruction with claims that surgical mesh (including acellular dermal matrix) can reduce complication rates. However, numerous surgical and implant advancements have occurred in the decades since the initial prepectoral studies, and it is unclear whether mesh is solely responsible for the touted benefits.

Methods: The authors conducted a systematic review of all English language articles reporting original data for prepectoral implant-based breast reconstruction. Articles presenting duplicate data were excluded. Complications were recorded and calculated on a per-breast basis and separated as mesh-assisted, no-mesh prior to 2006, and no-mesh after 2006 (date of first silicone gel–filled breast implant approval). Capsular contracture comparisons were adjusted for duration of follow-up.

Results: A total of 58 articles were included encompassing 3120 patients from 1966 to 2019. The majority of the included studies were retrospective case series. Reported complication outcomes were variable, with no significant difference between groups in hematoma, infection, or explantation rates. Capsular contracture rates were higher in historical no-mesh cohorts, whereas seroma rates were higher in contemporary no-mesh cohorts.

Conclusions: Limited data exist to understand the benefits of surgical mesh devices in prepectoral breast reconstruction. Level I studies with an appropriate control group are needed to better understand the specific role of mesh for these procedures. Existing data are inconclusive but suggest that prepectoral breast reconstruction can be safely performed without surgical mesh. (*Plast. Reconstr. Surg.* 147: 305, 2021.)

The use of surgical mesh, including acellular dermal matrices, to assist with prosthetic breast reconstruction is now preferred by the majority of reconstructive surgeons.[1] However, no mesh device has received approval by the U.S. Food and Drug Administration for breast surgery, making breast reconstruction an off-label use for these devices.[2] This discordance has become an increasingly important regulatory public health subject, ultimately culminating in discussion of breast indications for surgical mesh devices at the General and Plastic Surgery Advisory Committee Meeting on March 25 and 26, 2019.[3]

Prosthetic breast reconstruction after mastectomy has evolved substantially since the first descriptions of silicone breast implants in the 1960s.[4,5] Initially, reconstruction was performed by placing implants in the subcutaneous pocket because of the simplicity of directly replacing the absent breast tissue.[6] In the 1980s, surgeons

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transitioned to performing subpectoral reconstructions because of the unacceptably high complication rates observed with prepectoral placement and the potential for superior aesthetics with a smoother contour of the upper pole.[7]

Original descriptions of subpectoral implant reconstruction involved release of the pectoralis major muscle from the chest wall followed by insertion of the tissue expander or implant in the newly created submuscular pocket. The pectoralis muscle is generally only able to cover the superior portion of the prosthetic device; thus, the inferior aspect was either left exposed to subcutaneous tissue or the serratus muscle/fascia was elevated to provide complete muscular coverage and support.[8]

In 2005, the first description of acellular dermal matrix assistance for subpectoral breast reconstruction was reported.[9] By using the mesh device as an inferior sling, a complete pocket could be created, and the implant or expander could be supported and precisely positioned on the chest wall. This technique allowed increased initial fill volumes, provided an additional layer of coverage, and improved objective aesthetics.[10,11] Although this technique gained popularity and is now used by 80 percent of surgeons when performing submuscular breast reconstruction, manufacturers have never been granted this indication for their mesh products by the U.S. Food and Drug Administration.[1]

