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Patient reported outcome and cosmetic evaluation following implant-based breast-reconstruction with a titanized polypropylene mesh (TiLOOP® Bra): A prospective clinical study in 269 patients

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ABSTRACT

Introduction: Implant-based or expander-supported breast reconstruction is an established surgical method after mastectomies due to cancer or to prophylactic reasons. Patient reported outcome (PRO) and cosmetic outcome after breast reconstruction with a synthetic surgical mesh was investigated in a prospective, single-arm, multi-center study.

Material and methods: Primary or secondary implant-based breast reconstruction with support of TiLOOP® Bra was performed in 269 patients during the PRO-BRA study. PRO 12 months after breast reconstruction was evaluated using Breast-Q questionnaire. Cosmetic outcome was evaluated by two independent experts by means of pictures taken preoperatively and at the follow-up visits.

Results: Breast-Q and 12 months FU were completed by 210 women. Patients without adverse event had a significantly higher Breast-Q score for "sexual well-being" ($p = 0.001$); "psychosocial well-being" was negatively influenced by prior therapies ($p < 0.01$), and older patients had significantly lower scores at 12 months FU compared to pre-OP for "satisfaction with breasts" ($p < 0.01$) while the opposite was true for younger patients. Unilateral surgery resulted in reduced "satisfaction with breast" at 12 months FU ($p < 0.01$). Radiotherapy negatively influenced "satisfaction with breast", "sexual well-being" and "physical well-being chest". The cosmetic evaluation showed a significant difference ($p < 0.001$) in the evaluation by the patients and experts with the patients' assessment being worse compared to experts' assessment.

Conclusion: Our study showed that two years after implant-based breast reconstruction with support of TiLOOP® Bra PRO is influenced by different factors. This information can be used to improve the decision-making process for women who chose implant-based breast reconstruction.

Abbreviations: PRO-BRA, National, multicenter post-market surveillance study 'Patient Reported Outcome' in BR following mastectomy with titaniferously coated polypropylene mesh (TiLOOP® Bra); 12mFU, 12 months Follow-Up; BR, breast reconstruction; PRO, patient reported outcome; AE, adverse event; pre-OP, prior surgery; SSM, skin sparing mastectomy; NAC, nipple areolar complex; NSSM, nipple areolar complex sparing mastectomy.

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1. Introduction

In addition to the modified radical mastectomy the range of ablative procedures increasingly includes the skin sparing mastectomy (SSM) and NAC sparing ablative (nipple areola complex sparing mastectomy, NSSM) procedures for which operative variants and long-term results are demonstrated [1–4]. Overall, the indications for SSM/NSSM are also viewed positively by guidelines if clear margins between tumor manifestation and skin/NAC are given [5]. From the aesthetic and quality of life (QoL) perspective the skin and fat tissue preserving method has a clear advantage due to the ability to perform an immediate breast reconstruction (BR) which has little altering effect on the patient's body image. In addition, reconstructive operations show a positive influence on the overall survival of breast cancer patients [6,7]. This confirms both the safety of the aforementioned procedures and long-term safety with regard to local recurrence rate [3,8].

Thus, a shift in thinking is established regarding the demand on primary reconstructive procedures, such as flap reconstructions as well as expander- and implant-supported operation techniques. The latter combines the advantages of a lower stress level on the patient due to shorter operation time and postoperative hospitalization, a more favorable cost situation and the capacity for conversion into a flap reconstruction if complications occur [9]. However, disadvantages are an often sparse or insufficient coverage of the prostheses and the consecutive impairment of the skin mantle as well as a rather higher rate of follow-up operations [10]. The disadvantages can be avoided by the insertion of supporting, covering or interposing materials [11]. Currently, many different biological matrix and synthetic mesh products are available for sub- or prepectoral implant positioning [12,13].

Essentially, the habits and wishes are the most important conditions on the part of the patient for the operation to be selected. Therefore, evaluation of QoL is an important instrument to determine the value of a reconstruction method for the patient. Several different instruments for the measurement of QoL are available; one of them is the BREAST-Q questionnaire [14], an established modular questionnaire to assess patient reported outcome (PRO).

The aim of the present study was to evaluate 12 months after surgery PRO of patients who underwent implant-based BR with a titanized polypropylene mesh (TiLOOP® Bra) using the BREAST-Q and cosmetic outcome as evaluated by two independent experts.

