

#### **Preliminary Report**

## Shaping of the Unaffected Breast with Brava-Assisted Autologous Fat Grafting to Obtain Symmetry after Breast Reconstruction

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#### Abstract

Background: In breast reconstruction, symmetry is a vital issue. However, when the original breast is unusually shaped or the patient desires augmentation at the time of reconstruction, obtaining symmetrical breasts becomes difficult.

**Objectives:** The authors performed shaping of unaffected breasts by Brava-assisted autologous fat grafting to enhance breast symmetry, and evaluated the clinical results to validate this new approach.

Methods: Brava-assisted autologous fat grafting was performed to the unaffected breasts of 12 patients who had undergone unilateral breast reconstruction. The procedure was used for augmentation in six patients and to correct ptosis, volume, and tuberous breast deformity in three, two, and one patient, respectively. Clinical outcomes were assessed in all 12 patients.

Results: All patients could complete fat grafting within two sessions (one session in nine patients and two sessions in three patients). The mean volume of grafted fat per session was 211 cc in all patients. The mean retention rate of grafted fat was 58.9% in the 10 patients for whom the retention rate could be calculated using preoperative and postoperative magnetic resonance imaging (MRI). Postoperative MRI revealed small benign foci in two patients (16.7%), which were not palpable and did not become a clinical problem. A postoperative mammography revealed a small agglutinate calcification in one patient, which was determined to be benign through biopsy.

**Conclusions:** Shaping the unaffected breast by autologous fat grafting combined with Brava is predictable, effective, and feasible as an aesthetic adjunct to unilateral breast reconstruction to achieve breast symmetry.

#### Level of Evidence: 4

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In breast reconstruction, obtaining symmetrical breasts is one of the most essential issues. However, when the shape of the healthy breast is unusual, such as in cases of postpartum deflation, congenital deformities such as a tuberous breast, or strong micromastia, and the available implants are not of an adequate size, obtaining symmetry becomes difficult.<sup>1-3</sup> Furthermore, patients often wish to reconstruct their breasts to be larger than their original size after cancer surgery. In these situations, augmentation mammoplasty using an implant is usually performed on the healthy side. However, choosing an appropriate implant size to obtain symmetrical breasts is difficult in

the clinical practice. In addition, augmentation by implant has disadvantages, such as residual scarring in the insertion

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site and unnatural results, especially in comparison with autologous augmentation.

To overcome such drawbacks of breast implant augmentation and obtain symmetrical breasts, we decided to shape the unaffected breasts using autologous fat grafting and the perioperative use of the Brava system, in the expectation of achieving volume- and shape-controlled augmentation.

The Brava device, a vacuum-based external soft-tissue expansion system, was originally developed for nonsurgical breast augmentation<sup>4,5</sup> and has recently been successfully applied perioperatively, followed by fat grafting for breasts, to overcome the unpredictable results that arise from the unstable survival rate of grafted fat.<sup>6-9</sup>

Here, we describe our experience with this new approach and assess the effects, complications, and practical application of Brava-assisted fat grafting.

## **PATIENTS AND METHODS**

From April 2008 to May 2013, 12 selected patients were included in this series (Table 1). They all underwent breast

reconstruction after unilateral cancer surgery and then underwent Brava-assisted autologous fat grafting to the unaffected breast to achieve breast symmetry. We chose patients who had an unusual breast shape, such as those with postpartum deflation, congenital deformities such as a tuberous breast, and strong micromastia, knowing that obtaining symmetry would be difficult. Patients who wished to reconstruct their breasts to be larger than their original size after cancer surgery were also included in this study. Five patients underwent reconstruction with implants after immediate tissue expander insertion, and seven underwent immediate flap surgery. In six patients, the affected breast was reconstructed to be larger than its original size in accordance with the patients' request. Patients were excluded if they had any abnormal findings on the unreconstructed side or a genetically high risk of breast cancer, which might induce bilateral breast cancer. Autologous fat grafting to the unaffected side was carried out more than 6 months after breast reconstruction in all patients.

