Clinical results and patient-reported outcomes in breast reconstructive surgery

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CHAPTER 2

Patient reported outcomes after ADM-assisted implant-based breast reconstruction

A cross-sectional study

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ABSTRACT

Introduction Although the use of acellular dermal matrices (ADMs) in implant-based reconstruction increases, there is a lack of studies evaluating patient reported outcome measures (PROMs) after this reconstruction method. We aim to evaluate the patient satisfaction after ADM-assisted implant-based breast reconstruction (IBBR) in one of the largest series of patients undergoing ADM-assisted IBBR.

Methods Patients with ADM-assisted IBBR were invited to fill out the BREAST-Q, a validated and standardized questionnaire to measure patient satisfaction after a breast reconstruction. A retrospective chart review was performed to identify patient and surgical characteristics.

Results In total 208 patients (38.4%) responded and reported a mean satisfaction of 70.6 ± 20.2 with their breasts and 78.0 ± 20.5 with the outcome. An overall complication rate of 7.7% was noted, with 1.5% severe complications leading to hospital readmission (0.5%) and implant removal (0.5%). Patients with complications and unilateral reconstruction for oncological reasons reported overall less satisfaction rates compared to patients with bilateral, preventive surgery and an uncomplicated postoperative course. Strongly related domains indicate the importance of patient satisfaction with their breasts and outcome on psychosocial and sexual functioning and satisfaction with information on satisfaction with breasts, outcome and surgeon.

Conclusion There is an increased demand to PROMs in a changing practice to which the opinion of the patient assumes a larger role. With high satisfaction rates, ADM-assisted IBBR is a valuable reconstruction method, provided that complication rates remain low. Hence it should only be performed in a selected group of women.

INTRODUCTION

In high income countries, survival rates of breast cancer patients have increased to 80% or higher.[1] Since incidence rates of breast cancer, especially in Western countries, are high and still rising, the number of breast cancer survivors is increasing rapidly. For this reason, focus of health care has shifted towards quality of life after cancer treatment. In most cases breast surgery is required as part of cancer treatment, which entails either breast-conserving surgery or mastectomy. In women with an established high risk of breast cancer, mastectomy may also be performed prophylactically. In Western society, breast reconstruction has become an integral part of breast cancer treatment options. Breast reconstruction aims to approximate the "natural breast" as closely as possible with the ultimate goal to ameliorate the patients' quality of life.[2]

There are multiple techniques for breast reconstruction, of which implant based breast reconstruction (IBBR) is the most performed reconstruction method.[3] In recent years, acellular dermal matrices (ADMs) are increasingly being used in IBBR to augment the subpectoral pocket and to allow immediate implantation of an implant or tissue expander.[4] Supposed additional advantages are a better cosmetic outcome[4, 5] and, in the long term, possible a reduced capsular contraction rate.[6]

Data regarding the safety of ADM use in IBBR vary widely, with complication rates ranging from below 5% to more than 50%.[4, 7-9] Recent results indicate that expertise with both the technique and the careful selection of eligible patients are important factors for optimal clinical outcomes.[9, 10] However, in order to assess to what extent the eventual goal of breast reconstructive surgery is reached, i.e. to enhance the quality of life, measurement of patient reported outcomes (PROs) is essential. Therefore, we aim to assess the satisfaction and quality of life of women who underwent ADM-assisted IBBR.
Previously, Salzberg et al. reported on the clinical outcomes in one of the largest series of patients treated with ADM-assisted breast reconstruction. The overall complication rate was 8.6% and the cumulative incidence of capsular contraction was low (0.8%).[6, 8, 11] In this study, we have evaluated the PROs of these women using the BREAST-Q, which is a validated tool developed specifically to assess satisfaction and quality of life after breast surgery.[12]

METHODS

Patients

All patients who underwent implant-based breast reconstruction in the senior surgeons practice between September, 1988 and January, 2016 were invited via email to participate in the study. Patients' follow-up consisted of an appointment every 3 months during the first year and then annually or if needed.

