

A Prospective Pilot Study Comparing Rate of Processing Techniques in Autologous Fat Grafting

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Abstract

Background: Autologous fat grafting (AFG) is increasing in popularity to address a variety of defects. There is interest in developing techniques to harvest, process, and inject fat to improve clinical outcomes as well as operative efficiency.

Objectives: The purpose of this pilot study is to compare the rate of graft processing of two commercially available systems for graft preparation.

Methods: Twenty consecutive cases using an active filtration system (system-AF) were observed followed by 20 consecutive cases using a passive filtration system (system-PF) to compare efficiency rate. Fat processing rate was quantified in milliliters/minute.

Results: Forty patients underwent AFG with no differences in patient characteristics between the groups. There was 1 incidence of palpable fat necrosis per group (5%). For all patients, this was the first fat grafting procedure; 20% of patients (n = 4 per group) had additional fat grafting. Overall, the rate of adipose tissue preparation was significantly higher with system-AF compared to system-PF (19.8 mL/min vs 5.3 mL/min, $P \leq 0.001$). The resulting percent of graftable fat was comparable (AF: 41% vs PF: 42%; $P = 0.83$).

Conclusions: Time and motion studies such as this provide a means to systematically document each of the steps involved in fat grafting in a reliable fashion. The authors demonstrate a significantly higher rate of lipoaspirate processing using an active filtration system compared to a passive system. Further large-scale studies of the efficacy and cost analysis of AFG are a necessary component of determining best practices in the field.

Level of Evidence: 2

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Autologous fat grafting (AFG) is widely used in a variety of applications including congenital anomalies, aesthetic refinements, posttraumatic defects, and oncologic reconstruction. As the indications for AFG continue to expand and the number of lipofilling procedures increases, so have the number of techniques and commercial devices aimed to improve the efficiency of fat graft harvest. There are multiple methods to prepare fat for grafting, including washing, decanting, centrifugation, filtration, or enzymatic digestion.¹⁻³ However, despite its increasing popularity, there is a paucity of data to support or refute the differences among these assorted techniques in terms

of short- or long-term outcomes, graft retention, or cost.⁴ Furthermore, there have been few direct comparisons of these methods in clinical studies, and no consensus currently exists as to the advantages and disadvantages of

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these various techniques due to inadequate study design, power, and follow-up.⁵

The purpose of lipoaspirate processing is to remove potentially pro-inflammatory substances such as oil, blood, and cellular debris resulting from the mechanical damage of the harvesting process. In a recent survey of members of the American Society of Plastic Surgeons (ASPS), there was a relatively even distribution of respondents' preferred processing technique, including centrifugation (34%), filtration (34%), and washing or rinsing (28%).⁶ Since this survey was conducted, a few device-based processing systems have become commercially available and gained popularity.

The Puregraft™ system (Cytos Therapeutics, San Diego, CA, USA) is a passive filtration system (system-PF) and consists of a double-layer filtration bag with afferent and efferent ports allowing for the transfer of lipoaspirate and Lactated Ringer's (LR) solution for washing. Lipoaspirate can be harvested via a hand-held syringe or machine-assisted suction, depending on the system used. Once the graft collection is complete, the lipoaspirate is transferred to the filtration bag, rinsed for 30 seconds with LR, and passively drained by gravity through the efferent port for approximately 3 minutes. This process is repeated for a total of 2 washes.

The Revolve™ system (LifeCell™ Corporation, Branchburg, NJ, USA) is an active filtration fat processing system (system-AF) that similarly uses washing with LR. Lipoaspirate is harvested directly into the closed system using mechanical suction. The device consists of an outer canister and an inner filter basket that collects the lipoaspirate. The adipose tissue is washed with LR solution for 30 seconds, and the wash solution containing lysed cellular debris is drained from the fat in the inner filter basket to the outer canister and then out through a suction port. This process is repeated for a total of 3 washes.

