



Patient-reported outcomes after immediate breast reconstructive surgery: A prospective cross-sectional study at the National Cancer Institute, Cairo University.

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Abstract

Background

Immediate breast reconstruction (IBR) has been the subject of some controversy, particularly among those with locally advanced breast cancer and poor biological types. Several methods and surgical techniques have been developed for breast reconstruction after mastectomy. Generally, we can categorize into two broad categories: autologous reconstruction and implant-based reconstruction. This study aimed to analyze the satisfaction rate between these groups.

Aim: Measuring patient reported outcomes and the final aesthetic outcomes in patients underwent immediate breast reconstruction after total mastectomy.

Methods: All the patients who underwent a mastectomy and subsequent breast reconstruction surgery at our institution between January 1, 2019, and January 1, 2021, were invited to complete a BREAST-Q questionnaire. To compare the quality of life and complication rate between the autologous and implant-based reconstruction groups, data were collected from specific patients. All participants completed the Arabic version of the postoperative reconstruction module.

Results: Among 331 patients underwent immediate breast reconstruction, 190 patients (57%) underwent upfront mastectomy and IBR, and 141 patients (43%) received neoadjuvant systemic chemotherapy followed by mastectomy and IBR. 327 patients (99%) completed the domains of the BREAST-Q questionnaire, about the satisfaction with the reconstructed breast and satisfaction with the surgical outcome. These patients were divided into two groups according to the type of reconstruction: autologous (n = 261) 80% and implant-based (n = 66) 20%. The mean timing for follow up in our study was 35.1±8.2 days, there was neither a statistical significance in the satisfaction with the breast reconstruction nor the surgical outcome between the two groups. The majority of our cases with excellently satisfied with perioperative setting in 89% of cases, with 89% of patient's gives excellent grade for the confidence in the surgeon and surgical setting with 80% of patients reported that the overall satisfaction with surgical case was excellent. Our patients were largely pleased with the general appearance of the scar and give excellent grade in 70% of cases, while 69% of cases had an excellent body image satisfaction and overall appearance satisfaction.

Conclusion: Although there are many different surgical techniques to reconstruct the breast after mastectomy, there is still no specific surgical method that is perfect or well-suited for all patients undergoing breast re- construction surgery. In our study, we found that there was no significant difference in satisfaction between the Autologous IBR and Implant based IBR group.

Keywords: Breast reconstruction, Breast implant, Breast cancer, Patient-reported Outcome Satisfaction

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INTRODUCTION

Breast cancer, the most common cancer in females all over the world, affects women across all ages and ethnicities, which led the researchers to continuously advance its management modalities, Breast cancer is the most common form of cancer in women, with an estimated 85% survival rate in industrialized nations for women who are diagnosed within their lifespan. Around 45percent of all breast cancer patients still undergo a mastectomy for adequate local control, despite breakthroughs in various therapy regimens ^(1,2).

Patients who undergo mastectomy are less satisfied than those who undergo breast-conserving surgery due to poor cosmetic outcomes; thus, the usage of breast reconstruction after mastectomy has grown in breast cancer patients. About 45 percent of all breast cancer patients still require mastectomy operation for adequate local control, despite advances in various treatment modalities. This typically has a negative impact on those patients who suffer from distorted body image, sexuality, and diminished sense of femininity. As a result, the goal of rapid breast reconstruction is to lessen the emotional toll of mastectomy and boost patient satisfaction ⁽³⁾.

Immediate breast reconstruction following mastectomy have several reported advantages such as lowering the psychological burden for breast cancer patients, favorable aesthetic outcome, greater sense of self-esteem and avoiding additional operations. On the other hand IBR had potential disadvantages of increased incidence of postoperative complications which may lead to the adjuvant treatment delay for those patients and that may affect the oncologic safety in terms of increased the incidence of recurrence and survival rates ⁽³⁾.

However, the choice of a single ideal breast reconstruction technique for all patients is not possible as a lot of confounding variables; oncologic, socioeconomic, geographic, physical variables may influence the decision, hence the wide spectrum of reconstruction techniques and strategies available. Two major categories of breast reconstruction at present are autologous and implant-based breast reconstruction each having their own merits and disadvantages ⁽⁴⁾.