We undertook the study in accordance with the Declaration of Helsinki, guidelines for Good Clinical Practice and in accordance with the STROBE statement.[13]

Surgical technique

The surgical technique has been reported previously.[8, 14, 15] Briefly, a retropectoral pocket was created, extending from the lateral border of the pectoralis major muscle to the second rib superiorly, to the sternum medially, and to the level of the contralateral inframammary fold inferiorly. After placement of the implant into the retropectoral pocket, the ADM was placed to provide implant coverage and protection by extending the pectoralis muscle over the inferior third of the implant. The ADM is sutured to the chest wall, the lateral mammary fold, the serratus fascia and to the inferior border of the pectoralis major muscle. Two suction drains are then placed retropectoral and in the subcutaneous space.

Outcomes

A retrospective chart review was performed to identify baseline characteristics including age, indication, final pathology, type of surgery, side of reconstruction, radiotherapy, complications and interventions.

Patients were invited per email to fill out the BREAST-Q reconstruction module.[12] Patients who did not respond were sent a reminder up to 2 times. The BREAST-Q reconstruction module is a validated and standardized questionnaire for evaluating the results after mastectomy and subsequent breast reconstruction. It contains 14 domains regarding satisfaction with breasts (Q1), visibility (Q2a) and sensation of rippling (Q2b), satisfaction with outcome (Q3), psychosocial well-being (Q4), sexual well-being (Q5), physical well-being: chest and upper body (Q6), physical well-being with abdomen and trunk (Q7), and satisfaction with abdomen (Q8, Q9), satisfaction with nipples (Q10), satisfaction with care regarding information (Q11), surgeon (Q12), the medical team (Q13), and office staff (Q14).

The domains Q7-10 are not applicable to this population, because only patients who underwent IBBR were included in this study.

Statistical analyses

The QScore Scoring Software was used to convert the BREAST-Q scores ranging from 1 through 4 or 5 to a total score ranging from 0 to 100. A higher Q-Score indicates a higher patient satisfaction. Only scores of domains Q2a and Q2b are not converted, these scores range from 1 (very dissatisfied) to 4 (very satisfied).[16]

Differences between responding and non-responding patients were assessed regarding age, follow-up, reason for surgery and side (prohylactic, therapeutic uni of bilateral), type of surgery, and complications with student's t-test and chi-square tests. The correlation between the different domains of the BREAST-Q was assessed with a Spearman's rho test. A univariate analysis was performed to assess differences in satisfaction related to age, follow-up, reason for surgery, type of surgery and complications. For the univariate analyses the continue variables age and follow-up time were dichotomized. The domains satisfaction with breasts (Q1), satisfaction with outcome (Q3), psychosocial well-being (Q4), physical well-being: chest and upper body (Q6), satisfaction with nipples (Q10), and satisfaction with care regarding information (Q11) were taken into account.
A multivariate analysis was performed on q-scores that are related to at least one variable. Age and follow-up were used as continue variables in the multivariate model. Reason and side of surgery were defined as one variable, as most patients (95.2%) undergoing prophylactic surgery received a bilateral reconstruction. Age and follow-up were used as continuous variables in the multivariate model.
For the analyses, IBM SPSS statistics version 22 was used.

RESULTS

Response rate

We invited 541 women to participate in the study (Figure 1). The survey was returned by 208 (38.4%) patients, of which 181 women filled out the survey completely and 27 women partially. All patients filled out the BREAST-Q 1 Satisfaction with breasts domain. The number of completed questionnaires for each domain are listed in Table 3.

There were no statistical differences between women who did or did not respond regarding age, follow-up, reason for surgery, type of surgery, follow-up and complications. There was a difference in type of reconstruction between responders and non-responders; all responders underwent IBBR with an additional ADM, while 6.4% (n = 18) of the non-responders received a reconstruction with an implant only (p = 0.008) (Table 1).
In 3 patients in the non-responding group and 1 patient in the responding group, first expanders were placed and later replaced with definitive implants. These patients were excluded from the analyses.

