Int J Cancer Manag. 2023 December; 16(1):e130547. https://doi.org/10.5812/ijcm-130547.

Published online 2023 May 30. **Research Article**

Immediate Single Stage Implant-based Breast Reconstruction with or Without TIGR Mesh in Iranian Patients Undergoing Mastectomy: A Quasi-experimental Study

Nahid Nafissi [1], Ayoub Bagheri [1, *], Hamed Vaseghi [1], Leyla Shojaee [2], Mina Zolnouri [1], Stefano Pompei [3] and Batool Tayefi [4]

[1] Department of General Surgery, Rasool Akram Medical Complex Clinical Research Development Center (RCRDC), Iran University of Medical Sciences, Tehran, Iran
[2] Department of Surgery, School of Medicine, Mazandaran University of Medical Sciences, Sari, Iran
[3] Avivo Group & Fakeeh University Hospital, Dubai, UAE
[4] Department of Community and Family Medicine, Preventive Medicine and Public Health Research Center, Psychosocial Health Research Institute, School of Medicine, Iran University of Medical Sciences, Tehran, Iran

[*] *Corresponding author*: Department of General Surgery, Rasool Akram Medical Complex Clinical Research Development Center (RCRDC), Iran University of Medical Sciences, Tehran, Iran. Email: ayub.bagheri@gmail.com

Received 2022 August 15; **Revised** 2022 December 18; **Accepted** 2023 January 01.

Abstract

Background: Breast cancer is still a major contributing factor to the burden of the disease worldwide. A single-stage implant-based reconstruction (IBR) lowers tissue morbidity, thus increasing overall aesthetic outcome and patient satisfaction.
Objectives: Because of the high price of ADM and the lack of insurance coverage in Iran, we aimed at examining the results of using TIGR® mesh in patients with breast cancer.
Methods: This quasi-experimental study was conducted in Iran (Tehran) from 2016 to 2018. About 140 eligible patients with breast cancer were included and their information was collected and analyzed prospectively during the 3 years that they were referred to the surgery center in Tehran. The reconstruction was performed, as either direct-single staged, implant + TIGR MESH, or delayed-multistage. Patient satisfaction was calculated after 1 year of follow-up, using Body Checking Questionnaire (BCQ) by applying the VAS scale. All statistical analyses were performed at a 95% significance level, using SPSS statistical software version. (Evidence-based medicine level: Level III, a prospective cohort).
Results: The results of our study showed slightly more short-term complications than other studies due to the surgical team's first experience in the surgery. Complications were infection (7.1%), epidermal necrosis (15.9%), and severe capsular contracture (14.2%). Seven patients (6.2%) had full-thickness skin necrosis, and the prosthesis was finally removed. The use of the TIGR Mesh did not increase the rate of complications, and only 5 implant losses in this group and 2 in the tissue expander group were reported. The levels of patients' satisfaction in IBR and delayed-multistage groups were 44.4% and 12.7%, respectively.
Conclusions: Our results showed that placement of TIGR MESH for lower pole support during IBR does not increase the complication rate. Additionally, patients' satisfaction levels increased compared to traditional methods of reconstruction.

Keywords: Breast Implantation, Breast Reconstruction, Mastectomy, Complications, Tissue Expander

1. Background

Breast cancer is the most common cancer in women and a second cause of cancer deaths among them worldwide (1). The prevalence of this cancer in women in the United States and Iran was 26% and 23%, respectively, and according to its semi-good prognosis, breast cancer is the fifth cause of cancer death in Iran (2, 3).

Mastectomy (i.e., surgical breast removal) was performed in 28% to 60% of women diagnosed with breast cancer. In the past 2 decades, subcutaneous mastectomy was done for treating patients with cancers in stage 2 or after neoadjuvant chemotherapy in stage 3 breast cancer. Furthermore, this procedure is utilized as a prophylactic intervention in high-risk patients, for instance, female patients carrying BRCA genotype; in these cases, breast reconstruction (BR) can be performed (1). A technique for BR is implant insertion after tissue expander (TE) or direct-to-implant without using TE (4).

Since 2005, an acellular dermal matrix (ADM) has been used for implant coverage in the lower part of the BR technique (5, 6). Since the pectoralis major muscle does not provide sufficient inferolateral coverage, ADMs can be used as an appropriate auxiliary coverage for producing a sufficient sub-pectoral pocket to accommodate larger size implants, fill the space of inferolateral part, and create natural inframammary folds. The use of ADMs in implant-based immediate BR is increasing due to acceptable cosmetic results, less capsular contracture, and less pain after the surgery (7-10). In addition to ADM benefits, it has complications such as infection, cellulitis, seroma, hematoma, flap necrosis, dehiscence of the wound, capsular contracture, implant protrusion, explanation, and complete implant loss, though these complications might be due to this type of surgery (11). Biological ADM imposes a high cost on the health care system (12-14).

Recent studies have suggested the use of synthetic mesh as an alternative to ADM, which costs less than it (15). These meshes are made of plastic-like materials and have 3 categories: Absorbable (Vicryl), long-term absorbable (TIGR®), and non-absorbable (Prolenmesh or T-Loop®) (16). The TIGR® Matrix is a completely absorbable synthetic mesh, woven from 2 different types of degenerative fiber (17).

Studies have been performed to compare postoperative complications in 2 groups of biological ADM and synthetic mesh, and it has been suggested that the use of synthetic meshes was associated with equally cosmetic results and lower compilation rates plus lower cost than biological ADM (17).

2. Objectives

Comparative studies in this regard are rare. Because of the high price of ADM and lack of insurance coverage in Iran and also the lack of proper studies in this field, we decided to examine the results of using TIGR®mesh in BR.

