Fat grafting for breast reconstruction is predominantly used to correct minor contour deformities after reconstruction and small deformities after breast-conserving surgery. However, the procedure is not typically indicated for major deformities that may arise after total mastectomy or even after breast-conserving surgery, which might result in severe asymmetry of the breasts. To achieve good outcomes in the reconstruction of major breast deformities by fat grafting alone, the following steps are needed. First, the deficiency in the skin envelope must be recovered. Second, the condition of the donor site should be optimized to improve the survival rate of the grafted fat. Finally, from a practical standpoint, the total number of procedures should be minimized.

The Brava device (Brava, LLC, Miami, Fla.), a vacuum-based external soft-tissue expansion system, was originally developed for breast augmentation without surgical intervention. Recently, Brava and Autologous Fat Grafting for Breast Reconstruction after Cancer Surgery

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Background: Although autologous fat grafting is widely accepted for breast reconstruction, its indications remain limited to minor contour deformities after reconstruction and small deformities after breast-conserving surgery. The authors describe a case series of total or nearly total breast reconstructions treated with the perioperative use of a vacuum-based external tissue expander (i.e., the Brava device) followed by autologous fat grafting.

Methods: The authors assessed the clinical outcomes and aesthetic results in six nonirradiated total mastectomy cases and eight severely deformed irradiated breast-conserving surgery cases. Total Brava wearing time and skin complications were also investigated.

Results: The number of fat grafting procedures required ranged from one to four, and the mean amount of fat grafted during each procedure was 256 cc (range, 150 to 400 cc). Postoperative fat lysis and cellulitis occurred in two cases (14.3 percent). Brava worked effectively for total mastectomy cases, and improvement in the total aesthetic score was significantly higher than that in the breast-conserving surgery cases. All patients wore the device for more than 8 hours/day. The most frequent skin complication was dermatitis [n = 11 (79 percent)], which occurred in all breast-conserving surgery cases.

Conclusions: Brava was well tolerated by patients. Fat grafting with perioperative use of Brava is an alternative to total breast reconstruction in total mastectomy cases. However, for severely deformed breast-conserving surgery breasts treated with radiation therapy, the contracted skin was difficult to extend despite Brava use, and the results were less satisfactory. These cases also experienced a higher incidence of skin complications compared with the total mastectomy cases. (Plast. Reconstr. Surg. 133: 203, 2014.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

Disclosure: None of the authors has any financial interests in companies producing or distributing products used in this study.

Supplemental digital content is available for this article. Direct URL citations appear in the text; simply type the URL address into any Web browser to access this content. Clickable links to the material are provided in the HTML text of this article on the Journal’s Web site (www.PRSJournal.com).
the Brava system has been successfully applied perioptatively followed by fat grafting in cosmetic breast augmentation.8,9

We focused our attention on the potential application of the Brava device followed by fat grafting in patients who underwent total or nearly total reconstruction of severe breast deformities following cancer surgery. In this case series, we describe our early experience with this new treatment, and aim to assess the feasibility, complications, and practical application of perioperative Brava use followed by fat grafting.

**PATIENTS AND METHODS**

From 2008 to 2012, 14 patients with severe breast deformities were selected for this case series. Six had undergone total mastectomy, including conventional mastectomy (three patients) and skin- or nipple-sparing mastectomy (three patients), whereas the remaining eight had undergone breast-conserving surgery. None of the total mastectomy patients had undergone breast reconstruction because of the lack of opportunity for reconstruction or unwillingness to undergo reconstruction at the time of the original operation. All of the breast-conserving surgery patients underwent postoperative radiation therapy, and the first fat grafting procedure was delayed for at least 6 months after the completion of radiation. Patients were excluded if they experienced local recurrence or remote metastasis.

**Preoperative Brava Use**

The patients were asked to wear the Brava device for 10 hours/day for 4 weeks preoperatively. Because of the physical traction of the Brava device, we expected the withered skin to extend and the recipient space to expand, with concomitant angiogenesis, thus improving the conditions of the recipient bed for engraftment.8,9 To minimize the dermal adverse effects, daily steroid ointment (hydrocortisone butyrate, 0.1%) was applied after each Brava use. In cases of severe dermatitis or vesicle development, Brava use was temporarily discontinued (generally, 3 to 4 days) until the wound area had recovered. To maintain the Brava device’s negative pressure, a battery-powered, microcomputer-controlled, exclusive vacuum pump was used. This pump has pressure sensors and relief valves to maintain a vacuum pressure of 15 to 25 mmHg.

