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Quality of life in breast cancer patients and surgical results of immediate tissue expander/implant-based breast reconstruction after mastectomy

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Abstract

Objectives The purpose of this study was to analyze the effects of prior radiotherapy (RT) as well as postmastectomy radiotherapy (PMRT) on patient-reported quality of life (QoL) and on surgical/aesthetic outcomes in patients with expander-/implant-based delayed immediate reconstruction (EIBR) compared to patients that underwent EIBR without any RT.

Material and methods QoL was assessed by BREAST-Q, the surgical/aesthetic outcome by a structured examination and a picture analysis (BCCT.CORE software) and subsequently compared between the three cohorts.

Results Of 161 eligible patients, 97 followed the invitation (no RT $n=54$, 9 of them with bilateral EIBR; PMRT $n=26$; history of RT $n=15$). The surgical/aesthetic results were better in the RT-naive cohort than in the PMRT cohort, but satisfaction with outcome and psychosocial well-being were better in the PMRT cohort. The RT-naive cohort showed (significantly) higher scores in satisfaction with breast, satisfaction with implant and sexual well-being compared to the history of RT cohort, although satisfaction with outcome was comparable. The PMRT cohort reached significantly more points in almost all categories and better BCCT.CORE and examination results than the history of RT cohort. Of all patients, 92.7%, 84.6% and 78.6% (RT naive, PMRT, history of RT) would agree to undergo EIBR again.

Conclusion EIBR results in acceptable QoL and surgical results. In patients with a prior RT, QoL is significantly lower and surgical results are significantly worse. However, high acceptance rates suggest EIBR being a justifiable option even for this group. Prospective studies and long-term follow-up are required for definitive conclusions.

Keywords Breast cancer · Mastectomy · Post-mastectomy radiotherapy · Implant breast reconstruction · Expander

Introduction

Breast cancer is the most common malignancy in women worldwide with 1.7 million new cases diagnosed in 2012 [1]. Breast conserving therapy (BCT) replaced mastectomy as standard of care in primary breast cancer [2, 3]. However, in about 25–30% of all patients a mastectomy is mandatory due to locally advanced cancer, DCIS, multicentric or inflammatory disease [4]. The loss of the breast can be a traumatic experience decreasing the quality of life (QoL) [5, 6]. Thus, breast reconstruction after mastectomy has beneficial effects for the psychosocial outcome [7–11].

Mastectomy is recommended in most patients with locally relapsed breast cancer after BCT and adjuvant radiotherapy (RT). Previous RT of the breast is known for having a negative impact on expander/implant-based breast reconstruction (EIBR). The risk of infection is doubled, and the risk of capsular contraction is tripled when compared to patients without

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RT [12–14]. The results of patient-reported outcome are conflicting, with some studies finding no significant differences and other studies showing a decreased QoL [15, 16].

Indications for postmastectomy radiotherapy (PMRT) have broadened since RT has been shown to decrease the risk of local relapse and prolong survival [17–19]. Complications after PMRT are increased, i.e., infections, capsular contraction rates and overall reconstruction failure [20]. Surgical and aesthetic outcomes are inferior compared to patients without PMRT [15, 20–23].

One of the surgical options is an autologous breast reconstruction (ABR) in selected cases with adequate donor tissue sites and without severe comorbidities. ABR produces high levels of patient aesthetic and general satisfaction [8] and low complication rates [24]. Many patients opt for an implant-based breast reconstruction incorporating the long operation times of ABR and potential donor site morbidity.

The positive aspects of EIBR, when compared to a delayed reconstruction, can be a decreased risk of social and emotional difficulties [5] and better cosmetic results, given these patients already have a breast mound after the first operation. Moreover, using an EIBR gives the patients more time to consider breast reconstruction options. Where PMRT is necessary, they can still switch to an ABR following PMRT or finish the EIBR. For EIBR, many different options concerning surgical techniques are described and the timing of RT remains controversial. Some surgeons prefer to irradiate the permanent implant, others to irradiate the expander. There is also no agreed standard for the time intervals of expander/implant exchange [25–34]. Similar to our schedule, Peled et al. prolonged the interval of expander/implant exchange to at least six months after the end of PMRT, declining the expander–implant failure rate from 22.4 to 7.7% [35]. Moreover, postponing the expander/implant exchange offers the possibility of removing a capsule that already might have developed. Still, RT in context of EIBR remains an undesired event but it should not be considered a contraindication anymore [36].

In this study, we assessed and correlated QoL and surgical/aesthetic outcomes of patients with EIBR to provide more detailed information about a realistically expected result. Appreciating each woman´s wishes and properties may help patients and their physicians make better decisions in an informed consent and thus lead to high satisfaction levels in patients [37].

Material and methods

Outcome measures

The electronic hospital information system was screened for patients with an EIBR between 2008 and 2012. Only patients with a primary EIBR, meaning expander implantation at the time of mastectomy, were included. All surgeries were conducted by two surgeons (U.H. and M.B.).

Eligible patients were invited for an interview and structured physical examination by an independent breast surgeon of another clinic and a medical student. The form of the reconstructed breast, the scars, the symmetry, capsular contraction (Baker grade I–IV) and the overall result were assessed by a four-point rating (poor, fair, good, excellent). The two examiners rated independently through their subjective impression and, in case of a different result, they had to compromise. Patients were asked whether a further operation to symmetrize was desired/planned or already performed/not required/not desired.