Recently, surgeons have advocated for a return to prepectoral reconstruction, citing the benefits of reduced animation deformity and improvements in postoperative pain by limiting the extent of dissection.[12] Most surgeons who now perform prepectoral reconstruction have suggested that the addition of mesh coverage may be necessary for device placement in the prepectoral pocket to mitigate possible safety concerns reported in the initial prepectoral studies from several decades ago.[1] Specifically, some suggest that mesh devices allow for improved positioning on the chest wall, and that the acellular dermal matrix provides an additional layer of tissue to prevent implant extrusion in patients with thin skin flaps. However, modern tissue expanders have several tabs to allow numerous points of fixation without a mesh wrap, and many surgeons would likely return to the operating room for either exposed avascular cadaveric dermis or directly exposed expander. Therefore, these theoretical benefits may not always be appreciated in practice. Finally, it has been suggested that capsular contracture rates are prohibitively high without the use of a mesh wrap, although this reduction has never been demonstrated in a contemporary comparative study.[13] This hypothesis is primarily based on comparisons to data from prior publications on prepectoral reconstruction. However, significant reductions in capsular contracture over this same period have also been observed in cosmetic augmentation patients without the use of surgical mesh products.[14]

Many refinements in surgical technique and improvements to implant devices have been developed since the initial prepectoral reconstruction studies. For example, subclinical infection is now recognized as a potential underlying risk factor for capsular contracture, and antibiotic irrigation has become commonplace in prosthetic breast reconstruction.[14–17] In addition, implants used in the prior era had been cleared through the 510(k) process and were not necessarily scrutinized with clinical data for regulatory clearance.[5] Furthermore, breast implants used during the initial prepectoral period before the existence of the Center for Devices and Radiological Health in 1976 were manufactured and used without any regulatory oversight. Current breast implants have been approved through the more rigorous premarket approval process, which requires robust clinical data and extensive preclinical testing. These various surgical and device improvements have resulted in a dramatic reduction in capsular contracture rates in cosmetic augmentation patients without the introduction of mesh, and it is possible that a similar reduction would exist for reconstructive patients regardless of mesh use.

However, the safety concerns reported in the literature from several decades ago are sufficiently significant and widespread that mesh manufacturers have reported an inability to identify surgeons willing to perform prepectoral breast reconstruction without mesh. Nevertheless, the inclusion of no-mesh patients as a control group has become a requirement to satisfy the clinical data evidentiary expectations of the acellular dermal matrix, as confirmed at the Advisory Committee Meeting in 2019.[18] During the panel, the opinion was expressed that if enrolling a no-mesh prepectoral control group would be too unsafe based on historical data, a total submuscular cohort would have to serve as the control group despite being a markedly different procedure.[19]

We therefore reviewed the published literature to investigate whether the safety profile of prepectoral prosthetic breast reconstruction was impacted by the introduction of mesh devices. Specifically, we compared complication rates from

(exp mastectomy, subcutaneous/ or ((exp mammaplasty/ or exp mastectomy/ or (breast* adj5 reconstruct*).tw,kw) and (exp subcutaneous tissue/ or (prepector* or pre-pector* or subcutaneous*).tw,kw))) and (exp "prostheses and implants"/ or exp tissue expansion devices/ or (expander* or implant or implants or prosthe* or tissue expansion*).tw,kw)

Fig. 1. Complete MEDLINE search.

three different groups: (1) patients before 2006 (first breast implant approval), which was before mesh ("historical no-mesh"); (2) patients after 2006 who received some type of mesh-assistance; and (3) patients after 2006 who did not receive mesh assistance ("contemporary no-mesh"). Our primary goal was to assess the existing literature to determine whether prepectoral reconstruction without mesh could be safely performed to justify the enrollment of a no-mesh prepectoral control group for the upcoming mesh manufacturer clinical studies.

PATIENTS AND METHODS

A search for studies pertaining to prosthetic (implant or expander) prepectoral or subcutaneous breast reconstruction in any year of publication was conducted of the MEDLINE (Ovid), Embase (Elsevier), Web of Science (Clarivate Analytics), and Cochrane Central Register of Controlled Trials (Wiley Online Library) databases on August 7, 2019. Each search consisted of controlled terms (e.g., Medical Subject Headings) and title or abstract keywords. No language, date, or publication type restrictions were incorporated into the searches. Duplicate citations were removed in Endnote X6 (Clarivate Analytics). The final set of citations were imported into Distiller SR (Evidence Partners) for eligibility screening. The reproducible Ovid MEDLINE search is available in Figure 1. The remaining searches are available in the Appendix. (**See Appendix, Supplemental Digital Content 1**, which lists the remaining searches, ***http://links.lww.com/PRS/E308***.)

