Journal of Plastic, Reconstructive & Aesthetic Surgery (2014) 67, 1098–1105

JPRAS
An International Journal of Surgical Reconstruction
www.JPRASurg.com

Immediate breast reconstruction with acellular dermal matrix: Factors affecting outcome

Alessia M. Lardi [a,b,*], Mark Ho-Asjoe [a], Pari-Naz Mohanna [a], Jian Farhadi [a,b,c]

[a] *Department of Plastic & Reconstructive Surgery, Guy's and St. Thomas Hospital, London, UK*
[b] *Department of Plastic, Reconstructive, Aesthetic and Hand Surgery, University Hospital Basel, Basel, Switzerland*
[c] *Center for Plastic Surgery, Clinic Pyramide at the Lake, Zürich, Switzerland*

Received 10 September 2013; accepted 3 May 2014

KEYWORDS
Strattice;
Acellular dermis;
Breast reconstruction;
Implant-based;
Complications;
Learning curve

Summary *Background:* The use of acellular dermal matrix (ADM) for coverage of the lower pole in immediate implant-based breast reconstruction has changed surgeons' practice. We present our experience using a porcine ADM (Strattice), focusing on short-term outcomes, patient selection, and technique adaptations that may influence outcome.
Methods: A two-center, retrospective, cohort study was performed from December 2008 to October 2012 at Guy's and St. Thomas' Hospitals, London, and Clinic Pyramide, Zürich. The study period was divided into two periods: Period 1 which spanned from December 2008 to October 2010 and Period 2 from January 2011 to October 2012 wherein technique adaptations were introduced. Short-term complications after reconstructive surgery were compared between Periods 1 and 2.
Results: A total of 149 patients underwent 200 reconstructions (110 one-stage and 90 two-stage) following oncologic (134 breasts) or prophylactic (66 breasts) mastectomy. The mean follow-up was 22.2 months. The total complication rate was 32.5%, including infection, 11.5%; hematoma, 5%; seroma, 10.5%; skin necrosis, 3.5%; and serious wound breakdowns with implant exposure, 1.5%. Complications resulted in 3% requiring an early exchange of implant/expander and in 12.5% requiring explantation. A significant reduction in total complications, infection, implant exposure, and implant loss were noted in Period 2. Multivariate analysis showed time period of surgery (Period 1), single-stage reconstruction, and patient characteristics (mastectomy weight >600 g, or body mass index (BMI) > 30, or smoking) to be statistically significant risk factors for the development of postoperative complications. Neoadjuvant chemotherapy showed a trend towards higher complication rates.

* Corresponding author. Department of Plastic & Reconstructive Surgery, Guy's and St. Thomas Hospital, London, UK. Tel.: +41 78 896 00 74; fax: +41 0 207 188 5131.
E-mail addresses: Alessia.Lardi@usb.ch, alardi@usb.ch (A.M. Lardi).

http://dx.doi.org/10.1016/j.bjps.2014.05.020

Conclusion: The high rate of early complications in this study was mostly related to patient characteristics and learning curves and highlights the importance of patient selection and technique principles in optimizing the outcome.

Introduction

Over the past decade, the use of acellular dermal matrix (ADM) in immediate implant-based breast reconstruction has gained acceptance. Currently, half of all implant-based reconstructions are performed with the use of an ADM.[1] The reported benefits of using human ADM (HADM) include better aesthetic outcome due to better control of the inframammary fold and coverage of the implant,[2,3] creation of a larger implant pocket allowing for single-stage reconstruction,[4–11] and possible decrease in capsular contracture.[2,3,10,12–14]

The majority of the evidence base for the use of ADM in breast reconstruction lies with human ADMs and particularly AlloDerm® (LifeCell Corp., Branchburg, NJ, USA).[2,4,6,10,12,15–18] However, a number of other nonhuman ADMs, derived from bovine pericardium, bovine dermis, porcine dermis, and porcine small intestinal submucosa, are now available and are used in a similar capacity as human ADMs in breast reconstruction. Published experience with theses matrices is, however, limited and highlights a need to evaluate their efficacy and safety before widespread adoption.[14,19–23] The aim of this study was to report our early outcome using Strattice™ (LifeCell Corp., Branchburg, NJ, USA), a porcine ADM, in immediate implant-based breast reconstruction with particular emphasis on technique adaptations and learning curves that may influence outcomes.