Autologous reconstruction for a patient that tolerates it is often the best choice. Microvascular reconstruction can provide a natural, enduring breast that can be integrated with ease into a patient's body image. In addition, the transferred tissue adjusts well to changes in body weight and provides better wound healing. Nevertheless, this comes with the expense of longer more demanding surgeries, hospital stay, cost, and donor site morbidity ⁽⁴⁾.

On the other hand, reconstruction with implants is a less demanding surgery that is easier, faster, cheaper, and may be used in a wider variety of patients including those with high BMI, smokers, and diabetics. Nonetheless, implants' inherent issues pose some constraints on their application in reconstruction ⁽⁵⁾.

In this study, we analyzed the health-related quality of life of patients who underwent breast reconstruction surgery by using the BREAST-Q questionnaire, which is a well-designed and validated questionnaire that has been used in several international studies. Patient-reported outcomes (PROs) are one of the subjective measurements that may help in providing useful insights about patients.

MATERIALS AND METHODS

This study is a prospective randomized late phase II clinical trial (non inferiority study). conducted at the National Cancer Institute which included 331 Egyptian female breast cancer patients underwent mastectomy and axillary staging surgery either sentinel lymph node biopsy or axillary clearance with immediate breast reconstruction as primary treatment followed by adjuvant treatment in the period from January 2019 to January 2021. Patients were assessed with regular appointments at the outpatient clinics up to at least 2 years follow up after surgery.

The National Cancer Institute's multidisciplinary board evaluated patients. After approval by the Institutional Review Board and the Ethical Research Committee, all patients who participated in the study signed a consent form that included proper counseling regarding probable problems and their participation in the research (IRB Review Number: 201920045.3). Data collection and presentation were anonymous. The protection of patients' privacy and confidentiality was taken into consideration to the maximal possible standards. Any involved active participant will be included in any future publication for that work.

Measuring patient reported outcomes and aesthetic outcomes in patients underwent immediate breast reconstruction at their last visits after finishing radiation therapy if involved for their adjuvant treatment. Through (BREAST Q MODEL) which is an already developed patient reported outcome measure to assess the unique outcomes of breast surgery patients.

The frame work includes six domains: Breast satisfaction, overall outcome, and care process, mental, physical, and sexual health.

The questionnaire will assess the following;

Surgical care: satisfaction with information provided, information about healing; hand exercise, satisfaction with care; confidence in surgeon and surgical sitting and follow up care.

Aesthetic outcome: size, shape, visibility of scars, appearance of nipple and areola complex, symmetry, breast edema, skin color telangiectasia and overall cosmetic outcome.

Psychological wellbeing and self-concept: changes in mood, body image issues, self-esteem, changes in confidence level, feeling of femininity and cancer related concerns.

Relationship with friends and family: differences in how others respond to the patient, how the spouse feels about the situation, how the marriage is doing.

Expectations: fulfillment of expectations, willingness to recommend procedure, satisfaction with overall appearance.

A score will be given to each criteria ranging from 1: excellent to 4: poor

Aesthetic outcomes in our study for the group of patients that underwent upfront mastectomy with immediate breast reconstruction (group 1) and patients received neoadjuvant treatment followed by mastectomy and immediate breast reconstruction (group 2) assessed by both, the patient itself self and also by independent assessor with senior staff at the outpatient clinic during follow up

Aesthetic outcome assessed also with independent assessor, For each case of mastectomy and IBR will be reviewed by senior surgical staff at the outpatient clinic other than her surgeon for assessment of the following: Suitability of the technique, Complication for either donor or recipient sites or aesthetic results with regard the size and volume of the reconstructed breast, symmetry, ptosis, nipple and areola complex and the scars

Grading for both the patient and the assessor as the following

Grade 1: poor

Grade 2: fair

Grade 3: good

Grade 4: excellent

The questionnaire that was assigned by our patients in the following table.

<u>1)Surgical care:</u>	1	2	3	4	Y / N
Were you provided with adequate information given in the informed consent concerning the details of the procedure and possible complications?					
Were you provided with adequate information regarding post-operative care as the hand exercises and precautions?					
Confidence in the surgeon and surgical setting					
<u>2)Aesthetic outcome:</u>					
How was the follow up care quality?					
What is the overall satisfaction with the surgical care?					
How is the general appearance of the scar?					
Is there symmetry of both breasts?					
How is the appearance of nipple areola complex?					
Is there any breast edema?					
Do you have any skin color changes?					
Do you have any telangiectasia?					
What is your assessment of global cosmetic outcome?					
<u>3)Psychological well-being:</u>					
Did you experience any changes in mood and confidence?					
Do you any concern on your body image satisfaction?					
How is your self-esteem?					
How do you find your feeling of femininity?					
Do you have any cancer worries?					
<u>4)Relations with family and friends:</u>					
Was there any difference in your family attitude?					
Did you experience any difference in attitude in marital relation?					
What is the response in reactions of your family and friends after surgery?					
<u>5) Expectations:</u>					