3. Methods

3.1. Subjects Recruitment

This quasi-experimental study was conducted in Tehran from March 2016 to March 2018. About 140 eligible patients with breast cancer were included. Women were recruited in this study if they were undergoing bilateral or unilateral subcutaneous mastectomies and immediate BR either because of cancer treatment or prophylaxis. Patients' information was collected and analyzed prospectively during the 3 years that they were referred to the surgery center in Tehran from 2016 to 2018. This study was approved by the Ethics Committee of the Iran University of Medical Sciences.

3.2. Surgical Procedures

In this study, patients underwent the following methods based on their clinical conditions. Bilateral prophylactic mastectomy was performed for women carrying a BRCA1 or BRCA2 gene mutation and contralateral prophylactic mastectomy was performed for the patients, who underwent mastectomy for contralateral cancer according to patients' preferences (fearing of cancer or positive family history of cancer).

The patients who were involved in this study underwent subcutaneous mastectomies under one of NAC sparing mastectomy (NSM), skin-sparing mastectomy (SSM), or skin-reducing mastectomy (SRM) procedures. The types of BR used to treat these patients were implant-based, an implant plus TIGR®Matrix Surgical Mesh (Novus Scientific Pte Ltd, Singapore), or TE. TE was used for patients who had a high probability of skin necrosis instead of mesh and implant and was inserted under the pectoralis muscle. Mesh was used in the patients, who had immediate implants. During the surgery in implant plus TIGR®Matrix Surgical Mesh group, at first, hydrodissection solution (epinephrine: Normal saline 0.9%; 0.5/1000) was injected into the subcutaneous breast tissue. During hydrodissection, the breast skin was released from underlying breast tissue, using a scissor–for dissection–and a surgical knife–for cutting (Appendix 1 in the supplementary file). To avoid skin thermal injury, we did not use electrocautery at this stage. After mastectomy, the pectoralis major muscle was released from underlying tissues to make a packet for implant insertion. Then TIGR®Matrix Surgical Mesh was sutured to the inferior border of the pectoralis major muscle (Appendix 1B, C and D in the supplementary file). After implant insertion, the inferior edge of the mesh was sutured to the infra-mammary pole. Finally, the skin was sutured over the pectoralis muscle and mesh complex (Appendix 2 in the supplementary file). In the patients who underwent a skin-reducing mastectomy, the dermal flap was created in the lower pole and sutured to the inferior edge of the pectoralis major muscle, and the implant was inserted under this complex without using mesh. Finally, the skin is reconstructed like a reduction mammoplasty with a wise-pattern T incision over it (Appendix 3 in the supplementary file). In the tissue expander group, a lateral pectoral incision in the anterior axillary line was made, and then tissue dissection was performed under the pectoralis major muscle up to 1.5 cm upper portion of rectus shit without cutting it to create bigger space

for TE. Finally, TE was inserted under the pectoralis major muscle without using mesh and the skin was sutured (Appendix 4 in the supplementary file). In this study, the surgical procedure on each breast was considered 1 case, and if both breasts were under mastectomy surgery, they were considered 2 cases. BR and procedure types were selected based on the patient's and surgeon's preferences (Appendices 5 and 6 in the supplementary file).

3.3. Data Collection

In this study, the Body Checking Questionnaire (BCQ) was used for collecting the information obtained from 1 year of patients' follow-up after the surgery (18). Although the questionnaire has been designed as a self-report, in this study, the patients were asked the questions by the trained specialists and the questionnaire was filled for each patient separately. A checklist containing the variables under review was prepared and completed post-surgery and 1 year later with the information obtained from the patients' follow-up. Variables examined in these patients were age, body mass index (BMI), history of smoking, diabetes mellitus (DM), corticosteroid use, family history (FH) of breast cancer, the goal of the mastectomy (prophylactic or therapeutic surgery), procedure type, BR type, adjuvant RT, chemotherapy (adjuvant and neoadjuvant), complications as well as patients' satisfaction. We also collected information about clinical complications including hematoma, long-term seroma, severe capsular contracture, infection, necrosis, and implant extrusion.

3.4. Statistical Analysis

We used mean ± standard deviation (SD) and percentages to describe the quantitative and categorical variables, respectively. The chi-squared test was used to analyze the difference between qualitative variables. A comparison of quantitative variables was performed, using a student *t* test, and an independent *t* test (Mann-Whitney) was used in addition, in which quantitative variables did not have a normal distribution. All statistical analyses were performed at a 95% significance level, using SPSS statistical software version 16 (SPSS Inc., Chicago, IL, USA).

4. Results

A total of 140 patients were eligible for this study, though 27 (19.3%) did not complete the 1-year follow-up and were, therefore, excluded. Finally, 101 patients were recruited in this study, 12 of whom had bilateral mastectomies (i.e., 113 surgeries). The mean age of the subjects was estimated at 43 (± 10.97). The general characteristics were summarized in Table 1. Of these surgeries, 23% were prophylactic and 77% of them were performed for cancer treatment. The most common pathology was invasive ductal carcinoma (IDC) (53.3%). Also, 72% of the tumors were estrogen receptor (ER) positive. An immediate implant BR was performed in 86.7% of the surgeries (Table 2). Only 3 patients (2.6%) died after 2 years of follow-up.

Table 1. General Characteristics of Cases

Variables	Values
Age, years	43 ± 10.97
BMI, Kg/m^2	25.5 ± 5.4
Side of surgery	
Left	42 (37.2)
Right	47 (41.6)
Bilateral	24 (21.2)
History of DM	
Yes	6 (5.3)
No	107 (94.6)
History of smoking	
Yes	1 (0.9)
No	112 (99.1)
History of corticosteroid use	
Yes	1 (0.9)
No	112 (99.1)
FH of breast cancer	
Yes	49 (43.4)
No	64 (56.6)
Neoadjuvant chemotherapy	
Yes	15 (13.3)
No	98 (86.7)
Adjuvant chemotherapy	
Yes	46 (40.7)
No	67 (59.3)
Adjuvant RT	
Yes	22 (19.4)
No	91 (80.6)

Abbreviations: SD, standard deviation; BMI, body mass index; DM, diabetes mellitus; FH, family history; RT, radiotherapy.
[a] Values are expressed as Mean ± SD or No. (%).

