

Aesthetic Applications of Brava-Assisted Megavolume Fat Grafting to the Breasts: A 9-Year, 476-Patient, Multicenter Experience

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Background: Autologous fat grafting to the breasts was banned in 1987 because of unpredictable graft retention and cyst formation that could not be differentiated from cancer. Surgical and radiologic advances induced a lifting of the ban in 2009. Small- to moderate-volume autologous fat grafting to the breast has become common. The authors present their aesthetic applications of megavolume autologous fat grafting to the breast.

Methods: Autologous fat grafting with Brava preexpansion was performed on 294 patients for aesthetic augmentation, 45 patients for congenital deformity correction, 43 patients for iatrogenic deformity correction, and six patients for implant-to-fat conversion. Autologous fat grafting for implant-to-fat conversion was performed on 88 patients without Brava. A case example is presented for each indication. The baseline, perioperative, grafted, and postoperative volumes were recorded.

Results: Follow-up ranges from 6 months to 9 years (mean, 3.5 years). The mean volume grafted was 346 ml per breast, and the mean postoperative augmentation measured at least 6 months postoperatively was 266 ml per breast. No patients required open biopsy or were diagnosed with cancer. There was one pneumothorax, requiring a temporary chest tube, with no further complication.

Conclusion: Large-volume autologous fat grafting after Brava use or implant removal is a safe and effective alternative for breast augmentation and deformity correction. (*Plast. Reconstr. Surg.* 133: 796, 2014.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

In 1987, the American Society of Plastic Surgeons banned autologous fat transfer to the breasts because of unpredictable retention and the inability to differentiate fat necrosis from cancer.¹ Imaging technologies now allow radiologists to distinguish these two lesions.²⁻⁵ In 2007, the American Society of Plastic Surgeons concluded that autologous fat grafting to the breasts may be useful and safe, but the results were unpredictable.⁶ In 2009, the American Society of Plastic Surgeons lifted the ban, recommending cautious use.⁷ Although small- and moderate-volume autologous fat grafting for aesthetic breast augmentation is now widely used,⁸⁻¹³ we have developed techniques for successful megavolume autologous

fat grafting.^{14,15} By “megavolume,” we simply mean drastically larger amounts than previously reported (>300 ml grafted). These techniques allow us to take on a wider spectrum of aesthetic breast surgery challenges, including correction of congenital and iatrogenic deformities, and implant-to-fat conversions.

Disclosure: Roger K. Khouri, M.D., has an equity interest in the company, Brava, LLC, the manufacturer of the Brava device. He also has an equity interest in Lipocosm, the manufacturer and distributor of the Lipografter, consisting of the KVAC Syringe and AT-Valve. None of the other authors has any conflicts of interests to disclose.

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A Video Discussion by Daniel A. Del Vecchio, M.D., M.B.A., accompanies this article. Go to PRSJJournal.com and click on “Video Discussions” in the “Videos” tab to watch.

Breast augmentation became notable in our specialty with Thomas Cronin's presentation of the "natural feel" prosthesis at the 1964 International Confederation for Plastic, Reconstructive and Aesthetic Surgery meeting.¹⁶ Despite problems, the operation has served millions of patients. However, there are still patients who would prefer their own tissue to be used for augmentation rather than a manufactured device; however, until recently, this was not an option.

Brava uses a vacuum pump to expand the skin and stromal/vascular scaffold, so that many microribbons of fat can be diffusely injected without coalescence or significantly increased interstitial fluid pressure.^{14,15,17} Patient compliance with Brava wear is essential; they must triple their volume to obtain a final augmentation that is double the original volume.¹⁷ With liposuction and breast augmentation, we combine two of the most commonly performed cosmetic surgical procedures.¹⁸

Whereas Brava and autologous fat grafting augmentation is a straightforward exercise in fundamentals, we developed an assortment of ancillary techniques to resolve specific challenges. With our ability to shape the breast and release contractures, we can correct many deformities without making any incisions or creating any scars.