Abstracts were reviewed for inclusion of original safety outcomes data from a cohort of prepectoral breast reconstruction patients. Both direct-to-implant and tissue expander–to-implant cohorts were included, but cohorts with any concomitant flap operations were excluded because of the different safety profile of these procedures and the irrelevance to the primary study objective. Articles presenting duplicate data were excluded by preferentially including the article(s) that involved the maximal number of patients that satisfied inclusion criteria. For example, if an author published his or her series of 100 patients, and then 2 years later published an updated series on 120 patients, only the article with 120 patients would be included.

In cases where an article involved multiple cohorts, only the cohort(s) consisting of prepectoral patients with separately reported safety outcomes data were included. Cohorts with mixed surgical techniques that reported aggregate outcomes were also excluded. For example, if an article presented a cohort of prepectoral prosthetic breast reconstruction patients with 3 percent receiving latissimus flap coverage, but only reported total cohort outcomes for all patients, these articles were excluded. This was done to ensure that the aggregated outcomes were accurately representative of the prepectoral reconstruction experience without including complications from extraneous operations or variables.

Abstract-only studies were also excluded, as were non–English language studies. Review articles and meta-analyses were also excluded because they reported redundant data from other investigations and did not contribute original data. Studies with either immediate or delayed reconstruction were included.

Full-text article consensus review was conducted by three plastic surgery residents (M.R.D., V.J.T., and A.A.B.) according to the same inclusion and exclusion criteria. Articles that were ultimately included in the study were then summarized. Inconsistent methodology and variable reporting among the reviewed studies prevented a formal meta-analysis.

Individual complication rates (i.e., seroma, hematoma, infection) were recorded and calculated on a per-breast basis. If only the number of affected patients (rather than affected breasts) was reported along with the total number of patients and breasts in the series, breast-based complication rates were imputed by first assuming independence between breasts and among patients. The expected number of affected patients was then equated to the observed number to yield an imputation of the breast rate.

The articles were separated into three cohort groups based on years of patient enrollment:

mesh-assisted of any year, no-mesh prior to 2006, and no-mesh after 2006 (date of first silicone gel-filled breast implant approval). The data from the studies were combined by means of a logistic model for the event probability incorporating a fixed effect for group and a random effect to allow for heterogeneity among studies. For capsular contracture, the logistic model also included an adjustment for average follow-up time for the study because capsular contracture rates are known to be heavily time-dependent.

Additional variables included tissue expander versus direct to implant, oncologic mastectomy versus prophylactic, use of a drain, technique for mesh assistance, proportion of irradiated breasts, immediate versus delayed, type of mastectomy, and implant or expander volumes and types. However, these variables tended to be relatively inconsistently reported, which limited reliable summarization or adjusting.

RESULTS

A total of 1168 citations were independently screened for eligibility by two authors (M.R.D. and V.J.T.). Of the 1168, 697 were excluded during title and abstract review and an additional 413 during full-text review (Fig. 2). The remaining 58 articles were included, encompassing 3120 patients from 1966 to 2019 (Table 1).[1,6,7,20–75]

