

Patient Quality of Life After Subpectoral Implant-based Breast Reconstruction With Synthetic or Biological Materials

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Abstract. *Aim: Quality of life and patient satisfaction after subpectoral breast reconstruction with meshes or acellular dermal matrices (ADM) and implants were assessed using the BreastQ questionnaire to investigate a potential influence of the materials on these parameters. Patients and Methods: The BreastQ questionnaire was completed by 121 patients, who had received material-assisted, heterologous, subpectoral breast reconstruction between 2010 and 2018. Results: Answers were similar independent of the reconstruction materials used. After prophylactic mastectomy, the physical wellbeing (chest) improved significantly with all materials ($p=0.04$). Postoperative radiotherapy significantly reduced satisfaction with outcome ($p=0.005$). Patients under 50 years old had significantly better postoperative sexual wellbeing than older patients ($p=0.03$). Conclusion: No influence was detected of the materials on the postoperative quality of life and patient satisfaction. An overall better quality of life was reported by younger and normal-weight patients with prophylactic or nipple-sparing mastectomy without radiotherapy.*

The diagnosis of breast carcinoma can be threatening and life-changing for the patient. The period before the impending breast surgery is often accompanied by fear and uncertainty. After mastectomy, some patients feel as if they lost their femininity, which can lead to severe psychosocial disturbance (1). The Commission Mamma of the Working Group on Gynecologic Oncology (AGO-Mamma) defines oncoplastic surgery as "the use of plastic surgical techniques

at the time of tumour removal to achieve safe resection margins and allow for an aesthetic breast shape" (2). It is recommended a surgical technique be chosen that is least stressful for the patient and leads to a stable aesthetic result in the long term. For this reason, primary reconstruction after mastectomy has established itself as the gold standard in recent years (3). Interposition-based heterologous breast reconstruction helps affected patients regain normality and their normal quality of life (QoL). Titanium-coated polypropylene meshes, partially absorbable bicomponent meshes, and porcine acellular dermal matrices (ADM) help achieve a natural shape and feel of the reconstructed breast (4). In heterologous breast reconstruction, silicone breast implants were usually placed subpectorally until 2018 (5). However, after transection of the caudal and sometimes medial attachment, cranialization of the *pectoralis major* muscle often occurs. As a result, the *pectoralis major* muscle covers the implant only craniomedially. Interposition devices are used to cover the caudolateral portion of the implant, which should also prevent lateral implant dislocation (6).

In this study, the postoperative satisfaction of patients treated with TiLOOP[®]Bra, SERAGYN[®]BR, or Strattice[™] was analysed by means of the BreastQ questionnaire (version 1.0) (7) to assess potential clinically meaningful differences in patients' postoperative satisfaction and QoL depending on the interposition device used. TiLOOP[®]Bra is a lightweight, non-absorbable, titanium-coated polypropylene mesh. SERAGYN[®]BR is a bicomponent mesh composed of a non-absorbable polypropylene portion and an absorbable polyglyconic acid-caprolactone portion. Strattice[™] is a tissue matrix composed of porcine source cell clusters. In the current literature, only seven original articles exist on the topic of patient satisfaction after breast reconstruction using mesh or ADM. These studies are presented in Table I. Four of them examined TiLOOP[®]Bra (8-11) and one examined SERAGYN[®]BR (9), while none examine Strattice[™]. Studies conducted by our group and others suggest that the material may play an important role in the postoperative outcome (9,

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Key Words: Breast reconstruction, breast carcinoma, quality of life, patient satisfaction, BreastQ, TiLOOP[®]Bra, SERAGYN[®]BR, Strattice[™], subpectoral.

11, 12). While objective medical evidence exists to substantiate these differences, there is a knowledge gap regarding subjective outcome assessments in terms of patient-reported outcomes, which the present study aims to fill.

Patients and Methods

This study was a non-randomized, retrospective, monocentric observational study. Data were collected following approval by the Ethics Committee of the University of Greifswald based on the Declaration of Helsinki (13). The medical records of 324 patients who had received interposition-based heterologous breast reconstruction at Greifswald University Hospital between January 2010 and January 2018 were evaluated. Patient data were screened from the archive on an institute computer and selected using the following inclusion criteria: Female patient, 18-80 years of age, treated with unilateral or bilateral breast surgery and reconstruction using an interposition device (TiLOOP®Bra, SERAGYN®BR or Strattice™).