Standardized pictures were analyzed using the software BCCT.CORE (Breast Cancer Conservation Treatment.cosmetic results) that allows an objective, reproducible assessment of the aesthetic outcome after reconstructive surgery of the breast [38, 39]. Asymmetry, color differences and scar visibility are evaluated by this software using patient's digital pictures [39]. Corresponding to the structured physical examination, the BCCT.CORE result ranges from poor to excellent.

The QoL instrument was the questionnaire BreastQ post reconstruction module. This was analyzed using the software QScore. BreastQ consists of different domains, measuring QoL (psychosocial well-being, sexual well-being, physical well-being) and satisfaction (with breast, with implant (e.g., rippling), with outcome). Each domain can reach points between 0 and 100 [40, 41].

Surgical procedure

All patients had a simple mastectomy with or without a sentinel lymphnode biopsy (SLNB) or axillary lymphnode dissection (ALND). Expander was placed from laterally under the M. pectoralis major after preparation of the caudal part as far down as two centimeters below the prospective lower submammary fold. The lateral part of the expander was then covered with parts of the fascia of the M. serratus anterior. In no cases was a mesh or acellular dermal matrix used to cover the expander or implant. Two suction drainages in the implant pocket and premuscular space were placed before suturing the subdermis and dermis. At the end of the operation, the expander was filled with 100 ml of saline. Drainages were left in place until the 24 h volume was below 30 ml. During this time, the patients received antibiotic prophylaxis with cephalosporins. Subsequently the filling was continued about every two weeks with 50–100 ml of saline until the final volume with a slight overexpansion (approximately 10%) was reached.

If PMRT was required, the last 20% of the filling volume was applied after the end of RT. Expander–implant exchange

was usually scheduled 3–6 months after the expander implantation in the RT-naive and history of RT cohort. In the PMRT cohort, the exchange was performed at least 6 months after the end of RT.

Indication to the operation and treatment followed the German guidelines after informed consent. All patients were extensively informed about all possible heterologous and autologous breast reconstruction options.

Radiation therapy

RT followed standard protocols with 50 Gy tangential field irradiation dosage to the thoracic wall and, if required, to the supraclavicular region. RT started within 4–6 weeks after the operation or when adequate expander filling volume was reached.

Statistics

Statistical analyses were performed using IBM SPPS Statistics 22. The three cohorts RT naive, PMRT and history of RT were compared by *t* test, Chi square test and Fisher's exact test (patient related factors like tobacco use, diabetes, age). QoL scores were compared by linear regression analysis. Results of the examination and of BCCT.CORE were pooled into two groups (poor and fair versus good and excellent) and then compared by a binary regression model. These models were adjusted by the factors age, smoking status (yes/no) and application of chemotherapy (yes/no). All *p* values are two sided and believed to be significant if $p \leq 0.05$.

The study was approved by the local ethics commission and all patients gave their written consent.

Results

Of 161 eligible patients, 97 patients followed the invitation. Two patients with a history of RT following BCT again had an indication for a PMRT after local relapse and were, therefore, excluded. Most patients were RT naive, i.e., no history of RT and no PMRT ($n = 54$, bilateral EIBR in nine patients). A total of 26 patients underwent PMRT and 15 patients had a history of RT to the breast before mastectomy.

Bilateral synchronous EIBR was performed in 13 patients, but this did not improve the outcome compared to unilaterally operated patients. As some of these patients had, e.g., breast cancer on one side with PMRT and prophylactic operation on the other side, data refer to the number of treated breasts, if not otherwise specified.

Table 1 shows all data concerning patient and tumor characteristics, treatment and expander/implant exchange intervals and follow-up times.

Expander/implant exchange and follow-up time

In the PMRT cohort, expander/implant exchange was performed two months later than in the other two cohorts (median 11.6 months, range 3.4–18.4 in the PMRT cohort, 9.6 months (3.4–26.3) in the RT-naive cohort, 9.4 months (5.1–14.5) in the history of RT cohort, respectively ($p = 0.011$)). The interval to the end of PMRT was 6.2 months (2.6–15.3). Follow-up time was determined between expander/implant exchange and examination. Overall median follow-up was 17.8 months [in the RT-naive cohort 17.0 months (3.9–61.0), in the PMRT cohort 16.6 months (2.7–50.0) and in the history of RT cohort 21.7 months (9.5–64.9) ($p = 0.551$)].

QoL

Table 2 shows the BreastQ scores of all three cohorts in detail. The history of RT cohort had the lowest scores in all domains except physical well-being. The scores of the RT-naive and PMRT cohorts were mainly comparable. Satisfaction with outcome was best in the PMRT cohort.

The boxplots of Fig. 1 are visualizing the differences of the evaluated categories between the three cohorts.

Of all patients, 92.7%, 84.6% and 78.6% (cohorts 1, 2 and 3) stated that they would undergo the operation again.

BCCT.CORE and examination results

The details of BCCT.CORE and examination results are listed in Table 3.

The BCCT.CORE result of the history of RT cohort was excellent or good in 46.7% of the patients ($p = 0.541$) and thus comparable to the PMRT cohort (42.3%). In the RT-naive cohort, 71.4% of the patients had an excellent or good BCCT.CORE (see Figs. 2, 3).

The surgical outcome of the history of RT cohort was worse in almost all categories, compared to the other cohorts. A capsular contraction Baker III-IV was equally often present in the PMRT and history of RT cohorts (20.0% vs. 23.1%) compared to the RT-naive cohort (1.6%).

