

Plastic Surgeons Solve Autologous Fat Transfer Puzzle



By Michael Moretti, Editor and Scott Jorgensen, Contributing Editor

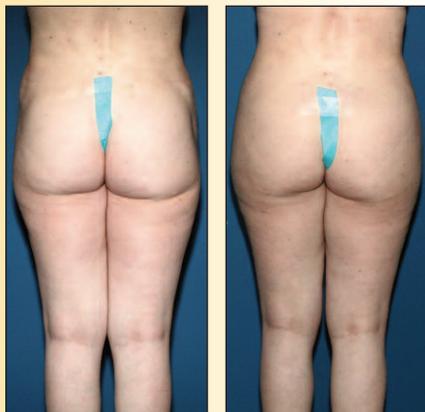
Among patients and physicians, the ability to remove unwanted fat from an area of the body and re-inject it into a more desirable location is one of the most fascinating treatments in the field of aesthetic medicine. On the surface, a patient's own fat is considered the ultimate natural filler with broad application; however, there are still several barriers impeding its widespread adoption. While many experts argue that fat grafting is too unpredictable, others swear by the procedure, calling autologous fat transfer the next aesthetic frontier as it experiences a popular resurgence.



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“Combination of soft tissue augmentation and regenerative capabilities from fat will become incredibly important. In five years, patient demand for autologous fat transfer will force physicians to become very familiar with its science and techniques. The regenerative discoveries will be phenomenal, providing cures to many illnesses, diseases and trauma injuries. The healing effects will be revealed and that will be the most important discovery of fat.”

— Sydney Coleman, M.D.



31 year old female after liposuction left her with an unnatural body shape with deficient hips and deep buttock creases

31 year old female ten months after fat transfer to each hip and below the buttock

Photos courtesy of Sydney Coleman, M.D.



35 year old female before Tx



35 year old female ten months after 5 cc of concentrated fat into the entire lower eyelid

Photos courtesy of Sydney Coleman, M.D.

Although the popularity of fat grafting is a recent development, the concept of transferring fat is not new. The first reported case occurred in 1893 by German physician Franz Neuber, who harvested fat from a patient's arms to augment facial depressions in the cheeks. The fat was successfully transferred, but there were several complications including infection, necrosis and a poor aesthetic result. Two years later, another German physician, Karl Czerny performed the first recorded use of autologous fat transfer in breasts when he grafted a fatty tumor from a patient's lumbar region to repair a breast defect.¹

While it has taken more than a century for the application of fat grafting to be embraced by plastic surgeons, not all are ready to jump in with both feet. James Namnoum, M.D., a plastic surgeon at Atlanta Plastic Surgery in Atlanta, Ga., feels the red siren today is primary breast augmentation. “Who really knows what we are putting in there. There is a real risk of injecting into virgin breasts without a known history of cancer or a clinical trial to hang your hat on,” he advised. “It's a dangerous area ripe for lawsuits and defensive medicine, which explains why the societies recommend that we proceed with caution.”

In 1987, the *American Society of Plastic Surgeons* (ASPS) published a position paper that predicted fat grafting could potentially conceal breast cancer detection and should therefore be prohibited.² In the absence of data from clinical trials, the application of fat transfer into breasts was viewed as controversial and was discouraged. For many years this stern position also had a dampening effect on plastic surgeons embracing fat grafting for other regions of the body. As Sydney Coleman, M.D., a plastic surgeon at Tribeca Plastic Surgery in New York, N.Y., explained, “If the societies tell you it is forbidden for the breast, then it is only logical that other areas of the body would be avoided as well, which is one of the reasons fat grafting has experienced such a challenging path.”



Sydney Coleman, M.D.
Plastic Surgeon
Tribeca Plastic Surgery
New York, NY

For 20 years Dr. Coleman and other pioneering surgeons continued to study and perform fat transfer procedures. In early 2007, ASPS and the *American Society for Aesthetic Plastic Surgery* (ASAPS) caused quite a stir when they issued a joint press release advising against the use of fat grafting for breast augmentation due to lack of clinical data and concern that it may interfere with accurate detection of cancer.³ That same year, ASPS recommended further research and formed a task force to assess the safety and efficacy of fat grafting, specifically to the breast.