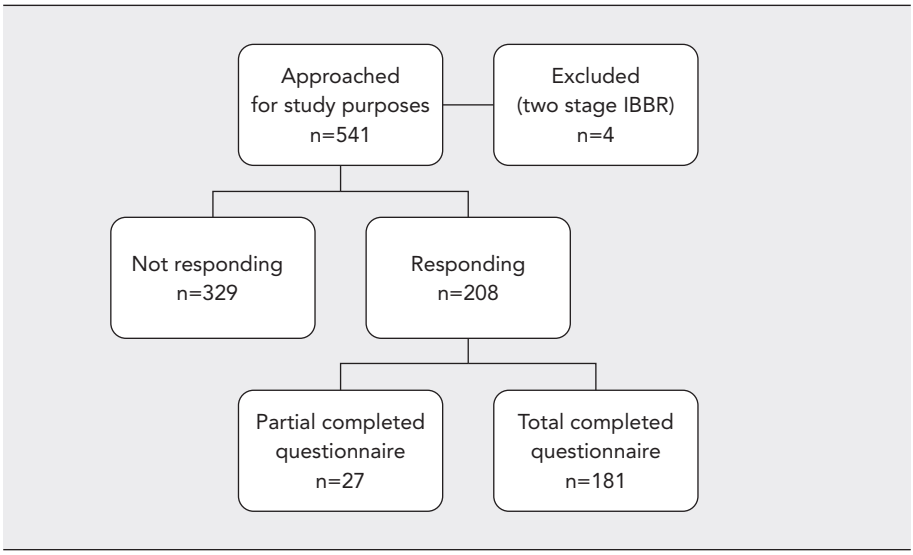

Figure 1 Inclusion of patients

Characteristics of responding patients (n = 208)

Patients were operated between June 21, 2002 and January 7, 2016. The mean age was 43.2 (± 10.1) years with a median follow-up of 5.0 (± 13.0) years. No patients were active smokers at time of surgery. Reasons for surgery were prophylactic in 50.0% and comprised of reconstruction with an implant, mainly combined with ADM (Alloderm) (86.4%). All reconstructions were performed in one stage. An overall complication rate of 7.7% was noted, of which 1.5% were severe complications including cellulitis (0.5%), positive retroareolar biopsy (0.5%) and loss of nipple due to necrosis (0.5%).[8, 11] This led to respectively hospital readmission (0.5%), removal of nipple (0.5%) or implant removal (0.5%) (Table 2).

	Responders (n = 208)	Non-responders (n = 329)	Combined (n = 537)	p-value
Age in years (mean ± SD)	43.2 ± 10.1 (n = 162)	44.0 ± 9.5 (n = 280)	43.7 ± 9.7 (n = 442)	0.335
Follow-up in years (median ± range)*	5.0 ± 13.0 (n = 190)	5.0 ± 27 (n = 327)	5.00 ± 27 (n = 517)	0.763
Reason for surgery				
Prophylactic	64.2% (n = 104)	71.7% (n = 198)	68.9% (n = 302)	
Not prophylactic**	35.8% (n = 58)	28.3% (n = 78)	31.1% (n = 136)	0.109
Type of surgery				
Implant + Alloderm	86.4% (n = 140)	81.4% (n = 228)	83.3% (n = 368)	**0.008**
Implant + Strattice	6.4% (n = 10)	3.9% (n = 11)	4.8% (n = 21)	
Implant + dermal grafts	7.4% (n = 12)	8.2% (n = 23)	7.9% (n = 35)	
Implant***	/	6.4% (n = 18)	4.1% (n = 18)	
Complications****	7.7% (n = 16)	6.1% (n = 20)	6.7% (n = 36)	0.159

* FU until follow-up; DCIS indicates ductal carcinoma in situ; LCIS indicates lobular carcinoma in situ; IDC indicates invasive ductal carcinoma; LD indicates latissimus dorsi; ROM indicates range of motion; and NAC indicates nipple areolar complex. ** Not prophylactic including carcinoma, DCIS, LCIS, atypical hyperplasia. *** N = 1 implant was combined with a mini LD. **** Reported complications were (wound) infection, ROM, positive retroareolar biopsy, loss of nipple (due to necrosis), mild or significant epidermolysis or echymosis, mild depigmentation around the NAC, cellulitis, hematoma, redness, eschar, anemia, thrombosis, drainage from wounds, mild skin loss or skin ischemia, prosthesis rupture, or a combination.