Expansion does not release congenital bands; it only loosens them. Because vacuum is an isotropic force, expansion occurs along the path of least resistance, and the deformity is temporarily worsened. To correct all congenital and iatrogenic breast deformities, we mesh-expand the lower pole of the breast, using percutaneous aponeurotomy and lipofilling.¹⁹ Thanks to Brava-induced increased capillary density, we can mesh more extensively and maintain a functional capillary network to preserve perfusion. Lectures on these principles and surgery videos of these techniques are available at the *Plastic and Reconstructive Surgery* Web site.^{20,21}

The same techniques for treating congenital deformities can be used for iatrogenic deformities. These are patients who simply cannot tolerate implants. Repeated implant removal, pocket exchanges, capsulectomies, and implant replacements often compound the scarring and worsen the deformity. These women, who longed for aesthetic improvement, end up with disfigured breasts that can be uniquely treated with these novel techniques.

In the United States, 300,000 women undergo breast implant surgery every year.¹⁸ Within 10 years, a significant number will undergo another operation to correct some implant-related problem.²² Most of these women would rather not have

implants reinserted; thus, implant-to-fat conversion can be a rewarding procedure.

Compared with unexpanded breasts, tissues of implanted breasts are stretched and have room for grafts. Therefore, we do not advocate the use of Brava over implants. Experimental data also suggest that the capsule of a silicone implant favors fat graft survival by increasing recipient-site vascularity.²³ Following implant removal, the horizontal fibers are loose and accordion-like folded, whereas the tight vertical fibers prevent the tissues from ballooning (Fig. 1). The volume of adipose tissue that was once spread over the large surface of the projecting implant now lies deflated. After releasing the vertical fibers and lipografting to capacity, we can usually achieve a full breast mound. However, in some cases where the implant is larger than 300 ml, releasing the vertical fibers of a thin breast rim fails to achieve enough central projection. In such cases, insertion of a smaller implant (50 percent of the original volume) restores projection. The combination of fat grafts and a smaller implant yields approximately the same volume as the original but has better feel and contour. Once implant-free, some implant-to-fat conversion patients desire even larger breasts and are then treated as aesthetic augmentation patients with Brava plus autologous fat grafting.

We present our experience with 565 consecutive megavolume autologous fat grafting procedures to the breast. With the help of illustrative case examples for each application, we outline possible outcomes and limitations.

PATIENTS AND METHODS

From 2004 to 2013 at the Miami Breast Center and the University of Verona Hospitals, we treated 846 breasts in 476 women with 565 megavolume autologous fat grafting procedures for aesthetic breast indications (73 patients had two procedures and eight patients had three procedures) under institutional review board approval.²⁴ Two hundred ninety-four patients underwent grafting for primary aesthetic augmentation (106 were unilateral augmentations of the contralateral Brava plus autologous fat grafting–reconstructed breast); 45 underwent grafting to correct congenital deformities; 43 underwent grafting to correct iatrogenic deformities; and 94 were implant-to-fat conversion patients. Patient ages ranged from 16 to 60 years (mean, 37.6 years), and body mass index ranged from 16.2 to 29.2 (mean, 21.6). The exclusion criteria included smoking, prolonged

