

Immediate-implant-based-breast-reconstruction with two-stage expander-implant reconstruction versus one-stage-reconstruction with acellular dermal matrix: analysis of patients' satisfaction

Alessandro Innocenti¹, Dario Melita¹, Marco Affortunati¹, Tommaso Susini², Marco Innocenti¹

¹Plastic and Reconstructive Microsurgery - Careggi University Hospital- Florence- Italy; ²Breast Unit – Gynecology Section – Department of Health Science - Careggi University Hospital - Florence- Italy

Abstract. *Background.* The aim of this retrospective study is to evaluate the patient-reported outcome after immediate ADM-assisted implant- based breast reconstruction. *Material and Methods:* Patients underwent breast reconstruction from 2015 to 2019 have been retrospectively divided into group A (partial subpectoral implant and ADM and group B (expander/implant). For each patient we evaluated retrospectively postoperative complications and patients' satisfaction. *Results:* 26 patients from the case group and 40 from the control group completed the BREAST-Q. The incidence of complications in the cases was 18.4%, while in the control group was 20.4%. We found no statistical difference in most of the domains and in the mean score of the questionnaire (mean score cases=69.0±14.4 vs controls=68.4±15.7; p=0.888). A significant difference results only in the domains Q2a and Q2b, sensation of rippling. *Conclusions:* The use of ADM in one-stage reconstruction allows to perform breast reconstruction in only one surgery, with similar complication rates and patient satisfaction. (www.actabiomedica.it)

Key words: breast reconstruction; immediate breast reconstruction; breast cancer; ADM; breast implant

Introduction

Breast cancer is the most common malign cancer worldwide with an incidence of 2.1 million people every year, representing the first cause of death by cancer in women (15% of all cancer deaths) (1,2). Although early diagnosis allowed a high rate of conservative therapy, mastectomy is currently very frequent and immediate-implant-based breast reconstruction (IIB-BR) remains nowadays the most popular reconstructive modality, including two-stages (expander/implant) and single-stage direct-to-implant approach (3,4).

The safety of the latter method, firstly introduced by Salzberg in 2006, is reported by several studies and

therefore its use is still increasing worldwide because of several advantages including patients' comfort, morbidity, number of surgical procedures, length of hospitalization, recovery time, return to social and work life (5). The introduction of matrices for implant coverage allowed an increase of one-stage direct-to-implant approach.

One-stage direct-to-implant breast reconstruction includes both total pre-pectoral, submuscular and partial submuscular implant placement (6). Upper pole coverage of the prosthesis is one of the most sensitive items in breast reconstruction. Concerning this point, muscle offers a more satisfactory coverage of the upper edge of the breast implant comparing to a completely pre-pectoral implant placement and, therefore we retain

that these two different placements of the prosthesis cannot be evenly compared. Therefore, we retained to exclude pre-pectoral reconstruction from this study.

Several synthetic and biological matrices are nowadays available for IIB – BR and each one has peculiar characteristics. Basing on our personal experience, the latter can offer a very natural integration, including sensation during palpation and less implant visibility. However, its integration could be affected by inflammatory reactions including prolonged seroma.

The aim of this study is to evaluate patients' satisfaction with partial submuscular IIB-BR recorded in a single Centre of Plastic and Reconstructive Surgery versus two stages expander/implant breast reconstruction.

Methods

Study design and participants

This monocentric retrospective study was conducted from January 2015 to January 2019, enrolling eighty-one consecutive patients underwent subcutaneous nipple-and-skin-sparing mastectomy. Patients' selection for eligibility with regard to one-stage IIB-BR or expander/implant two-stages breast reconstruction was based on discretion of three different senior plastic surgeons. Including criteria for partial submuscular IIB-BR: at least 1 cm thickness of post-mastectomy skin flap, vascularization status of the skin