Complications were hematoma (1.8%), long-term seroma of more than 20 days (4.4%), infection (7.1%), severe capsular contracture (14.2%) and partial epidermal

Table 2. Frequency of Tumor Pathology, Tumor Markers BR, and Procedure Types in Surgeries

Variables	Values
Tumor pathology	
IDC	57 (50.4)
ILC	4 (3.5)
Mix tumor	5 (4.4)
Pure DCIS	16 (14.2)
Recurrent tumor	4 (3.5)
Phyllodes	1 (0.9)
Tumor marker	
ER	82 (72.5)
PR	76 (67.2)
HER2	16 (14.1)
BR types	
Immediate implant	
With TIGR	48 (42.5)
Without TIGR	50 (44.2)
TE	15 (13.3)
Procedure types	
SSM	32 (28.3)
NSM	54 (47.8)
SRM	27 (23.9)

Abbreviations: IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; DCIS, ductal carcinoma in-situ; ER, estrogen receptor; PR, progesterone receptor; HER2, human epidermal growth factor receptor 2; BR, breast reconstruction; TE, tissue expander; SSM, skin-sparing mastectomy, NSM, NAC sparing mastectomy; SRM, skin reducing mastectomy.
[a] The percentage of tumor pathology was calculated from 87 (cancer treatment patients). The percentage of positive tumor markers has been written.
[b] Values are expressed as No. (%).

necrosis (22.1%) (Appendix 7 in the supplementary file) and in 7 patients (6.2%), the prosthesis was finally removed due to full-thickness skin necrosis (Appendices 8 and 9 in the supplementary file).

The results of this study showed that patients less than 43 years old and more than 43 years old have no significant difference in surgical complications. This finding was also observed for patients with BMI less than 25.8 and above 25.8. In the patients who received neoadjuvant chemotherapy and adjuvant RT, severe capsular contracture was significantly higher (P = 0.02 and P = 0.001, respectively). There was a remarkable relationship between adjuvant RT and infection as well as implant loss related to full-thickness skin necrosis (P = 0.02 and P = 0.009, respectively). The incidence of hematoma was significantly higher in diabetic patients in comparison to non-diabetics. (16.7% vs. 0.9%, P = 0.004) (Table 3). There was no significant association between BR, prophylactic, and cancer pathologies groups, and types of procedures performed or complications; however, no significant association was found in the case of capsular contracture (P = 004).

Moreover, there was no significant difference between implant removal and risk factors including DM, corticosteroid use, smoking, neoadjuvant chemotherapy, and adjuvant chemotherapy. Implant removal incidence was significantly higher when associated with hematoma, seroma, infection, and necrosis (P = 0.001) and adjuvant RT (P = 0.009) (Table 4). A total of 15% of SRM, 6% of SSM, and 1% of NSM implants were removed. The least implant loss between BR types occurred in the case of implant + TIGR® (4%). Comparison of implant loss according to the procedure and BR types and side of surgery showed no significant difference either.

The patients were asked about their satisfaction with the appearance of their breasts after surgery, regarding the cosmetic result, softness, capsule contracture, and symmetry in bilateral cases and the final visit (2 years later) individually, where the mean was 7.82 ± 2.33 (each patient scored from one to 10). The results of the study showed that the patients were significantly dissatisfied with necrosis (P = 0.005), infection (0.014), capsular contracture (0.02), and the need for prosthesis removal (P = 0.003) (Table 5). Procedure types and side of surgery BR types did not affect patients' satisfaction.

5. Discussion

According to the reasons stated in the introduction, in this study, we examined the results of using TIGR® mesh in BR. Based on the results of this study, among surgical complications in the patients, partial epidermal necrosis (15.9%) that healed without surgical interference and severe capsular contracture (14.2%) was the most prevalent. Other complications were infections (7.1%), implant extrusion (6.2%) due to full-thickness skin necrosis, long-term seroma (4.4%), and hematoma (1.8%) respectively. Prevalence of pooled complications in a systematic review on prosthetic-based BR with ADM/mesh was partial NAC necrosis at 4.5%, long-term seroma at 2.9%, hematoma, and wound healing complex at 2.3%, major flap necrosis 1.8%, as well as major infection and grade III/IV capsular contracture 1.2% full NAC necrosis, which were 2.6% in our results (17).

We summarized breast reconstruction complications in different studies in (Appendix 10 in the supplementary file) (19-26).

Among 25 cases of skin necrosis, only 7 had full-thickness NAC or skin necrosis, and finally, the