Table 1 Baseline characteristics of non-responders, responders and all patients

	Patients (n = 208)
Age in years (mean ± SD)	43.2 ± 10.1 (n = 162)
Follow-up in years (median ± range)	5.0 ± 13.0 (n = 190)
Reason and side of surgery	
Prophylactic (uni- and bilateral)	50.0% (n = 104)
Therapeutic unilateral	11.1% (n = 23)
Therapeutic bilateral	16.8% (n = 35)
	Missing: 22.1% (n = 46)
Type of reconstruction	
Implant + Alloderm*	86.4% (n = 140)
Implant + Strattice	6.4% (n = 10)
Implant + dermal grafts	7.4% (n = 12)
	Missing: 22.1% (n = 46)
Final pathology	
Benign	51.0% (n = 106)
DCIS	4.3% (n = 9)
LCIS	1.9% (n = 4)
IDC	8.7% (n = 18)
LDC	2.9% (n = 6)
ADH	1.9% (n = 4)
Other**	4.8% (n = 10)
	Missing 24.5% (n = 51)
Radiotherapy	
Yes	1.4% (n = 3)
Past	5.8% (n = 12)
No complications	92.3% (n = 193)

Table 2 Baseline characteristics of included patients

	Patients (n = 208)
Complications	7.7% (n = 16)
Mild	
ROM	0.5% (n = 1)
Epidermolysis	
Mild	3.4% (n = 7)
Significant	0.5% (n = 1)
Mild echymosis	0.5% (n = 1)
Mild depigmentation around NAC	1.0% (n = 2)
Hematoma	0.5% (n = 1)
Severe	
Cellulitis	0.5% (n = 1)
Positive retroareolar biopsy	0.5% (n = 1)
Loss of nipple due to necrosis	0.5% (n = 1)
No intervention	97.1% (n = 202)
Mild intervention	
HBO	0.5% (n = 1)
PT	0.5% (n = 1)
Evacuation of hematoma	0.5% (n = 1)
Severe intervention	
Readmission	0.5% (n = 1)
Removal of nipple	0.5% (n = 1)
HBO + implant removal	0.5% (n = 1)

* All reconstructions were direct-to-implant. In one patient, first expanders were inserted and replaced for definitive implants during a second procedure. ** Other including ADH and papillomas, DCIS with lobular extension, IDC left and LCIS or ALH right, IDC combined with DCIS right and ILC left ALH, unspecified or a combination.

Patient reported outcomes measured with the BREAST-Q

The mean satisfaction with breast and outcome measured with the BREAST-Q was 70.6 ± 20.2 and 78.0 ± 20.5 respectively. On psychosocial well-being an average score of 79.5 ± 22.7 was reported, on sexual well-being 60.8 ± 23.7 and on physical well-being with chest 80.5 ± 16.7. Satisfaction with nipples was moderate, with a mean score of 64.4 ± 33.2.

Patients were in general satisfied with the information (mean score 78.3 ± 20.3), their surgeon (89.9 ± 19.6), medical staff (92.3 ± 18.6) and office staff (94.3 ± 17.0) (Table 3).

BREAST-Q (mean ± SD)	Responders (n = 208)
Satisfaction with Breast (Q1; n = 208)	70.6 ± 20.2
Satisfied with implant rippling / wrinkling (Q2; n = 204)	
Visible	3.0 ± 1.0
Feeling	3.2 ± 0.9
Satisfaction with outcome (Q3; n = 205)	78.0 ± 20.5
Psychosocial well-being (Q4; n = 203)	79.5 ± 22.7
Sexual well-being (Q5; n = 192)	60.8 ± 23.7
Physical well-being: Chest (Q6; n = 198)	80.5 ± 16.7
Satisfaction with nipples (Q10; n = 79)	64.4 ± 33.2
Satisfaction with information (Q11; n = 190)	78.3 ± 20.3
Surgeon (Q12; n = 189)	89.9 ± 19.6
Medical staff (Q13; n = 185)	92.3 ± 18.6
Office staff (Q14; n = 184)	94.3 ± 17.0

Table 3 Details of patients' responses on BREAST-Q

Correlation BREAST-Q domains

Psychosocial well-being (Q4) and sexual well-being (Q5) were related strongly ($r = 0.752$, $p < 0.001$). Satisfaction with breasts (Q1) showed strong relationships ($r \geq 0.704$) with satisfaction with outcome (Q3), psychosocial well-being (Q4) and sexual well-being (Q5) ($p < 0.001$). Also, visibility (Q2a) and sensation (Q2b) of rippling ($r = 0.733$) and satisfaction with outcome (Q3) and psychosocial well-being (Q4) were correlated ($r = 0.687$) ($p < 0.001$). At length satisfaction with care regarding information (Q11) was correlated to satisfaction with breasts (Q1, $r = 0.652$), satisfaction with outcome (Q3, $r = 0.668$) and satisfaction with the surgeon (Q12, $r = 0.654$) (Table S1, supporting information).

