the Augmented Patient: Challenges and tips

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Did you know that Barbie had augmentation....

History Breast Implants

- Implants are not as new as commonly believed. The first known implant occurred in 1860s Germany, in which fat from a benign tumor was removed from a woman's back and implanted into her breast. Afterwards, the medical community started to experiment with implants of various materials, often paraffin.

- Attempts to improve the look of the breast were numerous; among the materials inserted in breast early on were ivory, glass balls, ground rubber, ox cartilage, and sponges, sacks and tapes made from various synthetic substances. Later came rubber, Teflon and silicone.
• The first use of silicone injections as breast-implant may have been by Japanese prostitutes in the time immediately after World War II, with the purpose of attracting American soldiers. In the 1940's, liquids like paraffin and petroleum jelly were also injected into women's chests.

• After this, American women started to use the injections, at first only topless dancers. These injections were believed to cause many complications in the women's bodies, due to the silicone leaking, including infections, blood clots to the lungs, cancer, and even death. Japanese doctors recorded in medical journals that women with the injections appeared to have suffered immune system disorders as well.

• 1960s
  The first silicone breast implants are developed by two plastic surgeons from Texas: Frank Gerow and Thomas Cronin.

• 1962
  Timmie Jean Lindsey becomes the first woman to receive silicone breast implants.
  • Surgery was at Jefferson Davis Charity Hospital, Houston, Tx

• That was fifty years ago. Timmie Jean Lindsey, who is now an 80-year-old great-grandmother, had been the guinea pig of Frank Gerow and Thomas Cronin. Who knows how it all got started? How old was she when she got her implants? What other surgery did she have at the same time?
Why would you consider augmentation

- You are bothered by the feeling that your breasts are too small
- Clothes that fit well around your hips are often too large at the bust line
- You feel self-conscious wearing a swimsuit or form-fitting top
- Your breasts have become smaller and lost their firmness after having children
- Weight loss has changed the size and shape of your breasts
- One of your breasts is noticeably smaller than the other

Why would you get implants if you have had breast cancer?

- Many women choose not to have breast reconstruction or implants. They may use a prosthesis (an artificial breast) in their bra that gives them a natural shape, or they may choose to use nothing at all.
- Women who have had a lumpectomy rarely need to have breast reconstruction.

Non Surgical Intervention

1. Botulinum Toxin Type A (6.7 million procedures, up 1 percent from 2014 and 759 percent since 2000)
2. Soft Tissue Fillers (2.4 million procedures, up 6 percent from 2014 and 274 percent since 2000)
3. Chemical Peel (1.3 million procedures, up 5 percent from 2014 and 14 percent since 2000)
4. Laser hair removal (1.1 million procedures, unchanged from 2014, but up 52 percent since 2000)
5. Microdermabrasion (800,340 procedures, down 9 percent from 2014 and 8 percent since 2000)
Top Cosmetic Surgical Ops 2015

- Breast lifts, up 89 percent (99,614 in 2015, up from 52,836 in 2000)
- Buttock lifts, up 252 percent (4,767 in 2015, up from 1,356 in 2000)
- Lower body lifts, up 3,973 percent (8,431 in 2015, up from 207 in 2000)
- Upper arm lifts, up 4,959 percent (17,099 in 2015, up from 338 in 2000)
- Breast augmentation (379,143 procedures, down 2 percent from 2014, up 31 percent from 2000)


- Liposuction (222,051 procedures, up 5% from 2014 but down 37 percent from 2000)
- Nose reshaping (217,979 procedures, unchanged from 2014, down 44 percent since 2000)
- Eyelid surgery (203,934 procedures, down 1 percent from 2014, down 38 percent since 2000)
- Tummy tuck (127,967 procedures, up 9 percent from 2014 and 104 percent since 2000)

Silicone Gel-Filled Breast Implants

Description:

Silicone gel-filled breast implants have a silicone outer shell that is filled with silicone gel. They come in different sizes and have either smooth or textured shells.