Table 3. Comparison of Surgical Complications

	N	Hematoma	Long Term Seroma	Infection	Epidermal Necrosis	SCC	Full-thickness Skin Necrosis [a]
Age							
< 43	58	1 (1.7)	1 (1.7)	2 (3.4)	6 (15.5)	11 (19)	3 (5.2)
≥ 43	55	1 (1.8)	4 (7.3)	6 (10.9)	12 (29.1)	5 (9.1)	4 (7.3)
P-value [b]		0.97	0.15	0.12	0.08	0.13	0.64
BMI							
< 25.5	36	1 (2.8)	1 (2.8)	3 (8.3)	10 (27.8)	7 (19.4)	4 (11.1)
≥ 25.5	36	1 (2.8)	4 (11.1)	5 (13.9)	8 (22.2)	8 (22.2)	3 (8.3)
P-value [b]		1	0.16	0.45	0.58	0.77	0.69
DM							
Yes	6	1 (16.7)	1 (16.7)	1 (16.7)	1 (16.7)	1 (16.7)	1 (16.7)
No	107	1 (0.9)	4 (3.7)	7 (6.5)	24 (22.4)	15 (14)	6 (5.6)
P-value [b]		0.004	0.13	0.34	0.74	0.85	0.27
Neoadjuvant chemotherapy							
Yes	15	0 (0)	1 (6.7)	1 (6.7)	1 (6.7)	5 (33.3)	1 (6.7)
No	98	2 (2)	4 (4.1)	7 (7.1)	24 (24.5)	11 (11.2)	6 (6.1)
P- value [b]		0.57	0.65	0.94	0.12	0.02	0.93
Adjuvant chemotherapy							
Yes	46	1 (2.2)	1 (2.2)	3 (6.5)	11 (23.9)	9 (19.6)	3 (6.5)
No	67	1 (1.5)	4 (6)	5 (7.5)	14 (20.9)	7 (10.4)	4 (6)
P- value [b]		0.78	0.33	0.85	0.7	0.17	0.9
Adjuvant RT							
Yes	22	1 (4.5)	2 (9.1)	4 (18.2)	7 (31.8)	8 (36.4)	4 (18.2)
No	91	1 (1.1)	3 (3.3)	4 (4.4)	18 (19.8)	8 (8.8)	3 (3.3)
P- value [b]		0.27	0.23	0.02	0.22	0.001	0.009
Procedure type							
NSM	54	0 (0)	2 (3.7)	2 (3.7)	9 (16.7)	6 (11.1)	1 (1.9)
SSM	32	1 (3.1)	3 (2.4)	4 (12.5)	6 (21.9)	8 (25)	2 (6.3)
SRM	27	1 (3.7)	0 (0)	2 (7.4)	9 (33.3)	2 (7.4)	4 (14.8)
P-value [b]		0.38	0.2	0.3	0.23	0.104	0.07
BR type							
Implant	50	1 (2)	1 (2)	3 (6)	15 (30)	3 (6)	5 (10)
TE	15	0 (0)	0 (0)	1 (6.7)	3 (20)	3 (20)	2 (7.5)
Implant + TIGR	48	1 (2.1)	4 (8.3)	4 (8.3)	7 (14.6)	10 (20.8)	2 (4.2)
P-value [b]		0.85	0.21	0.9	0.18	0.08	0.73
Pathology							
Cancer	70	1 (1.4)	3 (4.3)	5 (7.1)	14 (20)	14 (20)	4 (5.7)
Benign disease	17	1 (5.9%)	2 (11.8)	2 (11.8)	4 (23.5)	2 (11.8)	1 (5.9)
Prophylaxis	26	0 (0)	0 (0)	1 (3.8)	7 (26.9)	0 (0)	2 (7.7)
P-value [b]		0.33	0.18	0.61	0.75	0.04	0.93

Abbreviations: RT, radiotherapy; SCC, severe capsular contracture.
[a] Full-thickness skin necrosis or NAC necrosis and implant loss.
[b] Comparison of the association was performed, using the Pearson chi-square test. ignificance level was seen in cases of capsular contracture based on neoadjuvant chemotherapy and adjuvant radiotherapy and pathology, infection, and implant excised based on adjuvant radiotherapy and also hematoma based on DM.
[c] The benign disease includes phyllodes and ductal carcinoma in situ; cancer includes invasive ductal carcinoma, invasive lobular carcinoma, mix, and recurrent tumors.
[d] Values are expressed as No. (%).

Table 4. Comparison of the Relationship Between Implant Removal and Surgical Risk Factors

Risk Factors	Implant Removal		P-Value [a]
	Yes (N = 7)	No (N = 106)	
Pre-surgery risk factors			
DM	1 (14.3)	5 (5.7)	0.27
Corticosteroid use	0 (0)	1 (0.9)	0.79
Smoking	0 (0)	1 (0.9)	0.79
Neoadjuvant chemotherapy	1 (14.3)	14 (13.2)	0.93
Post-surgery risk factors			
Hematoma	2 (28.6)	0 (0)	0.001
Long term seroma	2 (28.6)	3 (2.8)	0.001
Infection	5 (71.4)	3 (2.8)	0.001
Necrosis	7 (100)	18 (17)	0.001
Severe capsular contracture	1 (14.3)	15 (14.2)	0.99
Adjuvant RT	4 (18.2)	3 (3.3)	0.009
Adjuvant chemotherapy	3 (42.9)	43 (40.6)	0.90

Abbreviation: RT, radiotherapy.
[a] Comparison of the association was performed, using Pearson chi-square test and Fisher's exact test.
[b] Values are expressed as No. (%).

Table 5. Comparison of Patients' Satisfaction Based on BMI and Surgical Complications

Variables	BCQ Score < 7.82 (N = 33)	BCQ Score ≥ 7.82 (N = 63)	P-Value [a]
BMI, kg/m^2	25.29 ± 2.89	26.37 ± 5.29	0.377
Severe capsular contracture	9 (27.3)	6 (9.5)	0.02
Necrosis	13 (39.4)	9 (14.3)	0.005
Hematoma	1 (3)	1 (1.6)	0.63
Infection	6 (18.3)	2 (3.2)	0.01
Long term seroma	2 (6.1)	3 (4.38)	0.78
Implant extrusion	6 (18.2)	1 (1.6)	0.003
Procedure types			0.46
NSM	13 (39.4)	33 (52.4)	
SSM	12 (36.4)	17 (27)	
SRM	8 (24.2)	13 (20.6)	
Side of surgery			0.66
Right	14 (42.4)	22 (34.9)	
Left	13 (39.4)	25 (39.7)	
Bilateral	6 (18.2)	16 (25.4)	
BR types			0.66
Implant	17 (51.5)	28 (44.4)	
TE	5 (15.2)	8 (12.7)	
Implant + TIGR	11 (33.3)	27 (42.9)	

Abbreviations: BCQ, the Body Checking Questionnaire; SD, standard deviation.
[a] Comparison of the association was performed, using the Pearson chi-square test and student *t* test. The significance level was considered in $P < 0.05$.
[b] Values are expressed as Mean ± SD or No. (%).