Influence of age, complications, reason for surgery and side of reconstruction

In the univariate model, younger patients were more satisfied with the outcome (Q3 mean 81.5 ± 18.5) and with the information of care provided (Q11 82.2 ± 16.9) compared to older patients (Q3 73.0 ± 21.9, $p = 0.001$; Q11 74.5 ± 22.5, $p = 0.010$). A shorter follow-up resulted in a lower physical well-being (Q6 76.1 ± 17.2, $p = 0.001$).

Patients with a mastectomy for therapeutical reasons and a unilateral reconstruction were in general less satisfied with the outcome (Q3 69.5 ± 21.4, $p = 0.045$), psychosocial well-being (Q4 70.0 ± 24.3, $p = 0.027$) and with their nipples (Q10 44.9 ± 27.0, $p = 0.011$). At length patients with a complication were significantly less satisfied with the outcome (Q3 mean 62.6 ± 22.0), their psychosocial well-being (Q4 mean 68.7 ± 27.5) and with the information provided (Q11 mean 66.4 ± 25.8) compared to patients with an uncomplicated course (Q3 mean 79.3 ± 19.9, $p = 0.002$, Q4 mean 80.5 ± 21.0, $p = 0.037$, Q11 mean 79.2 ± 19.4, $p = 0.027$) (Table S2, supporting information).

In the multivariate model patients with a shorter follow-up (< 5 years) reported less physical well-being (Q6, 7.6 (2.1, 13.1) $p = 0.007$). Patients with a mastectomy for therapeutical reasons and a unilateral reconstruction were less satisfied with their psychosocial well-being (Q4, -12.7 (-22.7, -2.6) $p = 0.014$) and their nipples (Q10 -26.2 (-45.6, -6.9) $p = 0.009$) compared to patients undergoing a preventive mastectomy. Patients with a complication reported less satisfaction with the outcome (Q3 -14.2 (24.8, -3.6) $p = 0.009$) and with the information provided (Q11 -12.1 (-23.7, -0.6) $p = 0.040$) (Table S3, supporting information).

DISCUSSION

In this study, we assessed patient reported outcomes in women who underwent ADM-assisted IBBR. In general, women were satisfied with the result of their breast reconstruction, with a satisfaction ranging from 60.8 ± 23.7 to 94.3 ± 17.0 in the various domains. Satisfaction was negatively influenced by the occurrence of a complication. Patients who were treated prophylactically and underwent bilateral reconstruction were most satisfied with the results.

Recently, normative baseline values for the BREAST-Q were obtained by Mundy et al. by inviting the Army of Women to fill out the different preoperative BREAST-Q's.[17] As no preoperative questionnaires were filled out in our study, it is most appropriate to compare our data to their results. Women in the present study are more satisfied with their breasts (mean difference 12.6 ± 1.5, $p < 0.001$), and score higher on psychosocial well-being (8.5 ± 1.7, $p < 0.001$) and sexual well-being (4.8 ± 1.8, $p = 0.01$). The normative values for physical well-being are higher in the cohort by Mundy et al (-12.5 ± 1.2, $p < 0.001$).[17]

Previous studies reported high satisfaction rates after direct-to-implant ADM-assisted breast reconstruction in two articles concerning 118 and 63 patients using the BREAST-Q[18, 19]. However, the actual numbers cannot be compared to our data, since they did not use the scoring conversion method as provided by the developers of the questionnaire.[18, 19] In general, it has been found that autologous breast reconstruction leads to a higher satisfaction rates compared with other reconstructions methods.[17, 20-22] Pusic et al conducted the large Mastectomy Reconstruction Outcomes Consortium (MROC) study, a 5-year, prospective, multicenter study including 1.632 patients to compare satisfaction and quality of life 1 year after immediate reconstruction within and between autologous and implant-based breast reconstruction. Only patients with breast cancer diagnosis were included, which hampers legitimate comparison with our results.[22] To our knowledge, no meta-analysis of the current literature is yet available comparing the patient reported outcomes after different reconstruction methods, which is necessary in order to proper compare outcomes and draw any conclusions.