Demographic information was incompletely reported by several articles, but weighted averages by number of breasts among articles that reported these data are as follows: average age, 51 years for mesh-assisted, 43 years for historical no-mesh, and 50 years for contemporary no-mesh. Immediate reconstruction was performed in 99 percent of reported mesh-assisted reconstructions, 41 percent of historical no-mesh reconstructions, and 100 percent of contemporary no-mesh reconstructions. Average body mass index was 26 kg/m^2 in the mesh-assisted group, not reported in the historic no-mesh articles, and 28 kg/m^2 in the contemporary no-mesh cohort. Direct-to-implant reconstruction was performed in 58 percent of mesh-assisted, 83 percent of historical no-mesh, and 20 percent of contemporary no-mesh cases. Radiotherapy was required in 16 percent of mesh-assisted, 27 percent of historical no-mesh, and 17 percent of contemporary no-mesh cases. However, it is important to note that these variables were relatively sparsely reported, and were not reported by many of the largest population studies, so these averages may not be accurately reflective of the true patient cohorts. The average follow-up was 13 months for mesh-assisted reconstruction, 31 months for historical no-mesh, and 26 months for contemporary no-mesh.

Full adverse events outcomes data are listed in Table 2. Infection rates were variable by study and were reported as 0 to 26 percent for mesh-assisted, 0 to 7 percent for historical mesh, and 0 to 12 percent for contemporary no-mesh (weighted means, 4.2 percent, 2.8 percent, and 4.1 percent, respectively; not statistically significant). Hematoma rates were reported as 0 to 7.7 percent for mesh-assisted, 0 to 27 percent for historical no-mesh, and 0 to 10 percent for contemporary no-mesh (weighted means, 1.3 percent, 4.6 percent, and 2.7 percent, respectively; not statistically significant). Explantation rates for medical necessity were reported as 0 to 30 percent for mesh-assisted, 0 to 23 percent for historical no-mesh, and 0 to 12 percent for contemporary no-mesh (weighted means, 4.4 percent, 6.2 percent, and 5.5 percent, respectively; not statistically significant). Reported seroma rates ranged from 0 to 23 percent for mesh-assisted, 0 to 13 percent for historical no-mesh, and 0 to 26 percent for contemporary no-mesh (weighted means, 2.9 percent, 5.7 percent, and 16 percent, respectively; mesh-assisted versus contemporary no-mesh, $p = 0.03$; others, nonsignificant). Interestingly, seroma rates were infrequently reported in no-mesh publications. Data were only available for 99 total patients in the historical no-mesh group and 150 total patients in the contemporary no-mesh group.

Capsular contracture rates were reported as 3.1% for mesh-assisted at 13-month average follow-up, 17.7 percent for historical no-mesh at 31 months, and 5.8 percent for contemporary no-mesh at 26 months. Because capsular contracture is a very time-dependent adverse event, a separate logistical model was created incorporating average time of follow-up for each article. Using this model that adjusted for average length of follow-up, no significant difference was observed between contemporary no-mesh and mesh-assisted cohorts; however, both had a significantly reduced rate of capsular contracture compared to the historical no-mesh cohort.

Subgroup analysis was then performed to compare these same outcomes by type of mesh, stratified as cadaveric, xenograft, and synthetic. Studies with mixed cohorts using two types of mesh without separately reported outcomes were excluded. Only two studies reported synthetic mesh, which

