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Implant Loss and Associated Risk Factors following Implant-based Breast Reconstructions

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Background: Implant loss is the most severe complication of implant-based breast reconstructions. This study aimed to evaluate the incidence of implant loss and other complications, identify associated risk factors, and create a risk model for implant loss.

Methods: This was a retrospective cohort study of all patients who underwent a mastectomy, followed by either a two-stage or a direct-to-implant breast reconstruction. Patient variables, operative characteristics, and postoperative complications were obtained from the patient records. A multivariate mixed-effects logistic regression model was used to create a risk model for implant loss.

Results: A total of 297 implant-based breast reconstructions were evaluated. Overall, the incidence of implant loss was 11.8%. Six risk factors were significantly associated with implant loss: obesity, a bra cup size larger than C, active smoking status, a nipple-preserving procedure, a direct-to-implant reconstruction, and a lower surgeon's volume. A risk model for implant loss was created, showing a predicted risk of 8.4%–13% in the presence of one risk factor, 21.9%–32.5% in the presence of two, 47.5%–59.3% in the presence of three, and over 78.2% in the presence of four risk factors.

Conclusions: The incidence of implant loss in this study was 11.8%. Six associated significant risk factors were identified. Our risk model for implant loss revealed that the predicted risk increased over 78.2% when four risk factors were present. This risk model can be used to better inform patients and decrease the risk of implant loss by optimizing surgery using personalized therapy. *(Plast Reconstr Surg Glob Open 2021;9:e3708; doi: 10.1097/GOX.0000000000003708; Published online 22 July 2021.)*

INTRODUCTION

Implant-based breast reconstruction remains the most popular method to reconstruct the breast after a mastectomy,[1] partly due to the notable increase in prophylactic bilateral mastectomies.[2,3] Generally, implant-based breast reconstruction is performed in two stages. First, a tissue expander (TE) is placed in the breast, which is replaced by a definitive implant during a second surgery. Alternatively, a single-stage surgery can be performed using a direct-to-implant (DTI) approach. Implant-based breast reconstruction is considered a simple, safe, and cost-effective technique without donor-site morbidity. Other advantages of implant-based breast reconstruction compared with autologous breast reconstructions are a shorter operative time, quicker overall recovery, and a shorter length of hospital stay.[4]

Among other complications, such as surgical site infections (SSI), skin flap/nipple necrosis, hematoma, and seroma,[5] implant loss is the most severe and is reported in 1.8%–16.9% of all implant-based breast reconstructions.[6–9] This wide range is presumably based on the variations in inclusion criteria, implant loss definitions, and follow-up time. Reoperations associated with implant loss result in a substantial increase in hospital costs and a significant decrease in patient satisfaction.[10]

A growing body of literature has emerged over the years, and several risk factors for implant loss have been

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described, such as an older age, obesity, an active smoking status, and DTI reconstruction.[10] However, a risk assessment model to improve patient information and decision-making for the optimum type of mastectomy and reconstruction has not been created. The objectives of this study were to evaluate the incidence of implant loss and other complications following implant-based breast reconstructions, identify the risk factors associated with implant loss, and create a practical risk model. Ultimately, the study findings could be used to help patients make informed decisions and decrease the risk of implant extrusion through personalized therapy.

METHODS

Study Design

All patients who underwent a mastectomy—followed by immediate breast reconstruction, either a two-stage or a DTI breast reconstruction—between January 2016 and December 2019 in Alrijne Hospital and Leiden University Medical Centre were retrospectively included in this study. The patient variables were extracted from the patient records, including age, body mass index (BMI), bra size, medical comorbidities, the American Society of Anesthesiologists score, smoking status, tumor characteristics, previous breast radiotherapy, and (neo-) adjuvant therapy. Additional surgical characteristics were collected, including mastectomy type (skin-sparing or nipple-sparing), duration of surgery, surgeon/plastic surgeon, type and size of the implant (TE/definitive prosthesis), initial TE saline fill volume, implant placement technique (submuscular/subglandular), and type of axillary surgery (sentinel node and/or axillary lymph node dissection). This study was conducted in accordance with the Declaration of Helsinki[11] and reported according to the Strengthening the Reporting of Observational Studies in Epidemiology statement.[12] The local institutional review boards approved the study protocol.