Of course, satisfaction is affected by more factors than the reconstruction method. Immediate reconstruction after a mastectomy for cancer treatment is a known risk factor for lower overall patient satisfaction, compared

to risk-reducing treatment.[23] Since prophylactic treatment is usually bilateral, while therapeutic treatment can be both, the separate effect of these factors (therapeutic/prophylactic and bi/ unilateral treatment) cannot easily be distinguished. As almost half of the patients (49.8%) underwent a prophylactic mastectomy, this contributes to the high satisfaction rate reported in this study.

In this study satisfaction was lower in patients who underwent unilateral therapeutic treatment. It is recommendable to discuss a preventive contralateral mastectomy with patients scheduled for a unilateral mastectomy. The occurrence of complications can negatively influence a patients' satisfaction[20], which was confirmed by our findings. In this cohort, the overall complication rate was low (7.7%). All patients in this cohort were nonsmokers and the majority of patients received a prophylactic mastectomy, which may contribute to the low complication rate. Furthermore, the operation surgeon is highly experienced with ADM-assisted IBBR, which also contributes to a lower complication rate.10, 24 Previous studies however, have shown a high variance in complication rate with this technique, ranging from only 5% up till 50%.[4, 7-9] It can be expected that patient reported satisfaction rates vary analogously, however, this has not been clearly established.

The domains satisfaction with breasts, satisfaction with outcome, psychosocial well-being and sexual well-being are most strongly interrelated ($r \geq 0.665$, $p < 0.001$). This underscores the importance of a womens' breast for her psychosocial and sexual functioning. Furthermore, satisfaction with information is strongly correlated to satisfaction with breasts, outcome and the surgeon, which indicates the importance of adequate information.

There are several questionnaires available to evaluate PROMs but they are mainly self-made and not validated.[25] The BREAST-Q is a questionnaire validated to measure patient reported outcomes after breast surgery.[12] There are 5 separate modules available and the post-mastectomy reconstruction module is increasingly used in studies reporting on breast reconstructive surgery.[26] PROMs are necessary to improve health care and are important to avoid observer bias.[26, 27] Although more studies focus on PROMs, they are not integrated in most health care systems. As stated by Black[27], PROMs should become part of daily care. It is important that at least future studies will take PROMs into account, and preferable all use the same questionnaire. Only with comparable outcomes we will be able to compare the results of future studies to each other.[26]

Limitations

This study is limited by its retrospective design, and consequently contains missing data. No preoperative questionnaires were administered, therefore the difference in patient satisfaction before and after the surgery could not be assessed. In this study 208 (38.4%) patients responded to the invitation and only the more recently treated patients responded. Although the groups were comparable regarding most baseline characteristics, there still might have been a bias regarding the patients that did or did not respond. This also concerns the type of reconstruction, since all patients receiving an implant only did not respond to the questionnaire. Dissatisfaction might be one of the reasons that the patients did not respond to the survey and this can diminish the validity of the data. In this cohort one patient in the responding group and three patients in the non-responding group received two-stage implant-based breast reconstruction. It is inherent in the reconstruction process that in selected cases an expander should be placed first, due to the worries about the mastectomy skin flap quality. In order to maintain clarity, these patients were excluded in the study.
At length, there are others factors that might affect the patient satisfaction and could not be assessed in this study due to missing data. These factors include implant size and whether the mastectomy was nipple sparing or not. Future studies could focus on these factors.

This is 1 of the first studies of a large cohort evaluating patient satisfaction after ADM-assisted implant-based breast reconstruction reporting with long-term follow-up. This procedure is associated with comparable or even higher satisfaction rates compared with other reconstruction methods. ADM-assisted IBBR is a valuable option for breast reconstruction, provided that complication rates remain low. Hence it should only be selected and performed in a group of women who meet the criteria for the procedure.