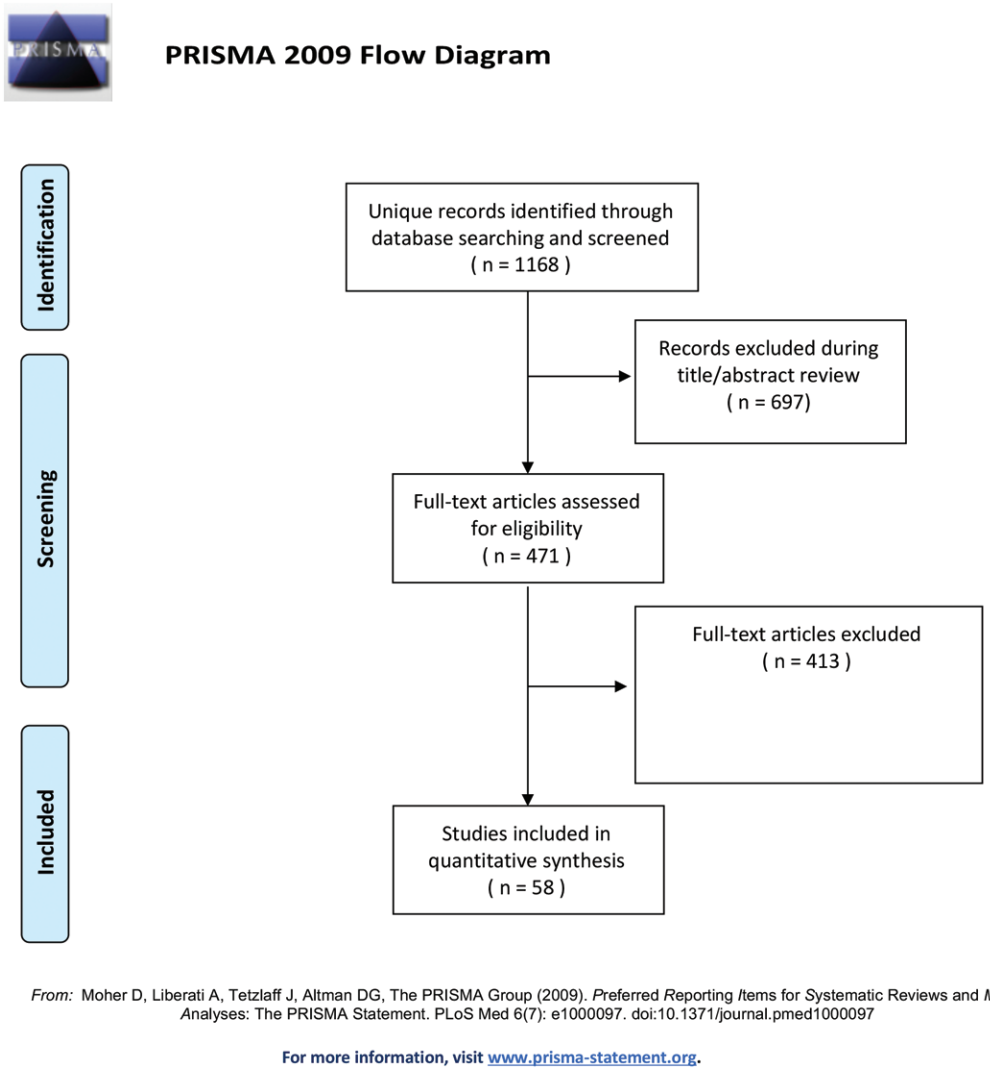

Fig. 2. Flowchart of inclusion and exclusion of articles.

was insufficient to include this group in the analysis. Ultimately, no significant differences were observed between xenograft and cadaveric dermal matrices (data not shown).

It was also acknowledged that direct-to-implant and tissue expander reconstructions can have different complication profiles, so a different subgroup analysis was conducted by making the same mesh group comparisons separately restricted to only tissue expander patients and to only direct-to-implant patients. It was noted that these separate subgroup results were identical to the aggregate results in both tissue expander and direct-to-implant subcohorts, except that implant removal was significantly lower in the contemporary no-mesh cohort compared to the other two cohorts in direct-to-implant patients ($p < 0.01$).

DISCUSSION

Surgical mesh is now used in the majority of prosthetic breast reconstruction procedures despite no product ever having received U.S. regulatory approval for use in breast operations. The U.S. Food and Drug Administration convened an Advisory Committee Meeting in March of 2019, in part to address the incongruity between clinical practice patterns and regulatory status of surgical mesh in breast operations.[3] Specifically, the panel was asked to evaluate and comment on the evidentiary standards for the clinical studies needed to support applications for mesh approval for breast reconstruction. The U.S. Food and Drug Administration provided the study attributes that they had been requesting from manufacturers, which are listed below[2]:

Table 1. Final List of Included Articles with Demographic Data

Technique and First Author	Year	ADM Product	No. of Patients	No. of Breasts	Mean Age (yr)	Mean BMI (kg/m^2)	Mean Follow-Up (mo)	Reconstructive Technique (DTI, TE, flap)	XRT
Mesh-assisted									
Bettinger	2017	AlloDerm	110	165	51		6	TE	37 breasts
Wormer	2019	AlloDerm	32	60	48	30	6		1 patient
Woo	2017	AlloDerm	79	135	50	27	10	DTI	
Sbitany	2017	AlloDerm	51	84	45	27	11	TE	7 breasts
Jones	2017	AlloDerm	50	73	47	27	12	DTI, TE	8 breasts
Jones	2019	AlloDerm	234	357			15	DTI	
Sigalove	2017	AlloDerm	207	353				DTI	27 breasts
Nahabedian	2017	AlloDerm	39	62	50	26	9	DTI, TE	15 breasts
Momeni	2019	AlloDerm, DermACELL	31	62	49	26	7	TE, flap	4 breasts
Elswick	2018	AlloDerm, Strattice	54	93	48	27	19	TE	54 breasts
Copeland-Halperin	2019	AlloDerm, DermACELL	94	160	49	23		TE	
Potter	2019	Nonspecific; biological and synthetic mesh	42	63				DTI	2 breasts
Cattelani	2017	Braxon	40	46	53		12	DTI	
Chandarana	2018	Braxon	61	71	50	26	10	DTI	19 patients
Berna	2017	Braxon		10	52	25	14	DTI	
Vidya	2017	Braxon	79	100	56	24	18	DTI	3 patients
Onseti	2017	Braxon	52	64	55	25	24	DTI	5 patients
Schaeffer	2019	Flex HD	24	45	50	29	6	TE	
Becker	2015	Flex HD, Vicryl	31	62	51		24		
Downs	2016	FlexHD, AlloDerm	45	79	47	24	23	DTI	34 patients
Paydar	2018	FlexHD, Pliable ADM	10	18	49	28	14	DTI, TE	1 patient
Gunnarsson	2018	Meso Biomatrix, Strattice, Vicryl	27	47			11	DTI	
Caputo	2016	Native porcine ADM	27	33	51		15	DTI	
Viezel-Mathieu	2019	Nonspecific; fenestrated	39	60	47		6	DTI	12 breasts
Baker	2018	Strattice	28	43	48	26	9	TE	
Sinnott	2018	Strattice	274	426	52	29	19	DTI	56 breasts
Reitsamer	2015	Strattice	13	22	45		6	DTI	
Highton	2017	Strattice, Artia		113	44	25	16	DTI	10 breasts
Casella	2019	TiLoop	397	521	56	25	38	DTI	131 patients
Walia	2018	Nonspecific	26		51			TE	3 patients
Kobraei	2016	Vicryl	13	23	50	28	10	DTI	3 patients
Total/average			2209	3450	51				
Historical no-mesh									
Capozzi	1981	None	54	104			36	DTI	
Radovan	1982	None	68	77	48		5	TE	
Engel	2013	None	22	23	45		6	TE	
Hudson	2002	None	11		49		11	DTI	
Bayram	2010	None	15	26	46		12		
Ward	1983	None	44	46	24		25	DTI	
Burnand	1980	None	32	59	42		36	DTI	
Vandamme	1985	None	18	19	47		40	DTI	11 patients
Hinton	1984	None		84			56	DTI	
Benediktsson	2006	None	87		54		60	DTI	24 patients
Khalil	1977	None	54					DTI	
Artz	1991	None	39	44			36	TE	
Slade	1984	None	39	19			71		
Schlenker	1978	None	39					DTI	
Kelly	1966	None	11						
Corso	1974	None	3	6				DTI	
Gruber	1981	None		30					
Angelchik	1975	None	40						
Bouman	1974	None		23				DTI	
Fredricks	1975	None	40	76	34			DTI	
Freeman	1969	None	44	87				DTI	
Inglis	1974	None	5	7	44			DTI	
Total/average			665	730	43		31	83% DTI	27%
Contemporary no-mesh									
Komorowska-Timek	2019	None	24	42	56	30	9	DTI	8 breasts
de Vita	2018	None	21	34	42	26	4	DTI	
Becker	2018	None	20	36			12	DTI	
Singla	2017	None	26	38			52	DTI	
Salibian	2017	None	155	250			56	TE	48 patients
Total/average			246	400	50	28	26	27% DTI	17%