Patients and methods

All patients who underwent Strattice-assisted implant-based breast reconstructions at Guy's and St. Thomas' Hospitals, London, and at Clinic Pyramide, Zürich, from December 2008 to October 2012 were retrospectively reviewed. Single-stage reconstruction was offered unless there was concern with skin viability or when patient had opted for simultaneous augmentation; in these cases, a two-stage procedure was performed.

Mastectomy was performed via a skin-sparing or nipple-sparing approach by breast surgeons in attendance of the plastic surgeon. Following mastectomy, the pectoralis major muscle was raised and a subpectoral pocket was created using standard techniques. Strattice was rinsed in saline solution according to manufacturer's recommendation prior to insertion. The inferior border of the Strattice was sutured to the chest wall along the inframammary fold, extending medially and laterally. A silicone cohesive gel implant or expander was placed into the pocket and the upper border of the Strattice was sutured to the inferior border of the freed pectoralis muscle in an underlay technique resulting in closure of the pocket. Extra care was taken to avoid creases or folds of the Strattice and dead space between the Strattice and host tissue. Two drains were placed, one in the pocket and the other subcutaneously along the inframammary fold. If axillary clearance was performed, a third drain was placed in the axilla. All drains were removed when drainage was <30 ml over 24 h. Typically, prophylactic intravenous antibiotics were commenced 30 min prior to surgery; this was followed by three more intravenous doses before switching to oral antibiotics, which were continued for 5 days. Tissue expansion was started in the outpatient clinic after wounds had healed, usually 2 weeks after surgery. The field over the port was cleaned with antiseptic solution and sterile instruments and gloves were used during expander filling. Expansion was stopped for chemo- and/or radiotherapy and continued after termination of cancer therapy, if needed.

During the second half of the study period (January 2011 to October 2012), adaptations to the technique of Strattice-assisted reconstruction were made starting from January 2011 after an intradepartmental audit. In particular, Strattice was rinsed in an antibiotic solution (1.2 g amoxicillin/clavulanic acid (1 g cephalosporin if allergic to penicillin) and 80 mg gentamicin) instead of a saline solution. Skin flap viability was more carefully assessed clinically (capillary refill, flap thickness, and change in skin color with inflation of sizer) and cut more generously if perfusion of the skin flap was critical. Drains were placed in a long subcutaneous tunnel to avoid communication from the outside to the Strattice. Particular attention was paid to leakproof and sterile drain dressings. Drain bottles created a slight compression of the breast, thus reducing the dead space between the layers. In addition, patients with more than one risk factor ($>$600 g estimated mastectomy weight, body mass index (BMI) $>$ 30, or smoking) were not operated with this procedure. Changes were introduced at both institutes at the same time after receiving consent from each institute's senior surgeon.

Patient charts were reviewed for demographic information (age and BMI), comorbid conditions (diabetes, hypertension, or smoker), type of reconstruction (single-stage or two-stage), implant or initial expander volume, adjunctive therapy (radio- and/or chemotherapy) use, length of patient follow-up, and type and incidence of early complications during the follow-up period. Early complications were defined as those occurring in the first 3 months after the procedure and included, but not limited to, infections requiring intravenous antibiotics, seroma requiring drainage, hematoma, and skin necrosis leading to operative intervention, and serious wound breakdown leading to

implant exposure and implant loss. Late complications (e.g., capsular contracture) were not evaluated in this study and will be presented in a follow-up study. The rate of complications were stratified and compared by the time periods (Period 1 vs. Period 2), type of reconstruction (single- vs. two-stage), and ADM patient selection criteria proposed by the joint guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons (mastectomy weight <600 g, or BMI <30, or nonsmoker vs. mastectomy weight >600 g, or BMI >30, or smoker).[24] Statistical analysis was performed using Fisher's exact test for categorical data and *t* test for continuous data. To explore the influence of risk factors on the total complication rates, a multivariate generalized estimating equations (GEE) model was applied. This model accounts for potential intrapatient correlation of results. Results were considered to be statistically significant at a *P* value of <0.05.

Results

A total of 149 patients with a mean age of 48 years (range: 27–76 years) who underwent 200 immediate Strattice-assisted implant-based breast reconstruction following a skin-sparing ($n = 163$) or nipple-sparing ($n = 37$) mastectomy were included in this study. Patient demographic data are summarized in Table 1.

