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A Study on Breast Augmentation Using Fat Grafting With Stromal Vascular Fraction

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Background: Stromal vascular fraction (SVF) and fat grafting are emerging alternatives to implants for breast augmentation. However, the lack of controlled clinical data has led to conflicting results regarding the effectiveness of surgical treatments. This study aimed to identify the key factors affecting the outcomes of fat grafting with SVF and to recognize novel methods to improve the retention rate.

Patients and Methods: In total, 384 women underwent breast augmentation using fat grafting with SVF. The patients were preoperatively and postoperatively managed and recalled for follow-up at 3, 6, and 18 months.

Results: The average volume of the injection in the left breast was 162.35 mL (range, 50–260 mL). The postoperative retention rates were 78.65% in 384 patients at 3 months, 77.17% in 273 patients at 6 months, and 77.48% in 102 patients at 18 months. The retention rates were compared based on the number of SVF cells; patients with more than 60 million cells had a retention rate of 70.77%, and those with less than 60 million cells had a retention rate of 85.60% at 18 months. The retention rates at the 18-month follow-up were 65.62% and 85.09% in stiff and soft breasts, respectively. A higher number of cells in the SVF was associated with a greater retention volume, and the retention volume was greater in patients with soft breasts.

Given the higher use of the right arm, after 18 months of the surgery, the retention rate of the right breast (60.35%) was lower than that of the left breast (77.48%) ($P < 0.05$; $t = -13.199$).

Conclusions: Limiting arm movement, increasing the number of cells in the SVF, and improving the skin tension might enhance the retention rate in patients undergoing breast augmentation.

Key Words: stromal vascular fraction, fat grafting, breast augmentation, adipose-derived stem cells

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Breast Augmentation Using Fat Grafting

Implants have been widely used for cosmetic breast augmentation worldwide. However, surgical methods using implants leave scars and are associated with the risk of bleeding, nerve damage, and capsular contracture. In addition, cancer may develop in some rare cases.^{1,2} An alternative breast augmentation method that uses fat grafting might lead to complications, such as fat necrosis, calcification, and formation of encapsulated fatty masses (cystic lesions), thus making it a less desirable technique.^{3,4} Consequently, most cosmetic surgeons are on the lookout for a more standardized surgical method.

The use of adipose-derived stem cells (ADSCs) has been reported after their extraction from stem cells obtained from adipose tissues by Zuk et al⁵ in 2001. Stromal vascular fraction (SVF) has made significant

advancements as a therapeutic modality in recent years and is used in clinical settings in many countries.⁶ In South Korea, SVF is extracted and used in patients without incubation (as per the disclosures of the Korean Ministry Food and Drug Safety). Hence, the author has been performing fat grafting using SVF since 2007.

Subsequent studies have demonstrated that ADSCs secrete angiogenic growth factors and differentiate into vascular endothelial cells, thereby promoting angiogenesis.^{7–11} This angiogenic property of ADSCs is thought to promote fat tissue engraftment. Therefore, breast augmentation using SVF and fat grafting has been performed based on the assumption that SVF contains large quantities of ADSCs and endothelial cells, which might prove beneficial for fat grafting; several studies have demonstrated the effectiveness of this method.^{12–23} Conversely, some studies reported that fat grafting methods using SVF are not superior to conventional fat grafting in terms of the patient outcome.^{24–27}

Therefore, this study aimed to identify the key factors affecting the outcomes of fat grafting with SVF and to analyze the factors affecting the retention rate. The preoperative and postoperative management for breast augmentation was standardized using the SVF and fat grafting method. Subsequently, breast augmentation was performed on 384 patients, and the clinical outcomes of this method were analyzed.

METHODS

General Data

This study included 384 healthy Asian (Korean) women aged 20 to 59 years who underwent breast augmentation using SVF and fat grafting between 2017 and 2019 at the SC301 clinic. Patients who visited the clinic for follow-up at 3, 6, and 18 months after the treatment were analyzed; those who did not visit the clinic during these appointments were excluded.