The RT-naive cohort showed the best results in almost all parts of the physical examination, but this was not significant compared to the PMRT cohort.

Discussion

The surgical management of implant-based breast reconstruction appears to be difficult if the patient had a prior RT or needs a PMRT. This is because the surgical and aesthetic results are worse and the complication rates are increased. Most studies focus on surgical results and

Table 1 All data concerning patient and tumor characteristics, treatment and expander/implant exchange intervals and follow-up times in detail are listed and comparing the three cohorts

	Radiotherapy-naive cohort	PMRT cohort	*p* value	Radiotherapy-naive cohort	History of RT cohort	*p* value	PMRT cohort	History of RT cohort	*p* value
No. of patients (total no. 95)	*54 (56.8%)*	**26 (27.4%)**		*54 (56.8%)*	15 (15.8%)		**26 (27.4%)**	15 (15.8%)	
No. of operated breasts (total no. 104)	*63 (60.6%[a])*	**26 (25.0%[a])**		*63 (60.6%[a])*	15 (14.4%[a])		**26 (25.0%[a])**	15 (14.4%[a])	
Mean age	*52.8*	**50.2**	0.305	*52.8*	61.0	0.001	**50.2**	61.0	0.001
Relapsed			1.000			0.000			0.000
Yes	*0*	**0**		*0*	12 (80.0%[a])		**0**	12 (80.0%[a])	
No	*63 (100%[a])*	**26 (100%[a])**		*63 (100%[a])*	3 (20.0%[a])		**26 (100%)**	3 (20.0%[a])	
T-Stage			0.000			1.000			0.021
pTis	*10 (15.9%[a])*	**0**		*10 (15.9%[a])*	2 (13.3%[a])		**0**	2 (13.3%[a])	
c/pT1	*34 (54.0%[a])*	**10 (38.5%[a])**		*34(54.0%[a])*	10 (66.7%[a])		**10 (38.5%[a])**	10 (66.7%[a])	
c/pT2	*11 (17.5%[a])*	**11(42.3%[a])**		*11 (17.5%[a])*	3 (20.0%[a])		**11(42.3%[a])**	3 (20.0%[a])	
c/pT3	*0*	**5 (19.2%[a])**		*0*	0		**5 (19.2%[a])**	0	
c/pT4	*0*	**0**		*0*	0		**0**	0	
Prophylactic	*8 (12.7%[a])*	**0**		*8 (12.7%[a])*	0		**0**	0	
N-stage			0.000 0.000[c]			0.024 1.000[c]			0.000 0.003[c]
c/pN0	*44 (69.8%[a])*	**4 (15.4%[a])**		*44 (69.8%[a])*	7 (46.7%[a])		**4 (15.4%[a])**	7 (46.7%)	
c/pN1	*10 (15.9%[a])*	**16 (61.5%[a])**		*10 (15.9%[a])*	1 (6.7%[a])		**16 (61.5%[a])**	0	
c/pN2	*0*	**2 (7.7%[a])**		*0*	0		**2 (7.7%[a])**	0	
c/pN3	*0*	**4(15.4%[a])**		*0*	0		**4(15.4%[a])**	0	
Nx	*9 (14.3%[a])*	**0**		*9 (14.3%[a])*	7 (46.7%[a])		**0**	7 (46.7%)	
ER-Status			0.330			0.230			1.000
Pos	*43 (68.3%[a])*	**17 (65.4%[a])**		*43 (68.3%[a])*	10 (66.7%[a])		**17 (65.4%[a])**	10 (66.7%[a])	
Neg	*12 (19.0%[a])*	**8 (30.8%[a])**		*12 (19.0%[a])*	4 (26.7%[a])		**8 (30.8%[a])**	4 (26.7%[a])	
Unknown[b]	*8 (12.7%[a])*	**1 (3.8%[a])**		*8 (12.7%[a])*	1 (6.7%[a])		**1 (3.8%[a])**	1 (6.7%[a])	
PR-Status			0.046			0.084			1.000
Pos	*41 (65.1%[a])*	**13 (50.0%[a])**		*41 (65.1%[a])*	8 (53.3%[a])		**13 (50.0%[a])**	8 (53.3%[a])	
Neg	*14 (22.2%[a])*	**12 (46.2%[a])**		*14 (22.2%[a])*	7 (40.0%[a])		**12 (46.2%[a])**	7 (40.0%[a])	
Unknown[b]	*8 (12.7%[a])*	**1 (3.8%[a])**		*8 (12.7%[a])*	1 (6.7%[a])		**1 (3.8%[a])**	1 (6.7%[a])	
Her2neu Status			0.212			0.678			1.000
Pos	*7 (11.1%[a])*	**7 (26.9%[a])**		*7 (11.1%[a])*	3 (20.0%[a])		**7 (26.9%[a])**	3 (20.0%[a])	
Neg	*38 (60.3%[a])*	**18 (69.2%[a])**		*38 (60.3%[a])*	10 (66.7%[a])		**18 (69.2%[a])**	10 (66.7%[a])	
Unknown[b]	*8 (12.7%[a])*	**1 (3.8%[a])**		*8 (12.7%[a])*	2 (13.3%[a])		**1 (3.8%[a])**	2 (13.3%[a])	
Tobacco use			0.723			0.576			0.884
Current	*7 (11.1%[a])*	**5 (19.2%[a])**		*7 (11.1%[a])*	3 (20.0%[a])		**5 (19.2%[a])**	3 (20.0%[a])	
Prior	*12 (19.0%[a])*	**4 (15.4%[a])**		*12 (19.0%[a])*	1 (6.7%[a])		**4 (15.4%[a])**	1 (6.7%[a])	
None	*42 (66.7%[a])*	**17 (65.4%[a])**		*42 (66.7%[a])*	11 (73.3%[a])		**17 (65.4%[a])**	11 (73.3%[a])	
Unknown	*2 (3.2%[a])*	**0**		*2 (3.2%[a])*	0		**0**	0	
Diabetes			1.000			.582			0.366
Yes	*1 (1.6%[a])*	**0**		*1 (1.6%[a])*	1 (6.7%[a])		**0**	1 (6.7%[a])	
No	*60 (95.2%[a])*	**26 (100%[a])**		*60 (95.2%[a])*	14 (93.3%[a])		**26 (100%[a])**	14 (93.3%[a])	
Unknown	*2 (3.2%[a])*	**0**		*2 (3.2%[a])*	0		**0**	0	
Axillary surgery			0.000			0.042			0.000
Sentinel only	*29 (46.0%[a])*	**2 (7.7%[a])**		*29 (46.0%[a])*	2 (13.3%[a])		**2 (7.7%[a])**	2 (13.3%[a])	
ALND	*7 (11.1%[a])*	**21 (80.8%[a])**		*7 (11.1%[a])*	2 (13.3%[a])		**21 (80.8%[a])**	2 (13.3%[a])	