Surgical Technique

In this study, the mastectomy technique used was either nipple-sparing or skin-sparing. Antibiotics were administered perioperatively (cefazolin) and (in most cases) postoperatively during hospital stay (Augmentin or flucloxacilline). The implants used were mostly smooth and round (manufactured by Eurosilicone and Mentor). No acellular dermal matrix or mesh was used. The implant placement was pre- or subpectoral. In most of the breasts, drains were used.

Clinical Course

The data on complications were collected retrospectively. Postoperative complications (seroma, hematoma, SSI, wound dehiscence, nipple/skin flap necrosis, and implant loss) were graded according to the Clavien-Dindo classification.[13] In grade 1 complications, the normal postoperative course did not deviate, and no interventions were necessary. Grade 2 complications required pharmacological treatment, grade 3 required a radiological or surgical intervention with or without general anesthesia, while grade 4 consisted of life-threatening complications requiring ICU admittance. Seroma was defined as a palpable, unexpected swelling along the operated area without signs of infection (erythema or fever). Hematoma was defined as postoperative hemorrhage or an area of blue/yellow color of the skin and subcutaneous fat. SSI was characterized by erythema, potentially combined with a palpable, unexpected fluctuating swelling along the operated area with or without fever. Wound dehiscence was defined as the widening of the surgical wound. Nipple or skin necrosis was defined as the darkening of the nipple or skin. Implant loss was defined as the need for a second surgery to expand the TE or prosthesis because of the visibility of the implant through the skin, implant infection, or any other reason. Salvage procedures were also scored as implant loss. Other data collected were the timing of drain removal, the reported timing of complication occurrence, and the timing and volume of the first TE saline filling.

Statistical Analyses

IBM SPSS statistics (version 26) was used for standard statistical analysis. Differences in baseline characteristics between the groups were tested with the Mann-Whitney U test, chi-square tests, or Fisher's exact test (in the case of small cell counts). Univariate logistic regression, using individual breasts as the unit of analysis, was performed to determine the association between patient or surgical risk factors and implant loss, providing odds ratios (ORs) with 95% confidence intervals (CIs) and *P* values. Cases with missing data on risk factors were excluded from the analysis. Multivariate mixed-effects logistic regression was used to adjust for confounders and correct for clustered data of patients who underwent bilateral mastectomies and therefore contributed two breasts to the analysis. All pre- and perioperative variables were considered potential confounders (obesity, age, bra size, comorbidities, smoking status, tumor type, year of operation, nipple-sparing procedure, sentinel node dissection, type of reconstruction, neoadjuvant chemotherapy, bilateral operation, and radiotherapy). In addition, the patients were divided into subgroups (TE and DTI) before repeating the analysis. Significant univariate risk factors were inserted into a multivariate logistic regression model, and backward stepwise selection was performed to develop a practical risk model. Risk factors with *P* values less than 0.05 were retained in the risk model. A maximum of four risk factors were included, based on the number of implant loss events. The multicollinearity of the individual risk factors was tested before introducing them to the logistic regression model. Surgeon's volume was not included in the risk model, as this factor cannot be generalized to other practices. The predicted and observed risk of implant loss was computed for each risk factor (accumulating from 0 to 4). Continuous data are presented as median (range) and categorical variables as frequency and percentages.

RESULTS

Study Population

A total of 297 implant-based breast reconstructions were performed among 225 patients during the study

period. Follow-up time varied from 1–4 years. The patients had a median age of 50 years (range: 22–72 years) and a median BMI of 24.3 (range: 16.5–44.1). In 27.6% of the patients, the bra cup size was larger than C, and in 6.2%, the American Society of Anesthesiologists score was 3 or more. Of the patients, 14.7% were active smokers. The median operative time was 137 minutes (range: 36–300 minutes).

In 50.8% of the implant-based breast reconstructions, the underlying cause was invasive carcinoma, while in 18.5%, the underlying cause was ductal carcinoma in situ. In 29.0% of the reconstructions, a prophylactic mastectomy was performed. The median weight of the resected specimen was 397 g (range: 39–1300 g). In 40.1%, a nipple-preserving mastectomy was performed. In 79.8%, a TE was placed, and in 20.2%, a DTI reconstruction was performed. Most implants (94.6%) were placed in the subpectoral pocket, and postoperative radiotherapy was administered in 19.9% of the breast reconstructions.