Patients who fulfilled the study selection criteria were provided with the postoperative BreastQ questionnaire and a prepaid return envelope by mail in January 2018; those who did not reply were sent another copy in April 2018. A cover letter explaining the study and requesting that the questionnaire be completed and returned to the University Hospital was enclosed. Patients were instructed not to enter their names or other identifiable information. The questionnaire used is a validated translation of the Memorial Sloan-Kettering Cancer Center and University of British Columbia BreastQ Reconstruction Module questionnaire, which is a patient-reported outcome used to measure patients' satisfaction after breast reconstruction (14). The BreastQ questionnaire includes two categories: Health-related QoL and patient satisfaction, each of which was further divided into six subgroups: psychosocial wellbeing, physical wellbeing, sexual wellbeing, satisfaction with breasts, satisfaction with outcome, and satisfaction with care (14). Patients were asked to answer the questionnaire in relation to how they had felt in the previous two weeks.

Baseline data (age, body mass index [BMI], radiotherapy [RT], surgical technique, immediate or secondary reconstruction) were analysed retrospectively in this study. A disadvantage of this type of data collection is that data cannot be verified and may be incomplete or even wrong (15).

Results

Of the 324 patients contacted, 121 (37%) participated in the study. At the time of questionnaire collection, the time elapsed since surgery was up to 1 year in 19 patients (16%), up to 2 years in 18 (15%), up to 3 years in 24 (20%), up to 4 years in 27 (22%), up to 5 years in 29 (24%), up to 6 years in two (1%), and up to 7 years in two (1%).

The patients studied had been treated with anatomical silicone implants manufactured by Allergan Specialty Pharmaceutical Co, Mentor®, POLYTECH, or SEBBIN. Of the 121 patients surveyed, 97 (80%) had received primary and 24 (20%) secondary breast reconstruction. Nipple-sparing mastectomy (NSM) had been performed in 66 patients (54%) and skin sparing mastectomy (SSM) in 55

patients (45%). Thirty (25%) of the operations performed were prophylactic and 91 (75%) were therapeutic. The number of patients below 50 years of age was 42 (35%). Sixty patients (49%) had normal weight ($BMI \leq 24 \text{ kg/m}^2$), 58 (48%) were overweight ($BMI > 24 \text{ kg/m}^2$), and three (2%) were underweight ($BMI < 18 \text{ kg/m}^2$). RT was not applied in 91 patients while 18 (15%) received breast RT, 8 (6%) of whom after previous breast-conserving surgery. Adjuvant RT was applied in 12 patients (9%).

The questionnaire was scored using the dedicated QScore scoring software. The scores are computed from the responses to the separate questions by adding them together and converting the score to a scale from 0 to 100 (similar to conversion into a percentage). A higher score means high satisfaction or better health-related QoL (14). The analysis was performed using SPSS (version 26; IBM Corp. Armonk, NY, USA) and JASP (version 0.11.1; retrieved from <https://jasp-stats.org>), searching for significant differences between data in a given category of questions within a group by means of a *t*-test.

For the analysis, patients were divided into three groups based on the interposition device used as follows: 55 (45%) patients had received TiLOOP®Bra, 14 (12%) patients had received Strattice™, and 52 (43%) patients had received SERAGYN®BR. In terms of comparability, the groups treated with TiLOOP®Bra and SERAGYN®BR were approximately the same size, while the group treated with Strattice™ was much smaller and thus potentially less comparable with the other two groups. To elicit possible differences between the interposition devices used and the postoperative satisfaction in each category, a mixed analysis of variance and a Kruskal-Wallis test were performed with the three-factor intersubject factor mesh type (SERAGYN®BR, TiLOOP®Bra, Strattice™). Equality of variances was checked with Levene's test and was confirmed between groups for all variables ($p > 0.05$). The analysis of variance showed no main effect between the groups [$F(2, 115) = 0.146, p = 0.864, \eta_p^2 = 0.003$]. The Kruskal-Wallis test likewise showed no significant differences between the three examined interposition devices and the satisfaction in the individual question categories. Results of this test, as well as the respective mean values of the examined question categories, are presented in Table II. Independent of the interposition device used, satisfaction with outcome (mean±SD) was 72.2 ± 24.5 , and satisfaction with breasts was 59.3 ± 19.7 . Satisfaction was 70.2 ± 19.8 for psychosocial wellbeing, 65.2 ± 13.7 for physical wellbeing (chest), and 54.1 ± 21.2 for sexual wellbeing.

