



ARTICLE



## The effect of implant loss after immediate breast reconstruction on patient satisfaction with outcome and quality of life after five years – a case-control study

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### ABSTRACT

Several advantages have been suggested for immediate breast reconstruction (IBR); however, there is little scientific high-quality evidence confirming those advantages. Disadvantages of IBR, compared to delayed breast reconstruction (DBR), include an increased risk for complications, such as implant loss (prevalence 5–10% vs. 1%). Little is known on how women experience implant loss and how it affects patients' long-term satisfaction and quality of life (QoL). The primary aim of our study was to compare patient satisfaction and QoL of women with implant loss after IBR, with that of women with a successful IBR. Breast-Q, Body Esteem Scale for Adults and Adolescents (BESAA) and Hospital Anxiety and Depression Scale (HADS) were sent to women who had experienced implant loss during the last 10 years. Women of a similar age who were reconstructed, without complications, during the same period were controls. The results suggest that there might be a more permanent negative effect on satisfaction and QoL following implant loss. The proportion of possible cases of depression was higher among patients who had experienced implant loss. The findings could indicate that in patients with an elevated risk for implant loss, the possible benefits with IBR should be carefully balanced against the effects of implant loss.

**Abbreviations:** BE: body-esteem; BESAA: body esteem scale for adults and adolescents; DBR: delayed breast reconstruction; HADS: hospital anxiety and depression scale; IBR: immediate breast reconstruction; PROMs: patient-reported outcome measures; QoL: quality of life

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### Introduction

Breast reconstruction can either be performed at the time of mastectomy (immediate breast reconstruction – IBR) or in a separate later operation (delayed breast reconstruction – DBR). In Sweden, about 2–30% of patients who undergo mastectomy have IBR, depending on geographic location [1]. Several advantages have been suggested for IBR, such as cost-effectiveness, better quality of life (QoL), psychosocial benefits and better aesthetic outcome [2]; although, the scientific high-quality evidence confirming these positive outcomes is limited [3–5]. Several studies have suggested that, after a few years, QoL and psychosocial function are similar for women who have had IBR and DBR [2,3,5–7]. Disadvantages of IBR, compared to DBR, include an increased risk for complications [3,5]. The most significant complication after breast reconstruction is reconstructive failure, that is implant loss or flap loss. The prevalence of implant loss has been reported to be around 5–10% in IBR compared to 1% in DBR [3,8,9]. The risk for implant loss is one important factor to consider when making the choice between IBR and DBR. However, little is known on how women experience implant loss and its association with patient satisfaction and QoL.

Although there are several studies on how complications following breast reconstruction affect women, results have been

contradictory. Some studies have suggested that complications have adverse effects on body image, satisfaction with breast reconstruction, QoL and may give rise to increased levels of depression and anxiety [10–14]. Other studies have demonstrated that complications do not affect patient satisfaction [15,16] and several studies have shown that only major [17] and early complications (<3 months post surgery) seem to have negative effects on satisfaction, QoL and psychological well-being and that most women recover within the first two years after surgery [10,12,13,18]. Comparisons between studies and generalization of results are difficult since studies utilize different patient-reported outcome measures (PROMs), and there is also a great variation in which complications are included and how they are defined. Moreover, the studies often include few patients with severe complications, which in turn may lead to biased results, reduces power and may hinder detection of effects.

To our knowledge, there are no quantitative studies specifically investigating implant loss and patient satisfaction after IBR using PROMs. In one study on complications after DBR, it was found that a total reconstruction failure was related to a temporary increase of depression levels one month after the failure. However, the study only included nine participants who had experienced implant loss [13], making it difficult to generalize the

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results to a broader population of women who have experienced implant loss following DBR. Three qualitative studies [19–21] have shown that reconstructive failure can be a difficult experience that give rise to body dissatisfaction, and that there is a need for better preoperative information along with better support when a woman suffers from implant loss. To provide patients with adequate information pre-operatively and aid patients' decision making, there is a need for better understanding of the effects of implant loss on the long-term outcome, including patient satisfaction, QoL and psychological well-being, of breasts reconstruction.

The primary aim of our study was to compare patient satisfaction and QoL of women with implant loss after IBR, with that of women with a successful IBR. Secondary aims were to compare symptoms of depression and anxiety in the two groups and to investigate association between satisfaction and QoL with age at mastectomy/IBR, time since implant loss, body-esteem (BE) and reason for mastectomy (therapeutic/prophylactic). We hypothesize that the group who experienced implant loss has a lower QoL and satisfaction with breast reconstruction as well as more symptoms of depression and anxiety, compared to the group who has had a successful IBR.