2. Material and methods

2.1. Patients and study design

The “PRO-BRA - National, multicenter post-market surveillance study ‘Patient Reported Outcome’ in BR following mastectomy with titaniferously coated polypropylene mesh (TiLOOP® Bra)” (clinicaltrials.gov, NCT01885572) is a prospective, single-arm, multicenter study performed in eight German centers. In this study, 269 women were included who underwent SSM, NSSM or modified radical mastectomy with immediate or delayed subpectoral BR with TiLOOP® Bra (pfm medical ag, Cologne, Germany), a large-pore mesh made from titanized monofilament polypropylene thread. Inclusion criteria were an indication for prophylactic (family history or genetic predisposition) or oncologic surgery due to a histologically confirmed breast cancer. Exclusion criteria were pregnancy or breast-feeding, metastatic breast cancer, medically treated diabetes with a blood sugar level >250 mg/dl, and inadequate bone marrow function. The primary endpoint of this study was the measurement of PRO 12 months after BR evaluated with the Breast-Q [14].

2.2. Breast-Q quality-of-life questionnaire

The Breast-Q [14] is an established modular questionnaire with a preoperative and a postoperative version for the assessment of PRO after BR. To measure PRO in the PRO-BRA study the Breast-Q reconstruction module version 1.0 was used. The responses of the single questions are transformed to a Q-score (0–100), with a higher Q-Score representing higher patient's satisfaction. As not all questions or categories have to be filled in a total score cannot be calculated.

2.3. Cosmetic outcome

Cosmetic outcome was determined by patient's self-assessment in the Breast-Q and by two independent physicians who had not been involved in patients' surgery and care. For the objective assessment photographs were taken from the patient's front standing in front of a blue background; the photographs' view ranged from the clavicle to the navel. The independent physicians answered five questions taken from the Breast-Q (satisfaction with the size of the breast, with how the breasts are positioned to each other, with the equality of the size of the breasts to each other, with the natural look of the breast, with the similarity of the breasts to each other). Cosmetic assessment of alignment, equal size and similarity was only completed, when the patient had surgery on both breasts. The answering options were very dissatisfied, somewhat dissatisfied, somewhat satisfied, and very satisfied and were afterwards scaled to 100 (adapted according to Ref. [15,16]). The answers of the two experts were combined and compared to the patients' self-evaluation.

2.4. Statistical analysis

Breast-Q scores were evaluated using Q-Score Scoring Software. Statistical analyses were performed with R statistical framework version 3.5.3. (R Foundation for Statistical Computing, Vienna, Austria, http://www.R-project.org/). PRO was analysed using a paired Wilcoxon test.

3. Results

3.1. Demography

From December 2013 to July 2016 277 patients were screened and 269 underwent BR with support of TiLOOP® Bra. The mean age of the patients was 49.3 years (19–77 years) and the mean body mass index (BMI) was 23 kg/m^2 (17–40 kg/m^2). Fourty-five patients were excluded after surgery and before 12 months follow-up (12mFU) visit due to adverse events resulting in explantation of the TiLOOP® Bra mesh (N = 21), lost to follow-up (N = 15) or wish of the patient (N = 9). The 12mFU was completed by 213 patients. Due to missing Breast-Q or picture data were available from 210 patients (Fig. 1). The majority of the 210 patients underwent primary (204/210 patients) and only six patients underwent secondary reconstruction. Most of the patients were non-smoker (171/210) while 39 patients reported to be smoker. Of the 210 patients completing the 12mFU 118 were pre-menopausal, 90 patients were menopausal, while no information was available of two patients. Most patients did not undergo radiotherapy neither before nor after surgery (158/210), 23 patients received neoadjuvant radiotherapy and 29 adjuvant patients (Table 1).

3.2. Evaluation of PRO

For the evaluation of PRO patients were asked to complete the Breast-Q before (pre-OP) and 12 months after surgery. PRO of the

patients was assessed by evaluation of the four Breast-Q scales "satisfaction with breasts", "psychosocial well-being", "sexual well-being" and "physical well-being: Chest". Completion rate of the Breast-Q after 12 months was 98.6% (207/210 patients). A clinical relevant difference was defined as a Breast-Q score difference of 10 points; the aim of this study was to show by a non-inferiority test, that the Breast-Q scales are not worse than before procedure defined by the threshold of 10 points. This threshold of 10 point difference is based on the studies by Norman et al. [17], Macadam, et al. [18] and Zhong et al. [19].