Saline-Filled Breast Implants

Description:

Saline-filled breast implants contain a silicone outer shell filled with a sterile saltwater (saline) solution. Some are pre-filled and others are filled during the implant operation. Saline-filled implants come in different sizes and have either smooth or textured shells.
The term “gummi bear breast implants” is commonly used to describe a specific type of breast implant that contains a cohesive silicone gel with a consistency comparable to the inside of a gummy bear. Though these implants are similar to other silicone implants, it’s this unique gel that sets them apart, and has made them a popular option among breast augmentation surgeons and patients.

The silicone gel inside gummi bear implants contains a special component that makes the molecules bind to one another, which helps the implants maintain a uniform shape. This quality is believed to give the implants a more natural look and feel than other types of implants – an important benefit for many breast augmentation patients.

Breast Implant FDA Timeline

- **1976** Congress passed the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act. Breast implants were placed into Class II and reviewed through the premarket notification (510(k)) process.

- **1988** In response to emerging safety concerns, the FDA re-classified breast implants to class III devices (requiring premarket approval). However, in accordance with the law, they continued to be reviewed through the 510(k) process until the FDA issued a rule calling for submission of premarket approval applications (PMAs).

- **1991 - April** The FDA issued a final rule calling for submission of PMAs for silicone gel-filled breast implants.

What is difference in I, II, III Medical Devices

- **Class I:** General Controls examples bandages, hand held surgical instruments
- **Class II:** General controls with special controls examples powered wheelchairs, infusion pumps
- **Class III:** General controls and premarket approval; examples pacemakers, breast implants, endosseous implants
• **1991 - November** The FDA held an Advisory Panel meeting to discuss several PMAs for silicone gel-filled breast implants. While the panel concluded that the manufacturers had failed to provide adequate safety and effectiveness data for their implants, they unanimously recommended that the FDA permit the implants to remain on the market.

• **1992 - April** The FDA concluded: None of the PMAs submitted for silicone gel-filled breast implants contained sufficient data to support approval.
  • Access to silicone gel-filled breast implants should continue for patients undergoing breast reconstruction or for replacement of existing silicone gel-filled breast implants (revision). Implants used for these indications should be considered to be investigational devices, and women who received them should be followed through adjunct clinical studies.

• **1992 - January** The FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that manufacturers stop supplying them and surgeons stop implanting them, while the FDA reviewed new safety and effectiveness information that had been submitted.

• **1992 - February** Based on new information, the FDA held a second Panel meeting to re-evaluate the safety of silicone gel-filled breast implants. This time the panel recommended that silicone gel-filled breast implants be removed from the market pending further evaluation of the new data.

• **1992 - July** The FDA approved Mentor’s Adjunct Study protocol for its silicone gel-filled breast implants for reconstruction and revision patients only.

• **1998 - March** The FDA approved Allergan’s Adjunct Study protocol for its silicone gel-filled breast implants for reconstruction and revision patients only.
• **2000 - March** The FDA held an Advisory Panel meeting to discuss three saline-filled breast implant PMAs. The Panel recommended that the FDA approve two of the PMAs but not the third.

• **2000 - August** The FDA approved Mentor’s implants for its silicone gel-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites.

• **PMA (Pre Market Approval)**

  Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. FDA regulations provide 180 days to review the PMA and make a determination.

• **2000 - May** The FDA approved the first PMAs for saline-filled breast implants. These implants were approved for augmentation in women age 18 and older and for reconstruction in women of any age.

• **2002 - July** The FDA held an Advisory Panel meeting to update the Panel on postmarket (after approval) information and data for the two approved saline-filled breast implant PMAs.

• **2003 - October** The FDA held an Advisory Panel meeting to review Allergan’s PMA for its silicone gel-filled implants. In a 9 to 6 vote, the panel recommended approval with conditions, including a minimum age requirement for augmentation.
• **2003 - December** Mentor submitted a PMA for its silicone gel-filled breast implants.

