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# Risk Analysis of Early Implant Loss after Immediate Breast Reconstruction: A Review of 14,585 Patients

John P Fischer, MD, Ari M Wes, BA, Charles T Tuggle III, MD, Joseph M Serletti, MD, FACS, Liza C Wu, MD, FACS

**BACKGROUND:** Early prosthesis loss is an infrequent but serious complication after breast reconstruction. We assessed perioperative risk factors associated with early device loss after immediate breast reconstruction (IBR) using the ACS-NSQIP datasets.

**STUDY DESIGN:** We reviewed the 2005 to 2011 ACS-NSQIP databases identifying encounters for CPT codes 19357 and 19340. Patients were identified as experiencing a "loss of graft/prosthetic" based on a standard dataset variable. Patients who experienced a device loss were compared with those who did not with respect to perioperative characteristics.

**RESULTS:** We identified 14,585 patients with an average age of 50.9 ± 10.6 years. A multivariate regression analysis determined that age (>55 years) (odds ratio [OR] 1.66, $p = 0.013$) (risk score = 1), class II obesity (OR 3.17, $p < 0.001$) (risk score = 3), class III obesity (OR 2.41, $p = 0.014$) (risk score = 3), active smoking (OR 2.95, $p < 0.001$) (risk score = 3), bilateral reconstruction (OR 1.67, $p = 0.007$) (risk score = 1), and direct-to-implant (DTI) reconstruction (OR 1.69, $p = 0.024$) (risk score = 1) were associated with early device loss. Odds ratios were used to assign weighted risk scores to each patient, and risk categories were broken into low risk (0 to 1, n = 9,349), intermediate risk (2 to 5, n = 5,001), and high risk (≥6, n = 233) groups. The risk of device loss was significantly higher with increased risk score (0.39% vs 1.48% vs 3.86%, $p < 0.001$).

**CONCLUSIONS:** Early device loss following IBR is a complex multifactorial process related to identifiable preoperative risk factors. This study demonstrated that age, obesity, smoking, bilateral procedures, and DTI reconstructions are associated with increased risk of implant loss. (J Am Coll Surg 2013;217:983–990. © 2013 by the American College of Surgeons)

Breast reconstruction affords a significant psychosocial and esthetic benefit for patients undergoing mastectomy.[1-4]

**CME questions for this article available at http://jacscme.facs.org**

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Ethical Approval: Deidentified patient information is freely available to all institutional members who comply with the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) Data Use Agreement. The Data Use Agreement implements the protections afforded by the Health Insurance Portability and Accountability Act of 1996. IRB exemption was approved by our institution.

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From the Divisions of Plastic Surgery, Hospital of the University of Pennsylvania, Philadelphia, PA (Fischer, Wes, Serletti, Wu) and Yale School of Medicine New Haven, CT (Tuggle).

Correspondence address: John P Fischer, MD, Division of Plastic Surgery, University of Pennsylvania, 3400 Spruce St, Philadelphia, PA 19104. email: John.Fischer2@uphs.upenn.edu

Although autologous reconstruction may create a more natural-appearing breast, implant-based breast reconstructions are shorter operations, have faster recoveries, and are without donor site morbidity.[5] Evolving patterns of mastectomy use, along with a rising trend in immediate, bilateral breast reconstruction (IBR), have solidified implant-based breast reconstruction as a standard in the United States.[6-8]

Implant loss is an infrequent but very serious complication after reconstruction and is linked to decreased patient satisfaction and added cost.[1,9] A growing body of literature has emerged assessing risk factors for implant failure,[10-20] but there is a need for better risk assessment data to enhance decision-making, and more generalizable, multi-institutional studies to improve patient counseling regarding modality choice and reconstructive timing. The addition of a clinical risk model and decision-support tool constructed from preoperatively identifiable patient and operative factors would greatly improve care and risk counseling.[20] In this analysis we used the American College of Surgeons National Surgical Quality

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**Abbreviations and Acronyms**
BMI = body mass index
CPT = Current Procedural Terminology
DTI = direct-to-implant
IBR = immediate breast reconstruction
OR = odds ratio
TE = tissue expander

Improvement Program (ACS-NSQIP) datasets to determine risk factors associated with early (30-day) implant loss.[21] With risk factors derived from our analysis, we created a simple risk assessment tool characterizing 30-day risk of device loss after IBR, which can be used to improve preoperative clinical decision-making.

