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Short-Term Complications Associated With Acellular Dermal Matrix-Assisted Direct-to-Implant Breast Reconstruction

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Background: Although direct-to-implant breast reconstruction is a more concise procedure than 2-stage expander/implant reconstruction, it is less frequently performed. Skeptics of direct-to-implant reconstruction cite risk of postoperative complications as a reason for its rejection. To determine whether these perceptions are valid, we evaluated our 13-year experience of acellular dermal matrix (ADM)-assisted, direct-to-implant breast reconstruction. We report complication and reoperation rates associated with this technique as well as predictors for these outcomes.

Methods: This retrospective study included all patients who underwent immediate, ADM-assisted, direct-to-implant, breast reconstruction from December 2001 to May 2014 at 2 practices. Postoperative complications, defined as those occurring within the first 12 months after reconstructive surgery, were evaluated. Univariate/multivariate analyses were performed to determine the influence of patient-, breast-, and surgery-related characteristics on the development of complications.

Results: A total of 1584 breast reconstructions (721 bilateral, 142 unilateral) in 863 patients were performed; 35% were oncologic, and 65% were prophylactic reconstructions. Complication rate was 8.6% and included skin necrosis (5.9%), infection (3.0%), implant loss (2.9%), seroma (1.1%), and hematoma (0.9%). Reoperative rate in breasts with complications was 3.2%. Age 50 years or older, smoking, nonnipple-sparing mastectomy, and implant size of 600 mL or greater strongly predicted the development of complications ($P < 0.001$).

Conclusions: Our cumulative 13-year experience demonstrates that immediate, ADM-assisted, direct-to-implant breast reconstruction is safe, effective, and reliable. Complication and reoperation rates are less than 10% and are comparable to those reported for 2-stage procedures in the published literature.

Key Words: direct-to-implant reconstruction, complications, acellular dermal matrix, risk factors, revisions

(*Ann Plast Surg* 2016;00: 00–00)

Tissue expander/implant breast reconstruction has become the standard of care for the majority of patients who undergo mastectomy. Approximately 70% of all breast reconstructions are performed as a 2-stage procedure.[1] Although direct-to-implant breast reconstruction is a more concise alternative that precludes the need for a second stage, it is less frequently performed, constituting only 8% of all breast reconstructions in 2014.[1]

Historically, direct-to-implant reconstruction has been limited by 2 factors: inadequate native skin envelope and suboptimal subpectoral volume. With the advent of skin and nipple-sparing mastectomy, skin quantity is no longer a limitation, though skin quality can be problematic. Inadequate subpectoral volume has been addressed by the utilization of acellular dermal matrices. In most patients, complete subpectoral coverage of the implant is impossible due to lack of subpectoral volume and noncompliance of the pectoralis major muscle. Releasing the origin and inferior aspects of the pectoralis muscle has helped, but window shading of the muscle and thinning of the lower pole tissue and their sequelae have proved unacceptable. Utilization of surrounding autologous tissue to supplement pectoralis muscle deficit at the lower pole likewise yielded suboptimal results. Acellular matrices provide a means to increase subpectoral volume and shape the lower pole without the attendant problems of donor-site morbidity or tissue flaps.[2–5]

Although skin and nipple-sparing mastectomy and utilization of acellular matrices have greatly facilitated direct-to-implant reconstruction, the adoption of this method of reconstruction remains low. Possible reasons may include perceived increased risk of postoperative complications (particularly skin necrosis, infection, and implant loss) compared with 2-stage procedures.[6,7] To determine whether these perceptions are valid, we evaluated our extensive 13-year experience of direct-to-implant breast reconstruction using acellular dermal matrix (ADM). We report on complication and reoperation rates associated with this technique as well as patient-, breast-, and surgery-related characteristics and their association with these outcomes.