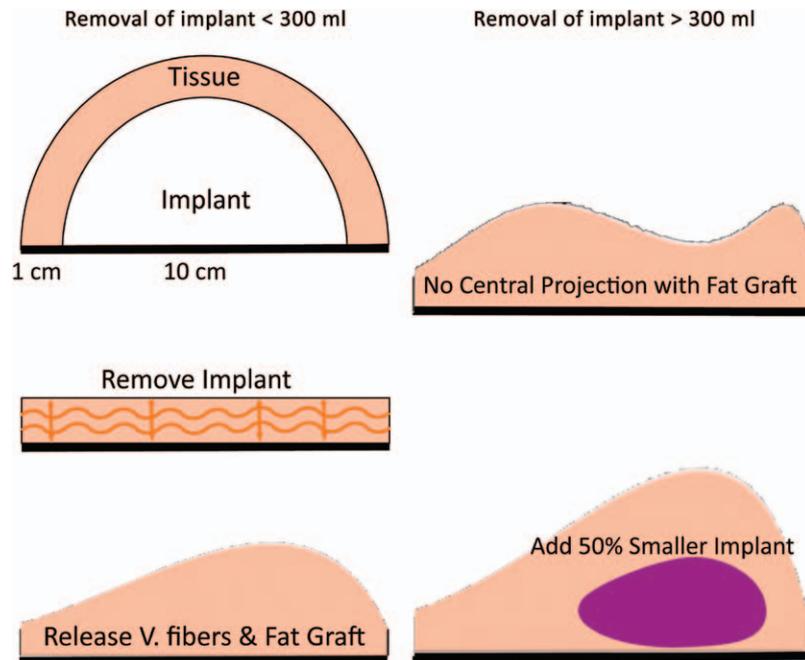


Fig. 1. (Above, left) The rim of breast tissue is stretch-expanded by the implants. If the base of the breast is 10 cm in diameter and the rim of tissue is 1 cm thick, then to simplify, if we calculate surface areas in two dimensions and extrapolate into three dimensions, the breast tissue area is: $\pi D/2 \times 1 = 16 \text{ cm}^2$. (Center, left) Following removal of the implant, the surface of the breast is 10 cm^2 . (Below, left) Resultant 16-cm^2 breast mound after releasing the vertical fibers and lipografting. (Above, right) In patients with large implants, this is not enough to achieve a central projection. (Below, right) Insertion of a smaller implant restores the central projection.

bleeding, unrealistic expectations, and multiple previous liposuction procedures.

Except for the 88 implant-to-fat conversion patients who did not require Brava expansion, to enroll, all patients had to tolerate a 20-minute Brava test trial in the office and understand the expansion requirement. They were asked to wear the original Brava device for 10 hours/day for 4 weeks. More recently, the Brava automatic cycling pump was used to obtain the same amount of pre-expansion after 2 weeks. Depending on patient tolerance, the automatic pump cycles between 60 and 80 mmHg of vacuum for 3 minutes and no pressure for 1 minute, taking advantage of the benefits of tissue expansion by cyclical forces.²⁵ They were asked to wear the Brava device without interruption for the last 24 to 48 hours preoperatively and come in wearing the device, inducing a temporary three-dimensional enlargement of the subcutaneous periglandular tissue into the larger vascular recipient matrix required.

We elaborated on the principles and techniques of megavolume fat grafting in previous publications.^{14,15} Briefly, even in patients with no localized adiposities, fat is diffusely and evenly

liposuctioned over a large area with a 12-hole, 2.7-mm cannula, fanning crisscrossing passes through multiple needle puncture entry sites to avoid contour irregularities. It is harvested with a 300-mmHg syringe (KVAK Syringe; Lipcosm, LLC, Key Biscayne, Fla.) and automatically transferred by means of a two-way valve (AT-Valve; Lipcosm) to collection bags that are centrifuged at 15 g for 2 minutes. It is then diffusely reinjected through multiple needle entry sites with a 2.4-mm single-hole cannula as fanning microribbons inside the expanded scaffold until the interstitial fluid pressure reaches 9 mmHg. This reinjection technique avoids coalescence of the microribbons into lakes too wide to survive²⁶ and interstitial fluid pressure levels that restrict capillary perfusion.^{27,28} We splint immobilize the graft on the second postoperative day with low-pressure Brava use for as many hours per day as tolerated for 3 to 4 weeks. Implant-to-fat conversion patients did not use the Brava device postoperatively, and their implant capsules were scored percutaneously and allowed to collapse without drains.

If the patient was not satisfied with the reconstruction at 1 to 2 months postoperatively, she

resumed Brava expansion for the 2 to 4 weeks before the next operation; the minimum time between operations was 8 weeks. The mean number of operations required to reach patient satisfaction was 1.1 for aesthetic augmentation, 1.2 for congenital deformity, 1.3 for iatrogenic deformity, and 1.4 for implant-to-fat conversion. For patients undergoing additional operations, the second operation led to a mean augmentation 1.4-fold greater than the first.

Patients were seen 1 month postoperatively and on a quarterly basis for 1 year. All women older than 40 years underwent mammography at 1 year and ultrasound examination whenever indicated by the radiologists. Eighty-seven percent of the patients underwent pretreatment baseline magnetic resonance imaging and, although required by the protocol and clearly informed about its importance, only 67 percent returned for follow-up magnetic resonance imaging. Only 62 percent of patients underwent baseline and follow-up magnetic resonance imaging. The average follow-up magnetic resonance imaging was at 9 months postoperatively.