## Methods

### Study design, protocol and ethics

This is a retrospective case-control cross-sectional study described in the Psychological Effects of Implant Loss protocol (ClinicalTrials.gov identifier NCT04503018). The study was reviewed and approved by the Swedish Ethical Review Authority (2019-06214 and 2020-04-729). The principles of the Helsinki Declaration were followed. All participants gave their written informed consent to participation in the study and to the publication of the results.

### Patients and controls

The study was performed in the Department of Plastic and Reconstructive Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden. The department performs about 400 breast reconstructions per year and the implant loss frequency after IBR has varied between 2% [22] and 11% [23], depending on the method used. Inclusion criteria were women >18 years of age who had experienced implant loss after IBR due to therapeutic or prophylactic mastectomy >6 months to 10 years ago. Hence, the sample size was based on the number of patients who have lost an implant during the last 10 years. All women who underwent surgery had a body mass index (BMI) <30 kg/m<sup>2</sup> and were non-smokers, in accordance with the Swedish guidelines [24]. Exclusion criteria were relapse of cancer, palliative disease, inability to give informed consent and inability to understand Swedish. A similar number of randomly chosen women who had had a successful IBR during the same time period were recruited as controls.

### Patient-reported outcomes and clinical variables

All patients and controls were sent information regarding the study, the questionnaires, a consent form and a stamped return envelope. Two reminders were sent. Information concerning demographics, details on the patients' breast diagnosis and reconstruction, and complications were collected through the patients' medical records. Three questionnaires were used: BREAST-Q,

Body-Esteem Scale for Adolescents and Adults (BESAA) and Hospital Anxiety and Depression Scale (HADS).

BREAST-Q [25] measures patient reported outcome after breast reconstruction. It includes two domains and six different sub-themes: health related QoL (physical, psychosocial and sexual well-being) and patient satisfaction (satisfaction with breasts, outcome and care). We included the following six scales in the analysis: satisfaction with breast, satisfaction with outcome, satisfaction with information, psychosocial well-being, sexual well-being and physical well-being. The instrument consists of 3-, 4- and 5-point Likert-scales. Each scale produces an independent score from 0 to 100, by adding the response items together and then converting the raw sum score to a scale score, using a conversion table. A higher score means greater satisfaction or better QoL, depending on the scale. Reliability of BREAST-Q has previously been established and the instrument has been translated to Swedish and the Swedish version has been extensively used [23,25].

BESAA [26] is a 23-item instrument designed to measure BE, that is how a person evaluates his/her body and appearance. It consists of three subscales: BE-appearance, BE-weight and BE-attribution. The respondents indicate their degree of agreement on a five-point Likert-scale. Negative items are reversely scored. The scores from the three subscales are aggregated to a total score. A higher score indicates more positive BE [26]. Reliability for BESAA has previously been established [26]. The instrument has previously been translated to Swedish and validated for Swedish conditions [27] and used in patients with breast cancer [28].

HADS [29] is a 14-item self-report questionnaire designed to measure anxiety and depression. It consists of two independent subscales, where half of the items relates to anxiety and the other half relates to depression. Answers are rated on a four-point Likert-scale. Six items are reversely scored. Each subscale has a maximum score of 21. For both domains, we defined scores of less than 7 indicate non-cases, whereas scores of 8–10 indicate possible cases and scores of >10 indicate probable cases, in accordance with Saboonchi et al.'s definition [30]. HADS has previously been found to be a reliable instrument and it has also previously been translated and validated for Swedish conditions [29,31,32] and has been used in studies on breast reconstruction [12].

### Statistical analyses

The primary outcome variables were defined as satisfaction with breast, satisfaction with outcome, sexual well-being, physical well-being and psychosocial well-being (all measured with Breast-Q), as the primary aim of our study was to compare patient satisfaction and QoL. If the patient had not undergone re-reconstruction after implant loss, the satisfaction with breast-subscale was excluded from analysis.