At present, there are no well-designed, large-volume studies examining the benefits of one type of fat grafting technique over another. With the increasing popularity of AFG in the field of cosmetic and reconstructive plastic surgery and continuing changes in reimbursement and healthcare, there is a need for controlled studies to decipher the utility of new products developed to improve clinical outcomes. Time and motion studies are 1 method to elucidate objective data on both the human and cost burden associated with a set of tasks. The data obtained allow assessments to be made regarding efficiency and performance and to identify areas for improvement. The purpose of this study is to compare the rate of fat graft processing of 2 commonly used commercially available systems. Our primary hypothesis was that preparation with an active filtration system connected to mechanical suction (Revolve™ system-AF) will reduce processing time and yield higher volumes of graftable adipose tissue compared to the closed system using gravity drainage (Puregraft™ 250 system-PF).

METHODS

We performed a prospective, observational, pilot study of 40 consecutive cases of AFG at the University of Texas MD Anderson Cancer Center over a 6-month study period, November 2013 to May 2014. The first 20 patients were assigned to system-AF, and the subsequent 20 patients were assigned to processing via system-PF. Prior to the study, a training in-service was performed for both techniques to ensure familiarity among the surgeons and operating room staff. While the primary objective was to compare the rate of tissue processing between the 2 systems, this study also served to establish the feasibility of a larger, more structured time and motion study of different fat grafting techniques. The protocol was approved by the Institutional Review Board at MD Anderson.

Surgical technique was performed according to a checklist protocol for each of the methods studied. Tumescence solution was used with either technique according to the surgeon's standard practice with a limit of 1 liter. With system-PF, lipoaspirate was harvested via a hand-held syringe (60 mL) and 3- or 4-mL cannulas. Once the graft collection was complete, the lipoaspirate was transferred to the filtration bag, rinsed for 30 seconds with LR, and passively drained by gravity through the efferent port for approximately 3 minutes. This process was repeated for a total of 2 washes. The resulting graft was then transferred to 10-mL syringes for grafting.

System-AF uses mechanical-assisted liposuction with 3- and 4-mL cannulas and a standard 700 mmHg setting. Lipoaspirate was harvested directly into the closed system, where the tissue is then rinsed with LR solution for 30 seconds and filtered or drained through a suction port. This process was repeated for a total of 3 washes. The resulting graft was transferred to 10-mL syringes for grafting.

The authors set a minimum lipoaspirate volume of 100 mL with the total amount being left to the surgeon's discretion. If the volume of lipoaspirate required was more than the capacity of the system used—250 mL for system-PF or 350 mL for system-AF—the unit could be refilled and reused 1 time according to the manufacturer's protocol. Graft injection technique was surgeon dependent but in general was performed in a multiplanar fashion using blunt-tipped Coleman cannulas with retrograde delivery. Use of rigotomies and the actual volume deposited per pass were not recorded in this study.

An independent observer was present in the operating room to prospectively record the timing of each step (harvesting, processing, and preparation) as well as volume of fat graft obtained for injection. Patient demographics were also reviewed, including age, body mass index (BMI), breast cancer surgery (mastectomy versus vs breast conservation therapy), prior chemotherapy, prior radiation therapy, type of breast reconstruction (implant based

versus vs autologous), and immediate postoperative complications. Overall complications included one 1 or more of the following:⁷ infection, hematoma, seroma, palpable fat necrosis, or fat embolism. The following definitions were developed for this study protocol: Adipose tissue harvested, defined as the volume (milliliters, mL) of lipoaspirate prior to processing. Adipose tissue prepared, defined as the volume (mL) of adipose tissue that remains after processing via each technique. Adipose injected, defined as the volume (mL) of adipose graft delivered to the recipient site. Percentage of graftable fat, defined as the ratio of adipose prepared to adipose harvested. Time to harvest, defined as the time (min) from when the liposuction cannula is introduced to the donor site to when liposuction is complete (for either mechanical- assisted or hand-assisted liposuction); for system-PF, this includes the transfer of lipoaspirate from the hand-held syringes to the processing apparatus; for system-AF, the lipoaspirate is collected in the processing apparatus. Time to process, defined as the time (min) from when the LR solution is introduced to the apparatus for rinsing until the adipose tissue is transferred to syringes for injection; for system-PF, 2 rinses were performed with the fluid and impurities allowed to drain after each cycle according to manufacturer's recommendations;⁸ for system-AF, 3 rinses were performed with the resulting fluid and impurities allowed to drain after each wash according to manufacturer's recommendations.⁹

Statistical Methods

Means and standard deviations were used to summarize continuous patient characteristics. Frequencies and proportions were used to present categorical patient characteristics. We compared patients' demographics, complications, and the time and volume of fat harvested and prepared between the 2 cohorts using the Chi-squared test or Fisher's exact test for categorical variables and Student's *t* test or a nonparametric test (Wilcoxon rank sum test) for continuous variables as based on the normality test. All tests were 2-sided. A *P* value of < 0.05 was considered significant. The analyses were performed in SAS 9.2 (SAS Institute Inc., Cary, NC).