**Fat Grafting**

One senior surgeon (H.U.) operated on all patients using the following technique. All procedures were performed under general anesthesia, using the tumescent technique. A 3-mm-diameter aspiration cannula was used with a liposuction aspirator set at a low negative pressure (<350 mmHg). Depending on the patient’s body type, the fat was aspirated from the thigh, abdomen, buttock, and/or waist. The harvested fat was centrifuged at 1200 g for 3 minutes, the supernatant oil was wicked off, and the fluid collected in the dependent portion of the syringe was decanted. The cellular components were transferred into a 50-cc syringe and then filled into a 2.5-cc syringe. The prepared adipose tissue was then injected into the defect area through a blunt Coleman cannula using the liposuction technique.10 In mastectomy patients, without a mammary gland, there was often only a thin space for the fat graft. In such cases, we attempted to perform grafting in all layers (i.e., subcutaneous, intramuscular, and submuscular spaces). Moreover, in cases of severe scar contracture and poor skin extensibility, we created multilevel, multispot, percutaneous scar nicks in a three-dimensional, mesh-like fashion using a sharp, 18-gauge needle to create sufficient space to permit fat infiltration and improve graft reception.8 In cases where this procedure did not create adequate release of the scar contracture, the adhesion was released directly from the initial incisional scar.

**Postoperative Brava Use**

Starting on postoperative day 1, patients again wore the Brava device and continued to do so for 2 weeks. Patients who tolerated the Brava device well continued to wear it for an additional few weeks. The main purpose of reapplying the Brava device was to immobilize the grafted fat and optimize blood circulation, thus stimulating proliferation of the engrafted adipose fat cells.8,9,11–13 Breast massage and intense exercise were strictly prohibited for 3 months after the operation to stabilize the recipient site.

**Aesthetic Analysis**

Aesthetic analysis was performed for each patient using clinical photographs of the preoperative and postoperative periods. Total mastectomy and breast-conserving surgery cases were evaluated separately. Follow-up postoperative photographs were obtained at least 6 months after the completion of fat grafting. Three board-certified plastic surgeons, not involved in the treatment of these cases, reviewed the photographs and scored the results on a three-point grading scale (range, 0 to 2); the average of their three scores was considered. The grading scale used was a modification.
of that originally described by Garbay et al.\textsuperscript{14} and modified by de Blacam et al.\textsuperscript{1} later.

Data collected included the volume, contour, and placement of the breast mound in comparison with the contralateral normal breast (Table 1). In addition, we compared the total preoperative and postoperative scores, and the improvement in the aesthetic score in individual total mastectomy and breast-conserving surgery cases. The Mann-Whitney \textit{U} test was used to calculate the statistical differences. A value of \( p < 0.05 \) was considered statistically significant.

**Radiographic Evaluation**

All patients were monitored by a multidisciplinary team consisting of a radiologist, plastic surgeon, and breast surgeon; monitoring included periodic radiographic imaging and clinical examinations, such as palpation and echography. More than 6 months after the final fat grafting session, all patients underwent magnetic resonance imaging to assess the quality of the grafted fat and examine for cyst formation. In breast-conserving surgery cases where the mammary glands were retained, mammography was performed annually to detect the presence of any calcifications after treatment.

**Evaluation of Patient Tolerance of Brava Use**

To evaluate patient tolerance of Brava use, the total time that each patient wore the device was investigated. Skin complications arising from wearing the system, including dermatitis, pigmentation, and blistering, were recorded.

**RESULTS**

The mean patient age was 50 years (range, 42 to 58 years); none of the 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. The mean patient body mass index was 20.07 kg/m\textsuperscript{2} (range, 17.28 to 25.49 kg/m\textsuperscript{2}). The first fat grafting procedure was performed an average of 22 months after breast cancer surgery (range, 6 to 55 months). A mean of 256 cc (range, 150 to 400 cc) of fat was grafted per session into each breast. The number of fat grafting procedures required ranged from one to four. Representative examples are shown in Figures 1 through 6 (cases 1 through 5). In general, the number of fat grafting procedures required was influenced by the degree of breast deformation, patient satisfaction, and the skin extensibility of the recipient site. In two irradiated breast-conserving surgery cases, the postoperative improvements in the breast deformities were considered minimal after the first fat grafting procedure, and the patients declined further treatment. With the exception of these two cases, at least two grafting procedures were required. Seven reconstructions (three total mastectomy cases and four breast-conserving surgery cases) required two grafting procedures, four reconstructions (two total mastectomy cases and two breast-conserving surgery cases) required three grafting procedures, and the remaining total mastectomy reconstructions required four grafting procedures to achieve patient satisfaction and/or an optimal cosmetic result.