MATERIALS AND METHODS

All consecutive patients who underwent immediate, direct-to-implant, breast reconstruction with the assistance of an ADM in the authors' practices were included in this retrospective study. The decision to undergo direct-to-implant reconstruction was made preoperatively in consultation with the patient, but the final decision was made intraoperatively after assessing the quantity and quality of the skin envelope postmastectomy. Reconstructive surgery was performed over a 13-year period from December 2001 to May 2014. Patients who underwent delayed reconstruction, 2-stage tissue expander/implant reconstruction, implant-based flap procedures, or implant-based revision reconstruction were excluded from the analyses. Those who received expandable implants were also excluded.

Direct-to-implant reconstruction with ADM assistance was performed as described previously.[2,8] Briefly, after nipple-sparing or skin-sparing mastectomy, the ADM (AlloDerm or Strattice; LifeCell Corp., Branchburg, NJ or FlexHD Pliable; Mentor Worldwide LLC, Santa Barbara, CA) was prepared according to manufacturers' recommendations. The inferolateral attachments of the pectoralis major muscle are released, and a retropectoral pocket is created. The pocket typically extends from the lateral border of the pectoralis major muscle to the second rib superiorly, to the sternum medially, and to the level of the contralateral inframammary fold inferiorly. A silicone or saline

Received June 29, 2015, and accepted for publication, after revision December 26, 2015.

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Conflicts of interest and sources of funding: an educational grant from LifeCell Corporation was utilized for data analyses and manuscript preparation.

C.A.S., L.M.H., and A.Y.A. are consultants to LifeCell Corporation. All other authors have no relevant disclosures.

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ISSN: 0148-7043/16/0000–0000
DOI: 10.1097/SAP.0000000000000742

implant is introduced into the retropectoral pocket under the overlying pectoralis major muscle. The muscle typically covers the superior two thirds of the implant, and the prepared sheet of ADM is used to extend the pectoralis muscle to the inferior third of the implant. The inferior border of the ADM is sutured to the chest wall and the lateral mammary fold to serratus fascia to recreate the folds if obliterated or to the fold itself. The superior border of the ADM is sutured to the inferior border of the freed pectoralis major muscle. Two suction drains are placed, one in the retropectoral, and the other in the subcutaneous space, via separate stab incisions, or in the axilla for better scar camouflage.

Patient charts were reviewed for postoperative complications, defined as those occurring within the first 12 months after reconstructive surgery, and included, but not limited to infection requiring antibiotic intervention, seroma or hematoma requiring drainage, and skin necrosis. The 12-month threshold was selected to limit complications to those that were directly related to the surgical intervention and to exclude long-term, implant-related complications, such as capsular contracture. Data were collected up to December 31, 2014. The incidence of each individual complication as well as the rate of total complications is presented. A comparative analysis of total complications

TABLE 1. Patient Demographics, Adjuvant Therapy, and Mastectomy and Implant Characteristics

	Total: Patients = 863, Breasts = 1584
	N (%)
Age	
Mean (SD), y	47.0 (10.0) (range, 21–77)
Body mass index	
Mean (SD), kg/m^2	24.4 (4.8) (range, 16–54)
Comorbidities, no. patients (%)	
Diabetes	14 (1.6)
Smoking	118 (13.7)
Current	47 (5.4)
Past	71 (8.2)
Hypertension	83 (9.6)
Obesity*	85 (9.8)
Chemotherapy	
No. patients, n (%)	227 (26.3)
Before mastectomy	65 (7.5)
After mastectomy	147 (17.0)
Prior history	15 (1.7)
Radiotherapy	
No. patients, n (%)	100 (11.6)
No. breasts, n (%)	104 (6.6)
Before mastectomy, n (%)	44 (42.3)
After mastectomy, n (%)	52 (50.0)
Prior history, n (%)	8 (7.7)
Mastectomy	
Bilateral, no. patients (%)	721 (83.5)
Unilateral, no. patients (%)	142 (16.5)
Prophylactic, no. breasts (%)	1024 (64.6)
Oncologic, no. breasts (%)	560 (35.4)
Weight, mean (SD), g	419.0 (313.4) (range, 35–2846)
Nipple-sparing, no. breasts (%)	
Yes	1043 (65.9)
No	541 (34.2)
Implant size, mean (SD), mL	484.8 (123.8) (range, 100–800)
Acellular dermal matrix used, no. of breasts (%)	
AlloDerm	1473 (93.0)
Strattice	109 (6.9)
FlexHD	2 (0.1)

*Body mass index ≥ 30 kg/m^2.

