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# BREAST

### OPEN

## Quality of Life 9 to 13 Years after Autologous or Alloplastic Breast Reconstruction: Which Breast Remains Best?

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**Background:** The aim of this study was to evaluate the long-term patient satisfaction and quality of life 9 to 13 years after autologous versus alloplastic breast reconstruction and compare the data to those of an earlier study.

**Methods:** This is a 9-year follow-up study of 92 women who underwent breast reconstruction (47 autologous and 45 alloplastic) between 2006 and 2010 and filled out the BREAST-Q questionnaire in 2010. Changes in BREAST-Q scores were analyzed by using a change score from baseline (2010) to follow-up (2019), which was presented by a mean change score with 95% confidence intervals. Linear regression analyses were performed to test which patient characteristics were related to the BREAST-Q change scores.

**Results:** The response rate at follow-up was 60% (25 autologous and 30 alloplastic). Responders at follow-up had a lower body mass index and had less frequently undergone unilateral breast reconstruction compared to the non-responders. Women undergoing both autologous and alloplastic breast reconstruction had significantly decreased satisfaction with breasts (-4 points), satisfaction with outcome (-8 points), and satisfaction with nipples (-20 points) over time. None of the patient characteristics, including reconstruction technique, were related to the BREAST-Q change scores.

**Conclusions:** Satisfaction with breasts, satisfaction with outcome, and satisfaction with nipples decreased slightly over time for women undergoing alloplastic and autologous breast reconstruction. Women undergoing autologous breast reconstruction seemed to remain more satisfied with their breasts 9 to 13 years after breast reconstruction compared to women undergoing alloplastic breast reconstruction. Because of the small sample size, conclusions should be carefully drawn. However, the results were in line with the expectations based on previous literature. *(Plast. Reconstr. Surg.* 151: 467, 2023.)

A n increasing number of women seek to have their breasts reconstructed following surgery for breast cancer.<sup>1</sup> Following mastectomy, breast reconstruction can generally be carried out using two techniques. The first is

Copyright © 2022 The Authors. Published by Wolters Kluwer Health, Inc. on behalf of the American Society of Plastic Surgeons. This is an open-access article distributed under the Creative Commons Attribution License 4.0 (CCBY), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. DOI: 10.1097/PRS.00000000009899 autologous breast reconstruction, in which the patient's own body tissue is the principal component to reconstruct the volume and lining of a new breast. The second is alloplastic breast reconstruction, in which breast implants are used for volume reconstruction. In the latter case, local or regional flaps are sometimes used to reconstruct skin shortages. Patient (body) characteristics and

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shared decision-making determine which reconstruction technique is selected.

High patient satisfaction and quality of life (QOL) as evaluated by the woman have become the most important goal to achieve now that morbidity and mortality control have reached the higher obtainable levels. A recent systematic review showed that patients who underwent autologous breast reconstruction have higher patient satisfaction and QOL compared to women who underwent alloplastic breast reconstruction.<sup>2,3</sup> The average follow-up of the evaluated studies was 24 months (range, 3 to 84 months).<sup>3</sup> To date, no study on patient satisfaction and QOL associated with type of breast reconstruction has presented data with a follow-up of more than 8 years.<sup>4–7</sup>

The aim of this study was to evaluate the change in patient satisfaction and QOL 9 to 13 years after breast reconstruction in women who underwent autologous breast reconstruction versus alloplastic breast reconstruction by comparing BREAST-Q scores from relatively shortly (0 to 4 years) after reconstruction to scores 9 years later. We hypothesized that BREAST-Q scores remained stable over time, with higher scores in the autologous group compared to the alloplastic group.

#### **PATIENTS AND METHODS**

#### **Study Design and Participants**

This study is a 9-year follow-up of the study by Eltahir et al. ("Which Breast Is Best? Successful Autologous or Alloplastic Breast Reconstruction: Patient-Reported Quality-of-Life Outcomes") and consists of the participants who were included in that study.<sup>2</sup> The initial cohort (n = 92) was a sample of women older than 18 years who underwent successful autologous (n = 47) or alloplastic (n = 45)breast reconstruction between 2006 and 2010 at a single tertiary care center who filled out questionnaires in November of 2010 (baseline). The median follow-up was 26 months (range, 5 to 52 months) for the autologous group and 23.5 months (range, 4 to 48 months) for the alloplastic group, which was when the first BREAST-Q data were collected (baseline). Successful breast reconstruction was defined as having a unilateral or bilateral breast reconstructed successfully. The occurrence of metastasis, severe illness, and reconstruction failure were exclusion criteria. Apart from information on sociodemographics, clinical data, treatment stage, and the complications that occurred during follow-up, data

were retrieved from the patient files.<sup>2</sup> The institutional review board at the University Medical Center Groningen granted a waiver for the initial study (METc 2010.191) and this follow-up study (METc 2019.268).

#### Procedure

The 92 participants originally included in the "Which Breast Is Best?" study were asked to participate in this follow-up study by means of an information letter in July of 2019. Before approaching women, we identified dead patients by using the electronic patient file selection screen without opening the patient file. The information letter was accompanied by the same questionnaires that were administered in 2010. Potential participants had 2 weeks to respond before a reminder was sent. Those willing to participate returned the filled out questionnaires including the signed informed consent form for use of their medical records.