## METHODS

### Datasets

The 2005 to 2011 ACS-NSQIP databases were accessed on December 1, 2012 and queried to identify all patients undergoing IBR using implants.[21] Per protocol, 240 Health Insurance Portability and Accountability Act (HIPAA)-compliant variables were collected for each encounter. These included patient demographic information, preoperative comorbidities and risk factors, perioperative laboratory results, information related to intraoperative proceedings and complications, as well as postoperative morbidity and mortality data for the subsequent 30-day period.

### Cohort identification and definitions

We identified patients undergoing breast reconstruction procedures using Current Procedural Terminology (CPT) codes for tissue expander (TE) placement (19357) and implant (19340).[20] Patients with combinations of CPT codes indicating multimodality reconstruction were excluded. Patients under the age of 18 were also excluded.

Patients were considered to have undergone IBR if a mastectomy was performed simultaneously with a reconstructive procedure; patients undergoing a reconstructive procedure without concurrent mastectomy were considered to have undergone delayed reconstruction and were excluded. The CPT codes used to identify mastectomy included partial mastectomy with (19102) and without axillary lymphadenectomy (19101), simple mastectomy (19103), subcutaneous mastectomy (19104), modified radical mastectomy (19107), and radical mastectomy (19105 and 19106).[22] Additionally, the laterality (either unilateral or bilateral) was assessed and noted for each patient.

In addition to predefined ACS-NSQIP variables, which can be accessed at the website (http://site.acsnsqip.org/), we calculated each patient's body mass index (BMI) (kg/m$^2$). The World Health Organization definition of obesity was used to classify patients with a BMI $< 30$ kg/m$^2$ as nonobese and those with BMI $\geq 30$ kg/m$^2$ as obese.[23] Patients were identified as follows: nonobese (BMI $< 30$ kg/m$^2$), class I obesity (BMI = 30 to 34.9 kg/m$^2$), class II obesity (BMI = 34.9 to 39.9 kg/m$^2$), and class III obesity (BMI $> 40$ kg/m$^2$).

### Variables

A variety of patient comorbidities and perioperative risk factors were selected from the NSQIP variables and subjected to univariate analysis. These included baseline health characteristics, past medical and surgical history, preoperative laboratory values, American Society of Anesthesiologists (ASA) physical status, and intraoperative factors such as operative time and intraoperative blood transfusion. The full list and definitions of NSQIP program variables can be found on the ACS-NSQIP website (http://site.acsnsqip.org/). All complications were defined as within 30 days of IBR. Prosthesis loss was defined as a failure of an extracardiac graft or prosthesis that required an unplanned return to the operating room.

### Statistical analysis

Categorical variables were analyzed using Pearson chi-square or Fisher's exact tests, while continuous variables were examined with Wilcoxon rank-sum or Mann-Whitney tests. Preoperative and intraoperative variables with a $p \leq 0.10$ on univariate analysis were included in a multivariate logistic regression analysis as independent variables, with implant loss as the dependent variable. All tests were 2-tailed, with statistical significance defined as $p < 0.05$. Analyses were performed using STATA IC 11.0 (StataCorp). Significant risk factors derived from multivariate regression analysis were weighted using odds ratios to create a composite risk score for each patient. Patients were stratified and analyzed based on their total preoperative risk score.

## RESULTS

There were 14,585 patients identified from the 2005 to 2011 ACS-NSQIP datasets, with an average age of 50.9 $\pm$ 10.6 years and BMI of 26.8 $\pm$ 6.3 kg/m$^2$. The majority of reconstructions were tissue expanders (TE) (85.0%) with direct-to-implant (DTI) reconstructions, totaling 2,190 patients (n = 15.0%). Of the study cohort, 4.6% were diabetic, 13.6% were active smokers, 25.7% were obese (BMI $\geq 30$ kg/m$^2$), and 22.9% had hypertension. A summary of preoperative conditions can be found in Table 1.

The majority of reconstructed wounds were clean (97.8%) and patients were most often American Society

of Anesthesiologists class I or II (80.9%). Operative time, on average, for unilateral reconstructions was 182.2 ± 78.2 minutes and 230.4 ± 87.8 minutes for bilateral reconstructions. Acellular dermal matrix was used in 18.5% of reconstruction. Average length of stay was 1.8 ± 3.8 days (Table 2). Implant loss occurred in 129 patients (0.8%).

