Journal of Plastic, Reconstructive & Aesthetic Surgery (2019) 72, 805–812

Subcutaneous expanders and synthetic mesh for breast reconstruction: Long-term and patient-reported BREAST-Q outcomes of a single-center prospective study

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Received 23 October 2018; accepted 10 December 2018

KEYWORDS
Nipple-sparing mastectomy (NSM);
TiLOOP;
Subcutaneous breast reconstruction;
Muscle sparing reconstruction;
BREAST-Q;
Prepectoral reconstruction

Summary Recently, prepectoral breast reconstruction is experiencing a revival. Despite the growing body of early reports about subcutaneous breast reconstruction, literature lacks in long-term results and studies focusing on patient-reported outcomes and health-related quality of life.

Between January 2012 and December 2016, patients undergoing mastectomy were enrolled at our institution. We selected patients diagnosed with breast cancer or genetic predisposition to breast cancer, undergoing conservative mastectomy, either nipple-sparing or skin-sparing mastectomy, and willing for prepectoral tissue expander reconstruction assisted by a synthetic mesh. Exclusion criteria were body mass index greater than 35 kg/m^2 and pregnancy. BREAST-Q questionnaire was administered prior to surgery and after 1 year. Capsular contracture was evaluated using Baker scale. Oncological, surgical, and esthetic outcomes along with the changes in BREAST-Q score were analyzed over time.

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https://doi.org/10.1016/j.bjps.2018.12.018

One hundred eighty-seven patients were enrolled, with an average age of 55.5 years. One hundred thirty-seven unilateral mastectomy and 50 bilateral mastectomy procedures were performed, accounting for a total of 237 operated breasts. The average follow-up period after the second stage was 36.5 months. Postoperative complications that require a second operation occurred in 16 cases (6.7%) (4 wound dehiscence, 2 skin-nipple necrosis, 7 infections, and 3 seroma cases). A locoregional recurrence occurred in 3 cases (1.9%) and a systemic recurrence occurred in 2 cases (1.3%). Patients scored high level of satisfaction with outcome. Overall satisfaction with breasts, psychosocial well-being, and sexual well-being was all significantly increased after the surgery ($p < 0.05$).

Two-stage expander reconstruction technique provides the preservation of the pectoralis major muscle with an acceptable rate of complications. We confirm satisfactory patient-reported and esthetic results, with high patient comfort.

Introduction

Presently, implant-based reconstruction is the predominant approach among postmastectomy breast reconstruction (BR) techniques.[1] In the past decades, subpectoral implant placement has been the generally accepted and recommended method, and several variations of this method have been introduced, involving implant placement, either completely or partially, behind the musculature of the anterior chest wall.[1,2]

Beyond the purported advantages of the technique in terms of low risk of capsular contracture (CC), implant rippling, and edges palpability, there are a number of concerns about the release of the pectoralis major muscle (PMM) and serratus anterior muscle (SAM).[3-5] The detachment of the PMM can cause chronic postoperative pain, resulting in the likelihood of prolongation of postoperative recovery, impaired adduction, anteversion, and inward rotation of the upper limb, as well as breast animation during its contraction. The detachment of SAM can result in tedious postoperative pain irradiating to the scapula.[3-5]

As the early experience with subcutaneous reconstruction was associated with higher rates of CC, implant exposure, and implant loss, subcutaneous approach has been shelved for many years.[5] Recently, the development of new materials along with considerable advances in oncologic surgery led to innovative approaches in BR.[2,6-14] The use of acellular dermal matrix (ADM) and synthetic mesh for wrapping around the implant enables a complete subcutaneous positioning of the prosthesis, accounting for an immediate, muscle-sparing BR.

Several studies reported the preliminary results of prepectoral direct-to-implant (DTI) or two-stage reconstruction, with implants/expanders wrapped by titanium-coated polypropylene mesh (TCPM) or ADM.[2,7-14] Despite the growing body of early reports about prepectoral BR, the literature lacks in long-term results and studies focusing on patient-reported outcomes and health-related quality of life (HRQOL).

