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A Prospective Study on Lipoaugmentation of the Breast

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Abstract

Background: The current standard for breast augmentation involves placement of an implant. As an alternative, surgeons have been exploring breast augmentation with autologous tissue in the form of injectable fat.

Objectives: The authors explore the efficacy and safety of lipoaugmentation of the breast, with specific interest in volume changes, fat retention, overall aesthetic improvement, and patient satisfaction.

Methods: Direct measurements, 2- and 3-dimensional images, mammograms, and magnetic resonance imaging (MRI) were obtained preoperatively from 10 consecutive patients undergoing augmentation mammaplasty with autologous fat transfer. These measurements were repeated 1 year postoperatively. Postoperative photo imaging was conducted at 3-month intervals for 1 year. Efficacy was evaluated by determining the volume of fat retention 1 year after the procedure with 3-dimensional imaging, standard breast MRI volume measurements, and subjective aesthetic comparisons.

Results: The average amount of fat injected was 236 cc (90-324; SD, 69.8) in the right breast and 250 cc (90-300; SD, 65.1) in the left. The mean volume change based on 3-dimensional imaging was 85.1 cc (36% retention) for the right breast and 98.1 cc (39.2% retention) for the left. The mean volume change based on MRI measurements was 30.0 cc (39.8% change) on the right and 29.3 cc (38.1% change) on the left. Blinded observers found substantial improvement in 1 patient (10%), moderate improvement in 5 patients (50%), and minimal to no improvement in 4 (40%). Overall patient satisfaction was high, as measured by the abbreviated BREAST-Q. Radiologic abnormalities and artifacts were common and required additional imaging.

Conclusions: Objective breast enlargement in this study was modest but yielded disproportionately high subjective patient satisfaction reports.

Level of Evidence: 2

Keywords

fat grafting, breast augmentation, lipoaugmentation, breast surgery, autologous fat transfer, mammaplasty

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The current standard for breast augmentation involves placement of an implant. Although implants are generally safe, they are foreign bodies and therefore have inherent risks, such as capsular contracture, infection, device failure, and malposition. As an alternative, surgeons have been exploring breast augmentation with autologous tissue in the form of injectable fat.

Although autologous fat grafting was first described more than 100 years ago, fat grafting for breast augmentation was not widely considered until Bircoll's description of the procedure in 1987.[1] Shortly after that, the American Society of Plastic and Reconstructive Surgeons Ad-Hoc Committee on New Procedures openly discouraged lipoaugmentation of the breast due to concerns over oncologic

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Table 1. Study Design

Inclusion Criteria	Study Parameters
Women aged 20-50 y	Follow-up visits at 3 wk and 3, 6, and 12 mo postoperatively
Residence less than 50 miles from Georgetown University Hospital	Volume measurements, weight measurement, and 2- and 3-dimensional photos at each visit
No previous breast surgery	Mammogram and magnetic resonance imaging preoperatively and 12 mo after the procedure
Body mass index of 22-29	BREAST-Q administered preoperatively and 12 mo after the procedure

safety.[2] For nearly 10 years after that report, fat grafting for breast augmentation in the United States remained outside the mainstream. However, with increasing understanding, new reports on fat grafting for reconstructive breast surgery, and improvements in imaging software and techniques, interest in autologous fat transfer in the breast has resurfaced. The increased interest in fat grafting for breast augmentation is demonstrated by the number of recent publications on the subject.[3-8]

In 2005, Spear et al reported on 37 patients who, over a 10-year period, underwent fat injections to improve contour deformities in their reconstructed breasts. The study found that fat injection was effective, safe, and able to spare patients from more invasive procedures.[3] Two years later, Coleman et al examined 17 breast procedures that used fat grafting as an adjunct to aesthetic and reconstructive procedures; all patients had significant improvement in the overall size and shape of their breasts.[9]

Early reports on autologous fat injections in the breast have been mixed, and increases in breast volume have generally been modest. There continue to be safety concerns regarding the procedure, including its possible interference with cancer detection by mammography or magnetic resonance imaging (MRI) and its potential complications, such as infection, pain, palpable lumps, cysts, and fat necrosis.