TABLE 2. Complications

	Total Breasts, N = 1584
	N (%)
Complications (total)*	137 (8.6)
Implant loss/explanted	46 (2.9)
Infection	48 (3.0)
Skin necrosis/breakdown	94 (5.9)
Ischemia (flap/nipple)	2 (0.1)
Seroma	17 (1.1)
Implant exposure	4 (0.3)
Hematoma	15 (0.9)
Acellular dermal matrix exposure	4 (0.3)

*Breasts with >1 complication were computed once.

TABLE 3. Complications Stratified by Patient-, Breast-, and Surgery-Related Characteristics

Characteristic	Complication Rate (%)	*P*
Patient-related		
Age, y ≥50 versus < 50	13.2 vs 5.0	0.00007*
Body mass index, kg/m^2 ≥30 vs < 30	13.5 vs 8.6	0.054
Smoking Yes vs no	20.4 vs 7.2	2.48×10^{-8}*
Hypertension Yes vs No	8.8 vs 10.6	0.664
Diabetes Yes vs no	3.2 vs 10.7	0.243
Chemotherapy Yes vs no	12.1 vs 8.2	0.027*
Breast-related		
Oncologic breast Yes vs no	11.8 vs 6.9	0.001*
Preoperative radiotherapy† Yes vs no	13.5 vs 8.6	0.210
Surgery-related		
Nipple-sparing mastectomy Yes vs no	4.8 vs 15.8	1.10×10^{-12}*
Mastectomy weight, g ≥600 vs < 600	18.1 vs 6.4	4.30×10^{-9}*
Implant size, mL ≥600 vs < 600	16.4 vs 6.3	2.46×10^{-8}*
Implant size ≤ mastectomy weight vs implant size > mastectomy weight	17.0 vs 5.8	5.2×10^{-10}*

*Statistically significant.

†Postoperative radiotherapy was not included as a variable because complications in postoperatively irradiated breasts occurred before irradiation.

stratified by patient-, breast-, and surgery-related characteristics was performed using χ^2 or Fisher's exact test (2-tailed). Results were considered to be statistically significant at a P value less than 0.05.

Six patient-related, 2 breast-related, and 4 surgery-related variables were evaluated as potential risk factors for the development of complications. Patient-related variables evaluated included age, body mass index (BMI), smoking, hypertension, diabetes, and chemotherapy use. Smoking included past or current smokers. Chemotherapy included preoperative or postoperative chemotherapy or history of chemotherapy. Breast-related variables evaluated included oncologic breast and radiotherapy use. Surgery-related variables evaluated included implant size, mastectomy weight, implant size> mastectomy weight (yes vs no), and mastectomy type (nipple-sparring mastectomy [NSM] vs non-NSM). These patient-, breast-, and surgery-related characteristics were selected based on published reports that have shown an association between these characteristics and outcomes in implant-based reconstruction.[9–14] To assess the association between patient/breast/surgery characteristics and incidence of complications, univariate analyses were initially performed with χ^2 test for categorical variables and logistic regression for continuous variables. For continuous variables, a threshold (beyond which complications increased substantially) was identified and used as the cutoff for conversion of the continuous variable to a binary variable. Variables that were statistically significant ($P < 0.05$) at the univariate level were reassessed in a multiple logistic regression model. Stepwise logistic regression was used to create the final predictive model. Univariate and multivariate analyses were performed with SAS version 9.3 software.