ADM, acellular dermal matrix; BMI, body mass index; DTI, direct to implant; TE, tissue expander; XRT, radiation therapy.

Table 2. Results of Comparative Analysis*

	Average Follow-Up (mo)	Infection	Hematoma	Explantation	Seroma	Capsular Contracture
Mesh-assisted	13					
Reported range		0–26%	0–8%	0–30%	0–23%	
Weighted mean		4.20%	1.30%	4.40%	2.90%	3.10%
Historical no-mesh	31					
Reported range		0–7%	0–27%	0–23%	0–13%	
Weighted mean		2.80%	4.60%	6.20%	5.70%	17.70%
Contemporary no-mesh	26					
Reported range		0–12%	0–10%	0–12%	0–26%	
Weighted mean		4.10%	2.70%	5.50%	16%	5.80%
Mesh-assisted vs historical no-mesh p		0.15	0.09	0.25	0.88	<0.01
Mesh-assisted vs. contemporary no-mesh p		0.83	0.31	0.93	0.03	0.45
Historical no-mesh vs. contemporary no-mesh p		0.21	0.78	0.42	0.13	<0.01

*Analyses performed between cohorts as pairs.

- Comparison to a control group that does not receive mesh.
- An assessment of at least one effectiveness endpoint.
- Inclusion and assessment of all relevant outcome variables.
- Analysis accounting for relevant confounding variables.
- Premarket follow-up of at least 1 year, or until quiescence of the inflammatory response and absorption.
- Evidence of favorable benefit-to-risk profile.

During the ensuing discussion, the panel was challenged with questions related to best methods for including an appropriate control group without mesh in the manufacturer pivotal studies.[19] It was acknowledged that manufacturers were likely to request "indications for use" to include prepectoral breast reconstruction. Thus, the discussion focused on the perceived dilemma that, because surgeons generally considered prepectoral breast reconstruction without surgical mesh to be too unsafe, the enrollment of a no-mesh control group for this procedure might not be possible. These concerns were seemingly largely based on references to historical data from several decades ago. However, numerous advances in surgical technique and implant technology have occurred since those preliminary studies, and it remains unclear whether mesh assistance is responsible for the reduced complication rates observed in contemporary series. With this context in mind, we conducted a review of all existing literature to determine whether prepectoral prosthetic breast reconstruction without mesh might be safely performed, thus allowing for a robust clinical study to determine the actual impact of surgical mesh on the safety and effectiveness of breast reconstruction.

Our review revealed a paucity of high-level data examining the role of surgical mesh in breast reconstruction. The majority of included studies were retrospective case series. Although average complication rates appeared to differ slightly, the variance in reported values between groups had significant overlap, and almost all of these differences were not statistically significant. The only significant difference observed was a higher seroma rate in contemporary no-mesh patients compared to mesh-assisted patients, which is contrary to previous reports regarding seroma rates with the use of acellular dermal matrices.[76,77] However, this comparison was limited by very few total patients with reported seroma rates in either of the no-mesh cohorts (99 and 150), and comprehensive data on drain use, output, and duration was too infrequently reported to include in the analysis in a meaningful way.

