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Research Article

Long-term oncologic safety of one-stage direct-to-implant immediate breast reconstruction without the use of acellular dermal matrix

Aselüler dermal matriks kullanılmadan gerçekleştirilen direkt implant ile tek aşamalı anında meme rekonstrüksiyonunun uzun dönem onkolojik güvenirliliği

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Abstract

Aim: This study aimed to evaluate the oncologic safety of direct-to-implant immediate breast reconstruction without the use of an acellular dermal matrix (ADM) or mesh following nipple-sparing and skin-sparing mastectomy in patients with primary breast cancer.

Material and Methods: The medical records of 175 patients who underwent one-stage direct-to-implant breast reconstruction following mastectomy at the Istanbul University Oncology Institute between 2014 and 2022 were retrospectively reviewed. The primary objective was to assess the oncologic safety, including locoregional recurrence, distant metastasis, and survival outcomes. The secondary objective was to evaluate reconstruction-related complications.

Results: The median age of the patients was 44 years (range: 25-74), with a median follow-up period of 53 months (range: 19-101). HR+/HER2-, HR+/HER2+, and pure HER2+ subtypes were observed in 101 patients (57.7%), 26 (14.9%), 23 (13%), respectively. Triple-negative breast cancer was present in 16 patients (9.1%). Neoadjuvant chemotherapy was administered to 87 patients (49.7%), with a pathological complete response (pCR) rate of 17.2%. Skin necrosis (9.1%) and capsular contracture (8.6%) were the most common complications, with implant loss (occurring) in seven patients. Locoregional recurrence and distant metastasis rates were 9.7% and 13.1%, respectively. The five-year locoregional recurrence-free survival and distant metastasis-free survival rates were 95.4% and 90.3%. Additionally, 83.5% of patients reported their satisfaction as "excellent" or "good."

Conclusion: One-stage direct-to-implant immediate breast reconstruction without the use of an acellular dermal matrix or mesh is oncologically safe, with acceptable complication rates, making it a viable alternative to two-stage breast reconstruction or conventional mastectomy.

Keywords: direct-to-implant; contracture; immediate breast reconstruction; mesh

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Öz

Amaç: Bu çalışmada, primer meme kanseri olan hastalarda meme başı koruyucu ve cilt koruyucu mastektomi sonrası hücresiz dermal matris veya meş kullanılmaksızın gerçekleştirilen doğrudan implant ile yapılan anında meme rekonstrüksiyonunun onkolojik güvenliğini değerlendirmek amaçlandı.

Gereç ve Yöntemler: 2014-2022 yılları arasında İstanbul Üniversitesi Onkoloji Enstitüsü'nde mastektomi sonrası doğrudan implant ile tek aşamalı meme rekonstrüksiyonu yapılan 175 hastanın tıbbi kayıtları geriye dönük incelendi. Birincil hedef, bölgesel nüks, uzak metastaz ve sağkalım analizleri dahil olmak üzere onkolojik güvenliği değerlendirmekti. İkincil hedef ise rekonstrüksiyonla ilişkili komplikasyonları değerlendirmekti.

Bulgular: Hastaların medyan (yaşı) 44 yıl (aralık: 25-74) olup, medyan takip süresi 53 ay (aralık: 19-101) idi. HR+/HER2-, HR+/HER2+ ve saf HER2+ alt tipleri sırasıyla 101 (%57,7), 26 (%14,9) ve 23 (%13,1) hastada gözlemlendi. Üçlü negatif meme kanseri ise 16 (%9,1) hastada mevcuttu. Neoadjuvan kemoterapi 87 (%49,7) hastaya uygulanmış olup, patolojik tam yanıt (pCR) oranı %17,2 idi. Cilt nekrozu (%9,1) ve kapsüler kontraktür (%8,6) en sık görülen komplikasyonlardı ve komplikasyon nedeniyle yedi hastada implant kaybı yaşandı. Lokal-bölgesel nüks ve uzak metastaz oranları sırasıyla %9,7 ve %13,1 olarak kaydedildi. Beş yıllık lokal-bölgesel nükssüz sağkalım ve uzak metastazsız sağkalım oranları sırasıyla %95,4 ve %90,3 olarak bulundu. Ayrıca, hastaların %83,5'i memnuniyetlerini "mükemmel" veya "iyi" olarak bildirdi.

