Patient-Reported Outcomes in Implant-Based Breast Reconstruction Alone or in Combination with a Titanium-Coated Polypropylene Mesh – A Detailed Analysis of the BREAST-Q and Overview of the Literature

Patienteneinschätzung und Zufriedenheit (Patient-Reported Outcomes) nach implantatgestützter Brustrekonstruktion alleine oder in Kombination mit einem titanbeschichteten Polypropylene-Netz – eine detaillierte Analyse des BREAST-Q und Literaturüberblick

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Key words
- breast reconstruction
- mesh
- quality of life
- TiLOOP® Bra
- BREAST-Q
- patient-reported outcome

Schlüsselwörter
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- Netz
- Lebensqualität
- TiLOOP® Bra
- BREAST-Q
- Patientenzufriedenheit

Abstract

Background: Complication rates and surgical outcomes are well reported for implant-based breast reconstruction (IBBR) using supportive materials for the inferior pole of the breast. Patient-reported outcomes (PRO) are underrepresented. The aim of this study was to compare PRO in IBBR using implants alone or in combination with a synthetic mesh.

Methods and Methods: PRO was measured in patients undergoing IBBR alone or in combination with a titanium-covered polypropylene mesh (TiLOOP® Bra). In this non-randomized observational trial PRO was retrospectively assessed using the validated self-reporting BREAST-Q. The raw responses of all questions applied in each domain and transformed BREAST-Q data using the Q-Score are presented.

Results: Of 90 eligible women, 42 received IBBR alone and 48 received IBBR in combination with mesh. No differences in complication rates were observed. The return rate was 67.7% and was comparable between the groups (p = 0.117). PRO revealed no differences regarding satisfaction with breast shape (p = 0.079), outcome (p = 0.604), nipple sensitivity (p = 0.502), preoperative information (p = 0.195), office staff (p = 0.462), psychosocial well-being (p = 0.370), sexual well-being (p = 0.508) and physical well-being (p = 0.654). Significant differences were noted regarding satisfaction with the surgeon (p = 0.013) and medical staff (p = 0.035) as well as the response behavior of certain questions of the sub-domains, thus helping to further stratify PRO with regards to aesthetic outcome. However, no differences were observed in the main BREAST-Q results.

Conclusion: Use of the TiLOOP® Bra in IBBR results in comparable BREAST-Q scores compared with IBBR alone. Evaluating the BREAST-Q subdomains helps to stratify PRO more profoundly

Zusammenfassung

Hintergrund: Studien zur Patienteneinschätzung und Zufriedenheit (Patient-Reported Outcomes [PRO]) sind im Rahmen der implantatgestützten Brustrekonstruktion (BR) mit Materialien zur Stabilisierung des unteren Brustpols unterrepräsentiert. Ziel dieser Arbeit war der Vergleich von PRO in der implantatgestützten BR mit oder ohne Anwendung eines synthetischen Netzes.

Material und Methoden: PRO wurde bei Patientinnen mit implantatgestützten BR alleine oder in Kombination mit einem titanbeschichteten Polypropylene-Netz (TiLOOP® Bra) untersucht. Mithilfe des selbstberichtenden BREAST-Q-Fragebogens wurde in dieser nicht randomisierten Beobachtungsstudie PRO restrospektiv ausgewertet. Rohscores aller Fragen der einzelnen Subdomains und die mit dem Q-Score transformierten BREAST-Q-Daten werden präsentiert.

Ergebnisse: Von 90 Patientinnen erhielten 42 eine BR mit Implantaten alleine und 48 eine Implantatrekonstruktion mit Netz. Kein Unterschied in der Komplikationsrate wurde beobachtet. Die Rücklaufquote des Fragebogens lag bei 67,7% und war zwischen den Gruppen vergleichbar (p = 0,117). PRO zeigte keine Unterschiede bez. Brustform (p = 0,079), Ergebnis (p = 0,604), Sensitivität des Nippels (p = 0,502), präoperativer Aufklärung (p = 0,195), Praxispersonal (p = 0,462), psychosozialer Zufriedenheit (p = 0,370), sexueller Zufriedenheit (p = 0,508) und physischer Zufriedenheit (p = 0,654). Signifikante Unterschiede zeigen sich bei Zufriedenheit mit Operateur (p = 0,013), medizinischem Personal (p = 0,035) sowie im Antwortverhalten bestimmter Fragen der Subdomains hilfreich, um PRO im Hinblick auf das ästhetische Ergebnis weiter zu stratifizieren.

Zusammenfassung: Die Verwendung von TiLOOP® Bra in der implantatgestützten BR resultiert in vergleichbaren BREAST-Q Ergebnissen im Vergleich zur BR mit Implantaten allein. Die Unter-

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and assists in interpreting the overall results and specific research questions.

suchung der Subdomains hilft, PRO weiter zu stratifizieren, und ist nützlich in der Interpretation der Gesamtergebnisse und spezifischer Forschungsfragen.

Background

Breast cancer (BC) is the leading cancer in women with nearly 75 000 and 234 000 new diagnoses in Germany and the U.S.A., respectively [1]. In addition to the fear of this life-changing diagnosis, women are concerned about disfiguring surgical procedures. Although it is possible to treat 70% of all BC patients with breast conserving surgery (BCS), mastectomy is indicated in the remaining 30% of patients [2]. To overcome the psychosocial and emotional distress after mastectomy, immediate breast reconstruction (IBR) can be offered to affected patients. Thus, the burden of waking up after surgery with a breast missing can be avoided as concerns regarding disfiguration and appearance following mastectomy are central fears of BC patients [3]. Silicone implants are used in approximately 70 to 80% of IBR procedures, and autologous procedures are performed in the remainder of cases [4]. Silicone breast implants have improved over the past years, and new medical products were introduced in implant-based breast reconstruction (IBBR) to improve the surgical outcome [5,6]. Acellular dermal matrices (ADM) and synthetic meshes are increasingly used in IBBR to support the lower pole of the breast and define the inframammary fold [4]. These supportive products are discussed controversially, and complication rates range from 3.2 to 45.7% [7,8]. How these differences in complication rates affect women's health-related quality of life (HR-QoL) when undergoing IBBR with or without supportive materials remains an unanswered question. Studies related to HR-QoL are underrepresented in reconstructive breast surgery, especially when using ADMs or meshes, and need to be investigated. Questions on the impact of daily life regarding personal, social and sexual relationships are important to women and must be addressed [9]. Comparative studies addressing these research questions are rare despite the fact that these materials are widely used. The BREAST-Q questionnaire gained more and more acceptance over the past years in evaluating HR-QoL in breast cancer patients undergoing different procedures of breast reconstruction [10].