Therefore, the aim of our study was to prospectively evaluate the long-term outcomes of prepectoral BR with expanders and TiLOOP® TCPM.

Materials and methods

Patients

Between January 2012 and December 2016, patients undergoing mastectomy were enrolled at our institutions, Azienda Ospedaliero-Universitaria Careggi, Florence and Breast Unit Integrata, Livorno, Cecina, Piombino, Elba, Azienda USL Toscana nord ovest. Prior to surgery, all patients were thoroughly informed about the different modalities of reconstruction and were evaluated for both autologous and alloplastic BRs. We selected patients diagnosed for breast cancer or genetic predisposition to breast cancer, undergoing conservative mastectomy, either nipple-sparing mastectomy (NSM) or skin-sparing mastectomy (SSM), and willing for prepectoral tissue expander reconstruction assisted by a synthetic mesh. Exclusion criteria were body mass index greater than 35 kg/m^2 and pregnancy. Patients not suitable for prepectoral criteria underwent reconstruction with other techniques. The TCPM prepectoral reconstruction is currently exploited in plastic surgery applications at our institutions, as approved by our institutional Ethics Committee, and our study was performed with respect to the ethical standards of the Declaration of Helsinki.

Operative technique

We described our surgical technique for immediate reconstruction with implant or expander and TiLOOP® Bra mesh in recent reports.[7-9] Briefly, in case of NSM, we separately sent a specimen (2 cm) of the tissue underlying the nipple-areola complex (NAC) to the pathologist for histological evaluation. After mastectomy, patients underwent reconstruction with expanders (Allergan®, Inc., Irvine, CA, USA) wrapped in a TCPM, specifically TiLOOP® Bra (TiLOOP® Bra, pfm medical, Cologne, Germany), following careful clinical evaluation of the skin flaps. Good viability was defined as normal skin color and active bleeding at the fresh cut edges. First, TiLOOP was shortly soaked in a gentamicin solution; then, using reabsorbable sutures, it was folded onto itself to create a pouch, which eventually served as a pocket for

the expanders. In case of an expander volume greater than 300 cc, two meshes were sutured to create the pocket. The pocket was tailored around the expander at its final expansion volume, which was then deflated to one-third before the implantation. The expander was then placed in a prepectoral pocket and sutured with apical, medial, and lateral absorbable stitches directly onto the fascia of the PMM. The first postoperative expansion was scheduled 3 weeks following discharge, unless a delay of wound healing occurred. Two other expansions were scheduled, and one-third of the final volume was injected at each time. The expander was replaced with definitive implant 6 months after the last expansion. In the second-stage reconstruction, the incision was made at the previous scar and highly cohesive anatomically shaped silicone gel-filled implants (Allergan®, Inc., Irvine, CA, USA) were used for the final reconstruction. At this time, a lipofilling was performed in patients who received radiotherapy; fat was harvested from the abdomen and injected in the plane between the skin and the neofascia surrounding the pocket. In both the stages, one vacuum drain was inserted in the inframammary fold, and the skin was closed in layers. All patients received perioperative intravenous antibiotics that continued for 24 h and then oral antibiotics until drain removal. Follow-up points were scheduled 1 month, 3 months, 6 months, 1 year, and 2 years after surgeries. The same surgeons (CD, MM, LB, and FLT) performed all the procedures.

Outcomes and measures

A prospective digital database was created to collect all data of patients and surgeries. Primary outcome was postoperative complications. Esthetic outcome, CC grade, any cancer recurrences, and HRQOL measurement were recorded as secondary outcomes. Any skin–nipple necrosis, seroma, wound dehiscence, wound infection, or hematoma requiring a second operation was considered a surgical complication. Esthetic complication requiring a reoperation (implant rippling, dystopia, or severe CC grade) was considered separately in the statistic analysis. The Baker scale was used for scoring CC during postoperative follow-ups.