After reconstructive surgery, patients were followed up for a mean of 22.2 months (range: 1.6–48.1 months). Early complications occurred in 65 breasts for an overall complication rate of 32.5% (Table 2). Complications included 25 implant losses (12.5%), 23 infections (11.5%), 21 seromas (10.5%), 10 hematomas (5.0%), seven skin necroses (3.5%), six implant exposures (3.0%), three wound breakdowns (1.5%), and four other complications (1.5%). Other complications included implant displacement (two, same patient), chronic pain (one), and early contracture (one). Of the 25 implant losses, 23 (92%) were subsequent to infection and two subsequent to skin necrosis. Of the six implant exposures, three were due to skin necrosis and three to wound healing problems. All complications occurred within 3 months of initial surgery.

Of the 200 mastectomies that were performed, 67% were for cancer treatment and 33% for risk reduction; axillary clearance was performed in 27%. Almost 41% of patients underwent radiotherapy and 58% chemotherapy. Sixteen of the 23 infections (69.6%) occurred during or after oncologic treatment (five after neoadjuvant chemotherapy (21.7%), eight during or after adjuvant chemotherapy (34.8%), and three during or after radiotherapy (13%)). Apart from these 16 infections, all other complications occurred before the commencement of radio- and/or chemotherapy.

Due to complications (17 infections, six seroma, two wound breakdown, and two skin necrosis) in 29 cases (22%), the planned postoperative oncological treatment (chemo- and/or radiotherapy) had to be postponed.

A total of 21 patients (27 breasts) received neoadjuvant chemotherapy. The total complication rate in these patients was 44.4%, which was higher than in those who did not receive neoadjuvant chemotherapy (30.6%, Table 3). All other complications, besides seroma, were also higher in those who had neoadjuvant chemotherapy, with wound breakdown significantly higher ($P = 0.048$).

Of the 200 reconstructions, 55% were single staged and 45% were two staged (Table 1). The mean implant volume

Table 1 Patient demographics and procedures (adjuvant/neoadjuvant therapy, mastectomy, and reconstruction) performed.

Patients, *n*	149
Breasts, *n*	200
Age, mean ± SD (range), *year*	48 ± 11 (27–76)
Body mass index, mean ± SD (range), kg/m^2	24.9 ± 4 (17.9–39)
Tobacco use, *n* (% of patients)	25 (16.8)
Diabetes, *n* (% of patients)	2 (1)
Radiotherapy, *n* (% of patients)	61 (40.9)
Intraoperative	1 (0.7)
Preoperative	3 (2.0)
Postoperative	57 (38.3)
Chemotherapy, *n* (% of patients)	86 (57.7)
Neoadjuvant	21 (14.1)
Adjuvant	65 (43.6)
Mastectomy, *n* (% of breasts)	
Oncologic	134 (67)
Prophylactic	66 (33)
With axillary clearance	54 (27)
Bilateral, *n* (% of patients)	51 (34.2)
Unilateral, *n* (% of patients)	98 (65.8)
Reconstruction	
Single-stage, *n* (% of breasts)	110 (55)
Implant volume, mean ± SD (range), mL	387.3 ± 143 (140–800)
Two-stage, *n* (% of breasts)	90 (45)
Intraoperative expander fill volume, mean ± SD (range), *mL*	259 ± 179 (0–650)
Duration of drains, mean ± SD (range), days	6.9 (1–20)
Hospital stay for first procedure, mean ± SD (range), *days*	5.6 (1–20)

SD, standard deviation.

Table 2 Short-term complications in the total population.

	Breasts $N = 200$ *n* (%)
Complications (total)[a]	65 (32.5)
Infection	23 (11.5)
Skin necrosis	7 (3.5)
Seroma	21 (10.5)
Hematoma	10 (5.0)
Wound breakdown	3 (1.5)
Implant exposure[b]	6 (3.0)
Implant loss	25 (12.5)
Other complications	4 (2.0)

[a] Breasts with more than one complication were computed once.
[b] Exposed implants were exchanged.

Table 3 Complications stratified by neoadjuvant chemotherapy use.

	Neoadjuvant Chemotherapy Number of breasts (%)		*P* value
	Yes $N = 27$	No $N = 173$	
Complications (total)[a]	12 (44.4)	53 (30.6)	0.19
Infection	5 (18.5)	18 (10.4)	0.21
Skin necrosis	1 (3.7)	6 (3.5)	1.00
Seroma	2 (7.4)	19 (11.0)	0.75
Hematoma	2 (7.4)	8 (4.6)	0.63
Wound breakdown	2 (7.4)	1 (0.6)	0.048
Implant exposure[b]	2 (7.4)	4 (2.3)	0.19
Implant loss	6 (22.2)	19 (11.0)	0.12
Other complications	0	4 (2.3)	1.00

[a] Breasts with more than one complication were computed once.
[b] Exposed implants were exchanged.

was 387.3 ml in direct to implant procedures while the mean intraoperative expander fill volume of expander-based reconstructions was 259 ml. Although individual complication rates were similar between patients who underwent single- versus two-stage reconstructions, the total complication rate was significantly higher in those who had single-stage reconstruction (Table 4).

