

Surgical Outcomes in Prepectoral Breast Reconstruction

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Background: Prepectoral breast reconstruction has reemerged as a popular option for prosthetic-based breast reconstruction. Recent published literature highlights good outcomes; however, techniques are evolving and options exist for different technologies. The aim of this study is to evaluate short-term complication rates of prepectoral reconstructions using Cortiva acellular dermal matrix.

Methods: A multicenter retrospective study was conducted of all patients who underwent mastectomy with immediate direct-to-implant or 2-stage prepectoral breast reconstruction with Cortiva (RTI Surgical, Alachua, Fla.) between January 2016 and September 2018. The incidence of surgical complications was determined and studied against patient demographics and procedural details.

Results: One-hundred eighteen patients met the inclusion criteria for a total of 183 individual breasts reconstructed with prepectoral implant. Average length of follow-up was 9.26 months (range, 1.0 month to 2.5 years). Thirty-two breasts (17.49%) experienced 1 or more complications. Prepectoral reconstruction was successful 89.07% of the time. Infection was the most common cause of both reoperation and implant failure, with 7.65% of all breasts requiring washout and 5.46% failing prosthetic reconstruction secondary to infection.

Conclusions: Surgical outcomes for prepectoral breast reconstruction using 2-stage and direct-to-implant are similar and comparable to the literature for dual-plane reconstruction, with infection being the main cause of failure. (*Plast Reconstr Surg Glob Open* 2020;8:e2744; doi: [10.1097/GOX.0000000000002744](https://doi.org/10.1097/GOX.0000000000002744); Published online 23 April 2020.)

INTRODUCTION

Prepectoral breast reconstruction continues to gain acceptance as a safe and effective technique for prosthetic-based breast reconstruction. Leaving the pectoralis muscle in place is inherently less invasive and has been demonstrated to result in quicker postoperative recovery, decreased pain scores, and improved esthetics compared with the current gold standard dual-plane technique.^{1,2} Early studies have shown prepectoral reconstruction with the use of acellular dermal matrix (ADM) produces a more natural projection, decreased rates of capsular contracture, and elimination of animation deformity.³⁻⁶ Although results remain favorable, the recent resurgence of this technique suffers from limited short- and long-term data on prepectoral reconstruction outcomes.

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Historically, more aggressive mastectomy procedures and their resultant inadequate soft tissue support led to high incidence of infection, capsular contracture, and implant loss when placed within the subcutaneous plane.⁷ The subsequent shift from subcutaneous to subpectoral reconstruction provided more substantial implant coverage and ultimately led to improved outcomes, although not without both functional and esthetic consequences.^{8,9} Disruption of the pectoral muscle has been shown to result in decreased strength of the ipsilateral arm, whereas muscle contraction and spasm around a submuscular implant have been shown to cause pain in as many as 50% of women at least 1 year after surgery.¹⁰⁻¹² In addition, both complete and partial muscular coverage approaches have been associated with unnatural breast animation on contraction.¹³ Although analysis of ADM use in partial muscular coverage procedures (ie, dual-plane technique) has revealed improved breast contour, projection, and inframammary fold definition, the other aforementioned functional complications and animation deformity remain.^{14,15}

Several fundamental differences exist today which have primed both breast and plastic surgeons for the revival of prepectoral reconstruction. Changes in mastectomy techniques to include a more generous layer of subcutaneous

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tissue between dermis and breast epithelium have helped to address the principle concern of insufficient soft tissue coverage.^{16–19} This, paired with the popularization of ADM and its role to safely bolster the breast pocket, is credited in part for early evidence of improved outcomes with prepectoral reconstruction in the modern era.^{20–25} A review of recent literature describes overall complication rates with immediate ADM-assisted prepectoral reconstruction ranging from 10%²³ to 17.9%²⁴ and rates of implant loss from 1.2%²⁴ to 10.2%.²² Importantly, several studies have demonstrated prepectoral and subpectoral prosthetic reconstructions to have comparable overall complication rates.^{24,26,27}

Various ADM products known to incorporate favorably exist, and it is important that surgeons know the options available for use in prepectoral reconstruction. The aim of this study is to evaluate short-term complication rates of direct-to-implant (DTI) and 2-stage prepectoral breast reconstruction using Cortiva human ADM.