All study participants provided informed consent, and the study was approved by the appropriate ethics review

## Table 1. Patient Data

No.	Age (y)	BMI (kg/m²)	Method of Breast Reconstruction	Original Breast	Number of Fat Grafts (Volume; cc)	MMG Category <sup>a</sup>	MRI	Retention Volume (cc) (Survival Rate)	Symmetry Score
1	44	20.5	Implant	Postpartum deflation	2 (160, 150)	1	Normal	174 (56%)	5.4
2	47	17.9	Implant	Micromastia	2 (180, 100)	1	Normal	143 (51%)	4.3
3	40	19.66	DIEP flap	Postpartum deflation	2 (260, 300)	1	Normal	332 (59%)	4.3
4	48	19.86	Implant <sup>b</sup>	Normal	1 (350)	1	Some small cysts	260 (74%)	5
5	35	19.69	DIEP flap	Tuberous	1 (220)	1	Normal	NR	5
6	48	16.87	Implant	Micromastia	1 (210)	1	Some small cysts	128 (61%)	4.7
7	39	20.02	DIEP flap	Postpartum deflation	1 (240)	1	Normal	124 (52%)	5.7
8	46	22.4	DIEP flap <sup>b</sup>	Normal	1 (190)	1	Normal	78 (41%)	5
9	36	22.42	Implant <sup>b</sup>	Normal	1 (200)	1	Normal	113 (57%)	3.7
10	48	19.47	DIEP flap <sup>b</sup>	Micromastia	1 (190)	3	Normal	145 (76%)	6
11	46	20.4	DIEP flap <sup>b</sup>	Micromastia	1 (150)	1	Normal	NR	2.7
12	46	20.04	DIEP flap <sup>b</sup>	Micromastia	1 (260)	1	Normal	161 (62%)	4.3
Mean	43	19.94			1.25 (211/ session)			165.8 (58.9%)	4.68

BMI, body mass index; DIEP, deep inferior epigastric perforator; MMG, mammography; MRI, magnetic resonance imaging; NA, not available (no preoperative MRI). <sup>a</sup>BI-RADS (Breast Imaging Reporting and Data System; American College of Radiology) category. <sup>b</sup>Patient underwent breast reconstruction larger than its original size in accordance with the patient's requests.

boards of our institution (Review Board of Jichi Medical University, Reference number; A14-059).

## Perioperative Brava Wearing and Fat Grafting

The Brava device was used perioperatively based on Khouri and Del Vecchio's protocol,<sup>10</sup> which is similar to the protocol we used previously.<sup>8</sup> Patients were asked to wear the Brava device for 10 hours/day for 4 weeks preoperatively. After fat grafting, they resumed wearing the Brava device on the day after surgery, again for 10 hours/day, and continued for a minimum of 2 weeks. When the patient could not wear the Brava for 10 hours because of postoperative pain, the wearing time was extended gradually, day by day. Patients who tolerated the Brava well continued to wear it for an additional few weeks.

Steroid ointment (hydrocortisone butyrate, 0.1%) was applied after each Brava wearing to minimize dermal adverse effects such as dermatitis. In harvesting grafted fat, a 3 mm diameter aspiration cannula was used with a liposuction aspirator set at a low negative pressure ( < 350 mmHg). At the first operation, the grafted fat was typically aspirated from the anterior and inside of the thigh, abdomen, and/or waist in the supine position. In patients who underwent a second session, fat was harvested from the posterior thigh, buttock, and waist in the prone position. Especially in our thin patients, we paid careful attention not to aspirate fat from the same portion, as much as possible, to prevent donor site irregularities. After centrifugation at 1200  $\times$  g for 3 minutes, the cellular components were transferred into a 50 cc syringe and then filled into a 2.5 cc syringe connected to a three-way stopcock through an extension tube. The fat was then injected into the unaffected breast in all layers (ie, subcutaneous, subglandular, intramuscular, and submuscular spaces) using a microdroplet technique. The surgeon attempted to create a symmetrical breast in comparison with the reconstructed breast.

Basically, the number of fat grafting procedures was decided according to patient requests. If the patient was satisfied with the result and did not require additional procedures, we did not perform an additional session even if a slight asymmetry of the breast remained.

