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ORIGINAL RESEARCH

A Prospective Control Trial Of Fat Graft Processing Technique At A Tertiary Care Hospital

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ABSTRACT

Introduction: Autologous fat grafting is an aesthetic and reconstructive procedure in which an individual's own fat is harvested and injected into the soft tissues to correct contour and other abnormalities. Fat graft is considered the ideal soft tissue filler for its biocompatibility, lack of immunogenicity and availability.

Materials and Methods: There were two groups and the first 25 patients were assigned to system-AF and the subsequent 25 patients were assigned to processing via system-PF. The operating surgeons and operating room staff were adequately trained before the procedure. Tumescence solution was used with either technique based on the surgeon's standard practice with a limit of 1 litre. Means and standard deviations were used to abstract the continuous patient characteristics. Frequencies and proportions were used to present categorical patient characteristics.

Results: All patients (n = 50) were female with a history of breast cancer. Mean age was 51.7 years (SD ± 8.3 years; range, 36-70 years). The average body mass index was 27.6 kg/m^2. The average follow-up was approximately 3 years (35.5 months; range, 12.4 - 47.2 months). All patients were reportedly undergone mastectomy earlier with breast reconstruction. More patients had completed 2-staged tissue expander to implant-based reconstruction (n = 32, 65%) compared to autologous reconstruction (n = 19, 38%). The majority of patients (n = 45, 90%) received chemotherapy, and less than half of patients received radiation therapy (n = 23, 45%) prior to their fat grafting. Five patients (10%) had a postoperative complication. There was 4 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; 25% of patients (n = 4 in each group) went on to have additional fat grafting. All other patients demographics and reconstruction parameters were not statistically different between the 2 groups.

Conclusion: AFG is essentially served as a valuable tool for majority of the plastic surgery that is increasing in its popularity that could possibly leading to new devices that were aimed to increase the efficacy and yield of injectable fat.

Keywords: Fat Graft, Fillers, Centrifugation, AFG.

INTRODUCTION

There are various ways documented in the literature in order to correct the soft tissue defects but autologous fat grafts which are used as a filling material are significantly better with good clinical outcomes. Fat is reportedly an ideal filling material since it is autologous, easily accessed, hugely abundant in the body, observably having low immunogenic and allergic reactivity.[1]But, fat grafts often observed to have high rates of resorption and major replacement with fibrous scar tissue or calcified oil cysts, which can easily promote the aftereffects and result in difficulties in interpreting various radiological images associated with breasts.[2]

Autologous fat grafting (AFG) is most widely used in vast clinical applications that majorly include various congenital anomalies, aesthetic refinements, posttraumatic defects and oncologic reconstruction. Since the indications associated for AFG continue to increase and the number of lipo-filling procedures indirectly increases in order to have the number of techniques and commercial devices that are helpful to enhance the efficacy of fat graft harvest. There are reportedly multiple methods to prepare fat for grafting that include washing, decanting, centrifugation, filtration, or enzymatic digestion.[3,4] Autologous fat grafting is a host-compatible, non-immunogenic and inexpensive and therefore allows easy and repeated harvesting.[1] Additionally, autologous fat is considered to be a ideal soft tissue filler because of its low complication rate and least possibility to induce foreign body reactions that occur with other materials. But the unpredictability of long-term graft retention because of the variable resorption rate of autologous fat has always been a demerit of free fat transfer; with resorption rates ranging between 20% and 80%.[5,6]There are few cases with the exception of involving multiple procedures. There are reportedly various factors that could possibly affect the survival of a fat graft which include hypoxia or tissue ischemia due to the lack of adequate neovascularization. This neovascularization principle has been documented as a mechanism that possibly lowers the survival rate. Although various methods have been recommended in order to improve the rate, the optimal technology for handling adipose tissue remains controversial.[4]

Modern-day AFG is both patient- and surgeon-oriented and it majorly involves identifying the optimal donor site with excess adipose tissue, harvesting fat through liposuction, processing that lipo-aspirate into an injectable form and adequately delivering the graft in small aliquots into the recipient site.[7]*Neuber's*prime observations with fat grafting proposed that "grafts larger than an almond would not give good results"—fat grafting has become more sophisticated.[1] One particular area to be emphasised is that the processing step that should be performed in order to minimise the contaminants within the lipo-aspirate while preserving adipocytes and other progenitor cells that are present in the graft which are observably fragile and highly sensitive to trauma and ischemia.[8]

