

**Current Applications and Safety of Autologous Fat Grafts:
A Report of the ASPS Fat Graft Task Force**

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Disclosure statement:

Dr. Gutowski serves as a paid advisor to AestheTec, a company that is developing fat grafting technology; however, he did not hold this position during the activities of the Task Force. Dr. Coleman receives a royalty for instruments sold by Byron Medical, Beacon & Mentor; is a medical advisor and has stock or the potential for stock options with Cytori Therapeutics, Zeltiq (unpaid), and Beacon Medical (unpaid); and is an unpaid consultant for the Armed Forces Institute of Regenerative Medicine. Dr. Rubin receives research support from Pfizer, Covidien, and Toucan Capital. The other authors have no financial interests related to fat grafting. No other members of the task force have financial interests related to fat grafting.

Products:

The manuscript does not include specific product names related to fat grafting.

TASK FORCE STATEMENT

In 2007, the ASPS formed a task force to conduct an assessment regarding the safety and efficacy of autologous fat grafting, specifically to the breast, and to make recommendations for future research. The Task Force formulated specific issues regarding fat grafting and then compiled them to focus on six broad-based questions:

1. What are the current and potential applications of fat grafting (specifically breast indications, and if data are available, other cosmetic and reconstructive applications)?
2. What risks and complications are associated with fat grafting?
3. How does technique affect outcomes, including safety and efficacy, of fat grafting?
4. What risk factors need to be considered for patient selection at this level of invasiveness?
5. What advancements in bench research/molecular biology potentially impact current or future methods of fat grafting?

To answer these questions, the Task Force reviewed the scientific literature, critically appraised the information available, and developed evidence-based practice recommendations. Although the primary issue of interest was fat grafting to the breast, other aspects of fat grafting were evaluated.

The Task Force was composed of ASPS members with expertise in fat grafts and research methodology and included: Karol A. Gutowski, MD, Chair; Stephen B. Baker, MD, DDS; Sydney R. Coleman, MD; Kamran Khoobehi, MD; H. Peter Lorenz, MD; Marga F. Massey, MD; Andrea Pusic, MD; and J. Peter Rubin, MD.

INTRODUCTION

A renewed clinical interest in fat grafting for both reconstructive and aesthetic purposes has prompted plastic surgeons and other medical practitioners to perform such procedures. While it appears that these procedures are being done more frequently and for broader indications, there is a relative lack of information for physicians to guide them in choosing optimal techniques, appropriate patient selection, and to offer realistic advice on outcomes and potential complications to their patients. By conducting an evidence-based review, this report will offer a graded summary of the evidence to help optimize the clinical use of fat grafts.

DISCLAIMER

This task force statement provides strategies for patient management, and was developed to assist physicians in clinical decision-making. This task force statement, based on a thorough evaluation of the present scientific literature and relevant clinical experience, describes a range of generally acceptable approaches to diagnosis, management, or prevention of specific diseases or conditions. This practice advisory attempts to define principles of practice that should generally meet the needs of most patients in most circumstances. However, this task force statement should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances presented by the patient, the diagnostic and treatment options available and available resources.

This task force statement is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance, and as practice patterns evolve. This task force statement reflects the state of knowledge current at the conclusion of the Task Force's activities (March, 2008). Given the inevitable changes in the state of scientific information and technology, periodic review and revision will be necessary.

Additionally, it is important to note that recommendations of the Task Force are based on evidence available in the published literature, which often reflects only positive findings; studies with negative findings are rarely published. In order for the Task Force to make a strong recommendation (Grade A) for or against fat grafting for specific applications, high-quality randomized controlled trials would be needed to further evaluate safety and efficacy.

METHODS

Literature Search and Admission of Evidence

This review involved a prospective, systematic method for identifying and evaluating current literature on autologous fat grafting. A comprehensive search of PubMed and the Cochrane Database of Systematic Reviews was performed by using the following search terms: autologous fat grafting, autogenous fat grafting, autologous fat transfer, autogenous fat transfer, autologous fat filler, autogenous fat filler, fat harvest, adipocyte harvest, lipoaspirate, lipotransfer, lipoinjection, lipoinfiltration, fat augmentation, adipose augmentation, adipocyte augmentation, and adipocyte graft.