## **Qualitative Evaluation of Grafted fat**

To assess the quality of the grafted fat and the risk of cyst formation, all patients underwent magnetic resonance imaging (MRI) more than 6 months after the last fat grafting session. Good retention of the grafted fat was determined by having low intensity on the MRI scan, which is indistinguishable from pre-existing subcutaneous fat tissue of the recipient breast. Furthermore, when grafted fat does not survive, becomes necrotic, and forms a foci, MRI clearly shows the cyst formation even if it is too small to palp clinically. The detailed surgical information was shared among the clinical team, consisting of a plastic surgeon, breast surgeon, and radiologist. Mammography (MMG) was also performed annually to detect the presence of any calcifications after treatment, along with clinical examinations such as palpation and echography.

## Quantitative Evaluation of the Retention Volume of Grafted fat

Both preoperative and postoperative MRIs taken more than 6 months after the last fat grafting session were used to measure the retention volume of the grafted fat. First, the chest wall plane of each patient was configured based on the individual's torso with axial MRI.<sup>11</sup> Next, the breast over the chest wall plane was plotted semiautomatically, and its volume was calculated by integrating all slices over the plotting area. These analyses were carried out using DICOM image viewer software, OsiriX version 5.9. The retention volume was determined by comparing the pre- and postoperative breast volumes. This evaluation was carried out in 10 patients (in patients 5 and 11, preoperative MRI was not performed). The raw data are shown in Table 1.

## **Evaluation of Symmetry**

Symmetry was evaluated using postoperative clinical photographs taken at least 6 months after the last fat grafting procedure. Three board-certified plastic surgeons not involved in the patients' treatment scored the volume, contour, and breast mound of each breast on a scale of 0 to 2. The three scores were added, and the average of the total score of the three surgeons was considered the symmetry score (Table 2). The grading scale used was a modification of that originally described by Garbay et al<sup>12</sup> and later modified by de Blacam et al,<sup>13</sup> which was also used in our previous paper.<sup>8</sup>

#### Table 2. Evaluation of Breast Symmetry

Subscale Score <sup>a</sup>	0	1	2		
Discrepancy in volume of breast	Marked	Moderate or Mild	None or nearly none		
Deformity of breast contour	Marked	Moderate or Mild	None or nearly none		
Displacement of breast mound	Marked	Moderate or Mild	None or nearly none		
Total symmetry score	4.68 (range, 2.7-6.0)				

<sup>a</sup>Modification of that originally described by Garbay et al<sup>12</sup> and later modified by Blacam et al.<sup>13</sup>

#### Table 3. Skin Complications During Brava use

	Total (n = 12)		
Delmatitis	7 (58.3%)		
Pigmentation <sup>a</sup>	3 (25.0%)		
Blistering	1 <sup>b</sup> (8.3%)		
No skin complication	5 (41.7%)		

<sup>a</sup>Pigmentation arose after dermatitis.

<sup>b</sup>This patient also had dermatitis and pigmentation.

# Evaluation of Skin Complications and Actual Brava Use

Skin complications including dermatitis, pigmentation, and blistering, which are thought to be the most severe complications that might prevent continuous use of the Brava device, were investigated (Table 3).

## RESULTS

Mean patient age at the time of surgery was 43 years (range, 35-48 years). The mean body mass index (BMI) was 19.94 kg/m<sup>2</sup> (range, 16.87-22.42 kg/m<sup>2</sup>). No patients were smokers or had comorbidities such as diabetes mellitus or peripheral vascular disease that might have influenced the survival rate of the fat grafts. A range of 100-350 cc (mean, 211 cc) of fat per session was grafted, and the mean total volume of the grafted fat was 263 cc (range, 150-560 cc). When grafting, we were careful to avoid overgrafting and peau d'orange skin change, which represents increased interstitial pressure and reduces fat engraftment.<sup>14</sup> All patients completed fat grafting within two sessions (one session in nine patients and two sessions in three patients). The mean retention rate of the grafted fat determined with MRI was 59% (range, 41-76%; SD, 10%; Table 1). Representative examples are shown in Figures 1 and 2 (patients 2 and 3, respectively) and Supplementary Figures 1-4 (patients 4, 5, 7, and 12, respectively). No acute complications such as infection occurred.

