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ORIGINAL ARTICLE

Breast

Comparative Study of Prepectoral and Subpectoral Expander-Based Breast Reconstruction and Clavien IIIb Score Outcomes

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Background: Prepectoral breast reconstruction is increasingly popular. This study compares complications between 2 subpectoral and 1 prepectoral breast reconstruction technique.

Methods: Between 2008 and 2015, 294 two-staged expander breast reconstructions in 213 patients were performed with 1 of 3 surgical techniques: (1) Prepectoral, (2) subpectoral with acellular dermal matrix (ADM) sling ("Classic"), or (3) subpectoral/subserratus expander placement without ADM ("No ADM"). Demographics, comorbidities, radiation therapy, and chemotherapy were assessed for correlation with Clavien IIIb score outcomes. Follow-up was a minimum of 6 months.

Results: Surgical cohorts (n = 165 Prepectoral; n = 77 Classic; n = 52 No ADM) had comparable demographics except Classic had more cardiac disease (P=0.03), No ADM had higher body mass index (BMI) (P=0.01), and the Prepectoral group had more nipple-sparing mastectomies (P<0.001). Univariate analysis showed higher expander complications with BMI \geq 40 (P=0.05), stage 4 breast cancer (P=0.01), and contralateral prophylactic mastectomy (P=0.1), whereas implant complications were associated with prior history of radiation (P<0.01). There was more skin necrosis (P=0.05) and overall expander complications (P=0.01) in the Classic cohort, whereas the No ADM group trended toward the lowest expander complications among the 3. Multivariate analysis showed no difference in overall expander complication rates between the 3 groups matching demographics, mastectomy surgery, risks, and surgical technique.

Conclusions: Prepectoral and subpectoral Classic and No ADM breast reconstructions demonstrated comparable grade IIIb Clavien score complications. BMI > 40, stage 4 cancer, and contralateral prophylactic mastectomy were associated with adverse expander outcomes and a prior history of radiation therapy adversely impacted implant outcomes. Ninety-day follow-up for expander and implant complications may be a better National Surgical Quality Improvement Program measure. (*Plast Reconstr Surg Glob Open 2017;5:e1433; doi: 10.1097/GOX.0000000000001433; Published online 26 July 2017.*)

INTRODUCTION

Breast reconstruction is an integral component of breast cancer and prophylactic mastectomy management.^{1,2} In the 1980s, prepectoral subcutaneous breast

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reconstruction was plagued with complications, particularly skin flap necrosis that lead to expander exposure and loss.^{3–5} Radovan's invention of the tissue expander and reposition of the expander to the subpectoral plane

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revolutionized breast reconstruction.⁶⁻⁸ The subpectoral expander method has been the most conventional breast reconstruction technique for the past 25 years.⁹

To our knowledge, there has been no expander-based breast reconstruction study comparing a new prepectoral technique using stacked acellular dermal matrix (ADM) to traditional subpectoral/ADM sling and subpectoral/seratus/no ADM surgical techniques. This study evaluated the outcomes of both stages of reconstruction between these 3 surgical techniques.

PATIENTS AND METHODS

A retrospective review of consecutive breast reconstructions was performed using EPIC electronic medical records (Epic Systems Corp., Wis.) at a single institution from June 2008 to July 2015. The study was restricted to breasts that underwent mastectomy for breast cancer or cancer prophylaxis. Excluded breasts were those that underwent immediate single-stage implant reconstruction, reconstructions with mesh other than LifeCell Alloderm ADM (Branchburg, N.J.), or revisions. Each breast was counted once and entered in the study at the time of expander placement. The specific surgical technique used was left to the discretion of the surgeon. Each surgeon performed all 3 techniques during this period. Surgical products were consistent, given the managed care setting. The type of mastectomy (skin-sparing, nipple-sparing, or modified radical) and the final stage of reconstruction (implant placement or conversion to free flap) were recorded. Patients who underwent initial "spacer" expander placement for planned adjuvant radiation therapy with subsequent autologous reconstruction were included in the expander outcomes. The minimum follow-up for both events ranged from 6 months to 6 years. The Kaiser Foundation Research Institute Institutional Review Board approved the study.