Search limits restricted results to English-language manuscripts that were indexed as human studies, clinical trials, randomized controlled trials, systematic reviews, case series, or case reports. As a Task Force member was fluent in French, French-language manuscripts were

included if they were relevant to the breast, which was the main focus of the Task Force. The original search resulted in 187 articles. Excluded from the literature selection were most articles addressing fat grafting with other types of grafts (i.e., dermal fat grafts) and fat grafting for non-plastic surgery applications. Articles of this nature were included only if deemed critical to the review (i.e., for review of complications). Also excluded were articles for which we were unable to access full text. Based on these final criteria, 110 articles were included in this review.

Critical Appraisal of the Literature

Relevant articles were categorized by study type: randomized controlled trial, systematic review, cohort study, case-control study, case series, or case report. Each article was critically appraised for study quality and assigned a corresponding level of evidence according to ASPS Evidence Rating Scales (Table 1).

[Insert Table 1: Evidence rating scale for studies reviewed.]

Development of Clinical Practice Recommendations

Practice recommendations were developed through critical appraisal of the literature and consensus of the ASPS Fat Graft Task Force. Recommendations are based on the strength of supporting evidence and graded according to the ASPS Grades of Recommendation Scale (Table 2). Grade A and B recommendations were made if there were high-quality studies supporting a specific use or technique associated with fat grafting, while Grade C or D recommendations were made if the level of evidence was low or inconsistent. Recommendations developed by the Task Force are provided throughout the document and also in Table 3.

[Insert Table 2: Scale for grading recommendations]

[Insert Table 3: Task Force recommendations regarding fat grafts]

RESULTS

1. What are the current and potential applications of autologous fat grafting (specifically breast indications, and if data are available, other cosmetic and reconstructive applications)?

The evidence regarding fat grafting applications consists mostly of case series and case reports and a few small, lesser-quality experimental studies. Preliminary results are encouraging and warrant further study in the area of fat grafting for various applications.

Breast Indications

While there is at least one registered prospective clinical trial (BRAVA, clinicaltrials.gov ID:NCT00466765) and other non-registered prospective trials involving fat grafting to the breast, no randomized controlled trials were identified during the literature search. The available literature consists mostly of case series, case reports and expert opinion, and describes fat grafting for various breast indications, both cosmetic and reconstructive.¹⁻¹⁰ [Evidence Level: IV, V]

Several small case series and a case report describe fat grafting to the breast for augmentation and/or correction of defects due to medical conditions or previous breast surgeries. Combined, 283 patients had fat grafting procedures; approximate age range was 21-73 years old.

In these reports, indications for fat grafting included:

- Micromastia
- Postaugmentation deformity, with and without removal of implant

- Tuberous breasts
- Poland's Syndrome
- Postlumpectomy deformity
- Postmastectomy deformity
- Deficits caused by conservative treatment or reconstruction with implants and/or flaps (latissimus dorsi or TRAM)
- Damaged tissue resulting from radiotherapy
- Nipple reconstruction

In most cases, fat grafting was accomplished by lipoinjection of autologous adipose tissue directly into breast tissue. Lipoinjection was performed in 1 to 3 stages, as needed. The amount of fat injected per operation per breast ranged 1.5cc to 2.5cc for nipple reconstruction, and 30cc to 460cc for augmentation and correction of defects. In contrast, one study injected fat into leaf-valve breast implants, thereby using fat as filler material instead of saline.