A total of 50 patients (70 reconstructions) had one or more of the clinical characteristics (mastectomy weight >600 g, or BMI >30, or smoking) that have previously been shown to have an association with an increased risk of complications after ADM-assisted breast reconstruction.[24] The rate of total complications as well as hematoma, wound breakdown, and implant exposure were significantly higher in patients with one of these clinical characteristics compared with those who did not have any of these characteristics (Table 5).

Table 4 Complications stratified by single- versus two-stage reconstruction.

	One-Stage Breasts, $N = 110$ *n* (%)	Two-Stage Breasts, $N = 90$ *n* (%)	*P* value
Complications (total)[a]	43 (39.1)	22 (24.4)	0.03
Infection	14 (12.7)	9 (10.0)	0.66
Skin necrosis	4 (3.6)	3 (3.3)	1.00
Seroma	13 (11.8)	8 (8.9)	0.64
Hematoma	8 (7.3)	2 (2.2)	0.19
Wound breakdown	2 (1.8)	1 (1.1)	1.00
Implant exposure[b]	3 (2.7)	3 (3.3)	1.00
Implant loss	15 (13.6)	10 (11.1)	0.67
Other complications	4 (3.6)	0	0.13

[a] Breasts with more than one complication were computed once.
[b] Exposed implants were exchanged.

Table 5 Complications stratified by patient clinical characteristics.

	Mastectomy weight <600 g or BMI <30 or nonsmoker Breasts, $N = 130$ *n* (%)	Mastectomy weight >600 g, BMI >30, or smoker Breasts, $N = 70$ *n* (%)	*P* value
Complications (total)[a]	34 (26.2)	31 (44.3)	0.011
Infection	12 (9.2)	11 (15.7)	0.244
Skin necrosis	4 (3.1)	3 (4.3)	0.697
Seroma	12 (9.2)	9 (12.9)	0.472
Hematoma	3 (2.3)	7 (10)	0.035
Wound breakdown	0	3 (4.3)	0.042
Implant exposure[b]	0	6 (8.6)	0.002
Implant loss	14 (10.8)	11 (15.7)	0.371
Other complications	4 (3.1)	0	0.300

[a] Breasts with more than one complication were computed once.
[b] Exposed implants were exchanged.

When complications were stratified by the two time periods, significant reductions in the rate of total complications, infection, implant exposure, and implant loss were noted in Period 2 (Table 6) after the introduction of modifications. Rates of seroma and hematoma did not differ between the two periods. Nine of the 17 infections in Period 1 and all six infections in Period 2 occurred in relation to oncological treatment (chemotherapy and/or radiotherapy). There were significant differences in patient characteristics (BMI, smoking status, and mastectomy weight), treatment-related factors (axillary clearance and radiotherapy use), reconstruction procedure-related

Table 6 Complications stratified Period 1 versus Period 2.

	Period 1 Breasts = 96 *n* (%)	Period 2 Breasts = 104 *n* (%)	*P*-value
Complications (total)[a]	38 (39.6)	27 (26.0)	0.0495
Infection	17 (17.7)	6 (5.8)	0.013
Skin necrosis	5 (5.2)	2 (1.9)	0.264
Seroma	10 (10.4)	11 (10.6)	1.000
Hematoma	5 (5.2)	5 (4.8)	1.000
Wound breakdown	3 (3.1)	0	0.109
Implant exposure[b]	6 (6.3)	0	0.011
Implant loss	18 (18.8)	7 (6.7)	0.017
Other complications	1 (1.0)	3 (2.9)	0.622

[a] Breasts with more than one complication were computed once.
[b] Exposed implants were exchanged.

factors (single- or two-stage reconstruction and implant volume), and follow-up period between the two time periods (Table 7).

A multivariate GEE model analysis showed that the time period of surgery (i.e., Period 1), type of reconstruction (i.e., single-stage reconstruction), and patient characteristics (mastectomy weight >600 g, or BMI >30, or smoking) were statistically significant risk factors for the development of postoperative complications (Table 8).