In 2009, based on a multitude of evidenced-based case series, patient reports and clinical trial results, the ASPS task force reported that “there is no indication that fat grafting is an unsafe procedure.” However, the report did not make strong recommendations in favor of or against fat grafting for specific applications or treatment regions, just that more research was needed.⁴

In Dr. Namnoum's opinion the societies' position was forced to evolve. “Yesterday, it was prohibited and today we are backtracking after the task force's report,” he stated. “Our industry will embrace it until there is a case that links it to breast cancer or proves fat interferes with detection. This category

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“The majority of surgeons will use fat for any kind of soft tissue reconstruction and augmentation. We may use new generations of expansion and hyper-oxygenation devices to assist in fat survivability. Some drawbacks will remain, but the aesthetic results will overshadow the trade-offs.”

— Kotaro Yoshimura, M.D.



Patient with breast implant capsular contracture before Tx



Patient one year after breast implant replacement with autologous fat transfer (Cell-assisted lipotransfer: CAL)

Photos courtesy of Kotaro Yoshimura, M.D.

lacks clarity, the space is very murky. We need good science and controlled randomized trials to carve through the fog.”

The softening stance of ASPS and ASAPS, combined with improved results, as well as increased research and investment serve as the driving forces behind fat’s renewed popularity. Current applications include soft tissue augmentation and volume restoration in the face and/or body to provide a more aesthetically attractive, youthful appearance and correct deformities or cosmetic defects. Some of the most common applications of fat transfer in facial and submental areas are the chin, nose, neck, jawline, nasolabial folds, marionette lines, brow, upper eyelids, cheeks, temples and lips. In the body, popular treatment areas include breasts, hands, buttocks, hips and thighs.

While the applications and effectiveness of fat transfer continue to grow and evolve, every procedure carries challenges and benefits. Fat grafting is a lengthy and tedious surgery requiring a highly skilled injection technique.

Success rests principally in the hands of the surgeon. “Initially we questioned whether it could be done, but we have passed that point,” said W. Grant Stevens, M.D., a plastic surgeon at Marina Plastic Surgery Associates in Marina Del Rey, Calif. “This procedure is extremely operator dependent, which has been its chief head wind.”

Other complexities include washing or cleaning fat prior to reinjection, cell viability, risk of overfilling to compensate for resorption, high variability of fat cell survival and the possibility of damaged or dead cells leading to necrosis or calcification. However, the advantages of using a patient’s own fat are significant. Fat is a biocompatible, natural filler that is readily available and inexpensive. It can also offer long lasting results if grafted fat cells develop a healthy blood supply.⁵

Data from ASPS reveals that in 2008 there were approximately 46,000 non-surgical, cosmetic fat transfer procedures performed in the U.S.⁶ As research advances, fat transfer has the potential to become a major category within aesthetic medicine. “In the coming years, the majority of surgeons will use fat for every type of soft tissue augmentation,” stated Kotaro Yoshimura, M.D., an associate professor of plastic surgery at the University of Tokyo (Tokyo, Japan) who has studied more than 400 patients using adipose stem cell-assisted fat transfer.⁷ “Improved devices will make the procedure more practical and standardized processes will make it more predictable.” Nevertheless, he advised that “some of the drawbacks will remain such as invasiveness and surgery time, but the aesthetic results will overshadow these trade-offs.”



Kotaro Yoshimura, M.D.

Associate Professor of Plastic Surgery
University of Tokyo
Tokyo, Japan

One of the biggest opportunities for autologous fat transfer is in the breast reconstruction market. In 2009, the *American Cancer Society* estimated that 192,370 new invasive breast cancer cases will be diagnosed and another 62,280 women will be diagnosed with *in situ* breast cancer in the U.S.⁸ Today, a lumpectomy is the most common type of breast cancer surgery performed because only part of the breast is removed, but the resulting physical appearance

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60 year old female with removal of breast implants and deflated breasts



60 year old female six months after 350 cc of fat grafting
Photos courtesy of Daniel Del Vecchio, M.D.



20 year old female who had a benign tumor excision as a child, with agenesis of the left breast



20 year old female nine months after breast reconstruction with 200 cc of fat grafting
Photos courtesy of Daniel Del Vecchio, M.D.

may be a disfigured, dented or uneven breast, which is a major drawback. In the end, women are often left with portions of their breasts removed and currently there are no implants that can adequately address these unique deformities. Many plastic surgeons are now approaching this obstacle by attempting to remodel and shape the breast with fat grafted from another area of the body.