Using the BREAST-Q questionnaire, it is possible to compare reconstructive results directly with other surgical procedures. The aim of this study was to investigate patient-reported outcome (PRO) in patients undergoing IBBR alone or in combination with a synthetic mesh widely used in Europe [11,12]. Additionally, the BREAST-Q was evaluated question by question to identify for differences within the sub-domains of each scale and to further stratify and interpret our results. The identification of complication rates were secondary study aims.

Patient and Methods

Study population

A retrospective single institute observational study and PRO using the BREAST-Q postoperative reconstruction module was performed. Patients with immediate IBBR undergoing skin-sparing (SSM) or nipple-sparing mastectomy (NSM) with silicone implants alone or in combination with titanium-coated polypropylene mesh (TiLOOP® Bra, pfm medical, Cologne, Germany) were included. The study was approved by the local ethics committee (registration number: A 2012-0093) and conformed to the Helsinki Declaration.

Study information, the patients' informed consent forms and BREAST-Q were submitted by mail, and a stamped addressed envelope was provided to return to the questionnaire. Nonresponders were contacted a second time three months after the first mailing to increase the return rate. Patient demographics were registered by a retrospective chart review. Certified breast surgeons from the Working Group for Plastic, Aesthetic and Reconstructive Surgery in Gynecology (AWOgyn) performed all of the surgeries [13]. Follow-up was provided for at least four weeks as required by the standard definition of surgical site infections by the Centers of Disease Control and Prevention and the National Nosocomial Infection Surveillance System [14]. Mean follow-up was defined as the interval from reconstruction to answering the questionnaire.

TiLOOP® Bra

TILOOP® Bra is a synthetic mesh that is approved for IBBR in Europe given its CE (Conformité Européenne) marking, which is the manufacturer's declaration that the product meets the requirements of applicable European Community directives. Its use has previously been described and therefore will not be described in detail here [11,12].

BREAST-Q

The BREAST-Q is a validated PRO instrument to measure HR-QoL that meets international standards [15]. It is an accepted questionnaire to compare PRO from various types of reconstructive breast surgery. The postoperative reconstruction module consists of 116 questions, which are separated into two themes:

1. Patient Satisfaction and
2. Health-related Quality of Life.

Satisfaction domains include satisfaction with breast, satisfaction with nipple, satisfaction with abdomen, satisfaction with outcome, and satisfaction with care. Quality of life domains include psychosocial, sexual, and physical well-being (chest and upper body, abdomen and trunk). The patients' responses to each scale's items were transformed using the Q-Score scoring software, which converts raw survey scores from 1 through 3 or 5 to continuous scores, thus generating a total score ranging from 0 to 100. A higher score indicates increased satisfaction or HR-QoL. The evaluation of the abdomen and trunk was omitted given that it was not applicable to IBBR. The German BREAST-Q reconstruction module (postoperative) was validated and applied in accordance with the agreement with the MAPI Trust (http://www.mapi-trust.org/).

Surgical technique

In general, all patients were evaluated for autologous or alloplastic BR based on patient preference, body habitus, co-morbidities, prior abdominal surgery, etc. Immediate heterologous BR with silicone implants was performed in standard fashion using an inverted-T horizontal skin reduction pattern in all patients. All implants were placed in a retropectoral pocket. Prior to IBBR, all patients were informed about the possible intraoperative use of this

mesh. The surgical technique and patient selection using this mesh has previously been described in detail [11, 12]. All patients received in-breast drainage and antibiotic prophylaxis for three days.

Complications

Complications were evaluated regardless of follow-up with a minimal follow-up requirement of 4 weeks. Capsular contraction was evaluated separately as an additional event.

Study aims

The primary study endpoint was the comparison of quality-of-life outcomes between patients undergoing IBBR alone or in combination with mesh.

Statistical analysis

Statistical analyses were performed using IBM® SPSS® 19.0. Categorical variables were assessed using the Pearson's chi-square test or Fisher's exact test when applicable. The Kolmogorov-Smirnov test was performed to test for normal distribution of continuous variables. The student's t-test or Mann-Whitney U-test was used for variable with a normal or non-normal distribution, respectively, to compare changes in mean scores. A p-value < 0.05 was considered significant.

Results

During the study period from January 2006 and January 2013, 90 patients underwent IBBR. Of these patients, 42 patients were subject to heterologous BR alone, and 48 patients received BR in combination with a mesh.

Patient characteristics

The overall return rate of the BREAST-Q was 67.7% (61 of 90), with 64.3% (n = 27) of patients in the IBBR alone group and 70.8% (n = 34) of patients in the mesh group (p = 0.117) being evaluated. The mean follow-up was comparable in both groups at 18.0 (range 1–40) and 17.5 (range 1–83) months, respectively (p = 0.827). Patients in the mesh group exhibited a decreased body mass index (p = 0.003; **Table 1**). Patients with IBBR alone had increased mastectomy specimen weights (p = 0.012, **Table 1**) and implant volumes (p = 0.042). An additional inferior dermal flap was more frequently dissected in the IBBR alone group (p = 0.005). Nipple-sparing mastectomy was increasingly performed in the mesh group (p = 0.057). Two patient examples are presented in **Figs. 1** and **2**.

