ISSN: 2573-9565

Research Article

Journal of Clinical Review & Case Reports

Novel Pre-Mastectomy Permanent Implant Reconstruction

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Submitted: 19 Jan 2020; **Accepted**: 25 Jan 2020; **Published**: 05 Feb 2021

citation: *Alwaleed Alammar, Luay Alsalmi, Ovais Habib, Shabeer Wani and Bandar AlHarthi (2021). Novel Pre-Mastectomy Permanent Implant Reconstruction. J Clin Rev Case Rep, 6(2): 569-573.*

Abstract

Background: *Breast reconstruction has been shown to have significant psychosocial benefits for breast cancer patients. Multiple techniques have been used to improve patient satisfaction, aesthetic outcomes, and decrease complications. However, while these techniques are advantageous, they have some significant disadvantages. We are presenting a novel two-stage, pre-mastectomy permanent implant reconstruction (PPIR) technique in an attempt to overcome some of these disadvantages.*

Methods: *Five patients met the essential criteria: they underwent PPIR by insertion of silicone implants three weeks before a proposed mastectomy. The Short Form-36 quality of life questionnaire and the Michigan Breast Reconstruction Outcomes Survey were used before and after the surgery to assess outcome and patient satisfaction. Paired sample t-tests were used to compare changes in the survey scores for various psychosocial subscales and to determine whether score changes after reconstruction were significant.*

Result: *Five patients underwent seven breast reconstructions using PPIR. None of the patients experienced surgical complications (e.g. mastectomy flap complication, wound dehiscence, surgical site infection, or implant-related complications). The PPIR technique resulted in improved psychosocial outcomes and body image with high patient satisfaction.*

Conclusion: *Pre-mastectomy permanent implant reconstruction is a promising potential technique with good aesthetic outcome and patient satisfaction that carries no tissue expander complications and eliminates multiple clinic visits and the usage of a dermal substitute.*

Keywords: Breast Reconstruction, Silicon, Mastectomy

Introduction

Oncoplastic breast reconstruction is linked with substantial improvements in both psychosocial and physical outcomes and has become an important consideration for a multidisciplinary approach to breast cancer.

Various techniques and methods have been developed to meet patient expectations and improve treatment outcomes in the field of oncoplastic breast reconstruction, and previous studies have demonstrated its positive effects on psychologic well-being, self-esteem, body image, and overall improved quality of life [1]. Alloplastic (implant-based) breast reconstruction is the most commonly used technique, accounting for almost 70% of all breast reconstructions in the USA [2-12].

Alloplastic breast reconstruction is a safe approach for breast reconstructive surgery: the need for long operation times is eliminated and donor site morbidities can be performed with a wide variety of comorbid conditions [7, 10]. It is also a cost-effective and reliable method. The alternative breast reconstruction modality is autologous (i.e. locoregional or free flap), and a combination of both techniques can be utilized in certain patients. Reconstruction can be simultaneously performed with a mastectomy as a single- (i.e. alloplastic or autologous) or two-stage procedure (i.e. expander to permanent implant or autologous reconstruction) or delayed and performed later as a single- or two-stage procedure, mostly in patients not fit for prolonged procedures. All methods have advantages; however, they also have some significant downsides. Single-stage alloplastic breast reconstruction offers definitive breast mound reconstruction at the time of oncologic resection

when reliable breast tissue is available, decreasing psychological trauma in patients. However, the likelihood of requiring a secondary procedure and the poor reliability of mastectomy flaps are some demerits of this method [3]. A dermal substitute, an adjunct for alloplastic reconstruction, is used for implant coverage in addition to local muscles; however, higher rates of infection, seroma, and the overall rate of complication (15.3%) limits its use [8, 9]. In contrast, a two-stage technique results in fewer mastectomy flap complications requiring multiple clinic visits, which incur patient complaints and can affect patients psychosocially, especially active young patients [7]. Implant extrusion is also of concern, and patient satisfaction is an important outcome that takes years to stabilize following breast reconstruction. In an attempt to overcome some of these limitations, the validity of a novel two-stage pre-mastectomy permanent implant reconstruction (PPIR) with preserved anatomical landmarks by the insertion of a permanent implant (i.e. definitive breast mound reconstruction) three weeks before a proposed mastectomy was evaluated using a prospective clinical pilot study.

Methods

Following ethical committee approval from the institutional review board at our tertiary care hospital, a pilot study was conducted. The surgical technique was approved by the tumor board committee as a reconstructive modality for patients with benign and early-stage breast malignancy undergoing surgical resection not requiring adjuvant radiotherapy. Written consent was obtained from all patients after explaining the course of the reconstruction, stages, risk, and expected complications. Five patients were enrolled in the study: all patients were diagnosed histologically based on a core needle biopsy.