Breast volumes were determined by three-dimensional reconstruction of the baseline and long-term follow-up magnetic resonance imaging scans; three-dimensional volumetric conversion of standard two-dimensional photographs; and for the latest 100 patients, three-dimensional photographic imaging at baseline, just before grafting, four days, and 6 to 12 months (mean, 9 months) after surgery. The 4-day delay between operating and obtaining three-dimensional images was to allow edema to be reabsorbed. Three-dimensional surface imaging has been shown to provide acceptable accuracy for breast volume.²⁹ Graft volumes were retrieved from operative records.

RESULTS

The average follow-up time was 3.5 years (range, 6 months to 9 years). Overall, the mean total volume of fat suspension grafted for each patient was 346 ml per breast, and the mean postoperative volume augmentation for each patient was 266 ml per breast (76.9 percent). The breasts had a natural, aesthetically pleasing appearance and feel, and 96 percent of patients were satisfied with their results. On follow-up magnetic resonance imaging, the grafted fat seemed identical to the endogenous preexisting tissue.

Complications

The number and severity of complications from the 565 procedures are relatively low and minor.

Magnetic resonance imaging revealed localized foci of fat necrosis in 19 percent of patients. In these patients, mammography at 1-year follow-up confirmed these as benign fat necrotic foci. The rate of necrosis decreased throughout the study; the key has been diffuse distribution of microdroplets and strict adherence to the 9-mmHg interstitial fluid pressure limit. Small palpable breast nodules were present in 15 percent of patients; however, imaging studies also confirmed these as benign. Thirteen of the 295 follow-up magnetic resonance imaging scans showed worrisome lesions. Three of these patients elected not to wait for repeated study and instead underwent needle biopsies that confirmed the benign nature. The others were cleared as benign with follow-up study. Minor infections in seven patients were treated successfully with antibiotics alone. One implant-to-fat conversion patient developed a pneumothorax, requiring the insertion of a chest tube for 1 day with no further complication. Asian and African women often developed postinflammatory hyperpigmentations from Brava use that eventually cleared with hydroquinone creams. A few of the congenital constricted breasts had difficult-to-treat milia-like skin nodules from the needle releases and the postoperative Brava suction that kept these puncture wounds open while edema fluid drained out. We have since stopped applying Brava postoperatively when we perform many Rigottomies.

Aesthetic Breast Augmentation

For the 294 patients (mean age, 36.6 years) who underwent aesthetic breast augmentation, the mean baseline breast volume for each patient was 319 ml per breast. Brava induced a 2.7-fold increase of the original volume. For each patient, the mean total volume grafted was 367 ml per breast, and the mean postoperative volume augmentation measured was 293 ml per breast (79.8 percent graft retention). One hundred six of these operations were unilateral augmentations on the contralateral side of a mastectomy reconstruction. When calculating means, each patient was weighted equally, regardless of whether their operation was unilateral or bilateral.

Illustrative Case

A 34-year-old woman presented with involutional atrophy of the breasts (Fig. 2). After 3 weeks of Brava use, she expanded her breast volume by greater than sixfold. The breasts had marked hyperemia, indicative of increased vascularity. Although she weighed less than 100 lb, we