Statistical analyses were performed using SPSS<sup>®</sup> version 26.0.0.0 (IBM, Armonk, NY). Data were presented as frequencies, median, range, mean and standard deviations (SDs). BREAST-Q scores were converted using QScore<sup>™</sup> (the Mapi Research Trust, Lyon, France). If at least half of the items of a subscale were answered, the item(s) with missing data were replaced with the mean of the answered items for each subscale. If more than half of the items were missing, the scale was excluded. Missing data were handled in the same way for all questionnaires.

A statistical analysis plan (SAP) was created before the data were collected. Non-parametric tests were used as the instruments used are Likert-type scales. To compare the two groups,

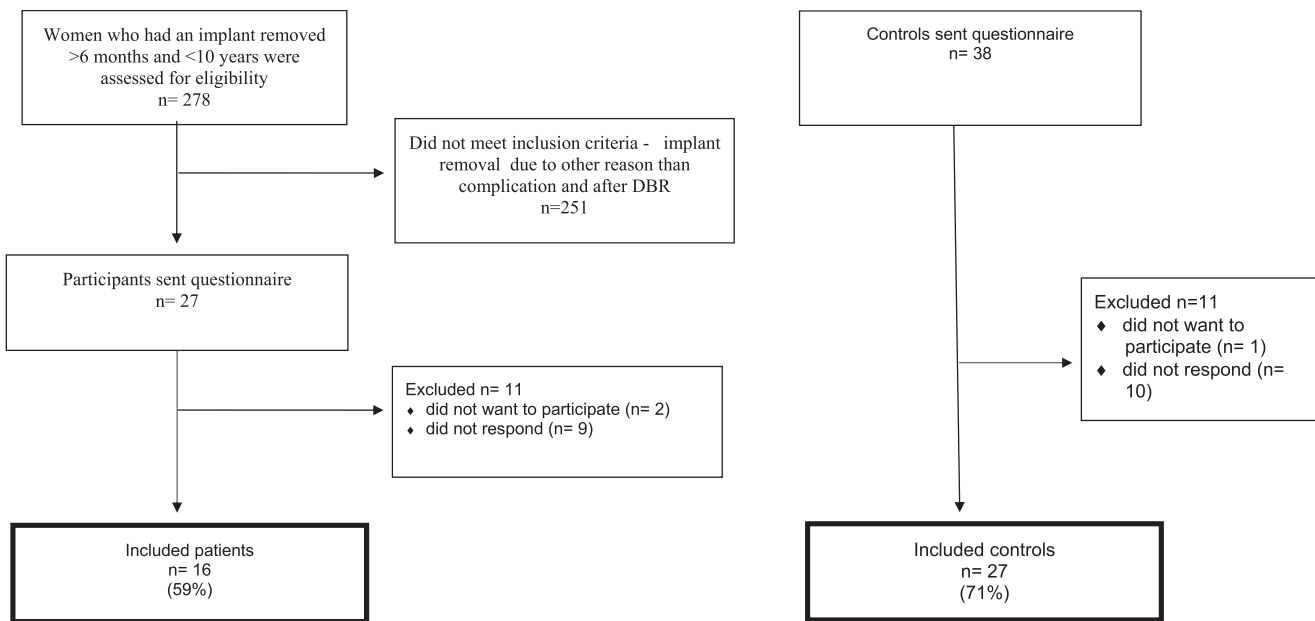


Figure 1. Patients and controls.

Mann–Whitney’s *U*-test for independent samples was used for ordinal (BREAST-Q) and categorical variables (HADS). For comparisons between the groups, possible and probable cases [30], as measured with HADS, were aggregated. Associations between patient satisfaction and QoL (BREAST-Q) and background variables (age at the time of mastectomy and IBR, time since implant loss, body image (BESAA) and reason for surgery) were tested with Spearman’s rank-order correlations. Scatter plots were drawn for statistically significant correlations. All tests were two-tailed and a *p* value of .05 was considered to indicate a statistically significant result.

## Results

### Participants and operations

Initially, 278 patients were identified through the operation planning program, of which 248 did not meet the inclusion criteria. The questionnaires were sent to 27 patients of which 16 met the inclusion criteria and responded (59%) (Figure 1). Among the 38 randomly chosen women who had been operated on with successful IBRs during the same time period, 27 responded (71%) (Figure 1). The patients and controls were of similar age and had the same level of BE (Table 1). The proportion of patients who have had a therapeutic mastectomy was higher in the control group (50 vs. 81%) and the follow-up time was slightly longer in the patient group (5.6 and 4.8 years, respectively) (Table 1). The patients had lost their implant a minimum of 2 years ago (median 5.5 years). Reasons for implant loss were necrosis (6/16) and infection (10/16). Fourteen of the patients had had re-reconstruction, with a median of 0.6 years between implant loss and re-reconstruction (Table 1). Type of re-reconstruction was either implant based (12/14) or with a latissimus dorsi flap and an implant (2/14) (Table 1).