Since the sample size for all tests was $n > 30$, a normal distribution was assumed (16). Cohen's *d* is reported as the effect size measure (17). Figure 1 shows the respective mean values of postoperative satisfaction in the question categories satisfaction with outcome, satisfaction with breasts, psychosocial wellbeing, sexual wellbeing, and physical wellbeing (chest).

Table I. Overview of the current literature regarding patient satisfaction after breast reconstruction using different materials.

Author (Ref)	Gschwantler-Kaulich <i>et al.</i> (8)	Eichler <i>et al.</i> (9)	Dieterich <i>et al.</i> (10)	Thill <i>et al.</i> (11)	Headon <i>et al.</i> (20)
Year	2016	2019	2015	2020	2016
Number of patients					
Total	48	320	90	269	118
Retrospective		x	x		x
Prospective	x			x	
Multicentre	x	x		x	
Monocentre			x		x
Age at surgery, years*					
Mean	48.6	TiLOOP®Bra: 48.8±13.5 SERAGYN®BR: 49.1±11.7	Range=35-72	49.3	50.1
Follow-up, months					
Mean	6	N/A	18	12	21
ADM					
Yes	x	x			x
Other	x	x			x
Synthetic mesh					
SERAGYN®BR		x			
TiLOOP®Bra	x	x	x	x	

ADM: Acellular dermal matrices, none of the studies used that of our study, Strattice™; N/A: not available. *With standard deviation where available.

Table II. Results of the Kruskal–Wallis test of question categories in relation to the interposition device used, including the implant.

	N	Mean±SD	H	df	p-Value
Satisfaction with outcome	117	72.2±24.5	2.289	2	0.318
Satisfaction with nipples	117	64.4±30.5	0.585	2	0.746
Satisfaction with information	116	68.3±20	4.643	2	0.098
Satisfaction with surgeon	114	88.4±16.3	1.813	2	0.404
Satisfaction with medical team	117	85.7±20.1	0.267	2	0.875
Satisfaction with office staff	117	88.4±17.4	1.514	2	0.469
Satisfaction with breasts	119	59.3±19.7	0.213	2	0.899
Psychosocial wellbeing	120	70.2±19.8	0.333	2	0.846
Sexual wellbeing	98	54.1±21.2	0.155	2	0.925
Physical wellbeing (chest)	118	65.2±13.7	2.077	2	0.354

There were no significant differences between patients treated more recently (<3 years) and patients treated longer ago in terms of postoperative satisfaction (satisfaction with breasts, $p=0.421$; psychosocial wellbeing, $p=0.437$; satisfaction with outcome, $p=0.561$; physical wellbeing [chest], $p=0.424$; and sexual wellbeing, $p=0.449$).

The following pairs of variables were tested for significant differences using the BreastQ questionnaire criteria by independent samples t -test: Patient age (<50 vs. ≥50 years), RT performed (yes vs. no, and adjuvant vs. neoadjuvant), surgical timing (primary vs. secondary), weight (BMI ≤24 kg/m² vs. >24 kg/m²), surgical technique (NSM vs. SSM), and whether the surgery was therapeutic or prophylactic. Equality of variances was first checked with Levene's test. Only for the

category sexual wellbeing was an inequality of variances found with respect to age, surgical technique, BMI, and prophylactic surgery with $p<0.05$, therefore significance was tested using the Mann–Whitney U -test in these cases. A significant difference between the prophylactic and therapeutic surgeries was found regarding physical wellbeing (chest) ($p=0.04$, $d=0.439$). Patients who had prophylactic surgery were more satisfied (mean±SD: 69.6±13.8) than those who had therapeutic surgery (63.7±13.3). A significant difference was also found between patients treated vs. those not treated with RT regarding satisfaction with the outcome of breast reconstruction ($p=0.005$, $d=0.735$). Patients who had not received RT were significantly more satisfied with the outcome (74.9±23.7) than those who had (57.4±23.0). A significant difference was also