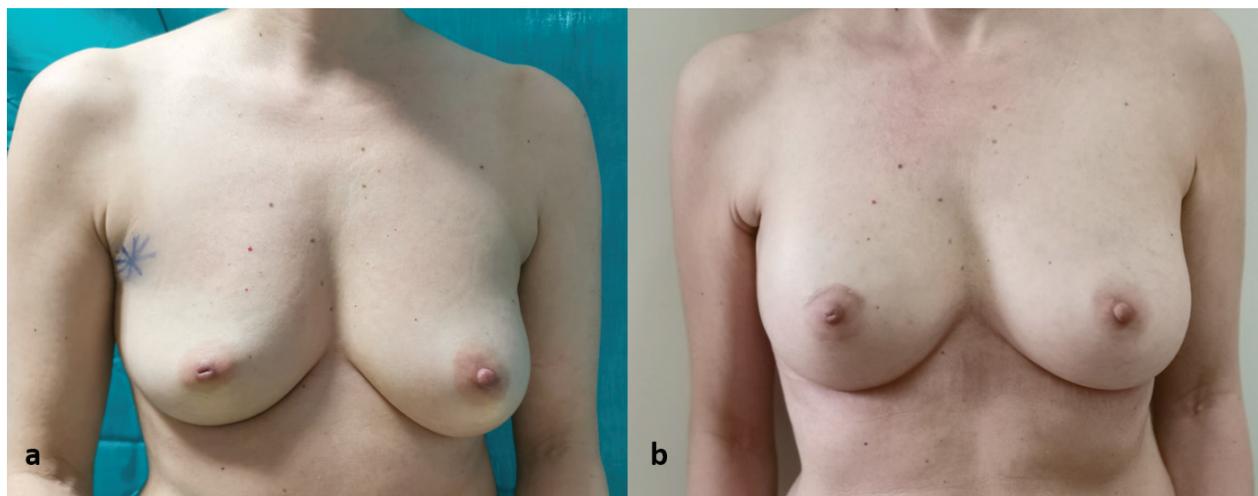


Figure 1. a) Preoperative photograph of right breast carcinoma; b) 12-months postoperative photograph after IIB-BR with ADM

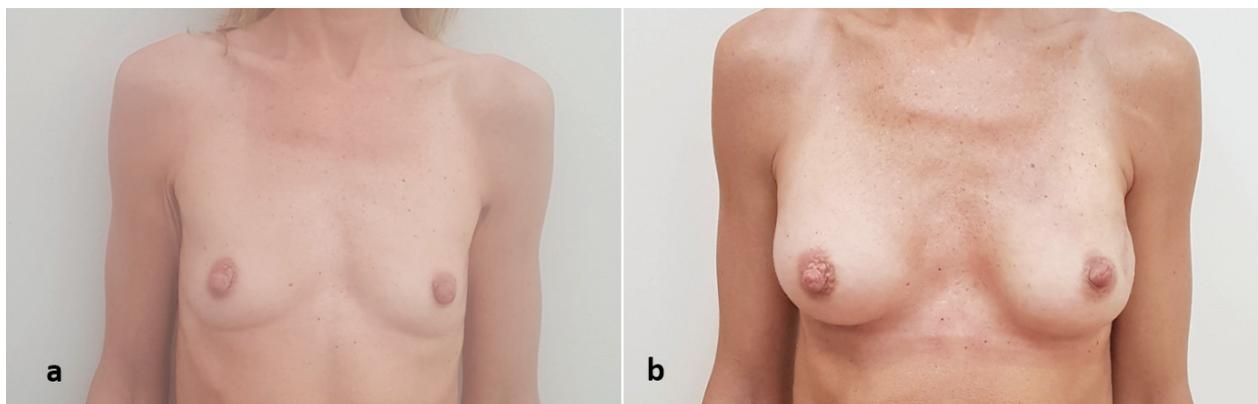


Figure 2. a) Preoperative photograph of left breast carcinoma; b) 12-months postoperative photograph after expander/implant breast reconstruction and contralateral augmentation mammoplasty

Table 1. Demographic and medical data.