TABLE 4. Univariate Analyses of Patient-, Breast-, and Surgery-Related Characteristics as Risk Factors for Complications

Characteristic	Odds Ratio	95% CI	*P*
Patient-related			
Age, y ≥50 vs <50	2.90	1.96–4.30	<0.0001*
Body mass index, kg/m^2 ≥30 vs <30	1.66	1.01–2.74	0.0452*
Smoking Yes vs no	3.29	2.22–4.88	<0.0001*
Hypertension Yes vs no	0.82	0.45–1.50	0.5209
Diabetes Yes vs no	0.28	0.04–2.07	0.1814
Chemotherapy Yes vs no	1.54	1.06–2.23	0.0214*
Breast-related			
Oncologic breast Yes vs no	1.82	1.28–2.59	0.0007*
Preoperative radiotherapy† Yes vs no	1.66	0.74–3.76	0.2100
Surgery-related			
Nipple-sparing mastectomy Yes vs no	0.27	0.19–0.39	<0.0001*
Mastectomy weight, g ≥600 vs < 600	3.23	2.22–4.71	<0.0001*
Implant size, mL ≥600 vs < 600	2.90	2.02–4.12	<0.0001*
Implant size > mastectomy weight Yes vs no	0.30	0.21–0.44	<0.0001*

*Statistically significant.

†Postoperative radiotherapy was not included as a variable because complications in postoperatively irradiated breasts occurred before irradiation.

TABLE 5. Multivariate Analyses of Patient-, Breast-, and Surgery-Related Characteristics as Risk Factors for Complications

Characteristic	Odds Ratio	95% CI	*P*
Patient-related			
Age, y ≥50 vs <50	2.000	1.258–3.185	0.0034*
Body mass index, kg/m^2 ≥30 vs <30	0.667	0.364–1.222	0.1906
Smoking Yes vs no	2.179	1.374–3.448	0.0009*
Chemotherapy Yes versus no	0.692	0.446–1.074	0.1005
Breast-related			
Oncologic breast Yes vs no	1.103	0.723–1.678	0.6513
Surgery-related			
Nipple-sparing mastectomy Yes vs no	0.272	0.168–0.439	<0.0001*
Mastectomy weight, g ≥600 vs < 600	1.017	0.506–2.045	0.9620
Implant size, mL ≥600 vs < 600	1.931	1.140–3.268	0.0143*
Implant size > mastectomy weight Yes vs no	0.776	0.430–1.401	0.4000

*Statistically significant.

RESULTS

A total of 863 patients met the inclusion criteria of having undergone immediate direct-to-implant breast reconstruction with the use of ADM and formed the analytical cohort of this study. The mean age of patients was 47.0 (10.0) years, and mean BMI was 24.4 (4.8) kg/m^2. Less than 15% of patients had comorbidities. Demographic and clinical characteristics of the patient population are summarized in Table 1.

A total of 1584 mastectomies (721 bilateral and 142 unilateral) were performed on the study population by 19 mastectomy surgeons at 10 different hospitals. Two thirds of the mastectomies were NSMs. Sixty-five percent of the mastectomies were for prophylactic, and

TABLE 6. Multivariate Analyses of Risk Factors for Complications: Final Model

Characteristic	Odds Ratio	95% CI	*P*
Patient-related			
Age, y ≥50 vs <50	2.212	1.439–3.413	0.0003*
Smoking Yes vs no	2.222	1.439–3.425	0.0003*
Surgery-related			
Nipple-sparing mastectomy Yes vs no	0.309	0.206–0.463	<0.0001*
Implant size, mL ≥600 versus < 600	2.151	1.453–3.185	0.0001*

*Statistically significant.

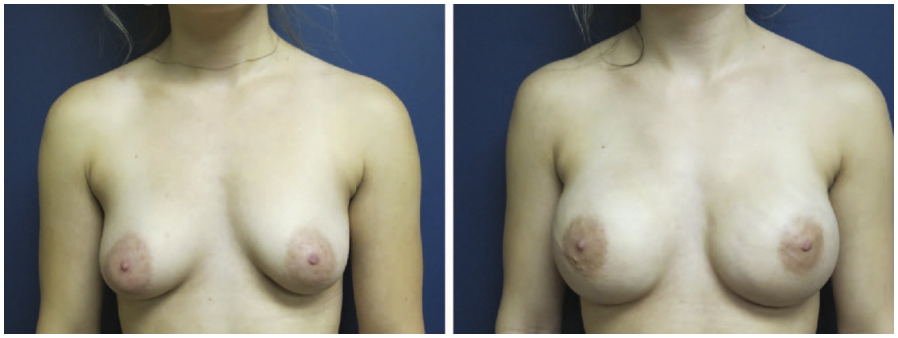

FIGURE 1. A 24-year-old woman with a strong family history of breast cancer and breast cancer gene positive. Bilateral prophylactic mastectomy and reconstruction with smooth, round, ultra-high profile, silicone gel implants (480 mL). Left: pre-operative; right: at 1 year postoperative.