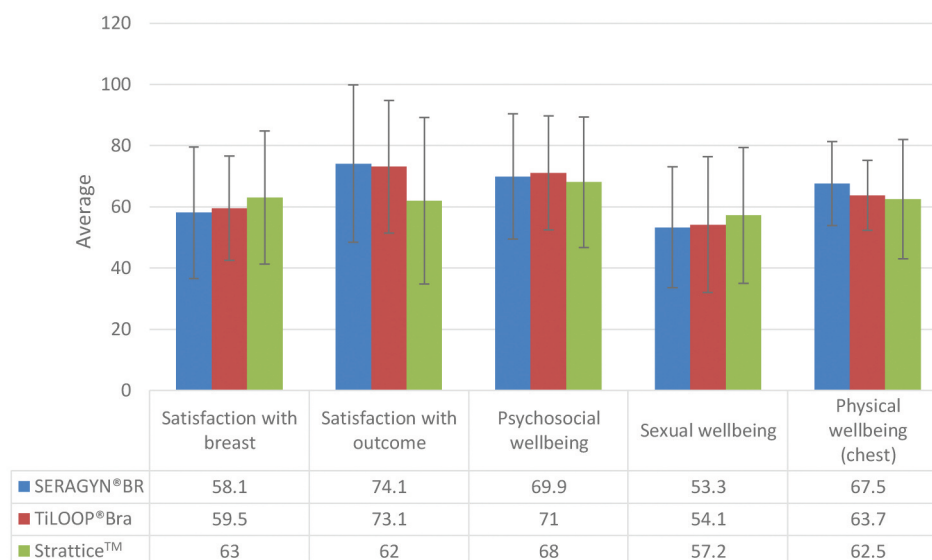


Figure 1. Comparison of the mean satisfaction values in the categories examined in relation to the interposition device used.

found regarding sexual wellbeing between the group of patients <50 years of age vs. older patients ($p=0.03$, $r=0.219$). On average, the younger group had better postoperative sexual wellbeing than older patients. None of the other calculations yielded statistically significant results. All results calculated regarding satisfaction with breast and satisfaction with outcome are presented in Table III. The results calculated regarding sexual wellbeing, physical wellbeing (chest) and psychosocial wellbeing can be found in Table IV.

Discussion

The comparison of the two groups of patients treated with titanium-coated polypropylene mesh (TiLOOP®Bra) or partially resorbable bicomponent mesh (SREAGYN®BR) was based on equally large and comparable groups with 55 patients (45%) and 52 patients (43%), respectively. Only 14 patients (12%) were treated with ADM, so this group was smaller by approximately 40 patients and thus potentially less comparable with the other groups.

The use of the different interposition devices was not associated with significant differences in any of the question categories of the BreastQ questionnaire. On average, postoperative satisfaction with breasts was rated between 58 and 63 in all patient groups. On the scale of 0 "very dissatisfied" to 100 "very satisfied" used here, these ratings indicated a good outcome of reconstructive therapy. Similar results have been obtained in other studies. Dieterich *et al.* found no significant differences in satisfaction with breasts between women who underwent heterologous breast

reconstruction alone vs. implant-supported heterologous reconstruction (18). Schmidt *et al.* found that some patients had difficulty integrating the reconstructed breast into their body image. In their study, those patients who attributed great importance to the female breast had significantly ($p=0.041$) reduced satisfaction with breasts after reconstruction (19). Headon *et al.* reported a high satisfaction with the outcome after reconstructive surgery using ADM (20).

Satisfaction with the breasts, with breast symmetry being of particular importance, is closely related to a patient's psychosocial wellbeing (21). In the question complex of psychosocial wellbeing, a postoperative satisfaction of approximately 70.2 ± 19.8 was found in the groups studied, indicating that the patients gained increased self-confidence and thus a high psychosocial wellbeing from the reconstruction. This result is consistent with the findings described in the current literature (22, 23). A study by Santosa *et al.* showed that patients had higher psychosocial wellbeing after reconstructive treatment than before reconstruction (22).