PATIENTS' DATA	Cases (n=29;38 procedures)	%	Controls (n=52, 54 procedures)	%
Mean age, years (SD)	48,510		50,19,3	
Mean follow-up, years (SD)	0,730,8		2,72,8	
Prophylactic mastectomy	7	18,4	3	5,6
Therapeutic mastectomy	31	81,6	51	94,4
NSM	30	78,9	36	66,7
SSM	8	21,1	11	20,4
NSM+SRM	-	-	6	11,1
MRM	-	-	1	1,9
Neoadjuvant chemotherapy	7	18,4	10	18,5
Previous breast surgery	6	15,8	5	9,3
Adjuvant chemotherapy	12	31,6	23	42,6
Adjuvant radiotherapy	4	10,5	9	16,7

Table 2. Complications rate

COMPLICATIONS	Group A (n=29;38 procedures)	%	Group B (n=52, 54 procedures)	%
Implant removal	4	10,5	8	14,8
seroma	1	2,63		
wound dehiscence	1	2,63		
implant displacement	1	2,63		
capsular contracture			1	1,85
skin necrosis			1	1,85
keloid			1	1,85

flap (intraoperatively evaluated) and intent of surgery (therapeutic or prophylactic). Excluding criteria: heavy smoking habits, implant size > 450 cc, neo adjuvant radiotherapy.

Enrolled patients were divided in two different groups: twenty-nine subjects (group A) underwent partial submuscular IIB-BR one-stage breast reconstruction (Figure. 1); fifty-five subjects (group B) underwent immediate expander/implant breast reconstruction (Figure. 2). All patients belong to group A underwent reconstruction with acellular dermal matrix (ADM) (Surgimend® PRS) (7). Only anatomical implants (Mentor®) were used in both groups.

Data and medical history were collected for each patient and reported in table 1.

Patients' satisfaction with the breast reconstruction was investigated with 1 to 6 BREAST-Q domains

(8). Questionnaire was administered with minimum 6 months and maximum 16 months follow up to group A while with minimum 24 months and maximum 50 months in group B.

Statistical analysis: descriptive statistics was used to evaluate demographic data and clinical outcomes, Fisher's exact test to compare the incidence of complications in the two groups ($\alpha=0,05$), Student's *t* test to compare the Breast-Q results of the two groups and to evaluate if the difference is statistically significant ($\alpha =0,05$).

Results

Mean age: - group A 48.5 years (SD 10); - group B 50.1 (SD 9.3).

Questionnaire mean follow-up was: group A 8.76 months and 32.4 months in group B.

Seven prophylactic mastectomies (18.4%) were reported in group A and three (5.6%) in group B. Nine bilateral reconstruction were performed among group A (23.7%) and two (3.70%) among group B. Thirty nipple-sparing mastectomies were recorded in group A (78.9%) and thirty-six (66.7%) in group B. Seven (18,4%) neo-adjuvant chemotherapy before surgery in group A and ten (18,5%) in group B were recorded. Twelve (31,6%) adjuvant chemotherapy after surgery in group A and twenty-three (42,6%) in group B were observed. Four patients (10.5%) and nine patients (16,7%) underwent adjuvant post-operative radiotherapy respectively in group A and group B.

Complications

Observed complications are reported in table 2. Incidence of complications: 18.4% was recorded in group A, and 20.4% in group B.

Patients' satisfaction

Fifteen patients, missing the Breast-Q, didn't respect the standard of the study and therefore were excluded. Breast-Q data were reported in Table 3.

Discussion

The introduction of matrices for implant coverage can be considered a satisfactory tool in breast

reconstructive box (9,10). By reducing number of surgical procedures, length of hospitalization, recovery time, return to social and work life and mostly patients' morbidity, matrices have increased one-stage direct-to-implant approach (11,12). Nowadays several biological and synthetic matrices are available for IIB – BR. Basing in our hands the first collects more satisfactory results even if they can report some specific complications such as inflammatory reactions including prolonged seroma.

Patients' satisfaction is a very sensitive item in breast reconstruction, but due to the high rate of incidence of breast cancer even economical aspects should be carefully considered. Although matrices represent an adjunctive cost, their use avoid the use of expanders and secondary surgery for its replacement with the definitive breast implant (13). Less secondary procedures mean faster surgical waiting lists and faster response to patients' need (14) Moreover, psychosocial benefits related to a definitive breast reconstruction at the same time of the mastectomy, the absence of secondary surgical procedures, including outpatient appointments for muscle expansion, reducing patients' discomfort and distress, should be strictly taken into consideration (15,16).