Patients experiencing an early prosthesis loss tended to be obese (BMI $\geq$ 30 kg/m$^2$) (25.4% vs 42.8%, $p < 0.0001$), older (50.9 vs 53.6 years, $p < 0.001$), diabetic (4.5% vs 8.4%, $p = 0.04$), active smokers (13.5% vs 29.4%, $p < 0.001$), and to have hypertension (22.8% vs 37.0%, $p = 0.001$). A summary of univariate statistics for preoperative risk factors associated with implant loss is found in Table 3. Patients experiencing loss also more frequently underwent DTI reconstructions (15.0% vs 21.8%, $p = 0.04$), bilateral reconstructions (37.1% vs 47.8%, $p = 0.009$), had longer operative times for unilateral (182.1 vs 209.4 minutes, $p < 0.0001$) and bilateral (230.2 vs 248.4 minutes, $p = 0.0002$) reconstructions, and experienced longer total lengths of stay (1.8 vs 2.1 days, $p = 0.0001$) (Table 4).

**Table 1.** Characteristics of Patients Undergoing Immediate Breast Reconstruction Using an Implant or Expander

| Characteristic | Data |
|---|---|
| Total, n | 14,585 |
| Age, mean ± SD | 50.9 ± 10.6 |
| World Health Organization Obesity Class, n (%) | |
| Nonobese (BMI <30 kg/m$^2$) | 10,844 (74.4) |
| Class I (30–34.9 kg/m$^2$) | 2,168 (14.9) |
| Class II (35-39.9 kg/m$^2$) | 909 (6.2) |
| Class III (≥40kg/m$^2$) | 664 (4.6) |
| Diabetes, n (%) | 666 (4.6) |
| Active smoking, n (%) | 1,988 (13.6) |
| Current alcohol use, n (%) | 151 (1.0) |
| Independent functional status, n (%) | 14,548 (99.7) |
| Chronic obstructive pulmonary disease, n (%) | 112 (0.8) |
| Previous percutaneous cardiac intervention, n (%) | 84 (0.6) |
| History of angina, n (%) | 11 (0.1) |
| Hypertension, n (%) | 3,338 (22.9) |
| Peripheral vascular disease, n (%) | 12 (0.1) |
| Previous transient ischemic attack, n (%) | 73 (0.5) |
| Previous cerebrovascular accident, n (%) | 82 (0.6) |
| Current use of steroids, n (%) | 135 (0.9) |
| Bleeding disorder, n (%) | 90 (0.6) |
| Chemotherapy within 30 d, n (%) | 627 (4.3) |
| Radiation within 90 d, n (%) | 46 (0.3) |
| Earlier operation within 30 d, n (%) | 309 (2.1) |

**Table 2.** Operative Characteristics of Patients Undergoing Immediate Breast Reconstruction Using an Implant or Expander

| Operative characteristic | Data |
|---|---|
| Total, n | 14,585 |
| ASA physical status, n (%) | |
| 1 | 1,531 (10.5) |
| 2 | 10,268 (70.4) |
| 3 | 2,741 (18.8) |
| 4 | 31 (0.2) |
| Type of reconstruction, n (%) | |
| Tissue expander | 12,395 (85.0) |
| Direct to implant | 2,190 (15.0) |
| Laterality, n (%) | |
| Unilateral | 9,153 (62.8) |
| Bilateral | 5,432 (37.2) |
| Acellular dermal matrix, n (%) | 2,703 (18.5) |
| Body mass index, kg/m$^2$, mean ± SD | 26.8 ± 6.3 |
| Operative time, min, mean ± SD | |
| Unilateral | 182.2 ± 78.2 |
| Bilateral | 230.4 ± 87.8 |
| Length of stay, d, mean (SD) | 1.8 ± 3.8 |

A multivariate regression analysis determined that age (>55 years) (odds ratio [OR] 1.66, $p = 0.013$) (risk score = 1), class II obesity (OR 3.17, $p < 0.001$) (risk score = 3), class III obesity (OR 2.41, $p = 0.014$) (risk score = 3), active smoking (OR 2.95, $p < 0.001$) (risk score = 3), bilateral reconstructions (OR 1.67, $p = 0.007$) (risk score = 1), and DTI reconstructions (OR 1.69, $p = 0.024$) (risk score = 1) were associated with early device loss (Table 5). The odds ratios derived from multivariable regression analysis were used to create a risk assessment tool. Composite, weighted risk scores were assigned for each patient, and risk categories included: low risk (0 to 1, n = 9,349), intermediate risk (2 to 5, n = 5,001), and high risk (≥6, n = 233) (Tables 6 and 7). The risk of device loss was significantly higher with increased risk category (0.39% vs 1.48% vs 3.86%, $p < 0.001$) (Fig. 1).