HRQOL outcome

The BREAST-Q patient-reported outcomes measure was designed to meet high standards of medical outcomes evaluation in patients undergoing breast surgery.[15,16] It has been extensively validated for research in BR and is routinely used at our institutions.[8] Enrolled patients received the preoperative questionnaire 1 month before surgery. Postoperative BREAST-Q modules for reconstructive surgery were administered 1 year after the completion of BR. At this time point, surveys were administered directly to patients during a follow-up visit. All aspects of the BREAST-Q reconstructive module (Satisfaction with Breasts, Satisfaction with Outcome, Psychosocial Well-Being, Physical Well-Being, and Sexual Well-Being) were analyzed.

Table 1 Demographic characteristics of patients.

Patient characteristic	All patient (n. 187)
Age [years, mean (range)]	55.5 (29–80)
BMI [kg/m^2, mean (range)]	24.9 (19–35)
Marital status (*n*, %)	
Married	153 (81.8)
Divorced	10 (5.4)
Separated	7 (3.7)
Single	17 (9.1)
Ethnicity (*n*, %)	
Caucasian	177 (94.8)
Hispanic	5 (2.6)
Asian	5 (2.6)
Comorbidities (*n*, %)	
Connective tissue diseases	3 (1.6)
Diabetes	12 (6.4)
Smoking (*n*, %)	
Never smoker	132 (70.6)
Past smoker	31 (16.6)
Active smoker	24 (12.8)
BRCA mutation carriers (*n*, %)	37 (17.6)
BRCA1	25 (11.9)
BRCA2	12 (5.7)
Previous breast surgery (*n*, %)	53 (28.3)
Wide local excision	16 (8.6)
Contralateral mastectomy	12 (6.4)
Homolateral QUART	15 (8)
Augmentation	3 (1.6)
Previous radiotherapy (*n*, %)	
NO	158 (84.5)
YES	29 (15.5)

Esthetic outcome

Esthetic outcome was objectively assessed by an expert panel of five physicians who did not perform any of the surgeries reported in the study. The breast appearance was evaluated based on the standardized photographs taken postoperatively 1 year after the reconstruction.[8,17,18] External experts scored photographs that were anonymized and presented randomly in a slide show. Evaluated parameters were symmetry, shape, volume, and position of the IMF. Outcomes were measured using 5-point Likert scales, with 1' indicating a very poor outcome and '5' indicating an excellent outcome. In addition, they were asked to give an overall evaluation score on a 10-point scale.

Statistical analysis

SPSS software (IBM Corp., Armonk, NY) was used for simple descriptive statistics, accounting for patient sociodemographic, clinical characteristics, complications, and CC grade. Using the QScore Scoring Software, BREAST-Q scores for each matrix were converted from survey raw scores (1 through 4 or 5) to a continuous range from 0 to 100, with a higher score representing greater satisfaction or better HRQOL. Absolute scores and their changes with time were studied. The Shapiro–Wilk test was used to verify the normal

Table 2 Baseline characteristics of surgeries included in the analysis.

Characteristic	All mastectomy ($n = 237$)
Mastectomy (*n*, %)	
Bilateral	50 (26.8)
Unilateral	137 (73.2)
Type of mastectomy (*n*, %)	
NSM	145 (61.2)
SSM	92 (38.8)
Axillary surgery (*n*, %)	
Axillary resection	23 (10.5)
Sentinel lymph node biopsy	89 (40.6)

distribution of continuous variables. Consequently, BREAST-Q scores and panel scores were analyzed as continuous variables using Student's *t*-test. P values less than 0.05 were considered statistically significant.

Results

Our cohort is composed of 187 patients who underwent mastectomy between January 2012 and December 2016. Table 1 accounts for complete baseline patients' characteristics. Average age of patients was 55.5 years (range 29–80 years). The mean BMI was 24.9 kg/m^2 (range 19–35 kg/m^2). Thirty-seven patients were diagnosed for *BRCA1/2* mutation (17.6%): 25 women (11.9%) were BRCA1 mutation carriers and 12 women (5.7%) were BRCA2 mutation carrier. Fifty-three women (28.3%) had already underwent breast surgery and 29 (15.5%) radiotherapy.