3.3. Adverse events and PRO

Up to the 12 months FU 273 adverse events (AE) occurred (Table 2). Comparing patients who experienced an AE before the 12mFU to those who did not show a significant difference for the scale "sexual well-being" at the 12mFU ($p = 0.001$); this difference was almost clinically relevant with a difference of 9.6 points (without AE: 65.4 ± 21.5; with AE: 55.8 ± 19.9) (Fig. 2). For "satisfaction with breast" patients with AE had a significantly lower score at 12mFU compared to pre-OP ($p < 0.05$); patients without AE had a significantly higher „psychosocial well-being" at 12mFU ($p < 0.001$). However, for none of the scales the difference exceeded 10 points and thus no clinical relevant difference was detected.

3.4. Prior therapies and PRO

Prior therapies were defined as prior breast surgery (Table 1), chemotherapy (58 patients) or radiotherapy (23 patients) preceding the BR; as one patient could have had more than one prior therapy, all in all 116 patients had such a prior therapy and 94 patients did not. A significant difference was only found for the scale „psychosocial well-being"; patients with at least one prior therapy had significantly higher Breast-Q scores at 12mFU compared to pre-OP (71.7 ± 21.8 vs. 66.8 ± 18.7, $p < 0.01$), however, this difference was not clinically relevant (Fig. 2b).

3.5. Patient's age and PRO

PRO was evaluated regarding patients' age at study inclusion. Patients were stratified in the groups ≤40 years (46 patients) and >40 years (164 patients) in order to achieve comparability to previously published studies [20,21]. Patients >40 years showed significantly lower scores at 12mFU compared to pre-OP for "satisfaction with breasts" (pre-OP: 66.6 ± 22.7,12mFU: 59.8 ± 19.0; $p < 0.01$) (Fig. 2c) and "physical well-being chest" (pre-OP: 73.4 ± 13.0, 12mFU: 70.2 ± 16.0; $p < 0.01$); the score for, "psychosocial well-being" was significantly higher at 12mFU compared to

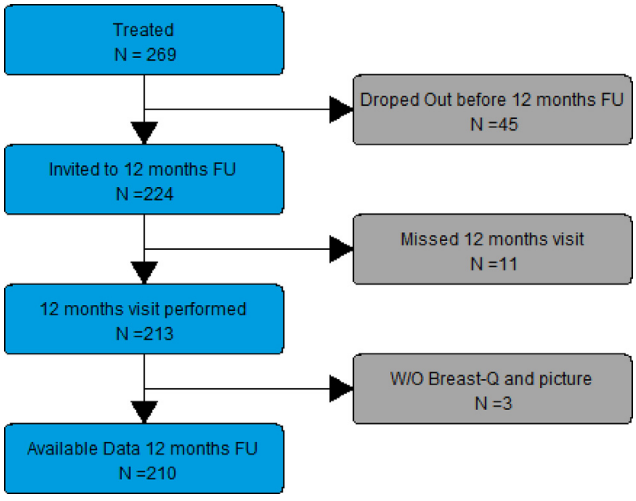

Fig. 1. Flow diagram of the patient cohort according to CONSORT 2010 [35]. The number of patients at screening, surgery and 12mFU as well as the number of excluded patients between the time points is given.

Table 1
Patient characteristics. Patient, tumor and treatment related characteristics.

Characteristic	Value (210 patients total)
Age in years: mean (range)	49.3 (19-77)
BMI mean (SD, range)	23 (3.5, 17–40 kg/m^2)
≤ 25 kg/m^2	168
> 25 kg/m^2	42
Diabetes	
No diabetes	206
Diabetes type 1	0
Diabetes type 2	4
Non-smoker/Smoker	
Non-smoker	171
< 10 cigarettes per day	19
> 10 cigarettes per day	20
Pre-menopausal/ menopausal	
Pre-menopausal	118
Menopausal	90
Unknown status	2
Laterality of reconstruction	
Unilateral	130
Bilateral	80
Primary/ Secondary reconstruction	
primary reconstruction	204
secondary reconstruction	6
Prior therapies	
segment resection	47
quadrant resection	13
sentinel lymphadenectomy	47
core biopsy	46
axillary dissection	17
UICC classification	
prophylactic surgery/UICC 0	57
Tis N0 M0	39
T0 N0 M0	11
UICC I	83
T1 N0 M0	51
T2 N0 M0	32
UICC II - III	70
T3 N0 M0	4
Every T-stage N1 M0	53
Every T-stage N2 M0	8
Every T-stage N3 M0	5
Radiotherapy	
no radiotherapy	158
radiotherapy only before surgery	23
radiotherapy only after surgery	29

Table 2
Adverse events up to the 12 months FU.