## DISCUSSION

In this analysis we used the ACS-NSQIP datasets to determine perioperative risk factors associated with early (30-day) implant loss after IBR. To date there are several studies characterizing the national, population-level changes in mastectomy type and reconstruction, which have identified a notable rise in bilateral, prophylactic mastectomy rates as well as increased use of IBR with implants.[7,8] The persisting popularity of implant use coupled with the negative psychosocial and fiscal impact of device loss underscore

**Table 3.** Comparison of Perioperative Factors Associated with Implant Failure in Immediate Breast Reconstruction

| Perioperative factor | None | Implant failure | p Value |
|---|---|---|---|
| Total, n (%) | 14,466 (99.2) | 119 (0.8) | |
| Age, y, mean ± SD | 50.9 ± 10.6 | 53.6 ± 98 | 0.002 |
| World Health Organization Obesity Class, n (%) | | | <0.001 |
| Nonobese (BMI <30 kg/m$^2$) | 10,776 (74.5) | 68 (57.1) | |
| Class I (30-34.9 kg/m$^2$) | 2,148 (14.8) | 20 (16.8) | |
| Class II (35-39.9 kg/m$^2$) | 889 (6.1) | 20 (16.8) | |
| Class III (≥40kg/m$^2$) | 653 (4.5) | 11 (9.2) | |
| Diabetes, n (%) | 656 (4.5) | 10 (8.4) | 0.04 |
| Active smoking, n (%) | 1,953 (13.5) | 35 (29.4) | <0.001 |
| Current alcohol use, n (%) | 149 (1.0) | 2 (1.7) | 0.65 |
| Independent functional status, n (%) | 14,429 (99.7) | 119 (100.0) | 1 |
| Chronic obstructive pulmonary disease, n (%) | 109 (0.8) | 3 (2.5) | 0.06 |
| Previous percutaneous cardiac intervention, n (%) | 82 (0.6) | 2 (1.7) | 0.18 |
| History of angina, n (%) | 11 (0.1) | 0 (0.0) | 1 |
| Hypertension, n (%) | 3,294 (22.8) | 44 (37.0) | <0.001 |
| Peripheral vascular disease, n (%) | 12 (0.1) | 0 (0.0) | 1 |
| Previous transient ischemic attack, n (%) | 72 (0.5) | 2 (1.7) | 0.15 |
| Previous cerebrovascular accident, n (%) | 82 (0.6) | 0 (0.0) | 1 |
| Current use of steroids, n (%) | 134 (0.9) | 1 (0.8) | 1 |
| Bleeding disorder, n (%) | 90 (0.6) | 0 (0.0) | 1 |
| Chemotherapy within 30 d, n (%) | 624 (4.3) | 3 (2.5) | 0.29 |
| Radiation within 90 d, n (%) | 46 (0.3) | 0 (0.0) | 1 |
| Earlier operation within 30 d, n (%) | 304 (2.1) | 5 (4.2) | 0.20 |

the importance of generalizable outcomes data assessing risk. To that effect, the aim of this work was to identify the incidence and risk factors for early (30-day) implant loss after IBR using the ACS-NSQIP database. We further sought to create a simple, usable clinical risk assessment tool for predicting loss.

Overall, there a very low rate (0.8%) of implant loss, reflecting the short follow-up time captured in this analysis.