The mean follow-up time from the final fat grafting procedure to symmetrical evaluation was 21 months (range, 6-55 months). The mean symmetrical score was 4.68 (range, 2.7-6.0; Table 2). There results were good compared with those of our initial study, in which we had assessed the results of breast cancer reconstruction by Brava-assisted fat grafting.<sup>7</sup> The scores in each case are also described in Table 1. In patients 2 and 4, who underwent implant-based reconstructions, the edge of the implant gradually became visible during the long follow-up period (Figure 1E and Supplementary Figure 1C). We recommended fat grafting to treat this irregularity. However, in the present study, they did not wish to undergo the procedure. In the clinical findings during the follow-up period, no palpable induration was present in any patient. On postoperative MRI, which was performed at a mean time of 14 months after the last fat grafting procedure (range, 6-28 months), a few small cystic regions were detected in two patients (16.7%). These cysts were not palpable and did not become clinical problems. During the annual MMGs, which were performed at a mean time of 37 months after the last session (range, 10-55 months), all patients except one were category 1 or 2 according to the Breast Imaging Reporting and Data System of the American College of Radiology, and no changes in any calcification were observed. In one patient, minute agglutinate calcifications were evaluated as category 3 and were diagnosed as benign calcifications on biopsy (Table 1).

Regarding the incidence of skin complications, dermatitisassociated itching occurred in seven patients (58.3%). Pigmentation changes after dermatitis also occurred in three patients (25.0%). Blistering was observed in one patient (8.3%) after fat grafting (Table 2).

## DISCUSSION

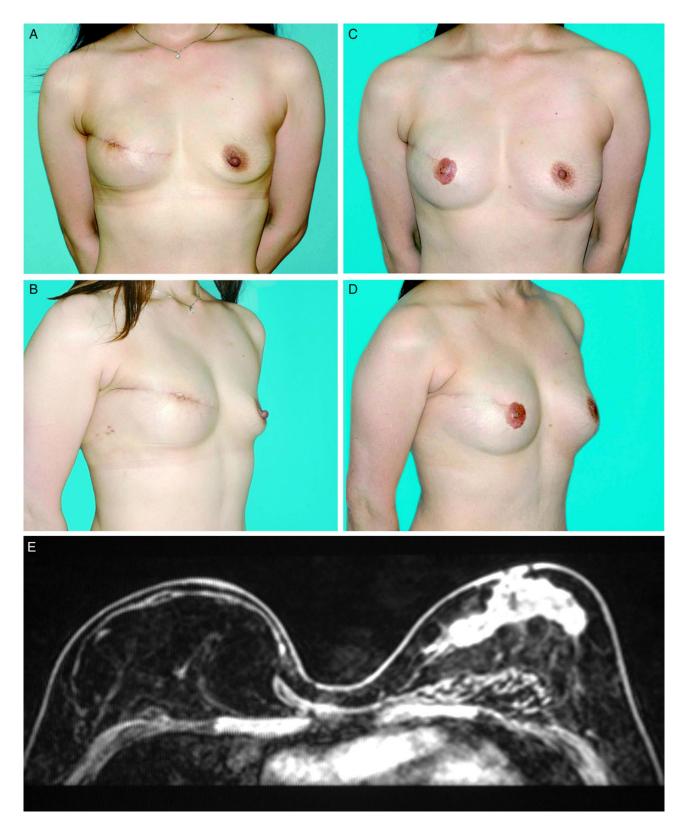
To obtain symmetrical breasts after breast reconstruction, shaping of the unaffected breast by fat grafting has several advantages in comparison with the conventional method of using an artificial implant. First, a soft and natural breast can be obtained without any breast scarring. Second, it is easy to perform controlled shaping to achieve symmetry with the reconstructed breast because of excellent handling. Third, additional fat grafting can be easily supplemented when asymmetry or shortfall persists after the first session.