In this Institutional Review Board–approved prospective study, funded by the Aesthetic Surgery Education and Research Foundation, we set out to explore the results of augmentation mammaplasty with autologous fat injection to the breast, with specific interest in volume changes, fat retention, overall aesthetic improvement, and patient satisfaction. Careful attention was given to pre- and postoperative imaging. The methodology was entirely consistent for all 10 patients, and ancillary procedures were intentionally excluded (eg, preoperative external expansion).

METHODS

Details on the design of this study (posted on http://clinicaltrials.gov) are shown in Table 1.

There were 550 patients who inquired about participating in the study between April 2007 and April 2011. Of these, 526 were excluded due to the presence of certain factors: a body mass index that fell outside the 22-29 range, previous breast surgery, or failure to meet geographical requirements (a residence fewer than 50 miles from Georgetown University Hospital). Twenty-four consultations were performed, and 13 patients were selected for this study. Two were subsequently excluded for abnormal preoperative radiographic findings, and 1 patient canceled, leaving 10 patients who would undergo augmentation mammoplasty using autologous fat transfer.

Autologous fat was harvested, typically from the abdomen or thighs, with standard low-pressure machine liposuction (500-600 mm Hg) and a 3-mm cannula. Fat was transferred into 10-cc syringes and centrifuged at 3000 rpm for 3 minutes. It was then infiltrated into multiple planes (subcutaneous, subglandular, and intramuscular) via blunt cannulae of varying caliber. The goal was to inject approximately 300 cc of fat per breast for each patient. We injected fat into the tissues until they were firm and appeared fully tumesced.

Direct measurements, 2- and 3-dimensional (2D and 3D) images, mammograms, and MRI were obtained preoperatively as baseline controls. For 1 year postoperatively, 2D and 3D imaging were repeated at 3-month intervals. Mammograms and MRI were repeated 1 year postoperatively, and a blinded board-certified radiologist with advanced training in breast imaging interpreted both preoperative and postoperative results.

Efficacy was evaluated by determining fat volume retention 1 year postoperatively. This was done by comparing baseline measurements and imaging with those taken 1 year postoperatively with VECTRA 3D imaging (Canfield Scientific, Inc, Fairfield, New Jersey) (Figure 1), standard breast MRI volume measurements taken with ImageChecker CAD software (Hologic, Bedford, Massachusetts), and subjective aesthetic comparisons based on 2D images. Due to limitations in machine calibration, only 7 of the 10 patients could be assessed with 3D imaging (Table 2). Soft tissue volume changes were derived by counting pixels within the frames of the MRI. Overall improvements in breast shape and aesthetics were evaluated on a 3-point scale (3 = substantial improvement, 2 = moderate improvement, 1 = minimal or no improvement) by a cohort of 14 blinded observers.

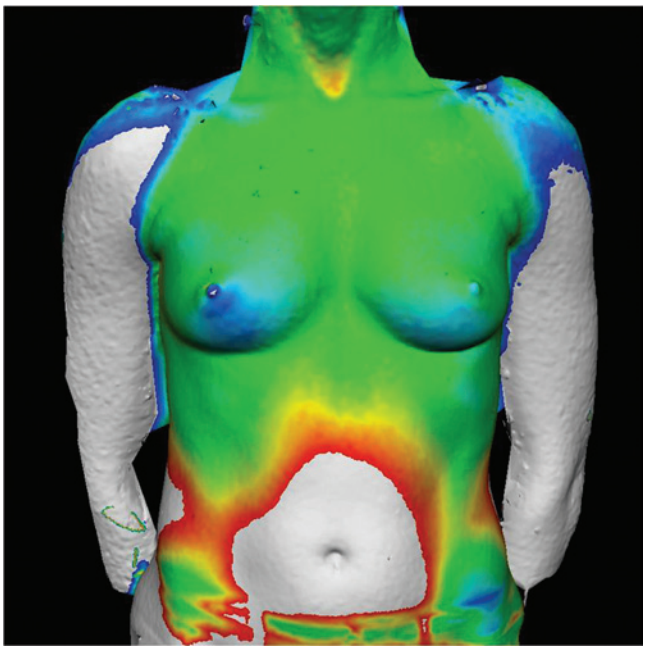

Figure 1. This VECTRA image demonstrates total volume distribution changes. Green areas indicate no change. Blue indicates an increase in volume (areas where fat was grafted). Red indicates a decrease in volume (liposuction donor site).