35% were for oncologic reasons. Eleven percent of patients underwent radiotherapy, and 26% had chemotherapy (Table 1).

Immediate reconstructive surgery was performed by 2 plastic and reconstructive surgeons (C.A.S. and L.M.H.). AlloDerm was used in 93% (n = 1473), Strattice in 6.9% (n = 109), and FlexHD in 0.1% (n = 2) of the reconstructions. Implant volume ranged from 100 to 800 mL, with a mean of 484.8 (123.8) mL.

During the 12 months after reconstructive surgery, complications occurred in 137 breasts for a total complication rate of 8.6% (Table 2). Complications included skin necrosis (5.9%), infection (3.0%), implant loss (reconstructive failure) (2.9%), seroma (1.1%), hematoma (0.9%), implant exposure (0.3%), and ADM exposure (0.3%). Breasts with complications had significantly larger implants than those that did not have complications. Mean implant volume of breasts with and without complications was 545 (140) mL and 479 (123) mL, respectively ($P < 0.0001$). Among breasts that had complications, 50 required reoperation, for an overall reoperative rate of 3.2% (50/1584). When total complications were stratified by patient-related characteristics, significantly higher complications were seen in patients who were 50 years or older, were smokers (current or with a history), had a BMI of 30 kg/m^2 or greater, and had received chemotherapy (Table 3). When stratified by breast- and surgery-related characteristics, total complications were significantly higher in breasts that had cancer; and breasts that had non-NSM, implants of 600 mL or greater, mastectomy weight of 600 g or greater, and implants that were less than or equal to mastectomy weight. The threshold for age, BMI, implant size, and mastectomy weight was derived from univariate analysis as described below.

Six patient- and 2 breast-, and 4 surgery-related characteristics were evaluated as potential predictors of complications. For the continuous variables, age, BMI, implant size, and mastectomy weight, a univariate analysis was performed to identify a threshold beyond which complications substantially increased, which was then used to convert the variable to a binary format. This analysis identified the threshold for age as 50 years or older, BMI as 30 kg/m^2 or greater, implant size as 600 mL or greater, and mastectomy weight as 600 g or greater. In univariate analysis, 50 years or older, smoking, chemotherapy use, non-NSM, oncologic breast, implant size of 600 mL or greater, mastectomy weight of 600 mL or greater, and implant size smaller than or equal to mastectomy weight were significant independent predictors of the development of complications (Table 4). A multivariate analysis was then performed to identify a set of predictive variables. When included in the full multiple logistic regression model, BMI, chemotherapy, oncologic breast, mastectomy weight, and implant size smaller than or equal to mastectomy weight were no longer significant predictors of complication (Table 5). The final model, including only significant predictors, identified 50 years or older, smoking, non-NSM, and implant size of 600 mL or greater as being significantly associated with complications (Table 6). The odds of developing complications were 2.2 times greater in patients aged 50 years or older, in smokers, and in those who had an implant size of 600 mL or greater and 3.2 times greater in those who underwent non-NSM (Table 6).

Representative outcomes of patients are shown in Figures 1–3.