However, as the volume of grafted fat increases in order to achieve augmentation of an entire breast, the interstitial pressure of the recipient tissue also increases, causing it to become ischemic and causing a decrease in the survival rate of grafted fat.<sup>7,9,14,15</sup> Especially in micromastia cases, the skin envelope is tight, and the interstitial pressure tends to increase easily.<sup>7</sup> To avoid this occurrence, multiple sessions with small volumes of fat grafting have been generally recommended.<sup>7,16-18</sup> However, this process adds a burden of time and cost efficiency for the patient in the clinical setting. To overcome this drawback, recently, Brava has been applied perioperatively and followed by fat grafting, and good results have been achieved in conditions that include cosmetic augmentation, congenital deformity, breast reconstruction after cancer surgery, and iatrogenic deformity correction.<sup>6-9</sup>

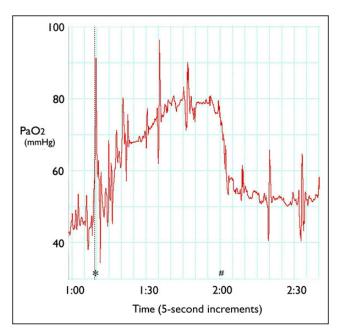
The effect of Brava suggests that mechanical stress stimulates cell proliferation and an increased scaffold of grafted space. These changes lead to a decrease in interstitial pressure on the recipient breast and an increase in the grafted volume of fat per session. Moreover, in experimental



**Figure 1.** A 47-year-old woman underwent left mastectomy and simultaneous insertion of a tissue expander. (A) Her original breast was very small, and no existing implants were of adequate size. After insertion of a 155 cc implant (CPG321, Mentor, Santa barbara, California) on the left side, she underwent Brava-assisted fat grafting twice to the right side (180 and 100 cc). During preoperative Brava use, the right breast enlarged, and the nipple color became more pigmented (B). Mammography of the right breast before (C) and after 3 weeks of 10 hour/day preoperative Brava use (D) shows increased intensity. (E) 51 months after two fat grafting sessions (180 and 100 cc).



**Figure 2.** A 40-year-old woman underwent right mastectomy and simultaneous insertion of a tissue expander. She underwent a free deep inferior epigastric perforator flap procedure at a later date. (A and B) Her unaffected left breast was atrophic due to postpartum deflation. Two sessions of Brava-assisted large-volume fat grafting (260 and 300 cc) were performed. (C and D) 57 months after the last fat grafting session. The effect of the inframammary creation of the left breast, which was performed later, was slightly insufficient and the volume, especially in the lower pole, may still look deficient. However, the volume was actually sufficient. (E) Postoperative MRI indicated that grafted fat was present in all layers: the subcutaneous, subglandular, and intra- and submuscular regions.



**Figure 3.** Oxygen partial pressure (*PaO*<sub>2</sub>) in subcutaneous fat of a normal breast. By applying external negative pressure via Brava (\*), *PaO*<sub>2</sub> gradually increased and then decreased rapidly after releasing the negative pressure (#; data from a real-time oxygen partial pressure monitor; Nihon Bioresearch, Inc., Tokyo, Japan).

results, it was confirmed that mechanical stress stimulates angiogenesis in the recipient bed and proliferation of blood vessels.<sup>19</sup> In our examination, we confirmed that the oxygen partial pressure in the subcutaneous fat tissue of the normal breast increased with exposure to the external negative pressure of Brava, indicating a gain in blood flow (Figure 3). In this manner, Brava appears to be a very unique device, which affects the condition of the recipient to increase the survival rate of grafted fat. It is also the only method that can extend the skin envelope and reduce interstitial pressure when grafting fat. All patients in this series demonstrated increased breast volume during the preoperative Brava-wearing period. In addition, we verified an increase of intensity via MMG during the preoperative Brava-wearing period in Patient 2, which was thought to reflect trabecular thickening and the increase of capillary vessels and blood flow to breast stromal tissue (Figure 1C and D). All of these findings were considered to indicate the improvement of recipient conditions for engraftment. Practically, most of our patients (9 of 12 patients, 75.0%) in this series completed fat grafting by a single session only. In addition, no clinical problems were encountered, such as palpable induration caused by fat necrosis, even though the grafted volume of fat per session was relatively large (mean, 211 cc; maximum, 350 cc).