Type of adverse event	number
Other	49
Planned surgery: resection due to R1 or recurrence of cancer	36
Capsular contracture	33
Seroma	31
Infection	23
Necrosis	23
Planned surgery: change expander to permanent implant	22
Wound dehiscence	20
Haematoma	10
Wound healing disturbance	9
Secondary bleeding	8
Planned surgery: delayed contralateral mastectomy	7
Dysesthesia	1
Implant dislocation	1
total number of adverse events	**273**

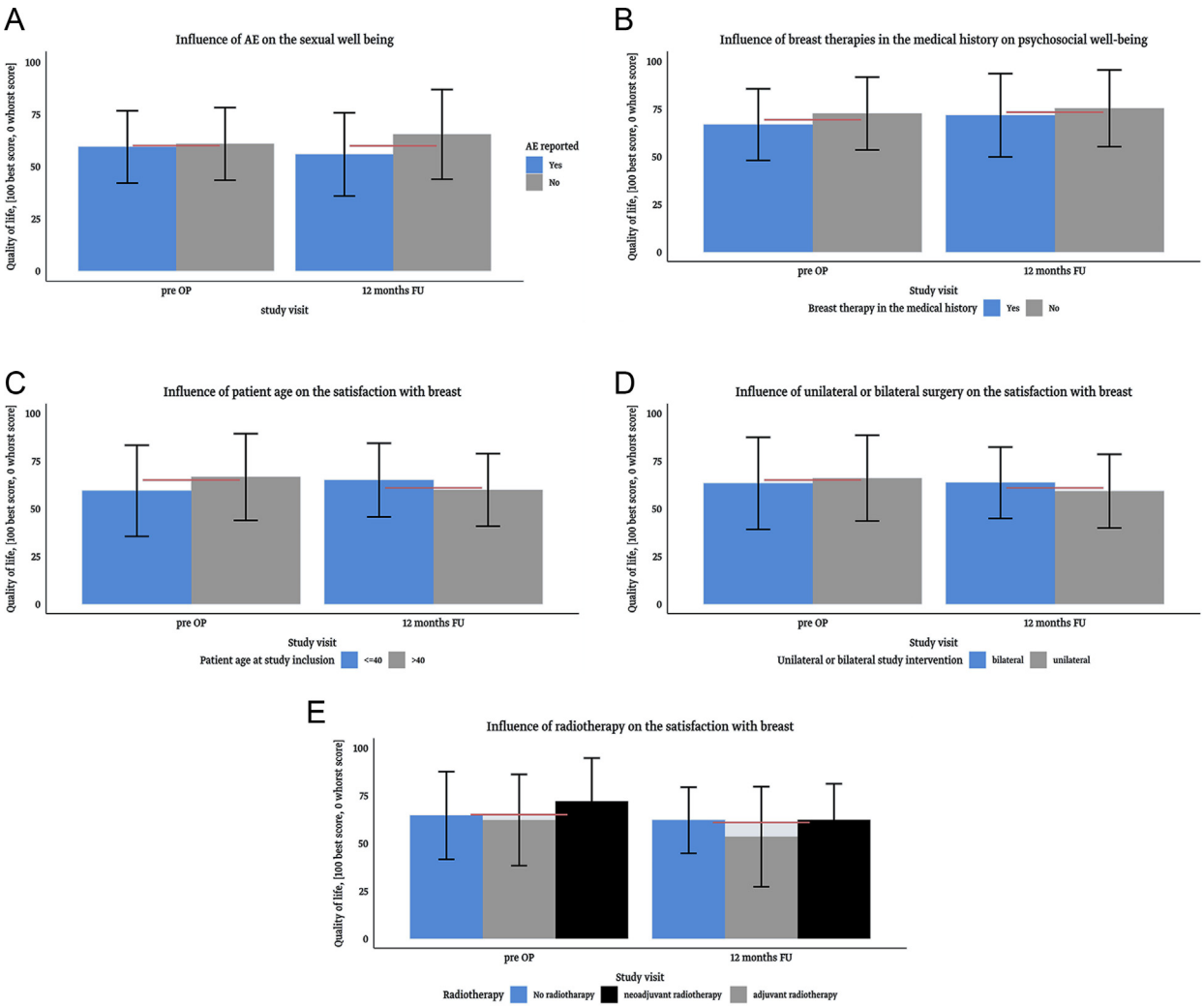

Fig. 2. Bar plot of the influence (a) of adverse events on "sexual well-being", (b) "psychosocial well-being" mean score and prior therapies, (c) "satisfaction with breast" mean score and patient age, (d) "satisfaction with breasts" and uni-/bilateral surgery, (e) "satisfaction with breasts" and radiotherapy groups. Mean Breast-Q scores and SD are given for pre-OP and at 12mFU. The red line indicates the mean over the two groups at the respective time points.