MATERIALS AND METHODS

After obtaining the proper clearance from the institutional ethical committee, we conducted a prospective, observational study which includes50 consecutive cases of AFG that were performed at our institution over a 6-month period. There were two groups and the first 25 patients were assigned to system-AF and the subsequent 25 patients were assigned to processing via system-PF. The operating surgeons and operating room staff were adequately trained before the procedure. Tumescence solution was used with either technique based on the surgeon's standard practice with a limit of 1 litre.

With system-PF, lipo-aspirate was harvested using a hand-held syringe (60 mL) and 3- or 4-mL cannulas. Once the graft collection was complete, the lipo-aspirate was transferred to the filtration bag, rinsed for 30 seconds with LR and was passively drained using gravity through

the efferent port for 3 minutes approximately. This process was repeated for a total of 2 washes. The resulting graft was then transferred to 10-mL syringes for grafting procedure.
System-AF uses mechanically-assisted liposuction with 3 and 4-mL cannulas and a standard 700 mmHg setting. Lipo-aspirate was harvested directly within the closed system where the tissue is then rinsed with LR solution for 30 seconds and filtered 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 following definitions were developed for this study protocol: Adipose tissue harvested (mL) of lipoaspirate before the processing. Adipose tissue prepared (mL) as the volume of adipose tissue that remains after processing through each technique. Adipose injected as the volume (mL) of adipose graft delivered to the recipient site. Percentage of graft able 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. 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 based upon the manufacturer's protocol;[9] for system-AF, 3 rinses were performed with the resulting fluid and impurities allowed to drain after each wash according to manufacturer's recommendations.[10]
Means and standard deviations were used to abstract the 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. A P value of <0.05 was considered statistically significant.

RESULTS

All patients (n = 50) were female with a history of breast cancer. Mean age was 51.7 years (SD ± 8.3 years; range, 36-70 years). The average body mass index was 27.6 kg/m^2.The average follow-up was approximately 3 years (35.5 months; range, 12.4-47.2 months). All patients were reportedly undergone mastectomy earlier with breast reconstruction. More patients had completed 2-staged tissue expander to implant-based reconstruction (n = 32, 65%) compared to autologous reconstruction (n = 19, 38%). The majority of patients (n = 45, 90%) received chemotherapy, and less than half of patients received radiation therapy (n = 23, 45%) prior to their fat grafting. Five patients (10%) had a postoperative complication. There was 4 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; 25% of patients (n = 4 in each group) went on to have additional fat grafting. All other patients demographics and reconstruction parameters were not statistically different between the 2 groups as depicted in Table 1.

Table 1: Patient Characteristics

Parameters	Overall (N = 50)	System – AF (N = 25)	System – PF (N = 25)	P – value
Age (years) Range	51.7 (8.3) 36 – 70	52.5 (7.7) 36 – 70	50.8 (9.2) 36 – 69	0.47
BMI (kg/m^2)	27.6	27.5	25.4	0.81
Follow – up range (months)	12.2 – 46.8	22.8 – 47.4	12.6 – 46.7	
Mastectomy	50 (100%)	25 (100%)	25 (100%)	>0.97

Chemotherapy	45 (90%)	22 (90%)	(90%)	>0.97
Radiation therapy	23 (46%)	9 (38%)	(55%)	0.22
Implants	32 (65%)	15 (60%)	(60%)	0.76
Autologous tissue	19 (38%)	7 (30%)	(42%)	0.76
Complications	5 (10%)	2 (10%)	2 (10%)	>0.97
Cellulitis	1 (3%)	1 (6%)	0 (0%)	>0.97
Hematoma	1 (3%)	0 (0%)	1 (5%)	>0.97
Fat necrosis	4 (8%)	2 (8%)	2 (8%)	>0.97
Fat embolism	0 (0%)	0 (0%)	0 (0%)	>0.97
Additional fat grafting	12 (25%)	6 (25%)	6 (25%)	>0.97

The volume of adipose tissue that were harvested and prepared was recorded at each step in the procedure as well as the time to achieve each step as defined in the Table - 2. There was significantly more lipo-aspirate harvested and prepared using system-AF compared to system-PF 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).

