



# Differences in complications and asymmetry in patients who did not receive a balancing procedure in two-stage and direct-to-implant breast reconstruction

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**Background** Implant-based immediate breast reconstruction surgery with nipple-sparing mastectomy has recently been favored by patients. However, in patients who do not wish to undergo balancing procedures, it is difficult to select the appropriate implant size, making it challenging to achieve a symmetrical breast shape. Therefore, this study investigated the differences in breast asymmetry and other complications in patients who underwent a two-stage procedure or direct-to-implant (DTI) breast reconstruction to determine whether the two-stage procedure can produce more favorable outcomes.

**Methods** The participants of this study were patients who underwent immediate two-stage breast reconstruction or DTI breast reconstruction from May 2018 to April 2022, did not receive postoperative radiotherapy, and did not wish to undergo any balancing procedures. An acellular dermal matrix was used for breast reconstruction in all patients, and a single reconstructive surgeon performed all the operations. Statistical significance was set at  $P < 0.05$ .

**Results** No significant differences in complications were found between the patients who underwent DTI breast reconstruction and those who underwent two-stage breast reconstruction. In the two-stage breast reconstruction group, breast volume asymmetry was observed in 18.4% (seven patients), which was significantly lower than the percentage of 44.7% (17 patients) observed in the DTI group.

**Conclusions** Breast asymmetry was observed in a significant proportion of the patients in both groups. However, because breast volume asymmetry was more common in the DTI group than in the two-stage breast reconstruction group, two-stage breast reconstruction may be a favorable method for patients who do not wish to undergo balancing procedures.

**Keywords** Mammoplasty / Breast implants / Complication

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## INTRODUCTION

The frequency of implant-based immediate breast reconstruction surgery involving nipple-sparing mastectomy (NSM) has increased. Common breast reconstruction methods include two-stage breast reconstruction and direct-to-implant (DTI) breast reconstruction. Balancing procedures are often necessary to achieve a symmetrical breast shape in patients with large, small, or ptotic breasts. However, implant-based breast reconstruction is challenging in patients who are reluctant to undergo these balancing procedures. More-

over, as the breast width, pocket width, and breast projection are important considerations for the selection of implants in implant-based breast reconstruction, it is difficult to achieve a symmetrical breast shape even after reinforcing the boundaries of the pocket using a thick artificial dermal matrix (ADM).

In patients who do not want to undergo balancing procedures despite their necessity, many surgeons expect that the two-stage procedure will lead to better outcomes than DTI breast reconstruction. Therefore, this study aimed to assess breast asymmetry and differences in other complications in patients who underwent two types of breast reconstruction surgery to investigate whether the two-stage procedure can lead to more favorable outcomes.

## METHODS

The participants of this study were patients who underwent immediate reconstruction via two-stage breast reconstruction or DTI breast reconstruction from May 2018 to April 2022, did not receive postoperative radiotherapy, and did not wish to undergo any balancing procedures (including contralateral augmentation, reduction, and mastopexy). In total, 38 patients were included in the two-stage breast reconstruction and DTI groups. The total participants' mean follow-up period was 25.2 months (12–47 months; two-stage breast reconstruction: 25.3 months, DTI: 25.0 months). Patients who were followed up for less than 1 year after reconstruction, had nipple-areolar complex (NAC) or skin flaps partially removed (skin-sparing mastectomy), underwent mastopexy to adjust the height of the NAC on either side of both breasts, or underwent bilateral breast reconstruction were excluded from the study.

The tissue expander and implants used in this study were the anatomical textured type (Mentor, 350–550 cc; Mentor Worldwide LLC) and the round type (BellaGel microtexture round implant, HansBiomed Co. Ltd. or Mentor smooth round implant, Mentor Worldwide LLC), respectively. All procedures were prepectoral implant-based breast reconstruction using an ADM (BellaCell, HansBiomed and MegaDerm, L&C Bio). Medical records were retrospectively evaluated to investigate the incidence of postoperative complications.

Both surgical methods (two-stage and DTI) were explained to each patient before surgery, and DTI could only be performed if there was no metastasis in the axillary node, the NAC was not resected, and the remaining skin flap was thick enough (> 5 mm). If any one of the three criteria was not satisfied, a two-stage surgical method was performed.

The two-stage breast reconstruction method was performed as follows: after NSM was conducted in the general surgery department, the pocket size was assessed, and the boundaries of the pocket, including the inframammary fold (IMF), were arranged to be consistent. Subsequently, the thickness of the skin flap and pocket width were assessed, and based on the weight and volume of the

resected tissue, a 350–550 cc Mentor textured anatomical expander was used. The expander was inflated immediately without obstructing the circulation of the skin flap. Approximately 50% of the medial, lateral, and bottom ends of the expander were covered with a 2- to 3-mm-thick ADM.