### Primary outcomes: satisfaction with breast and QoL

Patients who had lost an implant had a statistically significant lower physical well-being ( $p = .005$ ) and satisfaction with outcome ( $p = .020$ ) compared to the controls. Notable differences in

median scores between the groups could also be seen for psychosocial well-being, sexual-well-being and satisfaction with breast; albeit, not statistically significant (Table 1).

### Secondary outcomes: symptoms of depression and anxiety and satisfaction with information

The proportion of possible cases of depression was higher among the patients than the controls ( $p = .021$ ). There were no differences between the groups as regards level of anxiety and satisfaction with information (Table 1).

### Correlations between background variables, satisfaction and QoL

There was a significant correlation between patient satisfaction with outcome and time since implant loss, where the patients tended to be less satisfied with increasing time since implant loss (Table 2 and Figure 2). The patients’ body esteem was correlated with sexual and psychosocial well-being (Table 2 and Figure 2), while the controls’ BE was correlated with satisfaction with breast and with outcome, as well as with psychosocial well-being, but not sexual well-being (Table 3, Figure 3). There were no significant correlations between patient/control satisfaction and QoL with age at time for mastectomy and IBR, and reason for mastectomy (therapeutic/prophylactic) (Tables 2 and 3).

## Discussion

This is the first PROMs-based case-control study focusing on comparing patients who have lost an implant after IBR with those who have not. There is a clear tendency that women who have lost an implant previously are less satisfied with the outcome of breast reconstruction and have a lower QoL than women with a successful IBR.

Our results suggest that there might be a more permanent negative effect on satisfaction and QoL following implant loss, still lingering after 5–10 years. This is contradictory to previous findings stating that there is a temporary decrease in satisfaction and QoL and that most patients seem to recover within the first two

**Table 1.** Background variables and primary and secondary outcomes.

Demography/background variables	Patients (n = 16) Median (max–min) Mean (SD)	Controls (n = 27) Median (max–min) Mean (SD)	Difference between groups
<i>Demography/background variables</i>			
Age at time of mastectomy and IBR (years)	44 (27–64) 44 (11)	48 (26–67) 48 (10)	NC
Time since mastectomy and IBR (years)	5.6 (2.3–16) 5.8 (3.3)	4.8 (1.6–11) 5.3 (2.6)	NC
Reason for operation (n)			NC
Therapeutic	8	22	
Prophylactic	8	5	
Time since implant loss (years)	5.5 (1.9–10) 5.2 (2.3)	NA	NC
Reason for implant loss			NC
Necrosis	6	NA	
Infection	10		
Re-reconstruction			NC
Yes	14	NA	
No	2 (n = 14)	NA	NC
Time between implant loss and re-reconstruction (years)	0.6 (0.3–2.1) 0.7 (0.5)		
Type of re-reconstruction		NA	NC
Implant based	12		
LD and implant	2 (n = 14)		
Body image (BESAA)		(n = 26)	NC
Total score	60 (39–83) 61 (14)	62 (39–86) 59 (12)	
Primary outcomes (Mann–Whitney's U-test)			
Satisfaction with breast (BREAST-Q)	(n = 14) 61 (22–78) 57 (16)	67 (43–100) 69 (14)	0.063
Satisfaction with outcome (BREAST-Q)	61 (27–86) 58 (18)	75 (43–100) 72 (16)	0.020
Psychosocial well-being (BREAST-Q)	56 (37–100) 66 (25)	83 (39–100) 81 (20)	0.051
Sexual well-being (BREAST-Q)	49 (26–100) 52 (23)	(n = 24) 67 (0–100) 63 (24)	0.058
Physical well-being (BREAST-Q)	63 (50–100) 67 (14)	81 (53–100) 80 (13)	0.005**
Secondary outcomes (Mann–Whitney's U-test)			
Anxiety (HADS)	N	N	0.345
No cases	11	22	
Possible cases	4	4	
Probable cases	1	1	
Depression (n) (HADS)	N	N	0.021*
No cases	13	27	
Possible cases	0	0	
Probable cases	3	0	
Satisfaction with information (BREAST-Q)	56 (38–77) 58 (12)	65 (19–85) 61 (16)	0.263

BESAA: Body Esteem Scale for Adults and Adolescents; HADS: Hospital Anxiety and Depression Scale; IBR: immediate breast reconstruction; LD: latissimus dorsi flap; N: number of individuals; NC: not calculated; NA: not applicable; SD: standard deviation. \* =  $p \leq 0.05$  \*\* =  $p \leq 0.01$ .