Table 2 shows complete characteristics of performed surgeries. One hundred thirty-seven unilateral mastectomy (73.2%) and 50 bilateral mastectomy (26.8%) procedures were performed, accounting for a total of 237 operated breasts. One hundred forty-five mastectomies were NSM (61.2%) and 92 were SSM (38.8%). One hundred twelve patients underwent also axillary surgeries: 23 underwent axillary lymphadenectomy (10.5%) and 89 (40.6%) underwent a sentinel lymph node biopsy. Four patients had definitive diagnosis of positive sentinel lymph node and underwent lymphadenectomy. Twenty-four (11%) patients underwent adjuvant radiotherapy.

Primary and oncological outcome

The average follow-up period after the second stage of BR was 36.5 months (range 1 to 6 years). Postoperative complications that require a second operation occurred in 16 cases (6.7%) (4 wound dehiscence, 2 skin–nipple necrosis, 7 infections, and 3 seroma cases). In 9 cases, as the prosthesis resulted exposed, the expanders were removed and a savage BR was performed with submuscular expanders. 10 patients reported breast seroma, which healed uneventfully.

One patient who underwent prophylactic NSM had positive ductal carcinoma in situ at final histology, involving the margins of the retroareolar disc specimen. In this case, excision of the NAC was performed. Locoregional recurrences were calculated only in cases with cancer. A locoregional recurrence occurred in 3 cases (1.9%), and a systemic recurrence in 2 cases (1.3%). Safety and oncological outcomes are summarized in Table 3.

Table 3 Safety and oncological outcome.

Complications	Number of breasts ($n = 237$)
Complications (*n*, %)	
Yes	16 (6.7)
No	221 (93.3)
Type of complications (*n*, %)	
Skin-nipple necrosis	2 (0.8)
infection	7 (3.0)
Wound dehiscence	4 (1.7)
Seroma	3 (1.2)
Implant removal (*n*, %)	9 (3.8)
Tumor recurrence (*n*, %)	**Tumor ($n = 158$)**
Locoregional	3 (1.9)
Systemic	2 (1.3)
No recurrence	153 (96.8)

Table 4 Esthetic complications.

Esthetic complication requiring reoperation (*n*, %)	Number of breasts ($n = 237$)
Capsular contracture	9 (3.8)
Implant dystopia	2 (0.8)
Rippling	28 (11.8)
Total	39 (16.4)

Four complications were reported after the second stage of BR. Two cases of infections and 2 cases of wound dehiscence required to remove the implant. In these cases, submuscular BR was performed after clearing the infection. Two cases of wound dehiscence and 2 cases of seroma were treated with conservative therapies (Table 4).

Over an average period of 36.5 months, grade IV CC was detected in 6 breasts (2.5%), while 183 breasts were evaluated as grade I (77.2%), 45 breasts as grade II (19%), and 3 breasts as grade III (1.3%). The total rate of significant (Baker III–IV grade) CC was reported as low as 3.8%. In the case of severe contracture, implant replacement was performed. Implant rippling or palpability was detectable in 28 breasts (11.8%) after an average of 10 months after surgery, and a lipofilling was performed, successfully reducing implant visibility. The average of fat volume injected was 34.3 (range 20–80) ml per breast.

Measure of HRQOL

All the patients adequately filled the 5 domains of the questionnaire and were included in the analysis. Table 5 shows for the self-reported measures of HRQOL, evaluated with BREAST-Q questionnaire. The questionnaire was administered preoperative and during an office visit at 1- year follow-up. Patient scored high level of satisfaction with outcome. Overall satisfaction with breasts, psychosocial

Table 5 BREAST-Q scores recorded preoperatively and one year postoperatively, expressed as mean ± standard deviation. Changes in scores are expressed as delta (postoperative score minus preoperative score). *$P < 0.05$.