• **2005 - April** The FDA held an Advisory Panel meeting to review Allergan’s updated PMA and Mentor’s PMA. In a 5 to 4 vote, the panel did not recommend approval of Allergan’s PMA (due to a concern with one style in the application). In a 7 to 2 vote, the panel recommended approval with conditions for Mentor’s PMA. The panel recommended that FDA require conditions including a minimum age requirement for augmentation and Post-Approval Studies.

• **2006 - November** The FDA approved Allergan and Mentor’s PMAs for silicone gel-filled breast implants. This was the first time silicone gel-filled breast implants were available for augmentation, in addition to reconstruction and revision, since the moratorium was established in 1992.

• **2011 - January** The FDA issued a Safety Communication on Anaplastic Large Cell Lymphoma (ALCL) in women with breast implants. Based on a review of the scientific literature, the FDA believes that women with breast implants may have a very small but increased risk of developing this disease in the scar capsule adjacent to the implant.

• **2011 - January** With an estimated five to 10 million breast implant recipients worldwide, agency experts say the known ALCL cases are too few to say conclusively that breast implants cause the disease. FDA believes there are about 60 of these ALCL cases worldwide, though that number is difficult to verify because not all of them were chronicled in scientific publications and some reports may have been duplicated.

• **ALCL can initially appear either in the skin, in lymph nodes, or in organs throughout the body**
2011 - June The FDA issued an Update on the Safety of Silicone Gel-Filled Breast Implants. It included preliminary results of the post approval studies Allergan and Mentor were required to perform as conditions of their silicone gel-filled breast implant 2006 approval.

2011 - August The FDA held an Advisory Panel meeting to discuss and receive recommendations on post marketing issues related to silicone gel-filled breast implants.

FDA listed complications

• Asymmetry The breasts are uneven in appearance in terms of size, shape or breast level.
• Breast Pain Pain in the nipple or breast area
• Breast Tissue Atrophy Thinning and shrinking of the skin
• Calcification/Calcium Deposits Hard lumps under the skin around the implant. These can be mistaken for cancer during mammography, resulting in additional surgery

• Capsular Contracture Tightening of the tissue capsule around an implant, resulting in firmness or hardening of the breast and squeezing of the implant if severe
• **Chest Wall Deformity** Chest wall or underlying rib cage appears deformed.

**Deflation** Leakage of the saltwater (saline) solution from a saline-filled breast implant, often due to a valve leak or a tear or cut in the implant shell (rupture), with partial or complete collapse of the implant.

• **Delayed Wound Healing** Incision site fails to heal normally or takes longer to heal.

**Extrusion** The skin breaks down and the implant appears through the skin.

**Hematoma** Collection of blood near the surgical site. May cause swelling, bruising, and pain. Hematomas usually occur soon after surgery, but can occur any time there is injury to the breast. The body may absorb small hematomas, but large ones may require medical intervention, such as surgical draining.
• **Iatrogenic Injury/Damage** Injury or damage to tissue or implant as a result of implant surgery. Infection, including Toxic Shock Syndrome. Occurs when wounds are contaminated with microorganisms, such as bacteria or fungi. Most infections resulting from surgery appear within a few days to a week, but infection is possible any time after surgery. If an infection does not respond to antibiotics, the implant may need to be removed.

• **Inflammation/Irritation** Response by the body to an infection or injury. Demonstrated by redness, swelling, warmth, pain and/or loss of function.

• **Lymphedema or Lymphadenopathy** Swollen or enlarged lymph nodes. **Malposition/Displacement** The implant is not in the correct position in the breast. This can happen during surgery or afterwards if the implant moves or shifts from its original location. Shifting can be caused by factors such as gravity, trauma or capsular contracture.

• **Symmastia** describes the phenomenon where the breast implants cross the breast bone to touch each other over the midline of the chest where the cleavage area would normally be seen. Unnatural touching of implants across the breastbone with elevation of the pre-sternal skin (Kissing Implants).
• **Necrosis** Dead skin or tissue around the breast. Necrosis can be caused by infection, use of steroids in the surgical breast pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

• **Nipple/Breast Sensation Changes** An increase or decrease in the feeling in the nipple and/or breast. Can vary in degree and may be temporary or permanent. May affect sexual response or breast feeding.