Table 1 (continued)

	Radiotherapy-naive cohort	PMRT cohort	*p* value	Radiotherapy-naive cohort	History of RT cohort	*p* value	PMRT cohort	History of RT cohort	*p* value
None	*27 (42.9%[a])*	**3 (11.5%[a])**		*27 (42.9%[a])*	11 (73.4%[a])		**3 (11.5%[a])**	11 (73.4%[a])	
Chemotherapy			0.000			0.202			0.000
Neoadjuvant	*10 (15.9%[a])*	**12 (46.2%[a])**		*10 (15.9%[a])*	0 (0%[a])		**12 (46.2%[a])**	0 (0%[a])	
Adjuvant/palliative	*15 (23.8%[a])*	**11 (42.3%[a])**		*15 (23.8%[a])*	6 (40.0%[a])		**11 (42.3%[a])**	6 (40.0%[a])	
None	*38 (60.3%[a])*	**3 (11.5%[a])**		*38 (60.3%[a])*	9 (60.0%[a])		**3 (11.5%[a])**	9 (60.0%[a])	
Interval expander to implant exchange	Median months (range)	Median months (range)		Median months (range)	Median months (range)		Median months (range)	Median months (range)	
After expander implantation	*9.6 (3.4–26.3)*	**11.6 (3.4–18.4)**	0.019	*9.6 (3.4–26.3)*	9.4 (5.1–14.5)	0.670	**11.6 (3.4–18.4)**	9.4 (5.1–14.5)	0.011
After end of RT		**6.2 (2.6–15.3)**					**6.2 (2.6–15.3)**		
To examination date	*17.0 (3.9–61.0)*	**16.6 (2.7–50.0)**	0.551	*17.0 (3.9–61.0)*	21.7 (9.5–64.9)	0.456	**16.6 (2.7–50.0)**	21.7 (9.5–64.9)	0.239

Italics marks the radiotherapy-naive cohort, bold the PMRT cohort and underline the history of RT cohort

[a]Percent of operated breasts

[b]For example in cases of prophylactic mastectomy

[c]If cases with unknown nodal status excluded

Table 2 The BreastQ scores of each domain comparing the three cohorts (*p* value, *B* and 95% confidence interval (CI) for B)

	Radiotherapy-naive cohort	PMRT cohort	*p* value*** *B* 95% CI for *B*	Radiotherapy-naive cohort	History of RT cohort	*p* value*** *B* 95% CI for *B*	PMRT cohort	History of RT cohort	*p* value*** *B* 95% CI for *B*
Satisfaction with breast	*60.24* *63* *14.879*	**56.96** **26** **10.524**	0.336 − 1.816 − 5.546 to 1.915	*60.24* *63* *14.879*	49.47 15 14.774	0.042 − 9.662 − 18.943 to − 0.382	**56.96** **26** **10.524**	49.47 15 14.774	0.014 12.633 2.769 to 22.497
Satisfaction with breast implant	*73.32* *62* *17.662*	**70.77** **26** **15.063**	0.473 − 1.671 − 6.282 to 2.940	*73.32* *62* *17.662*	61.60 15 20.894	0.061 − 11.009 − 22.548 to 0.530	**70.77** **26** **15.063**	61.60 15 20.894	0.045 15.478 0.379 to 30.578
Satisfaction with outcome	*69.63* *62* *19.360*	**76.88** **26** **17.018**	0.231 2.903 − 1.883 to 7.688	*69.63* *62* *19.360*	66.53 15 24.724	0.183 − 8.314 − 20.641 to 4.013	**76.88** **26** **17.018**	66.53 15 24.724	0.004 22.366 7.623 to 37.108
Psychosocial well-being	*51.00* *56* *21.827*	**63.42** **24** **23.292**	0.060 5.960 − 0.259 to 12.180	*51.00* *56* *21.827*	50.69 13 35.158	0.611 − 4.400 − 21.616 to 12.816	**63.42** **24** **23.292**	50.69 13 35.158	0.010 31.432 8.213 to 54.651
Sexual well-being	*70.19* *63* *17.431*	**68.88** **26** **14.728**	0 .618 1.090 − 3.246 to 5.425	*70.19* *63* *17.431*	62.73 15 19.539	0.092 − 9.233 − 20.029 to 1.562	**68.88** **26** **14.728**	62.73 15 19.539	0.061 13.702 − 0.647 to 28.052
Physical well-being	*51.24* *62* *6.782*	**51.85** **26** **8.201**	0.604 0.505 − 1.422 to 2.431	*51.24* *62* *6.782*	52.40 15 8.716	0.243 2.593 − 1.795 to 6.981	**51.85** **26** **8.201**	52.40 15 8.716	0.982 0.080 − 7.022 to 7.181

