The Impact of Acellular Dermal Matrix on Tissue Expander/Implant Loss in Breast Reconstruction: An Analysis of the Tracking Outcomes and Operations in Plastic Surgery Database

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Background: Use of acellular dermal matrix in breast reconstruction has been associated with increased complications. However, existing studies are generally small, from single centers, and underpowered to control for confounding using regression techniques. Here, the Tracking Outcomes and Operations in Plastic Surgery database was used to examine the effect of acellular dermal matrix on expander/implant loss when controlling for other confounders.
Methods: Analysis was limited to patients having tissue expander or implant-based breast reconstruction. Surgeon-reported data, *International Classification of Diseases, Ninth Edition* codes, and Current Procedural Terminology codes were used to identify independent variables. The dependent variable of interest was 30-day rates of tissue expander or implant loss. Bivariate statistics were performed. Multivariable logistic regression identified independent predictors of expander/implant loss when controlling for other confounders.
Results: Data were available for 14,249 patients. The overall rate of expander/implant loss was 2.05 percent. Bivariate analysis demonstrated acellular dermal matrix was associated with an absolute increase in expander/implant loss of 0.7 percent (1.88 percent versus 2.58 percent, $p = 0.012$). The regression model demonstrated that rising body mass index, current smoking, and presence of diabetes were each independent predictors of expander/implant loss. When controlling for all other identified confounders, use of acellular dermal matrix was associated with a significant increase in expander/implant loss (odds ratio, 1.42; 95 percent confidence interval, 1.04 to 1.94; $p = 0.026$).
Conclusions: Thirty-day risk for expander/implant loss after tissue expander or implant-based breast reconstruction was 2.05 percent. Use of acellular dermal matrix was associated with a 0.7 percent absolute risk increase for expander/implant loss. (*Plast. Reconstr. Surg.* 132: 1, 2013.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Risk, III.

In 2011, American Society of Plastic Surgeons members performed over 96,000 reconstructive breast operations. Eighty percent of these operations were performed using a tissue expander or implant-based technique.[1] Acellular dermal matrix has recently become a mainstay of tissue expander/implant–based breast reconstruction. Its proponents cite many advantages, including decreased time to fill for tissue expansion,

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improved lower pole contour, and the ability to perform immediate-to-implant reconstruction.[2–8] However, critical analyses of the published literature have shown that mixed evidence-based support exists for some claims.[9,10]

Recent literature has associated use of acellular dermal matrix with increased risk for surgical complications, including seroma[4,11,12] and infection.[11,12] Acellular dermal matrix–based breast reconstruction has been associated with increased tissue expander/implant loss rates of 1.3 to 14 percent[2,3,5,8,11,13] compared with non–acellular dermal matrix breast reconstruction. However, existing studies that examine the relationship between acellular dermal matrix and postoperative complications are generally small, from single centers, and lack sufficient power to appropriately use multivariable regression modeling techniques.[2,3,8,14] Tissue expander/implant loss is a relatively rare event, and the potential risk of increased tissue expander/implant loss associated with acellular dermal matrix may be small. Thus, even published meta-analyses may be (1) insufficiently powered to detect differences in expander/implant loss associated with acellular dermal matrix[4,12,15] and (2) subject to bias secondary to criteria used for study inclusion and modeling methods chosen to estimate effect size. The true effect size of the relationship between acellular dermal matrix and postoperative tissue expander/implant loss, if real, remains unknown.

The Tracking Outcomes and Operations in Plastic Surgery (or TOPS) database is a voluntary, prospective surgical outcomes database overseen by the American Society of Plastic Surgeons. Since its inception in 2002, it has received complete data for over 618,000 surgical cases and 1,030,000 plastic surgery procedures. Nearly 1300 board-eligible or board-certified surgeons have submitted cases to the database. Demographic data indicate that the database's users constitute a reasonably representative sample of the overall American Society of Plastic Surgeons membership in terms of sex, age, practice type, geographic location, and reported case mix.[16]

The TOPS database, which contains high volumes of patient-level data from a representative sample of American Society of Plastic Surgeons board-eligible and board-certified surgeons, provides a unique opportunity to examine the phenomenon of tissue expander/implant loss in breast reconstruction. Here, we used the database to identify independent predictors of 30-day expander/implant loss in women who have tissue expander/implant–based breast reconstruction.