pre-OP (pre-OP: 71.0 ± 18.6, 12mFU: 74.1.±21.2; $p < 0.01$). However, none of the difference was clinically relevant. Patients ≤40 years reported increased Breast-Q scores at 12mFU for the scales "satisfaction with breast" (pre-OP: 59.4 ± 23.9, 12mFU: 65.0 ± 19.3) (Fig. 2c), "psychosocial well-being" (pre-OP: 63.7 ± 19.8, 12mFU: 70.5 ± 21.0), and "sexual well-being" (pre-OP: 59.5 ± 17.8, 12mFU: 63.3 ± 22.1); however, the differences were neither significant nor clinically relevant.

3.6. BMI and PRO

For the evaluation of the influence of the BMI at study inclusion patients were assigned to subgroups BMI≤25 kg/m^2 (168 patients) and >25 kg/m^2 (42 patients). Preoperatively significantly higher scores for the scales "satisfaction with breasts", "psychosocial well-being", and "sexual well-being" were found for the subgroup BMI≤25 compared to the subgroup BMI>25. These differences also exceeded the 10 points (15.0, 11.8, and 11.1, respectively) and thus were clinically relevant. At the 12mFU for none of the four Breast-Q scales any difference was detected between the two BMI groups.

3.7. Uni-/bilateral surgery and PRO

Unilateral surgery was performed in 130 and bilateral in 80 patients. Significant differences were found for the scales "satisfaction with breasts" and "psychosocial well-being". Unilaterally treated patients reported a significantly worse "satisfaction with breast" at 12mFU compared to pre-OP (59.2 ± 19.3 vs. 66.0 ± 22.5; $p < 0.01$). Bilaterally treated patients had comparable values for this scale prior surgery and at 12mFU (63.3 ± 24.1 vs. 63.6 ± 18.7, respectively) (Fig. 2d).

In contrast, „psychosocial well-being" was significantly higher at 12mFU in unilaterally treated patients (pre-OP: 70.8 ± 18.1; 12mFU: 74.7 ± 20.4; $p < 0.05$), while scores for patients with bilateral surgery did not differ significantly. However, none of the significant differences was clinically relevant.

3.8. Tumor stage, nodal status and PRO

The influence of the tumor stage and nodal status of the tumor on PRO was assessed. Therefore, the patients were assigned to the UICC groups according to their tumor stage and nodal status; none

of the patients had a distant metastasis as this was an exclusion criterium. The groups prophylactic/UICC 0 (prophylactic, pTis/pN0/cM0, pT0/pN0/cM0, 57 patients), UICC I (pT1/pN0/cM0, pT2/pN0/cM0, 83 patients), and UICC II-III (pT3/pN0/cM0, pT4/pN0/cM0, every pT-stage pN1/2/3 cM0, 70 patients) were compared. None of the score differences before surgery or at 12mFU exceeded the 10 points. Regarding "satisfaction with breasts" at 12mFU a 7.1 points difference was found comparing the group UICC II-III to prophylactic/UICC 0. For the scales "psychosocial well-being" and "physical well-being chest" the mean scores pre-OP and at 12mFU were comparable between the three UICC groups. A 6.1 points difference was found for "sexual well-being" at 12mFU comparing the groups UICC II-IV and UICC I (Table 3).