prosthesis was removed. All patients had some degree of capsular contracture, but we considered patients as positive, whose capsular contractures were severe (Baker class III and IV). Regarding seroma, the patients had closed the drain to a volume of less than 30 cc per day for 2 to 3 weeks. Only 5 patients had long-lasting seromas, and thus their drain was kept for more than a month. Severe capsular contracture incidence was higher in the patients with younger age in our study, but the difference was not statistically significant; it might be due to a stronger immune system between the ages of 22 and 43 years (27). Other complications were more prevalent in older patients. According to our findings, patients' age cannot be considered a risk factor for the onset of surgical complications. A study conducted by Zenn et al. showed that age more than 50 can increase the risk of BR complications, but another study, in line with our findings, showed that age is not a significant risk factor (5, 28). The reason for this difference could be because of the younger sample size in our study. It is suggested to conduct a study, where patients are divided into 2 groups of old and young to gain a better comparison of groups.

According to our results, only necrosis and implant extrusion were more prevalent in patients with BMI less than 25.8 kg/m2 in comparison to those who have a higher BMI, but it was not statistically significant; a possible reason for this difference may be less subcutaneous tissue in these patients and thinner skin flap. The difference between these two BMI groups was not also statistically significant in any complications, which could be due to the small study population. In a study by Bonomi et al., low BMI was introduced as a risk factor for postoperative complications, which was not in line with our study (28). However, patients in that study had been divided into two groups, above 23.8 kg/m2 and below it, which was different from our BMI cut point.

DM was positive in 5.3% of our patients. Our results showed that DM might be a risk factor for the occurrence of hematoma. Other complications except necrosis were higher in diabetic patients. Albeit, it was not statistically significant. In a study by Ibrahim et al., DM was associated with major complications and increased risk of wound disruption (29). A review by Zenn et al. also demonstrated that ADM was associated with an increased risk of BR complications (5).

A review study by Fischer et al. on perioperative risk factors for TE loss after IBR showed that active smokers are more in danger of TE loss (30). Other studies would also confirm this result (29). Due to the low number of smokers in our study, it was not possible to compare their complications based on this variable and further studies with larger sample sizes are required to evaluate the effect of this variable.

A systematic review and meta-analysis were conducted on surgical site infection (SSIs) risk factors following breast surgery and showed that older age, hypertension, higher BMI, DM, and neoadjuvant chemoradiation were associated with more SSIs. It also was concluded that smoking, immediate reconstruction, and corticosteroid usage did not have any statistically significant relationship with surgical complications (31). Cécile Zinzindohoué et al. in a study on IBR following neoadjuvant chemotherapy in invasive breast carcinoma showed that neoadjuvant chemotherapy was safe and had only local epidermal necrosis on 5 patients (10%) and they recovered by re-epithelialized without revision surgery that is similar to our study with 13.9% (32). Our study showed that the prevalence of severe capsular contracture was significantly higher in the patients who had neoadjuvant chemotherapy and adjuvant RT. The prevalence of infection and implant extrusion was also significantly higher in patients receiving adjuvant RT. Studies have shown that radiotherapy is associated with more capsular contracture and infection, which are in line with our study (33-35).

According to postoperative complications, necrosis was the most prevalent surgical complication overall. Its prevalence in the TE and implant groups was 20% and 30%, respectively. Necrosis prevalence was the least in the implant + TIGR® group (14.6%) in comparison to the other two groups. A study by Basta et al. on two groups of TE/implant and IBR showed that infection, seroma, and capsular contracture risk were similar between the groups. The patients in the IBR group had a higher risk of flap necrosis and implant extrusion (36). Nevertheless, Basta et al. did not mention whether BRs were supported by ADM/mesh or not. In our study, the patients undergoing TE had no hematoma or long-term seroma. Finally, there was no statistically significant difference between BR types based on the complications (36).

A study by Dieterich et al., conducted from 2008 to 2011, on implant-based BR using a titanium-coated polypropylene mesh (TiLOOPMesh) showed that procedure types including surgical type with TiLOOPMesh (NSM and SSM) and modified radical mastectomy (MRM) were not associated with any major complications (infection, necrosis, seroma, and hematoma requiring surgical intervention) or minor ones (no indication for surgical intervention) (26). Implant extrusion was not associated with NSM or SSM in this study either. Our study concurred with this study in all complications.

According to the results of this study, necrosis was the most prevalent postoperative complication in cancer (26.9%), prophylactic (23.5%), and benign disease (20%)

groups. The findings of our study showed that capsular contracture was significantly higher in the cancer group that need adjuvant RT. Studies in this field are very rare. A study by Billig et al. was done to compare costs and complications of contralateral prophylactic mastectomy in women with unilateral breast cancer and concluded higher costs plus slightly higher complication rates (which were not statistically significant) in the contralateral prophylactic mastectomy group (37).

In our study, there was no significant association between implant and DM, neoadjuvant chemotherapy, smoking, or corticosteroid use. The implant extrusion rate was significantly higher in patients having long-term seroma, infection, hematoma, and necrosis. The implant extrusion rate was lowest in the implants + TIGR® group. Moreover, the BR method of SSM or NSM or side of surgery was not determined as a risk factor for implant extrusion in our patients. Similar studies have achieved similar findings in this regard. A study by Dieterich et al. was conducted to evaluate the use of TiLOOP Mesh in implant-based BR (26). Implant removal in this study was not associated with DM, neoadjuvant or adjuvant chemotherapy, adjuvant RT, smoking, procedure types, pathology (prophylactic and therapeutic), and side (unilateral or bilateral) of the surgeries. This study also concluded that implant removal was associated with capsular fibrosis and skin necrosis. Another study by Pompei et al. on the use of TIGR® in BR and aesthetic breast surgeries showed lower rates of infection, seroma, and implant removal in the case of using this mesh compared with other synthetic meshes (19). Studies have shown positive aesthetic and satisfactory outcomes in the case of using ADM in BR surgeries (5, 38-43).