PATIENTS AND METHODS

Tracking Outcomes and Operations in Plastic Surgery Database

The TOPS database was launched in 2002 as a secure, password-protected, Health Insurance Portability and Accountability Act of 1996–compliant, Web-based data entry platform (http://tops.plasticsurgery.org). Data are stored remotely on a secure and confidential data server. For analysis purposes, American Society of Plastic Surgeons staff extracted deidentified data for all cases performed between 2008 and 2011 and populated Microsoft Excel (Microsoft Corp., Redmond, Wash.) spreadsheets. Data were provided to study researchers in September of 2012.

Data Handling and Variable Definitions

Data sets were cleaned, merged, and analyzed using the Stata11 statistical package (StataCorp, College Station, Texas). Analysis was limited to female patients with immediate or delayed expander/implant breast reconstruction, as identified with Current Procedural Terminology codes 19357 (immediate or delayed insertion of tissue expander), 11970 (replacement of tissue expander with prosthesis), or 19340 (immediate insertion of breast prosthesis after mastopexy or mastectomy). Code 19340 can also be used in mastopexy/augmentation patients, in concert with code 19316 (mastopexy). We identified mastopexy/augmentation patients who had the combination of codes 19340 and 19316 and excluded them from the analysis.

Variables

Demographic variables were created using surgeon-reported data and included age, body mass index, sex, presence or absence of smoking history, and diabetes (Figs. 1 and 2). Additional independent variables were created as shown in Table 1. Creation of variables using Current Procedural Terminology and *International Classification of Diseases, Ninth Revision* codes was performed in consultation with representatives from the University of Michigan Section of Plastic Surgery's coding and billing group.

Current Procedural Terminology coding for acellular dermal matrix use included codes 15330 or 15331. The data set used for this analysis (2008 to 2011) predated the 2012 revised coding for use of acellular dermal matrix (e.g., code 15777) for breast reconstruction. Thus, code 15777 was not reported for any patient.[17,18] To improve clinical relevance, the continuous variables age, operative

Name: _____ *Procedure Date: ___ /___/_____ Medical Record # _____
FIRST MIDDLE LAST MM DD YYYY

Demographics Tab

Birthday ___ /___/_____
MM DD YYYY

Gender ☐ Male ☐ Female

Patient Race/Ethnicity *(Check all that apply)*
☐ White ☐ Black or African-American ☐ Asian ☐ Hispanic or Latino
☐ American Indian or Alaskan Native ☐ Native Hawaiian or other Pacific Islander
☐ Other/Unknown _____

Clinical Tab

Tobacco Use ☐ Current Tobacco User ☐ Former Tobacco User ☐ Non-tobacco User

Height _____ft _____in OR _____cm

Weight _____._____ lb OR _____._____kg

*BMI _____

Does the patient have diabetes?
☐ Yes ☐ No ☐ Unknown

If yes, Diabetes Treatment
☐ Insulin ☐ Oral ☐ Diet-controlled

Patient ASA Status
☐ 1: Normal ☐ 4: Constant life threat
☐ 2: Mild systemic ☐ 5: Moribund
☐ 3: Severe systemic

Procedures

*Facility _____ ICD-9 Code(s) _____ _____

*Diagnosis Description _____

CPT Code 1

*Anatomy *(Check all that apply)*
☐ Breast ☐ Genitalia ☐ Hand ☐ Head and Neck ☐ Lower Extremity ☐ Trunk ☐ Upper Extremity

*Classification *(Check all that apply)*
☐ Burn ☐ Bone & Joint ☐ Cancer (non-skin) ☐ Congenital ☐ Contracture and Joint Stiffness ☐ Cosmetic
☐ General/Reconstructive ☐ Micro-Vascular ☐ Nerve ☐ Non-Operative ☐ Skin (including skin cancer) ☐ Trauma
☐ Tendon/Muscle ☐ Other

