



Imaging Findings of 3-Dimensional Bioabsorbable Breast Implant Device

Miral M. Patel MD, Megha M. Kapoor MD, Marion E. Scoggins MD

THE UNIVERSITY OF TEXAS

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Disclosure of Commercial Interest

Neither I nor my immediate family members have a financial relationship with a commercial organization that may have a direct or indirect interest in the content.

Goals & Objectives

By the end of this exhibit, the participant should:

1. Have a basic understanding of the basis of breast conserving therapy
2. Recognize the structure and purpose of 3-dimensional (3D) bioabsorbable breast implant device, BioZorb® (Hologic, Marlborough, MA) used by surgeons and radiation oncologists
3. Recognize the normal mammographic, sonographic, magnetic resonance (MR), computed tomography (CT), and chest radiographic appearances of the BioZorb®
4. Appreciate the imaging evolution over time of the BioZorb® on mammography and sonography
5. Recognize the mammographic, sonographic, and MRI appearance of recurrence at the site of breast conservation surgery with BioZorb®

Target audience: Radiologists, Radiation Oncologists, Oncologists, Surgeons, Radiology Technologists

Background

Understanding the basis for placing a bioabsorbable breast implant device requires a basic understanding of current trends in the management of breast cancer, including surgical techniques and current radiation therapy options.

Breast conservation surgery (BCS)

- Surgery to remove malignancy without performing a mastectomy (also known as: lumpectomy, segmental resection, wide local excision)
- Indications: Ductal carcinoma in situ (DCIS) or invasive breast cancer “clinically assessed as resectable with clear margins and with an acceptable cosmetic result”¹

Breast conservation therapy (BCT)

- BCS + radiation therapy
- Patients treated with mastectomy versus BCT have similar outcomes with respect to disease free survival and overall survival²
 - NSABP B-06 study evaluated total mastectomy versus BCT
 - No differences in disease free survival or overall survival
 - Established importance of radiation therapy in preventing local recurrence
- BCT is increasing in popularity

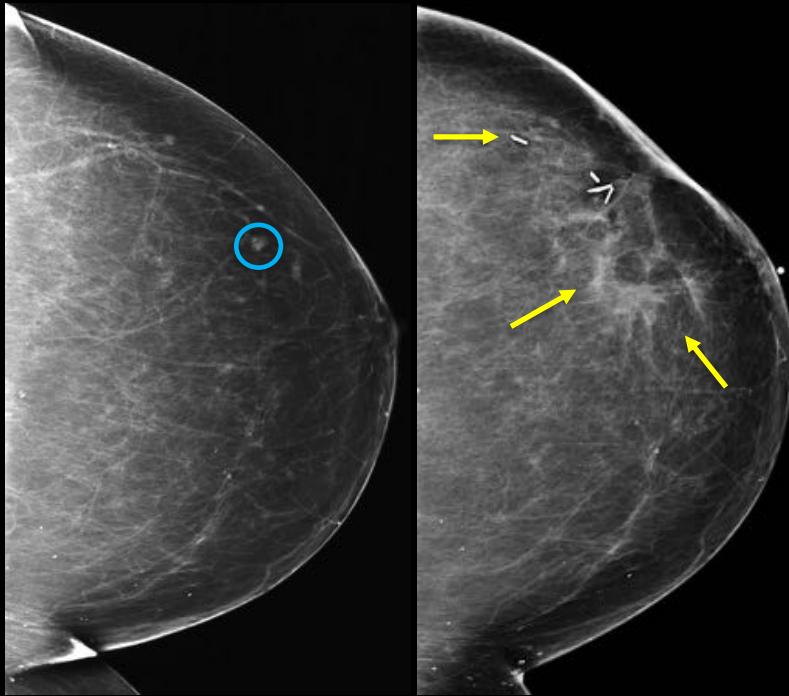
Oncoplastic Reconstruction

- Surgery to improve cosmetic outcome in conjunction with or after BCS
- May involve moving or removing existing tissue (tissue rearrangement, reduction, mastopexy) or filling in the defect with a tissue flap reconstruction

1. American Society of Breast Surgeons: Performance and Practice Guidelines for Breast-Conserving Surgery/Partial Mastectomy, 2018.

2. Black DM, Mittendorf EA. Landmark trials affecting the surgical management of invasive breast cancer. *Surg Clin North Am.* 2013;93(2):501–518. doi:10.1016/j.suc.2012.12.007

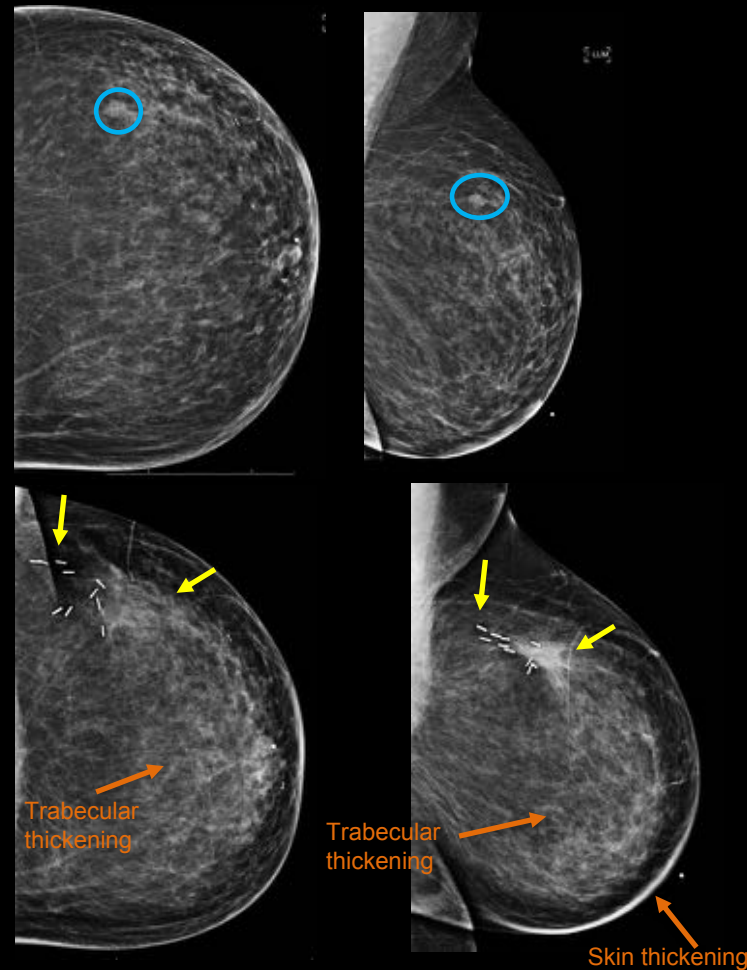
Breast conservation surgery (BCS)