The study was conducted according to the Declaration of Helsinki. The research objective, surgical methods, and associated cautions, risks, and side effects were thoroughly explained, and written informed consent was preoperatively obtained from each patient. The study was approved by the Korea Public Institutional Review Board Designated by Ministry of Health and Welfare (approval no.: P01-202207-01-037).

Preoperative Management

Photographs and 3-dimensional (3D) volume measurements (Axisthree, Germany) were obtained preoperatively from all patients. The Axisthree 3D scanner measures the volume by scanning the chest of the patient and assessing the volume changes using a computerized program.

The patients were carefully managed to soften the skin of their breasts preoperatively. Preoperative breast care was performed for 1 hour once a day (pressure, 300 mhg) for 5 days using a body and breast massage equipment (BARON.ST; HR Meditech, Seoul, South Korea). The frequency and pressure were adjusted according to the breast and skin condition of the patient (the parameters were extended up to 10 times at 500 mhg, if necessary).

Surgical Procedures

All the management procedures were performed by a single surgeon (S.D.J.), and the surgical procedures were performed in an aseptic environment (operation room, laboratory).

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AQ2 From the SC301 Clinic; and Anatomy School, Korea University, Seoul, South Korea. Conflicts of Interest and Source of Funding: None declared.

All stromal vascular fractions were extracted. Please check if this front matter footnote has been captured correctly. in the stem cell laboratory at the SC301 clinic. Statistical analysis was conducted by experts from MYSTATS, Korea.

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Fat Collection

The injection region in the chest and liposuction regions in the abdomen and thighs were marked. Subsequently, a circle (diameter, 12–18 cm) was drawn around the nipple and on the abdomen and thighs to demarcate the areas for fat extraction. After anesthesia, a 2-L tumescent solution (2-L normal saline +40-mL 2% lidocaine +2-mL epinephrine) was injected (cannula size, 2 × 35 cm) evenly into the abdomen and thighs, and liposuction (cannula size, 3 × 35 cm) was performed.

Stromal Vascular Fraction Isolation

All the SVFs were extracted in the stem cell laboratory at the SC301 clinic. Approximately 30 to 50 mL of SVF was extracted after purifying the collected fat via centrifugation. The fat collected was purified via centrifugation at 300g for 3 minutes. Collagenase (type 1) was added to 30 to 50 mL of the purified fat and mixed for 30 minutes. The mix was then centrifuged at 500g for 3 minutes to remove impurities, and the remaining SVF was collected. After washing twice with normal saline, the volume of the SVF was adjusted to 10 to 20 mL.

Fat Transplantation

The remaining purified fats and SVF (10–20 mL) were mixed (ratio, 9: 0.5; fat: SVF). After creating a needled hole between the breast and the armpit, the cannula (2 × 20 cm) was used to evenly inject the fat at the level below the pectoralis major muscle. Approximately 30% of the injection volume was injected at the level below the pectoralis major muscle, 30% at the level above it, and the remaining 40% between the subcutaneous and mammary tissues. Before fat grafting, the skin tension was classified as stiff or soft. The pinch test was used for the upper part of the breast and measured using a caliper (a thickness of <8 mm was classified as soft and does not get caught well or >8 mm was classified as stiff).

Postoperative Management

Oral antibiotics were prescribed for 5 days after surgery, and the dressing was changed the day after the surgery. The suture was removed 1 week after the surgery. Photographs of the breasts were taken, and volume changes were measured preoperatively and postoperatively (at 2 weeks, 1 month, 3 months, 6 months, and 18 months). The data collected from patients who visited the clinic at 3, 6, and 18 months were included in the present study.

For 6 postoperative months, the patients were advised to avoid excessive arm use and exercises, such as swimming, golf, and yoga. In addition, they were advised not to apply pressure on or massage their breasts. They were required to eat a regular diet with sufficient protein and to maintain a body weight higher than their weight on the day of the surgery.