*CPT Code _____ *Procedure Description _____ # of Times _____

Is this a procedure revision within 1 (one) year of the initial procedure? ☐ Yes ☐ No
Is this a revision of my own work? ☐ Yes ☐ No

CPT Code 2

*Anatomy *(Check all that apply)*
☐ Breast ☐ Genitalia ☐ Hand ☐ Head and Neck ☐ Lower Extremity ☐ Trunk ☐ Upper Extremity

*Classification *(Check all that apply)*
☐ Burn ☐ Bone & Joint ☐ Cancer (non-skin) ☐ Congenital ☐ Contracture and Joint Stiffness ☐ Cosmetic
☐ General/Reconstructive ☐ Micro-Vascular ☐ Nerve ☐ Non-Operative ☐ Skin (including skin cancer) ☐ Trauma
☐ Tendon/Muscle ☐ Other

*CPT Code _____ *Procedure Description _____ # of Times _____

Is this a procedure revision within 1 (one) year of the initial procedure? ☐ Yes ☐ No
Is this a revision of my own work? ☐ Yes ☐ No

*Procedure Duration (skin-to-skin) _____ : _____
HH MM

*Anesthesia Provided By:
☐ Anesthesiologists ☐ CRNA (Supervised by Anesthesiologist) ☐ CRNA (Supervised by procedural Surgeon)
☐ Procedural Surgeon ☐ RN supervised by procedural Surgeon ☐ Other _____ ☐ None

*Mode of Anesthesia *(Check all that apply)*
☐ Conscious Sedation ☐ MAC ☐ Spinal/Epidural ☐ Tumescent ☐ General ☐ Peripheral Block ☐ Topical/Local
☐ Other _____ ☐ None

** = required field*

Fig. 1. TOPS data collection form for demographic and perioperative risk factors.

Optional Modules

Bariatric Module

Procedure is Related to Massive Weight Loss?
☐ Yes ☐ No ☐ Unknown

Procedure is Related to Massive Weight Loss Due to Previous Bariatric Surgery Procedure?
☐ Yes ☐ No ☐ Unknown

Lipoplasty

Estimated volume of subcutaneous fluids infused _____
Estimated IV intake _____
Estimated total volume aspirated _____

Breast Implants	Right	Left
Implant Manufacturer	☐ Allergan ☐ Mentor ☐ Other	☐ Allergan ☐ Mentor ☐ Other
Shell Type	☐ Smooth ☐ Textured	☐ Smooth ☐ Textured
Implant Shape	☐ Round ☐ Contour	☐ Round ☐ Contour
Filler Type	☐ Saline ☐ Saline/Silicone Gel	☐ Saline ☐ Saline/Silicone Gel
Post Operative Adjustable?	☐	☐
Implant Position	☐ Sub-glandular ☐ Sub-muscular ☐ Subcutaneous	☐ Sub-glandular ☐ Sub-muscular ☐ Subcutaneous
Actual Filler Volume	_____._____	_____._____

Fig. 2. TOPS data collection form for demographic and perioperative risk factors (continued).

time, and body mass index were categorized at clinically relevant cut points.

Adverse outcomes are reported in the TOPS database as events that occur within the first 30 days after the procedure. Outcomes data past 30 days are not available. The dichotomous, surgeon-reported adverse outcome of implant/prosthesis loss was delineated as the outcome of interest (Fig. 3).

Methodologic Limitations

Current Procedural Terminology codes alone cannot be used to distinguish immediate versus

Table 1. Definitions of Selected Independent Variables

Variable	How Variable Was Defined
Breast cancer	1) "Cancer, non-skin" checkbox for breast procedure or 2) Use of ICD-9 codes 174.0 through 174.9 or 233.0
High risk for breast cancer	1) Use of ICD-9 codes V16.3 or 84.01 and 2) No ICD-9 code for breast cancer (174.0 through 174.9 or 233.0)
Bilateral procedure	1) Two 19340/11970/19357 codes reported or 2) Modifier -50 used
Multiple-site surgery	1) "Breast" checkbox for anatomical location and 2) Any other anatomical location checkbox
History of breast irradiation	1) Use of ICD-9 codes 909.2 or 990
Delayed breast reconstruction	1) Use of ICD-9 codes V10.3 or V45.71
Latissimus muscle flap	1) Use of CPT code 19361
Acellular dermal matrix	1) Use of CPT code 15330 or 15331. Of note, no patient in the TOPS database had code 15777 reported.