According to our results, patients' satisfaction was lower among those who had radiation or surgical complications. Moreover, the long-term result was equal in TIGR and other groups. A review by Logan Ellis et al. reported patients' satisfaction rate of 7.75 out of 10 after 28 months of BR using a non-absorbable mesh (Mersilene), which is similar to ours (15). The mean satisfaction level in our study was 7.86. In our study, the patients with higher rates of infection, severe capsular contracture, necrosis, and implant removal had a lower satisfaction level. The patients in implant + TIGR® and TE groups had the highest (44.4%) and lowest (12.7%) satisfaction levels, respectively. Using TIGR mesh leads to higher patients' satisfaction as well as higher cosmetic results in comparison to other groups.

5.1. Conclusions

According to the findings of this study, the placement of mesh would not increase the complications in patients and even reduce them in some cases, resulting in improving patients' satisfaction from surgery and the appearance of the breast. Thus, it is suggested to use TIGR in post-mastectomy BRs in lower pol to increase subcutaneous thickness. However, in cases where neoadjuvant chemotherapy and adjuvant radiotherapy treatment have been taken, the higher probability of capsule contracture must be considered.

The comparison of 3 groups of procedure and BR types made our study novel in this field. The results of this study can help and guide surgeons to use this cheaper material, and can also be used to design high volume and high-quality RCTs in our country.

Due to the lack of different patient groups for comparing different synthetic meshes, it is suggested that further studies need to be conducted to investigate the complications in this regard. Also, long-term studies in this field are required to evaluate long-term complications and patients' disclosure.

Supplementary Material

Supplementary material(s) is available here [To read supplementary materials, please refer to the journal website and open PDF/HTML].

Acknowledgments

The authors would like to thank Rasool Akram Medical Complex Clinical Research Development Center (RCRDC) for its technical and editorial assistance.

Footnotes

Authors' Contribution: Concept and design: NN; Collecting data: LS, MZ, SP, and BT; Analysis and interpretation of data: LS, MZ, and BT; Drafting: NN, AB, and HV; Final approval of the version to be published: All authors.

Conflict of Interests: There is no conflict of interest.

Data Reproducibility: The dataset presented in the study is available on request from the corresponding author during submission or after publication.

Ethical Approval: This study was approved by the Ethics Committee of Iran University of Medical Sciences with the ethical approval code: IR.IUMS.FMD.REC.1397.133.

Funding/Support: We have no funding support for this study.

Informed Consent: The entire participant signed an informed consent form before participating in the study.