Elective breast augmentations are already one of the hottest areas in aesthetic medicine. Daniel Del Vecchio, M.D., a plastic surgeon at Back Bay Plastic Surgery in Boston, Mass., believes autologous fat transfer will expand this segment even more. "Every year more than 350,000 women in the U.S. pay to have incisions on their bodies and breast prostheses inserted that may last ten years. Still there are over 40 million women per year in the U.S. who buy padded bras which means, for every one patient that elects implants there are over 100 women who wish their breasts were larger, but reject breast augmentation with implants," he reported. "Women want bigger breasts. Fat grafting offers a natural augmentation with broad appeal to a patient segment that is waiting for an option beyond saline or silicone implants."



Daniel Del Vecchio, M.D.
Plastic Surgeon
Back Bay Plastic Surgery
Boston, MA

"In the next five years, there may be three groups performing fat grafting: evidenced based plastic surgeons, physicians who perform fat grafting without following the science or standards and other non surgeon physicians who may be attracted to the procedure due to its large patient appeal and no need for incision."

— Daniel Del Vecchio, M.D.

One of the most logical areas for autologous fat transfer is facial volumizing and soft tissue filling. "Dermal fillers have experienced exponential growth over the years," Dr. Stevens' stated, "so there is little question in anybody's mind about the wrinkle and folds market going away. It seems obvious that the ideal soft tissue filler is a patient's own tissue. Once the harvesting and injecting processes become less awkward and more predictable, fat grafting will supersede non-autologous dermal fillers for facial rejuvenation."

However, before we can fully appreciate what the future has in store for autologous fat transfer, we must also understand the market limitations that serve as barriers to its widespread adoption. Potentially, time is one of the biggest hurdles. Fat grafting is a very tedious and physically demanding surgery that requires multiple hours (4 to 5 hours) depending on the volume of fat being harvested and injected.



Peter Rubin, M.D.
Associate Professor of Plastic Surgery
University of Pittsburgh
Pittsburgh, PA

Peter Rubin, M.D., an associate professor of plastic surgery at the University of Pittsburgh (Pittsburgh, Pa.) and member of the ASPS task force, questions whether the procedures can be improved to the point of being worth a surgeon's time. "What's more, in reconstruction cases, the reimbursement may be so out of line that it's not a good use of time economically for hospitals and institutions," he added.

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“It’s too early to tell where the category will be in five years. What appears to be taking a pole position are standardization of methods to achieve reliable and predictable outcomes and understanding stem cells as well as other additives to stimulate and enhance fat retention.”

– Peter Rubin, M.D.

“In the breast, we will have gone through the zealot phase and the research will still be ongoing. We will have useful techniques for reconstruction and asymmetries, but there will not be a solution for volume or core tissue projection replacement. Fat will be too dangerous from a medical / legal standpoint for augmentation and too impracticable from a practice management perspective.”

– William Adams, M.D.

“A vast majority of plastic surgeons will use fat for facial volumizing and body contouring defects. Fat in breasts will become less taboo. In selected patients it will become a viable alternative to breast augmentation. For supplementing breast reconstruction, it will become a standard of care as a key complementary procedure. The lumpectomy defect will be the hardest to crack, but it will be adopted for those patients.”

– Scott Spear, M.D.

William Adams, M.D., a plastic surgeon at WA Plastic Surgery in Dallas, Texas agrees, “Practice economics are just as much of a concern as safety and effectiveness, but rarely talked about.”



William Adams, M.D.
Plastic Surgeon
WA Plastic Surgery
Dallas, TX

Having watched this space closely, Scott Spear, M.D., chief of plastic surgery at Georgetown University in Washington, D.C., feels that the remaining barrier is a successful commercial model that delivers a less labor intensive system with superior efficacy. “Otherwise, how can we command the fee that 4 to 5 hours of surgery requires.”