How is your satisfaction with the overall appearance?					
Are you willing to repeat/recommend the procedure?					
How did the procedure fulfill your expectations?					
6) <u>Sexual outcome:</u>					
Is there a change in your marital status post-operative?					
Have you experienced any change in your sexual relation post-operative?					

INDEPENDENT ASSESSOR QUESTIONNAIRE.

○ SUITABILITY OF THE TECHNIQUE	<input type="text"/>	<input type="text"/>
○ COMPLICATION	<input type="text"/>	<input type="text"/>
DONOR SITE		<input type="text"/>
RECEPIENT SITE		<input type="text"/>
○ AETHESTIC RESULTS		
SIZE AND VOLUME OF THE RECONSTRUCTED BREAST		<input type="text"/>
SYMMETRY		<input type="text"/>
PTOSIS		<input type="text"/>
NIPPLE AND AREOLA		<input type="text"/>
SCARS		<input type="text"/>

Statistical analysis:

The information was gathered, coded, reviewed, and entered into Rstudio 2.3.2 of the Statistical Software for the Social Sciences. Quantitative data having a parametric distribution was provided as mean, standard deviation, and ranges; non-parametric data was presented as median and interquartile range (IQR). The Shapiro test was run to make sure everything was distributed normally. When comparing 2 groups based on qualitative data, the Chi-square test was utilized, whereas the Fisher exact test was used when the predicted count in any cell was < 5 .

Independent t-test was used in the comparison between two groups with quantitative data and parametric distribution and Wilcoxon Mann-Whitney test was used in the comparison between two groups with quantitative data and non-parametric distribution.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

$P > 0.05$: Non-significant (NS)

$P < 0.05$: Significant (S)

$P < 0.01$: Highly significant (HS)

RESULTS:

In our study IBR was carried out in the group (1) upfront mastectomy and IBR and group (2) patient received neoadjuvant chemotherapy followed by mastectomy and IBR as shown in the following table.

Type of reconstruction:	Group I N= 190	Group II N= 141
Expander	27 (14.2%)	11 (7.8%)
LD flap	141 (74.2%)	110 (78.0%)
LD flap + silicone implant	7 (3.7%)	7 (5.0%)
Silicon implant	13 (6.8%)	6 (4.3%)
TRAM FLAP	2 (1.1%)	7 (5.0%)

In our study autologous breast reconstruction was carried out in (143) patients in group (1). While it was in (117) patients in group (2). LD flap is a reliable surgical reconstruction technique that gives excellent aesthetic results, The majority of autologous flaps breast reconstruction were carried out with latissimus dorsi flap in (141) patients and only two cases of pediceled transversus rectus abdominis muscle flap was undertaken in group (1), and in the group that received neoadjuvant treatment followed by IBR latissimus dorsi flap was used in (117) patients and five cases underwent breast reconstruction with pediceled transversus rectus abdominis muscle flap and two cases of DIEP free flap. Among our study group of patient with IBR implant based breast reconstruction were carried out in 71 cases, of them combined autologous and implant breast reconstruction were carried out in 14 cases. IBR using silicone implant only was in 19 cases and delayed immediate breast reconstruction with temporary expander only was in 38 cases.

In the present study there was a significant higher incidence of postoperative complications in IBR group the most common complication was seroma formation were found in 87 patients (46 %) in group 1 and in 46 cases (33 %) in group 2, the next most common complication was wound gapping as were documented in 49 patients (26 %) in group 1 and in 33 case (23 %) in group 2. Other less common complications are postoperative bleeding, infection, sever pain, limitation of mobility was of non-significant difference between the study groups ($p = 0.738$).

As LD flap reconstruction was the most common type for reconstruction this was thought to be associated with a higher rate of post-operative complication in the form of seroma formation wound gapping, partial flap necrosis and postoperative pain and limitation of arm mobility. In spite of this those group of patients didn't experience delay to adjuvant treatment. This meant that there was a trend towards higher complication rate in the implant based reconstruction group that might be significant in a larger series of patients. We found that 19 out of 64 cases (30 %) of implant-based reconstruction developed postoperative complications in the form of implant

exposure in 8 cases and late complications as silicon rupture in one case, and capsular contracture in 10 cases.