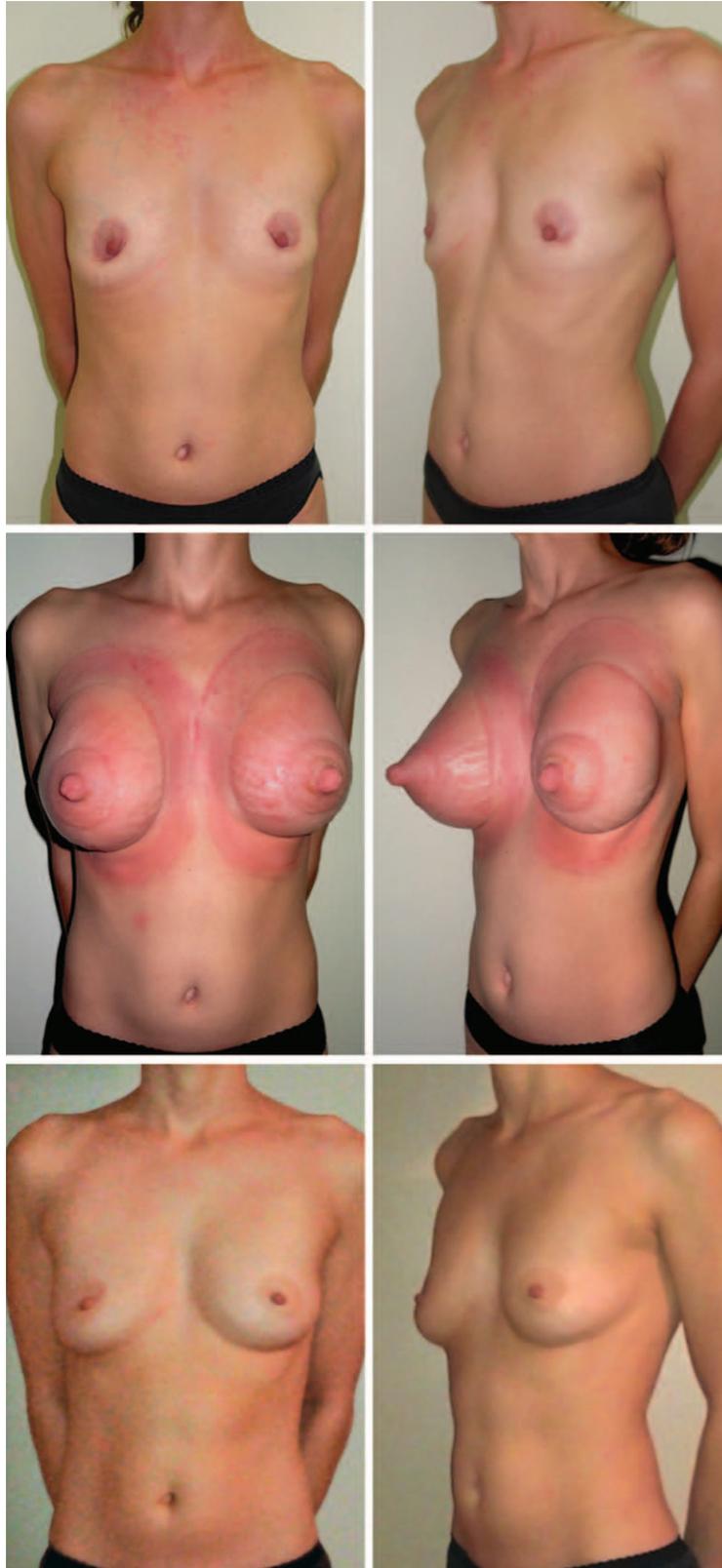


Fig. 2. (Above) A 34-year-old patient presented with involuntional atrophy of the breasts. (Center) Brava use expanded her breasts by over 600 percent. (Below) Nine months after fat grafting, each breast was augmented by 250 ml. (Reprinted from Khouri RK, Biggs TM. *Your Natural Breasts: A Better Way to Augment, Reconstruct, and Correct Using Your Own Fat*. Tallahassee, Fla: San Pedro Publishing; 2012.)

harvested and grafted 300 ml per breast to give her a 250-ml augmentation at 9-month follow-up.

Correction of Congenital Deformities

For the 45 patients (mean age, 27 years) who underwent correction of congenital deformities, the mean baseline volume was 210 ml per breast. Brava induced a 2.2-fold increase of the original volume. The mean total volume grafted was 300 ml per breast, and the mean postoperative volume augmentation was 240 ml per breast (79 percent graft retention).

Illustrative Case

A 22-year-old woman presented with tuberous breast congenital deformity (Fig. 3). After Brava wear for 3 weeks, her breasts were expanded by greater than three times their original volume. To correct her deformity, we grafted 300 ml per breast. Percutaneous aponeurotomy and lipofilling expanded the lower pole of her breast, and Rigotomies lowered the inframammary fold. At 9-month follow-up, she had a 240-ml augmentation and a better-sculptured breast contour.