Postoperative Outcomes

The most frequently reported complication was SSI, which occurred in 53 (17.7%) implant-based breast reconstructions, with 16 (5.4%) requiring surgical intervention (CD ≥ 3). SSI was reported at median postoperative day 18. Seroma was reported in 50 (16.8%) implant-based breast reconstructions and was reported in the electronic patient files at median postoperative day 13. One case of seroma (0.3%) resulted in a CD score of three or more. Skin or nipple necrosis was described in 32 (10.8%) implant-based breast reconstructions, which appeared on median postoperative day 11 and led to a CD score of three or more in 21 cases (7.1%). Implant loss occurred after 35 (11.8%) implant-based breast reconstructions, with a yearly variation in incidence of 5.5%–18.3%. The implant was surgically removed on median postoperative day 36. In 10 of the 35 breasts (28.6%), the extruded implant was replaced within the same surgical procedure. The underlying complications in these 10 breasts were SSI, necrosis, or wound dehiscence. Additional postoperative data are summarized in Table 1.

Baseline characteristics were compared between all implant-based breast reconstructions with and without implant loss (35 versus 262 breasts, respectively). A significantly higher BMI was reported in implant-based breast reconstructions with implant loss compared with those without implant loss (median 27.3 versus 24.1, $P = 0.007$). Furthermore, a bra cup size larger than C (48.6% versus 27.1%, $P = 0.012$) and active smoking (34.3% versus 13.4%, $P = 0.002$) were more frequently reported in the group with implant loss. Operative time was prolonged (median 170 versus 135 minutes, $p < 0.001$), mastectomy specimen weights were higher (median 571 versus 385 grams, $P = 0.003$), the nipple was more frequently preserved (62.8% versus 37.0%, $P = 0.002$), the TE size was larger (median 500 versus 400, $P = 0.005$), and a higher perioperative TE filling was applied (median 200 versus 150, $P = 0.008$) in the implant loss group compared with the group without implant loss. All preoperative and surgical characteristics for individual implant-based breast reconstructions with and without implant loss are summarized in Table 2.

Among the implant-based breast reconstructions with implant loss, the following additional complications were significantly more observed compared with those without implant loss: SSI (54.3% versus 13%, $P < 0.001$), wound dehiscence (22.9% versus 2.7%, $P < 0.001$), necrosis in general (62.9% versus 3.8%, $P < 0.001$), and necrosis of the nipple (40% versus 2.7%, $P < 0.001$). A comparison of all postoperative outcomes between these two groups is presented in Table 3.

Table 1. Summary of Clinical Course

Postoperative Outcomes	Number	Postoperative Day	CD ≥ 3
Seroma	50 (16.8)	13 (7–33)	1 (0.3)
SSI	53 (17.7)	18 (3–220)	16 (5.4)
Dehiscence	15 (5.1)	29 (8–137)	7 (2.4)
Necrosis	32 (10.8)	11 (0–29)	21 (7.1)
Implant leakage	7 (2.4)	192 (54–474)	7 (2.4)
Hematoma	36 (12.1)	11 (0–61)	5 (1.6)
Implant loss	35 (11.8)	36 (9–362)	35 (11.8)
Drainage days		3 (0–16)	

The data are numbers and percentages of total breast reconstructions (n = 297); postoperative day is presented as median and range. CD: Clavien-Dindo.

Individual Risk Factors

After adjusting for confounders, six factors were significantly associated with implant loss. These risk factors included obesity (defined as BMI > 30) (adjusted OR: 3.226, $P = 0.020$), a bra cup size larger than C (adjusted OR: 3.132, $P = 0.015$), active smoking status (adjusted OR: 3.935, $P = 0.009$), a nipple-preserving procedure (adjusted OR: 4.182, $P = 0.004$), DTI reconstruction (adjusted OR: 2.609, $P = 0.032$), and a lower surgeon's volume (adjusted OR: 3.070, $P = 0.019$ and adjusted OR: 4.086, $P = 0.010$ between a volume of >50 and 25–50 or <25, respectively). Subgroup analysis stratified for TE or DTI did not result in significant risk factors after adjusting for confounders. All factors and their correlation with implant loss before and after adjusting for confounders are summarized in Table 4.