#### **Questionnaires and Scoring**

The postoperative BREAST-Q reconstruction module,<sup>8</sup> the Hospital Anxiety and Depression Scale, and the 36-Item Short-Form Health Survey were used in this study.<sup>8,9</sup>

#### **BREAST-Q**

This questionnaire is designed to evaluate patient satisfaction and health-related QOL before and after breast surgery. The postoperative reconstruction module was used, which consists of six satisfaction domains [satisfaction with breasts, outcome, nipples, information, surgeon, medical team (18, seven, five, 15, 12, and seven items, respectively)] and three QOL domains [psychosocial, sexual well-being, and physical well-being: chest and abdomen (10, six, 16, and 13, items, respectively)]. The latter (physical well-being: abdomen) applied only to the women who underwent autologous breast reconstruction.<sup>7</sup> The responses on each BREAST-Q subscale were scored on a zero (worst) to 100 (best) scale.

#### Hospital Anxiety and Depression Scale

This questionnaire aims to detect symptoms of anxiety and depression in patients. Both domains, depression and anxiety (seven items each), are scored on a scale of 0 to 21 and then categorized (i.e., score of 0 to 7 = no symptoms of anxiety or depression, 8 to 10 = symptoms of anxiety or depression, and 11 to 21 = symptoms of severe anxiety or depression).<sup>9</sup>

#### **36-Item Short-Form Health Survey**

This questionnaire is a tool used frequently worldwide to assess health-related QOL and consists of eight different domains (i.e., physical functioning, role limitations attributable to physical health, role limitations attributable to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health (10, four, three, four, five, two, two, and five items, respectively). Each domain is scored on a zero (worst) to 100 (best) scale.<sup>10</sup>

#### **General Characteristics**

Based on data gathered in the past,<sup>2</sup> we asked questions on socioeconomic status to gather additional information on general characteristics from 2019. The following characteristics were measured: age, body mass index (BMI), smoking status, marital status, level of education, and occupational status.

#### Outcomes

The primary outcome of this study was the change in BREAST-Q score from baseline (0 to 4 years after breast reconstruction) to 9 years later at follow-up (9 to 13 years after breast reconstruction) for the following subscales: satisfaction with breasts, satisfaction with outcome, psychosocial well-being, sexual well-being, physical well-being, and satisfaction with nipples. Satisfaction with information, surgeon, medical staff, and office staff were considered the secondary outcomes.

#### Definitions

Autologous breast reconstruction included women who underwent deep inferior epigastric perforator flap or pedicled/free transverse abdominis muscle flap surgery. Alloplastic breast reconstruction included women who had undergone reconstruction using a breast implant or tissue expander followed by a breast implant, with or without a local or regional flap. The time between the reconstruction and the administration of the questionnaires at both baseline and followup was calculated in years. Age was calculated in years. BMI was calculated in kilograms per meter squared. The indication for breast reconstruction was categorized as prophylactic in case of bilateral breast reconstruction for BRCA gene carriers, and malignancy in case of unilateral or bilateral breast reconstruction related to a breast cancer diagnosis. Smoking status was defined as yes or no. Radiotherapy was defined as radiotherapy at the chest area and defined as yes or no. Subsequent procedures performed at the reconstructed breast(s) after 2010 were categorized as follows: 0,

no subsequent procedures; 1, nipple reconstruction/areola tattoo; and 2, subsequent procedures such as secondary scar, dog-ear corrections, lipofilling, liposuction, and replacement of implant because of capsular contracture.

#### **Statistical Analyses**

For participants' characteristics, descriptive statistics were used. Continuous variables were presented by means and standard deviations for normally distributed data and by medians and interquartile ranges for nonnormally distributed data. Nominal variables were described by counts and proportions. To estimate potential bias by selective dropout, the characteristics of the women included at follow-up were compared to the women who did not participate at followup. As for the participants included at follow-up, baseline characteristics from 2010 were compared to those from 2019 and compared between the autologous and alloplastic breast reconstruction groups. Group comparisons were performed using the paired sample or t test in case of normally distributed continuous variables, and Wilcoxon signed rank test or Mann-Whitney U test if data were nonnormally distributed.

BREAST-Q subscales were presented as means ± standard deviation and compared between autologous and alloplastic and between baseline and follow-up. Changes in BREAST-O scores over time were analyzed by using a change score, from baseline to follow-up, which was presented by a mean change score with 95% confidence intervals (CIs). Linear regression analyses were established to analyze which patient characteristics where related to the change score of the primary outcomes. Based on the literature and institutional experience, we chose to examine the following patient characteristics: age, BMI, reconstruction indication, bilateral breast reconstruction, radiotherapy, smoking, symptoms of anxiety and symptoms as measured by the Hospital Anxiety and Depression Scale, general health as measured by the 36-Item Short-Form Health Survey, and subsequent procedures performed after 2010.<sup>4,10</sup> A value of P < 0.05 was considered statistically significant. All analyses were conducted with IBM SPSS version 26 (IBM Corp., Armonk, NY).