Sexual wellbeing represents another important category. Patients with breast cancer often experience psychological and sexual limitations, which can have a negative impact on their QoL. The most frequently observed problem, which occurred in 44.8% of women, was a sensation of pain during sex (24).

In our study, no significant influence of the interposition devices used on sexual wellbeing was found ($p=0.925$). Similar results were obtained in other studies. Ng *et al.* (25) and Howes *et al.* (26) showed that postoperative sexual wellbeing was higher in patients with breast reconstruction than in patients who underwent mastectomy without breast reconstruction.

Table III. Results of *t*-test (for independent samples, two-sided) of postoperative patient satisfaction in relation to age, body mass index (BMI), primary or secondary reconstruction, surgical technique, prophylactic or therapeutic intent, and radiotherapy (RT).

		Satisfaction with breasts				Satisfaction with outcome			
		N	Mean	Levene's test <i>p</i> -Value	<i>t</i> -Test <i>p</i> -Value	N	Mean	Levene's test <i>p</i> -Value	<i>t</i> -Test <i>p</i> -Value
BMI	≤24 kg/m ²	59	59.51	0.139	0.775	57	73.51	0.758	0.62
	>24 kg/m ²	57	58.46			57	71.23		
Surgery	NSM	65	61.18	0.514	0.265	64	73.80	0.403	0.454
	SSM	54	57.11			53	70.36		
Tumour	Primary	96	59.97	0.557	0.478	97	71.19	0.919	0.511
	Secondary	23	56.70			24	74.88		
Intent	Prophylactic	30	65.33	0.817	0.054	29	76.45	0.329	0.29
	Therapeutic	89	57.31			88	70.85		
RT	Yes	17	52.65	0.759	0.133	18	57.39	0.997	0.005
	No	102	60.45			99	74.94		
	Neoadjuvant	6	60.83	0.126	0.192	6	67.50	0.995	0.21
	Adjuvant	11	48.18			12	52.33		
Age at time of surgery	<50 Years	42	61.21	0.937	0.447	40	74.10	0.154	0.558
	≥50 Years	77	58.31			77	71.27		

NSM: Nipple-sparing mastectomy; SSM: skin-sparing mastectomy. Statistically significant *p*-values are shown in bold.

Table IV. Results of *t*-test (for independent samples, two-sided) and of postoperative patient wellbeing in relation to age, body mass index (BMI), primary or secondary reconstruction, surgical technique, prophylactic or therapeutic intent, and radiotherapy (RT) details.

		Sexual wellbeing				Physical wellbeing (chest)				Psychosocial wellbeing			
		N	Mean	Levene's test <i>p</i> -Value	<i>t</i> -Test <i>p</i> -Value	N	Mean	Levene's test <i>p</i> -Value	<i>t</i> -Test <i>p</i> -Value	N	Mean	Levene's test <i>p</i> -Value	<i>t</i> -Test <i>p</i> -Value
BMI	≤24 kg/m ²	52	57.62	0.003	0.189*	60	64.08	0.838	0.397	60	70.25	0.568	0.887
	>24 kg/m ²	43	49.65			55	66.27			57	69.72		
Surgery	NSM	57	56.86	0.001	0.373*	64	66.03	0.186	0.471	66	71.18	0.113	0.553
	SSM	41	50.34			54	64.19			54	69.00		
Tumour	Primary	79	54.92	0.59	0.458	94	66.26	0.173	0.095	96	69.82	0.474	0.68
	Secondary	19	50.84			24	61.00			24	71.71		
Intent	Prophylactic	27	61.11	0.041	0.109*	30	69.63	0.857	0.04	30	74.30	0.419	0.194
	Therapeutic	71	51.48			88	63.67			90	68.83		
RT	Yes	13	44.38	0.666	0.077	17	64.71	0.747	0.877	18	68.72	0.76	0.734
	No	85	55.62			101	65.27			102	70.46		
	Neoadjuvant	4	37.75	0.899	0.417	6	66.00	0.257	0.617	6	72.00	0.257	0.617
	Adjuvant	9	47.33			11	64.00			12	67.08		
Age	<50 Years	40	60.10	0.037	0.03*	40	67.63	0.73	0.169	41	74.20	0.774	0.114
	≥50 Years	58	50.02			78	63.94			79	68.13		

*Mann-Whitney *U*-test (for interposition device-independent data) due to unequal variances. Statistically significant *p*-values are shown in bold.