ICD-9, *International Classification of Diseases, Ninth Revision*; CPR, Current Procedural Terminology; TOPS, Tracking Outcomes and Operations in Plastic Surgery.

Name: _____ *Procedure Date: ___ /___/_____ Medical Record # _____
FIRST MIDDLE LAST MM DD YYYY

Outcome 30 days Post op ☐ No Adverse Events ☐ Adverse Events ☐ Outcome Unknown

I. Unanticipated Resource Utilization
☐ Unplanned Emergency Room Visit ☐ Unplanned Hospital Admission ☐ Unplanned Return to Operating Room

II. Procedure Specific Occurrences

	Related CPT code(s)
☐ Seroma Requiring Drainage	_____
☐ Hematoma Requiring Drainage	_____
☐ Wound Disruption Superficial	_____
☐ Wound Disruption Deep/Fascia	_____
☐ Superficial Incisional Surgery Site Infection	_____
☐ Deep Incisional Surgery Site Infection	_____
☐ Organ/Space Surgery Site	_____
☐ IV Antibiotics	_____
☐ PO Antibiotics	_____
☐ Total Flap Loss (>90%)	_____
☐ Partial Flap Loss (10%-90%)	_____
☐ Total Graft Loss (>90%)	_____
☐ Partial Graft Loss (10%-90%)	_____
☐ Implant/Prosthesis Loss	_____
☐ ≦ 4 U RBC Postoperative Bleeding Req Transfusion	_____
☐ > 4 U RBC Postoperative Bleeding Req Transfusion	_____

III. Thromboembolic Occurrences
☐ DVT ☐ Pulmonary Embolism

V. Other Occurrences
☐ Adverse Drug Event ☐ Mortality within 30 days
☐ Puncture or laceration to other body organ/structure
Related CPT Code(s) _____
Which organ or structure _____

	Related CPT Code(s)
☐ Retained sponge/instrument	_____
☐ Wrong Site Surgery	_____
☐ Other	_____

IV. Systemic Occurrences

Cardiac System
☐ Cardiac Arrest Req CPR ☐ Myocardial Infarction
☐ Other Cardiac Occurrence

Nervous System
☐ Coma > 24 hours ☐ Peripheral Nerve Injury
☐ Stroke/CVA ☐ Other Nerve Occurrence

Respiratory
☐ On Ventilator > 48 hrs ☐ Pneumonia
☐ Unplanned intubation ☐ Other Respiratory Occurrence

System Sepsis
☐ Sepsis ☐ Septic Shock
☐ Systemic Inflammatory Response Syndrome

Urinary System
☐ Acute Renal Insufficiency
☐ Progressive Renal Insufficiency
☐ Urinary Tract Infection
☐ Other Urinary Tract Occurrence

VI. Comments

_____
_____
_____
_____

Fig. 3. TOPS data collection form for complications and outcomes.

delayed reconstruction, as code 19357 does not distinguish between the two. Instead, we used *International Classification of Diseases, Ninth Revision* codes (Table 1) to identify patients who had delayed reconstruction.

Data for implant characteristics (e.g., location with relation to the pectoralis major, and filler and shell characteristics) were available in less than 30 percent of cases. Incomplete data for implant characteristics were handled by removing these variables from the analysis.

Time-to-event data could not be incorporated into the analysis (survival analysis), as timing of events was not captured by the TOPS data entry sheet. Similarly, lack of time data on alternative adverse outcomes (wound disruption, hematoma, or infection) were not included into the regression analysis to prevent issues with multiple testing, as it is unknown whether these events may have presented at the same time, before, or after in the same patient as the outcome of interest (loss of expander/implant). Mean time to complication could not be estimated, as time to expander/implant loss could not be derived.