#### RESULTS

#### **Study Population**

Using the electronic patient file, we found that of the 92 women who participated at baseline, two women had died between 2010 and 2019. Therefore, we invited 90 to participate at follow-up. Unfortunately, the hospital's registration was not up to date, and we identified another six women who were dead. A total of 55 women responded and were included at follow-up [55 of 92 (60% inclusion rate)]. Of the 55 included participants, 25 underwent autologous breast reconstruction and 30 underwent alloplastic breast reconstruction. [See Figure, Supplemental Digital **Content 1**, which shows a flowchart of participant inclusion at follow-up. (First row) Initial number of included participants in the first study (baseline, 2010). (Left column) The autologous patients and those who dropped out from the initial cohort until the follow-up study (2019). (*Right column*) The numbers for the alloplastic group, http:// links.lww.com/PRS/F605.] Among the responders at follow-up, fewer women had undergone unilateral breast reconstruction for malignancy compared to the nonresponders (40% versus 65%; P=0.019). The responders had a lower BMI at baseline compared to the nonresponders (23 versus 26; P = 0.033) (Table 1).

The women included in this study who underwent alloplastic breast reconstruction were younger than the women who underwent autologous breast reconstruction (53 years versus 60 years; P = 0.004) at follow-up. Women who underwent alloplastic breast reconstruction had a slightly higher BMI at follow-up compared to baseline (24 kg/m<sup>2</sup> versus 23 kg/m<sup>2</sup>; P = 0.004) and had decreased in general health from baseline to follow-up (from 85 to 70; P = 0.030) (Table 2).

#### **Change in BREAST-Q subscales**

Most BREAST-Q subscales showed a decrease in score from baseline to follow-up for both the autologous and alloplastic breast reconstruction groups, and three subscales had significantly decreased (i.e., satisfaction with breasts, satisfaction with outcome, and satisfaction with nipples). Satisfaction with breasts decreased from baseline to follow-up with a mean of -4 (95% CI, -9to -1; P = 0.046) for the whole group. Women who underwent autologous breast reconstruction were more satisfied with their breasts in 2010 and remained more satisfied with their breasts in 2019 compared to women who underwent alloplastic breast reconstruction (P = 0.016) (Table 3). The decrease in satisfaction with breasts was similar in both groups [-4 (95% CI, -10 to 1)] and -4(95% CI, -9 to 0), respectively; P = 0.964]. [See Figure, Supplemental Digital Content 2, which

**Table 1. Assessment of Selection Bias: Participant Baseline Characteristics** 

Characteristic	Responders (%)	Nonresponders (%)	Р
No.	55 (60)	37 (40)	
Age, yr			0.77
Median	48.0	48.0	
IQR	41.0-53.0	41.0-52.5	
$BM\widetilde{I}, kg/m^2$			$0.03^{a}$
Median	23.4	26.2	
IQR	22.1-25.3	22.8-27.7	
Autologous or alloplastic			0.19
Autologous	25 (45)	22 (59)	
Alloplastic	30 (55)	15 (41)	
Bilateral reconstruction	31 (57.4)	12 (32.4)	0.01ª
Unilateral reconstruction for malignancy	22 (40.0)	24 (64.8)	$0.02^{a}$
Bilateral reconstruction for malignancy	2 (3.6)	1(2.7)	0.80
Bilateral prophylactic reconstruction	19 (34.5)	8 (21.6)	0.18
Unilateral reconstruction for malignancy and	12 (21.8)	4 (10.8)	0.17
contralateral prophylactic reconstruction			
Immediate reconstruction	29 (53.0)	16 (43.2)	0.27
Nipple-sparing mastectomy	2 (3.6)	0(0.0)	0.51
Total nipple reconstruction	35 (64.5)	22 (59.5)	0.38
Nipple reconstruction	35 (64.5)	21 (56.8)	0.36
Areola tattoo	26 (48.1)	16 (43.2)	0.57
Radiotherapy	13 (24.1)	12 (32.4)	0.25
TNM stage			0.36
0–IIB	26 (48.1)	20 (54.1)	
IIIA–IIIC	5 (9.3)	6 (16.2)	
BRCA mutation	24 (44.4)	10 (27.0)	0.13
Comorbidity	7 (13.0)	9 (24.3)	0.10
Smokers	10 (18.5)	10 (27.0)	0.23
Chemotherapy	18 (33.3)	17 (45.9)	0.24
Education, high	21 (38.9)	13 (35.1)	0.60
Partner	46 (85.2)	30 (81.1)	0.50

IQR, interquartile range; TNM, tumor, node, metastasis.