Sonuçlar: Hücresiz dermal matris veya mesh kullanılmadan doğrudan implant ile yapılan tek aşamalı anında meme rekonstrüksiyonu, onkolojik olarak güvenli olup kabul edilebilir komplikasyon oranlarına sahiptir. Ayrıca iki aşamalı meme rekonstrüksiyonu veya konvansiyonel mastektomiye iyi bir alternatif oluşturmaktadır.

Anahtar Kelimeler: direkt implant; kontraktür; anında meme rekonstrüksiyonu; meş

Introduction

Breast cancer is the most commonly diagnosed cancer worldwide with 2.3 million women diagnosed globally and 670,000 women dying from the disease annually, making it a significant health issue [1]. According to 2018 data, the incidence rate of breast cancer in Turkey is 48.6 per 100,000 women, with approximately 15,000 new cases diagnosed each year [2].

Early detection and advanced treatment methods have led to increased survival rates for breast cancer [3]. However, the treatment process presents significant physical and psychological challenges for patients. Since mastectomy involves the loss of a body part, it can be complemented with reconstructive surgery to address both aesthetic and psychological needs. This approach aims to restore the woman's body integrity, improve satisfaction with breast appearance, and enhance her quality of life [4].

Breast reconstruction can be performed either during the same surgical session (immediate) or at a later stage (delayed). The reconstruction may involve the use of the patient's own tissues or prosthetics, either through a single-stage or a two-stage procedure. Studies have reported varying oncologic outcomes and complication rates regarding the results of one-stage and two-stage procedures [5-7]. The timing of reconstruction is influenced by various factors, including the stage of the disease, the administration of radiotherapy, and the patient's preferences [8]. Concerns regarding the oncological safety of implant-based reconstruction have occasionally been raised, presenting challenges from a surgical standpoint.

The aim of this study is to evaluate whether one-stage direct-to-implant (ODTI) immediate breast reconstruction (IBR) following nipple-sparing mastectomy (NSM) and skin-sparing mastectomy (SSM) affects oncologic safety, including local recurrence, distant metastasis rates, and surgical complications.

Material and Methods

Between January 1, 2014, and December 31, 2022, a retrospective analysis was conducted on 323 consecutive breast cancer patients who underwent IBR following either NSM or SSM, using data prospectively collected from a surgical database at the Istanbul University Oncology Institute Breast Center, encompassing cases both before and after neoadjuvant chemotherapy (NACT).

Patients were included in the study based on TNM staging criteria, along with clinical and radiological imaging. Exclusion criteria were: distant metastases at diagnosis (n= 34), reconstruction using tissue expanders (n= 37), recurrent breast cancer (n= 46), and prophylactic mastectomy (n= 31). The analysis included 175 patients who underwent ODTI IBR with prostheses following NSM and SSM. Fine needle aspiration (FNA) was used for diagnosis in the presence of suspicious lymph nodes in the axilla, while core needle biopsy was employed for breast tissue. Routine radiological evaluations included ultrasonography (USG), mammography (MMG), and magnetic resonance imaging (MRI). When invasive tumors were present, staging was conducted using positron emission tomography-computed tomography (PET-CT).

The decision regarding neoadjuvant and adjuvant therapy, including the duration and methods to be employed, was made by oncologists during a multidisciplinary meeting at the institution. In patients receiving neoadjuvant therapy, clinical response was assessed according to the Response Evaluation Criteria in Solid Tumors (RECIST 1.1) criteria [9].

Clinical complete response was defined as the absence of a palpable lesion on physical examination and the absence of a contrast-enhancing lesion on MRI, along with the complete disappearance of the tumor on MMG and breast USG. A partial response was defined as a ≥30% reduction in tumor size. The absence of tumor size reduction despite treatment was classified as a progressive disease, while other scenarios were considered stable disease. In the context of neoadjuvant therapy, the ultimate goal, referred to as pathological complete response (pCR), was defined as the absence of invasive or in situ foci in the tumor assessment.

The study was approved by the Ethics Committee of Istanbul University Faculty of Medicine (Date: 23.12.2024, Decision Number: 3075139). Written informed consent was obtained from all patients prior to surgery.

Treatment

Neoadjuvant chemotherapy was administered based on institutional guidelines and the preference of the medical oncologist, utilizing (anthracycline and/or taxane-based regimens, with HER2+ tumors treated with trastuzumab and/or pertuzumab). Adjuvant radiotherapy (RT) was administered based on the radiation oncologist's decision for patients with axillary lymph node involvement or tumors larger than 5 cm. In most cases, the radiotherapy field included the chest wall, axillary region, supra- and infra clavicular areas.