Complication rates

The complication rate of the complete collective of 90 patients was 21.1%. For patients who returned the questionnaires, complications occurred in 25.9% (n = 7) of patients in the IBBR alone group and in 8.8% (n = 3) of patients in the mesh group (p = 0.075). No differences regarding seroma formation, skin infections, wound dehiscent or hematoma rate were observed. No difference in capsular contraction rate was observed between the groups (p = 0.390). Capsular contraction occurred in 11.1% (n = 3) of patients in the IBBR group. Two patients had postoperative radiotherapy and capsular contraction occurred 6 and 9 months later. The third patient developed capsular contraction 6 months after surgery and was correlated with a persistent seroma formation. In the mesh group 5.9% (n = 2) of patients developed a cap-

Table 1 Patient characteristics and surgical details.

	Implant reconstruction with mesh (n = 34)	Implant reconstruction alone (n = 27)	p-value
Mean age (in years)*	49.4 ± 8.4 (range 35–67)	52.8 ± 9.4 (range 35–72)	0.151†
Mean BMI (kg/m²)*	22.9 ± 2.8 (range 17.5–28.2)	25.5 ± 3.4 (range 19.1–31.8)	0.003†
Weight mastectomy specimen (g)*	240.9 ± 136.6 (range 100–609)	398.9 ± 229.2 (range 120–1 000)	0.012§
Volume implant (ml)*	225.4 ± 72.6 (range 135–475)	268.1 ± 82.8 (range 120–495)	0.042†
Smoking			0.743□
▸ Yes	10	9	
▸ No	24	18	
Tumor stage[T]			0.169□
▸ pT0	14	6	
▸ pT1	16	14	
▸ pT2	3	6	
General nodal status[T]			0.689[X]
▸ N negative	30	24	
▸ N positive	4	2	
Chemotherapy			0.615□
▸ None	23	14	
▸ Adjuvant	8	9	
▸ Neoadjuvant	1	2	
▸ In history	2	2	
Surgical Indication			0.916□
▸ Primary oncologic case	31	25	
▸ Local recurrence	1	1	
▸ Prophylactic mastectomy	2	1	
Previous surgeries			0.533□
▸ None	8	8	
▸ BCT	4	4	
▸ SLNB alone	7	7	
▸ BCT + SLNB/ALND	15/0	7/1	
Radiotherapy			0.405□
▸ None	30	21	
▸ After surgery	1	3	
▸ Before surgery	3	3	
Additional dermal flap			0.005□
▸ Yes	7	15	
▸ No	27	12	
Lymph node surgery during reconstruction			0.013□
▸ None	25	17	
▸ SLNB	9	4	
▸ ALND	0	6	
Reconstructive timing			0.646[X]
▸ Primary reconstruction	32	24	
▸ Delayed immediate reconstruction	2	3	
Type of reconstruction			0.057[X]
▸ SSM	24	25	
▸ NSM	10	2	

* Data are provided as the mean ± SD. † Student's t-test used to compare means of groups. § Mann-Whitney U test. □ Pearson's chi-squared test. [X] Fisher's Exact test. BMI: body mass index; CHT: chemotherapy; BCT: breast conserving therapy; SLNB: sentinel lymph node biopsy; ALND: axillary lymph node dissection; LN: lymph node; SSM: skin-sparing mastectomy; NSM: nipple-sparing mastectomy. [T] data not available for all patients

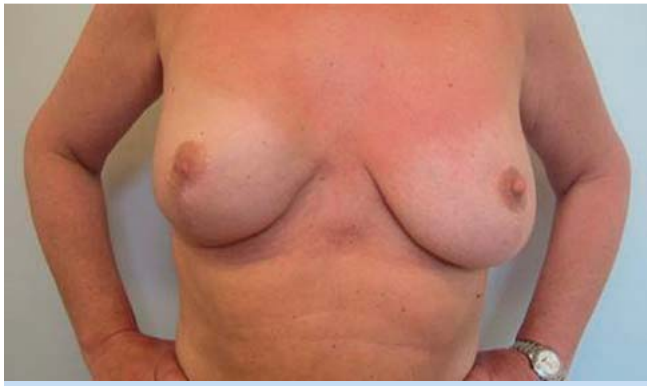

Fig. 1 Patient with invasive breast cancer of the right side, four years after nipple-sparing mastectomy without mesh.

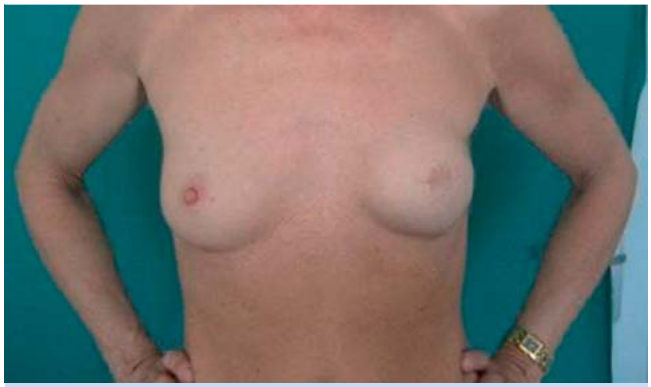

Fig. 2 Patient with invasive breast cancer of the left side, four years after skin-sparing mastectomy with mesh reconstruction.

Table 2 Mean BREAST-Q scores of patients undergoing heterologous breast reconstruction alone or in combination with mesh.