**Table 2.** Correlations among patients (Spearman's rank-order correlation test).

	Satisfaction with breast	Satisfaction with outcome	Psychosocial well-being	Sexual well-being	Physical well-being
Age at time of mastectomy and IBR	−0.161	−0.439	−0.046	0.286	−0.075
Time since implant loss	−0.392	−0.550*	−0.442	−0.369	−0.030
BESAA total	0.505	0.424	0.813**	0.880**	0.236
Reason for surgery (prophylactic/therapeutic)	−0.035	−0.232	−0.207	−0.272	0.082

BESAA: Body Esteem Scale for Adults and Adolescents; IBR: immediate breast reconstruction. \* =  $p \leq 0.05$  \*\* =  $p \leq 0.01$ .

years after the initial reconstruction [10,12,13], or that complications have no negative effect at all [15,16]. The biggest differences in median values between the two groups were identified for psychosocial and sexual well-being, and there was a significant difference between the groups on satisfaction with outcome. This is in accordance with findings of previous qualitative interview studies,

where women have described that neither the reconstruction process or results met their expectations, and some even regretted or questioned their decision to undergo IBR [20,21]. The interviews have also suggested that reconstructive failure can cause psychological distress and body image dissatisfaction with subsequently effects on women's relationships and daily lives,

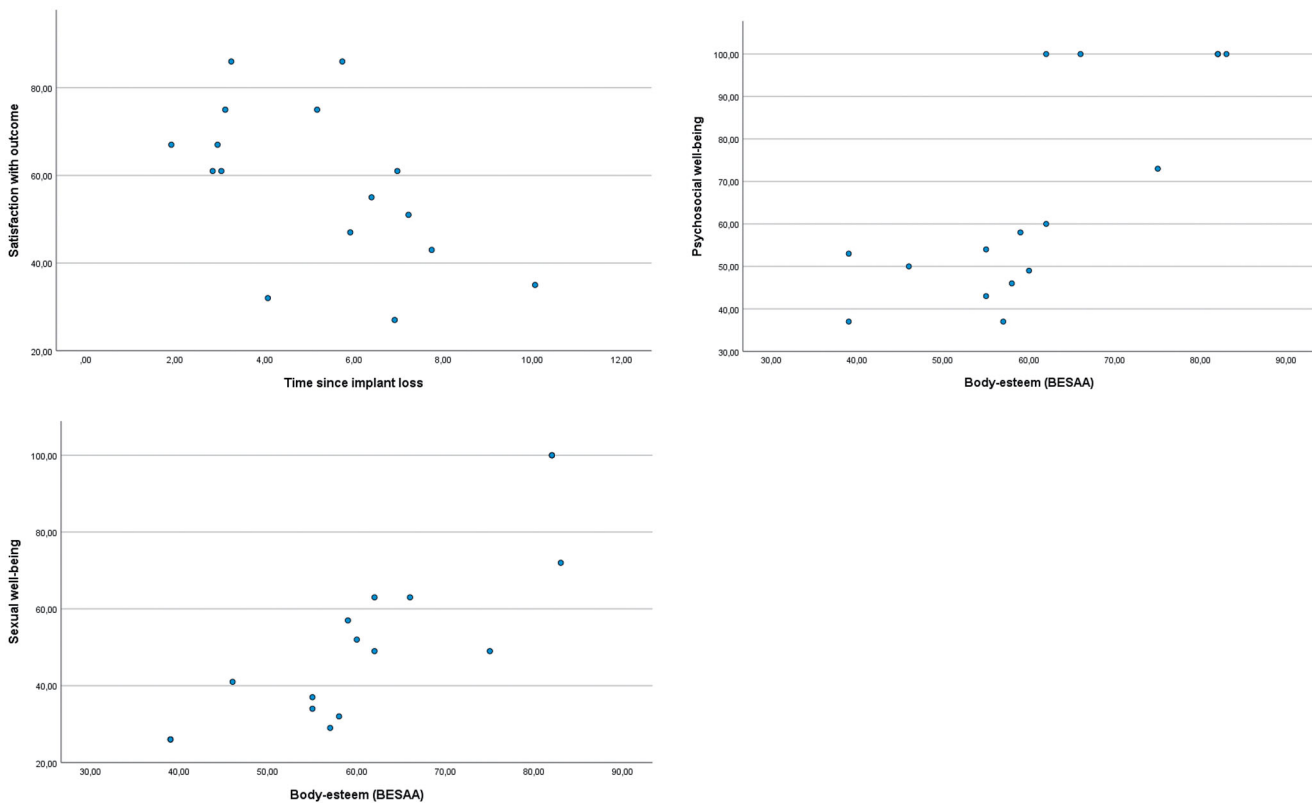


Figure 2. Scatter plots patients.

Table 3. Correlations among controls (Spearman’s rank-order correlation test).

	Satisfaction with breast	Satisfaction with outcome	Psychosocial well-being	Sexual well-being	Physical well-being
Age at time of mastectomy and IBR	-0.147	-0.300	-0.103	-0.248	0.132
Time since implant loss		-	-	-	-
BESAA total	0.550**	0.407*	0.392*	0.407	0.017
Reason for surgery (prophylactic/therapeutic)	-0.282	-0.156	-0.317	-0.134	-0.217

BESAA: Body Esteem Scale for Adults and Adolescents; IBR: immediate breast reconstruction. \* =  $p \leq 0.05$  \*\* =  $p \leq 0.01$ .

which still persists after several years [19–21]. The finding that there seems to be a difference in symptoms of depression between the two groups, further supports this argument.