DISCUSSION

This study, representing the 13-year cumulative experience of 2 geographically separated reconstructive surgeons, is the largest study to date assessing postoperative complications after immediate direct-to-implant breast reconstruction with the use of ADM. A total of 1584 reconstructions were assessed over the study period. The complication rate was 8.6%, reoperation rate was 3.2%, and reconstructive failure

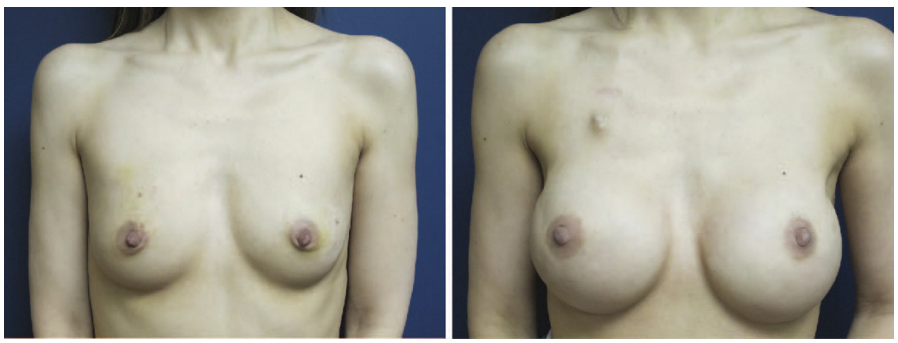

FIGURE 2. A 44-year-old woman with right breast ductal carcinoma in situ. Bilateral mastectomy and reconstruction with smooth, round, moderate-profile, silicone gel implants (400 mL). Left: pre-operative; right: at 1 year postoperative.

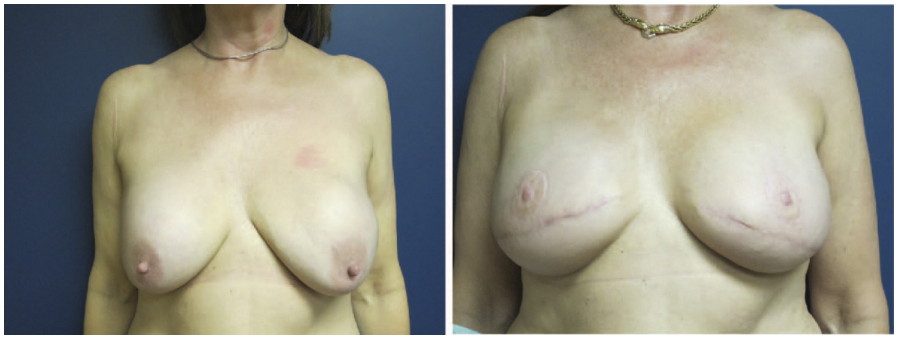

FIGURE 3. A 55-year-old woman with left breast invasive ductal carcinoma and ductal carcinoma in situ. Bilateral mastectomy and reconstruction with full thickness skin grafts and smooth, round, moderate-plus profile, silicone gel implants (800 mL). Left: preoperative; right: at 6 months postoperative.

(implant loss) rate was 2.9%. These results confirm that ADM-assisted, direct-to-implant reconstruction is safe and reliable.

Skeptics of direct-to-implant reconstruction cite a higher complication rate, particularly a significantly higher incidence of skin flap necrosis, with this procedure compared with the 2-stage procedure.[6,7] Our study did not include patients who underwent 2-stage reconstruction which precludes comparisons to be made between the 2 methods of reconstruction and is a limitation of our study. Nonetheless, a comparison of our complication rates with those reported in large studies in the published literature as well as in a meta-analysis of published studies of 2-stage reconstructions do not suggest a higher rate of complications with the direct-to-implant approach (Table 7).[15–17] Further, a study conducted at the Massachusetts General Hospital that compared direct-to-implant reconstruction (with the use of ADM) with 2-stage reconstruction (without the use of ADM) also reported similar complication rates between these 2 approaches.[18]

Our overall favorable outcomes may to some extent be related to favorable patient attributes, including an average BMI of 24 kg/m^2 and less than 15% of patients having comorbidities. Moreover, two thirds of reconstructions were done after prophylactic mastectomy. Nonetheless, our results do indicate that a number of patient- and surgery-specific characteristics, including older age (≥50 years), smoking, non-NSM, and large implant size (≥600 mL), may increase the risk of complications even in this relatively healthy cohort. These findings highlight the need to inform and counsel patients of the potential for complications with direct-to-implant reconstruction. Although age, non-NSM, and cancer are beyond the control of the patient, smoking and implant size are modifiable factors that patients can control to minimize the risk of complications. Patients who desire large implants should be informed of the threshold size for complications and may be better served with a 2-stage procedure.