Discussion

Our institutional experience with Strattice-assisted implant-based breast reconstruction was associated with an early total complication rate of 32.5% which is two to five times higher than those in previously published studies involving the use of Strattice (6.3–16.9%, Table 9).[14,20,21,25] The seroma (10.5% vs. 1.4–5.2%), hematoma (5% vs. 0–1.5%), infection (11.5% vs. 2.1–10.4%), and implant loss (12.5% vs. 1.4–13%) rates in this study were most notably higher. Additionally, our rates were also higher than those reported for HADM-assisted reconstructions and standard submuscular reconstructions (Table 9). Using multivariate GEE model analysis, we found that patient characteristics, single-stage reconstruction, and early time period of surgery that reflected the beginning of the learning curve of surgeons may have played a significant contributory role in the high rate of complications in our series.

More than a third of our patients had one or more of the characteristics (BMI >30, breast size >600 g, or smoking history) that have been identified to be associated with an increased risk of complications in patients undergoing ADM-assisted breast reconstruction.[24] High BMI is an independent risk factor for complications; for every five-unit increase in BMI, the odds of developing complications is 1.51.[26] High BMI also increases the risk of seroma and infection.[27] Breasts larger than 600 g (without skin necroses) are associated with an increased risk of infection.[13] Patients with a smoking history or who are current smokers have a higher risk of implant failure.[24] In concordance with these findings, our data indicate that patients with mastectomy weight >600 g, or BMI >30, or a history of smoking had a significantly higher total complication rate that included a significantly higher rate of hematoma, wound breakdown, and implant exposure. Because of the higher risk of complications associated with these risk factors, the joint guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons recommend caution in patients with these risk factors who undergo ADM-assisted breast reconstruction.[24]

Table 7 Patient demographics, adjuvant/neoadjuvant therapy, and mastectomy procedures performed in period 1 versus period 2.

	Period 1	Period 2	*P* value
Patients, *n*	76	73	–
Breasts, *n*	96	104	–
Age, mean ± SD (range), *yr*	48 ± 10.8 (26–72)	48 ± 10.7 (26–76)	0.961
Body mass index, mean ± SD (range), kg/m^2	25.6 ± 4.4 (17.9–39)	24.2 ± 3.2 (19.1–35.3)	0.029
Smoker, *n* (% of patients)	18 (23.4)	7 (9.7)	0.03
Diabetic, *n* (% of patients)	2 (2.6)	0 (0)	0.50
Axillary clearance, *n* (% of breasts)	33 (34.4)	21 (20.2)	0.03
Chemotherapy, *n* (% of patients)			
85 Total	46 (60.5)	39 (53.4)	
21 Neoadjuvant	10 (13.2)	11 (15.1)	
64 Adjuvant	36 (47.4)	28 (38.4)	0.411
Radiotherapy, *n* (% of breasts)			
61 Total	42 (43.8)	19 (18.3)	
3 Preoperative	2 (2.1)	1 (1.0)	
1 Intraoperative	1 (1.0)	0	
57 Postoperative	39 (41.7)	18 (17.3)	<0.001
Mastectomy			
Weight, mean ± SD (range), *g*	574.3 ± 336.1 (135–2238)	462.6 ± 243.1 (130–1061)	0.018
Prophylactic, *n* (% of breasts)	27 (28.1)	39 (37.5)	0.177
Oncologic, *n* (% of breasts)	69 (71.9)	65 (62.5)	
Reconstruction			
Single-stage, *n* (% of breasts)	31 (32.3)	79 (76)	<0.001
Implant volume, mean ± SD (range), *mL*	431.6 ± 169.2 (200–800)	371.9 ± 130.4 (140–740)	0.061
Two-stage, *n* (% of breasts)	65 (67.7)	25 (24)	<0.001
Intraoperative expander fill volume, mean ± SD (range), *mL*	258.5 ± 167.8 (0–650)	258.6 ± 212.5 (0–650)	1.000
Duration of drain, mean ± SD (range), *days*	6.9 ± 3.6 (1–20)	6.9 ± 3.6 (2–17)	0.870
Follow-up, mean ± SD (range), *months*	32.9 ± 5.9 (24.8–48.1)	12.3 ± 6.2 (1.6–23.2)	<0.001

SD, standard deviation.

Table 8 Exploration of risk factors for the occurrence of complication using a multivariate GEE model analysis.