Satisfaction with breast seems to be the aspect on which implant loss has the smallest impact and the score seen in the implant loss group in this study is similar to the America normative score (mean 28 and SD 18) [33], albeit lower than in the control group. On the other hand, physical well-being associated with their chest appears to be particularly affected, with a statistically significant difference between the groups. This could be explained by that implant loss usually leads to considerably more surgery, with extraction of the implants and the re-reconstruction, which may give rise to more scarring and effects in the chest area. In brief, the patients who have experienced implant loss seem to have a long-term effect on physical outcome, although the final cosmetic results might not be markedly different to what can normally be achieved with IBR.

There are statistically significant correlations between BE and psychosocial well-being in both groups, but only a significant correlation between BE and sexual well-being in the patient group. This can partly be explained by that the BREAST-Q domains and the BESAA have several similar items. Nonetheless, several

previous studies have demonstrated that body image distress could be linked to impaired QoL, and psychosocial and sexual well-being [34–39]. Body image problems can persist for a long time after breast reconstruction, even in the absence of implant loss [40,41]. Our findings corroborate previous findings [35], suggesting that it might be beneficial for patients if evaluation of body image was included before breast reconstruction and in the preoperative discussion with the patient. More studies are needed on the effect of body image on psychosocial and sexual consequences of implant loss.

This is the first study focusing on evaluating the relationship between implant loss and PROMs. Nonetheless, the study has several limitations including its retrospective design, small sample size and relative low response rate in both groups, which could have affected the results. It is inherently challenging to study rare complications as it is difficult to obtain an adequate sample size. In the present study, the lack of statistical difference between the group might be a sign that the study is underpowered rather than a lack of clinically significant differences between the groups; that is, there is a high risk of a type II error [42]. Nonetheless, the differences in medians between the groups were bigger than the MIDs [43], six for satisfaction with breast (MID 5), 27 for