RESULTS

Patient Characteristics

All patients (*n* = 40) were female with a history of breast cancer. Mean age was 51.5 years (SD ± 8.5 years; range, 37-70 years). The average body mass index was 27.3 kg/m² (SD ± 4.2 kg/m²; range, 19.4-39 kg/m²). The average follow-up was approximately 3 years (35.5 months; range, 12.4-47.2 months). All patients had previously undergone

mastectomy with breast reconstruction at our institution; there were no patients in either cohort who had breast conservation therapy. More patients had completed 2-staged tissue expander to implant-based reconstruction (*n* = 26, 65%) compared to autologous reconstruction (*n* = 14, 35%). The majority of patients (*n* = 36, 90%) received chemotherapy, and less than half of patients received radiation therapy (*n* = 18, 45%) prior to their fat grafting. Four patients (10%) had a postoperative complication. There was 1 incidence of palpable fat necrosis per group, and no fat emboli in the study population. For all patients, this was the first fat grafting procedure; 20% of patients (*n* = 4 in each group) went on to have additional fat grafting. All other patient demographics and reconstruction characteristics were not statistically different between the 2 groups (Table 1).

Adipose Tissue Processing

The volume of adipose tissue harvested and prepared was recorded at each step in the procedure as well as the time to accomplish each step as defined above (Table 2). There was significantly more lipoaspirate harvested and prepared using system-AF compared to system-PF (492 mL vs 352 mL, *P* = 0.02 and 196.4 mL vs 135.8 mL, *P* = 0.01, respectively), while the time to complete these steps was significantly less using system-AF compared to system-PF (12.6 min vs 17.8 min harvesting, *P* = 0.02; 10.3 min vs 26.1 min processing, *P* ≤ 0.001, respectively). Overall, the rate of adipose tissue harvesting and preparation were both significantly higher when using system-AF (40 mL/min vs 19.5 mL/min, *P* ≤ 0.001 and 19.8 mL/min vs 5.3 mL/min, *P* ≤ 0.001, respectively). The resulting percent of graftable fat was similar for both systems (41% system-AF vs 42% system-PF, *P* = 0.83).

DISCUSSION

AFG now represents a commonly employed technique in the plastic surgeon's armamentarium. As the number of these procedures continues to increase each year, there is value in determining strategies to optimize the efficiency of fat grafting. The present prospective study compared the rates of fat graft harvest and preparation and demonstrates that system-AF was significantly more efficient than system-PF. While there was no difference in the resulting percentage of injectable fat, the preliminary results of this pilot study demonstrate proof of concept for a larger study to examine the validity of implementation of time motion protocols in fat grafting, which is currently underway at our institution.

There is currently no consensus to support one fat grafting and processing technique over another. However,

Table 1. Patient Characteristics

Characteristics	All N = 40	System-AF N = 20	System-PF N = 20	P value
Age, yr	51.5 (8.5)	52.3 (7.5)	50.5 (9.5)	0.43
Range	37-70	37-70	37-68	
BMI, kg/m ²	27.3 (4.2)	27.2 (4.1)	27.5 (4.1)	0.80
Range	19.4-39	19.4-39	20-33.7	
Follow up, months	35.5 (7.7)	38.3 (6.2)	32.7 (9.1)	0.07
Range	12.4-47.2	23-47.2	12.4-46.2	
Mastectomy	40 (100%)	20 (100%)	20 (100%)	>0.99
Chemotherapy	36 (90%)	18 (90%)	18 (90%)	>0.99
Radiation therapy	18 (45%)	7 (35%)	11 (55%)	0.20
Implant	26 (65%)	14 (60%)	12 (60%)	0.74
Autologous tissue	14 (35%)	6 (30%)	8 (40%)	0.74
Overall complications	4 (10%)	2 (10%)	2 (10%)	>0.99
Cellulitis	1 (2.5%)	1 (5%)	0 (0%)	>0.99
Hematoma	1 (2.5%)	0 (0%)	1 (5%)	>0.99
Fat necrosis	2 (5%)	1 (5%)	1 (5%)	>0.99
Fat embolism	0 (0%)	0 (0%)	0 (0%)	>0.99
Additional fat grafting	8 (20%)	4 (20%)	4 (20%)	>0.99