**Palpability** The implant can be felt through the skin.
• **Ptosis**
Breast sagging that is usually the result of normal aging, pregnancy or weight loss.

**Redness/Brusing** Bleeding at the time of surgery can cause the skin to change color. This is an expected symptom due to surgery, and is likely temporary.

**Rupture** A tear or hole in the implant’s outer shell.

• **Seroma** Collection of fluid around the implant. May cause swelling, pain and bruising. The body may absorb small seromas. Large ones will require a surgical drain.

**Skin Rash** A rash on or around the breast.

**Unsatisfactory**

• **Style/Size** Patient or doctor is not satisfied with the overall look based on the style or size of the implant used.

**Visibility** The implant can be seen through the skin.
• **Wrinkling/Rippling** Wrinkling of the implant that can be felt or seen through the skin. A complete list of complications, as well as information on rates for those complications can be found in the patient labeling for the approved breast implants.

**Implant Placement**

Implants can be placed either sub-pectoral or sub-glandular.
Implant Reconstruction

The implants push the pectoral muscle out from the chest wall and act as a platform for development of pectoral muscles. Some patients have deformities of their chest wall, where muscle has not developed or the skeleton is asymmetrical. Use of pectoral implants for these patients leads to a balance in proportions of the chest wall.
Skin expansion. The most common technique combines skin expansion and subsequent insertion of an implant.

The expander is an elastic bag equipped with a valve. After it is in place, it is filled with a small amount of saline. The patient will return to the surgeon’s office every week or two to have more saline injected into the expander. Gradually, over three to six months, the skin and muscle will stretch; the expander will be removed and the permanent implant inserted in its place.

Implant complications

Patients with large implants, particularly those inserted subglandularly (on top of the muscle and under the breast glands), will have a major cosmetic deformity if they choose not to replace them or to undergo additional reconstructive surgery.

FDA recommendation: because implant breaks don’t cause immediate symptoms, patients should get an MRI scan five years after implant insertion and every two years after that. They should consider having broken implants removed to minimize risk of silicone oozing into the breast, or beyond.
Microscopic examination of the fibrous capsule from a silicone breast implant.
Breast Cancer and Implants
MQSA Regulation

- Breast Implants
- Should a patient with breast implants have a mammography exam to look for breast cancer?
- Yes, patients with breast implants who are in an age group for which routine screening is recommended can effectively have mammograms. (Those who have had implants as reconstruction after breast cancer surgery on both breasts should ask their doctors whether mammograms are still necessary.) When she schedules her appointment, she should do two things:
  - inform the facility that she has breast implants; and
  - ask if the facility has personnel with training and experience in implant imaging and interpretation.
- Skilled personnel will use special techniques that expose as much breast tissue as possible.
- If the facility has no personnel trained in implant imaging, ask to be referred to another facility.
MQSA Regulation

• Should mammograms be used to detect breast implant rupture?
• Although implant rupture can sometimes be seen by mammography, when possible, implant rupture is being evaluated by magnetic resonance imaging (MRI). MRI has been approved by FDA for detecting rupture or leaks.

• Is a facility required to use any specific implant displacement technique when imaging patients with breast implants?
• No. Because breast implant imaging techniques are evolving, FDA believes that it would be inappropriate to limit, by regulation, this imaging to only one technique.
Have you had any breast surgery?
No......

Medical History very important for Radiologist

Medical History very important for Radiologist
Positioning The Augmented Breast

ACR Recommendations

The Augmented Breast

Imaging the augmented breast presents special problems and challenges to the radiologist and the technologist.

The routine CC and MLO implant-included views require manually set exposure factors and the degree of compression is limited by the compressibility of the implant.

- In addition to these routine views, patients with augmented breast should have modified CC implant displaced and MLO implant displaced view.