BREAST-Q domain	No. completed	Mean score (range 0–100)	SD	Difference of SD between groups	p-value
Satisfaction with breasts					0.079§
▸ Implant alone	27	60.6 (41–85)	11.4		
▸ Implant with mesh	34	54.2 (25–100)	16.5		
				5.1	
Satisfaction with outcome					0.604§
▸ Implant alone	25	75.4 (27–100)	18.2		
▸ Implant with mesh	34	72.4 (21–100)	22.7		
				4.5	
Psychosocial well-being					0.370§
▸ Implant alone	27	71.3 (41–100)	15.9		
▸ Implant with mesh	34	68.1 (34–100)	21.9		
				6.0	
Sexual well-being					0.508§
▸ Implant alone	20	54.5 (16–100)	20.2		
▸ Implant with mesh	28	52.4 (34–100)	22.9		
				2.7	
Physical well-being: chest					0.654§
▸ Implant alone	27	64.5 (43–100)	14.7		
▸ Implant with mesh	33	65.7 (50–100)	12.1		
				2.6	
Satisfaction with nipples					0.502§
▸ Implant alone	10	55.7(0–100)	37.8		
▸ Implant with mesh	8	69.4 (0–100	33.1		
				4.7	
Satisfaction with information					0.195§
▸ Implant alone	27	69.8 (22–100)	20.1		
▸ Implant with mesh	34	64.1 (19–100)	19.3		
				0.8	
Satisfaction with surgeon					0.013X
▸ Implant alone	27	91.3 (58–100)	13.1		
▸ Implant with mesh	33	78.5 (19–100)	22.2		
				9.1	
Satisfaction with medical staff					0.035X
▸ Implant alone	27	91.7 (59–100)	14.0		
▸ Implant with mesh	34	82.5 (28–100)	19.5		
				5.5	
Satisfaction with office staff					0.462X
▸ Implant alone	26	89.6 (45–100)	17.7		
▸ Implant with mesh	34	87.0 (38–100)	18.9		
				1.2	

SD: standard deviation

§ Mann-Whitney U test was used for data lacking a normal distribution

X Student's t-test was used for normally distributed data

Table 3 Detailed analysis of the BREAST-Q domains regarding satisfaction of breast, nipple and outcome for patients undergoing heterologous breast reconstruction alone or in combination with mesh.

BREAST-Q domain	BR with implant alone (n = 27)			BR using mesh (n = 34)			
	n	Mean score	SD	n	Mean score	SD	p-value
Domain-specific questions							
Satisfaction with breasts (answers range from 1 to 4 points)							
▶ How you look in the mirror clothed	27	3.67	0.480	34	3.29	0.906	0.135§
▶ The shape of your reconstructed breast when you are wearing a bra	27	3.56	0.577	33	3.36	0.822	0.485§
▶ How normal you feel in your clothes	27	3.56	0.641	34	3.44	0.746	0.577§
▶ The size of your reconstructed breast	26	3.54	0.647	33	3.09	1.042	0.121§
▶ Being able to wear clothing that is more fitted	27	3.19	0.786	34	3.18	0.968	0.785§
▶ How your breasts are lined up in relation to each other	27	3.11	0.698	34	2.56	1.106	**0.044§**
▶ How comfortably your breasts fit	26	3.19	0.895	33	3.00	1.031	0.521§
▶ The softness of your reconstructed breast	27	2.85	0.864	34	2.59	0.892	0.290§
▶ How equal in size your breasts are to each other	27	2.78	0.934	34	2.56	1.050	0.425§
▶ How natural your reconstructed breast looks	27	2.96	0.706	33	2.67	0.890	0.237§
▶ How naturally your reconstructed breast sits/hangs	27	3.07	0.730	34	2.79	0.946	0.260§
▶ How your reconstructed breasts feels to the touch	27	2.81	0.834	33	2.39	0.966	0.101§
▶ How much your reconstructed breast feels like a natural part of your body	27	2.59	0.694	33	2.15	0.906	**0.046§**
▶ How closely matched your breasts are to each other	26	2.58	0.945	34	2.18	0.869	0.090§
▶ How your reconstructed breast looks now compared to before you had any breast surgery	26	2.96	0.916	30	2.53	1.008	0.102§
▶ How you look in the mirror unclothed	27	2.44	0.751	34	2.21	0.946	0.193§
Satisfaction with nipple reconstruction (answers range from 1 to 4 points)[Y]							
▶ The shape of the reconstructed nipple	10	2.90	1.197	7	3.43	0.787	0.290[X]
▶ How your reconstructed nipple and areola look	10	2.70	1.252	7	3.57	0.535	0.072[X]
▶ How natural your reconstructed nipple looks	10	2.70	1.252	7	3.71	0.488	**0.038[X]**
▶ The color of your reconstructed nipple/areola complex	9	2.56	1.424	7	3.43	0.535	0.119[X]
▶ The height (projection) of your reconstructed nipple	10	2.40	1.174	7	3.29	0.756	0.078[X]
Satisfaction with outcome (answers range from 1 to 4 points)							
(Questions about BR using implants)							
▶ The amount of rippling (wrinkling) of your implant that you can see	25	3.28	0.792	34	3.03	1.029	0.431§
▶ The amount of rippling (wrinkling) of your implant that you can feel	26	3.19	0.895	34	3.09	0.996	0.755§
Satisfaction with outcome (answers range from 1 to 3 points)							
(Questions about satisfaction with the breast reconstructive surgery)							
▶ Having reconstruction is much better than the alternative of having no breast.	25	2.88	0.440	34	2.85	0.500	0.899§
▶ I would encourage other women in my situation to have breast reconstructive surgery.	25	2.80	0.577	34	2.85	0.436	0.924§
▶ I would do it again.	25	2.88	0.440	34	2.79	0.592	0.619§
▶ I have no regrets about having the surgery.	25	2.92	0.400	34	2.79	0.592	0.302§
▶ Having this surgery changed my life for the better.	25	2.56	0.651	32	2.47	0.803	0.857§
▶ The outcome perfectly matched my expectations.	25	2.28	0.542	34	2.09	0.712	0.314§
▶ It turned out exactly as I have planned.	25	2.20	0.500	34	2.09	0.712	0.582§

BR: breast reconstruction; n = number completed; SD: standard deviation

[Y] if applicable after nipple-sparing mastectomy

§ Mann-Whitney U test was used for data lacking a normal distribution

[X] Student's t-test was used for normally distributed data

sular contraction. One patient had postoperative radiotherapy and capsular contraction was observed 5 months later. The second capsular contraction was seen about 5 months after initial surgery. Mesh removal was necessary in the patient after radiotherapy.