Risk Model

After multivariate stepwise backward regression analysis, the following risk factors remained significant and were included in the risk model: obesity, nipple-sparing procedure, active smoking status, and a DTI approach. The risk of implant loss was predicted by the number of risk factors present and is depicted in Table 5.

DISCUSSION

The risk of implant loss following an implant-based breast reconstruction in this study was 11.8%, with a yearly variation of 5.5%–18.3%. A growing body of literature has estimated several risk factors for implant loss, most of which are consistent with our findings. Six individual risk factors were associated with implant loss: obesity, a bra cup size larger than C, an active smoking status, a nipple-preserving procedure, a DTI approach, and a lower surgeon's volume.

Table 2. Preoperative and Surgical Characteristics: Baseline Characteristics of the Overall Group and Stratified for Implant Loss

Preoperative Characteristics	Total (n = 297)	No Implant Loss (n = 262)	Implant Loss (n = 35)	*P*
Age, y	48 (22–72)	48 (22–72)	50 (25–66)	0.863
BMI, L^2/m	24.3 (16.5–44.1)	24.1 (16.5–39.9)	27.3 (17.6–44.1)	*0.007*
Cup size				*0.012*
A, B, C	166 (55.9)	152 (58)	14 (40)	
D, E, F, H	88 (29.6)	71 (27.1)	17 (48.6)	
Missing	43 (14.5)	39 (14.9)	4 (11.4)	
ASA score				0.143
1–2	278 (93.6)	243 (92.7)	35 (100.0)	
3–4	19 (6.4)	19 (7.3)	0 (0.0)	
Comorbidity	93 (31.3)	80 (30.5)	13 (37.1)	0.428
Current smoker	47 (15.8)	35 (13.4)	12 (34.3)	*0.002*
Missing	7 (2.4)	7 (2.7)	0 (0.0)	
Indication surgery				0.581
Preventive	86 (29.0)	74 (28.2)	12 (34.3)	
Invasive carcinoma	151 (50.8)	136 (51.9)	8 (22.9)	
DCIS	55 (18.5)	47 (17.9)	15 (42.9)	
Other	5 (1.7)	5 (1.9)	0 (0.0)	
Neoadjuvant chemotherapy	87 (29.3)	78 (29.8)	9 (25.7)	0.594
Missing	11 (3.7)	10 (3.8)	1 (2.9)	
Surgical Characteristics	**Total (n = 297)**	**No Implant Loss (n = 262)**	**Implant Loss (n = 35)**	***P****
Operative time	137 (36–300)	135 (36–300)	170 (47–263)	*<0.001*
Weight resected specimen	397 (39–1300)	385 (39–1245)	571 (166–1300)	*0.003*
Mastectomy type				*0.002*
Nipple-sparing	119 (40.1)	97 (37.0)	22 (62.8)	
Skin-sparing	175 (58.9)	163 (62.2)	12 (34.3)	
Missing	3 (1.0)	2 (0.8)	1 (2.9)	
Sentinel node	183 (61.6)	163 (62.2)	20 (57.1)	0.662
Missing	3 (1.0)	2 (0.8)	1 (2.9)	
Axillary dissection	12 (4.0)	10 (3.8)	2 (5.7)	0.637
Missing	4 (1.3)	3 (1.1)	1 (2.9)	
Type of reconstruction				*0.002*
Prosthesis	60 (20.2)	46 (17.6)	14 (40.0)	
Tissue expander	237 (79.8)	216 (82.4)	21 (60.0)	
Prosthesis size	413 (175–750)	375 (175–750)	495 (240–680)	0.143
Tissue expander size	400 (200–800)	400 (200–800)	500 (300–800)	*0.005*
Perioperative filling	150 (40–400)	150 (40–400)	200 (100–400)	*0.008*
First filling day	27 (11–193)			
Location				1.000
Prepectoral	4 (1.3)	4 (1.5)	0 (0)	
Subpectoral	281 (94.6)	249 (95.0)	32 (91.4)	
Missing	12 (4.0)	9 (3.4)	3 (8.6)	
Radiotherapy				0.747
No	227 (76.4)	200 (76.3)	27 (77.1)	
Yes (postoperative)	59 (19.9)	53 (20.2)	6 (17.1)	
Preceding	11 (3.7)	9 (3.4)	2 (5.7)	
Hormonal therapy	118 (39.7)	106 (40.5)	12 (34.3)	0.483
Bilateral	145 (48.8)	124 (47.3)	21 (60.0)	0.159

Significant *P*-values are denoted in italics.
ASA, American Association of Anesthesiologists; DCIS, ductal carcinoma in situ.