 $^{a}P < 0.05.$ 

	Base	eline	Follow-Up			
Characteristic	Autologous	Alloplastic	Autologous	Alloplastic		
No.	25	30	25	30		
Age, yr						
Médian	51.0	44	60.0	53.0		
IQR	44.5-54.5	36.5–50.5ª	53.5–63.5 <sup>a</sup>	45.7–59.2 <sup>b,c</sup>		
Time <sup>d</sup>						
Median	2.0	2.2	11.0	11.1		
IQR	1.13-2.71	1.0 - 2.6	$10.1 - 11.7^{a}$	$9.7 - 11.5^{b}$		
BMI, kg/m <sup>e</sup>						
Median	24.5	23.3	25.1	24.0		
IQR	22.7-28.9	20.8 - 24.8	22.9-27.9	21.8-26.1 <sup>b</sup>		
Reason for reconstruction						
Malignancy <sup>e</sup>	22 (88)	14 (46.7)	n.c.	n.c.		
Prophylactic <sup>e</sup>	3 (12)	16 (53.3)	n.c.	n.c.		
Laterality						
Bilateral reconstruction <sup>f</sup>	10 (40)	23 (76.7)	n.c.	n.c.		
Unilateral reconstruction <sup>f</sup>	15 (60)	7 (23.3)	n.c.	n.c.		
Smoking		. ,				
Smokers	5 (20.0)	6 (20.0)	2 (8.0)	4.0 (13.3)		
Nonsmokers	20 (80.0)	23 (76.3)	22 (88.0)	25.0 (83.3)		
Radiotherapy			× ,	· · · ·		
Radiotherapy	10 (40.0)	$3 (10.0)^{a}$	10 (40.0)	3(10.0)		
No radiotherapy	15 (60.0)	27(90.0)	15 (60.0)	27 (90.0)		
Anxiety symptoms ≥8 <sup>g</sup>	5 (20.0)	3 (10.0)	5 (20.0)	9 (30.0)		
General health <sup>h</sup>				· · · · ·		
Median	75.0	85.0	75.0	70		
IOR	65.0-90.0	70.0-90.0	50.0-80.0	50.0-90.0 <sup>b</sup>		
No procedures <sup>i</sup>	n.a.	n.a.	13 (52)	14(46.7)		
Total nipple reconstruction	n.a.	n.a.	8 (32)	13 (43)		
Nipple reconstruction <sup>j</sup>	n.a.	n.a.	5 (20)	10 (33)		
Solemnly areola tattoo <sup>j</sup>	n.a.	n.a.	8 (32)	11 (37)		
Symmetrizing correction <sup>k</sup>	n.a.	n.a.	4(16.0)	2 ( <b>ô</b> .7)		
Scar/dog-ear correction <sup>k</sup>	n.a.	n.a.	2 (8.0)	1(3.3)		
New reconstruction <sup>k,l</sup>	n.a.	n.a.	2 (8.0)	4 (13.3)		

#### Table 2. Patient Characteristics by Reconstruction Type at Baseline and at Follow-Up

n.a., not applicable; n.c., no change, same as at baseline; IQR, interquartile range.

<sup>a</sup>Difference with autologous baseline (P < 0.05).

<sup>b</sup>Difference with alloplastic (P < 0.05).

<sup>c</sup>Difference with autologous follow-up (P < 0.05).

<sup>d</sup>Time between reconstruction and filling out questionnaire.

<sup>e</sup>Reconstruction for malignancy either unilateral or bilateral reconstruction related to a breast cancer diagnosis and prophylactic reconstruction in case of bilateral reconstruction for BRCA gene mutation.

<sup>f</sup>Reconstruction performed on both breasts.

<sup>g</sup>Anxiety score  $\geq \hat{8}$  as measured by the Hospital Anxiety and Depression Scale.

<sup>h</sup>General health score as measured by the 36-Item Short-Form Health Survey.

No subsequent procedures after 2010.

Nipple reconstruction/areola tattoo after 2010.

<sup>k</sup>Subsequent procedures such secondary (scar corrections after 2010).

In the autologous group, lipofilling/liposuction; in the alloplastic group, replacement of implant because of capsular contraction.

shows satisfaction with breasts. BREAST-Q scores of the subscale satisfaction with breasts (*y* axis) by reconstruction type for baseline (2010) and follow-up (2019) (*x* axis), with mean difference and 95% CI. Significance level is shown per group over time, indicated for the autologous group in *blue* and the alloplastic group in *red*, and is shown between groups behind the *curly bracket*, *http://links.lww.com/PRS/F606*.] Satisfaction with outcome decreased for the whole group [-8 (95% CI, -14 to -2); P = 0.011]. The decrease was -4 (95% CI, -12 to 4) for the autologous group and -12 (95% CI, -21 to -3) for the alloplastic group (P = 0.163). [See Figure, Supplemental Digital Content 3, which shows satisfaction with outcome.

BREAST-Q scores of the subscale satisfaction with outcome ( $\gamma$  axis) by reconstruction type for baseline (2010) and follow-up (2019) (x axis), with mean difference and 95% CI. Significance level is shown per group over time, indicated for the autologous group in *blue* and the alloplastic group in *red*, and is shown between groups behind the curly bracket, http://links.lww.com/PRS/F607.] Psychosocial well-being did not change from baseline to follow-up for the whole group [1 (95% CI, -4 to 6; P = 0.873]. The change was 4 (95% CI, -4 to 12) in the autologous group and -2 (95%) CI, -9 to 5) in the alloplastic group (P = 0.222). [See Figure, Supplemental Digital Content 4, which shows psychosocial well-being. BREAST-Q