PATIENTS AND METHODS

A multicenter retrospective study was conducted of all patients who underwent mastectomy with immediate implant-based prepectoral breast reconstruction with Cortiva (RTI Surgical, Alachua, FL) between January 2016 and September 2018. Data were collected from a prospectively maintained database at Emory University Hospital (A.L.) and Cancer Treatment Centers of America in Chicago (D.Z.L.). Both DTI and 2-stage procedures were included. Surgical technique included only those approaches which achieved either full (360 degrees) or partial (180 degrees) wrap coverage of the prosthesis with Cortiva.²⁸

The incidence of major surgical complications was determined and studied against patient demographics and procedural details. The data collected included patient age, body mass index, comorbidities, oncologic history, radiation exposure, and mastectomy procedure details. A complication was defined as major if it required readmission or return to the operating room within 60 days from reconstruction. Incidence of major infection, mastectomy skin or nipple necrosis, spontaneous implant exposure, hematoma, seroma, and delayed wound healing complications were documented. Reconstruction was deemed successful if the patient had an implant in the prepectoral space at the time of most recent follow-up, whereas reconstruction was considered a failure if the implant or expander was removed without subsequent replacement or exchange. Capsular contracture was documented if a patient presented with Baker grade III or IV contracture or required operative capsulectomy. Data were analyzed, and significance between variables was determined using a type I error of 5% ($\alpha = 0.05$).

RESULTS

One-hundred eighteen patients met the inclusion criteria for a total of 183 individual breasts reconstructed with prepectoral implant. The average age was 52 years with an average body mass index of 26.52 (Table 1). Forty-four patients had preoperative (n = 9) or postoperative (n = 35) radiation treatment (Table 2). The types of mastectomy included nipple-sparing (n = 103, 56.28%), skin-sparing (n

Table 1. Patient Demographics

	All Patients (n* = 118) (%)	Patients Who Experienced Major Complication (n* = 25) (%)
Mean age at surgery (yr)	52 (30–86)	53 (32–67)
Mean BMI	26.52 (18–41.1)	27.81 (19.7–41.1)
Current smoker	2 (1.69)	1 (4.00)
Diabetic	11 (9.32)	2 (8.00)
Hypertensive	38 (32.20)	13 (52.00)

*n expressed as number of patients.
BMI, body mass index.

Table 2. Major Complication Rates and Outcomes by Radiation Exposure

Major Complication	Pre- or Postmastectomy Radiation Exposure (n* = 44)	No Radiation Exposure (n* = 139)	P
All causes	7 (15.90)	25 (17.99)	0.057
Infection	1 (2.27)	13 (9.35)	0.106
Mastectomy skin/nipple necrosis	2 (4.55)	5 (3.60)	0.534
Implant exposure	1 (2.27)	2 (1.44)	0.564
Hematoma	0 (0)	3 (2.16)	0.436
Seroma	1 (2.27)	2 (1.44)	0.564
Delayed wound healing	2 (4.55)	0 (0)	
Implant/expander failure	4 (9.10)	15 (10.79)	0.501

*n expressed as number of breasts.

= 72, 39.34%), or skin-reducing (n = 8, 4.37%) (Table 3). Sixty-five patients underwent immediate bilateral mastectomy and reconstruction, whereas 53 patients had only unilateral procedures. There were 136 DTI reconstructions and 47 tissue expander (TE) reconstructions (Table 4). The average DTI implant volume was 407.90 mL (range, 130–700 mL) (Table 5). Average length of follow-up was 9.26 months (range, 1.0 month to 2.5 years).

Twenty-five patients (21.19%) and 32 breasts (17.49%) had 1 or more major complications, with 7 patients experiencing bilateral complications (Table 6). There was no statistical difference in the major complication rate when comparing DTI and TE reconstructions ($P = 0.824$) (Table 4). Infection was the most common reason for reoperation, occurring in 7.65% of all breasts. Prepectoral reconstruction was successful 89.62% of the time with infection being the inciting complication leading to failure in 52.63% of cases (Figs. 1, 2). Baker III/IV capsular contracture was found in 5.4% of breasts (n = 10).