Patient satisfaction was assessed with an abbreviated version of the BREAST-Q[10] (Memorial Sloan-Kettering Cancer Center, New York, New York, and University of British Columbia, Vancouver, Canada) in the form of a written questionnaire administered by a plastic surgery nurse preoperatively and 1 year after the procedure.

Table 3. Overall Volume Change[a]

	Mean Volume	
Breast	Change, cc	Retention, %
Right	85.1	36.0
Left	98.1	39.2

[a]Calculated with 3-dimensional imaging for 7 of 10 patients.

RESULTS

Average patient age at the time of surgery was 30 years (range, 21-42 years; standard deviation [SD], 6.16), and the average body mass index was 23.3 (range, 20-27; SD, 2.04). Patient demographics are listed in Table 3. Average total lipoaspirate harvested at the time of surgery was 1299 cc (range, 533-2000 cc; SD, 452.2 cc). The average amount of fat injected was 236 cc (range, 90-324 cc; SD, 69.8 cc) for the right breast and 250 cc (range, 90-300 cc; SD, 65.1 cc) for the left, indicating that total graftable fat was approximately 37.4% of the original lipoaspirate. Mean operative time for all procedures was approximately 3 hours.

Based on the comparison of 3D images, the mean volume change was 85.1 cc (36% retention) for the right breast and 98.1 cc (39.2% retention) for the left. The mean soft tissue volume change, calculated with MRI, was 30.0 cc (39.8%) for the right breast and 29.3 cc (38.1%) for the left (see Table 4).

The panel that assessed and compared patients' 2D photos found substantial improvement in 1 patient (10%), moderate improvement in 5 (50%), and minimal to no

Table 2. Patient Demographics

			Weight, lbs		Bra Size		Fat Injected, cc	
Patient	Age, y	BMI	Preoperative	Postoperative	Preoperative	Postoperative	Right Breast	Left Breast
1	35	20.0	120	117	34B	34B	280	280
2	21	27.0	155	190	36B	38C	260	240
3	26	22.6	140	148	36B	36B	90	90
4	42	26.0	177	172	36B	36B	260	280
5	24	22.0	141	134	32A	32B	240	280
6	35	24.0	153	143	36C	36C	150	300
7	24	25.0	192	194	36C	38D	300	300
8	32	22.5	147	145	36B	34C	280	170
9	33	22.0	132	135	34A	34B	180	255
10	28	22.0	160	162	34B	36C	325	300

Abbreviation: BMI, body mass index.

Table 4. Magnetic Resonance Imaging Volume Measurements (cc)[a]

	Volume		Change	
Breast	Preoperative	Postoperative	Volume	Percentage
Right	75.3 (22.8)	105.5 (36.4)	30.0 (22.0)	+39.8
Range	48.6 to 125.5	63.8 to 186.6	–2.5 to 77.9	
Left	76.9 (24.3)	106.2 (32.8)	29.3 (22.7)	+38.1
Range	55.3 to 137.5	67.8 to 171.2	–13.0 to 77.2	

[a]Derived by counting pixels within the frame. Values in mean (SD).