One-stage DTI IBR was performed only if there was no clinical, radiological, or pathological evidence of involvement of the breast skin. All patients who underwent IBR had either NSM or SSM. Before reconstruction, all patients underwent retroareolar biopsy with intraoperative frozen section examination. If tumor presence was identified in either the intraoperative or final pathology, the nipple, either alone or with the areola, was removed, and the surgical procedure was converted to SSM. No patient was converted to conventional mastectomy (CMx) for this reason. The surgeries were performed by experienced breast surgeons (HK, SB, BK).

Follow-Up

Postoperative patients were monitored every three months for the first two years, every six months from the third to the fifth year, and annually thereafter. For patients who missed follow-up appointments, their status was inquired about via telephone. Locoregional recurrence (LR) was defined as the presence of tumors in the same-side chest wall, axillary, infra- and supraclavicular lymph nodes, or internal mammary lymph nodes. To detect LR, procedures such as punch biopsy, fine-needle aspiration biopsy, core needle biopsy, or excisional biopsy were performed. In patients with detected LR, the implant was removed, and conventional mastectomy was performed.

Distant metastasis (DM) was defined as the presence of tumors in any tissue other than regional sites and was primarily detected using PET-CT scans. In some cases, conventional CT scans and/or bone scintigraphy were conducted based on the oncologist's decision. Biopsy diagnosis was not always required for the diagnosis of distant metastasis. Patients with distant metastasis received a metastatic regimen.

Patient satisfaction was assessed through an institutional questionnaire after the completion of adjuvant radiotherapy. The questionnaire, consisting of 20 questions, evaluated the following parameters: breast shape, position and symmetry of the nipple-areola complex (NAC), surgical incision scars, and the psychosocial and sexual effects of reconstruction with implants. The total score was categorized as follows: <20 points= very poor, 21-40 points= poor, 41-60 points= satisfactory, 61-80 points= good, >80 points= excellent.

Statistical Analysis

Continuous parameters were presented as median, range, and percentage. The Overall Survival (OAS) duration was defined as the time from the start of treatment to death or last follow-up. Disease-free survival (DFS) was defined as

the time from the date of surgery to the date of recurrence. Locoregional recurrence-free survival (LRFS) was defined as the time until locoregional recurrence occurred. Distant metastasis-free survival (DMFS) was defined as the time until distant metastasis occurred from the date of surgery. Survival analyses were estimated using the Kaplan-Meier method. A p-value of <0.05 was considered statistically significant. Analyses were performed using Microsoft Excel and IBM SPSS Statistics version 21 (SPSS, Chicago, IL, USA).

Results

Characteristics of Patients, Tumors, and Treatments in the Cohort

The study included 175 patients with a median age of 44 years (range: 25-74). The majority of patients had a body mass index (BMI) between 25 and 30 (48%), with a smaller proportion had a BMI greater than 30. Approximately 39.4% of patients had a C cup breast size, followed by B cup (29.7%), and A cup (18.9%) sizes, while 21 (12%) patients had macromastia (≥D cup). Mild to moderate ptosis was present in 90.9% of patients, while severe ptosis was observed in 9.1%. Additionally, 99 patients (56.6%) were smokers, and 32 (18.3%) had diabetes mellitus.

The most common clinical tumor size was T2, found in 93 patients (53.2%), followed by T3 in 67 patients (38.3%), Tinsitu in 9 patients (5.1%), and T1 in 6 patients (3.4%). Among the total of 99 patients with T1 and T2 tumors, the decision for mastectomy was based on preoperative assessments indicating the presence of multicentric tumors, detection of BRCA1/2 gene mutations, and stable or progressive disease after chemotherapy. Unifocal (UF) tumors were found in 70 patients (40%), multifocal/multicentric (MFMC) tumors in 96 patients (54.9%), and extensive ductal carcinoma in situ (DCIS) in nine patients (5.1%). According to the TNM cancer classification, the majority of patients had stage II B (46.9%), followed by III A (22.3%) and II A (21.7%). The least common stages were T1N0 with three patients (1.7%) and T3N3 with four patients (2.3%). Clinically, 98 patients (56%) had lymph node involvement.