Comparison between the two studied groups according to Complications:

		Group I N= 190	Group II N= 141	P-value
Post-operative Complications:				
BLEEDING	Yes	5 (2.6%)	3 (1.4%)	0.975
INFECTION	Yes	14 (7.4%)	93 (6.4%)	0.955
FLAP NECROSIS	Partial	23 (12.1%)	14 (9.9)	<0.001*
SEROMA FORMATION	Yes	87 (45.8%)	46 (32.4%)	0.004*
GAPPED WOUND	Yes	49 (25.8%)	33 (23.4%)	0.003*
Sever pain	Yes	12 (6.3%)	10 (7.1%)	0.787
Limitation of mobility	Yes	10 (5.3%)	6 (4.3%)	0.161
Others	Capsular contracture	4 (2%)	6 (4.2%)	0.172
	DVT	1 (0.5%)	0 (0.0)	
	Lumbar hernia	1 (0.5%)	0 (0.0)	
	Nipple necrosis	1 (0.5%)	0 (0.0)	
	Perforated peptic ulcer	1 (0.5%)	0 (0.0)	
	implant exposure	4 (2.1%)	4 (3.0%)	
	Silicon rupture	1 (0.5%)	0 (0.0)	
Intra-operative Complications:				
	Yes	1 (0.5%)	0 (0.0%)	

Aesthetic outcome was assessed by two different methods. The patient itself and surgeon other than the operating surgeon with breast reconstruction expertise independently evaluated each patient, in terms of volume, shape, scar, symmetry and nipple, and gave a score for their assessment. The mean score for their observations is calculated and compared for each parameter. A total aesthetic score (TAS) is then calculated by summing up the mean scores of parameters.

The majority of our cases were excellently satisfied with perioperative setting in 89% of cases, with 89% of patient's gives excellent grade for the confidence in the surgeon and surgical setting with

80% of patients reported that the overall satisfaction with surgical case was excellent. Our patients were largely pleased with the general appearance of the scar and give excellent grade in 70% of cases, while 69% of cases had an excellent body image satisfaction and overall appearance satisfaction.

In our study, patients of IBR group were stated that the procedure fulfill their expectations excellently in 73% (242 cases), and 18 % (57 cases) give good grade for their expectations with IBR, while only 3 cases were unpleased with the overall results.

Distribution of answers of questionnaire:

Marital status:		
	Single	10 (3%)
	Married	297 (90%)
	Divorced	7 (2%)
	Widow	7 (2%)
Activity:		
	House wife	238 (72%)
	Working	74 (22%)
Timing since surgery in months:		
	Mean (SD)	35.1 (8)
Type of reconstruction:		
	Autologous	261 (79%)
	Implant	66 (20%)
Timing of reconstruction:		
	Immediate	280 (85%)
	Delayed immediate	38 (11%)
Were you provided with adequate information given in the informed consent concerning the details of the procedure and possible complications?		
	No	22 (7%)
	Yes	293 (89%)
Were you provided with adequate information regarding post-operative care as the hand exercises and precautions?		
	No	15 (5%)
	Yes	300 (91%)
Confidence in the surgeon and surgical setting		
	Poor	3 (1%)
	Fair	5 (2%)
	Good	15 (5%)
	Excellent	292 (89%)
How was the follow up care quality?		
	Poor	6 (2%)
	Fair	3 (1%)
	Good	26 (8%)
	Excellent	276 (84%)
What is the overall satisfaction with the surgical care?		
	Poor	8 (2%)