Domain	Preoperative mean (±SD)	Postoperative mean (±SD)	Delta mean (±SD)
Satisfaction-breasts	59.2 ± 11.8	72.2 ± 9.9	13.1 ± 15.5*
Psychosocial wellness	64 ± 14	77.5 ± 11.9	13.3 ± 18.5*
Sexual well-being	57.3 ± 14.5	61.6 ± 12.8	4.2 ± 17*
Physical impact (chest)	77.1 ± 11.7	75.4 ± 13	−1.7 ± 17.4
Overall satisfaction with outcome	-	74 ± 12	-

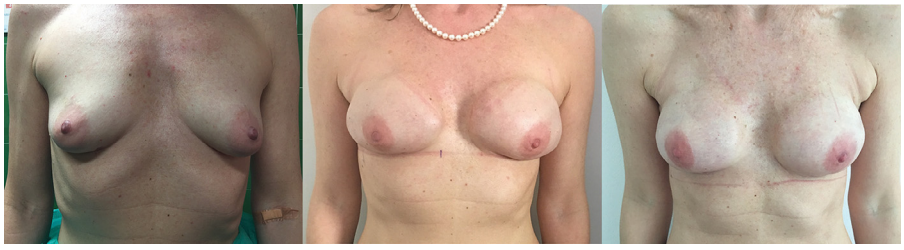

Figure 1 *Esthetic results*. A patient who underwent bilateral nipple sparing mastectomy through inframammary fold incision and two-stage prepectoral reconstruction: preoperative *(left)* picture, patient after last expansion *(center)*, and 1 year after second surgical stage *(right)*.

Table 6 Panel evaluation of postoperative results. Scores were rated on a five-point Likert scale ranging from 1 (very dissatisfied) to 5 (very satisfied). Overall esthetic result scored on a 10-point scale ranging from 1 (very poor result) to 10 (excellent result).

Scores	Postoperative mean (±SD)
Breast symmetry	3.8 ± 0.6
Breast shape	3.9 ± 0.6
Breast scars	3.9 ± 0.5
Breast volume	4 ± 0.5
Position of IMF	3.7 ± 0.5
Overall esthetic result	8.6 ± 0.6

well-being, and sexual well-being was all significantly increased after surgery ($p < 0.05$).

Esthetic outcome

Table 6 describes the panel's esthetic evaluation. According to the panel, patients scored high level of postoperative breast volume, shape, position of IMF, scars, and mean satisfaction with the overall esthetic result (Figures 1–3).

Discussion

Prosthetic submuscular BR is the most commonly performed reconstruction technique nowadays.[1,5] Placing the implant under the muscular plane has been considered a safe approach, given the higher rates of major complications with subcutaneous techniques reported by early studies. Although the detachment of PMM could be charged with several limitations such as pain or discomfort, limited expansion, implant dislocation, and breast animation, the suprapectoral reconstructive method has been overlooked for many years.[1]

Recently, plastic surgeons have revived prepectoral reconstruction, following the introduction of new devices, either biological or synthetic, that allow complete implant envelope, acting like an additional layer between the prosthesis and the subcutaneous tissue.[5] As subcutaneous approach has retrieved the main role in BR, a flood of new techniques and preliminary reports has been released. Several studies, even with short-term follow-up, presented acceptable complication rate, arguing that the prepectoral method provides a more natural esthetic result while avoiding the concerns about raising the PMM.[2,7,9,13,14]

In this prospective study, we report the surgical and BREAST-Q outcomes of a single institution series of 187 patients undergoing mastectomy and two-stage reconstruction with expander and TiLOOP® Bra mesh. We obtained encouraging results in terms of oncologic, esthetic, and patient-reported outcomes as well as CC rate over an average follow-up period of 36.5 months. We reported a highly acceptable complication rate (6.7%), with 9 cases of implant removal.

So far, no other study has examined the impact of prepectoral expander reconstruction on HRQOL. In our analysis, 1-year outcomes of the quality of life, measured by BREAST-Q questionnaire, confirmed high patient satisfaction. Patients reported significantly high rates in all the questionnaire matrices of overall satisfaction with outcome (74), overall satisfaction with breasts (72.2), psychosocial well-being (77.5), and sexual well-being (61.6), scoring a significant increase in these domains from the preoperative to the postoperative periods ($p < 0.05$). Indeed, all the postoperative data were evaluated both in absolute term and in relation to preoperative results, as changes in scores are considered a more reliable and comparable measurement.[8,11] We believe that without a baseline measurement