Evaluation

Breast volume changes and cell counts were measured by a well-trained technician at the laboratory in the hospital. The Axisthree 3D scanner (Germany) was used to measure the breast volume, and the cell counter ADAM (NanoEnTek, Korea) was used to count the available number of cells in the SVF (ADAM distinguishes whether the nuclear membrane is damaged or not). Subsequently, 12 μ L of a mixture containing 50- μ L SVF solution + reagent was placed into the

measuring kit using a pipette, and the kit was inserted into ADAM. The number of cells was automatically counted. The number of cells calculated using ADAM in this article is based on the number of living cells in which the nuclear membrane is maintained, except for red blood cells and cells whose nuclei are damaged.

Changes in the volume of the left breast were measured and analyzed to simplify the measurement method and minimize calculation errors.

Statistical Analysis

Associations between the surgical conditions and outcomes were analyzed using the paired *t* test. Paired-sample statistics and correlation coefficients were obtained based on the 95% confidence interval. All analyses in the current study were conducted using the SPSS software, version 26, and a *P* value less than 0.05 was considered significant.

RESULTS

General Status

The 384 female patients were aged 20 to 59 years. They were followed up until 18 months postoperatively. Those who missed a follow-up visit were excluded. Consequently, 384, 273, and 102 patients were examined 3, 6, and 18 months after surgery, respectively. In 5 patients, multiple cystic lumps were detected at the 6-month follow-up. No other adverse effects were observed. The cystic lumps were spontaneously absorbed about 2 years later without any treatment; these patients were included in the statistical analyses.

Primary Outcome

The average breast volume before surgery was 212.54 mL (range, 65–460 mL), and an average fat volume of 162.35 mL (range, 50–260 mL) was injected. The retention rate was calculated based on the amount of fat injected (100%) and the volume of breast expansion after surgery. The retention rates were 78.65% in the 384 patients at the 3-month follow-up, 77.17% in the 273 patients at the 6-month follow-up, and 77.48% in the 102 patients at the 18-month follow-up ($P < 0.05$; Table 1). **T1**

The number of extracted cells ranged from 14.9 to 262.5 millions based on the amount of fat used and the constitution of the individual. The cell counts were compared with a count of 60 millions, which was set as an intermediate value. The postoperative measurements showed a retention rate of 72.23% among 202 patients with less than 60 million cells at the 3-month follow-up; subsequently, retention rates of 69.19% and 70.77% were observed in 152 and 58 patients at the 6- and 18-month follow-up periods, respectively. In patients with more than 60 million cells, the retention rates were 85.60% in 182 patients at 3 months, 86.72% in 121 patients at 6 months, and 85.60% in 44 patients at 18 months. These findings indicated that the postoperative progress in patients with more than 60 million cells in the SVF was better than that in those with less than 60 million cells ($P < 0.05$; Fig. 1). **F1**

The breasts were classified according to the skin tension as stiff or soft to evaluate the effects of skin tension on the clinical outcome. The retention rates were 63.78% in 174 patients with stiff breasts at 3 months, 64.17% in 122 patients at 6 months, and 65.62% in 43 patients at

TABLE 1. Clinical Outcomes After Breast Augmentation With Stromal Vascular Fraction and Fat Transplantation

	3 mo (n = 384)	6 mo (n = 237)	18 mo (n = 102)
Average injection volume (range), mL	132.35 (50–260)	162.31 (50–260)	162.25 (70–250)
Average retention volume (range), mL	127.68 (25–280)	125.26 (23–234)	125.72 (27–221)
Retention rate	78.65%	77.17%	77.48%
// <i>P</i>	14.425/<0.05	13.472/<0.05	9.945/<0.05