The greatest advantage of direct-to-implant reconstruction is the 1-stage approach. By precluding a second reconstructive step, direct-to-implant reconstruction eliminates the attendant risks and morbidity of a second procedure. One less surgery may also translate into cost savings. In fact, cost analysis studies, performed in 3 different health care systems (the United Kingdom, Canada, and the United States) have all shown that the 1-stage procedure is associated with lower total costs even after factoring in the cost of ADM.[19–22]

Another advantage of the direct-to-implant approach is the maximal use of the skin envelope at the time of surgery before it contracts. In 2-stage procedures, the skin is allowed to contract around the expander in the early postoperative period, and then it is serially expanded. This further thins the soft tissue envelope especially over an integral injection port, creating a thinner base for nipple areolar reconstruction and lack of central projection. Using the skin envelope before it contracts, in our opinion, yields a more natural aesthetic outcome. Finally, the 1-step approach offers patients an earlier restoration of body image that would otherwise take months to achieve with a 2-stage approach.

Unfortunately, not all patients are candidates for direct-to-implant reconstruction. A key criterion is the availability of a healthy, well-perfused, skin envelope. Even when direct-to-implant reconstruction is planned before mastectomy, the decision to perform the procedure should be made after evaluating the quality of the skin postmastectomy. In addition, patient characteristics, such as obesity, smoking, implant/breast size, age, radiotherapy, and chemotherapy, may influence the risk of complications,[9–14,23–26] and the decision to perform direct-to-implant reconstruction in these patients should be

TABLE 7. Complications in Direct-To Implant Versus 2-Stage Reconstructions

	Hunsicker et al Direct-to-Implant (Current study) %	**Cordeiro et al,[15] 2-Stage, %**	**Kim et al,[16] 2-Stage, %**		**Davila et al,[17] 2-Stage (NSQIP) Registry, %**	
	Acellular Matrix N = 1584	No Acellular Matrix N = 1522	Acellular Matrix N = 2037	No Acellular Matrix N = 12 847	Acellular Matrix N = 1717	No Acellular Matrix N = 7442
Total complications	8.6	5.8	15.4	14.0	4.7	4.3
Seroma	1.1	0.2	4.8	3.5	NR	NR
Infection	3.0	2.5	5.3	4.7	3.8	3.3
Skin necrosis	5.9	2.0	6.9	4.9	NR	NR
Reconstructive failure*	2.9	2.7	3.8	3.8	1.0	0.8

*Device loss.NR, not reported; NSQIP, American College of Surgeon's National Surgical Quality Improvement Program.

carefully assessed. Morbidly, obese patients are poor candidates for this procedure and are recommended for autologous procedures. In our experience, a medium-breasted patient with grade 1 to 2 ptosis, and good quality skin envelope is the ideal candidate for this procedure. However, patients with grade 3 ptosis can still achieve good results.

CONCLUSIONS

Our cumulative 13-year experience with immediate direct-to-implant breast reconstruction with ADM demonstrates that this method of breast reconstruction is safe, effective, reliable, and produces aesthetically pleasing outcomes. Complication, reoperation, and reconstructive failure rates are less than 10%. Fifty years or older, smoking, nonnipple-sparing mastectomy, and implant size of 600 mL or greater strongly predicted the development of complications with this approach and should be considered when choosing patients for this technique. By eliminating a second reconstructive step, the direct-to-implant procedure streamlines implant-based procedures and should be strongly considered as an advantageous method of breast reconstruction.

ACKNOWLEDGMENT

The authors would like to thank Kalanethee Paul-Pletzer, PhD (LifeCell Corporation, Branchburg, NJ) for providing Medical Writing support and Leah Passmore Griffin, MS (Acelity, San Antonio, TX) for providing statistical analyses support for this manuscript.

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