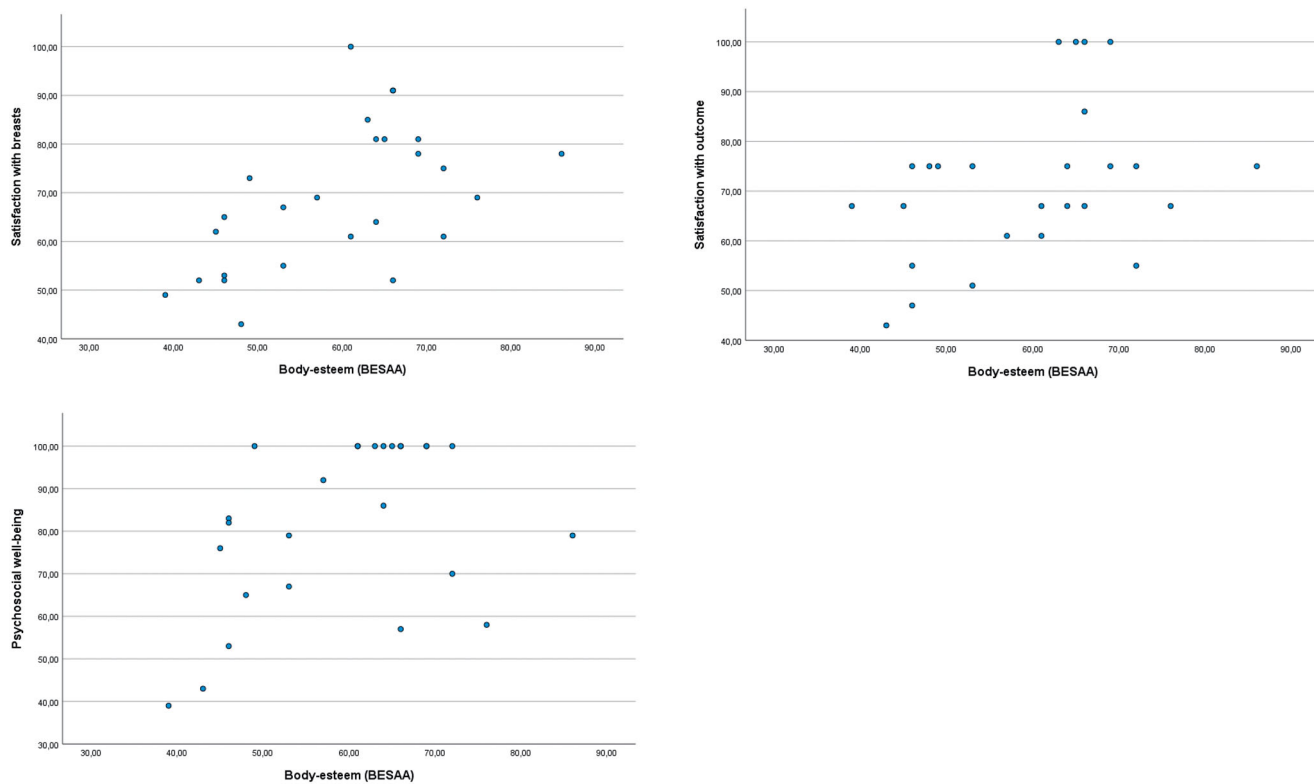


Figure 3. Scatter plots controls.

psychosocial well-being (MID 4), 18 for physical well-being chest (MID 3) and 18 for sexual well-being (MID 5), which indicate that there could be a true clinical difference between the groups. Unfortunately, analysis of non-responders could not be performed as they did not consent to chart review. The control group was randomly selected but matched with the study group regarding type of surgery (IBR) and time period. Age at time of mastectomy and time since mastectomy was similar in the two groups, but there was a difference regarding indication for surgery (therapeutic/prophylactic) that could have created a selection bias. The study could have been improved by matching for factors that can affect body image, depression and satisfaction, such as preoperative psychological well-being, as well as for risk factors for implant loss, such as weight of implants used [44]. However, such a design is not feasible retrospectively. Better quality data could be achieved by evaluating patients prospectively. As implant loss is a relatively rare complication, a multicenter study design might be advantageous; although, it brings in confounders of different reconstructive methods, as well as differences in pre- and postoperative care, that could be avoided in the present study.

### Conclusions

Patients who have suffered implant loss after IBR and had a re-reconstruction seem to have a long-term lower satisfaction, a lower QoL and more symptoms of depression than women who have had a successful IBR. The findings could indicate that in patients with an elevated risk for implant loss, the possible benefits with IBR should be carefully balanced against the effects of implant loss and DBR should be considered a viable option. The findings also suggest that more studies are needed on whether some women; for example, women with preoperative depression and anxiety, body image issues and/or a crisis reaction to a newly

diagnosed breast cancer, are more susceptible to negative effects of implant loss and whether these are factors that should be taken into consideration when timing of reconstruction is decided. It should also be explored if psychological interventions pre-operatively can help women cope with possible complications and thereby minimize the effects of implant loss.

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### Disclosure statement

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