Risk factor	Odds Ratio	95% Confidence Interval	*P* value
Period (2 vs. 1)	0.37	0.16—0.82	0.0149
Stages (2-stage vs. 1-stage reconstruction)	0.24	0.10—0.55	0.0008
Radiation (yes vs. no)	0.95	0.42—2.14	0.9071
Chemotherapy (yes vs. no)	1.27	0.59—2.76	0.5429
Mastectomy (oncologic vs. prophylactic)	1.62	0.75—3.48	0.2173
Patient characteristics[a] (yes vs. no)	2.16	1.07—4.33	0.0308

[a] Mastectomy weight >600 g or BMI >30 kg/m^2, or smoker.

About half of all reconstructions in our series were single staged. Over the study period, more one-stage procedures were performed towards the end of the study period (more than two-thirds of reconstructions in Period 2). Although there was a higher overall complication rate in single-stage procedures over the entire study period, the learning curve was significant in this study group ($P = 0.0016$). Infection and seroma in one-stage procedures were less than in two-stage procedures (5% vs. 8% and 10% vs. 12%, respectively) in the second time period (Period 2). There is less room for error in one-stage reconstruction as the flexibility of some deflation for minor wound dehiscence or expansion for reduction of dead space is no longer available. However, the reduction in complication rate in our one-stage reconstructions in the second period further confirms the steep learning curve for ADM-assisted breast reconstruction. We favored one-stage procedures whenever possible to reduce the number of procedures patients have to undergo without compromising aesthetic outcome.

As our institution is a university teaching hospital, the procedures were largely performed by trainees under supervision of the consultant. Although this provides training opportunities, it also introduces multiple learning curves of multiple surgeons. We strongly believe that the use of ADM in breast reconstruction is a simple technique but involves a steep learning curve to minimize complications. Our results thus represent realistic outcomes from a teaching hospital. With experience over time, patient selection, and adaptations of technique, we did see a reduction in total complications from 39.6% in Period 1—26% in Period 2 ($P = 0.0574$). The most significant reduction from Period 1 to Period 2 was in the infection rate (17.7—5.8%, $P < 0.05$). Rinsing Strattice in an antibiotic solution instead of only saline coupled with longer tunneling of drains may have contributed to the lower infection rate in Period 2.

There was also a reduction in the rate of skin flap necrosis from 5.2% in Period 1—1.9% in Period 2, although this was not statistically significant ($P = 0.376$). This reduction may have been influenced by an increased awareness of the risk of skin flap necrosis, improvement in skin/nipple sparing mastectomy technique by the breast surgeons, and a more thorough assessment of skin flap viability after the mastectomy, as well as more favorable patient characteristics. These results highlight the existence of a learning curve with Strattice-assisted breast reconstruction that can be surmounted with experience and refinements in technique and better patient selection. Other authors have also reported improved complication rates with ADM-associated breast reconstruction with experience and/or technique modifications.[11,28]

The adaptations introduced in Period 2 had minimal impact on seroma and hematoma rates, which remained virtually unchanged over the entire study period. Lowering the threshold for drain removal from <30 cc/24 h to <20 cc/24 h[28] could be a future consideration to improve the seroma rate. Additionally, improving skin/Strattice approximation for quicker incorporation of the tissue matrix and more aggressive use of drains in patients with axillary clearance are other future considerations.

Although multivariate analysis did not find chemotherapy or radiotherapy as significant risk factors for the development of postoperative complications in our series, other studies have shown this to be the case.[29—32] Two-thirds of the mastectomies in our study were for oncologic reasons. Approximately a quarter of all complications occurred either during or after chemo- or radiotherapy. In addition, of the 21 breasts that developed a seroma, five (23.8%) had also undergone axillary clearance at the time of reconstruction. Axillary dissection is an independent risk factor for the development of complications in ADM-assisted breast reconstruction.[26]

An interesting finding in our study was the high rate of complications in patients who had undergone neoadjuvant

Table 9 Complications in published series of Strattice-assisted implant-based breast reconstruction.