The following patient demographics were recorded: patient age, body mass index (BMI) at the time of the initial expander placement (categorized into 5 groups according to World Health Organization classification), presence of diabetes, cardiac disease (requiring medication for hypertension, coronary heart disease, or arrhythmia), smoking history (current, former), initial cancer stage, previous breast surgeries (prior lumpectomy, reduction mammoplasty, mastopexy, augmentation mammoplasty), radiation therapy (prior history, adjuvant therapy), chemotherapy (prior history, neoadjuvant or adjuvant therapy; Table 1).^{10,11} Complications were limited to a grade IIIb Clavien score (i.e., "requiring surgical, endoscopic, or radiological intervention under general anesthesia") for seroma, infection, hematoma, skin and nipple necrosis, expander deflation, and expander or implant loss (Table 2).12 It may be difficult to identify true surgical-site infections with ADM so patients given oral or intravenous antibiotics alone (Clavien type II) were not included.¹³

The cumulative incidence of postoperative complications was computed at 30, 90, and 180 days for expander and implant placement. Complications for the expander and implant were measured separately, each with a separate postoperative 6-month follow-up period. Although no time stipulation was made for the implant placement, it typically occurred 3 months after completion of chemotherapy and 6 months after adjuvant radiation therapy.

Surgical Techniques

The 3 surgical procedures were (1) prepectoral tissue expander placement over the pectoralis muscle with ADM coverage (Prepectoral), (2) subpectoral expander placement with ADM sling as an extension of the pectoralis muscle (Classic), (3) subpectoral/subserratus placement without ADM (No ADM). Although Sterile Alloderm became available during the study, the same antibiotics were used on all breasts. We did not compare outcomes among the different generations of Alloderm.

Prepectoral

After mastectomy, an 8×16cm "Thick" ADM (LifeCell Alloderm) is sutured in the subcutaneous pocket to the medial/parasternal border of the chest wall and along the inframammary fold. The lateral most 3-4cm of the 8×16cm ADM sheet is removed and sutured to the superior aspect of the ADM, covering the superior aspect of the Natrelle Style 133MV-T tabbed tissue expander (Allergan, Santa Barbara, Calif.) (Fig. 1). Bilateral reconstruction uses 16×20 cm, divided in half for each breast, to save costs. The partially filled expander is placed under the Alloderm. Expander tabs are then sutured to the pectoralis muscle and chest wall to maintain the expander position. The ADM is sutured laterally to create a tight pocket to prevent expander migration into the axilla. The subcutaneous layer is closed by catching the deep dermis and underlying ADM with each throw, preventing motion between the mastectomy skin flap and ADM with the intent to diminish seroma formation. A channel drain is placed over the ADM.

Classic

The leading edge of the pectoral muscle is elevated and a subpectoral pocket is fashioned. The lower medial origin muscle fibers are released for anatomical expander seating. An Alloderm sling is sutured from the leading edge of the pectoralis muscle to the inframammary fold (over the partially filled expander). The ADM is sutured laterally to close the expander pocket.

No ADM

A submuscular pocket is fashioned by elevating the pectoralis muscle and a lateral slip of the serratus anterior muscle and fascia. A partially filled expander is placed in the submuscular pocket. The serratus slip is sutured over the expander to the lateral pectoral muscle edge. ADM is not used.

Antibiotics were given uniformly throughout the study based on the current standard of care at the time of surgery. The types of expanders, dressings, postoperative drain management, and postoperative expansion schedules were similar for both expanders and implants among surgeons, given our group setting. The incisions were dressed with a gauze/transparent occlusive dressing. The drain was covered with a chlorhexidine Biopatch (Ethicon, Johnson & Johnson, New Brunswick, N.J.). Drain bulbs were infused daily with 5 cc of 0.125% Dakin's hypochlorite solution via needless syringe