Italics marks the radiotherapy-naive cohort, bold the PMRT cohort and underline the history of RT cohort

***Adjusted by RT, age, smoker (yes/no), chemotherapy (yes/no)

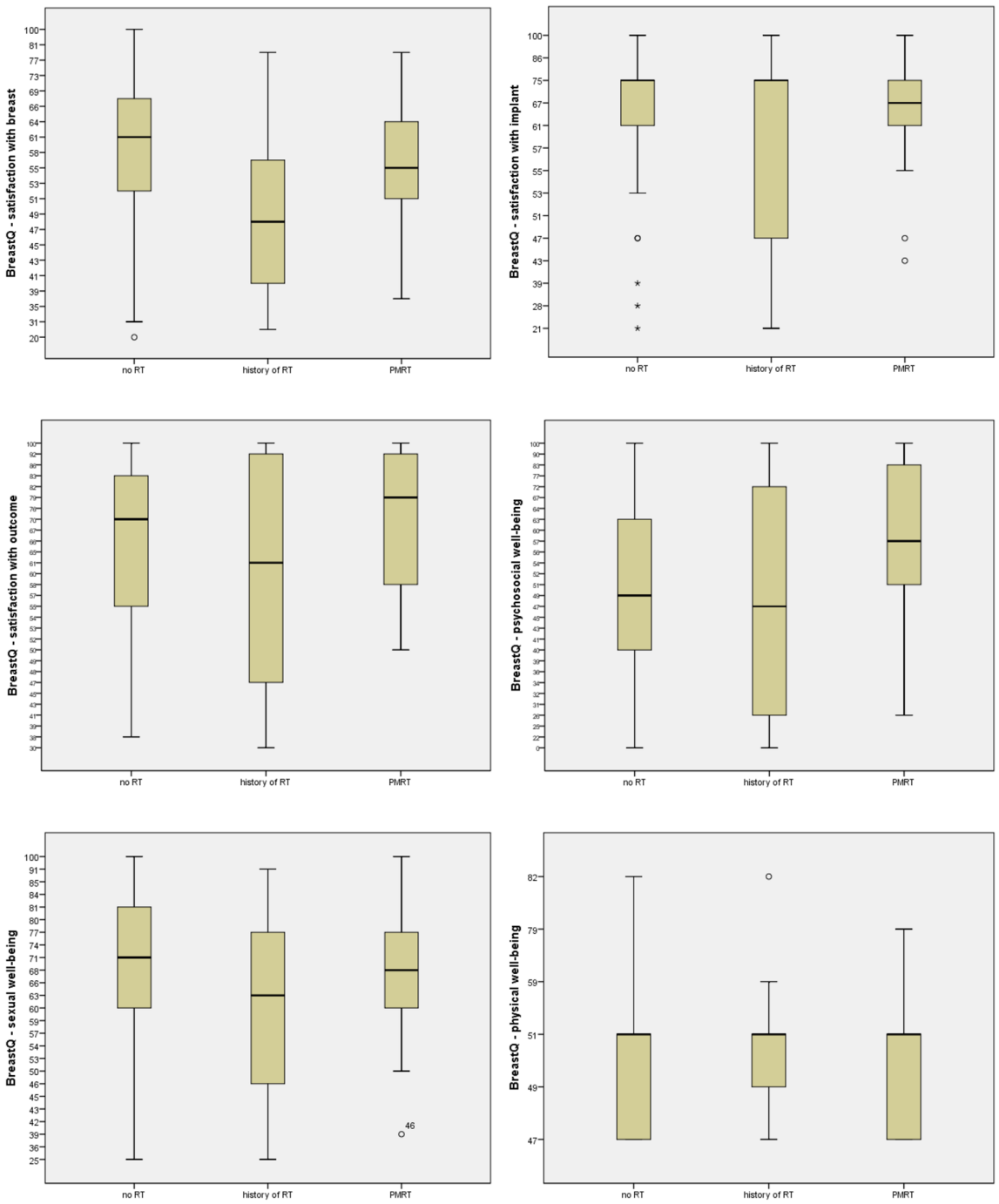

Fig. 1 The boxplots demonstrate the differences of the BreasQ scores of all six evaluated categories between the three cohorts

complication rates of breast reconstruction. So far, there are many publications existing about QoL but far less combining the QoL data with surgical/aesthetic outcome assessed by a clinical examination. Additionally, comparability is limited due to big variations concerning timing and techniques of EIBR. Patient satisfaction and QoL should be one of the main goals in reconstructive breast surgery in addition to oncological outcome and objective criteria like breast form and capsular contraction.