References

1. Rocco N, Rispoli C, Moja L, Amato B, Iannone L, Testa S, et al. Different types of implants for reconstructive breast surgery. *Cochrane Database Syst Rev*. 2016;**2016**(5):Cd010895. [PubMed ID: 27182693]. [PubMed Central ID: PMC7433293]. https://doi.org/10.1002/14651858.CD010895.pub2.
2. Akbari ME, Hassani M, Akbari A, Nafisi N, Naserinia SS, Jafari R, et al. What is the essential element(s) to avoid axillary involvement in breast cancer patients? *Breast J*. 2013;**19**(1):121–3. [PubMed ID: 23279445]. https://doi.org/10.1111/tbj.12061.
3. Nafissi N, Makhdoom A, Hoseini M, Akbari M, Hashemi M, Sarafzadeh A, et al. Investigating the health of resection margins for conducting intra-operative during breast conservative surgery. *Biomed Pharmacol J*. 2016;**9**(2):769–73. https://doi.org/10.13005/bpj/1001.
4. Breuing KH, Warren SM. Immediate bilateral breast reconstruction with implants and inferolateral AlloDerm slings. *Ann Plast Surg*. 2005;**55**(3):232–9. [PubMed ID: 16106158]. https://doi.org/10.1097/01.sap.0000168527.52472.3c.
5. Zenn M, Venturi M, Pittman T, Spear S, Gurtner G, Robb G, et al. Optimizing outcomes of postmastectomy breast reconstruction with acellular dermal matrix: a review of recent clinical data. *Eplasty*. 2017;**17**. e18. [PubMed ID: 28663773]. [PubMed Central ID: PMC5475305].
6. Colwell AS. Direct-to-implant breast reconstruction. *Gland Surg*. 2012;**1**(3):139–41. [PubMed ID: 25083436]. [PubMed Central ID: PMC4115696]. https://doi.org/10.3978/j.issn.2227-684X.2012.10.04.
7. Chun YS, Verma K, Rosen H, Lipsitz S, Morris D, Kenney P, et al. Implant-based breast reconstruction using acellular dermal matrix and the risk of postoperative complications. *Plast Reconstr Surg*. 2010;**125**(2):429–36. [PubMed ID: 20124828]. https://doi.org/10.1097/PRS.0b013e3181c82d90.
8. JoAnna Nguyen T, Carey JN, Wong AK. Use of human acellular dermal matrix in implant- based breast reconstruction: evaluating the evidence. *J Plast Reconstr Aesthet Surg*. 2011;**64**(12):1553–61. [PubMed ID: 21388901]. https://doi.org/10.1016/j.bjps.2011.02.001.
9. Spear SL, Pelletiere CV, Lockwood M. Immediate breast reconstruction with tissue expanders and AlloDerm. In: Spear SL, Willey SC, Robb GL, editors. *Surgery of the breast: principles and art*. 2nd ed. Philadelphia: Lippincott Williams & Wilkins; 2006. p. 484–8.
10. Israeli R. Complications of acellular dermal matrices in breast surgery. *Plast Reconstr Surg*. 2012;**130**(5 Suppl 2):159S–72S. [PubMed ID: 23096966]. https://doi.org/10.1097/PRS.0b013e3182634e62.
11. Serra-Renom JM, Fontdevila J, Monner J, Benito J. Mammary reconstruction using tissue expander and partial detachment of the pectoralis major muscle to expand the lower breast quadrants. *Ann Plast Surg*. 2004;**53**(4):317–21. [PubMed ID: 15385763]. https://doi.org/10.1097/01.sap.0000125497.04744.5c.
12. Lesavoy MA, Trussler AP, Dickinson BP. Difficulties with subpectoral augmentation mammaplasty and its correction: the role of subglandular site change in revision aesthetic breast surgery. *Plast Reconstr Surg*. 2010;**125**(1):363–71. [PubMed ID: 20048627]. https://doi.org/10.1097/PRS.0b013e3181c2a4b0.
13. Becker H, Lind JG,2nd. The use of synthetic mesh in reconstructive, revision, and cosmetic breast surgery. *Aesthetic Plast Surg*. 2013;**37**(5):914–21. [PubMed ID: 23860816]. [PubMed Central ID: PMC3778996]. https://doi.org/10.1007/s00266-013-0171-8.
14. Tessler O, Reish RG, Maman DY, Smith BL, Austen WG,Jr. Beyond biologics: absorbable mesh as a low-cost, low-complication sling for implant-based breast reconstruction. *Plast Reconstr Surg*. 2014;**133**(2):90–9. [PubMed ID: 24469217]. https://doi.org/10.1097/01.prs.0000437253.55457.63.
15. Logan Ellis H, Asaolu O, Nebo V, Kasem A. Biological and synthetic mesh use in breast reconstructive surgery: a literature review. *World J Surg Oncol*. 2016;**14**:121. [PubMed ID: 27102580]. [PubMed Central ID: PMC4839154]. https://doi.org/10.1186/s12957-016-0874-9.
16. Schrenk P. Immediate implant-based breast reconstruction using the TIGR® Matrix mesh. *Breast Cancer Manag*. 2016;**5**(2):53–9. https://doi.org/10.2217/bmt-2016-0003.
17. Salibian AA, Frey JD, Choi M, Karp NS. Subcutaneous Implant-based Breast Reconstruction with Acellular Dermal Matrix/Mesh: A Systematic Review. *Plast Reconstr Surg Glob Open*. 2016;**4**(11). e1139. [PubMed ID: 27975034]. [PubMed Central ID: PMC5142500]. https://doi.org/10.1097/GOX.0000000000001139.
18. Reas DL, Whisenhunt BL, Netemeyer R, Williamson DA. Development of the body checking questionnaire: a self-report measure of body checking behaviors. *Int J Eat Disord*. 2002;**31**(3):324–33. [PubMed ID: 11920995]. https://doi.org/10.1002/eat.10012.
19. Pompei S, Evangelidou D, Arelli F, Ferrante G. The use of TIGR matrix in breast aesthetic and reconstructive surgery: Is a resorbable synthetic mesh a viable alternative to acellular dermal matrices? *Clin Plast Surg*. 2018;**45**(1):65–73. [PubMed ID: 29080661]. https://doi.org/10.1016/j.cps.2017.08.005.
20. Berna G, Cawthorn SJ, Papaccio G, Balestrieri N. Evaluation of a novel breast reconstruction technique using the Braxon((R)) acellular dermal matrix: a new muscle-sparing breast reconstruction. *ANZ J Surg*. 2017;**87**(6):493–8. [PubMed ID: 25266930]. https://doi.org/10.1111/ans.12849.
21. Zhu L, Mohan AT, Abdelsattar JM, Wang Z, Vijayasekaran A, Hwang SM, et al. Comparison of subcutaneous versus submuscular expander placement in the first stage of immediate breast reconstruction. *J Plast Reconstr Aesthet Surg*. 2016;**69**(4):e77–86. [PubMed ID: 26922050]. https://doi.org/10.1016/j.bjps.2016.01.006.
22. Bernini M, Calabrese C, Cecconi L, Santi C, Gjondedaj U, Roselli J, et al. Subcutaneous direct-to-Implant breast reconstruction: Surgical, functional, and aesthetic results after long-Term follow-up. *Plast Reconstr Surg Glob Open*. 2015;**3**(12). e574. [PubMed ID: 26893999]. [PubMed Central ID: PMC4727683]. https://doi.org/10.1097/GOX.0000000000000533.
23. Casella D, Calabrese C, Bianchi S, Meattini I, Bernini M. Subcutaneous tissue expander placement with synthetic titanium-coated mesh in breast reconstruction: long-term results. *Plast Reconstr Surg Glob Open*. 2015;**3**(12). e577. [PubMed ID: 26894002]. [PubMed Central ID: PMC4727686]. https://doi.org/10.1097/GOX.0000000000000549.
24. Becker H, Lind JG,2nd, Hopkins EG. Immediate Implant-based prepectoral breast reconstruction using a vertical incision. *Plast Reconstr Surg Glob Open*. 2015;**3**(6). e412. [PubMed ID: 26180713]. [PubMed Central ID: PMC4494482]. https://doi.org/10.1097/GOX.0000000000000384.
25. Reitsamer R, Peintinger F. Prepectoral implant placement and complete coverage with porcine acellular dermal matrix: a new technique for direct-to-implant breast reconstruction after nipple-sparing mastectomy. *J Plast Reconstr Aesthet Surg*. 2015;**68**(2):162–7. [PubMed ID: 25455288]. https://doi.org/10.1016/j.bjps.2014.10.012.
26. Dieterich M, Paepke S, Zwiefel K, Dieterich H, Blohmer J, Faridi A, et al. Implant-based breast reconstruction using a titanium-coated polypropylene mesh (TiLOOP Bra): a multicenter study of 231 cases. *Plast Reconstr Surg*. 2013;**132**(1):8–19. [PubMed ID: 23806958]. https://doi.org/10.1097/PRS.0b013e318290f8a0.
27. Lawton G. You're only as young as your immune system. *New Sci*. 2020;**245**(3275):44–8. [PubMed ID: 32518464]. [PubMed Central ID: PMC7270427]. https://doi.org/10.1016/S0262-4079(20)30646-1.
28. Bonomi S, Sala L, Gennaro M, Ricci C, Cortinovis U. Skin-reducing mastectomy and direct-to-implant breast reconstruction with submuscular-dermal-mesh pocket. *Ann Plast Surg*. 2019;**82**(1):19–27. [PubMed ID: 30247191]. https://doi.org/10.1097/SAP.0000000000001614.
29. Ibrahim AMS, Shuster M, Koolen PGL, Kim K, Taghinia AH, Sinno HH, et al. Analysis of the national surgical quality improvement program database in 19,100 patients undergoing implant-based breast reconstruction: Complication rates with acellular dermal

matrix. *Plast Reconstr Surg*. 2013;**132**(5):1057–66. [PubMed ID: 24165587]. https://doi.org/10.1097/PRS.0b013e3182a3beec.