The molecular subtypes of the patients in the study group were as follows: 101 patients (57.7%) with HR+/HER2-, 26 patients (14.9%) with HR+/HER2+, 23 patients (13.1%) with HR-/HER2+, and 16 patients (9.1%) with triple-negative breast cancer (TNBC). The majority of patients (n= 136, 77.7%) had invasive ductal carcinoma, while invasive lobular carcinoma was seen in 13 patients (7.4%).

Upfront surgery was performed on 88 patients (50.3%), the majority of whom were hormone-positive, had ductal carcinoma in situ (DCIS), and had no axillary involvement. The number of patients who received neoadjuvant chemotherapy (NACT) was 87 (49.7%). The rates of pCR were 17.2% in the breast and 32.2% in the axilla. Intraoperatively, 61 patients (34.9%) with sentinel lymph node biopsy results reported as metastases underwent axillary lymph node dissection. Among the hormone-positive patients, 53 (30.3%) received only endocrine therapy as adjuvant treatment.

Excluding patients with DCIS reported in the final pathology, tumors smaller than 5 cm, and those without axillary lymph node metastasis, 75.4% of patients received adjuvant radiotherapy. Eight (4.6%) patients did not receive radiation therapy despite recommendations, due to various reasons including severe pneumonitis, cardiotoxicity, and patient preference (Details in Table 1).

Surgical Procedure

All patients underwent DTI IBR, with the approach being either subpectoral (89.7%) or prepectoral (10.3%). Nipple-sparing mastectomy was performed in 162 patients (92.6%). In 13 cases (7.4%), the procedure was converted to SSM due to tumor detection in the retroareolar biopsy results from intraoperative or final pathology reports. If necessary, excision of the nipple or nipple-areola complex was performed under sedoanalgesia during the postoperative period. In six patients (3.4%), the SSM procedure was conducted directly during surgery due to a very close tumor-to-nipple distance, along with the detection of invasive carcinoma or Paget's disease involving the nipple. No patient required conversion to a CMx for these reasons. The silicone gel implants used for reconstruction included: 1) Mentor CPG Gel Breast Implants (Johnson & Johnson Medical Ltd., USA) and 2) Allergan Breast Implants (AbbVie, USA).

Eleven out of 21 patients with larger cup sizes and severe ptosis underwent mastectomy with skin-reducing techniques, followed by prosthesis placement. The majority of patients had prostheses placed using the subpectoral reconstruction method (n= 157, 89.7%). In these cases, the exposed lateral part of the prosthesis was covered either with the fascia of the serratus anterior muscle or using separate, loose muscle-to-muscle sutures. Prepectoral reconstruction was preferred in 18 patients (10.3%) who were non-smokers, had no diabetes, had excess subcutaneous fat, and had preservation of the nipple-areola complex. In 20 patients with a BRCA1/2 gene mutation, contralateral prophylactic mastectomy and reconstruction with a prosthesis were included in the surgery (Details are provided in Table 1).

Table 1. Patients characteristics			
Patients, n (%)		175 (100)	
Follow-op, months, median (range)		53	(19-101)
Median age (range), years		44	(25-74)
Body mass index, kg/m2, n (%), mean (range)	≤25, n (%) >25-30, n (%) ≥30, n (%)	67 (38.3) 84 (48) 24 (13.7)	22.9 (16.3-24.8) 26.6 (25.1-29.4) 30.1 (32.1-36.2)
Smoking, n (%)	Yes No	76 (43.4) 99 (56.6)	
Diabetes mellitus, n (%)	Yes No	32 (18.3) 143 (81.7)	
Ptosis, n (%)	Mild Mild to moderate Severe	92 (52.6) 67 (38.3) 16 (9.1)	
Cup size, n (%)	A B C ≥D	33 (18.9) 52 (29.7) 69 (39.4) 21 (12)	
Clinical T stage, n (%)	Tins T1 T2 T3	9 (5.1) 6 (3.4) 93 (53.2) 67 (38.3)	
Clinical nodal status, n (%)	N0 N1 N2+	77(44) 78 (44.6) 20 (11.4)	
Clinical tumor size, n (%)			
Stage 0	TinsN0	9 (5.1)	
Stage I	T1N0	3 (1.7)	
Stage II A	T1N1 T2N0	3 (1.7) 35 (20)	
Stage II B	T2N1 T3N0	52 (29.7) 30 (17.2)	
Stage III A	T2N2 T3N1 T3N2	6 (3.4) 23 (13.2) 10 (5.7)	
Stage III C	T3N3	4 (2.3)	
Ki-67 index, n (%)	≤14 >14	42 (24) 133 (76)	
Invasive tumor focality, n (%)	UF MF/MC	70 (40) 96 (54.9)	

