

BACKGROUND

Approximately 80% of patients undergoing mastectomy in the US opt for implant-based breast reconstruction (IBR). A 2-stage IBR remains the most common technique worldwide. The main objective of IBR is restoration of the preoperative breast shape and mound. It is not surprising there is a positive correlation between the definitive implant size with the mastectomy weight ($r=81\%$, $p<.001$). Also, when compared to a DTI approach, 2-stage IBR has shown to provide significantly higher mean breast implant sizes once the tissue expander is exchanged (490-cm3 versus 373-cm3, $p<.0001$), perhaps due to the postoperative progressive expansion process. Considering previous studies have shown that a larger mastectomy weight is an independent risk factor for complications and implant loss in staged IBR, and that the mastectomy weight and implant size positively correlates, the possibility that the definitive implant size may affect the outcomes of IBR is plausible.

Implying that the implant size, as an absolute number, increases or decreases the incidence of certain complications would be impractical and inaccurate, as the preoperative breast size and inherent structural conformation of the breast envelope may play an important role. Therefore, the aim of this study was to determine the effect of the definitive implant's size with respect to the mastectomy specimen weight and final TE volume on the outcomes and complications following 2-stage IBR. Also, we determined the risk factors and independent predictors for complications after definitive implant placement.

PATIENTS AND METHODS

PATIENTS AND DEMOGRAPHICS:

- This was a retrospective electronic chart review study of 120 patients and 192 total breasts between 2011- 2015 who underwent two-stage IBR following a mastectomy at our institution. This study was approved by the University of Rochester Medical Center Institutional Review Board (IRB No: 5853, July 13, 2021).
- Inclusion criteria:** Women aged 18 years and older undergoing immediate two-stage reconstruction with placement of a TE at the time of prophylactic or therapeutic mastectomy.
- Exclusion criteria:** Women who were younger than 18 years, who underwent delayed TE placement or latissimus dorsi-assisted TE placement, direct-to implant reconstruction, or hybrid reconstruction with abdominal flaps were excluded.

STATISTICAL ANALYSIS

- The unpaired t-test and Mann-Whitney U test were implemented to analyze continuous data.
- Categorical data was analyzed with the Fisher's exact test or the X^2 test.
- Multivariate logistic regression analysis was conducted integrating statistically significant variables on univariate analysis to find independent predictors for complications.
- Haldane-Anscombe corrections were applied when necessary.
- Shapiro–Wilk test for normality was applied to evaluate the distribution of data. Odds ratios (OR), 95 percent confidence intervals (95%CI), and p-values were calculated for each outcome.
- A $p<.05$ was statistically significant. Each breast that underwent mastectomy and implant placement was regarded as an individual independent reconstructive case for our analysis.

RESULTS

Table 1: Patient demographics

Variables	Total, n (%)	Implant Volume > Mastectomy (%)	Implant Volume < Mastectomy (%)	P-value
Total patients	120			
Total breasts	192	91 (47.4)	101 (52.6)	
Age at surgery*	51.8 +/- 11.1	48.8 (9.93)	52.6 (11.62)	0.022
Laterality				
Unilateral	50 (26)	22 (24.2)	28 (27.7)	0.576
Bilateral	142 (74.0)	69 (75.8)	73 (72.3)	
BMI	26.7 +/- 4.78	24.6 (3.83)	28.5 (4.93)	<0.001
Current Smoking	16 (8.3)	14 (15.4)	2 (2.0)	<0.001
Comorbidities				
Diabetes	7 (5.8)	4 (4.4)	7 (6.9)	0.45
HTN	29 (24.2)	18 (19.8)	25 (24.8)	0.409
Follow-up Months (+/-)	60.2 (45.2)	60.9 (28.69)	61.8 (29.97)	0.871

Table 1 demonstrates patients' demographics in two different groups; implant volumes either less than mastectomy specimen weight or more than mastectomy weight. P values indicate that age, BMI, and current smokers were statistically significant. BMI: Body mass index, DM: Diabetes mellitus, HTN: Hypertension, *Mean (+/- standard deviation), +/- Median (IQR: 25-75%)

