ASPS Fat Grafting Guiding Principles & Next Steps

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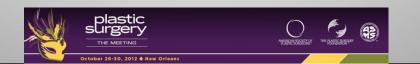


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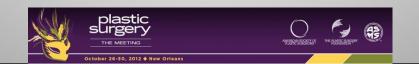
Speaker Disclosures

Instructor: Suneva Medical Advisory Board: The Doctors Company Speaker's Bureau: Angiotech Pharmaceuticals



Background

- 1987 ASPRS advised against fat injection in breast augmentation
- 2007 Task Force review of scientific evidence
- 2009 Guiding principals approved
- 2011 ASPS/ASAPS Position Statement
- 2012 Continued literature reviews
- 2012 & 2013 Start data collection



ASPS 2009



Fat Transfer/Fat Graft and Fat Injection ASPS Guiding Principles

- Complication rates are not unduly high
 - Severe complications & death extremely rare
- Interference with breast cancer detection not validated (limited studies)
 - Caution when considering patients at high-risk for breast cancer (expert opinion)
- Results dependent on a surgeon's technique and expertise
- Provide appropriate informed consent (available through ASPS)
- Body of evidence is mostly case series, case reports and expert opinion

Guiding Principals not meant to serve as the standard of medical care Based on a systematic review

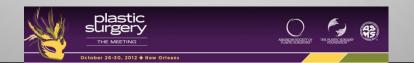


SPECIAL TOPIC

PRS 2009

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

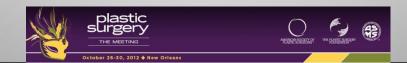
- 1. What are the current and potential applications of fat grafting?
- 2. What risks and complications are associated with fat grafting?
- 3. How does technique affect outcomes, including safety and efficacy?
- 4. What risk factors need to be considered for patient selection?
- 5. What advancements in bench research/molecular biology potentially impact current or future methods of fat grafting?





Joint ASPS & ASAPS Position Statement: Stem Cells and Fat Grafting

- Systematic review suggests adult stem cells <u>may produce</u> beneficial medical therapies
- Terms such as "stem cell therapy" or "stem cell procedure" should be reserved to describe treatments or techniques where the collection, concentration, manipulation, and therapeutic action of the stem cells is the primary goal, rather than a passive result, of the treatment
- Marketing & promotion of stem cell procedures in aesthetic surgery is not supported by clinical evidence
- Stem cell therapies conducted within clinical studies under IRB approval
- Stem cell procedures performed in compliance with FDA guidelines



Insurance & Payer Issues



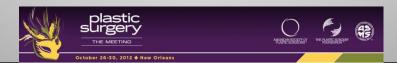
CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Breast Reconstruction Following Mastectomy or Lumpectomy

Effective Date	9/15/2011
Next Review Date	9/15/2012
Coverage Policy Number	0178

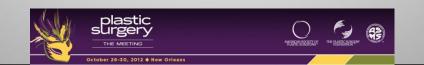
CIGNA does not cover autologous fat transplant (i.e., lipoinjection, lipofilling, lipomodeling) used in association with breast reconstruction because such treatment is considered experimental, investigational or unproven for this indication.



DRAFT: Post Mastectomy Fat Graft Guiding Principles

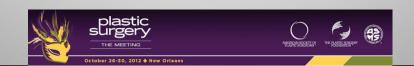
- Updated literature review (case series) by ASPS Patient Safety Committee 2012
- Recommendations limited to fat transfer to postmastectomy breast (no native breast tissue present)
- Pending approval end of 2012

Guiding Principals not meant to serve as the standard of medical care



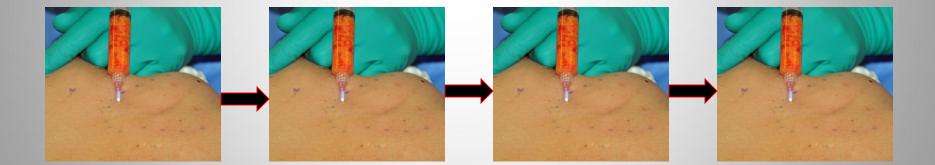
Complications

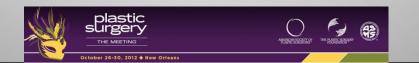
- Relatively low rate of complications
 - Bleeding
 - Calcifications
 - Fat embolism
 - Fat necrosis
 - Infection
 - Oil cysts
 - Graft volume loss
- Severe complications & death extremely rare
- No delay in cancer detection
- No increased cancer recurrence



Technique

- Number of fat grafting sessions required varies per patient
- Most patients require more than one fat grafting session
- Each additional session yields gradual improved outcome

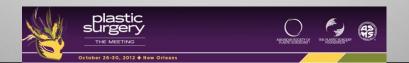




Aesthetic Results

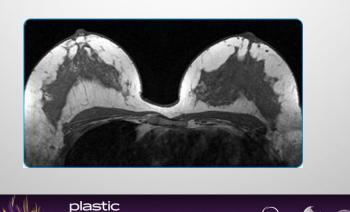
- Moderate to significant aesthetic improvement
 - Volume
 - Contour
 - Superomedial fullness
- Improved quality of irradiated skin
- Serial fat grafting improves outcome
- Overall patients satisfied

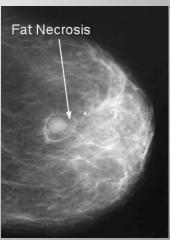




Breast Cancer Recurrence & Detection

- Fat grafting in post-mastectomy breast
 - Does not increase risk of breast cancer recurrence
 - Does not delay diagnosis of breast cancer
- Radiographic findings
 - Oil cysts
 - Fat necrosis
 - Distinguishable from suspicious lesions (experienced radiologists)





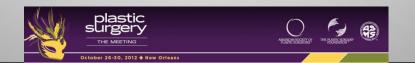
Radiation & Pain Syndrome

• Evidence suggests no increased risk of complications of fat grafting in previously irradiated tissue

• Evidence for fat grafting in treating post-mastectomy pain syndrome





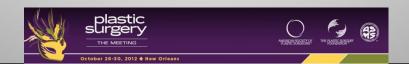


Aesthetic & Reconstructive Breast Fat Graft Registry

- Babak Mehrara, MD & Peter Rubin, MD
- First nationwide quality assurance registry
 - Safety and efficacy
 - Standardized outcomes measures
 - Validated patient reported questionnaires
- Open to Plastic Surgeons
- Data collection starts 2013







Fat Grafting: Oncologic Safety Study

- Clara Lee, MD & Terry Myckatyn, MD
- Evaluate relative risk of breast cancer recurrence after fat grafting in stages I-III breast cancer after mastectomy
- Study Sites:
 - MD Anderson
 - Memorial Sloan-Kettering
 - University of Chicago
 - University of North Carolina
- Data collection starts late 2012



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