Statistical Analysis

The chi-square test was used to compare rates of expander/implant loss based on the presence or absence of an independent variable. As we were not limited by a paucity of outcome events, a bivariate screen was not required for entry into the final model. Collinearity diagnostics were performed between all independent variables placed into the regression model. No independent variable demonstrated a variance inflation factor greater than 1.4. The mean variance inflation factor was 1.14. All independent variables were subsequently placed into a multivariable logistic regression model, with 30-day expander/implant loss as the dichotomous dependent variable.

Stratified analysis by year of surgery was performed to identify tissue expander/implant loss rates over time and trends in acellular dermal matrix use over time. A value of $p \leq 0.05$ was considered to be statistically significant.

RESULTS

Data were available for 14,249 patients who met inclusion criteria as above. The rate of 30-day expander/implant loss was 2.05 percent (292 patients).

Bivariate analyses identified associations between multiple independent risk factors and 30-day expander/implant loss (Table 2). When compared with the reference group, age 60 years or older (2.40 percent versus 1.68 percent, $p = 0.077$), body mass index 30 to 40 (3.56 percent versus 1.75 percent, $p < 0.001$), and body mass index greater than or equal to 40 (8.36 percent versus 1.75 percent, $p < 0.001$) were associated with higher expander/implant loss. Current smoking (4.45 percent versus 2.75 percent, $p = 0.009$) and presence of diabetes (7.67 percent versus 2.73 percent, $p < 0.001$) were both associated with significantly higher rates of expander/implant loss. Multiple-site surgery (1.05 percent versus 2.11 percent, $p = 0.047$) and use of a latissimus flap (1.86 percent versus 2.06 percent, $p = 0.69$) were protective against expander/implant loss. Use of acellular dermal matrix occurred in 3450 patients (24 percent). Patients in whom acellular dermal matrix was used had an absolute risk increase of 0.7 percent for expander/implant loss (2.58 percent versus 1.88 percent, $p = 0.012$).

Among the total cohort of 14,249 patients, 8746 had complete data for all independent variables. These 8746 patients were placed into the regression model. When controlling for other identified confounders, several variables that were significant on bivariate analyses (age ≥60 years, breast cancer, and multiple-site surgery) were not independent predictors of expander/implant loss. When compared with the reference group, body mass index of 30 to 40 (odds ratio, 1.90; 95 percent CI, 1.38 to 2.61; $p < 0.001$) and body mass index greater than or equal to 40 (odds ratio, 4.24; 95 percent CI, 2.66 to 6.76; $p < 0.001$) were independent predictors of expander/implant loss. Additional independent predictors included current smoker (odds ratio, 1.67; 95 percent CI, 1.11 to 2.50; $p = 0.014$) and diabetes (odds ratio, 1.72; 95 percent CI, 1.02 to 2.88; $p = 0.041$). When controlling for all other identified confounders, use of acellular dermal matrix was associated with a statistically significant increase in expander/implant loss (odds ratio, 1.42; 95 percent CI, 1.04 to 1.94; $p = 0.026$) (Table 3).

For patients who had tissue expander insertion (e.g., code 19357), 35.4 percent (2905 of 8197) of patients had acellular dermal matrix used in their reconstruction. The 30-day rate of expander loss was 2.72 percent (223 of 8197 patients). For patients with permanent implant insertion (e.g., codes 11970 or 19340), 9.1 percent (555 of 6100) of patients had acellular dermal matrix used in their reconstruction. The 30-day rate of implant loss was 1.13 percent (69 of 6100 patients). In total, 48 patients had simultaneous placement of an expander on one side and a permanent

Table 2. Bivariate Statistics Comparing Rates of Expander/Implant Loss in Patients Who Did or Did Not Have Individual Risk Factors*