Table 2: Adipose Tissue Processing Measures

Parameters	Overall (N = 50)	System – AF (N = 25)	System – PF (N = 25)	P – value
Tumescence (mL)	623.4	421.8	806.2	0.01
Fat harvested (mL)	421.7	492.3	351.9	0.02
Time to harvest (min)Mean	15.3 (6.7)	12.7 (4.8)	17.6 (7.7)	
Harvested fat/min (mL/min) Mean	32.7 (20.6)	43.7 (21.6)	21.7 (10.7)	
Fat prepared (mL)	166.3 (78.5)	196.2 (79.2)	135.8 (66.3)	0.01
Time to prepareMean	18.4 (10.7)	10.5 (4.4)	26.3 (9.9)	
Prepared fat/mi (mL/min) Mean	13.2 (1.4 - 69)	19.6 (6 - 69)	5.5 (1.3 – 13.5)	<0.001
Fat injected (mL)	133.3 (58.4)	154.2 (58.1)	112.7 (51.7)	0.02
Graf table fat %	0.44 (0.17)	0.43 (0.37)	0.45 (0.37)	0.84

DISCUSSION

AFG currently denoted a commonly employed technique in the plastic surgeon's armamentarium. Since the number of these procedures continues to grow each year, there is value in evaluating various strategies to optimize the efficiency of fat grafting. The present prospective study compared the rates of fat graft harvest, preparation and shows that system-AF was significantly more efficient than system-PF. While there was no difference in the resulting percentage of injectable fat, the preliminary result of this study probably depicts the proof of concept for a larger study to examine the validity of implementation of time motion protocols in fat grafting, which is currently underway. There is reportedly no literature to support one fat grafting and processing technique over another. But, there have been a various in vitro and animal studies that are comparing many techniques. When comparing the fat graft processing with washing and centrifugation to decanting alone, decanting was found to have worse adipocyte viability and increased oil contaminants.[11,12] When comparing the method of centrifugation with rolling the adipose tissue on gauze or Telfa, adipocyte viability was comparable to centrifugation[13,14] but the technique is not probably feasible for large-volume grafting cases. These days there are many new devices that are regularly emerging to streamline this process and increase the efficacy of fat grafting. Moreover, these new devices,

including the analysed in the present study, have also demonstrated greater purity of the fat graft obtained as well as greater adipocyte and stem cell that could yield when compared to traditional techniques.

With the advent of various new techniques for obtaining, processing and grafting fat material, more durable grafts could be obtained initially and thus presenting good results in the correction of soft tissue defects of the face and consecutively in certain other locations such as the breast. *Coleman & Saboeiro*[1]showed the restriction on the use of fat grafting by the American Society of Plastic and Reconstructive Surgery in 1987[1] and possibly argued that the same regions of calcifications and lipo-necrosis are observed after fat grafting procedures are also observed after other breast procedures like breast reduction and mastopexy.

The results of this study possibly showed certain significant differences in rate of adipose tissue graft processing, in millilitres per minute which might convert to savings such as reduced operative time. Comparing the cost of centrifugation vs the Revolve TM system in a single surgeon practice illustrated 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 TM and 1.77 mL/min for centrifugation.[15]Likewise, *Gabriel* and colleagues narrated their "rate of fat transfer" (volume of fat injected/operative time) and found 6.05 mL/min for Revolve TM and 0.98 mL/ min using centrifugation.[16,17]

The limitations of this study that were enclosed were the consecutive nature of the cases and non-randomized assignment and the lack of a centrifugation technique, which is observably the popular form of auto logous fat graft harvest. But the follow-up prospective, randomized study will basically include the *Coleman* technique in order 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. AT last, the overall volume of lipo-aspirate that was harvested in each technique might have an unintentional effect on processing. The researchers set a minimum volume of 100 mL but did not show the limit to the maximum volume.

CONCLUSION

AFG is essentially served as a valuable tool for majority of the plastic surgery that is increasing in its popularity that could possibly leading to new devices that were aimed to increase the efficacy and yield of injectable fat. Researchers demonstrate a difference in time, volume and hence the rate of tissue processing in 1 step of this process using 2 commercially available systems in the operating room.

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