Regarding aesthetical outcomes, pectoralis major muscle offers a satisfactory coverage of the medial-upper part of the breast implant comparing to completely pre-pectoral implant placement. On the other hand, covering the lateral-lower part of the implant with matrices allows a better projection of the inferior part of the new mammary cone comparing to anterior serratus muscle apron. Furthermore, leaving in place

Table 3. BREAST-Q results summary data

Domains	Cases (n=26)	Controls (n=40)	p-value
Q1-satisfaction with breasts	58,8±14,9	57,9±15,6	0,818
Q2a-visibility of rippling	2,80±0,8	3,35±0,7	0,004
Q2b-Sensation of rippling	2,64±0,7	3,21±0,7	0,003
Q3-satisfaction with outcome	80,6±17,1	80,3±23,3	0.939
Q4-psychosocial wellbeing	73,5±20,8	73,1±22,3	0.958
Q5-sexual wellbeing	55,6±22,6	56,0±25,0	0.956
Q6-Physical wellbeing	75,9±14,1	74,3±13,0	0.631
Total (average Q1, 3, 4, 5, 6)	69,0±14,4	68,4±15,7	0.888

the anterior serratus muscle means minor morbidity with less pain and discomfort (17).

While one stage IIB-BR reported high rate of complications initially, subsequently, the increased familiarity with this technique by the surgeons, reduced the incidence of adverse events, making the method safer and feasible (15-18).

In accordance to the present literature, in our study the global incidence of complications was very similar in the two groups (19). Among major complications, twelve implants removal were recorded in the two groups:

- four (10.5 %) in group A (three due to immune reactions to the mesh and one recurrence of the breast cancer);

- eight (14.8%) in group B (seven skin expanders and one definitive breast implant due to wound dehiscence); 5 (71,42%) skin expanders were removed for integrated-valve rupture, mostly occurred without referred traumas.

The minor incidence of implant removal observed in group A rather than in group B could be due to the smaller number of patients belong to the group A and therefore it could be considered a bias of the study, or it could be due to the skin expander procedure (20).

There are few studies in literature considering patient's satisfaction and quality of life comparing ADM assisted immediate one-stage breast reconstruction and the other reconstruction techniques. El Hage Chehade et al. and Headon et al. used the BREAST-Q to evaluate patient satisfaction after ADM assisted one-stage breast reconstruction but unlike our study, they didn't use the Q-Score program to calculate the score (21,22). Sirinvasa et al. compared ADM both assisted and non-assisted one-stage breast reconstruction versus skin-expander/implant two-stage reconstruction (23). To the best of our knowledge only Negenborn V. et al. compared ADM assisted one-stage and two stage expander/implant breast reconstruction showing, unlike our study, more satisfactory results with the first method (24). Negenborn proposed postoperatively the questionnaire at the same time in the two groups at 17-months follow-up. In our paper, being a retrospective study, we proposed the questionnaire with different time in the two groups. This difference could interfere with patients' self-confidence

with the reconstruction. The longer follow up reported in group B could interfere with the memory of the discomfort with skin expander, especially during the final part of the expansion, and the need for multiple surgical steps. Therefore, this could represent a bias of the study.

In our study, group A showed higher score in most Breast-Q domains except for domain 5, 2a and 2b. This could be due to the discomfort that group B patients previously experienced with tissue expansion which lead to a higher satisfaction when they were asked to evaluate their experience with the definitive implant.

Higher satisfaction in "Sexual well-being" in group B rather than in group A could be due the fact that return to sexual life and intimacy usually requires longer time, mostly due to the embarrassment for the change in the body image, to be accepted from the patients and therefore longer follow-up is sanatory and could explain the differences in the final outcomes evaluation.

In summary our study demonstrated that there is no significant difference in terms of incidence of complications between the two-stage expander-implant reconstruction and the one-stage matrices assisted IIB-BR. Even in terms of patient's satisfaction and wellbeing the results in the two groups are comparable. However, this is a preliminary study and therefore further studies with a larger cohort of patients' will be necessary to confirm this result.

Conflicts of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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Alessandro Innocenti

mail innocentialessandro@alice.it

mobile +393356556335

Viale Giacomo Matteotti 42 - 50132 - Firenze Italia