Complication (%)	This study (Strattice)	Salzberg et al. 2013[21] (Strattice)	Glasberg et al. 2012[20] (Strattice)	Israeli & Feingold 2012[a],[14] (Strattice)	Kim et al., 2012 Meta-analysis[25] (HADM)	Kim et al., 2012 Meta-analysis[25] (Standard submuscular)
Total	32.5	8.6	6.3	16.9	15.4	14
Seroma	10.5	1.9	1.4	5.2	4.8	3.5
Hematoma	5	0	0	1.3	1	1.5
Infection	11.5	3.8	2.1	10.4	5.3	4.7
Skin necrosis	3.5	2.9	1.4	7.8	6.9	4.9
Implant/expander loss	12.5	3.8	1.4	13.0	3.8	3.8

[a] Stage 1 complications. HADM = human acellular dermal matrix.

chemotherapy. The average time between completion of neoadjuvant chemotherapy and reconstructive surgery was 49 days, a period which is generally considered to be sufficient for tissue recovery. Our results suggest that this time period may not be sufficient and that tissue damage may persist longer than believed and/or there may be long-term memory retention by the tissue to past chemotherapy insult. This finding merits further investigation in a larger study, given its potential to impact the timing of the reconstructive procedure.

We are well aware of the interest in cost analysis in the usage of ADM and we will investigate this topic in a study with a longer follow-up.

In this largest study to date of Strattice-assisted breast reconstruction, our total complication rate was higher than in previously published data and was mostly related to patient characteristics and the learning curves of multiple surgeons. With experience, patient selection, and technique adaptation, particularly the introduction of antibiotic rinsing of the Strattice and careful handling of skin flaps, a reduction in infection and implant loss was seen resulting in a reduction in the total complication rate. There is a recognized learning curve with this technique and early experience may not be a true reflection of outcomes. Appropriate patient selection and technique principles are important to optimize outcome in ADM-assisted breast reconstruction.

Conflict of interest

Alessia M. Lardi, MD, received an educational grant (LifeCell Corporation). All other authors have no disclosure. No funds were received or utilized for this research. Ethic approval was not required for this study.