**Table 4.** Comparison of Operative Factors Associated with Implant Failure in Immediate Breast Reconstruction

| Operative factor | None | Implant failure | p Value |
|---|---|---|---|
| Total, n (%) | 14,466 (99.2) | 119 (0.8) | |
| ASA physical status, n (%) | | | 0.29 |
| 1 | 1,523 (10.5) | 8 (6.7) | |
| 2 | 10,187 (70.4) | 81 (68.1) | |
| 3 | 2,712 (18.7) | 29 (24.4) | |
| 4 | 31 (0.2) | 0 (0.0) | |
| Direct to implant, n (%) | 2,164 (15.0) | 26 (21.8) | 0.04 |
| Laterality, n (%) | | | 0.009 |
| Unilateral | 9,092 (62.9) | 61 (51.3) | |
| Bilateral | 5,374 (37.1) | 58 (48.7) | |
| Acellular dermal matrix, n (%) | 2,680 (18.5) | 23 (19.3) | 0.82 |
| Body mass index, kg/m$^2$, mean ± SD | 26.7 ± 6.3 | 30.4 ± 8.7 | <0.0001 |
| Operative time, min, mean ± SD | | | |
| Unilateral | 182.1 ± 78.2 | 209.4 ± 78.2 | <0.0001 |
| Bilateral | 230.2 ± 87.7 | 248.4 ± 94.4 | 0.002 |
| Length of stay, d, mean ± SD | 1.8 ± 3.8 | 2.1 ± 1.3 | 0.0001 |

ASA, American Society of Anesthesiologists.

**Table 5.** Summary of Multivariate Regression Analysis of Risk Factors Associated with Implant Failure after Immediate Breast Reconstruction

| Risk factors | Odds ratio | 95% CI | p Value |
|---|---|---|---|
| Age > 55 y | 1.66 | 1.11–2.47 | 0.013 |
| Class I obesity (30–34.9 kg/m$^2$) | 1.32 | 0.79–2.21 | 0.284 |
| Class II obesity (35–39.9 kg/m$^2$) | 3.17 | 1.88–5.36 | <0.001 |
| Class III obesity (≥ 40 kg/m$^2$) | 2.41 | 1.20–4.83 | 0.014 |
| Diabetes | 1.18 | 0.59–2.36 | 0.648 |
| Active smoking | 2.95 | 1.97–4.43 | <0.001 |
| COPD | 1.20 | 0.29–5.00 | 0.804 |
| Hypertension | 1.38 | 0.90–2.11 | 0.139 |
| Bilateral reconstruction | 1.67 | 1.15–2.42 | 0.007 |
| Direct to implant | 1.69 | 1.07–2.66 | 0.024 |

Our regression analysis demonstrated that early device loss was related to age, progressive obesity, smoking, bilateral reconstruction, and DTI reconstructions. Age, obesity, and smoking are consistent with our previously published work but the identification of other operative characteristics such as DTI reconstructions and bilateral procedures enhances the model.[20] Furthermore, the inclusion of only identifiable preoperative patient factors and operative characteristics improves the utility of this current model as a decision-support tool. By risk stratifying patients, a small but clinically and statistically significant rate of implant loss was observed with progressive risk (0.39% vs 1.48% vs 3.86%, $p < 0.001$). A 10-fold variation in risk of device loss was noted between low and high risk patients. These data suggest that progressive risk is associated with early device loss, especially in obese smokers who seek bilateral or DTI reconstructions. This group of patients should be carefully considered with respect to optimal reconstructive timing (delayed) and modality (autologous). Several of these findings merit further discussion.

Implant-based reconstruction has been established as a safe and reliable method of breast reconstruction across a wide variety of comorbid states.[13,14,17,18] Cordeiro and McCarthy,[18] in 2008, reported a large series of TE reconstructions delineating the overall low risk of early

**Table 6.** Summary of Significant Factors Derived from Multivariate Regression Analysis and Associated Weighted Scores for Risk Stratification

| Risk factor | Odds ratio | Weighted score |
|---|---|---|
| Age > 55 y | 1.66 | 1 |
| Class II obesity (35–39.9 kg/m$^2$) | 3.17 | 3 |
| Class III obesity (≥ 40 kg/m$^2$) | 2.41 | 3 |
| Active smoking | 2.95 | 3 |
| Bilateral reconstruction | 1.67 | 1 |
| Direct to implant | 1.69 | 1 |