Histological type,
n (%)
	Invasive
	  Ductal
	  Lobular
	  Mixt
	DCIS
	Other
		
		136 (77.7)
		13 (7.5)
		7 (4)
		9 (5.1)
		10 (5.7)	

Grade, n (%)	1-2 3	109 (62.3) 57 (37.7)	
Lenfovascular invasion, n (%)	Yok Var	88 (50.3) 87 (49.7)	
Molecular subtypes, n (%)	HR+/HER2- HR+/HER2+ HR-/HER2+ TNBC	101 (57.7) 26 (14.9) 23 (13.1) 16 (9.1)	
Systemic therapy, n (%)	NACT Adjuvant CT+ ET Adjuvant ET	87 (49.7) 58 (33.1) 53 (30.3)	
pCR, n (%)	Yes No	15 (17.2) 72 (82.8)	
Adj. radiation therapy, n (%)	Yes No Recommended but not received	132 (75.4) 35 (20) 8 (4.6)	
Mastectomy types, n (%)	NSM SSM	162 (92.6) 13 (7.4)	
Reconstruction types, n (%)	Sub-pectoral Pre-pectoral	157 (89.7) 18 (10.3)	
Abbreviations: UF, unifocality; MF/MC, multifocality/multicentricity; DCIS, ductal carcinoma insitu; HR, hormone receptor; HER2, human epidermal growth factor receptor-2; TN, triple negative; pCR, pathological complete response; CT, chemotherapy; NACT, neoadjuvant chemotherapy; ET, endocrine theraphy; NSM, nipple sparing mastectomy; SSM, skin sparing mastectomy; Adj, adjuvant			

Complications

Non-operative complications were observed in the study, including delayed wound healing in 27 patients (15.4%), which was particularly more common among diabetics and smokers. Additionally, non-severe cellulitis or mild infection, manageable with antibiotics, occurred in 14 patients (8%). Spontaneous resolution of seroma in 11 patients (6.3%), rippling in eight patients (4.6%), and chronic pain in seven patients (4%).

The complications requiring surgery were as follows: partial necrosis, the most common complication, was observed in 16 patients (9.1%) and was treated with debridement followed by suturing. Capsular contracture occurred in 15 patients (8.6%), who underwent capsulotomy and/or capsulectomy. Extensive hematoma and animation deformity were observed in seven patients (4%), while severe infection occurred in six patients (3.4%). As a result of these complications, seven patients (4%) had their implants removed, and subsequently, they underwent conventional mastectomy (Details in Table 2).

Table 2. Surgical complications

		n	%
Complications (no need for re-operation)	Delayed wound healing	27	15.4
	Mild enfection	14	8
	Seroma	11	6.3
	Rippling	8	4.6
	Chronic pain	7	4
Complications (requiring minör re-operation)	Partial ischemia / necrosis	16	9.1
	Capsular contracture	15	8.6
	Animation defect	7	4
	Extensive hematoma	7	4
	Severe infection	6	3.4
	Implant displacement	4	2.3
Implant loss	Due to complications	7	4
	Due to local recurrence	12	6.9

Rates of Satisfaction

In both early and late postoperative institutional satisfaction questionnaires, 146 patients (83.5%) rated their experience as "excellent" or "good." In contrast, satisfaction was notably lower among patients who experienced implant loss in the early postoperative period, with 6.3% rating their experience as "poor" or "very poor" (Details in Table 3).

Table 3. Rates of satisfaction

	NSM, n= 162		SSM, n= 13	
	n	%	n	%
Excellent	64	36.6	4	2.3
Good	75	42.9	3	1.7
Satisfactory	13	7.3	5	2.9
Poor	3	1.7	1	0.6
Very poor	7	4	0	0

Abbreviations: NSM, nipple-sparing mastectomy; SSM, skin-sparing mastectoimy.

Follow-up Period

The median follow-up time was 53 months (range: 19-101). During this period, LR was observed in 17 patients (9.7%), and DM occurred in 23 patients (13.1%). Both LR and DM were most prevalent in the TNBC group, with rates of 18.8% and 18.8%, respectively. The overall recurrence rate was 22.8% (n= 40). In 12 (6.9%) patients with local recurrence in the breast region, the prosthesis was removed, and conventional mastectomy was performed.