	Fair	17 (5%)
	Good	26 (8%)
	Excellent	264 (80%)
How is the general appearance of the scar?		
	Poor	10 (3%)
	Fair	22 (7%)
	Good	51 (16%)
	Excellent	232 (70%)
Is there symmetry of both breasts?		
	No	82 (245%)
	Yes	233 (71%)
How is the appearance of nipple areola complex?		
	Poor	12 (4%)
	Fair	78 (24%)
	Good	48 (15%)
	Excellent	175 (53%)
Is there any breast edema?		
	No	257 (78%)
	Yes	61 (19%)
Do you have any skin color changes?		
	No	266 (81%)
	Yes	52 (16%)
Do you have any telangectasia?		
	No	244 (74%)
	Yes	73 (22%)
What is your assessment of global cosmetic outcome?		
	Poor	8 (2%)
	Fair	42 (13%)
	Good	67 (20%)
	Excellent	199 (60%)
Did you experience any changes in mood and confidence?		
	No	233 (70%)
	Yes	84 (25%)
Do you any concern on your body image satisfaction?		
	No	226 (69%)
	Yes	91 (28%)
How is your self-esteem?		
	Poor	6 (2%)
	Fair	32 (10%)
	Good	46 (14%)
	Excellent	231 (70%)
How do you find your feeling of femininity?		
	Poor	4 (1%)
	Fair	8 (2%)
	Good	73 (22%)

	Excellent	230 (70%)
Do you have any cancer worries?		
	No	25 (7%)
	Yes	290 (88%)
was there any difference in your family attitude?		
	No	262 (79%)
	Yes	53 (16%)
Did you experience any difference in attitude in marital relation?		
	No	299 (91%)
	Yes	16 (5%)
what is the response in reactions of your family and friends after surgery?		
	Good	2 (1%)
	Excellent	313 (95%)
How is your satisfaction with the overall appearance?		
	No	84 (26%)
	Yes	232 (70%)
Are you willing to repeat/recommend the procedure?		
	No	293 (89%)
	Yes	21 (6%)
How did the procedure fulfill your expectations?		
	Poor	3 (1%)
	Fair	12 (4%)
	Good	57 (18%)
	Excellent	242 (73%)
Is there a change in your marital status post-operative?		
	No	294 (89%)
	Yes	21 (6%)
Have you experienced any change in your sexual relation post-operative?		
	No	225 (68%)
	Yes	90 (27%)

When our patients reviewed at the clinic with an independent assessor for assessment of the overall technique suitability and aesthetic results in the form of equally symmetry and volume, ptosis and any complication for the donor or recipient sites. The technique described to be suitable in 94% of our cases, also symmetrically reconstructed breast reported in 88% of the patients, equal volume of each breast was in 87% of patients, while donor site complication was in 5% of our study reconstructed groups.

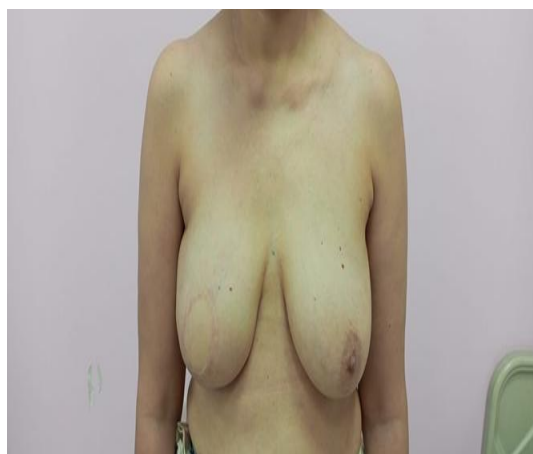
Distribution of answers of questionnaire of the independent senior staff assessor.

Suitability of the technique:		
		5 (2%)
	Yes	310 (94%)
Complication donor site:		
		298 (90%)
	Yes	17 (5%)

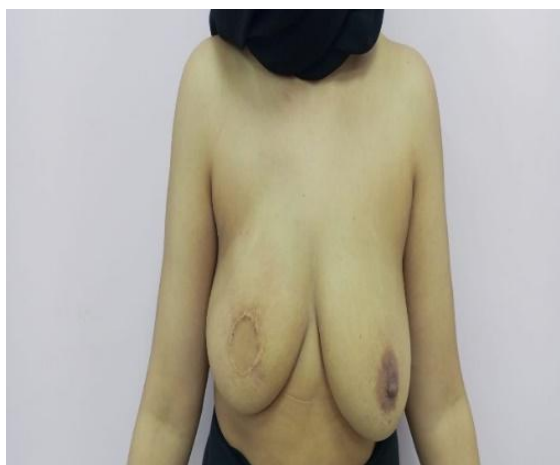
Complication recipient site:		
	No	305 (92%)
	Yes	11 (3%)
Size and volume of the reconstructed breast:		
	Equal volume	288 (87%)
	Not equal volume	27 (8%)
Symmetry:		
	Symmetrical	288 (88%)
	No symmetrical	27 (8%)
Ptosis:		
Equal ptosis of both breasts	Yes	284 (86%)
Unequal ptosis of both breasts	No	29 (9%)
Nipple and areola deviation or retraction:		
	Nipple deviation or retraction present	6 (2%)
	No nipple deviation or retraction	105 (32%)
	Needs further reconstruction	204 (62%)
Scar complications:		
	no	311 (94%)
	yes	3 (1%)

Examples from our study groups with patient scoring for the overall satisfaction and the comment of the independent assessor regarding the overall cosmetic outcomes.