- In the modified implant displaced views, the prosthesis is displaced posteriorly and superiorly against the chest wall while gently pulling the breast tissue anterior to the prosthesis onto the image receptor and holding it in place with the compression device.

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Imaging the Augmented Breast

Implant Displaced Views

- Improve visualization of tissue anterior to the implant by pulling the breast tissue over and in front of the breast tissue
- Allows for taut compression of anterior tissue free of implant
- Will not image posterior tissue surrounding the implant
- May use AEC phototimed technique

Standard CC View

- Visualization of the posterior tissue both medially and laterally
  - Evaluate implant
  - Manual Technique
  - Do not apply compression
  - Properly penetrate the tissue surrounding the implant

Compression

Just rest the paddle on the skin, just enough to hold it in place
Compressing the breast with the implant drives the implant forward and compacts the breast tissue surrounding it
No taut Compression!

5 Steps for the CC implant displaced views

1. Have the patient bend forward from the waist, use your fingers to pull the breast tissue forward while displacing the implant posteriorly, and have the patient stand again.

The Augmented Breast
Facilities must have procedures in place to inquire whether patients have breast implants prior to the actual mammographic examination. The facility and/or interpreting physician can then determine whether the woman with breast implants will be imaged at that facility. For asymptomatic women, mammography may be performed as a screening or, at the discretion of the facility, a diagnostic examination. However, if the facility does not provide implant imaging services, it should refer the patient to other facilities that provide such services.
5 Steps for CC implant displaced view

2. Have the patient place her contra lateral hand under breast and firmly against the ribs.

3. Gently pull the breast tissue onto the detector and place the edge of your fingers, holding the inferior tissue, against the edge of the detector.
5 Steps CC implant displaced view

• 4. Ask the patient to push her body against her hand resulting in further displacement of the implant.

5. Apply compression. Use a spatula if needed to hold the tissue forward and then use compression.
Standard MLO View

- Visualization of the posterior tissue both superior and inferior to the implant
- Evaluate implant
- Manual Technique
- Do not apply taut compression
- Properly penetrate the tissue surrounding the implant

5 Steps MLO implant displaced view

1. Have the patient bend forward from the waist, use your fingers to pull the breast tissue forward while displacing the implant posteriorly, and then have the patient stand again.

2. Ask the patient to place her hand on the handlebar with the corner of the detector posterior to the axilla.

3. Place the edge of your fingers, holding the lateral tissue, against the edge of detector.
5 Steps MLO implant displace view

4. Ask the patient whether she feels the bucky against her ribs or against her breast. If she states breast, then ask her to lean her body against the detector. If she replies ribs, you should start over because the implant is not sufficiently displaced correctly.

5. Apply compression

If the breast cannot be adequately displaced, a 90 degree lateral with the implant included should be added to the routine CC and MLO implant-included views.

ACR Mammography Quality Control Manual 1999
After implants, sometimes implants can be placed in the breast more medial or lateral.
Not so easy positioning
Make sure to look at your technique chart.
Reconstruction on contra-lateral breast

Patient’s Baseline Mammogram, Post Excisional Biopsy

Implant Case Studies

Interesting Case

- Patient went to have an excisional biopsy
- Pathology came back as benign
- Specimen x-ray came back with no calcifications noted
- Patient complained of breast pain four weeks after surgery
- Went for second opinion at another facility
Prescout – 8mm
No go on Stereo
Results were fibrocystic changes

Stereotactic Implant case
Thank you for being my friend.
Postmastectomy Imaging

This subject is controversial. Most facilities no longer image the reconstructed breast unless there is a clinical concern.

Most recurrences are found at the scar site.

Those who do recommend this procedure might include:

- A MLO view of the skin over the mastectomy site
- A spot view of any area of concern
- And/or an anteroposterior view of the axilla.

Positioning for an axillary view
Reduction Mammoplasty

Imaging the Reconstructed Breast

Tissue Flap Reconstruction