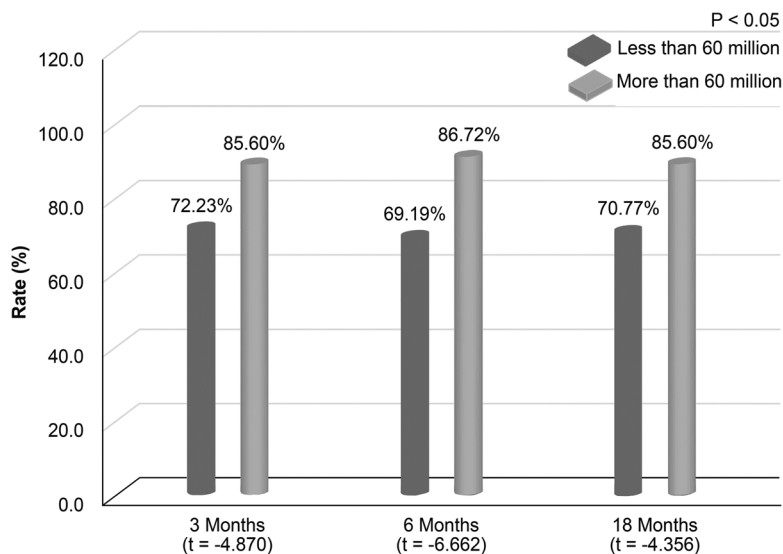


FIGURE 1. Analysis of the clinical outcomes based on the number of cells in the SVF.

18 months postoperatively. Likewise, the retention rates were 91.15%, 87.51%, and 85.09% in 210, 151, and 59 patients with soft breasts at 3, 6, and 18 months, respectively. These findings indicated that soft breasts had a greater retention volume than stiff breasts ($P < 0.05$; Fig. 2).

Case Examples of Patients After the 18-Month Follow-up

Of the 384 patients, 102 attended the 18-month postoperative follow-up with an average retention volume of 125.72 mL (77.48%). The following case examples consist of 2 patients who visited the clinic for the 6- and 18-month postoperative follow-ups. One patient presented with the highest retention rate (case 1), whereas the other presented with the lowest retention rate (case 2) among those who agreed to the use of their photographs.

Case 1 was a 40-year-old woman with a preoperative volume of 198 mL in the right breast and 189 mL in the left breast; the fat injection volumes in the right and left breasts were 180 and 166 mL, respectively

(Fig. 3). The volumes of the right and left breasts were 367 and 358 mL, respectively, at the 6-month follow-up and 366 and 350 mL, respectively, at the 18-month follow-up. The retention rates in the left breast at the 6- and 18-month follow-up periods were 80% and 96.99%, respectively.

Case 2 was a 30-year-old woman with preoperative volumes of 199 and 185 mL in the right and left breasts, respectively; the fat injection volumes in the right and left breasts were 190 and 160 mL, respectively (Fig. 4). The volumes of the right and left breasts at the 6-month follow-up were 260 and 272 mL, respectively; the corresponding values at the 18-month follow-up were 250 and 267 mL, respectively. The retention rates in the left breast at the 6- and 18-month follow-ups were 38% and 51.25%, respectively.

DISCUSSION

Breast augmentation using implants is widely performed worldwide as it allows women to obtain their desired breast size. However, the associated drawbacks include a relatively high risk of adverse effects

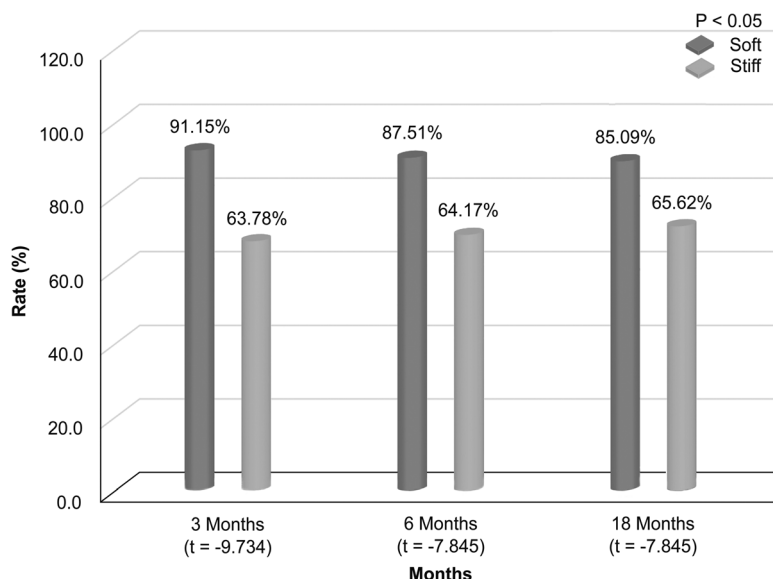


FIGURE 2. Effects of skin tension on the clinical outcomes.