There was no statistical difference between major complication rates of DTI reconstructions using implant volumes ≤ 450 mL versus those that used >450 mL ($P = 0.220$) (Table 5). However, patients with implants >450 mL were statistically more likely to experience implant failure ($P = 0.018$).

A full wrap technique was used in 115 breasts, whereas another 68 breasts were reconstructed with partial, anterior-only coverage. Of those breasts reconstructed using the full wrap technique, 16.52% (n = 19) experienced a major complication compared with 19.12% (n = 13) for partial coverage only.

Table 3. Mastectomy Procedure Details

	All Breasts (n* = 183)			Major Complication Group (n* = 32)			Implant/Expander Failure Group (n = 19)		
	All (n = 183) (%)	DTI (n = 136) (%)	TE (n = 47) (%)	All (n = 32) (%)	DTI (n = 23) (%)	TE (n = 9) (%)	All (n = 19) (%)	DTI (n = 14) (%)	TE (n = 5) (%)
NSM	103 (56.28)	94 (69.10)	9 (19.10)	12 (37.5)	11 (47.83)	1 (11.11)	8 (42.11)	8 (57.14)	0 (0)
SSM	72 (39.34)	42 (30.90)	30 (63.80)	20 (62.5)	12 (52.17)	8 (88.89)	11 (57.87)	6 (42.86)	5 (100.00)
SRM	8 (4.37)	0 (0)	8 (17.00)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

*n expressed as number of breasts.

NSM, nipple-sparing mastectomy; SRM, skin-reducing mastectomy; SSM, skin-sparing mastectomy.

Table 4. Major Complication Rates and Outcomes by Direct-to-Implant versus 2-stage Reconstruction

Major Complication*	DTI (n† = 136) (%)	TE (n† = 47) (%)	P
All causes	23 (16.91)	9 (19.15)	0.82
Infection	10 (7.35)	4 (8.51)	>0.05
Mastectomy skin/nipple necrosis	5 (3.68)	2 (4.26)	>0.05
Implant exposure	1 (0.74)	2 (4.26)	>0.05
Hematoma	3 (2.21)	0 (0)	>0.05
Seroma	3 (2.21)	0 (0)	>0.05
Delayed wound healing	1 (0.74)	1 (2.13)	>0.05
Implant/expander failure‡	14 (10.29)	5 (10.64)	1.00

*Defined as any complication which required OR or readmission <60 d from primary reconstruction.

†n expressed as number of breasts.

‡Defined as removal of implant/expander without subsequent replacement or exchange.

OR, operating room.

Table 5. Major Complication Rates and Outcomes for DTI Reconstructions by Implant Volume

	DTI ≤450 mL (n* = 93) (%)	DTI >450 mL (n* = 43) (%)	P
	Major complication†	13 (14.00)	
Implant failure‡	6 (6.50)	8 (18.60)	0.018
Capsular contracture§	7 (7.50)	2 (4.20)	0.719

*n expressed as number of breasts.

†Defined as any complication which required OR or readmission <60 d from primary reconstruction.

‡Defined as removal of implant/expander without subsequent replacement or exchange.

§Included only patients who presented with Baker grade III/IV or those requiring operative capsulectomy.

OR, operating room.

Of note, 27.78% of all skin-sparing mastectomies performed experienced a major complication compared with 11.65% of all nipple-sparing mastectomies. The failure rate was 15.28% for skin-sparing mastectomies compared with 7.77% for nipple-sparing mastectomies (Table 3).

DISCUSSION

Advancements in both breast oncology and the tools available for reconstruction have changed the landscape of breast reconstruction, making pursuit for improved esthetic and functional outcomes a reality for plastic surgeons. Recent literature seems to corroborate a role for prepectoral prosthesis placement in achieving these ideals, specifically as it relates to decreased animation

Table 6. Complication Rates and Outcomes among All Breasts in Series (n* = 183)

	n (%)
Major complications†	32 (17.49)
All causes	14 (7.65)
Infection	7 (3.83)
Mastectomy skin/nipple necrosis	3 (1.64)
Implant exposure	3 (1.64)
Hematoma	3 (1.64)
Seroma	2 (1.09)
Delayed wound healing	2 (1.09)
Implant/expander failure‡	19 (10.38)
All causes	10 (5.46)
Infection	8 (4.37)
Implant exposure	1 (0.55)
Seroma	10 (5.46)
Capsular contracture§	10 (5.46)

*n expressed as number of breasts.