Table 1. Patient/Breast Characteristics and Risk Factors

Characteristics	Total	Classic	No ADM	Prepectoral	P
No. breasts	294	52	77	165	
No. patients	213	40	63	110	
Age	50.95 ± 11.83	51.2 ± 13.71	51.7 ± 11.51	50.9 ± 11.38	0.75
Mean BMI					0.01†
18.5-24.9	132 (44.90)	22 (42.31)	30 (38.96)	80 (48.48)	,
25-29.9	88 (29.93)	15 (28.85)	24 (31.17)	49 (29.70)	
30-34.9	44 (14.97)	9 (17.31)	7 (9.09)	28 (16.97)	
35-39.9	22 (7.48)	6 (11.54)	10 (12.99)	6 (3.64)	
≥ 40	8 (2.72)	0 (0.00)	6 (7.79)	2 (1.21)	
Diabetes Mellitus	, ,	, ,	, ,	, ,	0.06
Yes	28 (9.52)	2 (3.85)	12 (15.58)	14 (8.48)	
Cardiac disease	(,	(() ()	(() () () ()	(3333)	0.03†
Yes	79 (26.96)	20 (38.46)	24 (31.17)	35 (21.34)	*****
Smoking history	, , , , ,	()	(3.11.1.)	(, , , ,	0.08
Current	6 (2.04)	3 (5.8)	1 (1.3)	2 (1.2)	
Former	57 (19.39)	14 (26.9)	14 (18.2)	29 (17.7)	
None	230 (78.23)	35 (67.3)	62 (80.5)	133 (81.1%)	
Cancer stage		()	== (====)	(,-,	0.16
Benign/stage 0	139 (47.27)	24 (8.16)	30 (10.2)	85 (28.9)	
Stage 1	72 (24.48)	15 (28.8)	21 (27.3)	36 (21.8)	
Stage 2–3	61 (20.74)	12 (4.1)	25 (8.5)	42 (14.3)	
Stage 4	4 (1.36)	1 (1.9)	1 (1.3)	2 (1.2)	
Previous breast surgery	1 (1100)	1 (1.0)	1 (1.0)	= (1.=)	0.07
Yes	28 (9.5)	2 (3.8)	12 (15.6)	14 (8.5)	0.07
Chemo	(e.e.)	_ (===)	()	(=.=)	0.20
Adjuvant	121 (41.16)	25 (48.08)	25 (32.47)	71 (43.03)	*****
Prior history	18 (6.12)	4 (7.69)	7 (9.09)	7 (4.24)	
Neoadjuvant	29 (9.86)	4 (7.69)	5 (6.49)	20 (12.12)	
Radiation	20 (0.00)	1 (7.00)	0 (0.10)	40 (14.14)	0.86
Adjuvant	41 (13.95)	8 (15.38)	10 (12.99)	23 (13.94)	0.00
Prior history	22 (7.48)	2 (3.85)	6 (7.79)	14 (8.48)	
Mastectomy type*	(n = 291)	= (0.00)	o (o)	11 (0.10)	
Skin-sparing	214 (73.5)	42 (80.8)	55 (71.4)	117 (70.9)	0.01†
Nipple-sparing	50 (17.1)	6 (11.54)	2 (2.60)	42 (25.45)	< 0.001†
Modified radical	27 (3.4)	4 (7.7)	17 (23)	6 (3.6)	< 0.01†
Surgery indication	1. (8.1)	1 (,,,)	1. (40)	0 (0.0)	(0.01)
Prophylactic (CL)	101 (34.35)	17 (32.69)	22 (28.57)	62 (37.58)	0.37
Prophylactic (BL)	31 (10.54)	6 (11.5)	9 (11.6)	16 (9.67)	0.07
Timing	31 (10.01)	0 (11.3)	5 (11.6)	10 (3.07)	
Immediate	269 (91.5)	50 (96.2)	55 (71.4)	164 (99.4)	< 0.001†
Conversion to flap at second	9 (3.1)	3 (5.8)	1 (1.3)	5 (3.0)	0.35
stage	5 (5.1)	0 (0.0)	1 (1.0)	0 (0.0)	0.00
Completion of reconstruction	235 (79.9)	41 (78.8)	67 (87)	127 (77)	0.17
		` '		,	

Previous breast surgery = formal lumpectomy, breast reduction, breast augmentation, mastopexy (does not include open breast biopsy); conversion to flap at second stage: autologous flap reconstruction occurred at the second stage of reconstruction due to either complication or patient choice instead of implant. Any expander complication recorded.

into the bulb port. ¹⁴ Drains were removed when output was <30 cc/24 hours \times 3 days. Implant choice was based on surgeon preference. Fat grafting was performed at implant placement to address any contour deficiencies.