In the entire cohort, 22 deaths occurred, of which 19 were due to breast cancer. The mean estimated time for local recurrence was 92.7±1.9 months (Figure 1). The mean estimated time for distant metastasis was 90.1±1.8 months (Figure 2). Overall survival was 93.2±2.0 months (Figure 3). Additionally, the 5-y LRFS and 5-y DMFS rates were 95.4% and 90.3%, respectively (Table 4).

Table 4. Rate of recurrences by molecular subtype and survival outcomes

Subtypes	n	LR, n (%)	DM, n (%)	Death, n (%) (Disease spesific)
HR+/HER2-	101	7 (6.9)	13 (12.9)	9 (8.9)
HR+/HER2+	26	3 (11.5)	3 (11.5)	4 (15.4)
HR-/HER2+	23	4 (17.4)	4 (17.4)	2 (8.7)
TNBC	16	3 (18.8)	3 (18.8)	4 (25)
DCIS	9	0	0	0
Recurrence rate	175	17 (9.7)	23 (13.1)	19 (10.9)
Survival outcomes	Mean, SD, (months)			
LRFS	92.7 ± 1.9			
DMFS	90.1 ± 1.8			
DFS	90.6 ± 1.8			
OAS	93.2 ± 2.0			
5-y LRFS (%)	95.4			
5-y DMFS (%)	90.3			
5-y DFS (%)	88.6			

Abbreviations: HR, hormone receptor; HER2, human epidermal growth factor receptor2; TNBC, triple negative breast cancer; SD, standard deviation; LR, locoregional recurrence; DM, distant metastasis; LRFS, locoregional recurrence free survival; DMFS, distant metastasis free survival; OAS, overall survival; DFS, disease free survival.