†Defined as any complication which required OR or readmission <60 d from primary reconstruction.

‡Defined as removal of implant/expander without subsequent replacement or exchange.

§Included only patients who presented with Baker grade III/IV or those requiring operative capsulectomy.

OR, operating room.

deformity, capsular contracture formation, and postoperative pain scores. Correspondingly, the popularity of prosthetic-based reconstruction in the prepectoral position has increased.

In our cohort of 183 breasts, prepectoral reconstruction was successful in 89.62% of cases. Over half of cases of implant failure were attributable to infection. Our overall rate of infection requiring operative washout was high at 7.65% of all breasts. In comparison, 2 large retrospective reviews of 353 and 135 prepectoral reconstructions with AlloDerm (LifeCell Corp., Branchburg, N.J.) demonstrated infection rates of 4.5% (Sigalove et al²⁹) and 2.0% (Woo et al²³), respectively. Differences in patient exclusion criteria cannot be ignored, however, because both of these studies excluded patients with history of radiation exposure. The inclusion of these patients in our report may explain our rates of infection and failure, given the known association between radiation exposure and increased risk of implant failure.^{30–32} Overall, our incidence of infection was within acceptable limits of published ADM-assisted breast reconstruction outcomes, where one meta-analysis of 16 retrospective cohort studies reported a pooled infection complication rate of 5.7% (95% CI, 4.3%–7.3%).³³

Many different types of human ADM are available and have been described.^{34–38} This report describes our experience with Cortiva. The use of ADM in prepectoral breast reconstruction provides support for the