74 year old status post BCS for left breast DCIS
Patient declined adjuvant radiation therapy

- (Left) Pre-biopsy craniocaudal (CC) view demonstrating **small irregular mass**
- (Right) Post-operative CC view shows expected postoperative changes including **post surgical scar and surgical clips located at the site of the original mass**

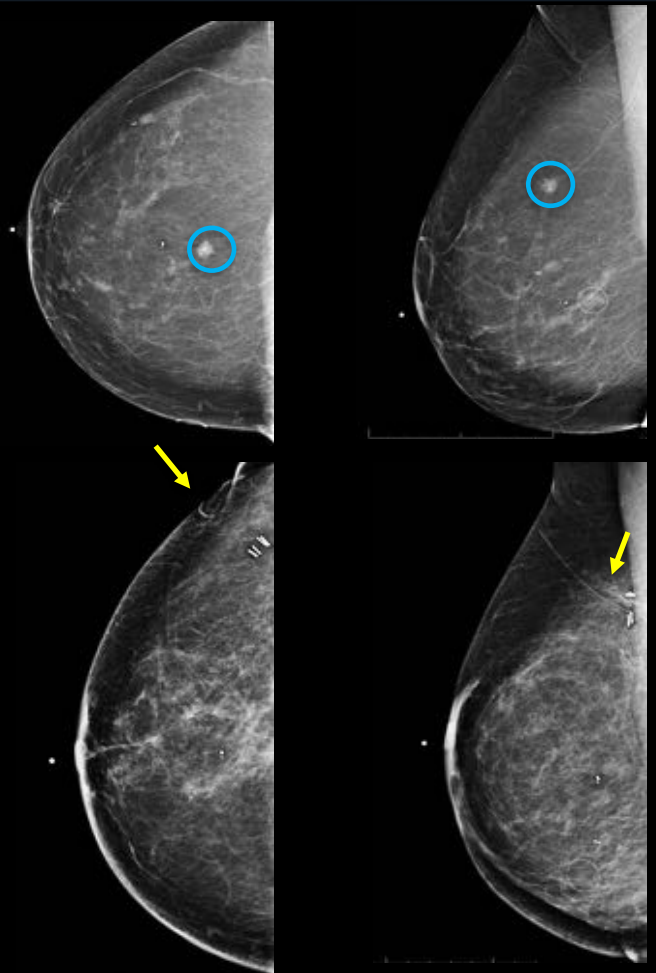
Breast conservation therapy (BCT)



46 year old status post BCT for invasive ductal carcinoma (IDC)

- (Top) CC and lateral pre-biopsy views demonstrate a **suspicious mass**
- (Bottom) CC and lateral views 6 months post radiation demonstrate **post-surgical scar and clips** located at the site of the original mass with **mild expected trabecular and skin thickening** related to radiation therapy

Oncoplastic Reconstruction



63 year old status post BCT for IDC with simultaneous reduction and tissue rearrangement

- (Top) CC and lateral pre-biopsy views demonstrate **small spiculated mass**. Additional benign biopsy clips noted.
- (Bottom) CC and lateral views post oncoplastic reconstruction demonstrate **scar marker and clips away from original tumor bed**

Radiation Therapy Basics

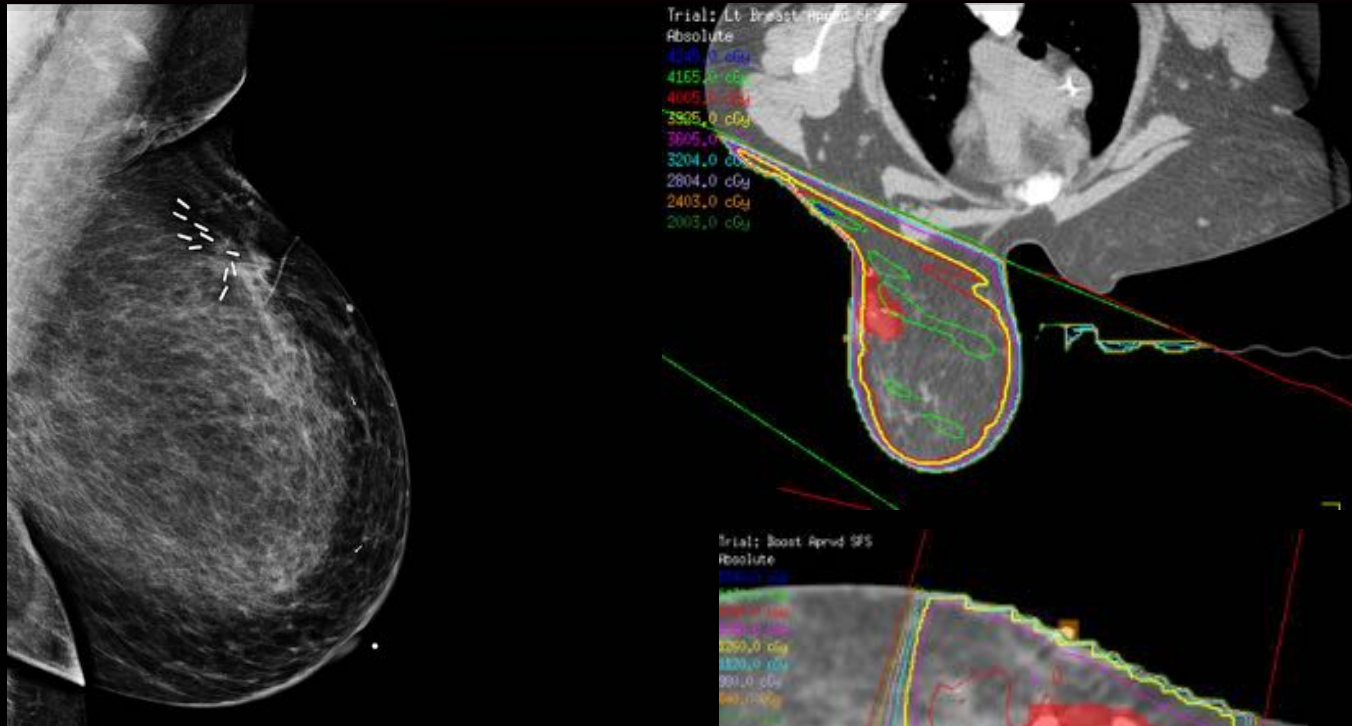
Whole Breast Irradiation (WBI)