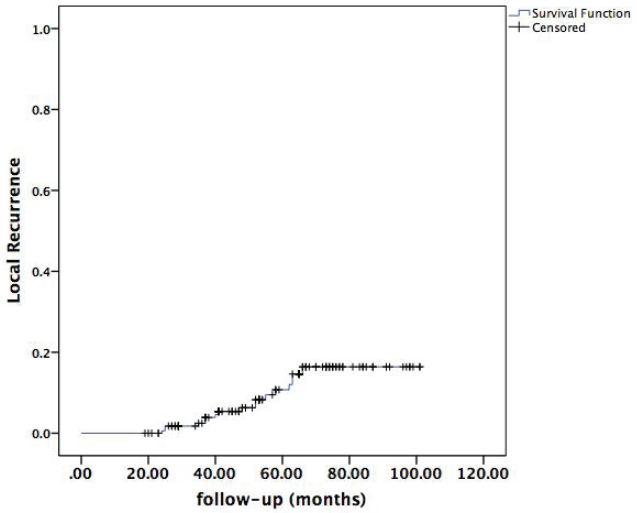

Figure 1: Estimated time for local recurrence

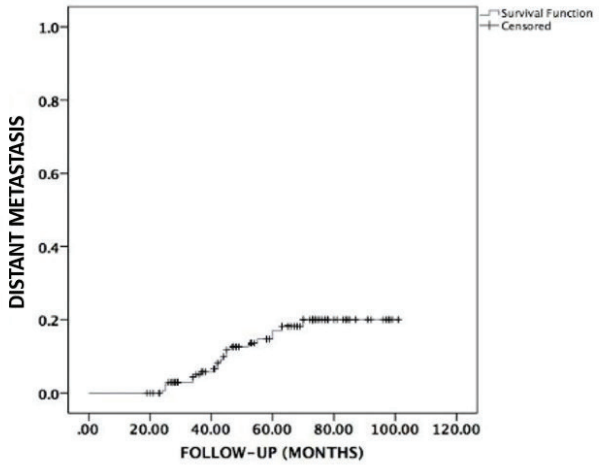

Figure 2: Estimated time for distant metastasis

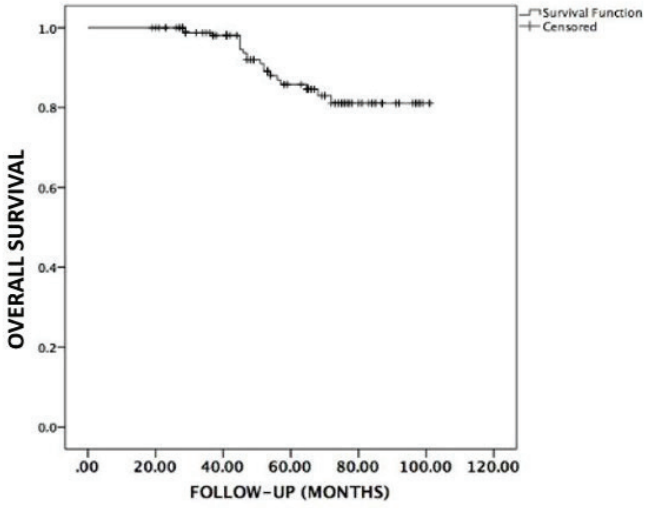

Figure 3: Overall survival

Discussion

In this study, with a median follow-up of 53 months (range: 19-101), a consecutive series of 175 patients underwent NSM or SSM followed by ODTI IBR. We found the LR rate of 9.7%, the DM rate of 13.1%, and the overall recurrence rate of 22.8%, alongside an acceptable rate of complications. Moreover, during this period, implant loss due to complications occurred in only seven patients (4%), and 83.5% of patients reported high satisfaction scores. These results indicate that ODTI IBR is safe from both an oncological and psychological perspective without the use of an acellular dermal matrix (ADM) or mesh, and it can be considered an alternative to CMx or the two-stage procedure. Furthermore, it is also more economically advantageous.

Surgical Techniques for Immediate Breast Reconstruction

Current breast reconstruction techniques include the use of tissue expanders and implants, as well as autologous tissue reconstruction utilizing pedicled, free, or perforator flaps. In recent years, implant-based breast reconstruction has gained increasing popularity. While the two-stage reconstruction approach that was common in the 1980s has largely been replaced by single-stage procedures, implants can now be placed either subcutaneously or submuscularly, depending on the surgeon's preference [10-12]. The use of an ADM has also become widespread in contemporary practice [13]. In our study, all patients underwent breast reconstruction with silicone implants featuring either anatomical or round designs and textured or smooth surfaces, without the use of ADM. The most suitable candidates for this technique are women without macromastia and severe ptosis [14]. In our cohort, 21 (12%) patients had macromastia or severe ptosis; 11 of these patients underwent reconstruction in conjunction with skin-reducing mastectomy.

The cost of ADM or mesh ranges from €1,200 to €2,400. Considering that the health insurance system in Turkey does not cover the costs of prostheses or ADM, the total surgery expenses can be significantly high. In our study, we performed breast reconstruction on 175 patients without using ADM or mesh, and our complication and prosthesis loss rates were comparable to those reported in series utilizing these materials. Furthermore, we achieved highly successful cosmetic results.

Follow-up and recurrence rates

The LR rate for conventional mastectomy (CM) has been reported to range between 6% and 16% in historical studies [15-17]. In another study, an LR rate of 8.8% and a DM rate of 14.8% were reported among 1.057 patients with stage 1-3 breast cancer who underwent a conventional mastectomy, with a median follow-up of six years [18]. In a cohort of 112 patients with locally advanced breast cancer, where 47.3% underwent reconstruction with a tissue expander and 32.1% with a silicone implant following mastectomy. During a median follow-up period of 50.7 months, LR and DM were 7.1% and 19.6%, respectively [19].

In our study, the highest recurrence rates were observed in patients with TNBC, followed by the HR-/HER2+ subtype, with the lowest rates occurring in the HR+/HER2- group. The overall cohort demonstrated an LR rate of 9.7% and a DM rate of 13.1%, which aligns with findings from other studies. Additionally, 5-year LRFS, DMFS, and DFS rates (95.4%, 90.3%, and 88.6%, respectively) were comparable to the outcomes reported in other studies.

Types of Implant, Complications and Radiotherapy

Anatomic cohesive gel implants were primarily used in breast reconstruction to achieve more natural aesthetic outcomes. However, smooth round implants were also utilized, particularly in patients who expressed a preference for them. Despite the frequent use of textured surface implants, polyurethane-coated implants were also chosen in suitable cases. Importantly, no cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), which has been increasingly reported in recent years, were observed among the patients in this study [20]. Delayed wound healing was the most commonly observed complication (15.4%). Rippling occurred in 4.6% of cases but did not require surgical intervention. The most common complication requiring minor re-operation was partial ischemia and/or necrosis (n= 16, 9.1%). In cases where healing was not achieved, necrotic tissue debridement was conducted, and the affected area was closed with primary sutures. Antibiotic therapy was administered until complete healing was attained. In the results of a 2015 meta-analysis comparing single-stage and traditional two-stage reconstruction, there were no statistically significant differences between the two groups in terms of infection, seroma, hematoma, and capsule contracture. However, flap necrosis and implant loss were higher in the single-stage surgery (p= 0.04) [21].