In the second stage, tissue expander removal and replacement with permanent implants were planned for 2 to 3 months after surgery, according to the patient's wishes, if chemotherapy was not scheduled post-surgery, or 1 month after chemotherapy if the patient was scheduled to undergo postoperative chemotherapy. The tissue expander was then removed using a previous incision. Following additional exfoliation to the medial, lateral, and upper ends of the pocket, areas expected to have excessive implant contours were primarily reinforced with one to four layers of ADM, which were mostly 3 mm thick. The ADM was fixed at the pocket boundary with anchoring sutures, and after drains were installed on the upper and lower parts of the implant, the breast shape was assessed in a semi-sitting position.

The DTI breast reconstruction method was mostly the same as the expander insertion method and was performed as follows: after NSM was conducted in the general surgery department, some of the remaining breast tissue was resected or additionally dissected so that the thickness of the skin flap was as constant as possible and that the boundary area of the pocket with the implant and ADM became natural. The wide and thick ADM (2–3 mm) covered the entire surface of the implant, except its base. The ADM was fixed and sutured according to the breast shape at the boundary of the pocket or the inner boundary of the skin flap, while confirming the contour position of the implant in the semi-sitting position.

Cases of Baker grade  $\geq 3$  contracture were also analyzed. As previously described in a study by Pantelides and Srinivasan [1], rippling was graded as mild, moderate, and severe (Table 1), and rippling of grade 2 or higher was investigated. Seromas that lasted for more than 1 month after drain removal and were treated with aspiration were analyzed. Breast asymmetry was evaluated based on the breast volume, NAC position, and IMF height. One year after surgery, any breast asymmetry that the patient complained of was investigated through an interview. Two plastic surgeons examined breast asymmetry by looking at five standardized photographs (frontal view, each lateral side, 45° angle) 1 year after surgery. Asymmetry was confirmed only when the patient complained of breast asymmetry and both plastic surgeons agreed that breast asymmetry was present.

**Table 1.** Grades of breast rippling

Grade	Severity of rippling
1	Mild: rippling is palpable but not visible
2	Moderate: rippling is visible only when the patient bends forward
3	Severe: rippling is visible with the patient upright

**Table 2.** The mean age and BMI of patients who underwent DTI breast reconstruction and two-stage breast reconstruction

Variable	Mean of two-stage patients	Mean of DTI patients	P-value
BMI (kg/m <sup>2</sup> )	24.2	23.4	0.247
Age (yr)	50.4	49.8	0.819
Specimen weight (g)	330.3	220.3	0.000
Implant size (cc)	326.3	251.6	< 0.001

BMI, body mass index; DTI, direct-to-implant.

**Table 3.** Complications of DTI breast reconstruction and two-stage breast reconstruction

Variable	Two-stage patients (n=38)	DTI patients (n=38)	P-value
Rippling	8 (21.1)	10 (26.3)	0.787
Capsular contracture	9 (23.7)	5 (13.2)	0.375
Scar contracture	7 (18.4)	4 (10.5)	0.514
Hematoma	0	3 (7.9)	0.239
Seroma	0	1 (2.6)	1.000
Infection	1 (2.6)	1 (2.6)	1.000

Values are presented as number (%).  
DTI, direct-to-implant.

All statistical analyses were performed using the R statistical package (version 4.2.1; R Core Team, 2022). The two-sample t-test was used to compare patients who received DTI reconstruction and those who received two-stage reconstruction in terms of numerical variables such as age and body mass index (BMI). Categorical variables, such as the differences in the size of both breasts, NAC position, and IMF height, were compared using the z-test for two proportions. Statistical significance was set at  $P < 0.05$ .

## RESULTS

The mean age and BMI of the 38 patients who underwent two-stage breast reconstruction were 50.4 years (range, 28–67 years) and 24.2 kg/m<sup>2</sup> (range, 19.2–37.6 kg/m<sup>2</sup>), respectively. The mean age and BMI of the 38 patients who underwent DTI breast reconstruction were 49.7 years (range, 23–71 years) and 23.4 kg/m<sup>2</sup> (range, 18.2–29.0 kg/m<sup>2</sup>), respectively. The mean specimen weight and implant size of the 38 patients who underwent two-stage breast reconstruction were 330.3 g (range, 148–608 g) and 326.3 cc (range, 170–500 cc), respectively. The mean specimen weight and implant size of the 38 patients who underwent DTI breast reconstruction were 220.3 g (range, 100–367 g) and 251.6 cc (range, 125–400 cc), respectively. There were no significant between-group differences in mean age or BMI, but there were significant between-group differences in specimen weight and implant size (Table 2).