		Baseline		Follow-Up					
BREAST-Q Subscale	Autologous	Alloplastic	Total	Autologous	Alloplastic	Total			
No.	25	30	55	25	30	55			
Satisfaction with breasts	$75 \pm 20$	$64 \pm 18^{a}$	$69 \pm 19$	$72 \pm 18$	$59 \pm 14^{c}$	$65 \pm 17$			
Satisfaction with outcome	$80 \pm 20$	$74 \pm 21$	$78 \pm 20$	$74 \pm 19$	$64 \pm 21^{b}$	$69 \pm 21$			
Psychosocial well-being	$71 \pm 19$	$76 \pm 17$	$74 \pm 18$	$75 \pm 19$	$73 \pm 16$	$74 \pm 17$			
Sexual well-being	$58 \pm 20$	$60 \pm 23$	$59 \pm 22$	$59 \pm 24$	$55 \pm 19^{b}$	$56 \pm 21$			
Physical well-being: chest	$76 \pm 15$	$70 \pm 16$	$73 \pm 16$	$75 \pm 19$	$68 \pm 13$	$71 \pm 16$			
Physical well-being: abdomen	$75 \pm 22$	n.a.	n.a.	$82 \pm 18$	n.a.	n.a.			
Satisfaction with nipples	$72 \pm 21$	$74 \pm 28$	$73 \pm 25$	$55 \pm 25^{a}$	$49 \pm 25^{b}$	$51 \pm 25$			
Satisfaction with information	$69 \pm 12$	$70 \pm 17$	$69 \pm 15$	$73 \pm 18$	$65 \pm 19$	$68 \pm 19$			
Satisfaction with surgeon	$92 \pm 15$	$86 \pm 20$	$88 \pm 18$	$92 \pm 14$	$82 \pm 22$	$86 \pm 20$			
Satisfaction with medical staff	$85 \pm 21$	$88 \pm 19$	$87 \pm 19$	$78 \pm 24$	$87 \pm 21$	$83 \pm 22$			
Satisfaction with office staff	$81 \pm 25$	$84 \pm 21$	$82 \pm 22$	$83 \pm 26$	$86 \pm 20$	$69 \pm 22$			

Table 3. BREAST-Q Scores by Reconstruction Type at Baseline in 2010 and at Follow-Up in 2019

n.a., not applicable because physical well-being: abdomen does not apply to the alloplastic group.

<sup>a</sup>Difference with autologous baseline (P < 0.05).

<sup>b</sup>Difference with alloplastic baseline (P < 0.05).

<sup>c</sup>Difference with autologous follow-up (P < 0.05).

<sup>d</sup>Difference with total at baseline (P < 0.05).

scores of the subscale psychosocial well-being (y axis) by reconstruction type for baseline (2010) and follow-up (2019) (x axis), with mean difference and 95% CI. Significance level is shown per group over time, indicated for the autologous group in *blue* and the alloplastic group in *red*, and is shown between groups behind the *curly* bracket, http://links.lww.com/PRS/F608.] Sexual well-being was -2 (95% CI, -8 to 3) (P = 0.122) for the whole group, 1 (95% CI, -6 to 7) for the autologous group, and -5 (95% CI, -13 to 3) for the alloplastic group (P = 0.286). [See Figure, Supplemental Digital Content 5, which shows sexual well-being. BREAST-Q scores of the subscale sexual well-being (y axis) by reconstruction type for baseline (2010) and follow-up (2019) (x axis), with mean difference and 95% CI. Significance level is shown per group over time, indicated for the autologous group in *blue* and the alloplastic group in *red*, and is shown between groups behind the curly bracket, http://links.lww.com/PRS/F609.] Physical well-being: chest was equal for the whole group [-1 (95% CI, -5 to 3); P = 0.479], which was similar in both groups [-1 (95% CI, -6 to 3)]and -2 (95% CI, -8 to 4), respectively; P = 0.718]. See Figure, Supplemental Digital Content 6, which shows physical well-being: chest. BREAST-Q scores of the subscale physical well-being: chest ( $\gamma$ axis) by reconstruction type for baseline (2010) and follow-up (2019) (x axis), with mean difference and 95% CI. Significance level is shown per group over time, indicated for the autologous group in *blue* and the alloplastic group in *red*, and is shown between groups behind the *curly bracket*, http://links.lww.com/PRS/F610.] Physical wellbeing: abdomen only applies to the autologous group and increased from baseline to follow-up,

although the difference was not significant [8 (95% CI, -2 to 17); P = 0.231]. [See Figure, Supplemental Digital Content 7, which shows BREAST-Q subscale physical well-being: abdomen. BREAST-Q scores of the subscale physical well-being: abdomen (y axis) for the autologous group for baseline (2010) and follow-up (2019) (x axis). This subscale does not apply to the alloplastic group. Mean difference and 95% CI are shown from baseline to follow-up. Significance level for change over time is shown in *blue* behind the graphed line, http://links.lww.com/PRS/F611.] Satisfaction with nipples showed the largest decrease from baseline to follow-up, which was significant [-20 (95% CI, -28 to -11); P < 0.000].[See Figure, Supplemental Digital Content 8, which shows BREAST-Q subscale: satisfaction with nipples. BREAST-Q scores of the subscale satisfaction with nipples ( $\gamma$  axis) by reconstruction type for baseline (2010) and follow-up (2019) (x axis), with mean difference and 95% CI. Significance level is shown per group over time, indicated for the autologous group in *blue* and the alloplastic group in *red*, and is shown between groups behind the curly bracket, http://links.lww.com/PRS/F612.] The decrease was -16 (95% CI, -28 to -4) for the autologous group and -23 (95% CI, -38 to -9) for the alloplastic group (P = 0.434) (Table 3).