BREAST-Q results

The time from surgery to completion of the BREAST-Q correlated with the follow-up data. The results of the corresponding BREAST-Q domains are presented in **Table 2**. In both groups mean "satisfaction with breast" scores were considerably reduced compared with the "satisfaction with outcome" scores. The lowest mean scores were observed for "sexual well-being". No differences were observed for items regarding aesthetic outcome after surgery. A tendency towards increased content regarding "satisfaction with breast" was observed in the IBBR alone group (60.6 vs. 54.2; p = 0.079). Patients in the mesh group were significantly less satisfied with regard to "satisfaction with surgeon" (p = 0.013) and "satisfaction with medical staff" (p = 0.035). A detailed question-by-question analysis of each BREAST-Q domain revealed only few items that significantly differed within the subgroups. A detailed analysis of "satisfaction with breast and nipple" revealed three questions with statistically significant differences (**Table 3**). Patients with implants alone had higher scores regarding "how breasts are lined up in relation to each other" (p = 0.044) and "how the reconstructed breast feels like a natural part of the body" (p = 0.046). Patients in the mesh group exhibited higher scores of satisfaction for "natural look of nipple"

Table 4 Detailed analysis of the BREAST-Q domain "psycho-social environment, sexuality and physical restrictions" of patients undergoing heterologous breast reconstruction alone or in combination with mesh.

	BR with implant alone (n = 27)			BR using mesh (n = 34)			
BREAST-Q domain	**n**	**Mean score**	**SD**	**n**	**Mean score**	**SD**	**p-value**
Domain-specific questions							
Psychosocial environment (answers from 1 to 5 points)							
▶ Confident in a social setting?	27	4.41	0.694	34	4.06	0.983	0.199§
▶ Emotionally able to do things that you want to do?	27	4.30	0.775	34	4.06	1.013	0.462§
▶ Emotionally healthy?	27	4.19	0.879	34	4.03	1.058	0.704§
▶ Of equal worth to other women?	27	4.15	1.099	34	3.94	1.205	0.490§
▶ Self-confident?	27	4.44	0.641	34	4.06	0.983	0.155§
▶ Feminine in your clothes?	27	4.44	0.641	34	4.32	0.843	0.760§
▶ Accepting of your body?	27	4.00	0.920	34	3.91	1.083	0.890§
▶ Normal?	27	4.22	0.641	34	3.79	1.225	0.300§
▶ Like other women?	26	4.08	0.796	34	3.68	1.296	0.419§
▶ Attractive?	26	3.88	0.864	34	3.62	1.129	0.395§
Sexuality (answers from 1 to 5 points and n. a.)							
▶ Sexually attractive in your clothes?	19	3.95	0.848	28	3.68	1.156	0.537§
▶ Comfortable/at ease during sexual activity?	19	3.26	1.240	28	3.14	1.353	0.755X
▶ Confident sexually?	19	3.26	1.195	28	3.14	1.407	0.754X
▶ Satisfied with your sex life?	19	3.53	1.219	28	3.15	1.167	0.233§
▶ Confident sexually about how your breast looks when unclosed?	19	2.89	1.197	28	2.86	1.297	0.876§
▶ Sexually attractive when unclosed?	19	2.68	1.108	28	2.79	1.287	0.806§
Physical restrictions (answers from 1 to 5 points)							
▶ Neck pain?	27	2.41	1.248	33	2.82	1.103	0.163§
▶ Upper back pain?	27	2.59	1.448	33	2.64	1.025	0.760§
▶ Shoulder pain?	27	2.56	1.311	33	2.67	1.242	0.334X
▶ Arm pain?	27	2.67	1.301	33	2.33	1.021	0.325§
▶ Rib pain?	27	1.89	1.086	33	1.55	0.711	0.341§
▶ Pain in the muscle of your chest?	27	2.52	1.221	33	2.52	1.093	0.969§
▶ Difficulty lifting or moving your arms?	27	2.52	1.369	33	2.18	1.261	0.342§
▶ Difficulty sleeping because of discomfort in your breast area?	26	2.23	0.992	33	1.94	1.088	0.234§
▶ Tightness in your breast area?	26	1.96	1.183	33	1.79	0.960	0.697§
▶ Pulling in your breast area?	26	2.50	0.860	32	2.59	1.043	0.699§
▶ Nagging feeling in your breast area?	27	2.56	1.188	33	2.48	1.121	0.945§
▶ Tenderness in your breast area?	27	2.52	1.369	33	2.61	1.223	0.788§
▶ Sharp pain in your breast area?	27	1.74	0.903	33	1.55	0.794	0.396§
▶ Shooting pain in your breast area?	27	1.96	0.980	33	1.67	0.692	0.289§
▶ Aching feeling in your breast area?	26	1.92	1.017	33	1.67	0.777	0.413§
▶ Throbbing feeling in your breast area?	27	1.44	0.698	33	1.24	0.502	0.249§

BR: breast reconstruction; n = number completed; SD: standard deviation

§ Mann-Whitney U test was used for not normally distributed data

X t-test was used for normally distributeddata

after reconstruction (p = 0.038). No differences were observed regarding "satisfaction with outcome" (**Table 3**). The same response behavior was observed for psychosocial environment, sexuality and physical restrictions (**Table 4**). **Table 5** describes deviations of the domain-specific answers of patients regarding "information received from reconstructive surgeon" and "opinion of reconstructive surgeon". In both domains, a high number of significantly different answers were observed. In addition, the final BREAST-Q score revealed significant differences for "satisfaction with surgeon" (p = 0.013, **Table 2**). Domain-specific questions on "opinion of medical team other than surgeon" demonstrated decreased satisfaction patterns for patients in the mesh group for the sub-domains "made me feel comfortable" (p = 0.032, **Table 5**) and "time for my concerns" (p = 0.003).