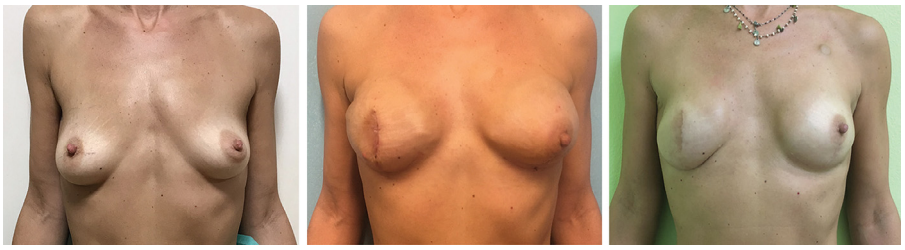

Figure 2 *Esthetic results*. A thin patient (BMI 19.8 km/m^2) who underwent right skin sparing mastectomy through vertical incision and left nipple sparing mastectomy: preoperative *(left)* picture, patient after last expansion *(center)*, and 1 year after second surgical stage *(right)*.

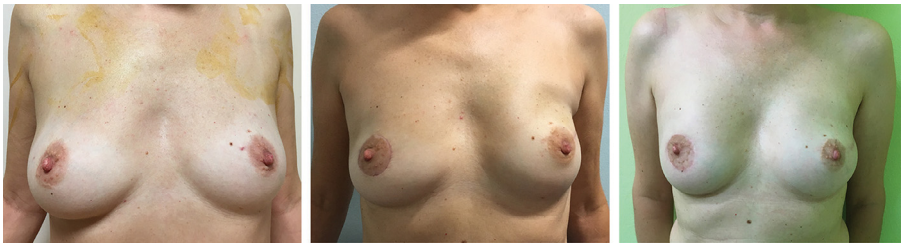

Figure 3 *Esthetic results*. An overweight patient (BMI 25.6 km/m^2) who underwent left skin nipple sparing mastectomy through lateral incision and contralateral reduction: preoperative *(left)* picture, patient after last expansion *(center)*, and 1 year after second surgical stage *(right)*.

it is difficult to evaluate if a score, even if high or at a long-term follow-up after surgery, is actually a change from the baseline score.

One of the main reasons why reconstructive surgeons preferred the submuscular approach to the prepectoral is the concern about CC rate. In recent reports, the use of the new devices showed acceptable CC rate, similar to total submuscular reconstruction, attributing the low CC to a diminished inflammatory response.[12-14] The mesh seemed to act like a sieve layer between the prosthesis and the subcutaneous tissue, reducing inflammatory response along with the likelihood of CC. In our study, we confirm these trends and we reported a rate of CC grade as low as 3.8%. Indeed, our experience does not have a long-term follow-up, limiting possible considerations about CC.

In this case series, complications requiring reintervention occurred in 16 patients (6.7%), who reported infection (7 cases), wound dehiscence (4 cases), skin-nipple necrosis (2 cases), and seroma (3 cases). Because of the extensive soft-tissue damage and prosthesis exposure, implant removal was necessary in 9 cases and patients underwent a second-stage reconstruction with submuscular expanders, followed by breast implant and lipofilling after 6 months. In this regard, positioning the implant in the prepectoral plane allowed surgeons to save another possibility for reconstruction, other than autologous approach, using the submuscular reconstruction as a second prosthetic rescue procedure.

In submuscular BR, it is challenging to expand the infraclavicular portion of the muscle, and this can lead to a step deformity in the upper border of the breast.[3,19] Suprapectoral expander insertion is more effective in filling also the infraclavicular areas and augmenting the medial aspect of the breast for better cleavage. In order to avoid this drawback, detachment of the PMM muscle higher up in the sternum has been exploited in several techniques, but this maneuver may cause fibrosis, along with dynamic or permanent skin retraction that requires correction.[3,19] On the other hand, prepectoral breast reconstruction (PBR) may increase the possibility of implant palpability, especially in thin patients.[14] Indeed, in our series, over a 5-years follow-up, we reported an acceptable rate of rippling cases, requiring a revision. In these patients, a lipofilling was successfully performed, with the injection of an average at volume of 34.3 ml per breast.