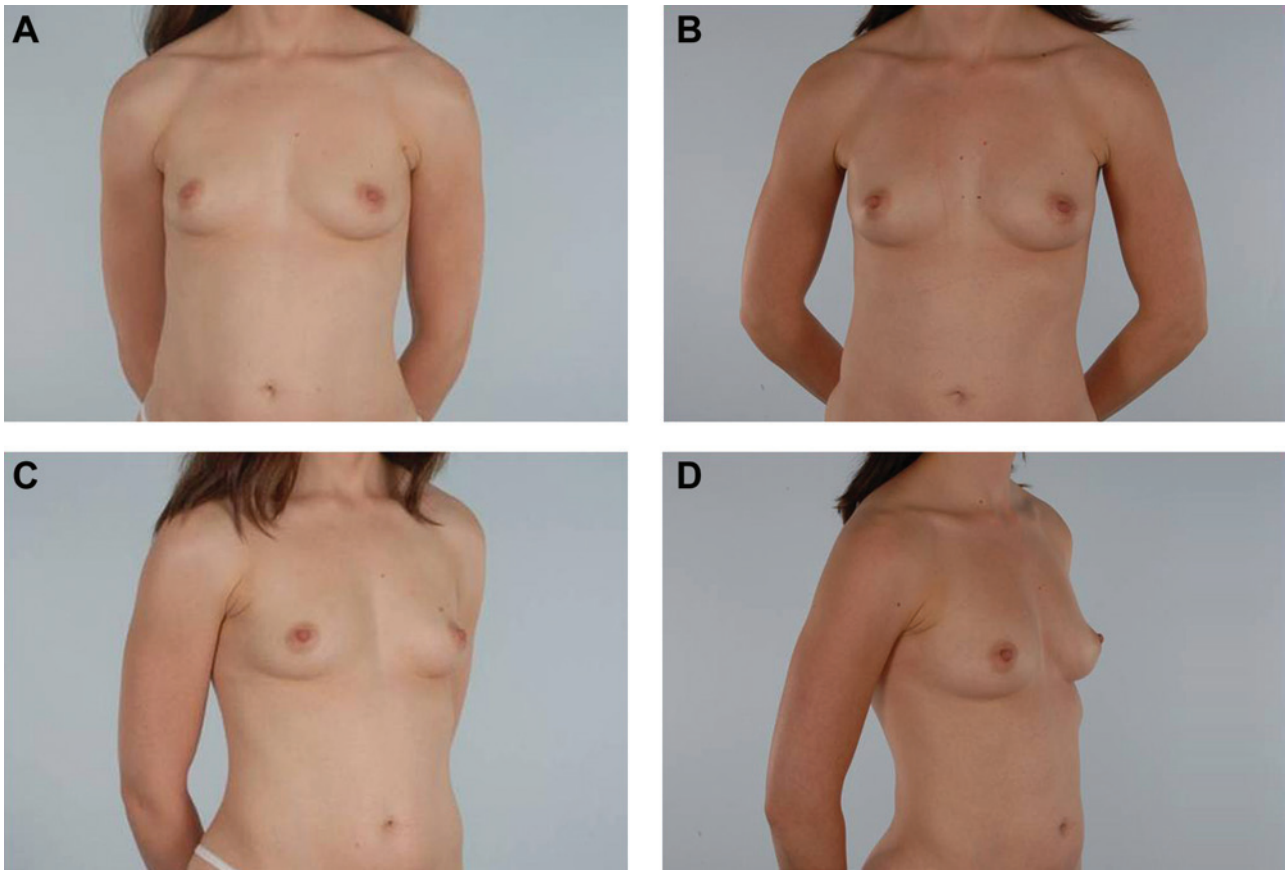

Figure 2. (A, C) This 35-year-old woman presented for lipoaugmentation of the breast. (B, D) One year after the procedure, in which total lipoaspirate was 1600 cc, yielding 560 cc of graftable fat (35%) with 280 cc of fat infiltrated on each side (50 cc, pectoral; 100 cc, subglandular; 130 cc, subcutaneous). Total volume of fat retained was 87 cc (31%) in the right breast and 123 cc (44%) in the left. This was the only patient that observers judged as having substantial improvement.

improvement in 4 (40%). There was little variation among the observers on any patient, and the mean SD among observer scores was 0.25.

Clinical results are shown in Figures 2-4, including patients who were deemed to have substantial improvement, moderate improvement, and minimal/no improvement.

There was substantial improvement in all patient-reported parameters according to the results of the questionnaire. Postoperatively, patients reported feeling pleased with the size of their breasts, more comfortable with their breasts (both clothed and unclothed), and more satisfied with the fit of their bras. In terms of sexual well-being, patients also reported feeling more attractive, sexually confident, and at ease during sexual activity. A summary of patient survey data is found in Table 5.