STATISTICAL ANALYSIS

First, descriptive statistics were performed to compare the demographic characteristics of the 3 surgical cohorts Chi-square and *t* tests were used to evaluate the statistical significance of differences within categorical and continuous variables, respectively, among the 3 surgical cohorts (Table 1). Second, breast complications from either expander or implant placement were evaluated across surgical approaches and differences between the 3 approaches were compared using the chi-square test (Table 2). Third, we performed a univariate logistic regression analysis examining the likelihood of developing complications during the expander and implant

procedure across a number of patient-level and surgical variables (Table 3). Lastly, a multivariate analysis was performed to specifically examine the effect of surgical technique as an independent predictor of developing a surgical complication, while controlling for a number of patient characteristics, surgical approaches, and variations in surgeon-specific techniques. Multivariate analysis of implant complications was not performed due to low numbers (Table 4).

Statistical analysis occurred at the level of the breast. All P values were 2-sided, with a P < 0.05 considered statistically significant. All statistical analyses were performed with SAS Studio 3.6 (SAS Institute, Cary, N.C.).

RESULTS

Three hundred thirty-one consecutive breast reconstructions were performed between June 2008 and July 2015. Two hundred ninety-four breasts met the inclusion

^{*}Three breasts had unknown mastectomy type.

[†]Values are statistically significant.

BL, bilateral prophylactic mastectomy; BMI, body mass index; CL, contralateral prophylactic mastectomy.

Table 2. Complications after Expander and Implant Surgery

Complications/breast	Total	Classic	No ADM	Prepectoral	\boldsymbol{P}
Expander	294	52	77	165	
No. breasts					
Any expander complications					
Ýes	40 (13.61)	13 (25.00)	5 (6.49)	22 (13.33)	0.01†
Loss					
Expander	25 (8.50)	8 (15.38)	2 (2.60)	14 (8.48)	0.09
Deflation	2 (0.68)	0 (0.00)	0 (0.00)	2 (0.68)	
Seroma					
Yes	13 (4.42)	3 (5.77)	5 (6.49)	5 (3.03)	0.44
Hematoma					
Yes	3 (1.02)	1 (1.92)	0 (0.00)	2 (1.21)	0.40
Infection					
Yes	20 (6.80)	6 (11.54)	3 (3.90)	11 (6.67)	0.37
Skin necrosis					
Yes	15 (5.10)	7 (13.46)	2 (2.60)	6 (3.64)	0.05†
Nipple necrosis					
Yes	5 (1.70)	2 (3.85)	0 (0.00)	3 (1.82)	0.25
Implant	Total	38	65	119	
No. breasts	222*				
Any implant complications					
Ýes	11 (4.95)	1 (2.63)	3 (4.62)	7 (5.88)	0.72
Loss					
Implant	7 (3.15)	1 (2.63)	1 (1.54)	5 (4.20)	0.21
Seroma					
Yes	6 (2.70)	0 (0.00)	1 (1.54)	5 (4.20)	0.22
Hematoma					
Yes	1 (1.45)	0 (0.00)	1 (1.54)	0 (0.00)	0.37
Infection	,	,	,	,	
Yes	5 (2.25)	0 (0.00)	1 (1.54)	4 (3.36)	0.11
Skin necrosis		,	,	,	
Yes	5 (2.25)	1 (2.63)	1 (1.54)	3 (2.52)	0.29
Nipple necrosis	- (/	(/		- (/	
Yes	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	_

^{*}Total number of breast reconstructions that underwent implant placement by study completion. †Values are statistically significant.

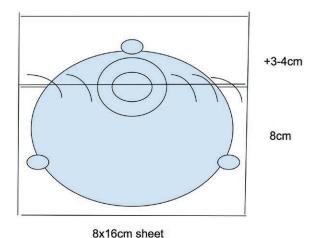


Fig. 1. Prepectoral reconstruction technique: Stacked ADM

criteria, which consisted of 165 Prepectoral, 77 Classic, and 52 No ADM reconstructions. The mean age for all groups was 50.95 (Table 1). Demographics were similar except the Classic cohort had higher rates of cardiac disease (P = 0.03) and a trend toward higher smoking rates (current and former; P = 0.08). BMI ≥ 35 was higher in the Classic group and the No ADM group (P = 0.01). A trend toward increased rates of diabetes in the No ADM group was also noted (P = 0.06).