**Table 7.** Risk Stratification of Patients Experiencing Early Implant Loss after Immediate Breast Reconstruction

| Risk | Score | n (%) | Complication, n (%) |
|---|---|---|---|
| Low | 0 to 1 | 9,349 (64.1) | 36 (0.39) |
| Intermediate | 2 to 5 | 5,001 (34.3) | 74 (1.48) |
| High | ≥6 | 233 (1.3) | 9 (3.86) |

complications in 1,221 patients with a rate of 5.8% and loss rate of 2.8%. This landmark study captured complications at up to 1 year, which far exceeds the scope of our study. Their work also elucidated several risk factors associated with complications after implant-based breast reconstruction, including smoking, obesity, hypertension, and previous radiation.[17] Important to note in our analysis is that the NSQIP dataset does not completely capture previous chest wall radiation because the defined variable includes only the previous 90 days before surgery. Our results further corroborated a number of these findings with regard to early loss, but also provided insight into several other variables importantly accounting for bilateral and DTI reconstructions. The benefit of a simple, clinically usable, risk assessment tool is realized in its ability to directly qualify risk and to potentially guide treatment and counseling. We believe that tailoring the delivery of care to a patient's risk profile may portend a better outcome, be associated with less morbidity, greater satisfaction, and more cost-efficient care delivery.

Smoking has been long established as a factor associated with postoperative complications, especially morbidity related to wound healing.[24] From a physiologic standpoint, active smoking imparts a negative effect on skin flap physiology and perfusion.[17,25–27] Carbon monoxide can alter the oxygen-carrying capacity of tissues, nicotine

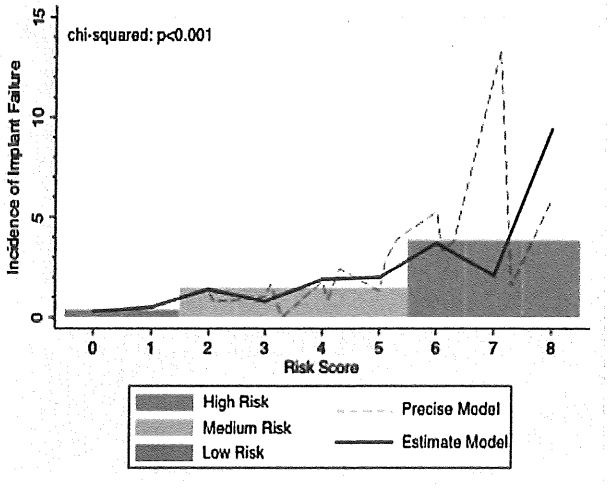


**Figure 1.** Risk stratification of implant loss in immediate breast reconstruction with precise and estimated models.

may serve to increase vasoconstriction, and hydrogen cyanide can alter enzymes involved in oxidative metabolism.[28,29] In IBR, the effects of active smoking inevitably alter tissue perfusion to both the mastectomy flaps and deeper tissues.[22,26] These ideas are demonstrated convincingly in the results of this study, which showed a 3-fold greater odd of TE loss with active smoking. Based on previous studies and from this large, national database, careful consideration of implants for IBR in active smokers is warranted. Sorensen and colleagues,[27] in a randomized control study, demonstrated that smoking is associated with wound complications and that smoking cessation 4 weeks before surgery will reduce risk.

Obesity is also established as a key predictor of perioperative surgical morbidity in breast reconstruction—both implant and autologous.[17,21,23-35] Recent work from the MD Anderson Cancer Center demonstrated a relative advantage of autologous breast reconstruction in IBR over TE based on lower rates of failure.[31] Continued investigation of the effects of obesity on outcomes will be needed to better understand the reconstruction-specific risk profiles at various levels of obesity. Furthermore, age has also been established as a risk factor for complications in breast surgery, but to date there are few studies characterizing the impact of age on outcomes and loss in TE reconstructions.[36] The results reported here represent a new and potentially important additional contribution to the literature. We showed that age (>55 years) is associated with greater risk of implant loss (OR 1.66, $p = 0.013$).

To date there are few studies that provide a direct comparative analysis of outcomes between TE and DTI reconstructions. We recognized up front that without complete knowledge of TE fill volume or implant size, that there is a notable degree of cofounding variables introduced. However, we believe that the large numbers of patients represented by this sample provides a strong association of the challenges seen with DTI, 1-stage reconstructions. The DTI has been shown to be associated with a higher rate of extrusion,[37] but its safety profile and cost-efficacy has been documented in the study by Colwell and associates.[38] Additionally, there are strong data to support DTI in select patients using acellular dermal matrix because it can be highly efficacious and associated with an acceptable complication rate.[39] The overall risk of implant loss after DTI can vary but has been shown to range from 1.5% to 3% in studies,[38,40] and was 1.2% in this study. The lower than normal rate seen in this analysis likely reflects the short, 30-day follow-up period. This study also demonstrates an added risk of early implant loss with DTI techniques (OR 1.69, $p = 0.024$). In comparing TE and DTI loss rates, there is a significant but clinically small difference in risk (0.8% vs 1.2%, $p = 0.04$). This may relate to altered tissue perfusion as a result of larger device placement and subsequent ischemia or extrusion risk. However, given that the exact implant size is not known, we are reluctant to make any definitive conclusions. Another interesting finding of our analysis revealed that bilateral reconstruction was associated with added risk (OR 1.67, $p = 0.007$).