All patients were found to have benign preoperative mammograms and MRI results. Of the 10 patients, 5 (50%) had abnormal radiologic studies after fat injection,

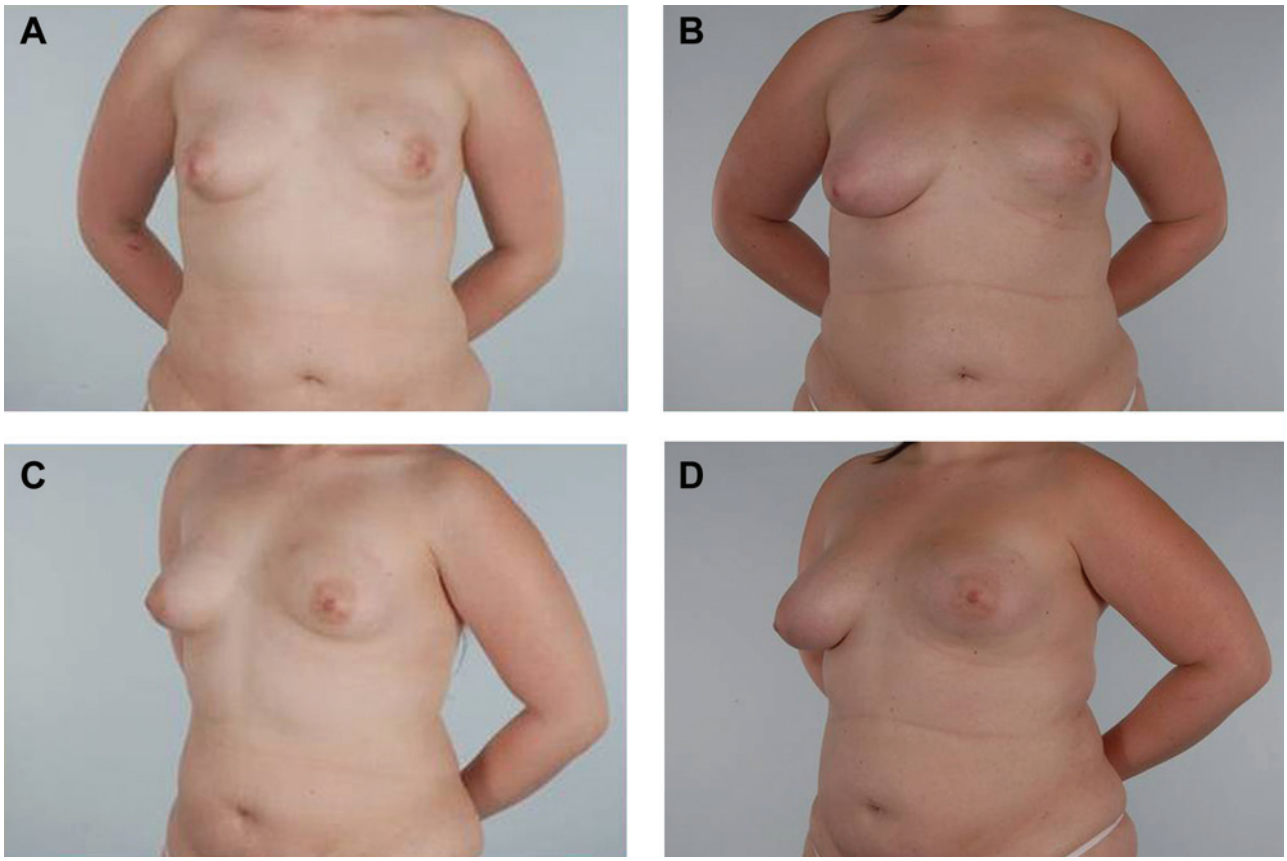

Figure 3. (A, C) This 21-year-old woman presented with severe constriction of the soft tissue envelope of the left breast and desired lipoaugmentation. (B, D) One year after the procedure, in which total lipoaspirate was 1260 cc, yielding 500 cc of graftable fat (40%) with 240 cc of fat injected into the right breast and 260 cc injected into the left. It was not possible to obtain postoperative VECTRA data on this patient due to poor calibration of the images. Magnetic resonance imaging measurements revealed a 77.9-cc volume increase in the right breast and a 77.2-cc increase on the left. This patient was judged as having minimal to no improvement by observers.

according to the Breast Imaging Reporting and Data System (BI-RADS; American College of Radiology, Reston, Virginia; Tables 6 and 7). Two (20%) patients had BI-RADS 0 postoperative mammograms. Five (50%) had postoperative BI-RADS 0 MRI, and 1 (10%) had a postoperative BI-RADS 4 mammogram (Table 7). Patients with BI-RADS 0 studies were required to undergo further imaging with breast ultrasound, and all follow-up imaging yielded negative results. The patient with the BI-RADS 4 study underwent a subsequent breast biopsy, also negative. BI-RADS classifications can be found in Table 7.