The introduction of foreign material into the body causes cell proliferation and fibrosis in the surrounding tissue as part of a foreign body reaction (27). A sheath is formed around the implant, which can acquire fibrosis and shrink as it progresses, leading to pain and deformity of the breast (27). Interposition devices attempt to counteract this. When

asked about postoperative physical wellbeing (chest), the mean satisfaction score was 69.6±13.7. This satisfaction score does not suggest that reconstruction may cause additional pain. No difference was found between the three groups studied in these sets of questions either (*p*=0.354). This suggests an increased general sense of wellbeing after

reconstructive surgery. Zhong *et al.* were able to show in their study that the self-image and consecutively self-confidence improved significantly after breast reconstruction compared with preoperative values (28). These values were in agreement with data reported by Eichler *et al.*, who already noted that there was no significant difference in postoperative complication rates between the interposition devices used (TiLOOP®Bra or SERAGYN®BR) (9).

Considering patient age, higher satisfaction was found in younger patients (<50 years) than in older patients (≥50 years) in all postoperative question categories examined. These differences were not significant except for sexual wellbeing ($p=0.03$, $r=0.219$). The results reported in the current literature are contradictory in this regard. Thill *et al.* had similar results with respect to sexual wellbeing, where patients aged ≤40 years of age at the time of reconstruction had higher scores in satisfaction with breasts and sexual wellbeing (11). However, in a study by Mundy *et al.* (29), patients under 40 years of age had lower scores in the question categories of psychosocial wellbeing, sexual wellbeing, and physical wellbeing (chest). Santosa *et al.* also found that older patients had higher satisfaction scores in sexual wellbeing after a 2-year follow-up. However, there was no effect of age on physical and psychosocial wellbeing (30).

Another significant result of our study was the difference in satisfaction with outcome in relation to RT ($p=0.005$, $d=0.735$). Those patients who received RT, regardless of whether it was administered before or after surgery, showed significantly lower satisfaction with outcome (mean±SD: 57.4 ± 23.0) than those who did not (mean±SD: 74.9 ± 23.7). A higher mean score was also found in all of the other question categories for patients who did not receive RT vs. those who did. Ohlinger *et al.* have already shown that RT leads to a higher postoperative complication rate, thus a lower patient satisfaction is to be expected (12).

Considering a possible influence of the timing of RT on postoperative satisfaction, no statistically significant result was obtained. However, it is evident from the higher mean values that neoadjuvant therapy leads to higher postoperative satisfaction in the physical and psychological aspects after breast reconstruction than adjuvant therapy. Previous studies had similar results, showing that adjuvant RT leads to lower postoperative satisfaction than neoadjuvant RT (11, 31, 32).

Finally, a significant difference ($p=0.04$, $d=0.439$) was found in postoperative physical wellbeing in relation to the breast between patients who had the surgery performed prophylactically and those treated therapeutically. With a mean value of 69.6 ± 13.8 , the prophylactically treated patients were 6 points more satisfied than those who were treated therapeutically (mean±SD: 63.6 ± 13.3). Prophylactically treated patients also had a higher average satisfaction in the remaining question categories examined, although the differences were not statistically significant. The decision to

have prophylactic mastectomy is difficult. Patients undergoing such surgery for prophylactic reasons usually have a high psychosocial burden, either due to an existing BRCA mutation or pronounced carcinophobia. Van Oostrom *et al.* studied the anxiety of mutation carriers over 5 years after testing and showed an increase in anxiety and depression during this period (33). It can be concluded that mastectomy can significantly alleviate carcinophobia and consequently lead to higher postoperative satisfaction. Similar results have already been obtained in previous studies. Postoperative satisfaction was as high as 97% (34, 35).