A challenge in the interpretation of QoL results is that the minimal important difference, defining a significant change or difference in QoL, is yet to be defined. For BreastQ, it seems to be at least seven points [42]. According to the BreastQ manual, a change of 5–10 points for one patient is

Table 3 The BCCT.CORE results and the results of the structured examination comparing the three cohorts (*p* value, Exp-*B* and 95% confidence interval (CI) for Exp-*B*)

	Radiotherapy-naive cohort	PMRT cohort	*p* value*** Exp(*B*) 95% CI	Radiotherapy-naive cohort	History of RT cohort	*p* value*** Exp(*B*) 95% CI	PMRT cohort	History of RT cohort	*p* value*** Exp(*B*) 95% CI
BCCT.CORE			0.087 2.640 0.868–8.028			0.541 1.552 0.379–6.366			0.757 0.731 0.100–5.327
Fair/poor	*18 (28.6%*)*	**15 (57.7%*)**		*18 (28.6%*)*	8 (53.3%*)		**15 (57.7%*)**	8 (53.3%*)	
Excellent/good	*45 (71.4%*)*	**11 (42.3%*)**		*45 (71.4%*)*	7 (46.7%*)		**11 (42.3%*)**	7 (46.7%*)	
Examination results									
Breast form			0.559 1.432 0.430–4.762			0.001 11.666 2.782–48.925			0.092 0.256 0.052–1.247
Fair and poor	*11 (17.5%*)*	**8 (30.8%*)**		*11 (17.5%*)*	11 (73.3%*)		**8 (30.8%*)**	11 (73.3%*)	
Excellent and good	*52 (82.5%*)*	**18 (69.2%*)**		*52 (82.5%*)*	4 (26.7%*)		**18 (69.2%*)**	4 (26.7%*)	
Symmetry			0.221 1.943 0.670–5.630			0.059 3.789 0.948–15.137			0.197 0.276 0.039–1.951
Fair and poor	*22 (34.9%*)*	**15 (57.7%*)**		*22 (34.9%*)*	11 (73.3%*)		**15 (57.7%*)**	11 (73.3%*)	
Excellent and good	*41 (65.1%*)*	**11 (42.3%*)**		*41 (65.1%*)*	4 (26.7%*)		**11 (42.3%*)**	4 (26.7%*)	
Contralateral adjustment			0.198 0.360 0.076–1.706			0.650 0.703 0.153–3.230			0.614 0.583 0.072–4.743
Not required/done	*53 (84.1%*)*	**21 (80.8%*)**		*53 (84.1%*)*	12 (80.0%*)		**21 (80.8%*)**	12 (80.0%*)	
Not done/not desired	*10 (15.9%*)*	**5 (19.2%*)**		*10 (15.9%*)*	3 (20.0%*)		**5 (19.2%*)**	3 (20.0%*)	
Scars			0.733 0.786 0.196–3.144			0.044 4.144 1.041–16.502			0.095 0.160 0.019–1.373
Fair and poor	*14 (22.2%*)*	**4 (15.4%*)**		*14 (22.2%*)*	6 (40.0%*)		**4 (15.4%*)**	6 (40.0%*)	
Excellent and good	*49 (77.8%*)*	**22 (84.6%*)**		*49 (77.8%*)*	9 (60.0%*)		**22 (84.6%*)**	9 (60.0%*)	
Capsular contraction			0.055 0.110 0.012–1.045			0.193 0.100 0.003–3.209			0.232 4.285 0.395–46.495
Baker I and II	*62 (98.4%*)*	**20 (76.9%*)**		*62 (98.4%*)*	12 (80.0%*)		**20 (76.9%*)**	12 (80.0%*)	
Baker III and IV	*1 (1.6%*)*	**6 (23.1%*)**		*1 (1.6%*)*	3 (20.0%*)		**6 (23.1%*)**	3 (20.0%*)	
Overall result			0.351 1.685 0.563–5.038			0.022 4.641 1.254–17.179			0.125 0.224 0.033–1.518
Fair and poor	*16 (25.4%*)*	**11 (42.3%*)**		*16 (25.4%*)*	10 (66.7%*)		**11 (42.3%*)**	10 (66.7%*)	
Excellent and good	*47 (74.6%*)*	**15 (57.7%*)**		*47 (74.6%*)*	5 (33.3%*)		**15 (57.7%*)**	5 (33.3%*)	

Italics marks the radiotherapy-naive cohort, bold the PMRT cohort and underline the history of RT cohort

***Adjusted by RT, age, smoker (yes/no), chemotherapy (yes/no)

believed to be minimal, 10–20 points moderate and more than 20 points significant. So far, there is no definition for a specific threshold of QoL-scores meaning a good QoL. Mundy et al. published normative data to ease the interpretation of BreastQ values. In their study, 1201 women of the Army of Women (AoW) (online community of women) without prior history of breast cancer or breast surgery completed the mastectomy, BCT and reconstruction pre-operative BreastQ scales [43].