There were no acute complications in any of the patients. None complained of increased pain or palpable lumps, not even those with questionable postoperative imaging. The only long-term complication involved fat necrosis that resulted in further imaging.

DISCUSSION

In this study, autologous fat injection to the breast as a means of augmentation mammaplasty resulted in modest breast enlargement, a low percentage of fat retention, and disproportionately high patient satisfaction.

Given that this was a pilot study, we have learned several things regarding the procedure. First, volume increase may have been limited by patients' tight skin envelopes. At some point, there is no additional space to inject fat. Studies in which preexpansion was performed before fat injection reported a 60% to 200% increase in volume,[8] compared to our increase of about 40%. Selecting patients with looser skin envelopes may improve the overall volume increase. With the basic technique from this study, fat retention of 30% to 40% of infiltrated volume is a reasonable expectation. With injection volumes of 300 to 400 cc and retention of 30% to 40%, the typical patient can expect a result equivalent to an implant of 90 to 160 cc.

Second, patient satisfaction was disproportionately high. This may be attributed, in part, to satisfaction with the liposuction procedure. Many women are pleased with the idea of moving excess fat from their stomach or hips to their breasts. The affordable price of the procedure may also have contributed to patients' positive survey responses.

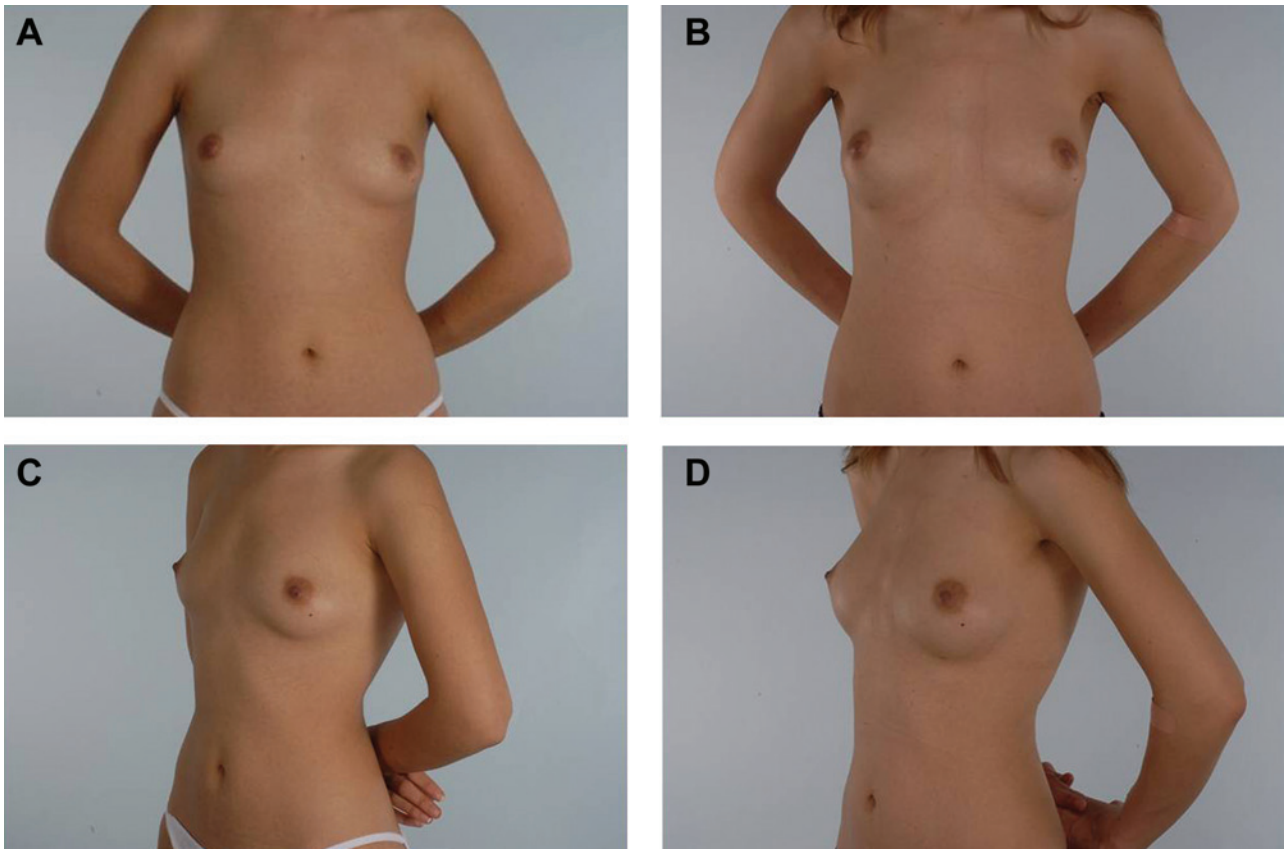

Figure 4. (A, C) This 24-year-old woman presented for lipoaugmentation of the breast. (B, D) One year after the procedure, in which total lipoaspirate was 1000 cc, yielding 540 cc of graftable fat (54%) with 280 cc of fat injected into the right breast and 260 cc injected into the left. It was not possible to obtain postoperative VECTRA data on this patient due to poor calibration of the images. Magnetic resonance imaging measurements revealed a 14.3-cc volume increase in the right breast and a 11.2-cc increase on the left. This patient was judged as having moderate improvement by the observers.

Table 5. BREAST-Q Results