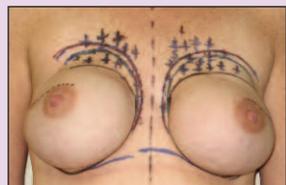
Scott Spear, M.D.
Chief of Plastic Surgery
Georgetown University
Washington, DC



1. 38 year old female day of consultation for bilateral prophylactic mastectomies



2. 38 year old female three months after bilateral mastectomies and immediate reconstruction with tissue expanders and alloderm



3. 38 year old female with markings for next surgery, bilateral exchange of expanders to implants and fat injections bilateral breast



4. 38 year old female two months after exchange of expanders to implants and fat injections

Photos courtesy of Scott Spear, M.D.



Alberto Goldman, M.D.
Plastic Surgeon
Clinica Goldman
Porto Alegre, Brazil

Alberto Goldman, M.D., a plastic surgeon at Clinica Goldman in Porto Alegre, Brazil, elaborated, “Keep in mind that fat is obtained from the patient free of charge and the cost of cannulas and centrifuge are not high. Until a manufacturer can prove superior results with its device, thereby justifying a large investment in the category, fat grafting’s market adoption will be restrained.” Currently, many different technologies and devices are being marketed for the purpose of autologous fat transfer. However, there is no clear dominating technology that has proven to be a true game-changer.

According to Dr. Rubin, another critical obstacle is that every plastic surgeon performs fat grafting differently. “Beyond the science, we need to identify the best practices to make fat grafting reliable in everybody’s hands.” For fat to achieve wider acceptance, successful standardized techniques must be created so surgeons can provide good, quality results in their initial cases. Otherwise, the category could experience a major backlash.

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“My vision for the future includes new indications like cellulite treatment, as well as increased knowledge about fat survival, safety, efficacy and dosing. The role of stem cells and other adjunctive techniques such as molecular biology, drug additives, hyperbaric approaches, cell cultures and other bio-activating factors represent the future of fat. That future is now!”

– Alberto Goldman, M.D.



35 year old female five years post saline augmentation sub-mammary



35 year old female with deflated implants prior to fat grafting



35 year old female one year after fat grafting
Photos courtesy of Kamran Khoobehi, M.D., F.A.C.S.



Patient before Tx

Patient after mastopexy, fat grafting and tummy tuck
Photos courtesy of Kamran Khoobehi, M.D., F.A.C.S.



62 year old female with hyperpigmentation and changes in skin texture of the hands before Tx



62 year old female one month after Nd:YAG laser and IPL Tx and fat injection in the dorsum of the hand

Photos courtesy of Alberto Goldman, M.D.



27 year old female before Tx



27 year old female six months after laser-assisted liposuction of the hips, buttocks and thighs for treatment of lipodystrophy and fat transfer of the buttocks

Photos courtesy of Alberto Goldman, M.D.



51 year old female before Tx



51 year old female ten months after fat injections in the lip, malar region and nasolabial folds

Photos courtesy of Alberto Goldman, M.D.

Furthermore, with any surgical procedure there is a learning curve effect. Dr. Del Vecchio believes that one of fat grafting's key barriers is its learning curve. "If you don't get good results you naturally blame the procedure as a whole, not your choice of technique. For example, if you continually over correct, over crowd or over centrifuge, your outcomes will be sub-optimal."

A patient's own weight and age may also impede market growth. "Fit patients will have challenges in identifying donor sites," Dr. Spear explained, "and major swings in weight gain or loss can either deform or erase your intended result." Conversely, being fit may also prove to be a key advantage. Kamran Khoobehi, M.D., F.A.C.S., a clinical professor of plastic surgery at the Louisiana State University Health Sciences Center School of Medicine in New Orleans, La., and member of the ASPS task force reported that, "fat from fit and normal weight patients is more resilient and has a much better survival rate compared to the fat from overweight patients."



Kamran Khoobehi, M.D., F.A.C.S.
Clinical Professor of Plastic Surgery
Louisiana State University Health
Sciences Center School of Medicine
New Orleans, LA

"Fat transfer procedures will become widely adopted and accepted in the next five years. The biggest application of fat grafting will be the combination of facial and breast enhancement procedures resulting from a loss of fat due to gastric bypass procedures. Organic aesthetics is the future."

– Kamran Khoobehi, M.D., F.A.C.S.

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Deflated right saline implant



One year after removal of both implants and fat injections
Photos courtesy of Kamran Khoobehi, M.D., F.A.C.S.



Implant rippling



One year after 28 cc fat grafting per side
Photos courtesy of Louis Bucky, M.D., F.A.C.S.