- Standard treatment = 6-7 weeks, daily
- Begins 3-6 weeks post surgery unless adjuvant chemotherapy is administered
- Typically includes a 'boost' to the lumpectomy cavity
- Hypofractionated WBI is essentially a higher dose delivered over a shorter period of time

Accelerated Partial Breast Irradiation (APBI)

- Ipsilateral recurrence is typically around the tumor bed, therefore, APBI increases radiation specifically to the tumor bed (higher dose per fraction) with decreased radiation to the surrounding tissues
- Delivery mechanisms:
 - Brachytherapy
 - External beam
 - Intraoperative
- Treatment time varies based on mechanism of delivery, but is typically less than 1 week

Radiation Treatment Planning



46 year old status post BCT for IDC, 6 month post radiation baseline mediolateral oblique (MLO) view (above)

- Patient received hypofractionated WBI and boost to tumor bed
- (Top Right) Image demonstrates radiation treatment plan for WBI. Note targeting of the post-surgical clips seen on mammography.
- (Bottom Right) Image demonstrates radiation treatment plan for 'boost' to tumor bed. Again, note targeting of the post-surgical clips seen on mammography.

- Goal: deliver prescribed dose in a homogeneous distribution and minimize exposure and dose to critical structures
- Simulation using CT guidance is used to map out the radiation field and dose at various areas
 - Boards, cradles or molds allow reproducibility of positioning over the course of treatment
- Typically, radiation oncologists use the visible findings of post-surgical change including scar, post-surgical clips, and/or seromas to specifically target the tumor bed
- With oncoplastic reconstruction at the time of initial surgery becoming more common, the visible findings of post-surgical change may not correspond with the tumor bed, making targeting of the tumor bed difficult

Overview of the BioZorb® Device

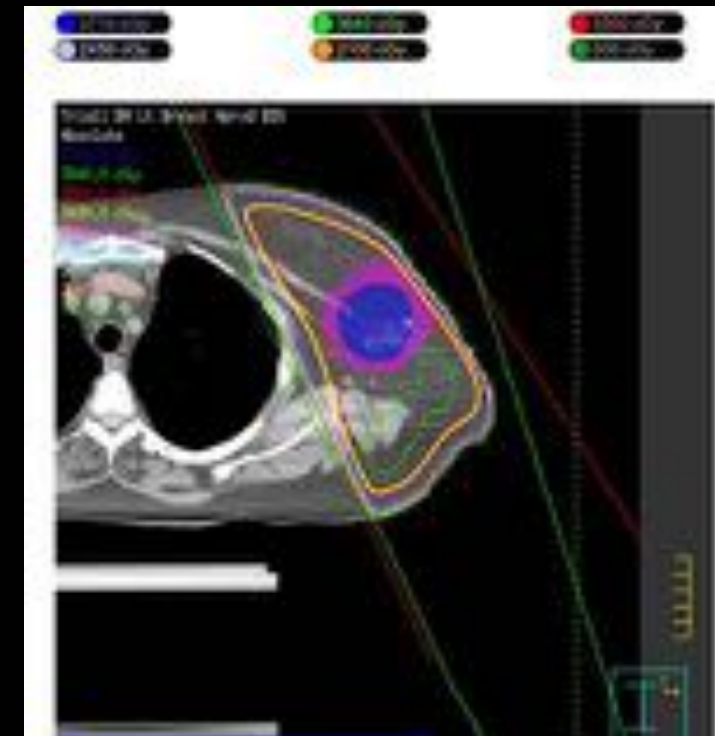
3-D bioabsorbable spiral frame



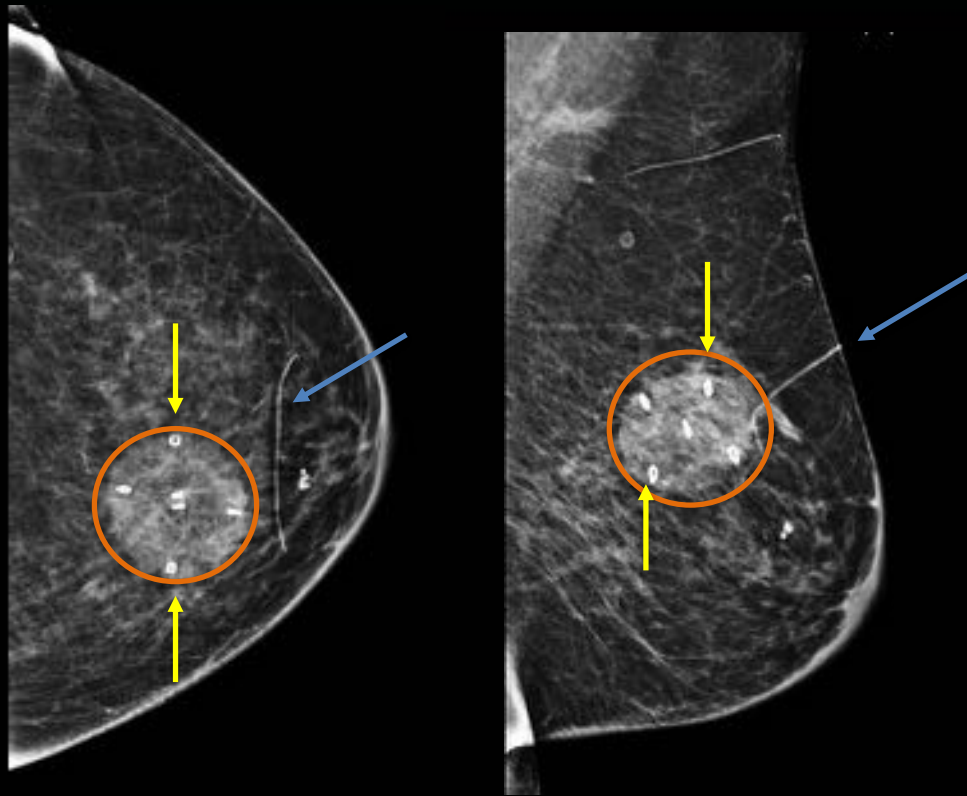
6 titanium marker clips (indicated by *)

- In order to better delineate the lumpectomy cavity, surgeons and radiation oncologists are now using a bioabsorbable 3D breast implant device called the BioZorb®
- The device is a marker sutured into the surgical cavity at the time of lumpectomy
- The six titanium clips of the BioZorb® device are radiopaque and therefore easily recognized on mammography, chest radiography and CT examination based on their unique configuration
 - Assists in delineating tumor bed on follow-up imaging when evaluating for recurrence
- The device serves as a target for radiation treatment, particularly in the setting of BCS with oncoplastic reconstruction where the surgical clips and scar may not match the original tumor bed
- The device also serves as an initial scaffold to improve cosmetic outcomes with radiation (reduce retraction) and is designed to eventually absorb into the body (over the course of several years)