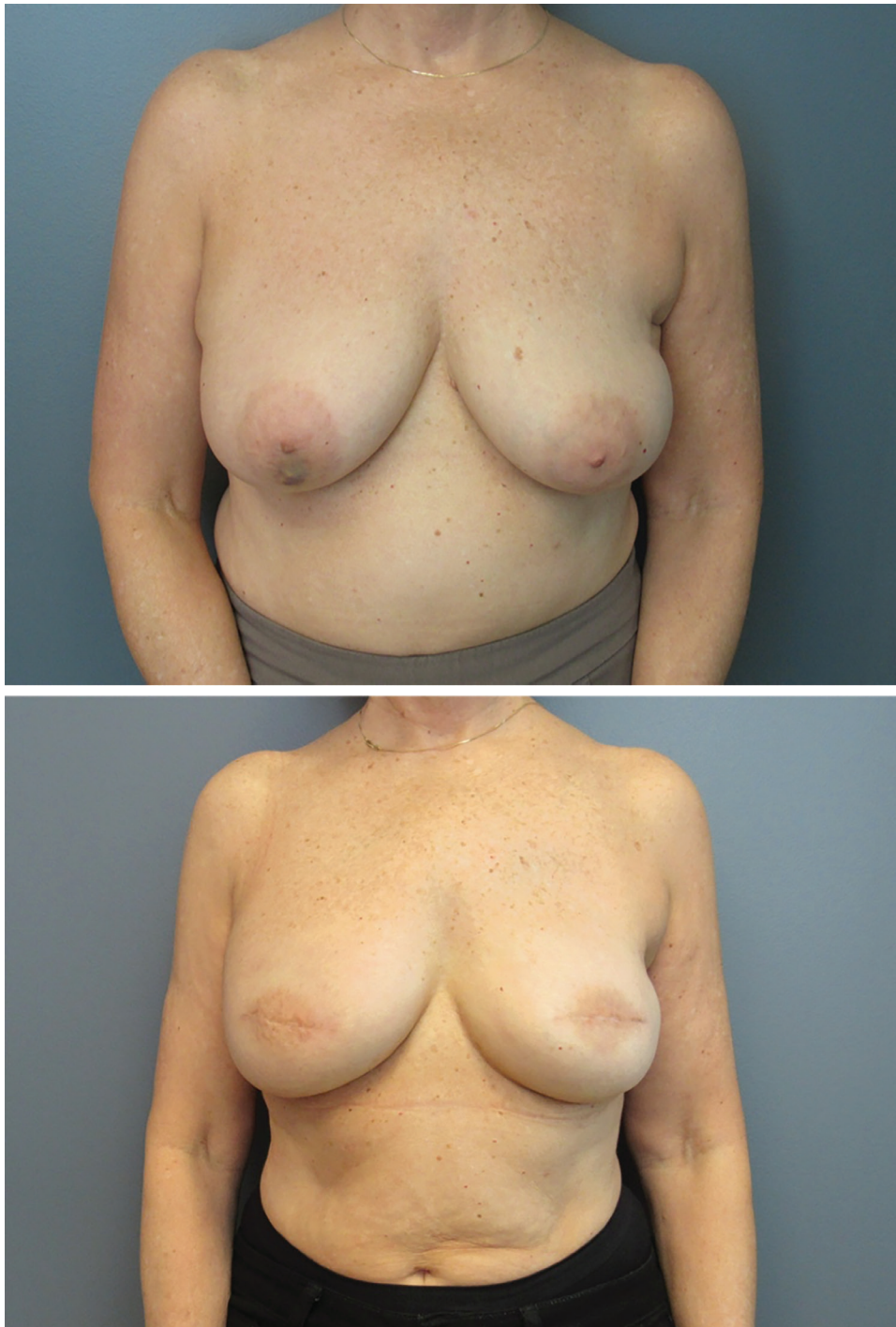


Fig. 1. This is a 47-year-old woman with breast cancer who underwent a bilateral areolar and skin-sparing mastectomy and direct-to-implant reconstruction. Her 500-mL gel implants were both placed in the prepectoral space with anterior ADM. She is shown at 1-year follow-up and is deferring additional nipple reconstruction.

implant and improved coverage. More importantly, it works to create a more favorable interface between the prosthesis and skin flaps. Previous clinical and histologic reports have shown similar clinical outcomes when comparing Alloderm to Cortiva,^{37,39} with histologic evidence demonstrating lower levels of TGF- β in

the Cortiva group.³⁸ Evidence that prepectoral prosthesis with the use of ADM may limit capsule formation is growing. Our experience supports this with a low incidence of capsular contracture formation (5.46%), albeit guarded given the short-term follow-up of this study. In addition, there was no significant difference