3.9. Radiotherapy and PRO

Regarding radiotherapy the three subgroups (1) no radiotherapy, (2) neoadjuvant radiotherapy, and (3) adjuvant radiotherapy were evaluated with respect to their influence on PRO. Patients of the subgroup (1) showed comparable values pre-OP and at 12mFU for all four Breast-Q scales. Patients who received neoadjuvant radiotherapy reported comparable scores for three of four Breast-Q scales ("psychosocial well-being", "sexual well-being", "physical well-being chest"); only for the scale "satisfactions with breast" the mean Breast-Q score for these patients was 9.7 points worse at 12mFU (62.3 ± 18.9) compared to pre-OP (72.0 ± 22.7). Patients of subgroup (3) had lower Breast-Q scores at 12mFU for "satisfaction with breast" (mean: 8.7 points; pre-OP 62.2 ± 23.9; 12mFU: 53.5 ± 26.2) (Fig. 2e), "sexual well-being" (mean: 9 points; pre-OP 64.1 ± 21.8; 12mFU: 55.1 ± 25.0), and "physical well-being chest" (mean: 8.6 points; pre-OP 69.8 ± 11.0; 12mFU: 61.2 ± 16.5). The values for "psychosocial well-being" were comparable from pre-OP to 12mFU.

3.10. Radiotherapy and cosmetic outcome

For the cosmetic assessment photographs were taken from each patient before surgery and at the FU visits. Pictures of two representative patients are shown in Fig. 3. Evaluable data were available from 206 patients and the experts could give an assessment for 197 patients.

Regarding radiotherapy the three subgroups (1) no radiotherapy (155/158 primary, 3/158 secondary reconstruction), (2) neoadjuvant radiotherapy (20/23 primary, 3/23 secondary reconstruction), and (3) adjuvant radiotherapy (29/29 primary reconstruction) were evaluated with respect to their influence on the cosmetic outcome. The results show a significant difference in the evaluation by the patients and experts ($p < 0.001$) (Fig. 4). The patients' self-assessment was comparable to the experts for subgroup (2) (patients score 63.0 ± 20.5, experts score 63.6 ± 22.4). For the subgroups (1) (patients score 65.0 ± 24-2, experts score 76.8 ± 21.5) and (3) (patients score 56.4 ± 33.2, experts score 69.8 ± 21.1) the patients' score was worse than the experts' score and the difference was clinically relevant (>10 points) in both subgroups (Fig. 4b).

4. Discussion

This study reports the data up to the 12mFU of PRO and subjective and objective cosmetic outcome during the PRO-BRA study.

Patients' satisfaction is known to be influenced by patients' expectations, preoperative education, personality characteristics and a variety of clinical and psychosocial factors [22–24]. Andrade et al. [22] and Colakoglu et al. [25] showed, for instance, dissatisfied patients having experienced more complications than those who were satisfied. Accordingly, in the present study significant worse scores were found for patients who had experienced an AE for "satisfaction with breast" at 12mFU compared to pre-OP; patients without AE, however, showed an increased „psychosocial well-being" at 12mFU. One of the clinical factors that might influence patients' satisfaction are prior therapies; patients without any prior therapy showed comparable values pre-OP and at 12mFU for all four Breast-Q scales. Patients who underwent any prior therapy reported on higher "psychosocial well-being" which might be due to a prior therapy reducing patients' expectations. Patients with higher UICC (II-IV) tumor stadium had lower scores for "satisfaction with breast" and "sexual well-being" at 12mFU compared to patients with lower UICC stadium. This might be due to a more invasive surgery or preceding surgeries resulting in big scars and a psychological burden thus affecting the outcome of the reconstruction.

Considering patient's age the present literature is contradictory; one study showed that age older than 45 years at time of reconstruction was predictive for aesthetic dissatisfaction [25] while another found a trend for dissatisfied patients being younger [22] or even no difference between younger and older patients [26]. In the PRO-BRA study patients >40 years at time of reconstruction had lower scores at 12mFU for "satisfaction with breasts" and "physical well-being chest" while "psychosocial well-being" was higher. The latter was also true for patients ≤40 years, while these patients showed higher scores for "satisfaction with breasts" and "sexual well-being", respectively. Mundy et al. [20] showed that patients >40 years had higher baseline scores for "psychosocial well-being", "sexual well-being" and "physical well-being chest". This finding could be confirmed by the present study. Santosa et al. [27] showed that older women reported lower "physical well-being" two years after reconstruction and an overall increase of "psychosocial well-being" irrespective of age; these two findings are also confirmed by the PRO-BRA results. The same workgroup showed two years later in the four years FU that "satisfaction with breast" and "sexual well-being" appeared to gradually worsen over time [28]. This might be since an implant-based reconstructed breast is unable to undergo ptosis to match the contralateral breast. This fact has been investigated in a different study comparing PRO of patient who

Table 3
Influence of UICC stadium on PRO. The mean values and SD for the UICC subgroups is given pre-OP and at 12mFU.