Image (below) demonstrates a radiation treatment plan in a patient with a BioZorb® device (note the blue circle indicating maximum radiation dose covering the BioZorb® device)

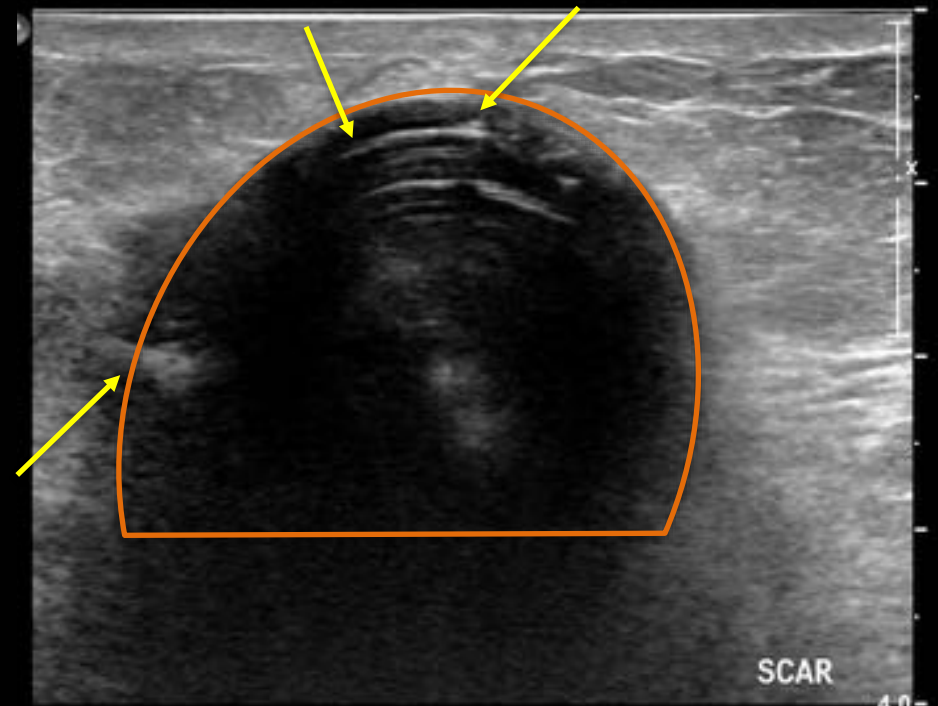


Normal Postoperative Imaging Findings: Mammogram & Ultrasound



Initial post-surgical baseline mammography (CC and MLO views) demonstrates a **post-surgical scar** with **six well-spaced radiopaque titanium clips** in a **well-circumscribed, oval, equal density mass**.

Initial post-surgical baseline ultrasound performed the same day demonstrates a post-surgical scar with an **area of shadowing** and associated **linear echogenic areas** similar to artifact seen with clips



Normal Postoperative Imaging Findings: Breast MRI

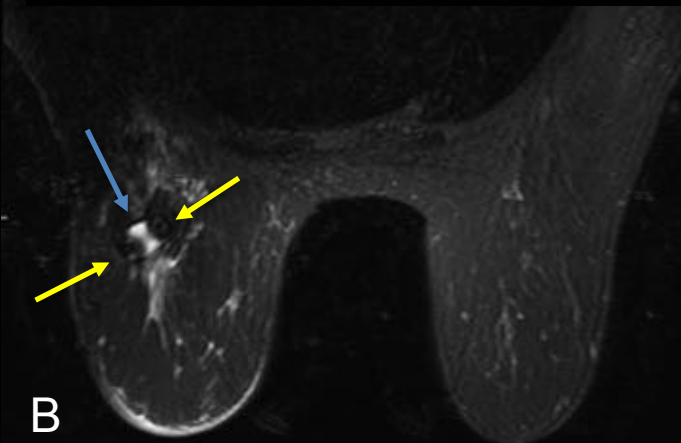
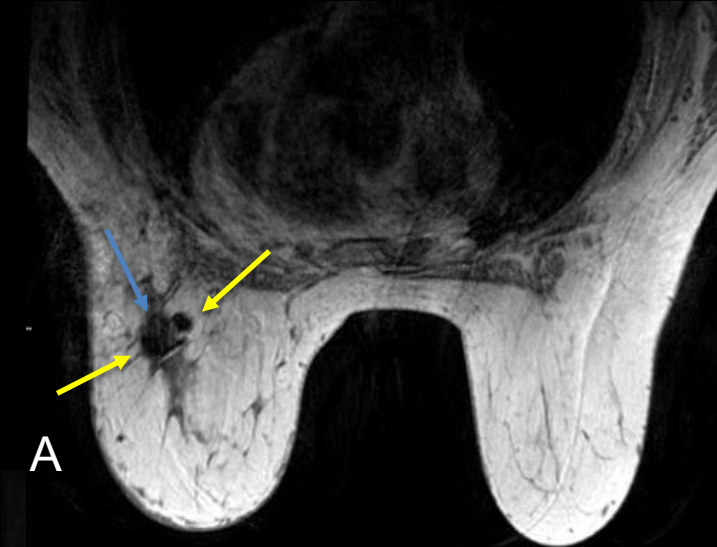
64 year old with history of left segmental mastectomy for metaplastic carcinoma and DCIS 1 year ago.

A. Axial T1-weighted image demonstrates post-surgical change with **two susceptibility artifacts** related to two of the six marker clips related to the BioZorb®

B. Axial T2-weighted image demonstrates **hyperintense signal related to post-surgical changes** with **two susceptibility artifacts** related to two of the six marker clips

C. Axial T1-weighted fat saturated post contrast image again demonstrates **susceptibility artifact** related to the BioZorb® clips with no abnormal enhancement of the surgical bed

D. Sagittal delayed post contrast T1-weighted fat saturated image demonstrates **susceptibility artifact** related to three of six marker clips arranged in the **typical helical configuration** with no abnormal enhancement of the surgical bed



Normal Postoperative Imaging Findings: CT Chest

Status post BCT approximately 1 year postop:



Post contrast axial CT images of the chest from superior to inferior (left to right) demonstrate the expected CT appearance of the BioZorb® device as **radio-opaque titanium clips** arranged in a “**spokewheel**” configuration with interspersed fat. This unique configuration helps to differentiate the device from artifact related to other titanium marker clips placed in the breast.