In the nonradiated total mastectomy cases, preoperative wearing of the Brava device resulted in good extension of the skin envelope. The Brava device was particularly effective after skin- and nipple-sparing mastectomies (Fig. 1). Furthermore, after some sessions, there was increased recipient space and the skin had softened, thus allowing the Brava device to function more effectively. However, strong skin adhesions to the chest wall could not be released by Brava use alone, and thus direct mechanical release was applied during the first operation (cases 1 and 2). In the irradiated breast-conserving surgery cases, there was barely any skin extension; therefore, improvement of the asymmetric nipple position and breast shape was very difficult (cases 4 and 5).

Two acute postoperative complications were noted, including fat lysis in a breast-conserving surgery patient where almost all of the grafted fat had drained from a fistula (case 4), and cellulitis in a total mastectomy patient. Both patients were

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**Table 1. Subscale Analysis of Breast Reconstruction**

<table>
<thead>
<tr>
<th>Subscale Score*</th>
<th>0</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discrepancy of volume of breast</td>
<td>Marked</td>
<td>Moderate or mild</td>
<td>None or nearly none</td>
</tr>
<tr>
<td>Deformity of contour of breast</td>
<td>Marked</td>
<td>Moderate or mild</td>
<td>None or nearly none</td>
</tr>
<tr>
<td>Displacement of breast mound</td>
<td>Marked</td>
<td>Moderate or mild</td>
<td>None or nearly none</td>
</tr>
</tbody>
</table>

successfully treated with a minor incision and drainage and/or oral antibiotics. However, in the former patient, induration occurred under the skin and the breast deformity worsened compared with that noted preoperatively. No other serious complications occurred after fat grafting.

Contrary to our expectations, all patients were able to tolerate wearing the Brava device for more than 8 hours/day; three patients (21.4 percent) wore the Brava device for nearly or more than 10 hours/day. The most frequent complication associated with Brava use involved the skin (Table 2), with dermatitis occurring in 11 patients (78.6 percent); in particular, dermatitis occurred in all of the irradiated breast-conserving surgery cases. Pigmentation changes after dermatitis also occurred in 10 cases (71.4 percent). Blistering was observed in five cases (35.7 percent) during Brava use immediately after fat grafting; in these cases, Brava use was discontinued until the skin healed. There were only three cases (21.4 percent) where there were no skin complications, and all were associated with nonirradiated total mastectomy cases. Thus, skin complications clearly tended to occur more frequently in irradiated patients.

The mean follow-up time from the final fat grafting procedure to aesthetic evaluation was 21 months (range, 6 to 54 months). In both total mastectomy and breast-conserving surgery cases, improvements were noted in all three subscales after fat grafting. However, the degree of improvement in each subscale was higher in the total mastectomy cases than in the breast-conserving surgery cases (Table 3). Furthermore, the total aesthetic score was also significantly higher for total mastectomy cases than for breast-conserving surgery cases (4.10 versus 1.63, \( p = 0.003 \)). The minimal improvement in breast shape and residual asymmetry of the nipple position appeared to markedly affect the aesthetic score.

In five cases (two total mastectomy cases and three breast-conserving surgery cases), cysts were detected on the 6-month magnetic resonance imaging scans. These cysts were identified as benign foci.
of fat necrosis and not clinically significant, with the exception of one breast-conserving surgery case where fat lysis had occurred (case 4). In this case, a hard induration, measuring approximately 30 mm in diameter, was palpable. Of the eight breast-conserving surgery cases that subsequently underwent...
DISCUSSION

Flap surgery is generally the first choice for autologous breast reconstruction in cases where severe breast deformities develop after cancer surgery. However, many patients prefer autologous reconstruction, without an invasive operation and its resultant scarring. In cosmetic breast augmentation, the mechanical stress caused by the Brava system extends the recipient skin and produces additional space, thus improving the survival rate of the grafted fat and increasing the volume of grafted fat per session. However, the recipient condition of our cases was quite different from that of normal, healthy breasts. Therefore, there were several unresolved questions regarding the Brava device’s effect on severely contracted breasts, tolerance of the vacuum expansion, complications related to vacuum-assisted expansion (including those on the skin), and whether the Brava device could be of perioperative value.