References

1. Gurunluoglu R, Gurunluoglu A, Williams SA, Tebockhorst S. Current trends in breast reconstruction: survey of American Society of Plastic Surgeons 2010. *Ann Plast Surg* 2013;**70**:103—10.
2. Spear SL, Parikh PM, Reisin E, Menon NG. Acellular dermis-assisted breast reconstruction. *Aesthetic Plast Surg* 2008;**32**:418—25.
3. Vardanian AJ, Clayton JL, Roostaeian J, et al. Comparison of implant-based immediate breast reconstruction with and without acellular dermal matrix. *Plast Reconstr Surg* 2011;**128**:403e—10e.
4. Breuing KH, Warren SM. Immediate bilateral breast reconstruction with implants and inferolateral AlloDerm slings. *Ann Plast Surg* 2005;**55**:232—9.
5. Breuing KH, Colwell AL. Inferolateral AlloDerm hammock for implant coverage in breast reconstruction. *Ann Plast Surg* 2007;**59**:250—5.
6. Zienowicz RJ, Karacaoglu E. Implant-based breast reconstruction with allograft. *Plast Reconstr Surg* 2007;**120**:373—81.
7. Topol BM, Dalton EF, Ponn T, Campbell CJ. Immediate single-stage breast reconstruction using implants and human acellular dermal tissue matrix with adjustment of the lower pole of the breast to reduce unwanted lift. *Ann Plast Surg* 2008;**61**:494—9.
8. Ashikari RH, Ashikari AY, Kelemen PR, Salzberg CA. Subcutaneous mastectomy and immediate reconstruction for prevention of breast cancer for high-risk patients. *Breast Cancer* 2008;**15**:185—91.
9. Cassileth L, Kohanzadeh S, Amersi F. One-stage immediate breast reconstruction with implants: a new option for immediate reconstruction. *Ann Plast Surg* 2012;**69**:134—8.
10. Salzberg CA, Ashikari AY, Koch RM, Chabner-Thompson E. An 8-year experience of direct-to-implant immediate breast reconstruction using human acellular dermal matrix (AlloDerm). *Plast Reconstr Surg* 2011;**127**:514—24.
11. Colwell AS, Damjanovic B, Zahedi B, Medford-Davis L, Hertl C, Austen Jr WG. Retrospective review of 331 consecutive immediate single-stage implant reconstructions with acellular dermal matrix: indications, complications, trends, and costs. *Plast Reconstr Surg* 2011;**128**:1170—8.
12. Becker S, Saint-Cyr M, Wong C, et al. AlloDerm versus DermaMatrix in immediate expander-based breast reconstruction: a preliminary comparison of complication profiles and material compliance. *Plast Reconstr Surg* 2009;**123**:1—6.
13. Lanier ST, Wang ED, Chen JJ, et al. The effect of acellular dermal matrix use on complication rates in tissue expander/-implant breast reconstruction. *Ann Plast Surg* 2010;**64**:674—8.
14. Israeli R, Feingold RS. Acellular dermal matrix in breast reconstruction in the setting of radiotherapy. *Aesthet Surg J* 2011;**31**(Suppl. 7):51S—64S.
15. Losken A. Early results using sterilized acellular human dermis (Neoform) in post-mastectomy tissue expander breast reconstruction. *Plast Reconstr Surg* 2009;**123**:1654—8.
16. Rawlani V, Buck 2nd DW, Johnson SA, Heyer KS, Kim JY. Tissue expander breast reconstruction using prehydrated human acellular dermis. *Ann Plast Surg* 2011;**66**:593—7.
17. Venturi ML, Mesbahi AN, Boehmler 4th JH, Marrogi AJ. Evaluating sterile human acellular dermal matrix in immediate expander-based breast reconstruction: a multicenter, prospective, cohort study. *Plast Reconstr Surg* 2013;**131**:9e—18e.
18. Seth AK, Persing S, Connor CM, et al. A comparative analysis of cryopreserved versus prehydrated human acellular dermal matrices in tissue expander breast reconstruction. *Ann Plast Surg* 2013;**70**:632—5.
19. Himsl I, Drinovac V, Lenhard M, Stöckl D, Weissenbacher T, Dian D. The use of porcine acellular dermal matrix in silicone implant-based breast reconstruction. *Arch Gynecol Obstet* 2012;**286**:187—92.
20. Glasberg SB, Light D. AlloDerm and Strattice in breast reconstruction: a comparison and techniques for optimizing outcomes. *Plast Reconstr Surg* 2012;**129**:1223—33.
21. Salzberg CA, Dunavant C, Nocera N. Immediate breast reconstruction using porcine acellular dermal matrix (Strattice™): long-term outcomes and complications. *J Plast Reconstr Aesthet Surg* 2013;**66**:323—8.
22. Mofid MM, Meininger MS, Lacey MS. Veritas® bovine pericardium for immediate breast reconstruction: a xenograft alternative to acellular dermal matrix products. *Eur J Plast Surg* 2012;**35**:717—22.
23. Butterfield JL. 440 consecutive immediate, implant-based, single-surgeon breast reconstructions in 281 patients: a comparison of early outcomes and costs between surgimend fetal bovine and alloderm human cadaveric acellular dermal matrices. *Plast Reconstr Surg* 2013;**131**:940—51.
24. Martin L, O'Donoghue JM, Horgan K, Thrush S, Johnson R, Gandhi A. Acellular dermal matrix (ADM) assisted breast reconstruction procedures: joint guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons. *Eur J Surg Oncol* 2013;**39**:425—9.
25. Kim JY, Davila AA, Persing S, et al. A meta-analysis of human acellular dermis and submuscular tissue expander breast reconstruction. *Plast Reconstr Surg* 2012;**129**:28—41.
26. Antony AK, McCarthy CM, Cordeiro PG, et al. Acellular human dermis implantation in 153 immediate two-stage tissue

expander breast reconstructions: determining the incidence and significant predictors of complications. *Plast Reconstr Surg* 2010;**125**:1606—14.
27. Chun YS, Verma K, Rosen H, et al. Implant-based breast reconstruction using acellular dermal matrix and the risk of postoperative complications. *Plast Reconstr Surg* 2010;**125**: 429—36.
28. Chun Y, Ganske I, Verma K, Rosen H, Eriksson E. Minimizing complications associated with use of acellular dermal matrix in implant-based breast reconstruction. *Plast Reconstr Surg* 2012; **130**(1S):67.
29. Olsen MA, Lefta M, Dietz JR, et al. Risk factors for surgical site infection after major breast operation. *J Am Coll Surg* 2008; **207**:326—35.
30. Mehrara BJ, Santoro TD, Arcilla E, Watson JP, Shaw WW, Da Lio AL. Complications after microvascular breast reconstruction: experience with 1195 flaps. *Plast Reconstr Surg* 2006; **118**:1100—9.
31. Francis SH, Ruberg RL, Stevenson KB, et al. Independent risk factors for infection in tissue expander breast reconstruction. *Plast Reconstr Surg* 2009;**124**:1790—6.
32. Cordeiro PG, McCarthy CM. A single surgeon's 12-year experience with tissue expander/implant breast reconstruction: part I. A prospective analysis of early complications. *Plast Reconstr Surg* 2006;**118**:825—31.