Table 3. Postoperative Outcomes of Implant-based Breast Reconstructions with and without Implant Loss

Postoperative Outcomes	No Implant Loss (n = 262)	Implant Loss (n = 35)	*P*
Seroma	46 (17.6)	4 (11.4)	0.363
SSI	34 (13.0)	19 (54.3)	*<0.001*
Dehiscence	7 (2.7)	8 (22.9)	*<0.001*
Necrosis (general)	10 (3.8)	22 (62.9)	*<0.001*
Nipple necrosis	7 (2.7)	14 (40)	*<0.001*
Hematoma	32 (12.2)	4 (11.4)	1.000
Drainage days	3 (0–16)	3 (0–8)	0.891

Significant *P*-values are denoted in italics.

Obesity is well known as a risk factor for complications following implant-based reconstructions. According to a theory proposed by Hirsch et al,[14] this might be caused by a proportionally larger breast with larger mastectomy flaps, accompanied by a decreased blood supply, more postoperative dead space, and prolonged duration of surgery, which increase the potential for complications. Our result is consistent with this theory, as obesity and a bra cup size larger than C were both significant risk factors for implant loss. A breast cup size larger than C has also been reported by Francis et al as a risk factor for implant loss.[15] Smoking is known to have an adverse effect on outcomes following implant-based breast reconstructions,[16,17] which is in line with our findings. This is probably due to the negative effect of nicotine as a vasoconstrictor that reduces nutritional blood flow to the skin.[18] Furthermore, previous studies have shown that complication rates after using a DTI approach are higher than after performing a two-stage procedure.[10] Our results confirm a significant relationship between the DTI approach and implant loss. This relationship also appears in the yearly variation of implant loss in this study. The highest incidence of implant loss (18.3%)

Table 4. Risk Factors Associated with Implant Loss

Risk Factors	Group	Event Rate (%)	Unadjusted OR	*P*	Adjusted OR	*P*
Obesity	BMI < 30 BMI > 30	9.6 23.4	1 2.877 (1.299–6.376)	*0.009*	1 3.226 (1.208–8.617)	*0.020*
Breast size	≤C cup >C cup	8.4 19.3	1 2.600 (1.214–5.566)	*0.014*	1 3.132 (1.249–7.858)	*0.015*
Active smoking	No yes	9.5 25.5	1 3.280 (1.498–7.181)	*0.003*	1 3.935 (1.414–10.950)	*0.009*
Nipple-preserving procedure	No yes	6.9 18.5	1 3.081 (1.460–6.502)	*0.003*	1 4.182 (1.596–10.964)	*0.004*
Reconstruction type	TE prosthesis	8.9 23.3	1 3.130 (1.483–6.610)	*0.003*	1 2.609 (1.089–6.252)	*0.032*
Duration of surgery	<140 min >140 min	7.5 17.4	1 2.320 (1.021–5.271)	*0.044*	1 1.476 (0.616–3.539)	0.381
Mastectomy specimen weight	<400 g >400 g	6.4 14.6	1 2.526 (1.055–6.047)	*0.037*	1 1.640 (0.420–6.690)	0.488
Surgeon's volume*	>50	6.1	1		1	
	25–50	16.7	2.881 (1.124–7.388)	*0.028*	3.070 (1.201–7.848)	*0.019*
	<25	18.9	3.550 (1.237–10.189)	*0.019*	4.086 (1.397–11.953)	*0.010*

Univariate and multivariate mixed-effects analysis of risk factors associated with implant loss, resulting in unadjusted and adjusted odds ratios (ORs), confidence intervals, and corresponding *P* values (significant values are denoted in italics). Event rate describes the rate of implant loss in breast reconstructions with and without the evaluated risk factor.

*Oncological surgeon's volume (number of mastectomies performed within the study period).