In the last part of our analysis, we weighted independent predictors using odds ratios derived from multivariate regression analysis, and we created a composite risk score for each patient, which ranged from 0 to 12. Risk categories were defined as follows: low risk (0 to 1, n = 9,349), intermediate risk (2 to 5, n = 5,001), high risk (≥6, n = 233). The risk of device loss was significant higher with increased risk category (0.39% vs 1.48% vs 3.86%, $p < 0.001$) (Fig. 1). Patients seeking immediate reconstruction, who are not candidates for autologous reconstruction or who are seeking implant-only, may be better counseled of risk using these identifiable preoperative factors. This may alter decision-making, including the opportunity to consider autologous reconstructions in suitable patients or considering a delayed reconstruction in the higher risk group. We believe, however, that the utility remains in the opportunity to better discuss risk and truly provide informed consent, which may improve patient satisfaction and outcomes.

Although many of the findings in this study may appear intuitive, and despite established limitations of the ACS-NSQIP datasets, there were several valuable findings in this study. First, this study confirmed and validated at the population level, several previously published findings regarding risk of complications with implant-based reconstruction. Specifically, age, obesity, active smoking, DTI, and bilateral reconstructions are factors that will increase risk. These findings underscore the critical need for a cost-benefit analysis in high-risk patients along with careful counseling and open discussions about alternative options with respect to reconstructive timing and modality. The utility of the risk stratification scheme presented is the added benefit in appropriately counseling patients, use for preoperative risk assessment, and the potential for evidence-based decisions regarding timing and reconstructive modality.

There are, however, clear limitations to this study and several key criticisms are worth exploring. First, these data allowed for analysis of only 30-day follow-up, so they did not give an accurate representation of the incidence of device failure over a 1-year period. Secondly, IBR does not provide a comprehensive evaluation of risk for device failure because we did not capture delayed reconstructions or direct-to-implant reconstructions. This study was designed to capture only IBR because we hypothesized that this would enable us to exclude patients with previous radiation therapy, since radiation therapy is not a variable completely characterized in this dataset. Specifically, only 0.3% of our cohort had

radiation within 90 days. Unfortunately, the variable of previous radiation therapy is not adequately addressed through the NSQIP dataset given the 90-day preoperative capture. Furthermore, hospital participation in the NSQIP program is voluntary, which may limit the applicability of our findings across national patient populations and institutions and create study design bias. Although this may be considered a significant flaw of this study, the data and results derived from this work are in close agreement with previously published work, have further confirmed findings at a population-level, and use the largest cohort to date. With regard to the risk assessment scale, we have not validated this tool, so it lacks external validity.

Although this study covered only 30-day outcomes and lacked many of the key historically defined operative characteristics used to assess outcomes, it represents the largest assessment of outcomes in IBR using implants and characterized several preoperative patient characteristics associated with early device loss. An important finding worth consideration is that active smoking conferred a 3-times greater odds of loss. Additionally, these data provide strong evidence that implants in IBR in obese patients are associated with greater risk of early device loss.

## CONCLUSIONS

Early device loss after IBR is a complex multifactorial process likely related to identifiable preoperative, modifiable risk factors including procedure type and patient comorbidities. This analysis highlights previous work demonstrating the added risk imparted by age, obesity, active smoking, and DTI reconstructions. The risk stratification scheme represents a potentially useful tool that may be used to optimally counsel, stratify, and better select candidates for implant-based IBR.

### Author Contributions

Study conception and design: Fischer, Wes, Tuggle
Acquisition of data: Fischer
Analysis and interpretation of data: Fischer, Wes, Tuggle, Serletti, Wu
Drafting of manuscript: Fischer
Critical revision: Fischer, Wes, Serletti, Wu

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