Of the 283 patients, most had satisfactory results, as reported by the patients and/or independent panels of surgeons. Follow up ranged from 1 month to 10 years. Eight procedures (2.8 %) were deemed unsuccessful (1 failure in patient receiving fat grafting to improve symptoms associated with radiotherapy damage; 7 breasts (2.5 %) showed no improvement from recontouring after reconstruction). Thirty-six complications (12.7 %) or unfavorable sequelae were reported: 3 (1.1 %) infections, 14 (4.9 %) calcifications, 16 (5.7 %) fat necroses, and 3 (1.1 %) unspecified superficial lumps. In one study, 2 cases of breast cancer were diagnosed after augmentation (1 in a non-grafted area; 1 in a potentially grafted area), but the investigators reported no delay in detection or treatment.

An additional case series involving 30 patients who had undergone reconstruction and fat grafting for breast cancer, investigated the ability of imaging technologies to detect suspicious lesions. No interference with breast cancer detection was noted. The authors emphasize the need for biopsy in cases where imaging cannot provide definitive diagnosis.¹¹

Other case reports describe complications associated with fat grafting to the breast (e.g., inflammation, calcifications, fat necrosis, and life-threatening sepsis);¹²⁻¹⁶ however, since most involve patients presenting to a surgeon who did not perform the procedure, details regarding the operating surgeon's technique and expertise are mostly unavailable. These reports were not included in the description of cases above.

Fat grafting may be considered for breast augmentation and correction of defects associated with medical conditions and previous breast surgeries; however, results are dependent on technique and surgeon expertise. *Because longevity of the graft is unknown, additional treatments may be necessary to obtain the desired effect. Additionally, fluctuations in body weight can affect graft volume over time.* [Recommendation Grade: B]

Other Indications

Fat grafting has also been used for the following applications; however, the Task Force is unable to make recommendations regarding these applications without further research and analysis:

- Gluteal augmentation and repair of contour deformities¹⁷⁻²¹ [Evidence Level: IV, V]
- Facial augmentation and correction of defects^{19, 22-46} [Evidence Level: III, IV, V]
- Hand rejuvenation⁴⁷⁻⁴⁹ [Evidence Level: II, IV]
- Lip augmentation⁵⁰⁻⁵⁴ [Evidence Level: II, IV]

- Penile enlargement and aesthetic improvement^{55, 56} [Evidence Level: IV, V]

2. What risks and complications are associated with fat grafting?

The evidence for associated risks and complications consists mainly of case series and case reports documenting complications associated with fat grafting for various plastic surgery applications.

Potential complications/risks include:

- Anesthesia-related: No cases of anesthetic complications were reported. These complications are uncommon, and considering this procedure is typically done under local anesthesia, with or without sedation, the risk is considered low.
- Infection:^{9, 14, 20, 36, 54} Cases of prolonged inflammation, septic shock, and *Staph* infections have been documented with these procedures. Most cases resolved with antibiotic therapy. [Evidence Level: IV, V]
- Bleeding:^{9, 21, 37, 46} Cases of seroma or hematoma have been documented with these procedures. However, no cases of unusual or severe bleeding have been presented. [Evidence Level: IV]
- Less than expected beneficial outcome:^{2, 11, 12, 23, 57-59} Results from these procedures are typically reported as excellent or good; however, no standardized rating scales are available to evaluate outcome. Overall, graft volume loss, via reabsorption or necrosis, is the primary cause of poor results. Initial overcorrection, performed by an experience surgeon, can often compensate for this outcome. Instances of graft hypertrophy or overgrowth have been documented; however, they appear to be rare. Other complications affecting aesthetic results include the formation of calcified and noncalcified masses. [Evidence Level: IV, V]

- Interference with breast cancer detection:^{2, 3, 9, 11-13} Fat grafting to the breast could potentially interfere with breast cancer detection; however, no evidence was found that strongly suggests this interference. Two cases of breast cancer were reported after fat grafting to the breast, but there was no delay in detection or treatment. Radiological studies suggest that imaging technologies (ultrasound, mammography, and MRI) can identify the grafted fat tissue, microcalcifications and suspicious lesions; biopsies may be performed if needed for additional clarification. *Based on a limited number of studies with few cases, there appears to be no interference with breast cancer detection; however, more studies are needed to confirm these preliminary findings.* [Evidence Level: IV, V]
- Other Risks:^{9, 14, 20, 36, 54, 60-63} Considering the level of invasiveness during this procedure the occurrence of unexpected, life-threatening complications should be measured. The available literature documents a low case number of fat embolism (including one pulmonary fat embolism resulting in death of the patient), strokes, a single case of lipid meningitis, as well as serious cases of infection including septic shock. [Evidence Level: I, IV, V]