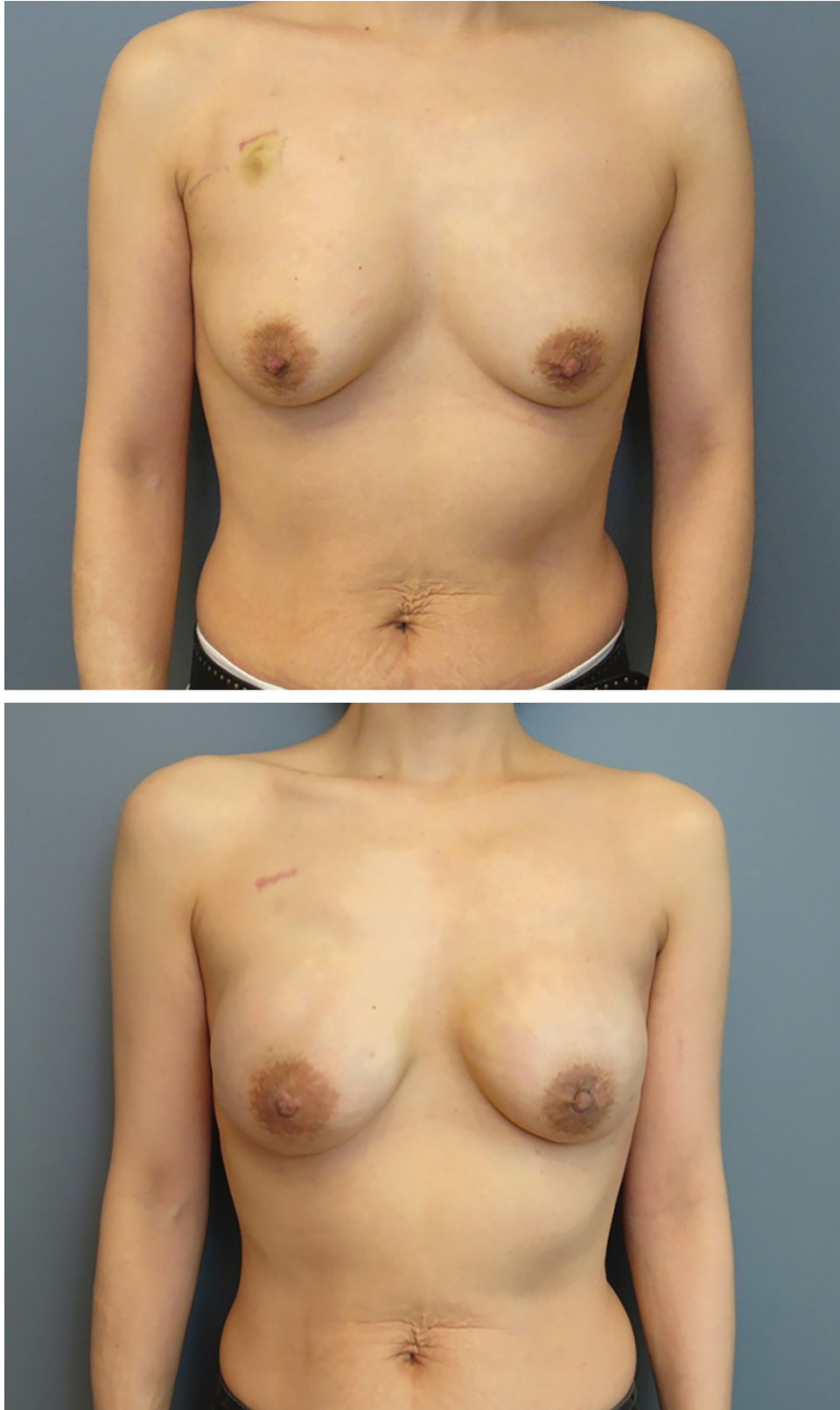


Fig. 2. This is a 39-year-old woman with left breast cancer who underwent a bilateral nipple-sparing mastectomy and prepectoral direct-to-implant reconstruction with anterior coverage ADM. The implant size was 250-mL moderate plus gel. She is shown 1.5 years following completion of left breast irradiation with a soft symmetric breast. She has some rippling in the upper pole on the left that could be addressed with autologous fat grafting.

in complications when comparing the full wrap versus partial coverage cohort.

Based on our data, there did not seem to be a difference in complications when comparing 2-staged TE reconstruction versus DTI. The prepectoral DTI approach did seem to be safer when used with implants <450 mL, likely due to the initial smaller breast size being protective against complications.

The purpose of this study was to evaluate short-term complications of prepectoral reconstructions using Cortiva. Our study was multicentered and included patients with history of radiation exposure. The authors recognize this as a strength of this study, given the known association with radiation exposure as a cause of implant infection and failure.^{30–32} A limitation of this report was the retrospective nature of data abstraction. Because this was not a randomized controlled trial, patients were selected to be good candidates for prepectoral reconstruction at the surgeon's discretion. Thus, our results may not be applicable to the general population. For future studies, longer follow-up was planned and will incorporate patient satisfaction scores and more adequate follow-up of long-term outcomes including capsular contracture.

CONCLUSIONS

Preliminary outcomes from this report suggest that prepectoral reconstruction with ADM is once again safe and feasible. The short-term major complication outcomes in this study of 183 breasts compare favorably with other immediate prepectoral reconstruction results in the literature.²¹ However, the heterogeneous prepectoral candidate exclusion criteria among patient cohorts in published reports, and the spectrum of technical considerations related to the use of ADM, make direct comparisons challenging. A call for a more standardized approach to prepectoral outcomes reporting may be needed, whereby there may be utility to data capture and comparison by means of a validated method like the American College of Surgeons National Surgical Quality Improvement Program. Large prospective studies comparing the use of different acellular dermal matrices are also needed before prepectoral implant placement may be considered the new standard of care for breast reconstruction.

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