	Average (Range)	
Patient Satisfaction[a]	Preoperative	Postoperative
How you look in the mirror, clothed	2.7 (1-4)	3.5 (3-4)
How you look in the mirror, unclothed	1.8 (1-3)	2.9 (2-4)
How well your breast size matches the rest of your body	2.0 (1-3)	3.1 (2-4)
How your bra fits	2.0 (1-3)	3.5 (3-4)
How much cleavage you have when you wear a bra	2.1 (1-3)	3.4 (3-4)
The size of your breasts	2.1 (1-3)	3.2 (3-4)
Sexual Well-Being[b]		
Sexually attractive in your clothes	3.4 (3-5)	4.4 (3-5)
Sexually attractive when unclothed	3.0 (1-4)	3.9 (1-5)
Comfortable/at ease during sexual activity	3.8 (2-5)	4.3 (2-5)
Confident sexually	3.7 (2-4)	4.2 (2-5)
Confident sexually in how your breasts look unclothed	2.2 (1-3)	3.8 (2-5)

[a]"In the last 2 weeks, how satisfied have you been with . . ." (4 = very satisfied, 1 = very dissatisfied).
[b]"How often do you generally feel . . ." (5 = all of the time, 1 = none of the time).

Table 6. American College of Radiology BI-RADS Categories

0: Incomplete, further imaging necessary
1: Negative
2: Benign
3: Probably benign, 6-mo follow-up recommended
4: Suspicious abnormality, consider biopsy
5: Highly suggestive of malignancy, take appropriate action
6: Known biopsy, proven malignant

Abbreviation: BI-RADS, Breast Imaging Reporting and Data System.

Table 7. Postoperative BI-RADS Results and Imaging Comments[a]

Patient	Mammogram Score	MRI Score	Findings
1	0	0	Low-density asymmetry on mammogram and enhancing foci on MRI
2	2	2	Benign
3	1	2	Negative, benign
4	0	0	Multiple areas of fat necrosis, focal asymmetries, and distortion on mammogram; significant background enhancement, hyperintense fat containing nodules and prominent axillary lymph nodes on MRI
5	2	2	Benign
6	4	0	Clustered microcalcifications in both breasts on mammogram, ovoid hyperintense enhancing nodule on MRI
7	1	2	Negative, benign
8	2	0	Left ductal dilatation with hemorrhagic or proteinaceous appearance on MRI
9	1	0	Focal area of enhancement in left breast on MRI
10	2	2	Benign

Abbreviation: BI-RADS, Breast Imaging Reporting and Data System; MRI, magnetic resonance imaging.
[a]All patients had negative or benign preoperative imaging.

Liposuction and lipofilling of the breast cost each patient approximately $2500.