Overall, complication rates associated with fat grafting are not unduly high, considering the level of invasiveness of the procedure. Cases of severe complications and death appear to be extremely rare, and causation in these cases could not be fully determined. Therefore, the Task Force found no compelling evidence that would warrant a strong recommendation against autologous fat grafting. The risks associated with fat grafting procedures may actually be lower than other types of surgery; however, no high-level studies comparing fat grafting to other procedures are available, and as such, surgeons should exercise appropriate caution. Fat grafting can be

medical conditions. With infection being a primary concern, the need for sterile technique should be emphasized. Patients should be made aware of the potential complications and should provide written informed consent acknowledging their understanding of these risks. A sample consent form (Figure 1) is included with this report. [Recommendation Grade: B]

3. How does technique affect outcomes (safety and efficacy)?

The evidence consists mainly of case series, case reports and animal studies describing specific techniques for several aspects of fat grafting. Evidence summaries for each aspect of fat grafting technique are presented below; however, the Task Force is unable to make recommendations without further research and analysis.

- Harvest technique: ^{3, 24, 28, 49, 64-73} The primary concerns to be addressed during tissue harvest are level of invasiveness (patient safety) and tissue viability (efficacy). With this in mind, exposure to air and mechanical damage should be minimized at this step. It is suggested that tissue harvest be performed using a ~3 to 4mm blunt cannula or similar needle, while utilizing minimal amounts of suction required for tissue extraction.

[Evidence Level: IV, V]

- Harvest site: ^{74, 2004} The primary concerns to be addressed during choice of harvest site are adequate tissue volume, which is patient specific, and patient/physician preference. There is no compelling evidence regarding harvest site and efficacy of fat grafting.

[Evidence Level: V]

- Graft preparation: ^{2, 3, 8, 25, 28, 44, 48, 49, 52, 65, 68, 70, 74-77} To avoid contamination and maximize tissue viability, exposure to air and mechanical damage should be minimized. Many studies suggest that viable adipocytes should be separated from blood, serum, and damaged adipocytes via centrifugation (~3000 rpm for 3 min) while still within the harvest syringe. Note, however, that centrifugation is typically described in revolutions

per minute (RPM), not in terms of relative centrifugal force (RCF) expressed in units of gravity (g). Since many microcentrifuges have settings only for speed, a formula for conversion is required to ensure that the appropriate setting is used. The relationship between RPM and RCF is as follows: $g = (1.118 \times 10^{-5}) R S^2$ where R = radius of rotor (center of rotor to sample), cm; and S = speed, RPM.⁷⁸ [Evidence Level: IV, V]

- Injection technique:^{3, 19, 24, 28, 49, 66, 77} To optimize fat graft viability, mechanical damage of the tissue to be injected should be minimized. Graft injection should be performed using a ~2 to 2.5mm blunt-tipped infusion cannula or a similar blunt needle, and with injection occurring in multiple passes in the area of augmentation, resulting in small fat deposited with each pass. [Evidence Level: IV, V]
- Injection site:^{7, 43, 69, 79-83} The primary concern to be addressed during choice of injection site involves the desired outcome of the procedure, which is patient specific. The evidence does not indicate whether or not injection site significantly effects graft viability. [Evidence Level: IV, V]
- Graft storage:^{51, 84-90} Overall, tissue viability tends to drop significantly upon storage, which in turn may decrease fat graft efficacy. It is suggested that fat tissue be used fresh. [Evidence Level: IV, V]
- Use of epinephrine and lidocaine at the donor site:⁹¹ The use of either epinephrine or lidocaine has not been shown to affect graft viability, though thorough investigations have not been performed. It is suggested that use of anesthetics at the injection site be minimally applied. [Evidence Level: V]

4. What risk factors need to be considered for patient selection at this level of invasiveness?

No evidence was found that specifically addressed patient selection. Therefore the recommendation was developed by consensus of the Task Force and is considered expert opinion.