Hemifacial atrophy

Eight years after fat grafting
Photos courtesy of Louis Bucky, M.D., F.A.C.S.



Before Tx



One year after rhinoplasty and two procedures of facial fat grafting
Photos courtesy of Ali Mojallal, M.D.



Poliomyelitis atrophy



Six months after calf augmentation after three procedures of fat grafting
Photos courtesy of Ali Mojallal, M.D.

A patient's age may also prove to be a key consideration. "One limitation of fat in the face is retention in older patients," explained Louis Bucky, M.D., F.A.C.S., an associate professor of plastic surgery at the University of Pennsylvania (Philadelphia, Pa.). "Unfortunately, these are the patients that need it the most, but their fat cells are more fragile and less viable for transfer."



Louis Bucky, M.D., F.A.C.S.
Associate Professor of Plastic Surgery
University of Pennsylvania
Philadelphia, PA

"Fat transfer procedures will become routine in facial cosmetic surgery with countless volume restoration and skin rejuvenation benefits. For breast reconstruction, it will become a standard of care, like acellular dermal matrices (ADM) are quickly approaching today. With the advancements in ADM, fat transfer, nipple sparing and incision techniques, we could get really close to delivering 100% restoration. On the other hand, lumpectomies will require the most work to clarify due to the associated complications. While for breast augmentation, it will be an option for those seeking moderate volume without an implant, as well as mild asymmetry cases, assuming sufficient donor sites."

— Louis Bucky, M.D., F.A.C.S.



Ali Mojallal, M.D.
Assistant Professor of Plastic Surgery
University of Lyon
Lyon, France

Of all the market barriers, the unknown risk surrounding breast cancer detection remains at the top of the list. Although, the societies recently exchanged their stop sign for a yield, the jury is still out for many. "Interaction between breast cancer and fat grafting is still a poorly documented issue. We need more scientific and rigorous data," observed Ali Mojallal, M.D., an assistant professor of plastic surgery at the University of Lyon (Lyon, France). "If I transfer fat into the breast and a few years later my patient develops breast cancer, I cannot prove with our current scientific literature that there's no correlation between the two." However, Dr. Bucky reiterated that plastic surgeons have been safely utilizing autologous tissue in the breast for decades via trans-flap reconstructions.

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“Autologous fat has a major role to play as the most important, easily available source of mesenchymal stem cells. Tissue engineering is the future in my opinion.”

– Ali Mojallal, M.D.



Total modified radical mastectomy



18 months after breast reconstruction with thoracoabdominal advancement flap, latissimus dorsi reshaped by three procedures of fat grafting, contralateral mastopexy

Photos courtesy of Ali Mojallal, M.D.



Localized atrophy of the hip after orthopedic surgery



One year after liposuction of the trochanteric area and fat grafting of the atrophic zone

Photos courtesy of Ali Mojallal, M.D.

A major piece of the fat puzzle is where to direct future research in order to overcome these market barriers. According to Patrick Maxwell, M.D., a clinical professor of plastic surgery at Vanderbilt University in Nashville, Tenn., “Fat transfer is absolutely the future of aesthetic medicine, but it’s not just about the fat. It’s about improving the recipient bed and identifying what processes to minimize and/or optimize. It’s about understanding the stromovascular elements and stem cells, looking at specific reactions and promoting best practices.”

As we begin to uncover the category’s future, many new applications and advancements will emerge. Some have been talked about for years, such as stem cells and site expansion. While other, new applications and developments such as skin rejuvenation and tissue engineering are commanding significant interest.



Patrick Maxwell, M.D.
Clinical Professor of Plastic Surgery
Vanderbilt University
Nashville, TN



34 year old female with breast cancer who underwent left nipple-sparing mastectomy with sentinel node biopsy, opposite total mastectomy and tissue expander/ADM reconstruction



34 year old female after 410 Gummy Bear implants, ADM and fat grafting

Photos courtesy of Patrick Maxwell, M.D.



43 year old female with breast cancer who underwent right nipple-sparing mastectomy with sentinel node biopsy, opposite total mastectomy and tissue expander/ADM reconstruction



43 year old female after 410 Gummy Bear implants, ADM and fat grafting

Photos courtesy of Patrick Maxwell, M.D.