Risk Factor	Expander or Implant Loss		
	No (n = 13,957) (%)	Yes (n = 292) (%)	p
Age			
<40 yr	2108 (16.7)	36 (12.4)	Reference
40–60 yr	7999 (61.4)	182 (62.8)	0.12
≥60 yr	2932 (22.5)	72 (24.8)	0.077
Body mass index			
<30	6866 (77.5)	122 (57.8)	Reference
30–40	1707 (19.3)	63 (29.9)	<0.001
≥40	285 (3.2)	26 (12.3)	<0.001
Current smoker	708 (8.8)	33 (13.8)	0.009
Diabetes	277 (3.6)	23 (9.8)	<0.001
Breast cancer	8307 (59.5)	225 (77.1)	<0.001
High risk for breast cancer	200 (1.4)	3 (1.0)	0.56
History of irradiation	67 (0.5)	3 (1.0)	0.19
Delayed reconstruction	5287 (37.9)	152 (52.1)	<0.001
Surgery duration			
<2 hr	6493 (46.5)	144 (49.3)	Reference
2–4 hr	6152 (44.1)	124 (42.5)	0.44
≥4 hr	1312 (9.4)	24 (8.2)	0.39
General anesthesia	12,460 (89.3)	286 (98.0)	<0.001
Multiple-site surgery	751 (5.4)	8 (2.7)	0.047
Bilateral breast procedure	6280 (45.0)	140 (48.0)	0.32
Use of latissimus flap	793 (5.7)	15 (5.1)	0.69
Use of acellular dermal matrix	3361 (24.1)	89 (30.5)	0.012

*Data are presented as the number (%) of patients within the cohort who had the individual risk factor. The total number of patients was 14,249. The total number for individual risk factors does not add up to 14,249 in all cases because of incomplete data.

implant on the other. None of these patients experienced an expander/implant loss. Stratified analysis by year surgery was performed demonstrated a significant decrease in tissue expander/implant loss rates over time (Fig. 4). There were no clear trends in acellular dermal matrix use over time (Fig. 5).

DISCUSSION

Loss of an expander or implant is devastating for breast reconstruction patients. Expander/implant loss typically results in at least two (in the case of lost tissue expanders) and possibly three (in the case of lost implants) additional operative procedures, which results in a significant burden to the patient, surgeon, and health care system. Previous work has associated acellular dermal matrix use with increased tissue expander/implant loss after reconstructive breast surgery.[2,3,5,8,11,13] Here, we confirm this relationship using a large-database approach that included surgeon-reported data for over 14,000 patients. Our results indicate that acellular dermal matrix use is associated with an absolute risk increase of 0.7 percent for expander/implant loss. To state this differently, for every 143 patients in whom acellular dermal matrix is used, one additional patient will experience an expander/implant loss. This higher rate, though notable, is much lower than the 1.3 to 14 percent loss rates reported previously.[2,3,5,8,11,13]

Keeping the expander or implant in situ is not the only goal of reconstructive breast surgery. When considering whether or not to use acellular dermal matrix, interpretation of our results must be guided both by the slight increased risk of tissue expander/implant loss and by the final reconstructive outcome. Many surgeons believe that acellular dermal matrix improves the reconstructive outcome, particularly as it relates to decreased time for expansion (and thus decreased time to completion of reconstruction), improved contour of the lower pole of the reconstructed breast, and the ability to perform immediate, implant-based reconstructive techniques.[2–5,7,8] Primate models have shown that acellular dermal matrix prevents capsule formation in areas where the acellular dermal matrix abuts an implant.[19] In humans, acellular dermal matrix may decrease capsular contracture rates up to fivefold.[7,12,20] We agree with Ho and colleagues, who note that "if this phenomenon continues to be true, [decreased risk for capsular contracture] might justify the moderately higher complication rates" seen with acellular dermal matrix.[12]

The 0.7 percent higher risk for tissue expander/implant loss with acellular dermal matrix was statistically significant. However,

Table 3. Predictors of Expander/Implant Loss from a Multivariable Logistic Regression Model*