Table 2: Clinical Characteristics

Characteristics	Total, n (%)	Implant Volume > Mastectomy (%)	Implant Volume < Mastectomy (%)	P-value
Pathology				
Benign pathology	66 (65.5)			
DCIS	20 (10.4)			
LCIS	1 (0.5)			
IDC	85 (44.3)			
ILC	16 (8.3)			
Other	4 (2.1)			
Indication of mastectomy				
Prophylactic	66 (34.4)	28 (30.8)	38 (37.6)	
Therapeutic	126 (65.6)	63 (69.2)	63 (62.4)	0.318
Mastectomy Type				
Nipple sparing	7 (3.6)	6 (6.6)	1 (1.0)	
Skin sparing	156 (81.3)	72 (79.1)	84 (83.2)	
Modified radical	29 (15.1)	13 (14.2)	16 (15.8)	0.117
ADM use	169 (88)	81 (89.0)	88 (87.1)	0.688
Oncologic treatment				
Chemotherapy				
Neoadjuvant	20 (10.4)	8 (8.8)	12 (11.9)	0.484
Adjuvant	68 (35.4)	35 (38.5)	33(32.7)	0.402
Radiotherapy	33 (17.2)	22 (24.2)	11 (10.9)	0.015

Table 2 shows clinical characteristics; breast cancer pathology, intention of mastectomy, type of mastectomy received, use of ADM and oncologic treatment. The statistically significant p value demonstrated that amongst radiotherapy treated patients majority were patients with a greater implant volume than mastectomy specimen weight. DCIS: Ductal carcinoma in-situ, LCIS: Lobular carcinoma in situ, IDC: Invasive ductal carcinoma, ILC: Invasive lobular carcinoma, ADM: Acellular dermal matrix

Table 3: Intraoperative Parameters

Variables	Implant Volume > Mastectomy (%)	Implant Volume < Mastectomy (%)	P-value
Breast	91 (47.4)	101 (52.6)	
Final TE volume	453.8 +/- 130.11	494.6 +/- 153.96	0.079
Implant size (mL)	514.6 +/- 141.5	517.6 +/- 146.37	0.886
Mastectomy (g)			
>516 grams	15 (16.5)	81 (80.2)	<0.001
<516 grams	76 (83.5)	20 (19.8)	
Implant volume > TE	56 (61.5)	51 (50.5)	0.124
Implant volume < TE	35 (38.5)	50 (49.5)	
TE > Mastectomy	69 (75.8)	6 (5.9)	<0.001
TE < Mastectomy	22 (24.2)	95 (94.1)	
Type of Implant			
Smooth	25 (27.5)	37 (36.6)	0.175
Textured	66 (72.5)	64 (63.4)	
Complications during First Stage	32 (35.2)	48 (47.5)	0.083
Complications Requiring Intervention during First Stage	16 (17.6)	28 (27.7)	0.095

Table 3 displays intraoperative parameters. Among variables, the mastectomy specimen weight greater than 516gm (15 patients out of 96) and TE greater than mastectomy specimen (69 patients out of 75) have a link with greater implant volumes, as indicated by P-value.

RESULTS

Table 4: Analysis of Postoperative Outcomes

Complications	Total, n (%)	Implant Volume > Mastectomy (%)	Implant Volume < Mastectomy (%)	P-value	RR	95% CI
Seroma	4	1 (1.1)	3 (3.0)	0.365	0.37	0.039
Dehiscence	6	4 (4.4)	2 (2.0)	0.337	2.22	0.415
Infection	11	6 (6.6)	5 (5.0)	0.625	1.33	0.421
Capsular Contracture	26	17 (18.7)	9 (8.9)	0.048	2.1	0.984
Fat Necrosis	5	0 (0)	5 (5.0)	0.032	0	0
Implant Displacement	9	2 (2.2)	7 (6.9)	0.121	0.317	0.068
Implant Rupture	7	2 (2.2)	5 (5.0)	0.310	0.44	0.089
Implant Extrusion	1	0 (0)	1 (1.0)	0.341	0	0
Overall Complications	56	24 (26.4)	32 (31.7)	0.419	0.832	0.532
Complications Requiring Intervention	31	16 (17.6)	15 (14.9)	0.608	1.18	0.621
Failure	5	2 (2.2)	3 (3.0)	0.737	0.74	0.126

Table 4 exhibits analysis of postoperative outcomes. The P- value indicates that capsular contracture occurred in patients with greater implant volume and fat necrosis is linked to individuals with lesser implant volume.