Satisfaction with information was stable for the whole group [-1 (95% CI, -4 to 3); P =0.699] but significantly different between groups [4 (95% CI, -4 to 8) and -5 (95% CI, -10 to -1), respectively; P = 0.012]. Satisfaction with surgeon was -1 (95% CI, -4 to 3) (P = 0.502) for the whole group and equal in both groups [0 (95% CI, 4 to 4) and -1 (95% CI, -7 to 4), respectively; P = 0.742]. Satisfaction with medical staff was -3

		faction Breasts		faction outcome		nosocial l-Being		exual I-Being	Well	ysical -Being: hestª	Well	ysical -Being: lomenª		action ipples <sup>a</sup>
Confounders	β	95% CI	β	95% CI	β	95% CI	β	95% CI	β	95% CI	β	95% CI	β	95% CI
Reconstruc- tion tech- nique <sup>b</sup>	-0.16	-7.24 to 6.93	-8.23	-19.91 to 3.44	-6.21	-16.30 to 3.88	-5.71	-16.33 to 4.91	-1.44	-9.40 to 6.52	n.a.	n.a.	-7.18	-25.63 to 11.27
Indication, prophylac- tic yes <sup>c</sup>	-0.42	-7.79 to 6.50	-3.32	-15.82 to 9.21	-11.00 <sup>1</sup>	<sup>h</sup> -21.39 to -0.61 <sup>h</sup>	-3.69	-15.00 to 7.62	-2.85	-11.15 to 5.45	n.a.	n.a.	-15.22	-33.55 to -3.11
Bilateral reconstruc- tion	-1.15	-8.36 to 6.07	-11.30 <sup>i</sup>	-23.00 to $0.40^{i}$	-9.22	-19.29 to -0.85	-3.79	-14.63 to 7.06	-3.00	-11.05 to 5.05	n.a.	n.a.	-7.46	-26.16 to 11.24
Age	-0.18	-0.56 to 0.21	-0.20	-0.85 to 0.46	-0.00	-0.57 to -0.56	-0.01	-0.60 to 0.59	0.04	-0.41 to 0.48	-0.56	-2.05 to 0.93	-0.12	-1.25 to 1.01
BMI	-0.04	-1.06 to 0.97	0.32	-1.44 to 2.08	0.94		0.35		0.16	-0.99 to 1.31	0.11		-0.23	-3.03 to 2.58
Smoking yes	6.75	-1.89 to 15.39	3.83	-11.19 to 18.85	3.10	-9.46 to 15.66	-2.29		9.62	-0.52 to 19.29	-0.41		15.96	-6.30 to 38.23
Radiotherapy yes	0.03	-8.52 to 8.58	6.15	-8.03 to 20.32	-0.34	–12.35 to 11.67	1.67	-10.99 to 14.33	-7.73 <sup>i</sup>	–16.88 to 1.42 <sup>i</sup>	n.a.	n.a.	14.14	-8.70 to 36.99
Anxiety <sup>d</sup>	-0.92	-10.83 to 8.98	6.31	-10.75 to 23.37	-0.23	-14.60 to 14.14	-4.05	-19.08 to 10.98	-2.23	-13.46 to 9.00	0.97	-23.7 to 26.07	4.78	-21.42 to 30.98
General health <sup>e</sup>	0.03	-0.17 to 0.22	0.28	-0.07 to 0.62	0.00	-0.28 to 0.29	0.16	-0.14 to 0.45	-0.12	-0.34 to 0.11	0.20	-0.28 to 0.67	-0.28	-0.80 to 0.25
Nipple/are- ola tattoo <sup>f</sup>	-4.56	-12.69 to 3.58	6.30		-6.11	-17.92 to 5.71	0.26		-0.35		n.a.	n.a.	-9.90	-31.53 to 11.72
Corrections <sup>g</sup>	9.83 <sup>h</sup>	2.06 to 17.60 <sup>h,j</sup>	2.15	-11.41 to 15.70	4.70	-6.87 to 16.28	5.59	-6.53 to 17.71	-3.47	-12.52; 5.59	n.a.	n.a.	23.77 <sup>i</sup>	-1.05 to $48.59^{i}$

### Table 4. Linear Regression Analyses on Difference Score in BREAST-Q Scales from Baseline in 2010 to Follow Up in 2019 for Potential Cofounders

n.a., not applicable.

<sup>a</sup>Anxiety = 3, prophylactic in case of bilateral prophylactic breast reconstruction (yes = 1, no = 0 in case of unilateral or bilateral breast reconstruction related to a breast cancer diagnosis on either one of two reconstructed breasts); General health = 4, general health score as measured by the 36-Item Short-Form Health Survey continuous; Nipple/areola tattoo = 5, nipple reconstruction/areola tattoo after 2010 (yes = 1, no = 0); and Corrections = 6, subsequent procedures such secondary (scar) corrections after 2010 (yes = 1, no = 0).

<sup>b</sup>Autologous/alloplastic.

<sup>c</sup>Prophylactic in case of bilateral prophylactic breast reconstruction (yes = 1, no = 0 in case of unilateral or bilateral breast reconstruction related to a breast cancer diagnosis on either one of two reconstructed breasts).

<sup>d</sup>Anxiety score  $\geq 8$  as measured by the Hospital Anxiety and Depression Scale (yes = 1, no = 0).

<sup>e</sup>General health score as measured by the 36-Item Short-Form Health Survey continuous.

<sup>f</sup>Nipple reconstruction/areola tattoo after 2010 (yes = 1, no = 0).

<sup>g</sup>Subsequent procedures such secondary (scar) corrections after 2010 (yes = 1, no = 0).