Discussion

This study is one of the few to directly compare PRO in heterologous BR using a supportive mesh to support the lower pole of the breast. In the presented collective, we observed BREAST-Q scores comparable to other surgical procedures in IBBR, and scores for the mesh group were generally lower (**Table 6**). A detailed analysis of the BREAST-Q was useful to gain additional information regarding our specific research questions.

Although no differences were observed regarding "satisfaction for breast" within the two groups, answers to three questions on the questionnaire were significantly different. Specifically, "how the reconstructed breast feels like a natural part of the body" was of particular interest for our study population. The different raw scores for this specific question might be attributed to the fact that the mesh is more palpable in the skin than initially expected. The feel of the implant alone without mesh might provide a bet-

Table 5 Detailed analysis of the BREAST-Q domain "information/opinion from/of reconstructive surgeon and opinion of the medical team and about office staff" of patients undergoing heterologous breast reconstruction alone or in combination with mesh.

BREAST-Q domain	BR with Implant alone (n = 27)			BR using mesh (n = 34)			
	n	Mean score	SD	n	Mean score	SD	p-value
Domain-specific questions							
Information received from reconstructive surgeon (answers from 1 to 4 points)							
▶ How the breast reconstruction surgery was to be done?	27	3.52	0.893	34	3.44	0.786	0.437§
▶ Healing and recovery time?	27	3.37	0.839	33	3.12	0.960	0.313§
▶ Possible complications?	27	3.44	0.801	33	3.21	0.893	0.294§
▶ The options you were given regarding the types of breast reconstruction?	27	3.30	0.993	33	3.33	0.777	0.768§
▶ The options you were given regarding timing of your breast reconstruction?	27	3.59	0.797	32	3.59	0.756	0.899§
▶ The pros and cons of timing of your breast reconstruction?	26	3.58	0.809	31	3.29	0.864	0.097§
▶ How long the process of breast reconstruction would take from start to finish?	26	3.46	0.811	33	3.33	0.854	0.536§
▶ What size you could expect your breasts to be after reconstructive surgery?	26	3.38	0.898	33	3.27	0.944	0.619§
▶ How much pain to expect during recovery?	26	3.35	0.892	32	2.88	1.129	0.107§
▶ What you could expect your breasts look like after surgery?	26	3.31	0.788	33	3.12	0.960	0.536§
▶ How long after reconstruction surgery it would take to feel like yourself/ feel normal again?	26	3.27	0.778	32	2.75	0.984	**0.045§**
▶ How the surgery could affect future breast cancer screening?	25	3.16	0.898	32	2.97	0.967	0.464§
▶ Lack of sensation in your reconstructed breast and nipple?	22	3.05	0.899	32	2.84	1.019	0.512§
▶ What other women experienced with their breast reconstruction surgery?	31	2.78	0.736	31	2.48	1.061	0.237§
▶ What the scars would look like?	32	3.20	0.707	32	3.00	1.016	0.657§
Opinion of reconstructive surgeon (answers from 1to 4 points)							
▶ Was a professional?	25	3.96	0.192	32	3.88	0.336	0.231§
▶ Gave you confidence?	27	3.93	0.267	33	3.64	0.742	0.074§
▶ Involved you in the decision-making process?	27	3.74	0.594	33	3.57	0.708	0.241§
▶ Was reassuring?	27	3.89	0.320	33	3.52	0.795	**0.035§**
▶ Answered all your questions?	27	3.93	0.267	33	3.55	0.666	**0.005§**
▶ Made you feel comfortable?	27	3.81	0.396	33	3.36	0.929	**0.046§**
▶ Was thorough?	27	3.81	0.396	33	3.73	0.674	0.938§
▶ Was easy to talk to?	27	3.89	0.320	33	3.45	0.794	**0.011§**
▶ Understood what you wanted?	26	3.85	0.368	33	3.52	0.755	0.059§
▶ Was sensitive?	27	3.85	0.362	33	3.36	0.859	**0.008§**
▶ Made time for your concerns?	27	3.89	0.320	32	3.38	0.833	**0.004§**
▶ Was available when you had concerns?	27	3.67	0.555	32	3.31	0.780	0.058§
Opinion of medical team other than surgeon (answers from 1–4 points)							
▶ Were professional?	27	3.78	0.424	34	3.47	0.615	0.038§
▶ Treated you with respect?	27	3.89	0.320	34	3.65	0.646	0.115§
▶ Were knowledgeable?	27	3.74	0.526	33	3.67	0.540	0.512§
▶ Were friendly and kind?	27	3.85	0.362	34	3.65	0.646	0.226§
▶ Made you feel comfortable?	27	3.85	0.362	34	3.47	0.788	0.032§
▶ Were thorough?	27	3.78	0.424	34	3.53	0.706	0.153§
▶ Made time for your concerns?	27	3.81	0.396	34	3.26	0.828	0.003§
Opinion of medical office (answers from 1 to 4 points)							
▶ Were professional?	26	3.77	0.514	34	3.65	0.646	0.395§
▶ Treated you with respect?	26	3.81	0.402	34	3.74	0.448	0.515§
▶ Were knowledgeable?	26	3.73	0.452	33	3.76	0.435	0.816§
▶ Were friendly and kind?	26	3.77	0.430	34	3.76	0.431	0.968§
▶ Made you feel comfortable?	26	3.73	0.452	34	3.59	0.609	0.419§
▶ Were thorough?	26	3.77	0.514	34	3.65	0.544	0.287§
▶ Made time for my concerns?	26	3.69	0.549	34	3.53	0.615	0.261§

BR: breast reconstruction; n = number completed; SD: standard deviation; n. a.: not available

§ Mann-Whitney U test was used for not normally distributed data

ter sensation for the patient; however, the main BREAST-Q result for "satisfaction with breast" did not exhibit any differences.