When determining whether or not a patient is an appropriate candidate for autologous fat grafting to the breast, physicians should exercise caution when considering high-risk patients (i.e., those with risk factors for breast cancer: BRCA-1, BRCA-2, and/or personal or familial history of breast cancer). Baseline mammography (within American College of Surgeons or American Cancer Society guidelines) is recommended. [Recommendation Grade: D]

5. What advancements in bench research/molecular biology potentially impact current or future methods of autologous fat grafting?

The current evidence consists primarily of in vitro and animal studies describing cell/tissue manipulation to improve viability.^{41, 80, 84, 86-89, 92-111} These studies include variations in co-injection additives, pretreatment of graft site and/or adipose tissue studies addressing compensatory increase fat response, oxygen requirements for graft viability, cell-culture techniques, graft storage and cryopreservation, and assays for graft survival. No randomized controlled trials were identified during the literature search. The nature of this question and lack of human data limit our ability to make recommendations; however, many of the studies indicate potential efficacy, justifying further research in these areas. [Evidence Level: V]

CONCLUSIONS

Clinical Applications

Based on a review of the current literature and a lack of strong data, the Task Force cannot make specific recommendations for the clinical use of fat grafts. Although fat grafts may be considered for use in the breast and other sites, the specific techniques of graft harvesting, preparation, and injection are not standardized. The results therefore may vary depending on the surgeon's technique and experience with the procedure. Although there are little data to provide evidence for long-term safety and efficacy of fat grafting, the reported complications suggest that there are associated risks. Regarding fat grafting to the breast, there are no reports suggesting an increased

risk of malignancy associated with fat grafting. There is a potential risk of fat grafts interfering with breast physical examination or breast cancer detection; however, the limited data available suggests that fat grafts may not interfere with radiologic imaging in detecting breast cancer.

Future Research

The Task Force believes autologous fat grafting is a promising and clinically relevant research topic. The current fat grafting literature is limited primarily to case studies, leaving a tremendous need for high-quality clinical studies. While this evidence-based review resulted in few, if any, new data that would prompt a substantial change in the current state of fat grafting, the lack of new information poses two important questions: (1) are current methods of fat grafting still the "gold standard," or (2) is more research needed and should funding be directed toward new studies? For many aspects of fat grafting, the Task Force found the latter to be true and has suggested the following areas for future research:

- Randomized controlled trials to assess safety and efficacy of fat grafting for different indications
- Randomized controlled trials to assess safety and efficacy of specific fat grafting techniques
- Studies to further assess the effect of fat grafting on breast cancer detection and treatment.
- Studies to identify risk factors and improve patient selection for procedures involving fat grafting.
- Studies to investigate aspects of cell/tissue viability and graft survival, as well as long-term storage and banking of fat grafts.

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[Insert Figure 1. Consent form for fat transfer procedures.]

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Table 1. Evidence rating scale for studies reviewed.

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies
III	Retrospective comparative study; case-control study; or systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research or “first principles”

Table 2. Scale for grading recommendations

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V: Little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

Table 3. Task Force recommendations regarding fat grafts

Recommendation	Level of Evidence	Grade
<p>Fat grafting may be considered for breast augmentation and correction of defects associated with medical conditions and previous breast surgeries; however, results are dependent on technique and surgeon expertise. <i>Because longevity of the graft is unknown, additional treatments may be necessary to obtain the desired effect. Additionally, fluctuations in body weight can affect graft volume over time.</i></p>	IV, V	B
<p>Fat grafting can be considered a safe method of augmentation and correction of defects associated with various medical conditions. With infection being a primary concern, the need for sterile technique should be emphasized. Patients should be made aware of the potential complications and should provide written informed consent acknowledging their understanding of these risks.</p>	I, II, III, IV	B
<p>When determining whether or not a patient is an appropriate candidate for autologous fat grafting to the breast, physicians should exercise caution when considering high-risk patients (i.e., those with risk factors for breast cancer: BRCA-1, BRCA-2, and/or personal or familial history of breast cancer). Baseline mammography (within American College of Surgeons or American Cancer Society guidelines) is recommended.</p>	V (Expert Opinion)	D