Correction of Iatrogenic Deformities

For the 43 patients (mean age, 39 years) who underwent correction of iatrogenic deformities, the mean baseline volume was 280 ml per breast. Brava expansion induced an average 2.3-fold increase in volume. The mean total volume grafted was 350 ml per breast, and the mean postoperative augmentation was 280 ml per breast (79 percent graft retention).

Illustrative Case

A 43-year-old woman presented with bilateral iatrogenic breast deformities (Figs. 4 through 6). She had recurrent capsular contracture, despite having had four previous implant replacements, capsulectomies, and pocket exchanges. The lower poles of her breasts were severely scarred and deficient. After 3 weeks of Brava use, the lower pole contracture was loosened but not totally released. We grafted loosely centrifuged fat to place the restrictive scar under tension. We then used Rigotomies to preferentially divide the fibrous bands under tension, turning the restrictive cicatrix into a recipient scaffold to correct the deformity without creating cavities or opening tissue planes. We then grafted more fat into the mesh-expanded matrix, respecting interstitial fluid pressure limitations.

Implant-to-Fat Conversion

For the 94 patients (mean age, 45.2 years) who underwent implant-to-fat conversion, the

mean volume of implant removed was 290 ml. The mean total volume grafted was 300 ml per breast, and the mean postoperative augmentation (exclusive of the removed implant) was 190 ml per breast (64 percent graft retention). Thirty-seven percent of patients had at least one additional operation either to remove the implant inserted at the first procedure, to further enlarge the breast, or to correct residual contour defects. This group had the highest complication rate: cysts, 21 percent; infection, 3.2 percent; and pneumothorax, 1.1 percent.

Illustrative Case

Twelve years after aesthetic silicone implant augmentation, a 45-year-old woman presented with grade IV capsular contracture and ruptured implants (Fig. 7). Preoperative magnetic resonance imaging-derived breast volume, exclusive of the implant, was 342 ml. Once the 300-ml implants were removed, there was complete loss of projection and volume. We grafted her deflated breasts with 309 ml of graft suspension. At 1 year postoperatively, we measured 185 ml of autologous fat augmentation. Although her breasts were smaller in volume, they had a much better shape and feel.

DISCUSSION

For decades, surgeons have been successfully grafting small volumes of fat to the well-vascularized face^{30–41} and large volumes to the buttocks.^{42–44} However, until recently,¹⁷ large-volume autologous fat grafting to small breasts was not a dependable option. This report shows that Brava plus autologous fat grafting is a safe and effective method for breast augmentation and a viable alternative to implants. It also is an invaluable method for the correction of iatrogenic and congenital deformities. Furthermore, for women who wish to remove their implants, properly performed implant-to-fat conversion leads to improved breast aesthetics and feel without much compromise in volume.

The 293-ml mean augmentation and 79.8 percent retention rate for our aesthetic augmentation with Brava plus autologous fat grafting is significantly larger than reports of autologous fat grafting without preexpansion. A recent meta-analysis of six studies on 355 patients who underwent autologous fat grafting without preexpansion had a mean augmentation of 134 ml and a 53.8 percent retention rate.¹⁷ To achieve the average reported 134-ml augmentation on a tight non-pre-expanded breast, only 168 ml needs to be grafted



Fig. 3. (Above) A 22-year-old patient presented with tuberous breasts. (Center) Brava use expanded her breasts by over 300 percent. Numbered markings show the needlestick entry sites for the grafting cannula and the percutaneous slits for the mesh expansion. (Below) Nine months postoperatively, each breast had a 240-ml augmentation and improved contour.