 $^{\rm h}P < 0.05.$ 

 ${}^{i}P < 0.10.$  ${}^{j}P = 0.014.$ 

(95% CI, -9 to 2) (P=0.211) for the whole group and equal in both groups [-6 (95% CI, -17 to 5) and -1 (95% CI, -7 to 5), respectively; P=0.414]. Satisfaction with office staff was 4 (95% CI, -2 to 10) (P=0.261) for the whole group and equal in both groups [3 (95% CI, -4 to 11) and 5 (95% CI, 1 to 10), respectively; P=0.826].

#### Factors Related to Change in BREAST-Q Scores

The performance of subsequent procedures after 2010 had a positive effect on satisfaction with breasts [10 (95% CI, 2 to 18); P = 0.014]. Prophylactic reconstruction had a negative

effect on psychosocial well-being [11 (95% CI, -21 to 1); P = 0.038]. As for the subscales satisfaction with outcome, satisfaction with nipples, sexual well-being, and physical well-being, none of the measured patient characteristics (i.e., reconstruction technique, reconstruction indication, bilateral reconstruction, age, BMI, smoking, radiotherapy, symptoms of anxiety, general health, nipple reconstruction, secondary corrections) were associated with the change score or could explain the decrease in BREAST-Q scores over time (Table 4). [See Table, Supplemental Digital Content 9, which shows the patient characteristics in relation to the remaining subscales

and linear regression analysis on secondary outcomes. Analysis was performed on the difference scores from baseline (2010) to follow-up (2019) for potential cofounders for the subscales satisfaction with information, satisfaction with surgeon, and satisfaction with medical and office staff, *http://links.lww.com/PRS/F613.*]

#### DISCUSSION

This study shows that satisfaction with breasts, outcome, and nipples decreases over time for women who underwent both autologous and alloplastic breast reconstruction. Womens' breast satisfaction decreased 4 points from 2010 to 2019, which was similar for both breast reconstruction groups (P = 0.964). Satisfaction with outcome decreased 8 points over time and decreased more in the alloplastic group (12 points) compared to the autologous group (4 points), although this difference was not significant (P = 0.163). The satisfaction with nipples scale showed the largest decrease (20 points) regardless of the fact that 40% of women underwent nipple reconstruction after 2010. This might be explained by (partial) loss of projection of the reconstructed nipple and/or (partial) fading of the areola tattoo. The decrease in BREAST-Q scores could not be explained by patient characteristics at baseline.4,7,11 The physical well-being: abdomen subscale seemed to increase over time (8 points; P= 0.231), indicating that when the baseline questionnaire was taken, most women who underwent autologous breast reconstruction had possibly not yet fully recovered from the abdominal surgery.

#### **Comparison to the Literature**

We confirm the findings of previous studies, that women who underwent autologous breast reconstruction are more satisfied with their breasts, both at baseline and at follow-up, compared to women who underwent alloplastic breast reconstruction.<sup>3,4,7</sup> The two other longitudinal studies comparing autologous and alloplastic breast reconstruction found BREAST-Q scores to remain stable over time. Their samples were larger than the sample in our study, but their response rates were much lower (10% and 14%, respectively). It is possible that women who were less satisfied dropped out of the studies, which could have resulted in selection bias. Furthermore, those studies had a shorter follow-up, which could explain why they did not find a decrease over time.4,7 In our study population, women undergoing prophylactic breast reconstruction had a significant decrease in psychosocial well-being over the 9 years of follow-up. Another study focusing on BREAST-Q scores after prophylactic breast reconstruction found higher psychosocial well-being scores at 2 years postoperatively.<sup>12</sup> Our results could be a reflection of a possible delay in the psychological burden of *BRCA* gene mutation, prophylactic mastectomy, and breast reconstruction.

#### Strengths and Limitations

The main strength of this study was the long follow-up time of approximately 11 years after breast reconstruction. To the best of our knowledge, this study has the longest follow-up published thus far. Also, the response rate reached the follow-up threshold of 60% to 80%.<sup>13</sup>

The main limitation of this study is the relatively small sample size (n = 55), which is partly a result of the long follow-up time and the already limited number of women included in the original study (n = 92). Compared with other studies published thus far, we do have a high response rate. Conclusions should be drawn with care. However, the results of this study were in line with the expectations based on previous literature. Our small sample size probably explains why some of our results are not significant despite quite large differences/changes between both groups. The small sample size could also be an explanation for why almost none of the studied patient characteristics were associated with a change in satisfaction with breasts, satisfaction with outcome, satisfaction with nipples, psychosocial well-being, sexual well-being, and physical well-being. For example, multiple studies have shown that bilateral breast reconstruction and radiotherapy greatly impact BREAST-Q scores.<sup>4</sup> Another limitation is the absence of preoperative questionnaires, which made adjustment for baseline scores impossible. However, preoperative data were not necessary to answer our research question about long-term stability of BREAST-Q scores.

We examined the presence of selection bias in our study and found that more prophylactic bilateral breast reconstructions were included in the study and that women included at follow-up had a lower BMI. The former could be explained by the fact that some of the women who underwent reconstruction for malignancy were most likely the women who died between the two measurement moments as the result of recurrent disease. It could be that the women undergoing breast reconstruction for malignancy had a higher BMI initially because of the use of adjuvant therapies such as hormonal therapy, which would explain the change. In 16 women, it was unclear why they did not respond to the invitation. It is possible that they moved to a new address or that they did not wish to participate.