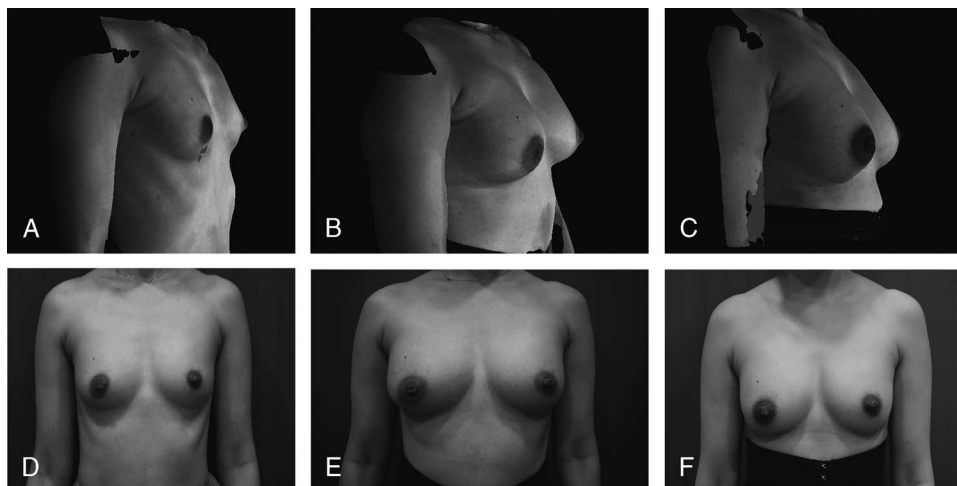


FIGURE 3. Images of a 40-year-old female patient with the highest retention rate (case 1). A and D, Preoperative image showing breast volumes of 198 and 189 mL in the right and left breasts, respectively. B and E, Six-month postoperative image showing breast volumes of 367 and 358 mL in the right and left breasts, respectively. C and F, Eighteen-month postoperative image showing breast volumes of 366 and 350 mL in the right and left breasts, respectively.

and poor durability over time. In addition, breast augmentation using fat grafting has a low retention level, which lessens patient satisfaction. Therefore, the methods using SVF and fat grafting for breast enlargement have been proposed as alternatives.

He et al¹² reported that the effects of transplantation might be enhanced after the implantation of fat particles mixed with ASCs and suggested the use of this method in the clinical setting. In addition, Schendel¹³ reported a positive correlation between the amount of retained fat by volume and the number of cells in the SVF.

Several authors have demonstrated the safety and effectiveness of using SVF.^{20–22} This article also supports demonstrated the safety and effectiveness of using SVF (Fig. 1). The findings of the current study indicate the safety of the procedure used as no other adverse effects were observed other than the presence of multiple cystic lumps in 5 patients. However, one study²⁵ reported that the use of SVF for autologous fat grafting during breast augmentation was not beneficial for graft survival or postoperative complications. Likewise, Peltoniemi et al²⁶ did not report any advantages of using the stem cell enrichment method with the Celution

system during cosmetic fat transplantation in the breast. These conflicting conclusions could be attributed to several variables. A lack of universal consensus in minimizing the effect on retention volume may result in a different outcome.

Four factors must be considered when viewing the results of the current study. First, the condition of the fat and the cell count in SVF might vary among patients. Close attention should be paid to balancing the amount of fat used between SVF extraction and the injection of fat volume.^{28,29} In this study, the group with more than 60 million cells in the SVF had better postoperative progress than the group with fewer cells ($P < 0.05$). These results indicate that the higher the number of cells in the SVF, the higher the retention rate (Fig. 1).