Procedure

The surgical reconstruction was carried out in two stages and performed under general anesthesia. Stage 1: Using a 5-cm incision, 1 cm inferior and parallel to the inframammary fold (started 1 cm medial to the breast meridian), guarded medial and lateral dissection was undertaken utilizing a sub-pectoral plane without muscle release from breast tissue to ensure no penetration to the tumor. Using a no-touch technique, a textured round silicone implant 50 cc smaller than the smallest size recommended by the breast implant manufacturer based on breast base width was used to ensure full muscular coverage of the implant. No drains were used (Figure 1). Stage 2: All patients underwent a mastectomy three weeks after the insertion of the silicone implant. The implants were found fully covered by the pectoralis major, with adequate mastectomy flaps available to fully re-drape the reconstructed breast (Figure 2 & Figure 3).

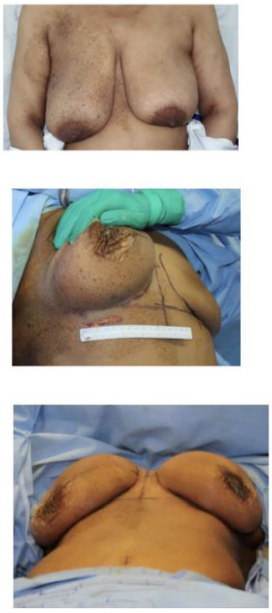

Figure 1: A 55-years-old lady with Right breast cancer who underwent bilateral mastectomy, (Right breast Invasive Ductal Carcinoma (IDC), left prophylactic mastectomy)
1a: Pre-operative picture (Right breast cancer, left normal breast)
1b: Intra operative pictures showing use of a limited low inframammary incision
1c: After insertion of the silicone implant

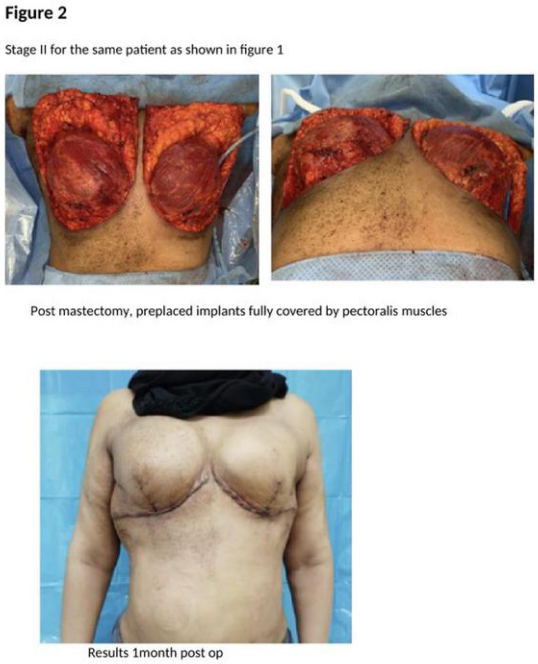

Figure 2: Stage II for the same patient as shown in figure 1
2a: Post mastectomy, preplaced implants fully covered by pectoralis muscles
2b: Results 1month post op

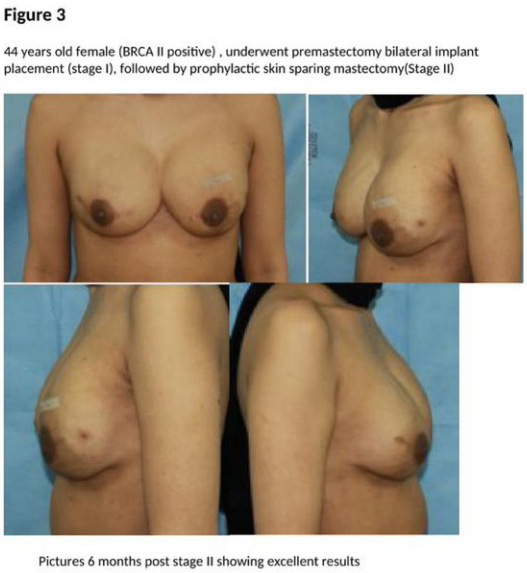

Figure 3: 44 years old female (BRCA II positive), underwent premastectomy bilateral implant placement (stage I), followed by prophylactic skin sparing mastectomy (Stage II)
3a, b, c: Pictures 6 months' post stage II showing excellent results

Data Collection

The psychometric battery of instruments used in this study included two previously published, validated health-related quality of life surveys. The questionnaires were approved by our institutional review board and translated into native language.

The medical outcome study Short Form-36 (SF-36), a 36-item self-administered questionnaire, is commonly used in various healthcare settings to assess treatment outcome changes in symptoms for patients undergoing medical therapy. This questionnaire consists of eight health domains: physical functioning, pain, role limitations due to physical health problems, role limitations due to emotional problems, mental well-being, social functioning, energy/fatigue, and general health perceptions. Scores for each domain range from 0 to 100, with a higher score defining a more favorable health state.

The SF-36 questionnaire was given to the patients during their first clinic visit after discussing the course of the reconstruction. The questionnaire was completed by the patients in their homes and returned to the study coordinator during their next follow-up clinic. Six months after their reconstruction, the SF-36 questionnaire was again given to the patients along with the Michigan Breast Reconstruction Outcomes Survey, consisting of seven questions (questions 1 through 5 assess general satisfaction and questions 6 and 7 assess aesthetic satisfaction (Table 3) that assess changes in each score and the effect of breast reconstruction on patient well-being.