30. Fischer JP, Nelson JA, Serletti JM, Wu LC. Peri-operative risk factors associated with early tissue expander (TE) loss following immediate breast reconstruction (IBR): a review of 9305 patients from the 2005-2010 ACS-NSQIP datasets. *J Plast Reconstr Aesthet Surg*. 2013;**66**(11):1504–12. [PubMed ID: 23845908]. https://doi.org/10.1016/j.bjps.2013.06.030.
31. Xue DQ, Qian C, Yang L, Wang XF. Risk factors for surgical site infections after breast surgery: a systematic review and meta-analysis. *Eur J Surg Oncol*. 2012;**38**(5):375–81. [PubMed ID: 22421530]. https://doi.org/10.1016/j.ejso.2012.02.179.
32. Zinzindohoue C, Bertrand P, Michel A, Monrigal E, Miramand B, Sterckers N, et al. A prospective study on skin-sparing mastectomy for immediate breast reconstruction with latissimus dorsi flap after neoadjuvant chemotherapy and radiotherapy in invasive breast carcinoma. *Ann Surg Oncol*. 2016;**23**(7):2350–6. [PubMed ID: 26957504]. https://doi.org/10.1245/s10434-016-5146-y.
33. Colwell AS, Damjanovic B, Zahedi B, Medford-Davis L, Hertl C, Austen WG,Jr. Retrospective review of 331 consecutive immediate single-stage implant reconstructions with acellular dermal matrix: indications, complications, trends, and costs. *Plast Reconstr Surg*. 2011;**128**(6):1170–8. [PubMed ID: 22094736]. https://doi.org/10.1097/PRS.0b013e318230c2f6.
34. Salzberg CA, Ashikari AY, Koch RM, Chabner-Thompson E. An 8-year experience of direct-to-implant immediate breast reconstruction using human acellular dermal matrix (AlloDerm). *Plast Reconstr Surg*. 2011;**127**(2):514–24. [PubMed ID: 21285756]. https://doi.org/10.1097/PRS.0b013e318200a961.
35. Hvilsom GB, Friis S, Frederiksen K, Steding-Jessen M, Henriksen TF, Lipworth L, et al. The clinical course of immediate breast implant reconstruction after breast cancer. *Acta Oncol*. 2011;**50**(7):1045–52. [PubMed ID: 21604960]. https://doi.org/10.3109/0284186X.2011.581690.
36. Basta MN, Gerety PA, Serletti JM, Kovach SJ, Fischer JP. A systematic review and head-to-head meta-analysis of outcomes following direct-to-implant versus conventional two-stage implant reconstruction. *Plast Reconstr Surg*. 2015;**136**(6):1135–44. [PubMed ID: 26595013]. https://doi.org/10.1097/PRS.0000000000001749.
37. Billig JI, Duncan A, Zhong L, Aliu O, Sears ED, Chung KC, et al. The cost of contralateral prophylactic mastectomy in women with unilateral breast cancer. *Plast Reconstr Surg*. 2018;**141**(5):1094–102. [PubMed ID: 29659447]. [PubMed Central ID: PMC5922428]. https://doi.org/10.1097/PRS.0000000000004272.
38. Forsberg CG, Kelly DA, Wood BC, Mastrangelo SL, DeFranzo AJ, Thompson JT, et al. Aesthetic outcomes of acellular dermal matrix in tissue expander/implant-based breast reconstruction. *Ann Plast Surg*. 2014;**72**(6):S116–20. [PubMed ID: 24374398]. https://doi.org/10.1097/SAP.0000000000000098.
39. Vardanian AJ, Clayton JL, Roostaeian J, Shirvanian V, Da Lio A, Lipa JE, et al. Comparison of implant-based immediate breast reconstruction with and without acellular dermal matrix. *Plast Reconstr Surg*. 2011;**128**(5):403–10. [PubMed ID: 22030500]. https://doi.org/10.1097/PRS.0b013e31822b6637.
40. Gamboa-Bobadilla GM. Implant breast reconstruction using acellular dermal matrix. *Ann Plast Surg*. 2006;**56**(1):22–5. [PubMed ID: 16374090]. https://doi.org/10.1097/01.sap.0000185460.31188.c1.
41. Spear SL, Parikh PM, Reisin E, Menon NG. Acellular dermis-assisted breast reconstruction. *Aesthetic Plast Surg*. 2008;**32**(3):418–25. [PubMed ID: 18338102]. https://doi.org/10.1007/s00266-008-9128-8.
42. Salzberg CA. Nonexpansive immediate breast reconstruction using human acellular tissue matrix graft (AlloDerm). *Ann Plast Surg*. 2006;**57**(1):1–5. [PubMed ID: 16799299]. https://doi.org/10.1097/01.sap.0000214873.13102.9f.
43. Zienowicz RJ, Karacaoglu E. Implant-based breast reconstruction with allograft. *Plast Reconstr Surg*. 2007;**120**(2):373–81. [PubMed ID: 17632337]. https://doi.org/10.1097/01.prs.0000267340.31742.1.