Considering the effect of the surgical technique, it was found that patients who were treated with NSM showed higher satisfaction in all question categories than those who were treated with SSM. However, these differences were not statistically significant ($p>0.05$ in all categories). Since the loss of the nipple has a great psychological impact (36), these results can be explained by the fact that the patients who underwent NSM never had to experience this loss, leading to higher satisfaction in the psychological aspects investigated. These results are in accordance with the current literature. Metcalfe *et al.* showed that patients treated with NSM had significantly higher satisfaction with breasts, satisfaction with outcome, and sexual wellbeing than patients treated with SSM (37).

Furthermore, we found that normal-weight patients (BMI ≤24 kg/m²) had higher satisfaction in all question categories than overweight patients (BMI >24 kg/m²), although these observations were not statistically significant. Similar data were reported in previous studies. Thill *et al.* found that patients with BMI ≤25 kg/m² scored higher in the following categories: satisfaction with breasts, psychosocial wellbeing, and sexual wellbeing (11). Similarly, a study by Mundy *et al.* showed that women with a BMI ≥30 kg/m² scored lower in the following question categories: satisfaction with breasts, psychosocial wellbeing, sexual wellbeing, and physical wellbeing (chest) (29).

A study by Zhong *et al.* demonstrated that patients who underwent secondary breast reconstruction had lower satisfaction with breasts, sexual wellbeing, and body image before the reconstructive surgery. After primary breast reconstruction and after a follow-up of 18 months following secondary breast reconstruction, the scores improved in all categories mentioned (28). Hence, their study demonstrated that primary breast reconstruction achieved higher satisfaction and QoL than secondary breast reconstruction. In our study, patients who underwent primary reconstruction achieved higher mean scores in the categories of satisfaction with breast, sexual wellbeing, and physical wellbeing (chest) than patients who underwent secondary reconstruction.

In our study, it was shown that the titanium-coated polypropylene mesh TiLOOP®Bra, the partially absorbable bicomponent mesh SERAGYN®BR, and the acellular

porcine dermis Strattice™ were suitable for supporting heterologous reconstruction of a breast damaged by a breast carcinoma and led to a satisfactory QoL for the patients. The choice of the interposition device did not result in significant differences in postoperative satisfaction and QoL. An ancillary finding was an overall better QoL in younger and normal-weight patients with prophylactic mastectomy or NSM without RT. Prospective standardized multicentre studies should be initiated in the future to confirm the results of this study.

Conflicts of Interest

Patricia Fröhlich, Florian Nawroth, Katharina Schuler, Zaher Alwafai, Marek Zygmunt: have no conflicts of interest to disclose. Stefan Paepke: Consultant of PFM Medical AG, Cologne, Germany; Novusscientific, Sweden; Triconmed, Germany; Sysmex, Germany; Sysmex, Europe; Neodynamics, Sweden; MBN, Germany; Invitrocue Europe GmbH; Dynamesh, Germany; Scientific grants: RTI Surgical; PFM Medical AG; Novusscientific, Sweden; AG, Germany; GBG, Germany; Support of workshops: Roche, Grenzach – Whylen; Sysmex, Germany; Philips GmbH; Triconmed, Germany; in the past: Consultant of Serag Wiessner AG (<5 years); Consultant of KCI (>3 years); DZIG, Berlin (<5 years); Allergan (>3 years). Ralf Ohlinger: Consultant and support of workshops of PFM Medical AG, Cologne; Serag Wiessner AG, and KCI in the past.

Authors' Contributions

Marek Zygmunt planned the study and edited the paper. Ralf Ohlinger planned the study, recruited the patients, performed the surgery, wrote and edited the manuscript and supervised the project. Patricia Fröhlich recruited the patients, performed the analytic calculations and wrote and edited the manuscript. Stefan Paepke analysed the Data, wrote and edited the manuscript. Katharina Schuler recruited the patients and edited the manuscript. Zaher Alwafai helped gain approval by the Ethics Committee of the University of Greifswald. Florian Nawroth helped gain approval by the Ethics Committee of the University of Greifswald and edited the manuscript.

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Received April 7, 2021

Revised April 21, 2021

Accepted April 29, 2021