Risk Factor	Adjusted OR (95% CI)	*p*
Age		
<40 yr	Reference	—
40–60 yr	1.18 (0.76–1.85)	0.46
≥60 yr	1.36 (0.83–2.24)	0.22
Body mass index		
<30	Reference	—
30–40	1.90 (1.38–2.62)	<0.001
≥40	4.24 (2.66–6.76)	<0.001
Smoking history		
Nonsmoker	Reference	—
Current smoker	1.66 (1.11–2.50)	0.014
Unknown	0.26 (0.07–0.95)	0.041
Diabetes		
No	Reference	—
Yes	1.72 (1.02–2.88)	0.041
Unknown	0.49 (0.18–1.30)	0.17
Breast cancer	1.08 (.76–1.55)	0.67
High risk for breast cancer	0.74 (0.23–2.40)	0.62
History of irradiation	1.36 (0.32–5.74)	0.68
Delayed reconstruction	0.99 (0.74–1.31)	0.93
Surgery duration		
<2 hr	Reference	—
2–4 hr	0.93 (0.68–1.26)	0.63
≥4 hr	0.85 (0.46–1.55)	0.59
General anesthesia	0.84 (0.34–1.98)	0.69
Multiple-site surgery	0.65 (0.28–1.52)	0.32
Bilateral breast procedure	1.01 (0.75–1.36)	0.94
Use of latissimus flap	0.72 (0.35–1.51)	0.39
Use of acellular dermal matrix	1.42 (1.04–1.94)	0.026

*n = 8746, with 210 total expander/implant losses.

statistical significance is not synonymous with clinical relevance. We agree with Januszyk and Gurtner, who note that "clinically trivial results may exhibit statistical significance and, likewise, results that fail to achieve statistical significance may nonetheless be clinically relevant."[21] We urge surgeons to not only focus on the loss rates presented in this article but also consider how acellular dermal matrix may improve their ability to perform breast reconstruction. For those surgeons who conclude that acellular dermal matrix improves their outcomes, the increased risk for expander/implant loss of 0.7 percent may be justifiable. In addition, patients who have additional risk factors for expander/implant loss identified in this analysis (higher body mass index, presence of diabetes, or current smoking) should be counseled on the increased risk for expander/implant loss.

Stratified analyses showed a significant decrease in tissue expander/implant loss over time (Fig. 4). This likely reflects the "learning curve" of a new technique or product, including changes in patient selection and technical refinements such as antibiotic irrigation, use of closed-suction drainage, and perioperative antibiotic prophylaxis.[3,11,13,22] We did not observe a clear trend in rates of acellular dermal matrix use over time (Fig. 5).

Limitations

This analysis was limited by several factors. For fiscal year 2012, only 6.5 percent of American Society of Plastic Surgeons members (354 of 5469 surgeons) entered data into the system. However, these 6.5 percent have been shown to be reasonably representative of the overall American Society of Plastic Surgeons population.[16] Of note, TOPS users are slightly younger than the general American Society of Plastic Surgeons membership, and thus patients of younger surgeons are likely disproportionately represented within the data. This represents a notable confounding variable for which we cannot control. In what direction this

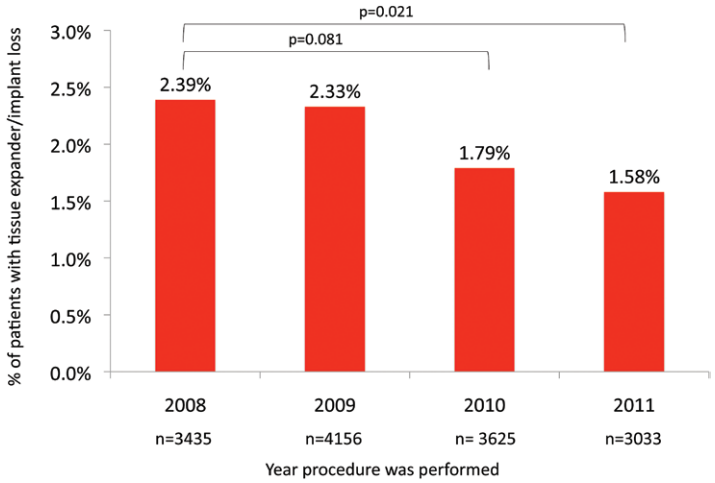

Fig. 4. Observed rates of 30-day tissue expander/implant loss stratified by year of surgical procedure.