The main limitation of this study was the lack of comparison with a control group, such as a simple fat grafting group without Brava. Therefore, we could not strictly conclude that the use of Brava has significant effects in clinical results, especially the retention rate of grafted fat. However, Spear and Pittman reported that the retention rate of breast lipoaugmentation without Brava was 36% for the right breast and 39.2% for the left breast in seven patients in their prospective study.<sup>20</sup> In our series, we achieved a high retention rate of 59%, which is similar to that of another published series of Brava-assisted breast lipoaugmentation cases, in which the retention rate was 64% in 12 patients (22 breasts).<sup>6</sup> These results demonstrate the clinical effect of Brava and indicate that large-volume fat grafting can be achieved safely using the Brava device.

The three patients who underwent two sessions of fat grafting were thin, with a mean BMI of  $19.4 \text{ kg/m}^2$  (range,  $17.9-20.5 \text{ kg/m}^2$ ). Thus, the necessity of two sessions was not related to absorption of the fat but to difficulty harvesting a sufficient volume of fat by single aspiration. In light of these results, it appears that Brava-assisted fat grafting overcame the limitations of fat grafting, such as unpredictable results and limited volume of grafted fat per session, and that shaping the unaffected breast by Brava-assisted fat grafting obtains predictable and consistent results by controlled shaping with excellent handling.

The most frequent complication caused by Brava wearing was itching due to dermatitis. This bothersome problem occurred in 58.3% of patients, similar to the rate observed in our initial report.<sup>8</sup> Pigmentation after dermatitis, which occurs frequently in Asian populations, was another bothersome complication that affected half of the patients who developed dermatitis. However, these complications were temporary, and prophylactic use of steroid ointment was effective to prevent and limit dermatitis. Pigmentation also responded well to bleaching treatment with tretinoin and hydroquinone.

Regarding postoperative radiographic diagnoses, MRIs were useful for the quantitative assessment of grafted fat. No abnormal findings were observed on MRIs in 11 of 14 patients (78.6%), and grafted fat was indistinguishable from preexisting subcutaneous fat tissue. In two patients, some small cysts were detected, which were easily identified as benign foci of fat necrosis and were not clinically significant. Additionally, to sensitively detect calcification, MMG was indispensable. Recent imaging technology has been reported to distinguish the calcification resulting from fat necrosis from neoplastic calcification, and fat grafting to the breast does not interfere with breast cancer detection.<sup>21,22</sup> However, the need for biopsy is also emphasized in cases of doubt and for additional clarification.<sup>23,24</sup> In our series, although calcification was detected in only one patient, biopsy was performed to confirm diagnosis because of its ambiguity. Moreover, because new calcifications may occur from small cysts of fat necrosis over a long period, ongoing periodic MMG follow-up is necessary.

All of our patients had unilateral breast cancer and are therefore generally considered more prone to cancer of the unaffected breast.<sup>25-27</sup> To date, some reports have indicated no clinical effect of grafted fat in causing cancer.<sup>14,23,28</sup> During this follow-up period, none of our patients developed breast cancer of the unaffected side, to which fat had been grafted. However, our series is limited by its small sample size. Reliable data based on a high level of evidence, such as systematic reviews and randomized controlled trials, are still insufficient, and the theoretical and potential risk of breast cancer induction by fat grafting cannot yet be ruled out.<sup>29</sup> Therefore, when fat grafting to the unaffected breast is performed in breast cancer patients, it is necessary to follow the postoperative course all the more carefully. Radiographic examination with MRI and MMG should be performed postoperatively. Moreover, plastic surgeons, radiologists, and breast surgeons must adopt a team attitude and effectively share information about patients, including surgery details and postoperative examinations. To establish reliable information concerning the safety of fat grafting to the breast, both further basic and clinical studies involving large series are necessary.

## **CONCLUSIONS**

In cases of unilateral breast reconstruction after cancer surgery, shaping the breast of the unaffected side by fat grafting in conjunction with the Brava system was effective for obtaining symmetrical breasts. Although the Brava system has some disadvantages, such as skin complications and the extensive duration of wearing the device, the Bravaassisted fat grafting approach overcomes the limitations of fat grafting to the breast alone, such as unpredictable graft retention, necessity of multiple sessions due to the restriction of grafted fat volume per session, and the development of a painful induration after fat necrosis.

## **Supplementary Material**

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

## Disclosures

The authors declare no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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