So far, the majority of patients receiving radiation therapy are expected to have a better result when the BR is performed in two stages and are usually discouraged from prepectoral reconstruction.[3,19] Of the 47 patients with a history of preoperative or postoperative radiotherapy, 9 patients reported complications. The group of radiated patients scored good result at both HRQOL and esthetic assessments. These results with prepectoral reconstruction in irradiated patients may be because of the observation that prepectoral placement allow a faster expansion, owing to the lack of muscular tension over the expanders. This modality of expansion maintains breast shape and skin softness more than the expansion of the irradiated fibrotic muscle.[20,21] In patients, who underwent postoperative radiation therapy, we performed a lipofilling during the second stage of reconstruction in order to ameliorate the subcutaneous softness and thickness, following the evidences about to the trophic property of adipose tissue and liposuction fluid.[22-26]

Indeed, in our clinical experience, we found that patients at lower BMI and/or radiated undergoing one-stage DTI PBR were more prone to develop a complication or CC than the patients undergoing two-stage expander-assisted PBR.[27] Furthermore, recent reports have evaluated the role of these emerging techniques in the context of radiotherapy. A retrospective analysis evaluating subcutaneous

versus submuscular placed expanders confirmed a higher intraoperative and first postoperative expansion ratio without increased complication rates in the prepectoral group.[19] Another study reported the early data of two stages PBR in patients with postmastectomy radiation therapy, arguing that no risk factors, including radiation and weight, were associated with any complication.[28] Following these findings and our experience, even at lower levels of BMI and if postoperative radiotherapy is planned, two-stage expander assisted PBR can be considered a reliable approach.

Interestingly, we reported 12 cases of seroma, only 2 of them requiring a second operation. Although the use of ADM has been associated with an increased rate of seroma, recent studies reported a low rate of seroma for mesh-assisted BR.[7-9] A possible explanation to this issue could rely on the loose knitting of our mesh, which, conversely to other devices, allows an easy fluid drainage. Furthermore, in two-stage subcutaneous BR, we were able to manage seroma with a conservative approach, which involves simultaneous drainage of the fluid and expansion of the implant in the same session, filling the dead space previously occupied by seroma, and decreasing the likelihood of any recurrence.[29]

In conclusion, in our patient series, two-stage expander reconstruction technique provides the preservation of the PMM with an acceptable rate of complications. We confirm satisfactory patient-reported and esthetic results, with high patient comfort. These results might support the evaluation of the two-stage muscle-sparing prepectoral approach as a valid alternative to traditional submuscular expander reconstruction.

Author contributions

Donato Casella: Conception and design; Surgery performance; Administrative support; Provision of study material or patients; Collection and assembly of data; Data analysis and interpretation;
Giuseppe Di Taranto: Collection and assembly of data; Data analysis and interpretation; Manuscript writing;
Marco Marcasciano: Surgery performance; Collection and assembly of data; Data analysis and interpretation,
Federico Lo Torto: Surgery performance; Provision of study material or patients; Collection and assembly of data;
Leonardo Barellini: Surgery performance; Administrative support; Collection and assembly of data; Data analysis and interpretation;
Silvia Sordi: Conception and design; Collection and assembly of data; Data analysis and interpretation; Manuscript writing;
Ilaria Gaggelli: Assembly of data; Data analysis and interpretation; Administrative support;
Roncella Manuela: Assembly of data; Data analysis and interpretation;
Claudio Calabrese: Surgery performance; Conception and design; Administrative support; Provision of study material or patients; Collection and assembly of data; Data analysis and interpretation;
Diego Ribuffo: Conception and design; Administrative support; Data analysis and interpretation; Manuscript writing.

Acknowledgments

We report that the author Donato Casella has been recently contracted (March 2018) for attending events and workshop as guest speaker, on an “ad hoc” basis contractor or freelance consultant agreement with Pfm Medical, TiLOOP Bra manufacturing company. The rest of the authors have nothing to disclose.

Funding

No funding was received for this article.

Financial interest

None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

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