Normal Postoperative Imaging Findings: Chest Xray



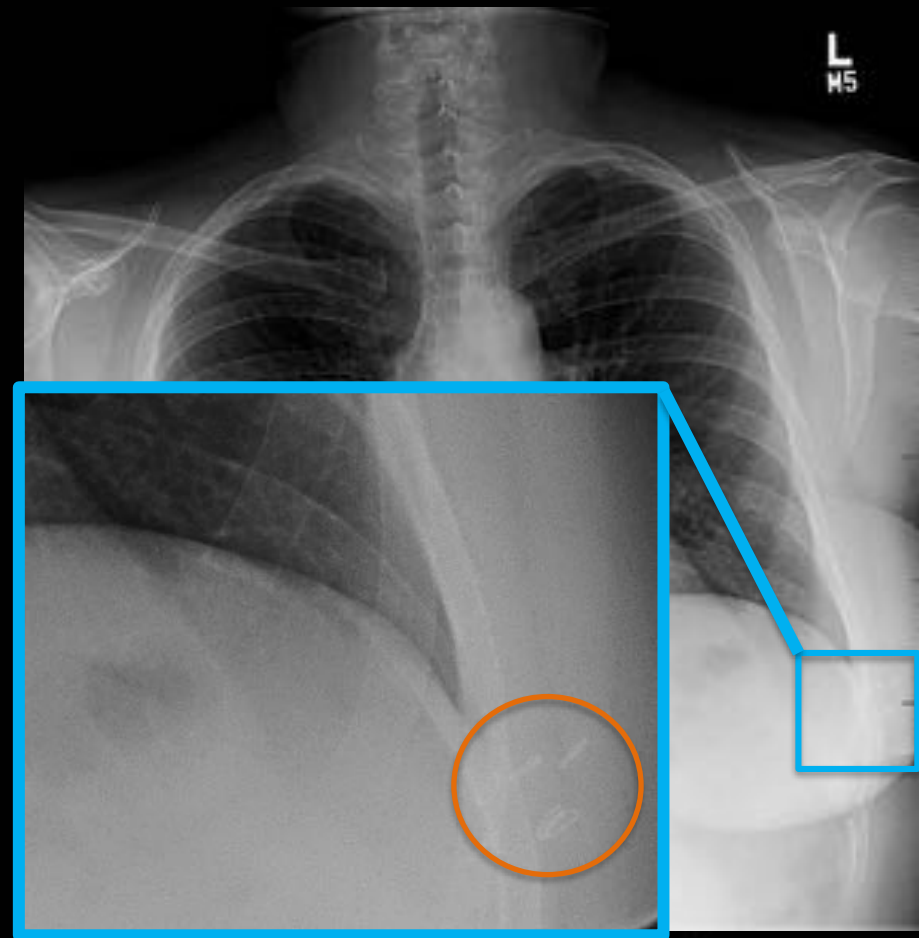
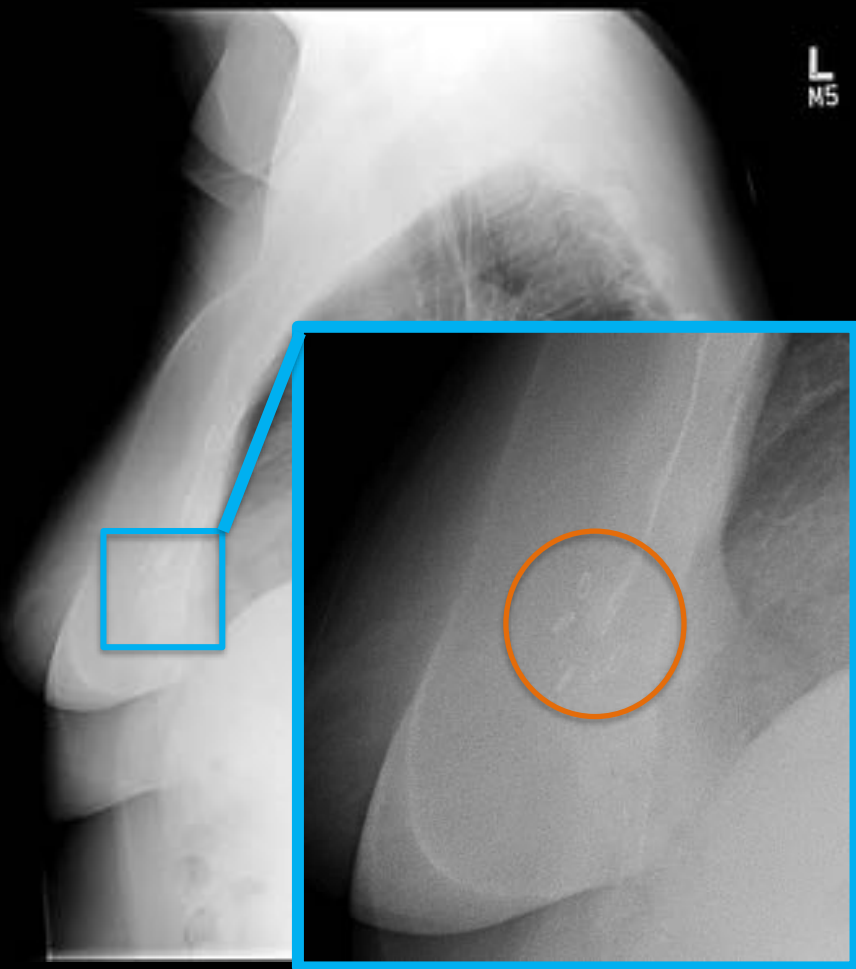
Can you find
the device?