Table 5: Comparison of Postoperative Outcomes

Variables	Complications (%)	No Complications (%)	P-value	OR	95% CI
Age	49.3 (11.74)	51.4 (10.65)	0.179		
BMI >30	14 (25.0)	32 (23.5)	0.828	1.08	0.526
Current Smoker	4 (7.1)	12 (8.8)	0.702	0.795	0.245
Diabetes	4 (7.1)	7 (5.1)	0.589	1.42	0.398
HTN	14 (25.0)	29 (21.3)	0.579	1.23	0.592
Therapeutic	38 (67.9)	88 (64.7)	0.676	1.15	0.594
Final TE Volume (mL)*	496.9 (+/-142.13)	466.4 (144.66)	0.182		
Implant size (mL)*	532.1 (+/-136.52)	509.6 (146.56)	0.325		
Follow-up	67.8 (30.3)	58.7 (28.56)	0.067		
Neoadjuvant Radiotherapy	1 (1.8)	3 (2.2)	0.853	0.806	0.806
Neoadjuvant Chemotherapy	7 (12.5)	13 (9.6)	0.544	1.35	1.35
Type of Mastectomy					
Modified Radical	12 (21.4)	17 (12.5)	0.08		
SSM	44 (78.6)	112 (82.4)			
NSM	0 (0)	7 (5.1)			
Unilateral	18 (32.1)	32 (23.5)	0.216	1.54	0.775
Mastectomy >516 grams	31 (55.4)	65 (47.8)	0.341	1.35	0.725
ADM use	46 (82.1)	123 (90.4)	0.108	0.486	0.199
Implant > TE	29 (51.8)	78 (57.4)	0.48	0.799	0.428
Implant > Mastectomy Weight	24 (42.9)	67 (49.3)	0.419	0.772	0.413
Type of Implant					
Smooth	14 (25.0)	48 (35.3)	0.166	0.611	0.304
Textured	42 (75.0)	88 (64.7)			
Fat Grafting	8 (14.3)	11 (8.1)	0.191	1.89	0.718
Adjuvant Radiotherapy	18 (32.1)	11 (8.1)	<0.001	5.38	2.34
History of Radiotherapy	19 (33.9)	14 (12.2)	<0.001	4.47	2.05
Adjuvant Chemotherapy	28 (50.0)	40 (29.4)	0.007	2.4	1.26
Complications during First Stage	25 (44.6)	55 (40.4)	0.591	1.19	0.634
Complications during First Stage requiring Intervention	13 (23.2)	31 (22.8)	0.95	1.02	0.489

Table 5 demonstrates postoperative complications for different variables such as different comorbidities, kind of mastectomy, implant kind, treatment type, and complications arising during first stage. The P value indicates that adjuvant radiotherapy (18 out of 29 patients), adjuvant chemotherapy (28 out of 68), and the patients with history of radiotherapy (19 out of 33) have more complications.

SUMMARY OF RESULTS

Postoperative Outcomes

- Overall, 56 (29.2%) breasts had complications.
- Capsular contracture occurred more frequently in patients with an implant volume greater than mastectomy specimen weight ($p=0.048$; RR 2.1; 95%CI 0.984).
- Patients with an implant volume less than mastectomy specimen weight demonstrated an increased likelihood of fat necrosis ($p=0.032$).
- Patients whose implant volume greater than mastectomy specimen weight did not increase the odds of overall complications ($p=0.419$), infection ($p=0.625$), seroma ($p=0.65$), fat necrosis ($p=0.048$) or further surgical management ($p= 0.32$)

Comparison of Postoperative Outcomes

- Patients who underwent adjuvant radiotherapy demonstrated increased complications (18 (32.1%) breasts with complications and 11 (8.1%) breasts without complications) ($p<0.001$)
- History of radiotherapy showed increased complications (19 (33.9%) breast with complications vs 14 breast (12.2%) with no complications) ($p<0.001$).
- Adjuvant chemotherapy displayed a higher percentage of complications than patients with no complications (50% vs 29.4%, respectively) ($P = 0.007$).

CONCLUSION

Although a large implant size does not increase the rate of implant removal or IBR failure, reconstructions receiving a larger implant with respect to the mastectomy weight have an increased rate of capsular contracture. On the other hand, reconstructions receiving a lower implant volume with respect to the mastectomy weight presented a higher rate of fat necrosis. Overall, adjuvant radiotherapy and chemotherapy were found to be independent predictors for overall complications.