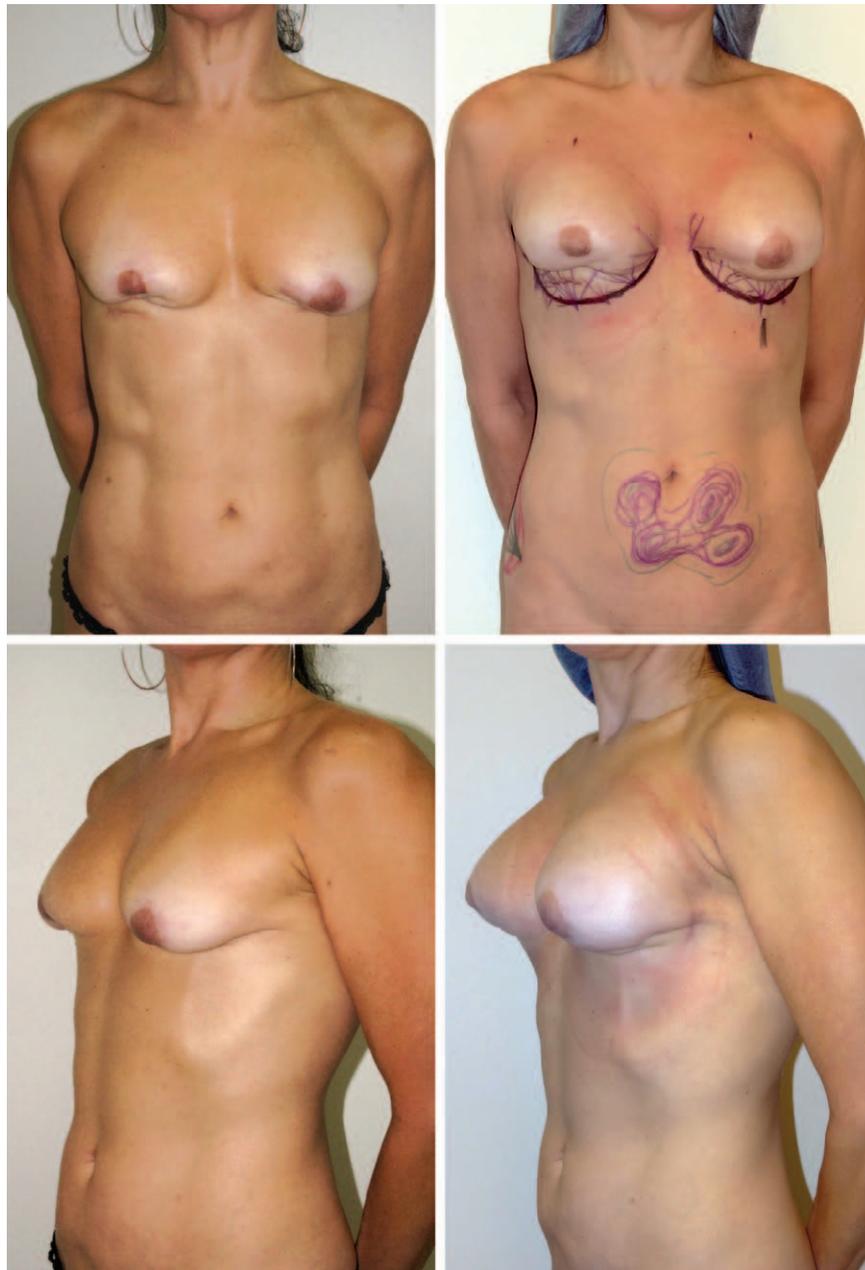


Fig. 4. A 43-year-old patient with bilateral iatrogenic breast deformities. (Right) Brava loosened the lower pole contracture.

(inverse of 79.8 percent). Attempts to graft more fat in the limited space are counterproductive. However, if by following our method, the same breast is Brava-expanded to two to three times its original volume, it can easily accept 336 ml and still retain approximately 79.8 percent or 268 ml in one procedure. Our aesthetic augmentations are in the range of reported mean breast implant volumes: 246 ml in Denmark,⁴⁵ 270 ml in the United Kingdom,⁴⁶ and 370 ml in the United States.⁴⁷

In a recent study on the use of autologous fat grafting to correct tuberous breasts without

preexpansion, 45 percent of patients required only one fat transfer of a mean volume of 158 ml, and 55 percent required a second fat transfer of a mean volume of 226 ml.⁴⁸ In our experience with the use of autologous fat grafting plus Brava to correct congenital breast deformities, 82 percent of patients required only one fat transfer of a mean volume of 210 ml, and only 18 percent required a second fat transfer of a mean volume of 350 ml. In our experience with the use of autologous fat grafting plus Brava use to correct iatrogenic breast deformities, 70 percent of patients



Fig. 5. We grafted fat and performed Rigottomies.