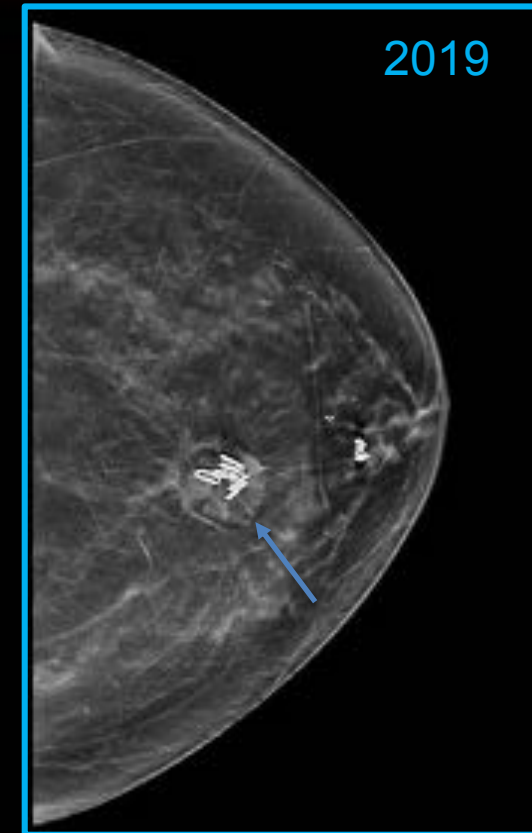
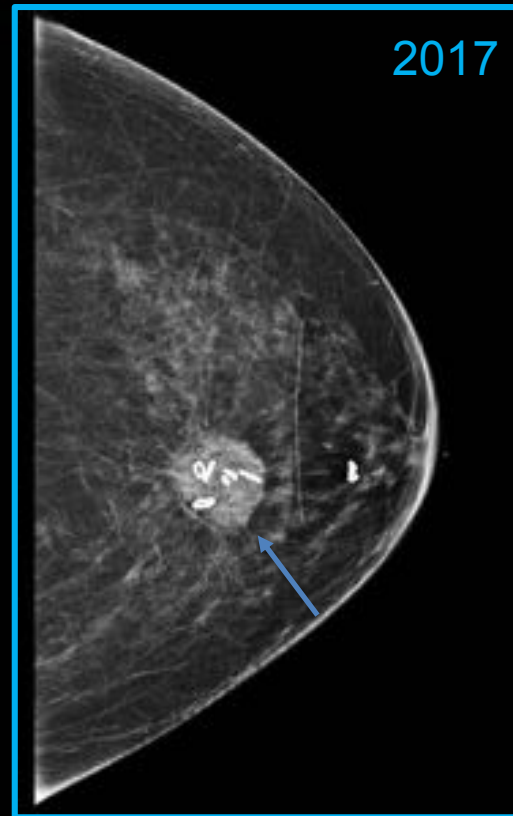
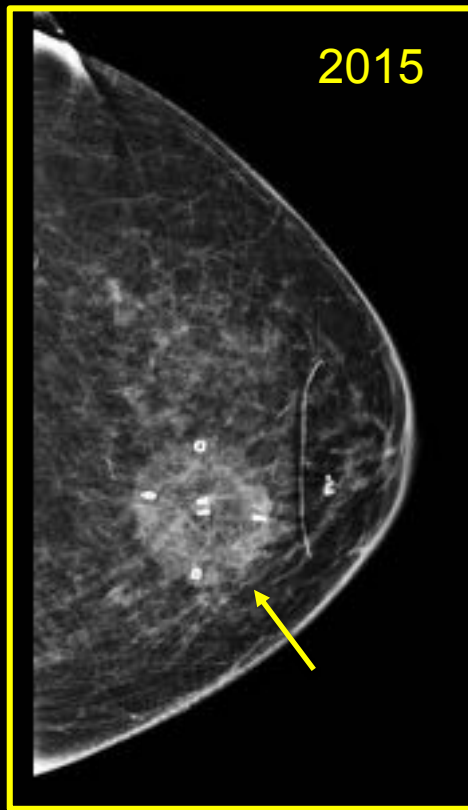
Normal Postoperative Imaging Findings: Chest Xray

Status post BCT
approximately 1 year postop:

Lateral and posteroanterior (PA) radiographs and magnified views of the chest demonstrate the expected “**spokewheel**” configuration of six radiopaque titanium marker clips located **within the soft tissues of the left breast** consistent with the BioZorb®



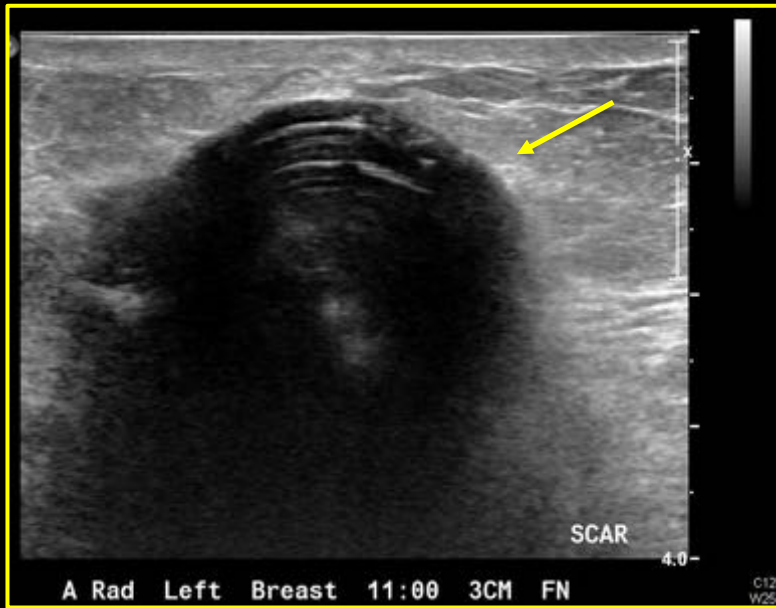
Normal Evolution on Postoperative Imaging: Mammogram



Initial post-surgical baseline mammogram and subsequent follow-up examinations over the course of 4 years (CC views) demonstrate **well-spaced titanium clips in a well-circumscribed, oval, equal density mass on initial imaging.** Over the course of follow-up, the expected evolution on mammography is a decrease in size of the oval mass with less space noted between the titanium marker clips.

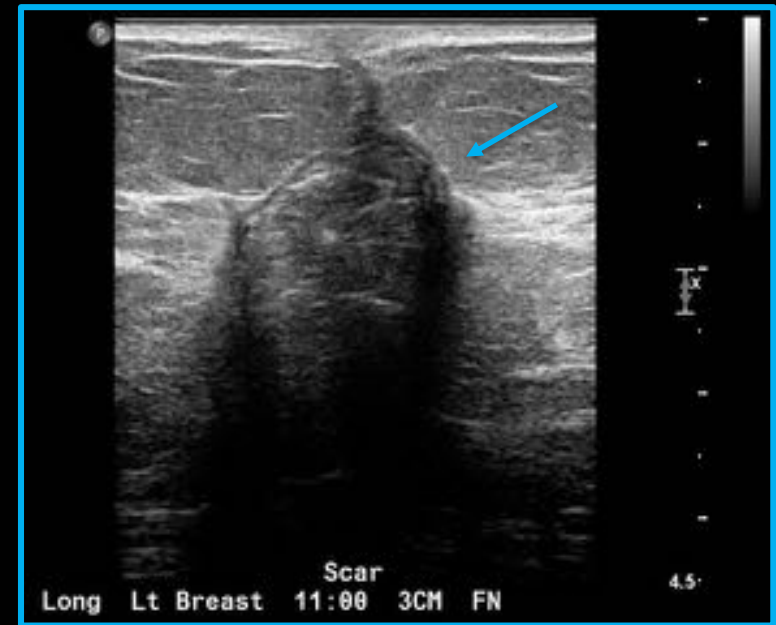
Normal Evolution on Postoperative Imaging: Ultrasound