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		Q1	Q2a	Q2b	Q3	Q4	Q5	Q6	Q10	Q11	Q12	Q13	Q14
Q1	Satisfaction with breasts	-	0.502 < 0.001	0.494 < 0.001	**0.704** < 0.001	**0.748** < 0.001	**0.717** < 0.001	0.446 < 0.001	0.278 0.013	**0.652** < 0.001	0.677 < 0.001	0.343 < 0.001	0.374 < 0.001
Q2a	Visibility of rippling	n = 204	-	**0.733** < 0.001	0.479 < 0.001	0.465 < 0.001	0.410 < 0.001	0.273 0.001	0.280 0.013	0.442 < 0.001	0.398 < 0.001	0.201 0.006	0.270 0.002
Q2b	Sensation of rippling	n = 204	n = 204	-	0.479 < 0.001	0.409 < 0.001	0.452 < 0.001	0.297 < 0.001	0.262 0.021	0.443 < 0.001	0.386 < 0.001	0.200 0.007	0.309 < 0.001
Q3	Satisfaction with outcome	n = 205	n = 204	n = 204	-	**0.687** < 0.001	0.591 < 0.001	0.414 < 0.001	0.349 0.002	**0.668** < 0.001	0.588 < 0.001	0.343 < 0.001	0.359 < 0.001
Q4	Psychosocial well-being	n = 203	n = 202	n = 202	n = 203	-	**0.752** < 0.001	0.533 < 0.001	0.340 0.002	0.542 < 0.001	0.519 < 0.001	0.296 0.001	0.322 < 0.001
Q5	Sexual well-being	n = 192	n = 191	n = 191	n = 192	n = 191	-	0.431 < 0.001	0.281 0.015	0.506 < 0.001	0.492 < 0.001	0.278 < 0.001	0.341 < 0.001
Q6	Physical well-being: chest and upper body	n = 198	n = 197	n = 197	n = 198	n = 197	n = 188	-	0.252 0.025	0.391 < 0.001	0.451 < 0.001	0.261 < 0.001	0.225 0.002
Q10	Satisfaction with nipples	n = 79	n = 78	n = 78	n = 79	n = 78	n = 75	n = 79	-	0.211 0.071	0.147 0.212	0.039 0.745	0.030 0.808
Q11	Satisfaction with care regarding information	n = 190	n = 189	n = 189	n = 190	n = 189	n = 181	n = 190	n = 74	-	**0.654** < 0.001	0.377 < 0.001	0.360 < 0.001
Q12	Satisfaction with surgeon	n = 189	n = 188	n = 188	n = 189	n = 189	n = 180	n = 189	n = 74	n = 190	-	0.480 < 0.001	0.490 < 0.001
Q13	Satisfaction with the medical team	n = 185	n = 184	n = 184	n = 184	n = 185	n = 176	n = 185	n = 71	n = 185	n = 185	-	0.431 < 0.001

Table S1 Supporting information. Spearman's correlation between BREAST-Q modules

Table S2 Supporting information. Influence of age, follow-up, reason for surgery and side of reconstruction, and complications on patient reported outcomes (univariate model)