In the two-stage breast reconstruction group, capsular contrac-

**Table 4.** Asymmetry in the volume, IMF height, and NAC position of both breasts

Variable	Two-stage patients	DTI patients	P-value
Asymmetry in the volume of both breasts	7 (18.4)	17 (44.7)	0.026
Asymmetry in the IMF height of both breasts	5 (13.2)	1 (2.6)	0.202
Asymmetry in the NAC position of both breasts	3 (7.9)	0	0.239
Asymmetry in the volume, IMF height, or NAC position of both breasts	9 (23.7)	18 (47.4)	0.055

Values are presented as number (%).  
IMF, inframammary fold; NAC, nipple-areolar complex; DTI, direct-to-implant.

ture, rippling, and scar contracture were observed in nine (23.7%), eight (21.1%), and seven (18.4%) patients, respectively. In the DTI group, capsular contracture, rippling, and scar contracture were noted in five (13.2%), 10 (26.3%), and four (10.5%) patients, respectively (Table 3).

In the two-stage breast reconstruction group, seven (18.4%), five (13.2%), and three (7.9%) patients showed asymmetry in the volume, IMF height, and NAC position of both breasts, respectively. In the DTI group, 17 (44.7%) patients and one (2.6%) patient showed asymmetry in the volume and IMF height of both breasts. None of the patients showed differences in the NAC position of either breast (Table 4).

## DISCUSSION

Previously, compared to implant-based breast reconstruction, autologous breast reconstruction was associated with higher overall satisfaction and sexual and psychological well-being items in the Breast-Q questionnaire [2], and autologous breast reconstruction was preferred because implant-based breast reconstruction had risks of capsular contracture and implant malpositioning [3]. Other studies have also demonstrated that implant-based breast reconstruction is more susceptible to postoperative infection than autologous breast reconstruction [4]. However, despite these limitations, implant-based breast reconstruction is often preferred by patients due to its shorter recovery time and absence of a donor site scar and by patients with insufficient body tissue to undergo autologous breast reconstruction [3]. As the health insurance coverage of the National Health Insurance Service in Korea expanded to cover breast reconstruction in 2015, the number of mastectomy and immediate breast reconstruction procedures has significantly increased, and patients' preferences for implant-based breast reconstruction have also gradually increased [5]. Similarly, in the United States, implant-based breast reconstruction is preferred to autologous breast reconstruction. In the 2020 Plastic Surgery Statistics Report (American Society of Plastic Surgeons), implant-based breast reconstruction and autologous breast reconstruction were performed in 79.5% and

20.5% of patients, respectively, reflecting a strong preference for implant-based breast reconstruction [6].

In addition, according to the 2020 Plastic Surgery Statistics Report (American Society of Plastic Surgeons), DTI and two-stage breast reconstruction were conducted in 19.3% and 80.7% of patients, respectively [6]. DTI breast reconstruction has a higher risk of reconstruction failure and more overall complications than two-stage breast reconstruction [7]. However, in Korea, the DTI and two-stage breast reconstruction rates are similar [5]. This may be attributed to the preference for a single surgical session rather than two operations.

In patients with small breasts, balancing procedures are often required before reconstruction surgery to achieve symmetrical breast shape. In particular, as it is challenging to achieve symmetry of both breasts even with the smallest implant after breast reconstruction in patients with small breasts, simultaneous contralateral breast augmentation can lead to more satisfactory cosmetic outcomes [8]. However, patients may not wish to undergo surgery for the contralateral breast, which presents difficulties for surgeons. To reconstruct the breast according to the shape of the unaffected breast, two-stage breast reconstruction is recommended over DTI breast reconstruction because it is thought to be more favorable for these purposes. However, if the patient prefers DTI breast reconstruction when radiation therapy is not scheduled after surgery, breast reconstruction surgery becomes more complicated. In DTI breast reconstruction, selecting the implant based on pocket width leads to an asymmetrical breast volume and, in particular, greater projection of the reconstructed side than the contralateral side. Therefore, the surgeon can only attempt to reconstruct the natural breast shape with less visible contours of the implant by selecting a small implant according to the possible amount of resected tissue and reinforcing the medial, lateral, and upper parts of the implant with ADM.