When restricting to just mesh-assisted patients to compare outcomes based on type of surgical mesh (cadaveric, xenograft, and synthetic), no significant differences were observed between cadaveric and xenograft. There were insufficient data with synthetic mesh to include in the analysis. A separate analysis restricted to only direct-to-implant or to only tissue expander patients was conducted with identical results to the aggregate analysis, except that implant removal was less likely in contemporary no-mesh direct-to-implant patients compared to mesh-assisted and historical no-mesh cohorts.

However, there are inherent limitations to our approach, as with any meta-analysis. The level of these aggregated data are limited by the level of data from the original studies and the poolability of their cohorts. Follow-up times were significantly different between groups (13 months for mesh-assisted, 31 months for historical no-mesh, and 26 months for contemporary no-mesh), which may

affect the reported complication rates. Except for capsular contracture, there was no adjustment for average time of follow-up because it was assumed that most of these perioperative complications would occur soon after surgery and would not be linearly correlated with time. However, the likelihood of experiencing these events is still dependent on time, and the unequal average follow-up durations may be a contributor to differences observed in complication rates.

When adjusted for follow-up time in a logistic model, capsular contracture rates were not significantly different between contemporary no-mesh and mesh-assisted groups, although both were significantly lower than historical no-mesh. These data provide preliminary evidence that capsular contracture rates are more significantly impacted by improvements in implant devices and surgical practice rather than the introduction of mesh, as similarly observed in cosmetic augmentation patients.

Our analysis is limited to a superficial comparison of complication rates in the literature without the ability to perform a robust aggregate meta-analysis with granular patient data. A systematic review of this type also is limited to published literature and is subject to data publication biases. By comparing outcomes among numerous case series by different surgeons with separate techniques, we found a wide range of reported outcomes. With such variable data, it is difficult to reliably assess the specific benefits of mesh products for prepectoral breast reconstruction. Therefore, these results are not intended to be considered a conclusive report of relative safety with and without mesh assistance. However, the current data do not appear to raise sufficient safety concerns to preclude a rigorous study with no-mesh control patients. A well-designed study with randomization would provide significantly better evidence to evaluate the performance of mesh products for this indication.

This study also does not address effectiveness outcomes, which are often difficult to capture objectively. The U.S. Food and Drug Administration has required that mesh manufacturers include at least one effectiveness endpoint because a surgically implanted device should ideally demonstrate some patient benefit to justify its use.[2] However, the panel suggested that various effectiveness outcomes may be considered acceptable. For example, surgical mesh may improve the appearance of the final reconstruction, as captured by the BREAST-Q or another validated instrument, or may reduce pain and operative time. These outcomes are not reliably reported in articles in a consistent manner to allow data pooling and comparisons. Many prior studies on surgical mesh assistance have not focused on the potential benefits of mesh as measured by standardized patient questionnaires. Prior review has demonstrated that, for submuscular tissue expander reconstruction, surgical mesh may improve aesthetics as judged by external observers, but reproducibly does not improve patient satisfaction with their result.[78] Deciding which of these outcomes is most relevant or important may be crucial to the potential approval of surgical mesh for breast reconstruction. However, an investigation of effectiveness outcomes was not the goal of this study. Our intention was to determine whether prepectoral prosthetic breast reconstruction could be considered safe enough to allow for Level I study, which could ultimately reveal the relative safety and effectiveness of mesh devices for this indication.

Although our results are based on relatively superficial comparisons from the literature, the safety benefits of surgical mesh for prosthetic breast reconstruction are not immediately clear. Ideally, future studies would rigorously compare the outcomes using mesh products to appropriate control patients who are undergoing the same procedure and do not receive mesh to determine the safety or effectiveness of mesh for prepectoral breast reconstruction

CONCLUSIONS

Limited data exist to understand the benefits of surgical mesh devices in prepectoral breast reconstruction. Level I studies with an appropriate control group are needed to better understand the specific role of mesh for these procedures. Existing data are inconclusive but suggest that prepectoral breast reconstruction can be safely performed without mesh. Mesh manufacturer pivotal studies should ideally include a no-mesh prepectoral control group.

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