In our study, patient-reported outcome in the cohorts RT-naive or PMRT showed comparable QoL scores in almost all categories although the latter underwent more therapy

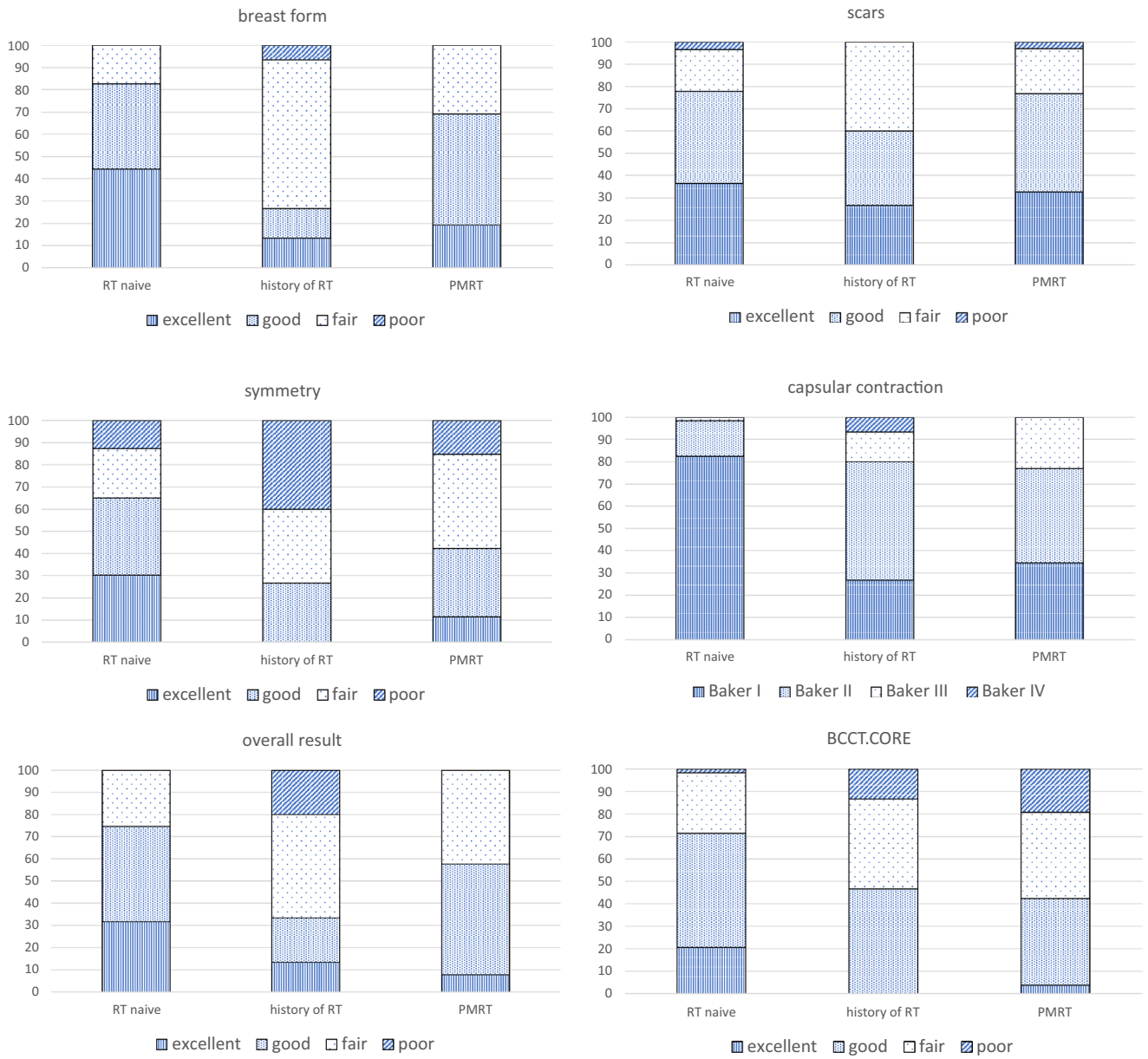

Fig. 2 The stacked bar graphs show the distribution of the examination results in percent in the examination areas breast form, symmetry, scars, capsular contraction and overall result

(e.g., ALND, CT, NACT), potentially decreasing QoL and objective outcome [31]. However, compared to normative data satisfaction with breast is comparable (58 vs 60 and 57 points, respectively) whereas physical well-being (93 vs 51 and 52 points) and psychosocial well-being (71 vs 51 and 63 points) are worse. In contrast, sexual well-being is better in our study (53 vs 70 and 69 points) [43]. Also, in comparison to the study of Albornoz et al., physical and psychosocial well-being are worse, satisfaction with breast and outcome is comparable, and sexual well-being is even superior [15]. We do not have an explanation why our patients with an outcome comparable to other studies perceive a worse physical and psychosocial well-being. For further interpretation, data of pre-reconstruction module might be helpful. As it is very unlikely that sexual well-being improves after BC treatment, it seems more likely that pre-operative data of our study population were different from that of the AoW.

The surgical results (BCCT.CORE and structured examination) were not significantly worse in the PMRT group compared to the RT-naive cohort with a less favorable overall result and a higher rate of capsular contraction. By contrast, the PMRT cohort showed even better results concerning satisfaction with outcome and psychosocial well-being exceeding the minimal important difference

This patient had an invasive breast cancer with extensive DCIS of the right breast and received a mastectomy with EIBR (+ reconstruction of the nipple-areola-complex) on the right site and an augmentation of the left breast. There was no indication for a RT.

This BRCA-2 mutation carrier developed an invasive breast cancer on the right site with multicentric disease and extensive lymphnode involvement. A bilateral mastectomy with EIBR was performed. The picture shows the result 1 year after PMRT to the right thoracic wall (and the supra-clavicular lymphnodes) and before the planned reconstruction of the nipple-areola-complex.