Effects of Brava Use

In mechanobiology, mechanical stimulation is well known to greatly affect the proliferation of cells. In nonirradiated total mastectomy cases, we observed a good physical effect of Brava use. Preoperative use extended the skin well and increased the recipient space in the area where the residual tissue continued to be soft. Mechanical stimuli have been suggested to directly stimulate cell proliferation of the recipient bed. These
changes lead to decreased interstitial pressure and increased graft volumes per session. In addition, simultaneous induction of neoangiogenesis can also contribute to improved outcomes after engraftment.9,18 In contrast, in irradiated breast-conserving surgery cases, there was barely any extension of the skin. We hypothesize that the radiation therapy had an extremely adverse effect on the skin and subcutaneous tissue, resulting in the limited efficacy of preoperative Brava use.

Postoperative Brava use was expected to result in increased local blood circulation in the recipient bed, which would be advantageous for the engraftment. Figure 7 illustrates the oxygen partial pressure values in the subcutaneous fat tissue of normal breasts. External negative pressure exerts an obvious increase in oxygen partial pressure, indicating a rapid increase in blood flow in the subcutaneous adipose tissue. This phenomenon occurs following postoperative Brava use clinically and is effective in promoting engraftment. Generally, mature adipocytes have the highest oxygen partial pressure in the body (approximately 50 mmHg) and are very vulnerable to a low-oxygen state.19 In ischemic environments, many adipocytes tend to become necrotic or apoptotic within 3 days after transplantation.19,20 Therefore, the Brava device should be used as early as possible after surgery. Eto et al. reported that after grafting, replacement of degenerated fat began on postoperative days 5 through 7, and regenerative adipogenic changes started on postoperative day 14.20 Therefore, a 2-week use of the Brava device, after grafting, should be theoretically adequate.

**Patient Tolerance of the Brava Device**

Initially, we expected that wearing the Brava device for 10 hours/day would not be well tolerated. However, we noted that the total Brava wearing time was higher than expected, which may be attributable to several factors. First, before surgery, the importance of wearing the device was strongly
emphasized. Second, the duration of Brava use was clearly set at 6 weeks from the beginning. Finally, the patients were highly motivated, as they were to undergo the breast reconstruction procedure—a major event in their breast cancer journey—in the near future. Ultimately, to ensure compliance with Brava use, a thorough explanation of its importance was essential to yield the discipline and a high level of commitment to its use.9

**Brava-Related Skin Complications**

The biggest drawbacks of Brava use were skin complications. To date, these complications have not been described appropriately despite the many clinical reports of Brava use.6−9 In our cases, despite prophylactic use of steroid ointment, contact dermatitis occurred in 11 patients (78.6 percent), and the duration of Brava use was affected because of pruritus. Postinflammatory pigmentation, which occurs frequently in Asian populations, was another bothersome complication, as it could occasionally be prolonged.

Of note, these skin complications occurred at a high rate in the irradiated cases. Radiation therapy caused thinning of the epithelial tissue, affected the blood circulation in the dermal tissue, and decreased dermal appendages, thus inhibiting the regenerative ability of the skin.21

**Table 2. Skin Complications during Brava Use**

<table>
<thead>
<tr>
<th></th>
<th>Bt Cases (%)</th>
<th>Bp Cases (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>Dermatitis</td>
<td>3 (50)</td>
<td>8 (100)</td>
<td>11 (78.6)</td>
</tr>
<tr>
<td>Pigmentation</td>
<td>2 (33)</td>
<td>8 (100)</td>
<td>10 (71.4)</td>
</tr>
<tr>
<td>Blistering</td>
<td>1 (17)</td>
<td>4 (50)</td>
<td>5 (35.7)</td>
</tr>
<tr>
<td>No skin complication</td>
<td>3 (50)</td>
<td>0 (0)</td>
<td>3 (21.4)</td>
</tr>
</tbody>
</table>

Bt, total mastectomy; Bp, breast-conserving surgery.

**Table 3. Change in Mean Aesthetic Scores before and after Treatment**

<table>
<thead>
<tr>
<th></th>
<th>Bt Cases (n = 6)</th>
<th>Bp Cases (n = 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T0</td>
<td>T1</td>
</tr>
<tr>
<td>Discrepancy of volume of breast</td>
<td>0.33</td>
<td>1.83</td>
</tr>
<tr>
<td>Deformity of contour of breast</td>
<td>0.33</td>
<td>1.50</td>
</tr>
<tr>
<td>Displacement of breast mound</td>
<td>0.33</td>
<td>1.67</td>
</tr>
<tr>
<td>Total (change in score*)</td>
<td>0.99</td>
<td>5.00 (4.10)</td>
</tr>
</tbody>
</table>

Bt, total mastectomy; Bp, breast-conserving surgery; T0, score before treatment; T1, score after treatment.