2015

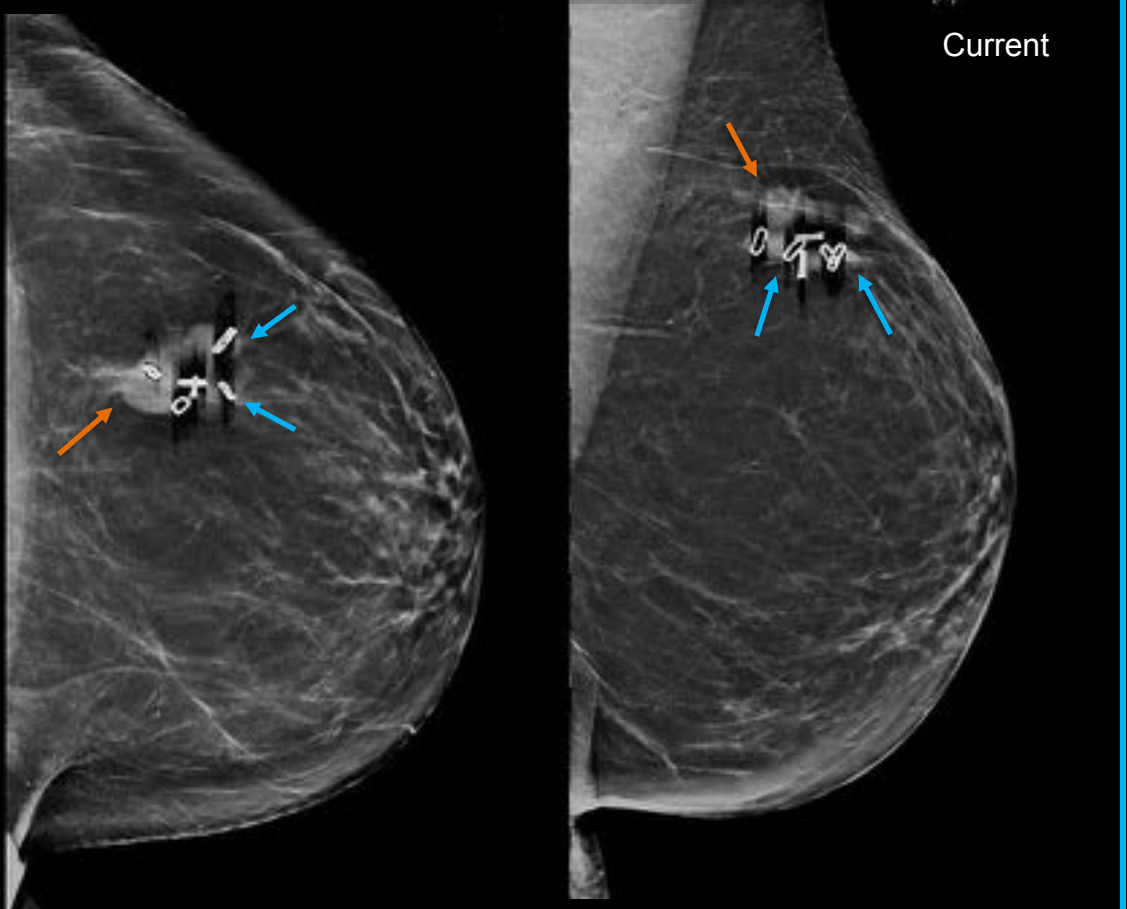


Similar associated findings are identified sonographically in the same patient, with the **initial baseline ultrasound demonstrating an oval area of shadowing at the scar and echogenic lines associated with BioZorb® device**, with subsequent decrease **in size of the area of shadowing which begins to demonstrate an isoechoic appearance**. No associated increased vascularity was identified.