Among mastectomy techniques, there were more nipple-sparing mastectomies in the Prepectoral group (P< 0.001) and more skin-sparing mastectomies in the Classic and No ADM groups (P = 0.01). Unfortunately, we were not able to identify information for mastectomy type for 3 patients, and these were excluded from analysis. There were similar rates of prophylactic mastectomy in the 3 groups. No difference was noted between the 3 groups in the final stage of reconstruction (i.e., successful completion) or second-stage conversion rate to autologous flap reconstruction (Table 1).

Multiple complication variables were often seen in the same patient, causing higher complication numbers. For instance, an infected breast with necrotic skin flaps might be associated with loss of expander, recording 3 complications in a single breast. All complications were recorded in a "genomic-type format" to show this interrelationship. No pattern emerged with any of the surgical cohorts.

We looked at complications per patient as well as per breast. However, we found that complications were better examined per breast as each breast had its own individual risk factors. For example, a reconstructed breast may undergo radiation (higher risk), whereas the other breast does not but still undergoes prophylactic mastectomy (lower risk).

Expander Complications

The overall infection rate was 6.80% for expander surgery. The difference in infection among the 3 surgical

Table 3. Univariate Logistic Regression Analysis Predicting Development of Expander and Implant Complications

Characteristics	Expander No.	Rate (%)	OR (95% CI)	P	Implant No.	Rate (%)	OR (95% CI)	P
Technique								
Classic	13	25.00	1 (Reference)	_	1	2.63	1 (Reference)	_
No ADM	5	6.49	$0.21\ (0.07 - 0.63)$	$0.01\dagger$		4.62	$0.56 \ (0.06-5.57)$	0.84
Prepectoral	22	13.33	$0.46 \ (0.21-1.00)$	0.98	7	5.88	$0.43 \ (0.05 - 3.63)$	0.44
Age*	51.38	12.28	1.004 (0.976–1.032)	0.80	50.45	10.83	1.00 (0.95–1.05)	0.99
BMI			,				,	
18.5-24.9	15	11.36	1 (Reference)	_	2	1.52	1 (Reference)	
25-29.9	10	11.36	1.00 (0.43-2.34)	0.43	4	4.55	3.03 (0.54–17.02)	0.47
30-34.9	11	25.00	2.600 (1.09-6.20)	0.09	2	4.55	3.57 (0.48-26.50)	0.74
35-39.9	1	4.55	0.37(0.05-2.96)	0.12	2	9.09	6.68 (0.87–50.95)	0.56
≥ 40	3	37.50	4.680 (1.01–21.59)	$0.05 \dagger$		12.50	25.00 (1.55–402.46)	0.09
Diabetes				,				
No	35	13.16	1 (Reference)	_		4.43	1 (Reference)	_
Yes	5	17.86	1.42 (0.51–3.97)	0.51		10.53	2.54 (0.51–12.69)	0.26
Cardiac disease		11.00	1112 (0.01 0.01)	0.01		10.00	101 (001 1200)	0.40
No	26	12.15	1 (Reference)		6	3.47	1 (Reference)	_
Yes	14	17.72	1.54 (0.76–3.13)	0.23	5	10.20	3.16 (0.92–10.85)	0.07
Smoking	**	17.72	1.01 (0.70 0.10)	0.40	Ü	10.20	3.10 (0.32 10.03)	0.07
No	32	13.85	1 (Reference)		10	5.75	1 (Reference)	_
Former or current	8	12.90	0.91 (0.40–2.09)	0.83	1	2.08	0.35 (0.04–2.80)	0.32
Cancer stage	O	12.30	0.31 (0.10 2.03)	0.00	1	2.00	0.55 (0.01 2.00)	0.02
Benign/stage 0	19	15.20	1 (Reference)		6	4.80	1 (Reference)	
Stage 1	12	19.67	1.366 (0.62–3.04)	0.16	3	4.92	1.53 (0.362–6.49)	0.94
Stage 2–3	5	22.73	1.641 (0.54–4.98)	0.10	0	0.00	1.55 (0.502-0.45)	0.95
Stage 4	4	4.76	0.279 (0.09–0.85)	0.14		2.38	0.48 (0.09–2.45)	0.96
Previous breast surgery	T	1.70	0.273 (0.03-0.03)	0.01	4	2.30	0.40 (0.03-2.43)	0.50
No	32	12.75	1 (Reference)		9	4.76	1 (Reference)	
Yes	8	18.60	1.60 (0.68–3.75)	0.28	2	6.06	1.29 (0.27–6.26)	0.75
Chemo	O	10.00	1.00 (0.00–3.73)	0.40	4	0.00	1.23 (0.27-0.20)	0.75
None	15	11.90	1 (Reference)		4	3.70	1 (Reference)	_
Adjuvant	15	12.40	1.058 (0.49–2.27)	0.36	6	6.98	1.96 (0.53–7.17)	0.95
Prior history	3	16.67	1.46 (0.38–5.67)	0.90	1	9.09	2.58 (0.26–25.31)	0.94
Neoadjuvant	7	24.14	2.33 (0.85–6.38)	0.16	0	0.00	2.30 (0.20-23.31)	-
Radiation	,	44.14	2.33 (0.65–0.36)	0.10	U	0.00	_	_
None	27	11.69	1 (Reference)		6	3.31	1 (Reference)	_
Adjuvant	8	19.51	1.81 (0.76–4.33)	0.72	1	3.57	1.08 (0.13–9.32)	0.24
Prior history	5	22.73	2.34 (0.79–6.90)	0.72	4	30.77	12.96 (3.10–54.25)	< 0.01†
Stage of reconstruction	3	22.73	2.34 (0.75-0.50)	0.34	т	30.77	12.30 (3.10–34.23)	< 0.01
No expander/implant	12	57.14	1 (Reference)	_	3	27.27	1 (Reference)	
Expander in place	8	21.05	0.200 (0.06–0.64)	0.55	0	0.00	1 (Reference)	
Second stage finished	20	8.51	0.070 (0.03–0.19)	< 0.01†		3.70	0.03 (0.01–0.18)	0.99
Skin-sparing	20	0.51	0.070 (0.03-0.13)	< 0.01	О	3.70	0.03 (0.01-0.16)	0.55
No	9	13.85	1 (Reference)		4	8.70	1 (Deference)	
Yes	31		,	0.98	7		1 (Reference)	0.20
	31	13.54	0.99 (0.45–2.20)	0.98	,	3.98	0.44 (0.12–1.56)	0.40
Nipple-sparing	99	19 50	1 (Defence as)		0	4.01	1 (Defenses)	
No Voc	33 7	13.52	1 (Reference)	0.95	9 2	4.81	1 (Reference)	0.82
Yes	/	14.00	1.03 (0.43–2.47)	0.95	Z	5.71	1.20 (0.25–5.80)	0.82
Contralateral prophylactic								
mastectomy	9.4	15.00	1 /D C		-	4.00	1 /D C	
No	34	17.62	1 (Reference)		7	4.93	1 (Reference)	
Yes	6	5.94	0.30 (0.12–0.74)	0.01†	4	5.00	1.01 (0.29–3.58)	0.98