Figure 1

**INFORMED CONSENT FOR
FAT TRANSFER PROCEDURES
(FAT GRAFTS AND FAT INJECTIONS)**

(PLEASE REVIEW AND BRING WITH YOU ON THE DAY OF YOUR PROCEDURE)

PATIENT NAME _____

Patient Initials _____

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you concerning **fat transfer (fat grafts or fat injection procedures)**, its risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page, and sign the consent for the procedure or surgery as proposed by your plastic surgeon.

INTRODUCTION

A person's own fat may be used to improve the appearance of the body by moving it from an area where it is less needed (usually the thighs or abdomen) to an area that has lost tissue volume due to aging, trauma, surgery, birth defects, or other causes. Typically, the transferred fat results in an increase in volume of the body site being treated. Before the procedure, the areas from where the fat is being removed may be injected with a fluid to minimized bruising and discomfort. The fat may be removed from the body by a narrow surgical instrument (cannula) through a small incision or may be excised (cut out) directly through a larger incision. In some cases the fat may be prepared in a specific way before being replaced back in the body. This preparation may include washing, filtering, and centrifugation (spinning) of the fat. The fat is then placed into the desired area using either a smaller cannula or needle, or it may be placed directly through an incision. Since some of the fat that is transferred does not maintain its volume over time, your surgeon may inject more than is needed at the time to achieve the desired end result. Over a few weeks, the amount of transferred fat will decrease. At times, more fat may need to be transferred to maintain the desired results. Fat transfer procedures may be done using a local anesthetic, sedation, or general anesthesia depending on the extent of the procedure.

ALTERNATIVE TREATMENTS

Alternative forms of nonsurgical and surgical management consist of injections of man-made substances to improve tissue volume (such as hyanuronic acid, polylactic acid, etc.), use of man-made implants, or other surgical procedures that transfer fat from the body (flaps).

Risks and potential complications are associated with alternative forms of treatment.

RISKS of FAT TRANSFER PROCEDURES-

Every procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo a procedure is based on the comparison of the risk to its potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of the procedure.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after this procedure. Should bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). Do not take any blood thinning medications, aspirin, or nonsteroidal anti-inflammatory medications (acetaminophen is acceptable) for ten days before the procedure, as these may contribute to a greater risk of bleeding or significant bruising. Tell your surgeon if you are on any of these medications before stopping them.

Seroma- Although unlikely, a collection of fluid may appear at the site where the fat was removed. This is usually treated by draining the fluid with a needle.

Infection- Infection is unusual after this procedure. Should an infection occur, additional treatment including antibiotics or surgery may be necessary.

Scarring- All invasive procedures leave scars, some more visible than others. Although good wound healing after a procedure is expected, abnormal scars may occur both within the skin and in the deeper tissues. Scars may be unattractive and of different color than the surrounding skin. There is the possibility of visible marks from sutures used to close the wound. Scars may also limit motion and function. Additional treatments including surgery may be needed to treat scarring.

Risks of Fat Transfer Procedures, continued

Change in Appearance- Typically the transferred fat loses some of its volume over time and then becomes stable. It is possible that more treatments may be needed to maintain the desired volume of the transferred fat and resulting appearance. Less commonly, if you experience significant weight gain, the transferred fat may increase in volume and cause an undesirable appearance. It is important to understand that more than one treatment may be needed and therefore to discuss with your surgeon the costs associated of repeat treatments.

Firmness and Lumpiness- While most transferred fat results in a natural feel, it is possible that some or all of the fat may become firm, hard, or lumpy. If some of the fat does not survive the transfer, it may result in fat necrosis (death of transferred fat tissue), causing firmness and discomfort or pain. Cysts may also form at the site of the transferred fat. Surgery may be required to improve such conditions.