BMI, body mass index; system-AF, active filtration, REVOLVE™ fat grafting system; system-PF, passive filtration, Puregraft™ 250 fat grafting system.

there have been a number of *in vitro* and animal studies comparing different techniques. When comparing fat graft processing with washing and centrifugation to decanting alone, decanting was found to have worse adipocyte viability and increased oil contaminants.^{4,10} When centrifugation was compared to rolling the adipose tissue on gauze or Telfa, adipocyte viability was comparable to centrifugation,¹¹⁻¹³ but the technique is not feasible for large-volume grafting cases. Not surprising, new devices are regularly emerging to streamline this process and increase the efficiency of fat grafting. Further, these new devices, including the 2 analyzed in the present study, have also demonstrated increased purity of the fat graft obtained as well as greater adipocyte and stem cell yield compared to traditional techniques.^{14,15} To our knowledge, this is the first clinical study in the literature directly comparing the 2 systems included in the present study.

Clinical outcomes studies are limited in patient volume, retrospective design, and poorly defined outcome measures. Establishing reliable and reproducible best practices is a challenge given the high variability in graft resorption. Furthermore, there are no well-established objective measures to determine resorption or retention, and patient reported outcome measures such as the BREAST-Q are not

specific to the graft procedure but rather the reconstruction as a whole. Prospective comparative protocols and a core outcomes set are required for meaningful clinical data moving forward.

As an alternative or parallel outcome measure, time and motion (TM) studies offer quantitative data collection of the duration and steps to complete a set task and may offer insight to improve efficiency. Such non-interventional studies in healthcare have identified inefficiencies in documentation, medication administration, and clinical care coordination in surgical and intensive care units.¹⁶⁻¹⁸ Though relatively under-utilized in plastic surgery, data based on TM principles have led individual optimal practices in breast augmentation¹⁹ and limb preparation.²⁰ Tebbetts extensively analyzed the patient pathway in breast augmentation not only to improve surgical performance and patient experience, but develop reproducible outcomes each step of the way.²¹⁻²³ TM analysis was applied to patient and staff education, preoperative planning, setup and instrumentation, surgical technique, and postoperative recovery. In the setting of AFG, the steps to complete the task at hand can be categorized as tissue harvest, graft processing, and reinjection or graft placement. The variability in methodology of each step can potentially

Table 2. Adipose Tissue Processing Measures

Measurement	All N = 40	System-AF N = 20	System-PF N = 20	P value
Tumescence (mL), mean (STD)	623.7 (401.6)	422.2 (393.8)	805.0 (319.9)	0.01
Fat harvested (mL)	422.3 (193.5)	492.0 (170.9)	352.0 (193.1)	0.02
Time to harvest (min)				
Median (range)	15.2 (7-32)	11.0 (7-24)	15.0 (7-32)	0.02
Mean (STD)	15.2 (6.9)	12.6 (4.6)	17.8 (7.8)	-
Harvested fat per minute (mL/min)				
Median (range)	30.6 (7.6-100)	40.0 (11.5-100.0)	19.5 (7.6-38.5)	<0.001
Mean (STD)	32.8 (20.4)	44.0 (21.8)	21.5 (10.4)	-
Fat prepared (mL), mean (STD)	166.1 (78.3)	196.4 (79.1)	135.8 (66.1)	0.01
Time to prepare				
Median (range)	15.5 (4-48)	9.5 (4-20)	26.5 (8-48)	<0.001
Mean (STD)	18.2 (10.9)	10.3 (4.3)	26.1 (9.7)	-
Prepared fat per minute (mL/min)				
Median (range)	13.0 (1.2-70)	19.8 (5-70)	5.3 (1.2-13.8)	<0.001
Mean (STD)	14.0 (12.9)	22.2 (13.8)	5.7 (3.1)	-
Fat injected (mL), mean (STD)	133.2 (58.3)	154.0 (58.2)	112.5 (51.8)	0.02
Percentage of graftable fat* Mean (STD)	0.42 (0.15)	0.41 (0.35)	0.42 (0.35)	0.83