^{*}For continuous variable age, we report the mean age of patients who developed complications along with the SD. Chemotherapy and radiation: prior history, before, and not related to current surgical intervention, that is, related to previous diagnosis of breast cancer.
†Values are statistically significant.

Table 4. Association between Surgical Technique and Expander Complications

Technique	Total Complications (Breasts)	Raw Overall Complication Rate (%)	Unadjusted Risk Ratio	P	Adjusted* Risk Ratio, (95% CI)	P
Classic	13	25.00	1 (Reference)		1 (Reference)	
No ADM	5	6.49	0.21 (0.07-0.63)	$0.02 \dagger$	0.12 (0.02-0.72)	0.10
Prepectoral	22	13.33	0.46 (0.21-1.00)	NS	0.25 (0.06–1.00)	NS

^{*}N = 291, adjusted for 3 unknown variables for mastectomy type and for patient characteristics (including age, BMI, cancer stage, cardiac disease, smoking status, diabetes, chemotherapy, radiation and previous breast surgery, timing) + considerations in surgical approach [including mastectomy type (skin-sparing, nipple-sparing, and contralateral prophylactic mastectomy)] and stage of reconstruction + effects attributable to surgeon variation. Unknown breast reconstructions (n = 3) were excluded in this analysis since the type of mastectomy was unknown.
†Values are statistically significant.