#### **Clinical Relevance and Recommendations**

Cano et al. found the minimally important difference in BREAST-Q scores to be 4 points.<sup>14</sup> Our study found a significant decrease of 4 points in satisfaction with breasts over 9 years. This means that, in our study, patients report a relevant decrease in BREAST-Q scores, although this decrease is of borderline relevance. Multiple follow-up studies, with preferably a larger sample size, should determine whether there really is a relevant decline in breast satisfaction at long-term follow-up.

We found no evidence for any of the patient characteristics to cause a decrease in satisfaction with breasts and satisfaction with outcome. The question arises: What causes satisfaction with breasts and satisfaction with outcome to decrease? We speculate that possibly aesthetic changes occur in the reconstructed breast(s) over time (e.g., volumetric changes, occurrence of inhomogeneities, or increasing asymmetry). In the alloplastic group, capsular formation and contracture could play a role, and in the autologous breast reconstruction group, breast ptosis might become more prominent because of the lack of Cooper ligaments in the autologously reconstructed breast(s). Breast ptosis changes the ideal upper-to-lower pole ratio of the breast, which could cause women to be less satisfied with the shape of their breast(s). It would be interesting to see what actually occurs with the reconstructed breast over a span of approximately 10 years and objectively measure volumetric and shape changes in breast appearance. This could be one of the goals of future research. The results showed a steep decrease in satisfaction with nipples for the women in both the autologous and alloplastic breast reconstruction groups (-16 and -23, respectively). With this knowledge in mind, it is important to inform women who consider nipple reconstruction and/or areola tattoo about the long-term satisfaction to adjust expectations and avoid disappointment in the long run.

#### **CONCLUSIONS**

Satisfaction with breasts decreases over a time span of 9 years by 4 points for women undergoing both autologous and alloplastic reconstruction. Women who underwent autologous breast reconstruction seem to remain more satisfied with their breasts 9 to 13 years after breast reconstruction compared to women who underwent alloplastic breast reconstruction. Satisfaction with outcome decreases by 8 points over time and seemed to decrease more in the alloplastic group compared to the autologous group (12-point versus 4-point decrease). The decrease was not related to patient characteristics measured in this study. Research on the physical changes of reconstructed breasts over the years might help clarify why BREAST-Q scores decrease slightly over time.

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#### REFERENCES

- 1. American Society of Plastic Surgeons. 2018 Plastic surgery statistics. Available at: https://www.plasticsurgery.org/news/plastic-surgery-statistics. Accessed May 21, 2019.
- Eltahir Y, Werners LLCH, Dreise MM, Zeijlmans van Emmichoven IA, Werker PMN, de Bock GH. Which breast is the best? Successful autologous or alloplastic breast reconstruction: patient-reported quality-of-life outcomes. *Plast Reconstr Surg.* 2015;135:43–50.
- 3. Eltahir Y, Krabbe-Timmerman IS, Sadok N, Werker PMN, de Bock GH. Outcome of quality of life for women undergoing autologous versus alloplastic breast reconstruction following mastectomy: a systematic review and meta-analysis. *Plast Reconstr Surg.* 2020;145:1109–1123.
- Santosa KB, Qi J, Kim HM, Hamill JB, Wilkins EG, Pusic AL. Long-term patient-reported outcomes in postmastectomy breast reconstruction. *JAMA Surg.* 2018;153:891–899.
- Lagendijk M, van Egdom LSE, Richel C, et al. Patient reported outcome measures in breast cancer patients. *Eur J Surg Oncol.* 2018;44:963–968.
- Johnson DB, Lapin B, Wang C, et al. Advanced age does not worsen recovery or long-term morbidity after postmastectomy breast reconstruction. *Ann Plast Surg.* 2016;76:164–169.
- 7. Nelson JA, Allen RJ Jr, Polanco T, et al. Long-term patientreported outcomes following postmastectomy breast

reconstruction: an 8-year examination of 3268 patients. *Ann Surg*. 2019;270:473–483.

- 8. Q. BREAST-Q user manual version 2.0. Available at: http:// qportfolio.org/breast-q/. Accessed June 19, 2019.
- 9. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand.* 1983;67:361–370.
- RAND Corp. 36-Item Short Form Survey (SF-36). Available at: https://www.rand.org/health-care/surveys\_tools/mos/36-itemshort-form/survey-instrument.html. Accessed June 19, 2019.
- Mundy LR, Homa K, Klassen AF, Pusic AL, Kerrigan CL. Breast cancer and reconstruction: normative data for interpreting the BREAST-Q. *Plast Reconstr Surg.* 2017;139:1046e–1055e.
- 12. Casella D, Di Taranto G, Marcasciano M, et al. Nipplesparing bilateral prophylactic mastectomy and immediate reconstruction with TiLoop Bra mesh in BRCA1/2 mutation carriers: a prospective study of long-term and patient reported outcomes using the BREAST-Q. *Breast* 2018;39:8–13.
- 13. Kristman V, Manno M, Côté P. Loss to follow-up in cohort studies: how much is too much? *Eur J Epidemiol.* 2004;19:751–760.
- 14. Cano SJ, Klassen AF, Scott A, Alderman A, Pusic AL. Interpreting clinical differences in BREAST-Q scores: minimal important difference. *Plast Reconstr Surg.* 2014;134:173e–175e.