		Univariate model mean ± SD					
BREAST-Q module		**Q1**	**Q3**	**Q4**	**Q6**	**Q10**	**Q11**
Age							
≤ 42 years (n = 81)		71.0 ± 19.0	81.5 ± 18.5	79.9 ± 20.9	81.2 ± 15.7	65.1 ± 38.1	82.2 ± 16.9
> 42 years (n = 81)		69.2 ± 21.9	73.0 ± 21.9	78.7 ± 23.3	80.5 ± 18.2	61.1 ± 32.2	74.5 ± 22.5
	p-value	0.067	**0.001**	0.304	0.694	0.816	**0.003**
Follow-up							
< 5 years (n = 92)		70.9 ± 22.4	75.6 ± 22.8	77.1 ± 22.5	76.1 ± 17.2	65.6 ± 33.0	78.4 ± 23.0
≥ 5 years (n = 99)		69.9 ± 18.2	79.0 ± 18.3	81.3 ± 20.7	83.8 ± 15.4	64.4 ± 35.3	78.1 ± 18.0
	p-value	0.719	0.259	0.184	**0.002**	0.890	0.934
Reason and side of surgery							
Prophylactic (uni- and bilateral) (n = 104)		72.3 ± 20.2	80.1 ± 20.6	82.6 ± 21.3	82.6 ± 14.4	71.4 ± 35.6	81.0 ± 19.0
Therapeutic unilateral (n = 23)		63.0 ± 20.4	69.5 ± 21.4	70.0 ± 24.3	74.2 ± 22.1	44.9 ± 27.0	70.3 ± 25.4
Therapeutic bilateral (n = 35)		68.3 ± 20.7	73.9 ± 18.9	75.8 ± 21.0	80.3 ± 18.9	73.7 ± 33.3	76.6 ± 18.1
	p-value	0.124	**0.045**	**0.027**	0.096	**0.011**	0.060
Type of reconstruction							
Implant + Alloderm (n = 140)		70.1 ± 20.7	75.8 ± 21.2	78.3 ± 22.2	80.1 ± 15.8	61.0 ± 34.0	77.3 ± 20.7
Implant + Strattice (n = 10)		72.0 ± 14.4	88.9 ± 12.9	87.1 ± 19.1	86.1 ± 14.7	/ (100.0)	88.6 ± 14.0
Implant + dermal grafts (n = 12)		68.7 ± 23.1	84.3 ± 14.7	83.6 ± 20.9	85.3 ± 2.0	67.8 ± 43.1	83.7 ± 15.0
	p-value	0.931	0.069	0.376	0.396	0.280	0.183
Complications							
No (n = 192)		71.3 ± 19.3	79.3 ± 19.9	80.5 ± 21.0	80.3 ± 16.7	65.2 ± 33.3	79.2 ± 19.4
Yes (n = 16)		62.7 ± 27.9	62.6 ± 22.0	68.7 ± 27.5	82.7 ± 16.4	58.2 ± 33.7	66.4 ± 25.8
	p-value	0.101	**0.002**	**0.037**	0.604	0.556	**0.027**

	Multivariate model Difference scores											
BREAST-Q module	**Q1**	**p-value**	**Q3**	**p-value**	**Q4**	**p-value**	**Q6**	**p-value**	**Q10**	**p-value**	**Q11**	**p-value**
Constant value (ref)	75.5		92.6		77.8		77.1		88.9		96.5	
Age in years	0.0 (-0.4, 0.3)	0.880	-0.3 (-0.6, 0.0)	0.070	0.1 (-0.3, 0.4)	0.503	0.00 (-0.3, 0.3)	0.966	-0.4 (-1.3, 0.6)	0.457	-0.3 (-0.6, 0.0)	0.074
Follow-up in years	-2.3 (-8.9, 4.7)	0.495	1.8 (-4.7, 8.3)	0.592	3.1 (-4.0, 10.1)	0.396	7.6 (2.1, 13.1)	**0.007**	-0.9 (-18.8, 17.0)	0.921	-2.9 (-9.5, 3.8)	0.395
Reason and side of surgery												
Prophylactic (uni- + bilateral) (n = 104)	Ref		Ref		Ref		Ref		Ref		Ref	
Therapeutic unilateral (n = 23)	-9.4 (-18.9, 0.1)	0.052	-8.7 (-18.0, 0.5)	0.063	-12.7 (-22.7, -2.6)	**0.014**	-7.6 (-15.3, 0.2)	0.056	-26.2 (-45.6, -6.9)	**0.009**	-9.0 (-18.2, 0.3)	0.057
Therapeutic bilateral (n = 36)	-3.4 (-11.5, 4.7)	0.403	-3.6 (-11.5, 4.3)	0.375	-6.5 (-15.1, 2.1)	0.139	-2.0 (-8.8, 4.8)	0.562	3.5 (-21.4, 28.3)	0.781	-1.5 (-12.1, 5.9)	0.728
Complications	-8.7 (-19.6, 2.2)	0.118	-14.2 (-24.8, -3.6)	**0.009**	-10.7 (-22.3, 2.1)	0.139	4.4 (-4.7, 13.5)	0.339	-8.0 (-33.0, 17.0)	0.524	-12.1 (-23.7, -0.6)	**0.040**

Table S3 Supporting information. Influence of age, follow-up, reason for surgery and side of reconstruction, and complications on patient reported outcomes (multivariate model)