In the past, decisions regarding the stages of reconstruction were often influenced by whether the patient was scheduled to receive adjuvant RT. If adjuvant RT was planned, a two-stage reconstruction approach was generally preferred. However, recent advancements in RT technology and the increased experience of radiation oncologists and surgeons have allowed for one-stage reconstructions to be performed even in patients who will undergo RT. The effects of RT on reconstruction outcomes remain a topic of debate. Some studies suggest that RT increases the risk of capsular formation and infection, while others indicate no significant effect [22,23]. In our study, the proportion of patients requiring reoperation due to capsular formation was relatively low at 8.6%. Notably, all patients with capsular contracture, except one with ductal carcinoma in situ (DCIS), had received RT. We believe that while radiotherapy may increase the rate of complications, it is not an absolute contraindication for single-stage reconstruction. The critical factors for successful one-stage reconstruction include the quality of the flaps and the adequacy of vascular circulation.

Prosthesis displacement was infrequent, occurring in only 2.3% of cases, which we attribute to the loosening of the sutures used to cover the serratus anterior fascia. However, this problem was resolved with a re-operation. While our complication rates were elevated compared to conventional mastectomy, they were comparable to those reported in the literature for prosthetic reconstruction using the DTI technique [24,25]. A total of seven (4%) prosthesis losses occurred due to early complications, primarily caused by necrosis and severe infections that did not respond to antibiotic therapy. Although this rate was slightly higher, it remained similar to the 3.86% rate observed in a review of 14,585 cases, where factors such as older age, obesity, and smoking increased the risk of implant loss [26]. In 12 (6.9%) patients, prosthesis loss was related to re-surgery conducted due to local recurrence in the long term. Importantly, none of the patients, including those who required re-operation, experienced any delay in the administration of adjuvant therapy.

Cosmetic outcomes

The cosmetic results of ODTI IBR are generally favorable, with many patients reporting high levels of satisfaction [27,28]. This approach facilitates immediate breast reconstruction following mastectomy, minimizing the need for additional surgeries and often yielding a more natural appearance. Patients benefit from shorter recovery time and achieve their desired aesthetic outcomes in a single procedure.

In the early postoperative period, seven patients who experienced implant loss rated their satisfaction as "very poor." Overall, 83.5% of patients rated their satisfaction as "good" or "excellent," primarily due to the presence of reconstruction as an alternative to mastectomy.

Limitations

This is one of the few studies in the literature employing the DTI technique without using mesh. Despite demonstrating oncological safety and high patient satisfaction, our study has several limitations. These include the study's single-center retrospective nature and the absence of a control group. Since the research data are derived from a specific patient group, there may be selection bias and confounding factors; therefore, we opted to evaluate our long-term outcomes. However, oncologically safe results, manageable complication rates, and the method's feasibility of inappropriate patient selection demonstrate its applicability.

Conclusion

One-stage DTI IBR appears to be a safe approach for patients with breast cancer who receive neoadjuvant or adjuvant

chemotherapy followed by RT. The preference for a one-stage procedure, along with demonstrated oncological safety, low complication rates, and high patient satisfaction, supports its viability as an option for suitable candidates.

Breast reconstructions performed without mesh or using ADM can reduce costs while providing oncologically safe and economically viable options for patients. However, to better establish the appropriate indications for ODTI IBR, prospective randomized trials with well-defined study designs and outcome measures are necessary.

Financial support and conflict of interest

There is no person/organization that financially supports the study and the authors have no conflict of interest

Ethics Committee Approval

This study received approval from the Istanbul University Ethics Committee (Approval Date: 23.12.2024 with number 3075139)

Informed Consent

The need for informed consent was waived under the approval of the Local Ethics Committee due to the retrospective design.

Author Contributions

Concept, Design, Data collection and/or processing, Writing: B.K., Analysis and/ or interpretation: B.I., Critical review and Supervision: H.K. All authors read and approved the final version of the manuscript.

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