Second, skin tension is another important variable that can affect the retention rate of the fat graft. In their study on breast augmentation using cell-assisted lipotransfer, Jung et al³⁰ reported that skin tension could be an essential factor affecting the absorption pattern of grafted fat. A novel method to improve the surgical outcome must be developed as dense breasts are common among Asian (Korean) women. Systematic

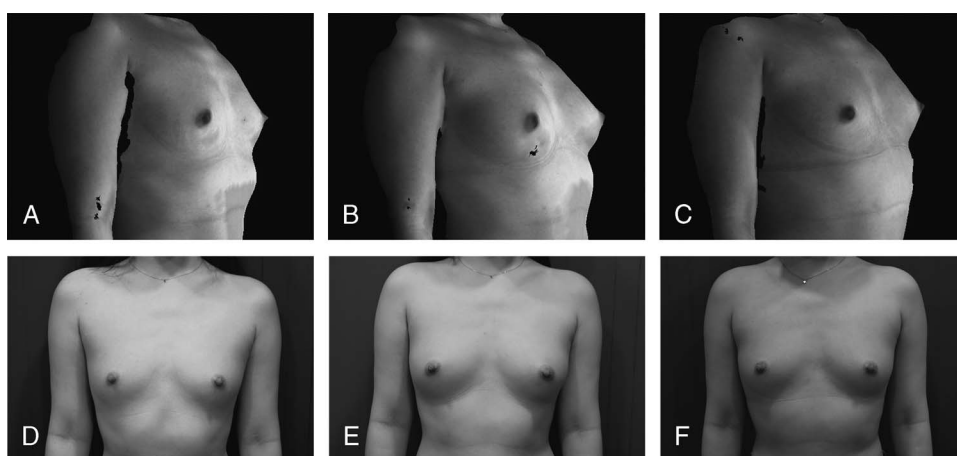


FIGURE 4. Images of a 30-year-old female patient with the lowest retention rate (case 2). A and D, Preoperative image showing breast volumes of 199 and 185 mL in the right and left breasts, respectively. B and E, Six-month postoperative image showing breast volumes of 260 and 272 mL in the right and left breasts, respectively. C and F, Eighteen-month postoperative image showing breast volumes of 250 and 267 mL in the right and left breasts, respectively.

preoperative management was used in an attempt to solve this problem in the current study. The retention rates at 18 months after surgery were 65.62% and 85.09% in stiff and soft breasts, respectively; soft skin tension was associated with a more desirable outcome ($P < 0.05$). These findings suggest that better results can be obtained if the skin tension is improved through active preoperative management (Fig. 2).

Third, frequent or strenuous activities that involve arm movement could decrease the effectiveness of the surgical procedure; thus, patients were advised to avoid arm exercise and arm use as much as possible during the first 6 months after surgery. At 18 months postoperatively, the retention rate of the right breast (60.35%) was lower than that of the left breast (77.48%) ($P < 0.05$; $t = -13.199$). This might be due to the high use of the right arm. There is no direct evidence of higher retention rates in nondominant arm. We also asked patients to limit the use of their arms, but these patients' behaviors could not be quantified and presented as statistics in the article. However, in the authors' experience, patients who mainly used the left arm had higher retention rates of the right breast, and patients who confessed to doing some exercise had lower retention rates than other patients. We believe that the most reasonable explanation among many other possibilities is that less use of arm. Avoiding the use of the arm might increase the retention rate.³¹

Fourth, the use of the SVF and fat for breast augmentation might not allow for the injection of the desired volume of fat by the operator due to the development of adverse effects or the lack of sufficient fat for enlargement. Korean women usually use 250 to 300 mL of implants for breast augmentation with breast implants.³² However, in the current study, the average retention volumes for breast augmentation using SVF and fat were 108.36 and 125.72 mL for the right and left breast, respectively, at the 18-month follow-up. This can be an important cause for the reduction in both patient and operator satisfaction.

In this study, we were unable to directly compare cases using SVF and those not using SVF. Moreover, we were unable to quantify the use of the arm; thus, we could not directly analyze the effect of using the arm. Nevertheless, factors that affected the retention rate were identified through indirect comparison.

CONCLUSIONS

In this study, the number of cells in the SVF and skin tension affected the retention rates in patients who underwent breast augmentation surgery. Furthermore, arm movement was found to decrease the effect of the surgery. Therefore, it is important to identify methods for increasing the number of cells in the SVF and improving skin tension to achieve better surgical outcomes.

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