Although the numerical values for "satisfaction with breast" and "outcome" were rather poor, most patients would undergo the same surgical procedure again. With mean scores of 2.88 (IBBR group) and 2.79 (mesh group, answers from 1–3 points), this was regardless of whether mesh was used and was evaluated in the subgroup "satisfaction with outcome". Patients also reported no regrets with their respective surgery, as reflected by high mean scores in both groups (**Table 4**); however, the outcome did not perfectly align with patient expectations. This finding is an indication that patients themselves might be more satisfied with the surgical outcome compared with a surgeon's point of view. BC patients seemingly do not rate their aesthetic outcome primarily by the aesthetic result. Rather, the outcome is influenced by multiple factors, whereas surgeons overestimate the

Table 6 Comparison of BREAST-Q scores.

Author (year)	Surgical procedure (n)	Satisfaction with breast (n)[a]	Satisfaction with outcome (n)[a]	Sexual well-being (n)[a]	Psychosocial well-being (n)[a]	Physical well-being: chest (n)[a]	Satisfaction with nipple (n)[a]
Own results (2015)	One-Stage IBBR alone (27) One-Stage mesh assisted IBBR (34)	60.6 (27) 54.2 (34)	75.4 (25) 72.4 (34)	54.5(20) 52.4 (28)	71.3 (27) 68.1 (34)	64.5 (27) 65.7 (33)	55.7 (10) 69.4 (8)
Lee et al. (2014) [18]	IBBR using a LDF – traditional surgery (27) IBBR using a LDF – scarless surgery (30)	≈ 64 (n. a.) ≈ 61 (n. a.)	≈ 77 (n. a.) ≈ 70 (n. a.)	≈ 45 (n. a.) ≈ 51 (n. a.)	≈ 70 (n. a.) ≈ 69 (n. a.)	≈ 70 (n. a.) ≈ 69 (n. a.)	≈ 70 (n. a.) ≈ 81 (n. a.)
Albornez et al. (2014) [19]	IBBR alone without radiation (414) IBBR and irradiation[b] (219)	64.0 (n. a.) 58.3 (n. a.)	71.4 (n. a.) 66.8 (n. a.)	52.3 (n. a.) 47.0 (n. a.)	70.9 (n. a.) 66.7 (n. a.)	75.1 (n. a.) 71.8 (n. a.)	n. a. n. a.
Davis et al. (2014)[c] [20]	IBBR alone and autologous BR (65)	61 (24)	80 (26)	65 (33)	77 (24)	68 (21)	n. a.
Susarla et al. (2014) [21]	One-stage IBBR (65) Two-stage IBBR (203)	≈ 65 ≈ 67	≈ 72 ≈ 76	≈ 68 ≈ 52	≈ 79 ≈ 77	≈ 79 ≈ 78	≈ 44 ≈ 40
Eltahir et al. (2014) [22]	IBBR (45) Autologous BR (47)	65.5 (n. a.) 75.2 (n. a.)	74.5 (n. a.) 81.8 (n. a.)	61.1 (n. a.) 60.9 (n. a.)	77.5 (n. a.) n. a.	71.2 (n. a.) 77.1 (n. a.)	63.6 (n. a.) 65.3 (n. a.)
Liu et al. (2014) [23]	IBBR alone (48) Autologous BR (26)	64.2 (48) 80.4 (26)	63.3 (48) 79.2 (26)	52.1 (48) 64.8 (26)	75.5 (48) 86.1 (26)	78.7 (48) 79.1 (26)	n. a.
Peled et al. (2014) [24]	Total Skin-Sparing Mastectomy (28) (after 1 year of surgery)	67.8 (n. a.)	68.1 (n. a.)	57.7 (n. a.)	74.9 (n. a.)	72.5 (n. a.)	76.4 (n. a.)
Sugrue et al. (2013) [25]	Immediate postmastectomy BR[d] (30)	64 (n. a.)	(n. a.)	54 (n. a.)	69 (n. a.)	81 (n. a.)	92 (n. a.)
Macadam et al. (2013) [26]	IBBR using anatomical implants (63) IBBR using round implants (65)	64.5 (63) 64.5 (65)	76.8 (63) 74.6 (65)	50.1 (61) 56.8 (62)	73.3 (63) 77.9 (65)	74.7 (62) 76.1 (65)	n. a.
Salgarello et al. (2012) [27]	One-stage IBBR using the inverted-T skin-reducing mastectomy (14)	79.2 (14)	80.4 (14)	83.5 (10)	85.7 (14)	88.4 (14)	84.9 (9)
Goyal et al. (2011) [28]	Autologous dermal sling assisted IBBR (28)	60.0 (14)	75.0 (14)	54.8 (14)	69.6 (14)	75.1 (14)	n. a.
McCarthy et al. (2010)[e, f] [29]	IBBR silicone implants (176) IBBR using saline implants (306)	58.0 (176) 52.5 (306)	n. a.	n. a.	n. a.	n. a.	n. a.
Macadam et al. (2009)[e] [30]	IBBR silicone implants (75) IBBR using saline implants (68)	63.8 (75) 56.9 (67)	75.4 (75) 69.5 (68)	54.4 (71) 47.6 (65)	77.6 (75) 70.8 (67)	76.2 (74) 73.4 (68)	n. a.

IBBR: implant-based breast reconstruction; BR: breast reconstruction; LDF: latissimus dorsi flap; PMRT: post mastectomy radiotherapy; n. a.: not available

[a] n = number completing/corresponding to the specific domain

[b] Includes prior lumpectomy with radiation and PMRT of tissue expander or permanent implant

[c] No differentiation was made between IBBR or autologous BR; thus, patients were evaluated together.

[d] Including patients with autologous and heterologous BR

[e] Patients with immediate and delayed IBBR were included.