One concerning finding of the study was the presence of postoperative artifacts in imaging. Of the 10 patients, 5 (50%) required follow-up imaging due to BI-RADS 0 studies. The American Society of Plastic Surgeons Fat Graft Task Force's 2009 statement noted continued concern regarding interference with cancer screening after fat grafting.[11] Fat necrosis has been reported in up to 25% of mammograms on imaging after fat injection.[12]

It has been argued that clustered microcalcifications are common after fat grafting and warrant immediate biopsy. Wang et al found that 8 of 48 patients presented with lesions suspicious for carcinoma after fat grafting, and although all lesions were found to be benign fat necroses, all patients were subjected to breast biopsies.[13]

Although fat grafting to the breast has been shown to yield fewer overall mammographic changes and lower BI-RADS ratings compared to breast reduction (a much more widely accepted procedure[14]), postoperative artifacts are concerning and must be weighed against the procedure's expected or realized benefits. Radiologic artifacts have probably been underreported by fat injection advocates and remain one of the biggest, if not the biggest, issues. While a board-certified radiologist with specialized fellowship training in breast imaging may be able to differentiate between benign fat necrosis and malignancy,[15] it is unclear how these imaging artifacts will be handled in a wider setting.

The injection of stem cell–rich material into a cancer-prone part of the body also remains a concern. Reconstructive patients who have undergone total mastectomy and fat injection for contour irregularities should be subject to more specific postoperative surveillance with clinical exam rather than imaging. Patients undergoing cosmetic fat grafting to the breast are still at risk of developing a primary cancer and will need screening mammograms with a much lower index of suspicion.

One in 8 women will develop breast cancer during her lifetime. Statistically, a percentage of patients who have had fat grafting will develop malignancy of the breast. In Coleman's 17-patient cohort, 2 women developed cancer after fat grafting—1 in the area of grafting and 1 in an area that had not been grafted.[9] Although it is highly unlikely that the fat and stem cells injected during the procedure caused the malignancy, it is a reminder of the possibility of liability in patients who develop a malignancy after fat grafting.

A limitation of this study was the assessment of preoperative and postoperative volume changes with MRI and 3D imaging. MRI volume measurements were extrapolated from pixels in the imaging. Given the nature of the sagittal cut on the MRI, it was difficult to measure the breast parenchyma fully without including fat (or pixels) along the sternum and the lateral chest wall (Figure 5). Even with the most careful analysis, standardization of these images was more difficult than anticipated.

Analyzing breast volume changes based on predetermined landmarks on the chest wall has been described as "mammometrics."[16] Three-dimensional breast imaging allows for volumetric analysis, specifically volume changes,[17] but careful attention must be given to calibration of the system and standardized patient position. Unfortunately, early in our preoperative 3D imaging, we did not appreciate this and therefore were only able to analyze volume changes using 3D imaging for 7 of the 10 patients. Mammometrics is very user-dependent and requires high-quality equipment and careful application.

Figure 5. (A) Preoperative and (B) postoperative magnetic resonance images showing volume measurements of fat extrapolated from pixels. Note the difficulty in assessing the breast parenchyma without including the sternum or lateral chest wall.

The most recent publication on guiding principles for fat transfer and injection—issued jointly by the American Society of Plastic Surgeons and the American Society for Aesthetic Plastic Surgery—highlights the following: First, fat grafting may interfere with postoperative cancer surveillance and imaging and should therefore be used with caution, particularly in women who are at high risk for developing breast cancer (eg, those with positive BRCA-1, BRCA-2, or a personal/family history of breast cancer). Second, results are surgeon dependent. Third, every patient should be provided with informed consent that acknowledges the limited evidence to verify the safety and efficacy of the procedure. Finally, physicians should use professional judgment when using these principles to guide their individual practice.[18]

CONCLUSIONS

This baseline study demonstrates that lipoaugmentation of the breast is effective and produces high patient satisfaction. It also shows that there is significant room for improvement in patient selection, site preparation, minimization of radiologic artifacts, and fat harvesting, processing, and retention. Serial fat injection and physical manipulation of the recipient site by external expansion are possible advances for this procedure. Surgeons who perform lipoaugmentation of the breast should be aware that our knowledge of this procedure remains incomplete, and patients should be informed accordingly.

Disclosures

Dr Spear is a paid consultant for Lifecell Corporation (Branchburg, New Jersey) and Allergan, Inc (Irvine, California). Dr Pittman has nothing to disclose.

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