UICC stadium	study visit	satisfaction with breasts (mean ± SD)	psychosocial well-being (mean ± SD)	sexual well-being (mean ± SD)	physical well being chest (mean ± SD)
prophylactic/UICC 0	pre OP	69.1 ± 23.5	68.6 ± 20.1	58.6 ± 18.0	73.8 ± 13.4
prophylactic/UICC 0	12 months FU	64.6 ± 18.0	74.4 ± 20.7	60.5 ± 19.2	73.8 ± 16.1
UICC I	pre OP	65.3 ± 21.7	69.1 ± 17.8	59.5 ± 15.0	72.7 ± 12.0
UICC I	12 months FU	61.2 ± 17.3	74.7 ± 18.5	62.7 ± 20.0	70.7 ± 14.1
UICC II - III	pre OP	61.4 ± 24.3	70.3 ± 20.0	61.7 ± 19.2	72.6 ± 13.9
UICC II - III	12 months FU	57.5 ± 21.5	71.0 ± 24.1	56.6 ± 23.4	66.4 ± 16.4

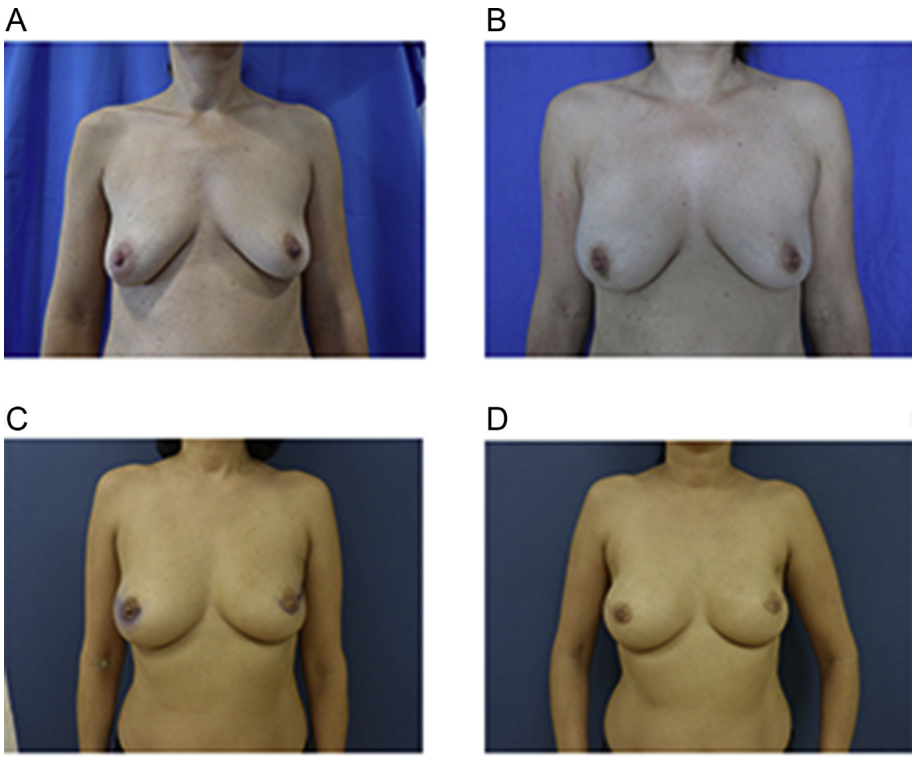

Fig. 3. Cosmetic outcome. Representative photos of two patients pre-operative (A,C) and at 12mFU (B, D) are shown. Patient 1 (A, B), age at surgery 45 years, had a unilateral BR in the right breast; Patient 2 (C,D), age at surgery 49 years, had a bilateral surgery.