“Every advanced plastic surgeon will be harvesting and utilizing fat across the board in its enhanced cellular state. Fat on the reconstruction side will serve as an attractive complement to device reconstruction with acellular dermal grafts. Next-generation breast reconstruction will include minimally invasive incisions, preserving of nipples and enhancing of the soft tissue, leading to beautifully restored breasts. More and more women will opt for full mastectomy over breast conserving (lumpectomy) surgery because the outcome will have improved far beyond today’s standards while avoiding the damaging effects of radiation.”

– Patrick Maxwell, M.D.

Clearly, the most noteworthy discovery in the world of autologous fat transfer is stem cells and their regenerative capabilities. Researchers have discovered that stem cells have the power to heal and even reverse the effects of damaged tissues, potentially offering a cure for some diseases. Dr. Coleman considers the most exciting advancement of autologous fat to be its regenerative effects. “Being able to inject fat into the face or breast, and in almost all cases reverse the harmful effects of radiation damage, signals that we may have discovered a cure for radiation injury. This leads me to believe that other diseases and illnesses will be treated with fat – this is the beginning of truly regenerative medicine.”

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37 year old female following excessive liposuction of the inner-mid thighs and insufficient suction in the upper inner thighs performed elsewhere



37 year old female after additional suction of the upper inner thigh and autologous fat transfer into the mid inner thighs

Photos courtesy of Peter Fodor, M.D.

“Fat transfer will be widely adopted. Specifically, fat will play a major role in correcting skin compromises (e.g. chronic radiated tissues, hardness and pigmentation changes). More clinical knowledge about fat retention and manipulation in the face will be revealed.”

– Peter Fodor, M.D

Still, one question that remains is will it be necessary to enhance the fat graft with enriched stem cells to improve fat survivability and trigger this regenerative result. Dr. Bucky pointed out, “We must remember that there is a population of stem cells in any large amount of autologous fat. So unless we are isolating, purifying and concentrating the cells in a meaningful way, we are not doing anything really different or better. If we could, stem cells would greatly assist us in wound healing and modification, while fat itself acts as the volume replacer.”

Another major development is the concept of site expansion using negative pressure, as well as external expansion systems on the recipient site to obtain soft-tissue expansion and improve fat graft survivability. Researchers have discovered that fat needs space to vascularize and breathe essentially. In Japan, Dr. Yoshimura reports that research is underway to study the effects of site expansion in animals. “We are also trying to evaluate the impact of hyper-oxygenation after fat transfer by giving animals 60% oxygen for 48 to 72 hours post-surgery to see if the expansion and/or the oxygen promote fat survivability.”

Another interesting discovery to be observed with fat grafting is its rejuvenation properties. Many surgeons have commented on its remarkable ability to greatly improve the skin’s texture, appearance, softness and overall health and youthfulness. For Dr. Namnoum the biggest wow factor with fat has been in the face. “It’s the x-factor for a complete facial rejuvenation procedure,” he stated. “Generally with a face-lift the goal is to reposition the natural anatomical structures and treat the texture of the face, including wrinkles and folds. Now, with fat, we can restore facial volume and decrease the pulling effect. The fat makes patients’ skin look so much younger and vibrant.”

These skin rejuvenation effects are not just seen in the face. According to Peter Fodor, M.D., a plastic surgeon at Century Aesthetics in Los Angeles, Calif., “I have numerous patients come to me with permanent pigmentation changes and contouring defects as a result of bad liposuction procedures. Utilizing fat, I can smooth the irregularities and better yet, I have observed a complete revitalization of the damaged pigmentation and dermis.”



Peter Fodor, M.D.
Plastic Surgeon
Century Aesthetics
Los Angeles, CA

Beyond skin damage, the presence of cellulite is a significant source of patient dissatisfaction and currently there is no consistently effective treatment for it. Dr. Goldman was part of a recently completed study that analyzed the effects of combining laser and fat transfer for the safe and effective treatment of severe cellulite. “This represents another important indication for fat transfer.”⁹

The combination of cellular additives, polymer scaffolds or even platelet rich plasma during the preparation of autologous fat has been observed to increase fat survival and accelerate the healing process as well. Dr. Del Vecchio believes the concept of combining platelet rich plasma with fat is a potentially huge, unexplored opportunity that may prove to be a major breakthrough. “What’s so intriguing is that it does not upset the work flow. Since the source is the patient’s venous blood, it can be done by ancillary staff while other steps are being performed,” he noted. “It has been around for

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Cytori's PureGraft 250/System and Cellbrush



Adding Lactate Ringers to wash the tissue



Series of filters separates the graft from tumescent fluid, lipid and debris



Cellbrush precision micro droplets
Photos courtesy of Cytori Therapeutics

years without any negative biases or historical issues related to carcinogenesis and it has a solid scientific background of efficacy in other medical applications."