STD, standard deviation; system-AF, active filtration, REVOLVE™ fat grafting system; system-PF, passive filtration, Puregraft™ 250 fat grafting system. * Percentage of graftable fat defined as the ratio of adipose prepared to adipose harvested.

affect not only the clinical outcomes—yet to be adequately determined—but the duration of the procedure as well. With evolving technologies and reimbursement policies, our objective is to quantify the effect of different tissue processing techniques on the dynamics of the operation. The information obtained will lead to more efficient fat grafting procedures, reducing operative times and patient exposure to anesthesia, and establish best practices for AFG.

The results of this pilot study demonstrate significant differences in rate of adipose tissue graft processing, in milliliters per minute, which may translate to savings such as reduced operative time. A recent cost comparison of centrifugation vs the Revolve™ system in a single surgeon practice demonstrated an economical benefit in cases with planned volumes > 75 mL graft with an average “rate of fat transfer” (defined as volume of fat injected/operative time) of 4.69 mL/min for Revolve™ and 1.77 mL/min for centrifugation.²⁴ Similarly, Gabriel and colleagues reviewed their “rate of fat transfer” (volume of fat injected/operative time) and found 6.05 mL/min for Revolve™ and 0.98 mL/min using centrifugation.²⁵ While there may be some validity to these studies, there is the risk of bias given the authors’ industry involvement and conflicts of interest.²⁶

While the evidence to support safety and effectiveness of fat grafting for breast reconstruction increases among the various techniques, the efficiency remains open for debate. Prospective TM studies such as this provide a means to document each of the steps involved in fat grafting in a systematic way. Thus, there may be an opportunity for cost and time savings based on the technique employed.

The limitations of this study include the consecutive nature of the cases and non-randomized assignment. Another limitation of the study is the lack of a centrifugation technique, which is the most popular form of autologous fat graft harvest used by ASPS members. However, our follow-up prospective, randomized study will include the Coleman technique to serve as a control. The phenomenon of a learning curve is another potential confounding factor in the present study, as the majority of surgeons had more experience using system-PF compared to system-AF, which was recently made available at our institution. Finally, the overall volume of lipoaspirate harvested in each technique may have an unintentional effect on processing. The authors set a minimum volume of 100 mL but did not limit the maximum volume. The total volume was left to surgeon preference with the expectation that the volumes

would be similar among the systems over the 20 patients, based on similar overall body habitus and distribution of implant and flap-based reconstructions. However, there was a significantly higher volume of lipoaspirate in the PF cohort compared to the AF cohort. Consequently, based on the findings of this pilot study, we developed protocols and implemented uniform training sessions for each system based on manufacturer's instructions and best practices in an effort to standardize and control for variability among surgeons and operating room staff.

CONCLUSIONS

AFG is a valuable tool in nearly all aspects of plastic surgery that is growing in popularity, leading to new devices aimed to increase efficiency and yield of injectable fat. We demonstrate a difference in time, volume, and, therefore, rate of tissue processing in 1 step of this process using 2 commercially available systems in the operating room. The present pilot study demonstrates the need and feasibility of a larger scale, randomized prospective study examining TM analysis, operative efficiency, and costs associated with AFG.

Disclosures

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

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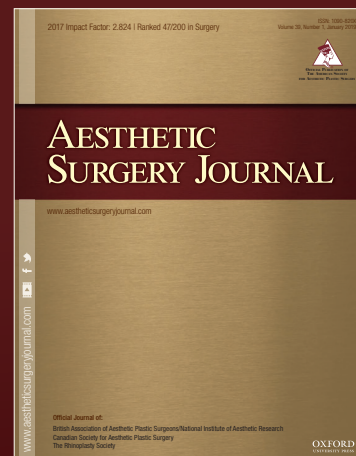
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