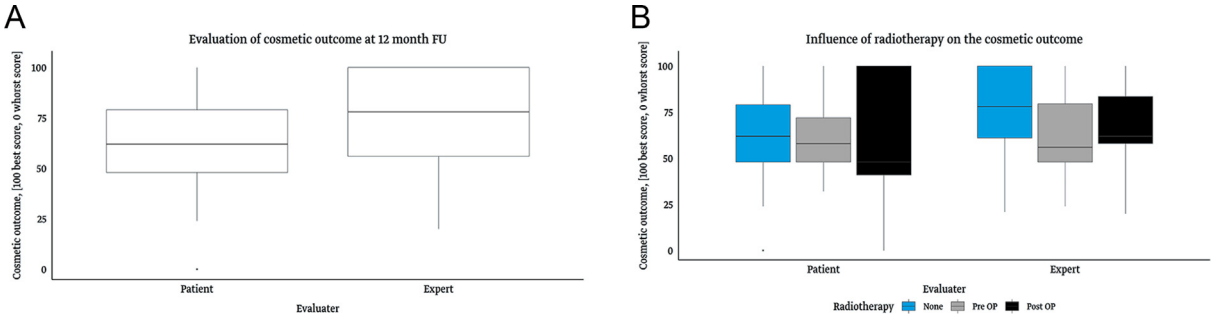

Fig. 4. Evaluation of cosmetic outcome. (a) Comparison of patients' self-assessment and experts' assessment at 12mFU. The assessment of the two experts was combined. (b) Influence of radiotherapy on the cosmetic outcome. Two independent physicians (Expert 1 and Expert 2) and the patients rated the cosmetic outcome. The patients were divided in the subgroups (1) no radiotherapy neither before nor after surgery ("None"), (2) radiotherapy only before surgery ("Pre-OP"), and (3) radiotherapy only after surgery ("Post-OP").

underwent contralateral augmentation to those who had no symmetry procedure [29]. Patients with contralateral augmentation had significantly higher scores for "satisfaction with breast" and "satisfaction with outcome". This finding can be confirmed by a decrease of the Breast-Q score for "satisfaction with breasts" from pre- to post-OP for patients with unilateral. Therefore, expectations of the patients concerning the aesthetic outcome of the breast might not be fulfilled. The fact of more satisfaction after bilateral surgery has already been reported previously [30].

The evaluation of the BMI on PRO revealed clinically relevant lower scores for the scales "satisfaction with breast", "psychosocial well-being", and "sexual well-being" for patients with higher BMI pre-OP. At the 12mFU no difference was detected. These findings are in line with results of a study to gain normative data concerning the Breast-Q on 1201 women without prior history of breast cancer or breast surgery; women with a BMI$\geq$30 kg/m^2 had lower Breast-Q scores for "satisfaction with breasts", "psychosocial well-being", "sexual well-being", and "physical well-being chest" compared to women with BMI<30 kg/m^2 [20]. Regarding the follow-up after BR, a study by Teo et al. [31] also did not find an influence of the BMI on any Breast-Q scale.

Evaluation of aesthetic outcome of BR with photographs and questionnaires is current practice. However, photographs are two-dimensional, not showing e.g. defects of projection or movement of the breast. To obtain reliable results, photographs must be standardized [32]. In the present study, photographs were taken from the front side of the patients standing in front of a blue background; the photographs' view ranged from the clavicle to the navel. The present data show significantly worse patients' compared to the experts' assessment. This is explainable by patients' expectations and a critical self-image; in contrast, the experts' assessment is objective and unbiased by emotions. However, other studies showed a high correlation between surgeon and patient scoring overall impression [32,33]. Furthermore, it should be considered that the mode of answering the questionnaire (e.g. at home, in presence of the surgeon) may influence the responses. In the case of the presence of the surgeon the social

desirability bias not to affront the surgeon with a potentially bad response is high, in the case of a postal (at home) or electronic (eMail) questionnaire this effect is low [34].

5. Conclusions

The primary endpoint of the PRO-BRA study was the evaluation of PRO using the Breast-Q. The strength of this study is a large, prospective, multi-center cohort thus limiting surgeon specific impact. The presented data show that PRO is influenced by different factors either demographic (e.g. age, BMI) or therapy related (e.g. radiotherapy, prior therapies, uni-/bilateral). These findings can be used to improve the decision-making process for women who chose implant-based BR.

To our knowledge, this is the first study to compare PRO outcome as assessed by the Breast-Q to cosmetic evaluation by two independent experts.

Author contribution

"Patient Reported Outcome and cosmetic evaluation following implant-based breast-reconstruction with a titanized polypropylene mesh (TiLOOP® Bra): a prospective clinical study in 269 patients".

Marc Thill: Investigation, Resources, Writing - Review & Editing, Supervision

Andree Faridi: Investigation, Resources

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Claudia Gerber-Schäfer: Investigation, Resources

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Christine Mau: Investigation, Resources

Sabrina Tofall: Writing - Original Draft

Elke Nolte: Formal analysis, Writing - Original Draft

Hans-Joachim Strittmatter: Investigation, Resources

Ralf Ohlinger: Investigation, Resources

Stefan Paepke: Conceptualization, Investigation, Resources, Supervision

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