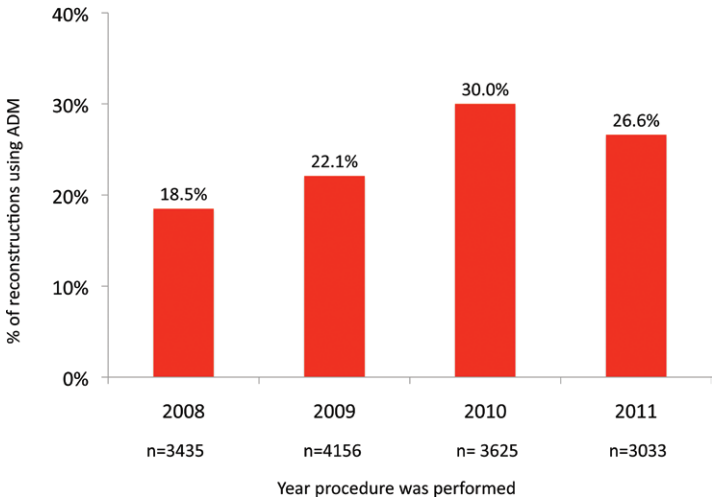

Fig. 5. Proportion of reconstructions using acellular dermal matrix (*ADM*) stratified by year of surgical procedure.

might influence data remains unclear—younger surgeons are less experienced overall but may have had increased exposure to acellular dermal matrix use within their residency training. TOPS might consider addition of surgeon-level variables, such as years in practice and practice type, to the data acquisition process to allow researchers to control for clustering effects by surgeon.

The goal of this study was to test a distinct hypothesis with a clear endpoint. Tissue expander/implant loss is a concrete, dichotomous endpoint whose consequence is easily understood. In contrast, the diagnosis of complications such as seroma and infection are subject to interpretation, and their clinical consequence cannot be ascertained from TOPS data. As noted above, the database does not contain time-to-complication data; this precluded use of seroma or infection as an independent variable in our regression model. Based on these inherent limitations of TOPS data, we chose not to analyze other complications recorded in the database in this article.

Our analysis indicates that a discrepancy exists between rates of tissue expander loss (2.72 percent) and permanent implant loss (1.13 percent). This finding is likely multifactorial. Mastectomy flaps that are less robust due to thinness, impaired vascularity, or inadequacy of tissue flaps are typically less likely to undergo a single-stage type reconstruction using a permanent implant and more likely to have a tissue expander placed in which a reduced expansion volume can be placed. It is plausible that permanent implants may only be used in selective situations that are less high risk. Given this, it is unknown whether the increased loss rate is attributable to the status of the mastectomy flaps and/or the increased use of acellular dermal matrix and other factors. As the TOPS database does not contain a variable with which to assess either qualitative (surgeon evaluation) or quantitative (device-based perfusion or other objective measure) assessment of mastectomy flaps, there is no current way to incorporate this variable into the analysis.

Data were available in the TOPS database on unilateral versus bilateral procedures (Table 1). However, tissue expander/implant loss in the database is tracked as a patient-level variable instead of side-specific (implant loss, left; or implant loss, right). Thus, we were unable to rigorously control for clustering effects by patient. For this analysis, tissue expander/implant loss was examined as a patient-level occurrence, not as a side-specific occurrence.

A limitation of our data concerns incomplete data. Our initial data merge identified 14,249 patients who met our inclusion criteria. However, only 61 percent (8746 patients) had complete data for all independent variables in the regression model. We are unable to determine whether patients with missing data are systematically different than patients with complete data, although we would not expect specific trend biases. Similarly, we were unable to incorporate potentially important confounders such as expander/implant location, texture, and type into the regression model; over 70 percent of the study cohort (all of whom had expander/implant-based reconstruction) had incomplete data recorded on the breast expander/implant characteristics.

Finally, the TOPS database tracks adverse outcomes to 30 days from the index operation. The

observed 30-day risk for expander/implant loss of 2.05 percent likely underestimates the true event rate. This is because expanders or implants removed after 30 days are not recorded as adverse events in the database.

CONCLUSIONS

Risk for expander/implant loss in breast reconstruction is approximately 2 percent within the first 30 days after surgery. This risk is higher in obese patients, patients who are currently smoking, and diabetic patients. Use of acellular dermal matrix in breast reconstruction is associated with an absolute risk increase of 0.7 percent for expander/implant loss. Surgeons must individually determine whether the slight increased risk for expander/implant loss is justified by perceived improvements in aesthetic and functional gains when acellular dermal matrix is used.

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