Asymmetry- Symmetrical body appearance may not result from a fat transfer procedure. Factors such as skin tone, fatty deposits, bony prominence, and muscle tone may contribute to normal asymmetry in body features.

Long term effects- Subsequent changes in the shape or appearance of the area where the fat was removed or placed may occur as the result of aging, weight loss or gain, or other circumstances not related to the fat transfer procedure.

Pain- Chronic pain may occur rarely after fat removal or transfer.

Tissue Loss- In rare cases, the transferred fat may cause the skin over the treated area to be injured resulting in loss of the skin and surrounding tissue. This may leave scars and disfigurement and require surgery for treatment.

Fat Transfer to Breasts- Fat transfer has been used to improve the appearance of breasts reconstructed after cancer treatment, to improve the appearance of breast deformities, and to enlarge breasts for cosmetic purposes. While there is limited information regarding the long-term implications of such procedures, there are some potential concerns especially with regards to breast cancer detection. Since the transferred fat may become firm and cause lumps, it may be necessary to have radiological studies (mammogram, ultrasound, or MRI) performed to be sure these lumps are not due to cancer. It is also possible that the firmness may make it more difficult for you or your doctor to examine the breasts. It is also possible that a biopsy may be needed if there is concern about any abnormal findings in your breasts. However, there is no reason to believe that fat transfer procedures may cause breast cancer.

Damage to deeper structures- Deeper structures such as nerves, blood vessels, or muscles may be damaged during the course of this procedure. The potential for this to occur varies according to where on the body the procedure is being performed. Injury to deeper structures may be temporary or permanent.

Unsatisfactory result- There is the possibility of an unsatisfactory result from the procedure, resulting in unacceptable visible deformities, loss of function, wound disruption, skin death, or loss of sensation. You may be disappointed with the results of the procedure.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions, which are more serious, may result from drugs used during the procedure or prescription medicines. Allergic reactions may require additional treatment.

Surgical anesthesia- Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Risks of Fat Transfer Procedures, continued

Serious Complications- Although serious complications have been reported to be associated with fat transfer procedures, these are very rare. Such conditions include, but are not limited to: **Fat embolism** (a piece of fat may find its way into the blood stream and result in a serious or life threatening condition), **stroke, meningitis** (inflammation of the brain), **serious infection, blindness or loss of vision, or death.**

Blood clots- Blood clots in the veins of the arms, legs, or pelvis may result from from fat transfer if it is done as a surgical procedure. These clots may cause problems with the veins or may break off and flow to the lungs where they may cause serious breathing problems.

Pulmonary complications- Pulmonary (lung and breathing) complications may occur from both blood clots (pulmonary emboli) and partial collapse of the lungs after general anesthesia. Should either of these complications occur, you may require hospitalization and additional treatment. Pulmonary emboli can be life-threatening or fatal in some circumstances. Fat embolism syndrome occurs when fat droplets are trapped in the lungs. This is a very rare and possibly fatal complication of fat transfer procedures.

ADDITIONAL SURGERY NECESSARY

In some situations, it may not be possible to achieve optimal results with a single procedure. Multiple procedures may be necessary. Should complications occur, surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited above are the ones that are particularly associated with fat transfer procedures. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there cannot be any guarantee or warranty expressed or implied on the results that may be obtained.

FINANCIAL RESPONSIBILITIES

The cost of the procedure involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, and possible hospital charges, depending on where the surgery is performed. Depending on whether the cost of the procedure is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. Additional costs may occur should complications develop from the procedure. Secondary surgery or hospital day-surgery charges involved with revisionary surgery would also be your responsibility.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY, PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ and such assistants as may be selected to perform the following procedure or treatment:

Fat transfer including fat injections and fat grafts

I have received the following information sheet:

INFORMED-CONSENT FAT TRANSFER PROCEDURES

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
9. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____