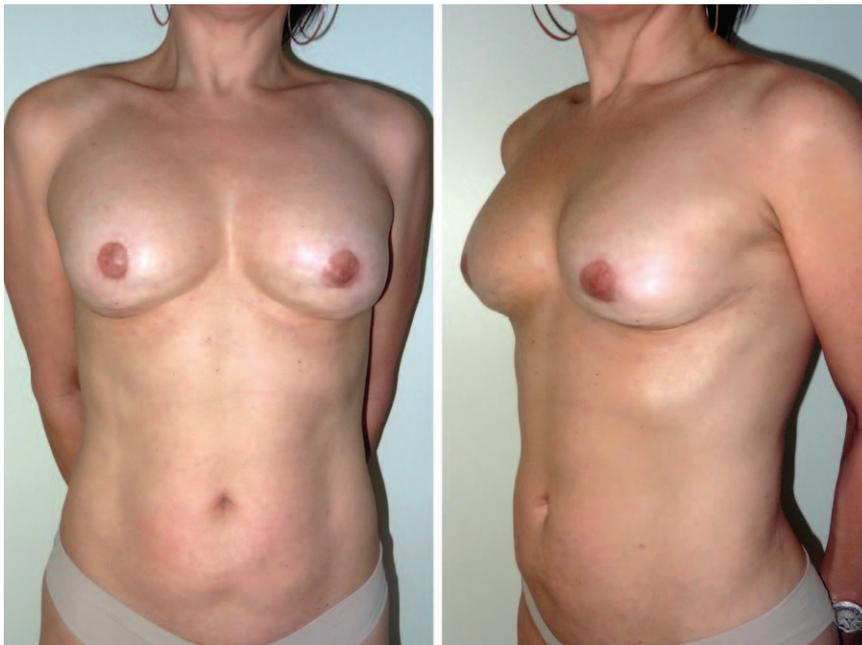


Fig. 6. Results 6 months after fat grafting and Rigottomies.



Fig. 7. (Above, left and above, center) A 45-year-old patient presented with contracted and ruptured implants. (Right) Intraoperative photograph after implant removal. (Below, left and below, center) Nine-month follow-up after Rigottomy autologous fat grafting.

required only one fat transfer of a mean volume of 240 ml, and 30 percent required a second fat transfer of a mean volume of 350 ml. In almost all cases, the surgeon and patient were very satisfied with the improved volume, contour, and feel.

The lower graft retention for implant-to-fat conversion patients (64 percent) was expected

because a deflated recipient site is not as suitable for nurturing grafts as a large, edematous, well-vascularized breast that has been preexpanded. Most patients are still very happy to replace the foreign implants with their own tissue.

Our mean body mass index of 21.6 was low because we rarely turn away patients for lack of

available fat. Our described techniques allow us to harvest enough fat to adequately augment the breasts of almost any patient,¹⁵ and our high retention rate leads to satisfactory augmentation in this low-body-mass index population.

Of the 846 breasts operated on in the present study, 19 percent had foci of fat necrosis that were easily identified by imaging studies. Although very few were large enough to require percutaneous drainage, the vast majority of these were small and of no consequence. The false-positive rate from postoperative magnetic resonance imaging (4.4 percent) is in the same range as the reported false-positive rate of breast magnetic resonance imaging screenings (4.9 percent).⁴⁹ This supports other studies suggesting that fat grafting does not hinder breast imaging.²⁻⁵ Nonetheless, it is crucial to maintain a high index of suspicion and not to dismiss any palpable mass as fat necrosis without radiographic confirmation.

It is also very relevant to note that, according to National Cancer Institute statistics,⁵⁰ at least one or two women out of our patient population cohort would be expected to develop breast cancer during this follow-up period, whereas in fact, none of our patients have. This further suggests that unprocessed autologous fat grafts are safe and do not induce cancer.^{2,6}

CONCLUSIONS

Megavolume autologous fat grafting to the breasts is a versatile procedure that can be used in many aesthetic applications. The principles and techniques described^{14,15} lead to clinical results that are safe, predictable, and satisfactory. Brava plus autologous fat grafting should be an alternative offered to all women considering aesthetic breast augmentation.

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