Table 5. Risk Model Accumulating Number of Risk Factors and Corresponding Predicted Implant Loss Rates

Risk Factors	Predicted Risk	Observed Risk
0	<3.6%	2%
1	8.4%–13.0%	10.5%
2	21.9%–32.5%	23.0%
3	47.5%–59.3%	60.0%
4	>78.2%	—

Additionally, the observed implant loss rates are summarized.

was in the first year, in which in 53.7% of the procedures, a DTI approach was used. This high rate resulted in a shift toward two-stage reconstructions in the following years.

Nipple-preserving surgery appeared to be the most significant risk factor for implant loss in this study. A review of the literature showed that this is the first time that nipple preservation proved to have a negative effect on surgical outcomes, specifically on implant loss. The most common complication that led to a surgical intervention was nipple necrosis (65.6%). Nipple necrosis occurred significantly more often in the implant loss group compared with the group without implant loss, supporting that a nipple-preserving procedure is a significant risk factor.

A risk model for implant loss was created based on four of the risk factors found in this study (obesity, active smoking, a nipple-preserving procedure, and a DTI approach). This risk model showed the direct relationship between the number of risk factors present and the predicted risk of implant loss. The predicted risk in the presence of one risk factor was 8.4%–13.0%, which increased to 21.9%–32.5% in the presence of two risk factors. In the case of three risk factors, the predicted risk was 47.5%–59.3%, which increased to more than 78.2% in the presence of four risk factors. For example, the calculated predicted risk of implant loss was 21.9%–32.5% in a patient with obesity and active smoking status. Based on our risk model, a nipple-preserving mastectomy or a DTI approach is not recommended in this patient because of the increased risk of implant loss of 47.5% to over 78.2% if both procedures were to be performed. Our recommendation would be to not exceed these two risk factors if they are already present in a patient; rather, to choose a safer skin-sparing mastectomy technique with a two-stage reconstruction. These findings would help patients to make informed decisions and could be used to decrease the risk of implant extrusion through personalized therapy.

A total of nine oncological surgeons were included in this study, and their contribution to the number of surgical procedures varied widely. A significantly higher risk of implant loss was observed when the surgeon had performed fewer than 50 procedures in four years. It is hypothesized that this may be caused by the quality of the mastectomy flaps, which may be affected by the expertise of the surgeon. However, information on the quality of the skin flaps is absent in this study.

Radiotherapy is commonly described in the literature as a risk factor for implant loss.[8,14] However, the risk of radiotherapy on implant loss was not observed in this study. A reason for this might be the retrospective design of the study, thereby lacking accurate data on the amount and timing of radiotherapy. Therefore, the correlation between the exact timing of radiotherapy and implant loss could not be examined.

Furthermore, diabetes mellitus and hypertension were found to be predictors for implant loss, but due to the small number of patients (<10% of the total), they could not be interpreted as significant risk factors even though hypertension is a risk factor supported by the literature.[16]

This study has several limitations. The first limitation is that the data were obtained from only two medical centers with overlapping plastic surgeons and may therefore not be generalizable to the reconstructive population at large. The second limitation is the retrospective approach. Because of the retrospective approach, some data, such as the details and timing of radiotherapy, some comorbidities, and information about the decision-making process were lacking. Ultimately, the present results should be tested in a larger cohort to confirm the validity of this risk model.

It is hypothesized that preservation of the pectoral fascia may influence the rates of implant loss as well. Removal of the pectoral fascia is routinely performed during oncological mastectomies and was performed preceding all implant-based breast reconstructions included in this study. Therefore, this hypothesis could not be tested in this study. A previous systematic review on this topic showed that preservation of the pectoral fascia may improve breast reconstructive outcomes by enhancing

prosthesis coverage, thereby reducing implant extrusion rates and improving cosmetic outcomes. It may also decrease seroma formation, postoperative bleeding, and postoperative pain.[19] The incidence of implant extrusion in mastectomies with pectoral fascia preservation varies in the literature—from 0.9% to 1.6%[20,21]—which is substantially lower than the incidence of implant loss in our study. However, current evidence on this topic is limited. For this reason, the effect of pectoral fascia preservation on complications, including implant loss, postoperative pain, and reconstructive outcomes, will be investigated by our study group.

CONCLUSIONS

Implant loss after implant-based breast reconstructions occurred in 11.8% of the study population. The following risk factors were significantly associated with implant loss: obesity, a bra cup size larger than C, active smoking, a nipple-preserving procedure, a DTI approach, and a lower oncological surgeon's volume. A risk model was created based on the following risk factors: obesity, active smoking, a nipple-preserving procedure, and a DTI approach. This model showed that the predicted risk increased up to over 78.2% when the number of present risk factors accumulated. This risk model could be used to better inform patients and decrease the risk of implant extrusion by optimizing the surgical strategy in a personalized fashion.

