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FDA Part 15 Hearing
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FAT GRAFTING: CLINICAL ASPECTS

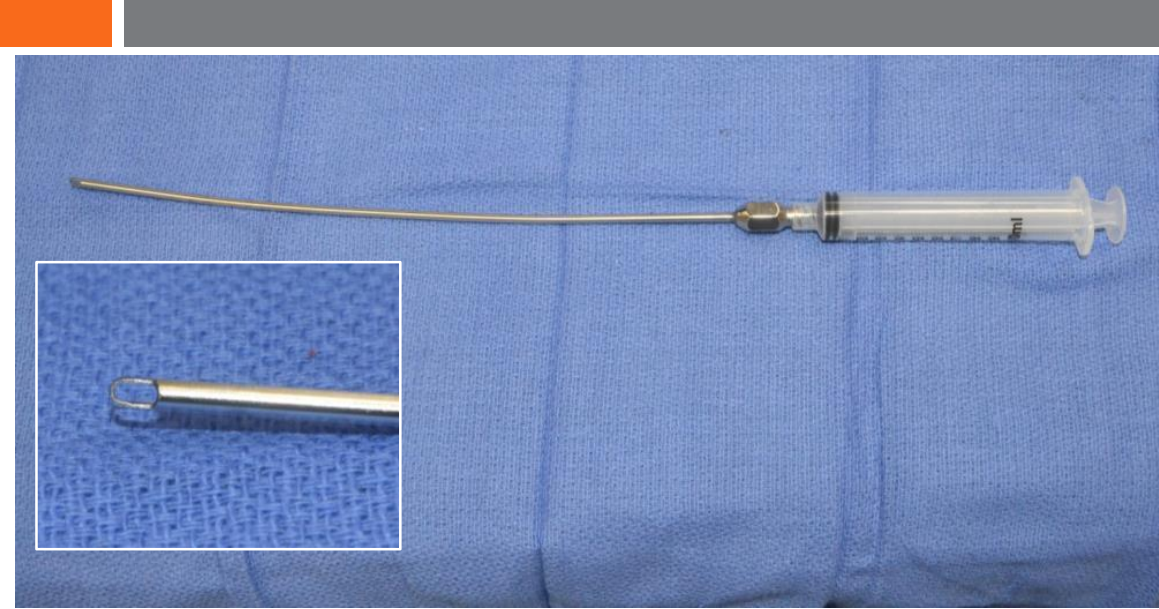
About ASPS

- The **American Society of Plastic Surgeons (ASPS)** is the largest plastic surgery specialty organization in the world. Founded in 1931, the Society represents 94% of all board-certified plastic surgeons in the U.S., and more than a thousand plastic surgeons worldwide, making ASPS a global institution and leading authority on cosmetic and reconstructive plastic surgery.

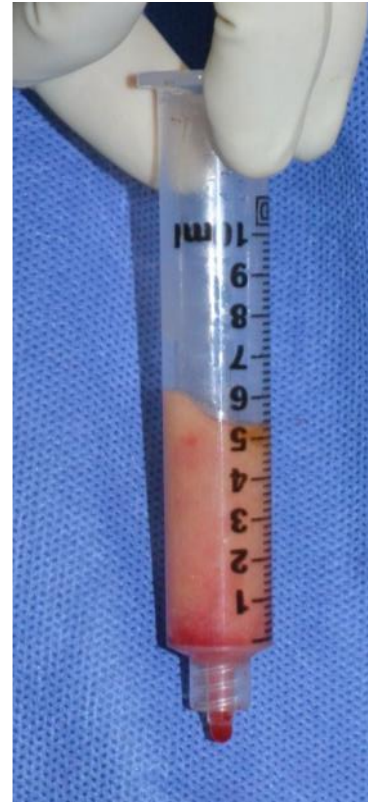
Autologous Fat Grafting

- Autologous fat grafting is a form of **tissue grafting** in which fat is moved from another part of the body
- Commonly used in plastic surgery for decades
- Other common tissue grafting procedures used in surgery
 - ▣ Skin grafts
 - ▣ Bone grafts
 - ▣ Cartilage grafts
 - ▣ Tendon grafts
 - ▣ Nerve grafts