The patient had an invasive cancer of the left breast 10 years ago. At that time breast conserving therapy with postoperative radiotherapy was performed. Due to relapse, she received a mastectomy with EIBR. Capsular contraction Baker grade III appeared after just one year.

Fig. 3 Picture examples of each cohort

of seven points. This may be a result of our practice to inform these patients very carefully prior to surgery about the potentially negative impact of RT such as capsular contraction, less favorable overall result and higher risk of implant removal. This may lead to lower expectations and thus higher satisfaction [44] even though PMRT is known to have higher complication rates [22, 27, 45] that are an important predictor of dissatisfaction with reconstruction [46, 47]. Still, even in the PMRT group, psychosocial well-being is 8 points lower compared to the normative data whereas sexual well-being is better in all three cohorts (56 vs 70/69/63 points) [43].

In general, complication rates seem to be lower if PMRT is applied to the permanent implant instead of the expander [20, 27, 48]. At our institution, we chose another schedule with PMRT to the expander and a relatively long interval between end of RT and expander–implant exchange resulting in a low number of complications and reconstruction failures. The mean expander–implant exchange interval was 6.2 months after finishing RT. This is consistent with Peled et al. who described a significantly lower expander–implant failure rate of 7.7% (vs. 22%) after increasing the time to expander–implant exchange to more than six months [35]. A rationale for a later exchange is that radiation effects like endothelial cell loss occurs 2 to 6 months after RT, leading to reduced dermal blood flow. This effect is regressing between 6 and 9 months after RT [49, 50].

Other studies also showed acceptable aesthetic results and a high percentage of patients satisfied with the outcome after PMRT [20, 27, 48, 51]. In contrast, Albornoz et al. showed significantly lower satisfaction scores in almost all BreastQ scales, exceeding a mean score difference of five points, if patients underwent PMRT [15].

Patients with a history of RT had a worse outcome. They showed significantly worse results in the structured examination with only 33.3% of the patients having a good or excellent overall result. This is also mirrored by significantly lower BreastQ scores with a mean difference of 11 points in the category satisfaction with breast and a numerical difference of more than 7 points in the categories satisfaction with breast implant and sexual well-being. On the other hand, satisfaction with outcome and psychosocial and physical well-being were as good as in the RT-naive cohort. Other authors found similar results, with worse aesthetic outcomes and higher complication rates in patients with prior RT [52–54]. Nevertheless, they conclude that EIBR can be an option in previously irradiated patients, emphasizing that a careful selection concerning tissue and skin quality is important. Capsular contraction Baker III or IV occurred in 20% which is comparable to other studies [55, 56].

In contrast to our results, Albornoz et al. [15] found no significant differences for QoL scores between RT-naive patients and patients with prior RT. Another group found comparable rates of overall complications and

dissatisfaction, but a higher incidence of mastectomy skin flap loss [16].

Despite the less favorable outcome in the history of RT cohort, 78.6% of the patients would undergo the operation again compared to 92.7% in the RT-naive cohort and 84.6% in the PRMT cohort, demonstrating that this procedure may be still an option for these patients.

This study has several limitations. The RT cohorts are quite small, so random effects cannot be excluded. Additionally, the patients were not randomized to the type of reconstruction and EIBR was only offered to patients that seemed to be appropriate for EIBR. A potential bias is that non-participants might have worse results, thus leading to lower satisfaction and willingness to participate. However, the baseline characteristics did not differ significantly between participating and non-participating patients who met the inclusion criteria (data not shown). Another potential bias might be the fact that patients without expander/implant exchange were excluded from statistical analysis. Data derived from the pre-reconstruction module would have been helpful for the interpretation of the outcome. These data were not collected because the study was not planned initially. Additionally, a follow-up period of 16.6–21.7 months after exchange may have been too short to show late developing differences and long-term results. The surgical outcome deteriorates from more than 80% acceptable results after two years, to about 54% after five years [57]. On the other hand, this study represents a quite homogenous collective as all operations were performed by only two surgeons in a highly standardized procedure, thus leading to a good comparability of the three cohorts.

Conclusion

This study confirms the negative impact of RT on EIBR. After a short follow-up time, EIBR seems to be an option for breast reconstruction resulting in an acceptable QoL and surgical results, even if PMRT is required. In patients with a prior RT, QoL and surgical results are significantly worse compared to the other groups, but this difference is still moderate.

However, patients' acceptance of EIBR is high. Therefore, EIBR as a first step can be offered to patients that are not suitable for ABR or that opt for a "smaller" surgical intervention with the possibility to switch to ABR if EIBR fails. Prospective studies with larger cohorts and long-term follow-up are required for definitive conclusions.

Author contributions All authors participated in collecting the patient data and analyzed and interpreted the patient data. MB and MH were responsible for the outline of the research and data interpretation. MH and MP were the major contributors in writing the manuscript. All authors read and approved the final manuscript.

Compliance with ethical standards

Conflict of interest Author M. Hamann declares that he has no conflict of interest. Author M. Brunnbauer declares that she has no conflict of interest. Author H. Scheithauer declares that she has no conflict of interest. Author U. Hamann declares that he has no conflict of interest. Author M. Braun declares that he has no conflict of interest. Author M. Pölcher declares that he has no conflict of interest.

Research involving human participants All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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