The eventual development of tissue-engineered fat will also be a significant breakthrough with massive application across all of medicine and most welcomed by plastic surgeons. This area is very nascent in its development and science, but the future of cellular suspension and tissue amplification will prove to have unlimited applications, including filling soft tissue defects for patients without sufficient donor sites.

Dr. Mojallal considers tissue engineering and banking to be one of the most exciting areas of fat. "Imagine harvesting fat from a patient, isolating stem cells from it and keeping a sample of these stem cells frozen in a bank of tissue. As needed, you could take cells, reproduce them and then differentiate the engineered tissue into whatever you want. There will be no more need for invasive surgery," he noted. "I'm not certain that we will be there in five years, but fat tissue engineering is the future in my opinion."

With such vast potential for the future, fat grafting has been attracting much attention from aesthetic device companies. Currently, there are many technologies and devices being marketed for the purpose of fat grafting in both cosmetic and reconstructive procedures. More recently, a variety of both established and emerging device manufacturers have introduced systems or are in the process of conducting clinical trials in the area of autologous fat transfer.

Cytori Therapeutics, Inc. (San Diego, Calif.) is developing a treatment modality for women whose partial mastectomy or lumpectomy has left a soft tissue deformity. Lumpectomy patients who have undergone surgery and radiation are difficult cases for plastic surgeons. The irradiated breast tissue is damaged and less receptive to a fat graft. Cytori's approach uses its proprietary technology to process fat cells and increase the concentration of adipose stem cells before injection. The company calls this procedure a cell-enriched fat graft. Cytori recently shared the interim results of its breast reconstruction technology at the 32nd annual *San Antonio Breast Cancer Symposium*. Highlighted data from a follow-up study demonstrated that 73% of patients and 82% of physicians were satisfied with the overall outcome six months after a single treatment.¹⁰

The company is seeking FDA approval of its Celution® stem cell concentration system. In July 2009 the FDA determined that the system should be regulated as a medical device, clearing the way for an indication of use "as a medical device in aesthetic body contouring and/or for filling of soft tissue voids."¹¹ According to Marc Hedrick, M.D., president of Cytori, "Celution has treated well over 1,000 patients, demonstrating a strong safety profile. At this time, it's not clear if the FDA is going to require a clinical trial, but we should know sometime in 2010 either way."

Cytori also offers the PureGraft™ system, which gained FDA 510(k) clearance in January 2010. PureGraft is a single use, bag-based, closed loop filtration system that removes debris, oil, tumescent fluids, free lipids and other possible contaminants. It eliminates the need for centrifugation, thus minimizing potential harmful effects and allowing for a cleaner graft in less time compared to traditional methods.¹²

Genesis Biosystems, Inc. (Lewisville, Texas) offers LipiVage, a sterile, single use, closed loop disposable syringe system for harvesting, filtering and transferring