Autologous Fat Grafting: Simple Harvest



Autologous Fat Grafting: Simple Methods



Fat Grafting Has a Long History

Process of fat grafting – developed and refined by plastic surgeons for more than a century

1893: Gustav Neuber transplanted adipose from the arm to the lower orbit to in order to improve unsightly, depressed, adherent scars.

1910: Eugene Holländer was the first to describe fat grafting by injection in order to modulate scars. **INTRODUCED REGENERATIVE USE, MORE THAN JUST VOLUME**

1912: Holländer published photographs of fat grafting by injection.

1919: Erich Lexer published a two-volume book, which devoted 300 pages to fat grafting and described fat grafting to the breast.

Fat Grafting History

1920: Sir Harold Gilles published a book based on his experiences in WWI entitled “Plastic Surgery of the Face based on selected cases of War Injuries of the Face”.

1922: The literature introduces the use of fat grafts to repair intestinal ruptures, bladder, liver and uterine injuries.

1926: Conrad Miller described the use of fat grafts to treat 36 cases of cicatricial contracture of the face and neck with only “moderate shrinkage of the fat.”

Fat Grafting: Key To Plastic Surgery

- Used for aesthetic/cosmetic and reconstructive purposes
- Examples include:
 - ▣ Facial volume restoration for aesthetic use
 - ▣ Facial reconstruction after cancer therapy
 - ▣ Facial reconstruction after trauma
 - ▣ Buttock augmentation
 - ▣ Breast reconstruction
 - ▣ Breast augmentation

Fat Grafting is Standard of Care

- Estimated Number of Procedures Performed in 2015
 - ▣ Buttock augmentation with fat grafting – 14,705 procedures
 - ▣ Fat as a cosmetic minimally-invasive soft tissue filler – 70,283 procedures
 - ▣ Breast reconstruction – 29,774 procedures*
 - ▣ Breast augmentation – 5,583 procedures*
- ~ 120,000 procedures in 2015.

*preliminary data

Fat Grafting: Breast Reconstruction

- In a recent ASPS survey, 70% of U.S. plastic surgeons have used fat grafting techniques for breast operations.
- 88% of plastic surgeons who currently perform fat grafting to the breast said they use fat grafting for breast reconstruction techniques and often apply fat grafting along with implants or flap procedures.
- Fat grafting for breast reconstruction is the an option for reconstructing the breast and the sole option for treating other post-mastectomy conditions, including:
 - Reversing damage caused by therapeutic radiation
 - Reducing implant breast pain and post-mastectomy pain.

Breast Reconstruction is Very Important

- 1 in 8 women will get breast cancer
- Breast reconstruction restores a woman's body
- Federal legislation
 - ▣ The Women's Health and Cancer Rights Act (WHCRA), 1998
 - ▣ Breast Cancer Patient Education Act (BCPEA), 2015
- Traditional Procedures
 - ▣ Implant based
 - ▣ Based on Fat Tissue

Specific Language: Adipose

- Example B-3: Adipose tissue is recovered and processed for injection into the breast, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent, for non-implant breast augmentation. The breast is composed of lobes of glandular tissue and branching ducts, interspersed with fat and ligaments that support the breast and give it shape; and nerves, blood vessels, and lymphatic tissues. The basic function of breast tissue is to produce milk (lactation) after childbirth. Because this is not a basic function of adipose tissue, using HCT/Ps from adipose tissues for breast augmentation would generally be considered a non-homologous use.