*The improvement degree of total aesthetic score in Bt cases was significantly higher than that in Bp cases (4.10 versus 1.63, p = 0.003).
intraoperatively (cases 1 and 2). In particular, Brava worked effectively in skin- or nipple-sparing mastectomy cases, where the skin defect was small or non-existent. (See Video, Supplemental Digital Content 1, which demonstrates the soft and natural appearance of the breast of the patient in case 2, http://links.lww.com/PRS/A934.) Even when there was only thin space for fat injection, the recipient space became broader and the survival rate of the grafted fat seemed to increase with repeating Brava use and fat grafting. (See Figure, Supplemental Digital Content 2, which displays gradual changes of the patient’s appearance during treatment, http://links.lww.com/PRS/A935.) In conventional mastectomy cases, reproducing the rich inframammary region was challenging because of the large skin defects. Nevertheless, with careful patient selection, good outcomes could be obtained. (See Video, Supplemental Digital Content 3, which demonstrates the soft and natural appearance of the patient’s breast in case 3, http://links.lww.com/PRS/A936.) Therefore, we believe that fat grafting involving Brava use can be an alternative breast reconstruction procedure in nonirradiated total mastectomy cases.

In contrast, in irradiated breast-conserving surgery cases, little skin extension occurred following Brava use, and this was reflected in the poor cosmetic scores. Asymmetry of the nipple position was

![Image of oxygen partial pressure graph](http://links.lww.com/PRS/A934)

**Fig. 7.** Oxygen partial pressure ($p_{aO_2}$) in subcutaneous fat tissue of a normal breast following initiation of negative pressure with the Brava device (black arrow). The oxygen partial pressure clearly increased (using a real-time oxygen partial pressure monitor; Nihon Bioresearch, Inc., Tokyo, Japan).

![Video 1](http://links.lww.com/PRS/A934)

**Video 1.** Supplemental Digital Content 1 which demonstrates the soft and natural appearance of the breast of the patient in case 2, http://links.lww.com/PRS/A934.

![Video 2](http://links.lww.com/PRS/A936)

**Video 2.** Supplemental Digital Content 3 further illustrates the soft and natural appearance of the patient’s breast in case 3, http://links.lww.com/PRS/A936.
particularly difficult to improve, even though the volume of the affected side was nearly identical to that of the normal side (case 5). In addition, skin complications resulting from Brava use occurred at a high rate in irradiated cases. Some studies have recommended multiple treatments (more than four) and small volumes of fat grafting for irradiated breasts.\textsuperscript{22−24} However, considering the time and cost efficiency, we believe that this is not practical in a clinical setting. Thus, in irradiated cases, the skin deficiency is difficult to resolve with fat grafting alone, regardless of Brava use. Furthermore, the survival rate of the engraftment itself would be low in comparison with nonirradiated cases.\textsuperscript{23,25} When fat injection is applied to patients with such poor conditions, the patient and physician should recognize that outcomes will likely be worse than the preoperative breast form, even when the Brava device is used (as in case 4). Therefore, fat grafting may be useful only in irradiated cases where there is little to no skin deficiency and the deformity is mild.\textsuperscript{4} In addition, the theoretical risk of cancer and associated cancer screening requirements are controversial, particularly in breast-conserving surgery cases, because the mammary glands remain in situ and patients are believed to be prone to cancer recurrence.\textsuperscript{26−28} Therefore, in the management of irradiated breast-conserving surgery cases with severe breast deformities, we suggest carefully considering the use of not only the Brava device but also fat grafting.

CONCLUSIONS

Although this case series is limited by its small sample size, fat grafting involving perioperative Brava use can potentially be an alternative for total breast reconstruction in nonirradiated total mastectomy cases. However, the results tend to be unsatisfactory in breast-conserving surgery cases because of the effects of radiation therapy. To achieve good outcomes for breast-conserving surgery cases, further research is required to determine how to acquire sufficient skin and optimize the survival rate of the grafted fat. Moreover, a prospective study with a larger sample size is needed to demonstrate the oncologic safety of this new technique in cancer-prone breast-conserving surgery cases.

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