[f] Includes patients with PMRT, which was significantly associated with decreased "satisfaction with breast".

surgical outcome as a single parameter for general satisfaction. This observation is supported by a recent study comparing assessments by patients and medical professionals regarding aesthetic outcome following IBBR [16]. Patients rated superior outcomes compared with medical professionals with regard to breast size, form, IMF position and symmetry as well as scar look and scar position. Gerber et al. reported only minimal differences when patients or medical professional evaluated the aesthetic result after SSM with IBBR or autologous reconstruction. Yet, superior aesthetic ratings for both procedures were noted by the patients [17]. One reason for this observation might be that patients undergoing BC therapy have concerns other than a "perfect breast", thus pushing the aesthetic result to the background. The additional use of supportive materials in combination with implants did not appear to increase the aesthetic outcome or influence patient activity or daily life given that differences in physical restrictions were not observed in the final BREAST-Q or domain-specific questions. Due to the lack of tissue for reinforcement of the inferior pole of the breast, patients in the mesh group were more challenging. Using a mesh in these more complicated cases did not negatively influence the overall outcome compared with patients with sufficient tissue for the lower pole definition.

Although no difference was observed for the BREAST-Q domain "information received from reconstructive surgeon", significant differences within the domain-specific questions were observed. Patients in the mesh group were less satisfied with information provided regarding how the breast surgery would be performed. With 3.44 of a maximal 4 points, the ratings were still high compared with 3.52 in the IBBR alone group. Interestingly, we observed decreased "satisfaction with surgeon" for the mesh group. Six differing responses were noted in the sub-domain "opinion of reconstructive surgeon", all of which were in favor of the IBBR alone group. This finding potentially indicates an increased need for information from patients undergoing IBBR with the possibility of additional supportive materials. In addition, decreased satisfaction for "opinion on medical staff other than surgeon" was

observed in the mesh group. With 82.5 points, the scores were still high. Nevertheless, more preoperative information for mesh patients appears to be necessary. As long-term results for these products are limited, informed consent discussions before surgery are more complex compared with patients undergoing IBBR alone. Uncertainties that can lead to patient dissatisfaction remain particularly when complications attributed to the mesh occur after surgery. Is the indication for postoperative radiotherapy known before surgery, the reconstruction should be postponed after radiation due to the increased risk of capsular contraction and autologeous tissue should be preferred.

Consistent with other PRO, we observed decreased "satisfaction for breast" in the entire study population and subsequently increased "satisfaction with outcome" scores [18–30]. In previous reports, this finding was observed regardless of whether autologous, heterologous or ADM-assisted BR was performed. An explanation for this finding potentially involves the different questions associated with each domain. On the other hand, aesthetic outcome is not the sole indicator of patient satisfaction [16]. Otherwise, decreased "satisfaction with breast" scales for the mesh group can indicate a more challenging group of patients with increased expectations. Patients were younger with lower BMIs, which are known to influence inferior aesthetic results in IBBR [31, 32]. With this information, a two-stage expander to implant approach could be favorable for patients with mesh BR given that additional refinements can be made during the second procedure.

The few studies available that evaluate PRO in autologous BR indicate increased satisfaction compared with IBBR [22]. Although increased Q-scores are observed for autologous BR, not all patients are eligible for or able to undergo autologous BR. This limitation is due to patient-related or geographic restrictions and a shortage of high-volume hospitals offering such demanding surgeries [23]. IBBR with or without supporting materials is therefore an adequate option with acceptable PRO. Patients in the mesh group had a significant lower BMI and it is known that in these patients the preparation of an additional dermal flap is often not possible. Especially in this group of patients the use of mesh can be of value to overcome restrictions that can be solved with the preparation of an additional dermal flap [10]. A limitation of our study is its retrospective design with a possible selection bias. Nevertheless this bias can be limited as patients without mesh had increased mastectomy weight specimens, higher BMIs, and consequently an additional dermal flap could more frequently be dissected. From the authors point of view patients in the mesh group could not been treated in an equal way, as in patients with mesh the definition of the IMF, the stabilization of the implant pocket and an additional coverage between implant and skin could not be been achieved in an satisfactory way. A further limitation is that patients were not randomized but by the breast surgeon during surgery self-selected into the corresponding treatment groups. Randomized clinical trials are difficult to perform in a surgical setting trying to evaluate the additional benefit of meshes or ADMs in IBBR. Firstly, companies have no interest in financing trials of two directly competing products, complicating the funding of such investigations. Secondly, a randomized controlled trial raises ethical questions for this population, as not all patients are in need for these products and using mesh or ADM in patients without any approved indication seems questionable. A controlled one-sided blinded clinical study might be an alternative approach and should be taken into consideration for further trials. Although we obtained a high return rate, patients experiencing good results are potentially more likely to respond, biasing the PRO. The return rate in both groups did not statistically differ. A medium-sized patient sample was investigated, which is partially consistent with previous reports. Thus, data should be carefully interpreted. A prospective approach of evaluating PRO at different time frames after surgery would reveal even more information. Cost analyses and comparisons were not included in this study. A strength of our study is the high response rate and the comparative approach. The study is not single armed and is comparable to earlier publications using ADM or mesh in IBBR.

Conclusion

Mesh use in IBBR results in comparable aesthetic BREAST-Q scores compared with IBBR alone. Although "satisfaction with breast" was decreased in the mesh group the "satisfaction with outcome" was comparable between the two groups. Using the BREAST-Q supports the critical medical indication for this mesh, whereas the experience of the surgeon is of central importance. Nevertheless, this product has its value in selected patients. Evaluating the BREAST-Q sub-domains aids in the stratification of patient outcomes more effectively. The system can also assist in the identification of important differences to better interpret the overall results of an individual research question.

Responsibilities

Max Dieterich, MD: idea, initiator, data collection, writing, coordination; Jan Angres: data collecting, reviewing; Johannes Stubert, MD: writing, surgeon, reviewing; Angrit Stachs, MD: writing, reviewing; Toralf Reimer, MD, PhD: reviewing, writing, surgeon; Bernd Gerber, MD, PhD: Reviewing, writing, surgeon.

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Conflict of Interest

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