BMI, body mass index; CI, confidence interval; OR, odds ratio.

CI, confidence interval; NS, not significant.

180 Day Expander Complications

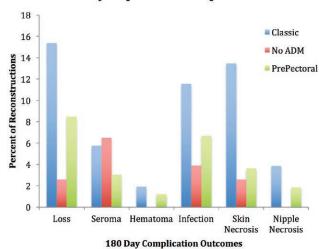


Fig. 2. Expander complications at 180 days. Percentage of reconstruction complications.

groups was not statistically significant, and the incidence of seroma was similar among all 3 groups (P = 0.44).

The Classic cohort had significantly more skin necrosis (P=0.05) and overall expander complications (P=0.01) than the other 2 surgical techniques (Fig. 2); there were more current and former smokers in the Classic group (P=0.08). There was no statistical difference in nipple necrosis in nipple-sparing mastectomy among the surgical groups but the numbers were low (Table 2). With univariate analysis, there was a trend toward a higher loss of expander in the Classic group (P=0.09). However, when placed in a multivariate analysis, this trend disappeared, and all 3 techniques had similar expander complication rates (Table 4).

On the other hand, the No ADM technique had the least number of expander complications among the 3 groups (P = 0.02) in a univariate analysis. Although a trend persisted when analyzed in a multivariate fashion, the statistical significance was lost (P = 0.12).

Implant Complications

The overall infection rate for implant surgery was 2.25% and the seroma formation rate was 2.70%. There was no statistically significant difference in implant complications between the Classic, Prepectoral, and No ADM surgical groups using univariate analysis (Table 2). The number of implant complications was too low to perform multivariate analysis.

Risk Factors

Of the 294 breasts entered in the study, 13.6% (n = 40) had complications related to the expander, whereas 3.7% (n = 11) were implant-related. A history of radiation before initial expander placement appeared to show a nonsignificant increase in expander complications but a striking increase (30%) in implant complications (P < 0.01; Table 3). Of the total number of implant complications, almost half (5/11 = 45%) were associated with either adjuvant or preexpander radiation. Although the numbers

were low, implant loss in the Prepectoral group was seen either with radiation (3/5 = 60%) or cardiac disease (2/5 = 40%). Chemotherapy, whether neoadjuvant, adjuvant, or a prior history, did not increase the risk of complications for expander or implant surgery (Table 3).

With univariate analysis, there was a significantly higher rate of overall expander complications for patients with a BMI of 40 or greater (P = 0.05) in all surgical cohorts. There was no difference in outcome complications with both expander and implant placement among patients with diabetes (P = 0.26). Despite the higher rate of cardiac disease in the Classic group, univariate analysis did not reach significance to indicate that cardiac disease was associated with higher rates of complications; however, there was a trend toward significance that may suggest an association if the power of the test is increased (P = 0.07).

Previous breast surgery did not affect outcomes among the 3 surgical cohorts. There was no statistical difference in outcomes with respect to mastectomy type and unilateral prophylactic mastectomy between the 3 surgical cohorts (Table 3). Bilateral prophylactic mastectomy reconstructions had too few complication numbers to perform this analysis.

DISCUSSION

With increasing prophylactic breast reconstruction and nipple-sparing mastectomy for both cancer and cancer prophylaxis, women are demanding a breast comparable with their natural breast, with less discomfort, less contour deformity with minimal surgical sequela, scarring, and downtime. A renewed interest has been seen with suprapectoral reconstruction (thick mastectomy flaps without ADM) and prepectoral reconstruction techniques that now use ADM to avoid the dynamic deformity sometimes seen with subpectoral reconstruction. ^{15–20} A "bioengineered" biodimensional subpectoral breast reconstruction including ADM both at mastectomy and implant surgery, an anatomical/form-stable implant, and fat grafting aims to recreate a better breast. ²¹

Fewer complications have been noted in reconstructions without ADM. ^{22,23} Adverse outcomes with ADM have been inconsistent in the literature but generally associated higher rates of seroma, infection, skin necrosis, and increased loss of expander are seen. ^{24–32} In this study, seroma formation requiring surgical intervention was 4.42% overall for expanders and 2.70% for implants. We did not find a statistical difference in seroma or infection rates when comparing techniques that did and did not use ADM.