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REFERENCES

1. Bertozzi N, Pesce M, Santi P, et al. Tissue expansion for breast reconstruction: methods and techniques. *Ann Med Surg (Lond).* 2017;21:34–44.
2. Cemal Y, Albornoz CR, Disa JJ, et al. A paradigm shift in U.S. breast reconstruction: Part 2. The influence of changing mastectomy patterns on reconstructive rate and method. *Plast Reconstr Surg.* 2013;131:320e–326e.
3. Albornoz CR, Bach PB, Mehrara BJ, et al. A paradigm shift in U.S. breast reconstruction: increasing implant rates. *Plast Reconstr Surg.* 2013;131:15–23.
4. Sinha I, Pusic AL, Wilkins EG, et al. Late surgical-site infection in immediate implant-based breast reconstruction. *Plast Reconstr Surg.* 2017;139:20–28.
5. Poppler LH, Mundschenk MB, Linkugel A, et al. Tissue expander complications do not preclude a second successful implant-based breast reconstruction. *Plast Reconstr Surg.* 2019;143:24–34.
6. Darragh L, Robb A, Hardie CM, et al. Reducing implant loss rates in immediate breast reconstructions. *Breast.* 2017;31:208–213.
7. Knight HJ, Musgrove JJ, Youssef MMG, et al. Significantly reducing implant loss rates in immediate implant-based breast reconstruction: A protocol and completed audit of quality assurance. *J Plast Reconstr Aesthet Surg.* 2020;73:1043–1049.
8. Ozturk CN, Ozturk C, Soucise A, et al. Expander/implant removal after breast reconstruction: analysis of risk factors and timeline. *Aesthetic Plast Surg.* 2018;42:64–72.
9. Sue GR, Sun BJ, Lee GK. Complications after two-stage expander implant breast reconstruction requiring reoperation: a critical analysis of outcomes. *Ann Plast Surg.* 2018;80(5S suppl 5):S292–S294.
10. Fischer JP, Wes AM, Tuggle CT 3rd, et al. Risk analysis of early implant loss after immediate breast reconstruction: a review of 14,585 patients. *J Am Coll Surg.* 2013;217:983–990.
11. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA.* 2013;310:2191–2194.
12. von Elm E, Altman DG, Egger M, et al; STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ.* 2007;335:806–808.
13. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg.* 2004;240:205–213.
14. Hirsch EM, Seth AK, Kim JYS, et al. Analysis of risk factors for complications in expander/implant breast reconstruction by stage of reconstruction. *Plast Reconstr Surg.* 2014;134:692e–699e.
15. Francis SH, Ruberg RL, Stevenson KB, et al. Independent risk factors for infection in tissue expander breast reconstruction. *Plast Reconstr Surg.* 2009;124:1790–1796.
16. McCarthy CM, Mehrara BJ, Riedel E, et al. Predicting complications following expander/implant breast reconstruction: an outcomes analysis based on preoperative clinical risk. *Plast Reconstr Surg.* 2008;121:1886–1892.
17. Woerdeman LA, Hage JJ, Hofland MM, et al. A prospective assessment of surgical risk factors in 400 cases of skin-sparing mastectomy and immediate breast reconstruction with implants to establish selection criteria. *Plast Reconstr Surg.* 2007;119:455–463.
18. Silverstein P. Smoking and wound healing. *Am J Med.* 1992;93:22S–24S.
19. Suijker J, Blok YL, de Vries R, et al. Pectoral fascia preservation in oncological mastectomy to reduce complications and improve reconstructions: a systematic review. *Plast Reconstr Surg Glob Open.* 2020;8:e2700.
20. Salgarello M, Barone-Adesi L, Terribile D, et al. Update on one-stage immediate breast reconstruction with definitive prosthesis after sparing mastectomies. *Breast.* 2011;20:7–14.
21. Sandelin K, Wickman M, Billgren AM. Oncological outcome after immediate breast reconstruction for invasive breast cancer: a long-term study. *Breast.* 2004;13:210–218.