In contrast, in two-stage breast reconstruction, the pocket size can be naturally stabilized using a tissue expander, and the second surgical step provides an opportunity to further consider balancing procedures. In the second stage, ADM is used for a more precise modification of breast reconstruction. This enables a more symmetrical breast shape than that in DTI breast reconstruction. In the current study, although the surgeon became capable of reconstructing a more natural breast shape over time, asymmetry was still observed in 18 (47.4%) patients in the DTI group who did not wish to undergo contralateral breast augmentation and in nine (23.7%) patients in the two-stage breast reconstruction group. Although two-stage breast reconstruction reduced asymmetry by 50% compared with DTI breast reconstruction, asymmetry was inevitably observed in a small number of patients. However, our findings suggest that two-stage breast reconstruction can reduce breast asymmetry more than DTI breast reconstruction. In particular, two-stage breast reconstruction may be the better choice between the two surgical methods to correct the volume of both breasts.

Among the other complications, rippling was more common in the two-stage breast reconstruction group than in the DTI group. Although thick ADMs are used on the inner surface of thin skin flaps, differences in pocket size and implant surface area inevitably lead to rippling. In contrast, capsular contracture was more common in the two-stage breast reconstruction group than in the DTI group. This difference may be attributed to changes in pocket shape, the prohibition of breast massage initially after surgery due to the use of a textured tissue expander, seroma after insertion of the tissue expander, and contraction of the pocket. In addition, scar contracture was more common in the two-stage breast reconstruction group than in the DTI group due to the presence of two incisions in the same area.

The method of using ADM in breast reconstruction changed after this study. During the period of this study, an ADM with a thickness of 2 to 3 mm was fixed to the inner surface of the skin flap at approximately 50% of the lower end of the pocket when the tissue expander was inserted during two-stage breast reconstruction. In the second stage, two to four layers of ADM, 3 mm or thicker, were fixed to reinforce the medial, lateral, and upper boundaries of the implant. In DTI breast reconstruction, a 2- to 3-mm-thick ADM was used to wrap the front of the implant in one layer and separately reinforce the medial, lateral, and upper parts of the implant. After this study, to reduce complications such as asymmetry, rippling, and capsular contracture, 2- to 3-mm-thick ADM was only used in patients with thick skin flaps, and in other patients, ADM thicker than 3 mm was used. In particular, when inserting a tissue expander in two-stage breast reconstruction, the entire front of the tissue expander, except for the upper and lower boundaries, is now covered with the ADM. Moreover, the medial and lateral parts of the tissue expander are reinforced with parts of the ADM in advance. These modifications have reduced complications, and the results will be reported in future studies.

In implant-based reconstruction of small breasts, contralateral breast augmentation is necessary to achieve a symmetrical breast shape. However, for contralateral breast augmentation, the tissue expander inserted into the reconstructed breast must be inflated, which may lead to skin flap thinning [9]. In particular, studies have reported that wound dehiscence and revision operation rates were higher when the breast to be reconstructed after mastectomy was expanded using an expander for breast augmentation [10]. Therefore, it is fundamental to explain the advantages and disadvantages of balancing augmentation for a symmetrical breast shape to patients before surgery to enable a careful decision on balancing augmentation in patients who require excessively large breast reconstruction, have too thin skin flaps, and have a high risk of infection.

In implant-based reconstruction of small breasts, the lack of balancing augmentation can lead to difficulties in achieving symmetrical breasts despite adequate use of small implants and ADM based on the possible resection amount, breast volume, and pocket size.

As expected, asymmetry was more common in the DTI group than in the two-stage breast reconstruction group; however, breast asymmetry was still observed in approximately one out of four patients. Therefore, it is essential to fully explain the necessity and complications of balancing augmentation to patients before breast reconstruction surgery to obtain a symmetrical breast shape.

This study was limited by its retrospective design. Additionally, this study had the limitation of analyzing only 76 cases, which may not have been sufficient for statistical significance. Therefore, larger studies are required in the future. However, surgery was performed at a single hospital, by a single surgeon, and using the same method, so we believe that the results are still meaningful. Finally, the measurement of breast asymmetry was not objective; however, to facilitate a greater degree of objectivity, we used Vectra 3D (Canfield Scientific) before and after surgery and measured breast asymmetry based on these results.

## NOTES

### Conflict of interest

No potential conflict of interest relevant to this article was reported.

### Ethical approval

This study was approved by the Institutional Review Board of the Pusan National University Yangsan Hospital (approval number: 05-2022-189). Given the retrospective nature of this study, the requirement for informed consent was waived.

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