Increased complication rates have been noted in patients with diabetes, hypertension, BMI > 30, and contralateral prophylactic mastectomy. $^{33-37}$ In this study, diabetes did not cause a higher complication rate among the 3 groups. Univariate analysis showed statistically higher expander complications with BMI \geq 40 (P= 0.05) and stage 4 cancer but not in final implant placement. We also found reconstructed breasts with a contralateral prophylactic mastectomy had more overall expander complications (P= 0.01).

The Classic cohort had a statistically greater incidence of cardiac disease (P = 0.03), more skin necrosis

(P=0.05), and a higher overall expander complication rate (P=0.01). More skin necrosis was found with the Classic cohort in which surgical release of the pectoralis lower medial border is usually performed for anatomical seating of the expander but not performed in Prepectoral or No ADM. Like others, we observed "window-shading" of scarred, anatomically foreshortened pectoralis muscles intraoperatively for surgical complications in the Classic cohort. This window-shading may contribute to poorer chest skin/pericapsular vascularity. In contrast, in No ADM, the pectoralis lateral margin is anchored inferiorly by the serratus slip, counteracting window-shading. Prepectoral reconstruction involves no disruption of the muscle origin or division of the underlying perforators.

An increase in nipple necrosis has been seen with neo-adjuvant and adjuvant chemotherapy with suprapectoral reconstruction and nipple-sparing mastectomy, but we did not see this in our study (Table 3).³⁸ Timing of radiation is known to influence both expander and implant outcomes.^{39,40} We found no statistical increase in complications with adjuvant radiation therapy alone, but there was a 10-fold increase in implant complication rate with prior history of radiation (i.e., before expander).

We find that expander/implant complications are not always captured by the 30-day National Surgical Quality Improvement Program (NSQIP) benchmark. 41,42 Periprosthetic joint literature divides complications into "early" at 90 days and "late" at 6 months or later. 43,44 We tracked our complications at 30, 90, and 180 days postoperatively. All our complications occurred within 90 days for both expander and implant placement. Our study outcomes would lead us to conclude that 90 days "early" follow-up is more accurate than existing 30-day NSQIP measures and a "late" follow-up of 180 days is appropriate.

The results of our study seem to indicate that for those breasts with increased risk, subpectoral/serratus reconstruction results in fewer complications. Subpectoral/ADM sling reconstruction should be more closely studied for the vascular impact of window-shading particularly in the setting of cardiac disease and a history of smoking. Prepectoral breast reconstruction appears to be impacted by radiation before implant surgery, similar to subpectoral techniques. Contralateral prophylactic mastectomy reconstruction carries greater overall complications and should be shared with patients in their decision making.

Strengths and Limitations

Study strengths include a comparative study designed to evaluate major complication outcomes requiring surgical intervention with the prepectoral breast reconstruction technique compared with traditional methods of subpectoral breast reconstruction with 30, 90, and 180-day follow-up of both expander and implant outcomes.

Study limitations include small cohorts in a retrospective review at a single institution. Randomization to a surgical technique would not be ethical. We did not evaluate "phase 2" efficacy for capsular contracture nor contour deformity. The Pusic's Breast Q score questionnaire could be valuable for patient satisfaction. ⁴⁵ Cost analysis would be important as prepectoral reconstruction uses the larg-

est ADM sheet, whereas No ADM uses none. We did not perform a power analysis, given a potential risk of type II error. The results of this study should be interpreted in the context of relatively low numbers. Further studies with larger numbers are warranted.

CONCLUSIONS

All 3 surgical cohorts had comparable Clavien IIIb score outcomes with the No ADM trending to the lowest complication rate. BMI ≥ 40, stage 4 cancer, and contralateral prophylactic mastectomy were associated with adverse expander outcomes. Prior radiation therapy caused an overall 10-fold increase in implant loss among the 3 surgical groups. Diabetes, prior breast surgery, type of mastectomy, and chemotherapy played no role in complications in our study. We did not see a higher rate of seroma in the cohorts with ADM techniques. A higher rate of skin necrosis in the Classic group may have been related to higher incidence of cardiac disease or the impact of windowshading of the pectoralis muscle. NSQIP may consider tracking 90-day outcomes for expander/implant surgery, rather than 30 days. Larger, prospective studies including aesthetic outcomes would be beneficial.

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