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 16. Sound Surgical Technologies Press Release “New Study Reveals VASER® Lipo to be the New Standard of Care for Body Contouring and Fat Transfer Procedures.” August 24, 2009.
- autologous fat. With a 510(k) clearance, the LipiVage system attempts to simplify and reduce the steps involved in the collection and transfer of autologous fat. Once inside the cannula the fat is separated from oils and fluids by an integrated filter. As a result, the harvested fat is less traumatized and risk of contamination is lowered since the fat never leaves the harvesting syringe until re-injection.
- LipiVage may be an ideal modality for procedures such as buttock augmentation and post-bariatric treatments. “We have seen a significant time savings with LipiVage for large volume fat transfers,” advised Jim Lafferty, president of Genesis Biosystems. “In a typical gluteal augmentation, LipiVage can harvest 600 cc to 800 cc of fat that can be immediately re-injected back into the patient in under 45 minutes.”¹³ The company promotes LipiVage as simpler to use, gentler on fat cells and a time saver over traditional approaches, given that no centrifuging, waiting or decanting is needed in order to prepare the fat for transfer. In 2008, a study was conducted to compare LipiVage to conventional liposuction harvesting. While both modalities revealed normal structures of fatty tissue, LipiVage had a higher viable adipocyte count and a higher level of intracellular enzyme activity, which suggests that this device is a preferred method for high volume fat graft harvesting procedures.¹⁴
- Through a marketing and distribution partnership with Eclipsemed, Ltd. (Dallas, Texas), Human Med AG (Schwerin, Germany) introduced Body-Jet, a water jet-assisted liposuction system, to the U.S. Body-Jet includes AquaShape LipoCollector II, a fat transfer collection system to harvest, wash, filter and process viable, high-quality autologous fat for transfer. This collection system captures adipocytes safely and effectively by transferring the aspirated fat into a chamber, which contains a variety of filters to help separate viable fat cells.
- Body-Jet’s unique water jet-assisted harvesting modality also serves as a filtering process by washing the fat during collection, which keeps the fat moist and minimizes exposure to air and other contaminants. A chamber captures thicker, fibrous material, leaving a virtually purified autologous fat ready for transfer via a set of ten LipoCollector Syringes. Dr. Fodor is intrigued by the Body-Jet device. “Collected fat is washed and kept sterile. Obviously, this method helps to discard debris and oils as opposed to centrifugation, which risks damage to the lipocytes,” he said.
- Eclipse markets Body-Jet and AquaShape LipoCollector II under a 510(k) clearance received in late 2008. Recently, a study was conducted to compare Body-Jet’s fat cell viability to conventional liposuction and laser-assisted liposuction techniques. Gordon H. Sasaki, M.D., a plastic surgeon in Pasadena, Calif., performed a fat cell viability study using trypan blue dye to stain harvested cells. “Fat cells absorb the dye then kick it back out, unless they are dead, in which case the cells remain stained,” he explained. Results showed that traditional, mechanical traumatic cannula harvesting offered about 75% to 80% viability. Cell populations collected with a laser-assisted technique were between 30% and 50% viable. Those using Body-Jet were in the range of 90% viable.”¹⁵
- In October 2008 Sound Surgical Technologies, LLC (Louisville, Colo.), manufacturer of VASER, teamed with Shippert Medical Technologies Corporation (Centennial, Colo.), manufacturer of Tissu-Trans Fat Transfer products, in a marketing and distribution partnership. This collaboration positions them as a one-stop shop for advanced body sculpting and fat transfer procedures.
- The VASER Lipo System uses advanced ultrasonic energy to selectively break apart unwanted fat while preserving important tissue structures. Once the standard tumescent solution is infused, the fat is emulsified. Upon aspiration, Tissu-Trans is placed between the harvest cannula and the vacuum source, allowing fat to be collected, filtered and decanted all within the sterile Tissu-Trans container,

without exposure to air. Waste is filtered and drained out after harvesting. Sterile fat is drawn out of the sterile canister with a luer lock syringe and ready for injection without further preparation or centrifuge. Similar to LipiVage, Tissu-Trans allows the surgeon to harvest, filter, irrigate, treat with an additive (if so desired) and re-inject fat all from the same, sterile syringe.

Sound Surgical markets VASER and the Tissu-Trans Fat Transfer under 510(k) clearances. Recently, the VASER approach was clinically proven to be a safe and effective treatment option for fat transfer procedures, according to a study conducted at Stanford University (Palo Alto, Calif.) and published in *Plastic and Reconstructive Surgery*. Research results confirmed that VASER is an "enhanced fat removal and transfer system versus traditional suction-assisted liposuction." The study also demonstrated that VASER removes and delivers sterile and viable fat cells for reinjection. Furthermore, the common misconception that VASER's ultrasonic energy destroys fat cells was also addressed with reports that VASER could be better for fat grafting due to the fine cellular emulsion that is created through the ultrasound action.¹⁶

While fat grafting is garnering a tremendous amount of attention and respect from the medical aesthetic community, considerable barriers still exist. There is no denying the abundant potential available in this exciting area; however, the category's inherent market limitations will need to be eliminated first. This will be achieved through continued research and innovation, driven by the series of corporate exhibitions already underway. Serious investment will unlock autologous fat transfer's ultimate market potential and establish it as the next aesthetic frontier. ■

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