Table 1: Patient demographics

BMI* body mass index, IDC* invasive ductal carcinoma

	Age	BMI*	Co-morbidities	Tumor	Breast cup size	Surgery	Contralateral breast
Patient 1	43	23	None	Bilateral sclerosing adenosis	D	Bilateral PPIR	
Patient 2	44	26	Hypothyroidism	Left IDC*	C	Left PPIR	None
Patient 3	44	34	None	Right IDC*	D	Right PPIR	None
Patient 4	46	28	Hypertension	Right IDC*	D	Right PPIR	Balancing mastopexy
Patient 5	55	27	None	Right IDC*	DD	Bilateral PPIR	Prophylactic mastectomy + PPIR
Mean	46.4	27.6					

Analysis

Each subscale of the SF-36 survey was summed and then transformed into a scale from 0 to 100 to facilitate a comparison of pre- and postoperative psychosocial scores for the medical outcome study SF-36 scores to actualize this examination using paired sample t-tests (Table 2).

Table 2: Comparison of Pre- and 6 months Postoperative Psychosocial Scores in Patients with PPIR Reconstruction the medical outcome study short form-36 (SF-36)

	N	Pre-reconstruction Mean Score	Post-reconstruction Mean Score	Mean Difference	SD	P
Physical functioning	5	82.80	84.42	1.62	3.19	0.002
Role limitations due to physical health	5	68.84	72.72	3.88	3.82	0.055
Role limitations due to emotional problems	5	65.12	84.44	19.32	2.68	0.000
Energy/fatigue	5	69.00	76.00	7	1.87	0.001
Mental health	5	65.68	75.12	9.44	4.85	0.000
Social functioning	5	62.22	79.56	17.34	8.71	0.004
Pain	5	75.84	78.54	2.7	3.51	0.069
General health	5	66.38	80.40	14.02	1.33	0.001

Results

All our patients were middle-aged (43, 44, 44, 46, or 55 years old) with a mean age of 46.4 years. The mean body mass index of the patients was 27.6 (23–34). Among the five patients recruited for the study, four patients were diagnosed with invasive ductal carcinoma and one patient had sclerosing adenosis. Two patients underwent bilateral reconstruction, one patient had bilateral sclerosing adenosis, and one patient with a right breast invasive ductal carcinoma underwent contralateral a prophylactic mastectomy (Table 1). None of the patients had acute surgical complications (e.g. mastectomy flap necrosis or wound dehiscence) or medical complications (deep venous thrombosis, atelectasis, or pneumonia).

Table 3. Michigan breast reconstruction outcomes survey.

General Satisfaction
Knowing what I know today, I would definitely choose to have breast reconstruction.
Knowing what I know today, I would definitely choose to have the type of reconstruction I had.
Overall, I am satisfied with my reconstruction.
I would recommend the type of reconstructive procedure that I had to a friend.
I felt that I received sufficient information about my reconstruction options to make an informed choice among several procedures.
Aesthetic Satisfaction
The size and shape of my breast are the same.
My reconstructed breast(s) feel soft to touch.

SF-36

The comparison between the pre- and postoperative scores showed a statistically significant difference in favor of the post-reconstruction scores of the health status of the patients at the level of six of the eight parameters (all fields except for role limitations due to physical health and pain).

Michigan Breast Reconstruction Outcomes Survey

All the patients responded as being satisfied for all the survey parameters.

Discussion

Improved survival of breast cancer due to developments in both diagnosis and treatment has led to quality of life measures becoming an increasingly significant sign of successful treatment compared to mortality rates alone. Quality of life after a mastectomy is mainly dependent on aesthetic outcome and patient satisfaction resulting from breast reconstruction [6]. Oncoplastic breast surgery techniques have emerged over recent years and facilitated the achievement of better cosmetic results while maintaining good oncological principles [5, 13, 14]. Implant-based breast reconstruction is the most commonly used technique and offers a safe, simple approach to reconstructive surgery without the need for long operations or the use of donor site tissue [1-3]. The main debate among patients undertaking implant-based reconstruction is the application of either a single-stage (i.e. direct to implant) or two-stage (i.e. expander to implant) technique [7]. Both of these traditional techniques are associated with disadvantages. Single-stage reconstruction results in less psychological trauma to the patient, but has higher rate of complications and revision

surgeries [3, 4, 7]. Two-stage reconstruction subject's patients to psychological stress, multiple clinic visits, the risk of implant extrusion, a lack of control over the position of the inframammary fold, and a flat unnatural look, making it difficult to achieve natural-looking ptosis.

Our potential novel PPIR method effectively balances the risks and outcomes of breast reconstruction by reconstructing the breast mound while anatomical landmarks are preserved and provides a reliable expanded mastectomy flap without the use of scaffolding to fully cover the prosthesis. The main weakness of the current study is a lack of a control sample, small size and long-term follow-up to confirm the safety and reliability of this technique.

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