This Language is Problematic and Has Unintended Consequences

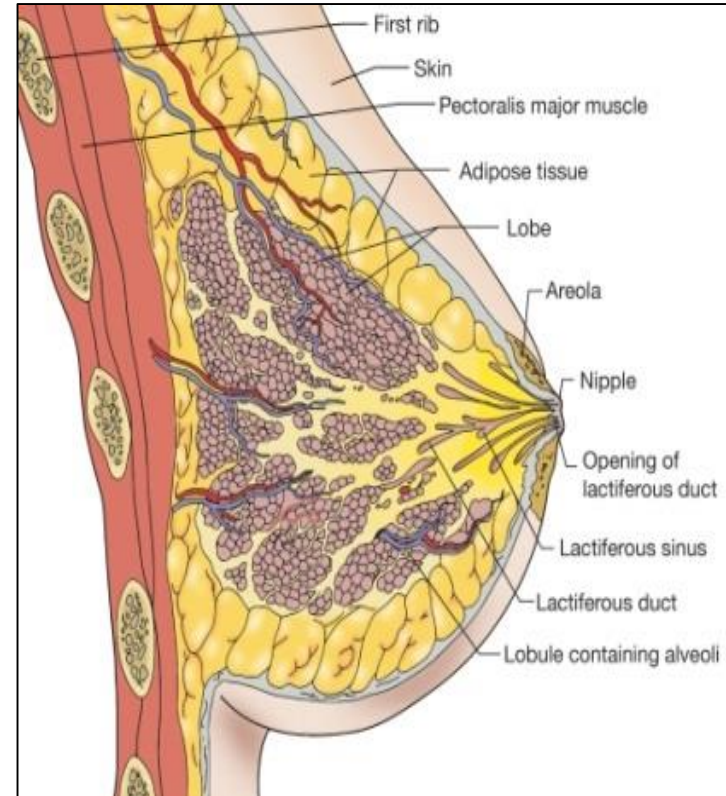
Fat Grafting to the Breast is a HOMOLOGOUS Use

- Lactation is not the sole function of the breast
 - ▣ Lactation is only a function of the breast during a very limited period following childbirth.
 - ▣ In contrast, throughout a woman's adolescence and adulthood, the breast's main function is that of a secondary sex organ.
 - ▣ Adipose tissue, which is naturally present in breast tissue, is injected to the breast to preserve the structure and function of a secondary sex organ.

Fat Grafting to the Breast is a HOMOLOGOUS Use

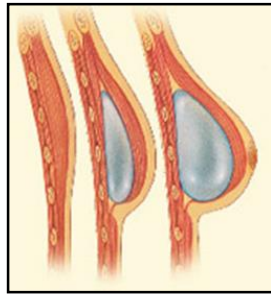
Structural replacement of the interspersed adipose tissue in the breast therefore constitutes homologous use.

The basic function of adipose includes providing structural support to assist with contours within the human body. Autologous adipose is used to supplement, repair, and replace the breast tissue during breast augmentation or reconstruction. Therefore, this is a homologous use of adipose.

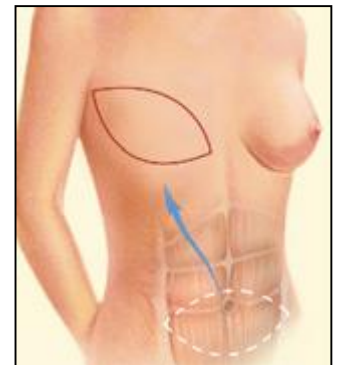


No Method of Breast Reconstruction Restores Lactation

- Implant based reconstruction restores form, but not lactation



- Fat based breast reconstruction has been used for decades and also does restore lactation
- Importantly, a breast free-flap procedure is an HCT/P and therefore the “gold standard” operation would not be allowed



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 - Should not distinguish between breast augmentation and breast reconstruction (same processes, same functions)
 - Should acknowledge that the breast has multiple functions and not rely upon “basic function”

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 - The language should not distinguish between breast augmentation and breast reconstruction (same processes, same functions)
 - The language should acknowledge that the breast has multiple functions and not rely upon “basic function”



- Thank you!