Autologous breast reconstruction with LD flap:



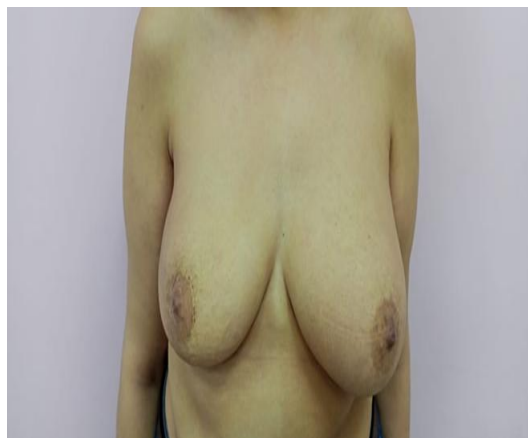
Patient grade: 4
Assessor grade: 4



Patient grade: 4
Assessor grade: 4



Patient grade: 4
Assessor grade: 4



Patient grade: 4
Assessor grade: 4

Breast reconstruction with Combined LD flap and silicon implant:



Patient grade: 4
Assessor grade: 4



Patient grade: 4
Assessor grade: 4

Breast reconstruction with silicone implant:



Patient grade: 4
Assessor grade: 4



Patient grade: 4
Assessor grade: 4

DISCUSSION

Breast reconstruction is considered an important step in the management of breast cancer as it not only brings shape to a new breast, but restores the patient's body image and quality of life as Presence of the breast mound soon after radical breast surgery is also known to add to the psychological benefits while reducing the psychological anxiety that a mastectomy procedure causes. The management of breast cancer must address both the long-term oncological safety and the final aesthetic outcome. These can only be achieved if the patient's assessment and treatment options are analyzed within a multidisciplinary team composed of the oncologist, the specialized breast surgeon, the radiotherapy specialist, the pathologist, the plastic surgeon and the patient herself who must be sufficiently well-informed to be able to participate in the decision-making step concerning the course of her treatment and reconstruction process⁽⁶⁾.

PROs provide an insight into surgical outcomes from the patient's perspective rather than from the surgeon's. PRO is one of the important assessment methods in the surgical field to improve patient-centered care. The BREAST-Q questionnaire is one of the most reliable, validated, and effective tools to study the satisfaction rate in multiple domains: satisfaction with breast, surgical outcome, physical well-being, and the surgeon^(7,8,9).

Previous publications conducted in different countries have shown a significant difference between mastectomy alone without reconstruction group and immediate reconstruction after mastectomy groups in regard to the quality of life and satisfaction. The results encourage breast cancer patients to have their breast reconstructed for a better quality of life and greater satisfaction⁽¹⁰⁾.

Breast-conserving surgeries have been found to be associated with lower physical well-being and quality of life following breast reconstruction as showed by Howes et al. They also conclude that mastectomy without reconstruction has the lowest score of satisfaction between their three study groups⁽¹¹⁾. With all these studies confirming that breast reconstruction is a major component in completing the treatment circle of breast cancer patients, we should standardize the reconstruction surgery for all patients and determine which reconstruction is suitable for individual patients, considering the patient's perspective.

Our results are similar to those of other studies, with no statistically significant difference in the general satisfaction between autologous and implant based breast reconstruction groups^(12,13,14,15). Obviously the type of reconstruction affect the quality of life, the mentality, expectation, and pre-operative psychological status of patients can affect their decisions and subsequent satisfaction⁽¹⁶⁾.

CONCLUSION

IBR is an important component of multidisciplinary breast cancer care; many factors influence reconstruction decisions and their timing including the risk of delaying breast cancer treatment. Patient satisfaction tends to be individual-specific because several factors can contribute toward reducing patient satisfaction. In conclusion, we found that there was no statistically significant difference in satisfaction between the IBR groups as reported in many similar studies in the existing literature.

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