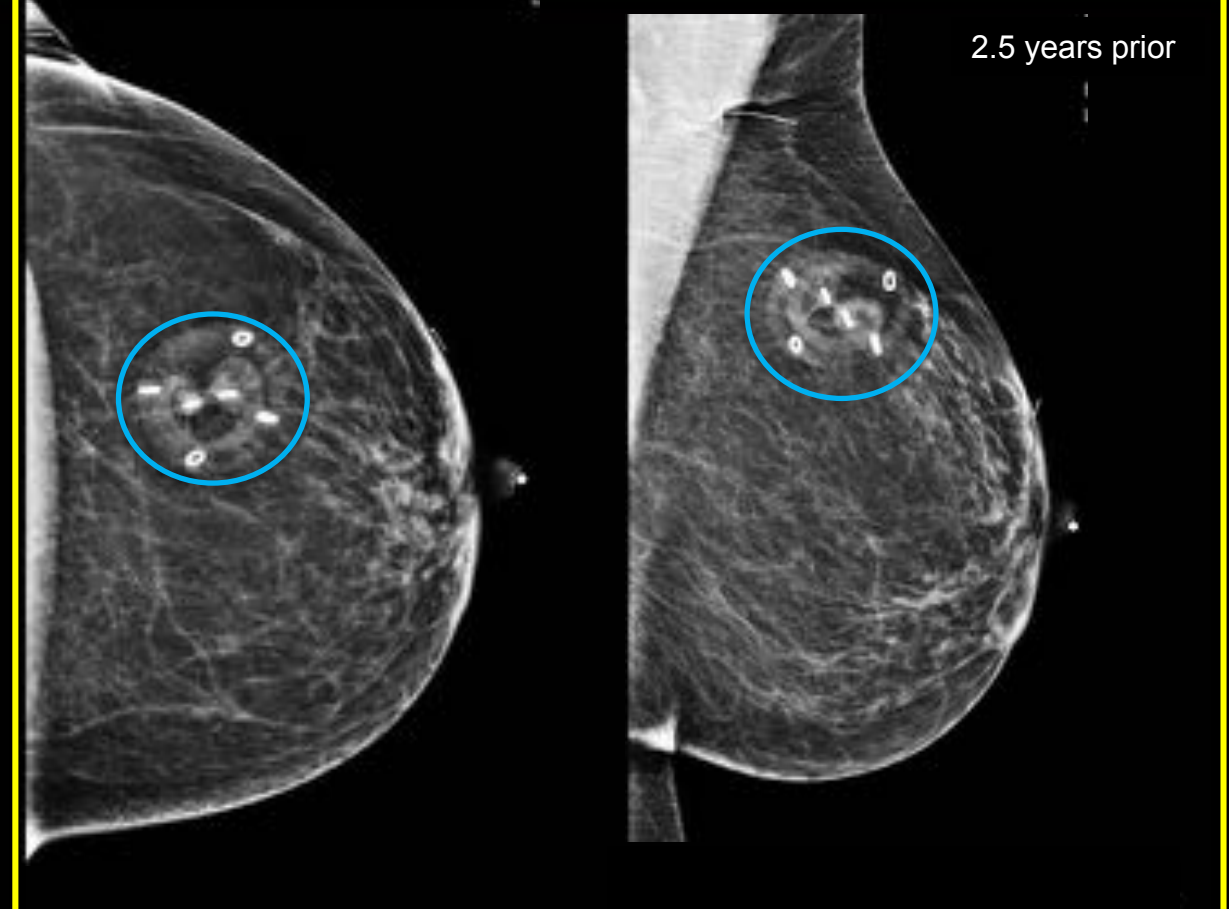
2018



Case 1: 64 year old with history of invasive breast cancer 3 years ago presenting for annual examination



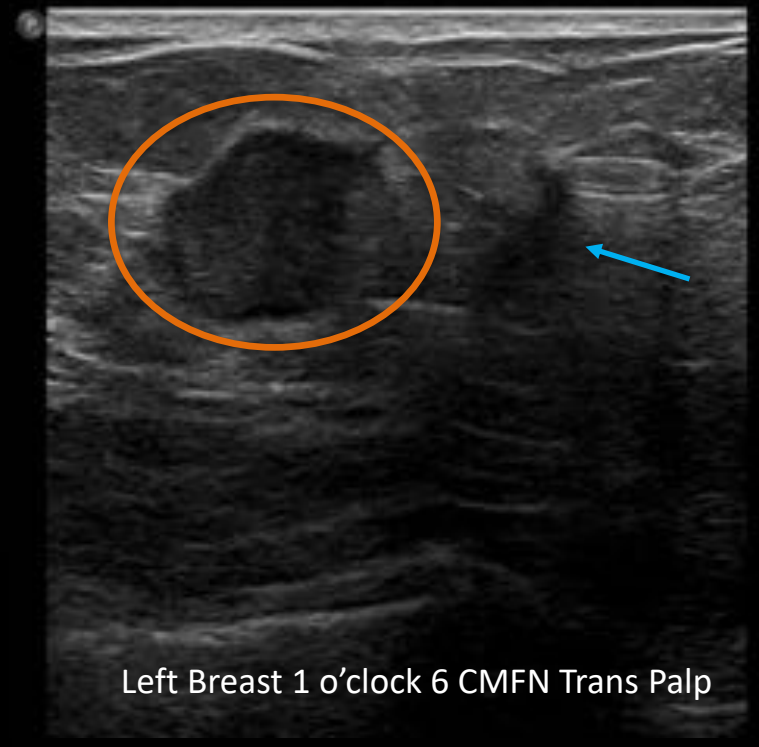
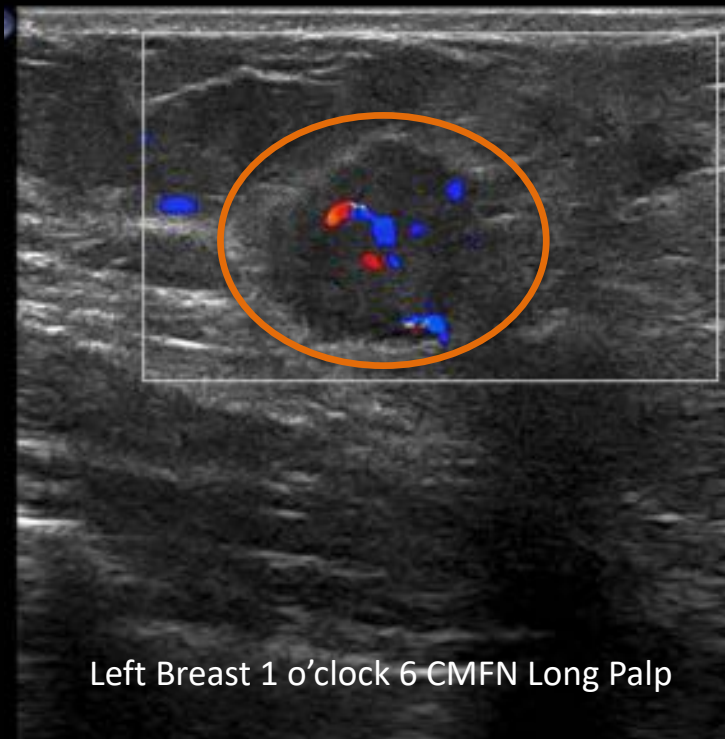
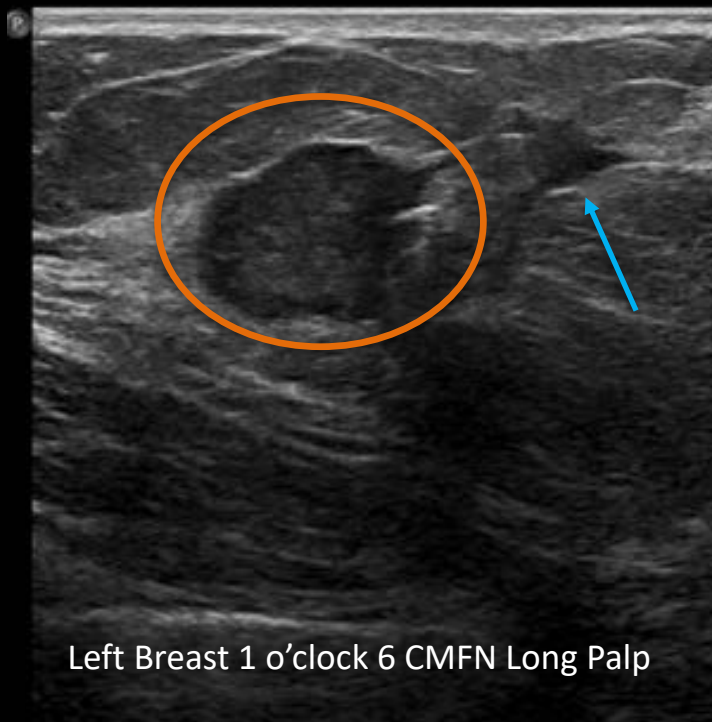
Current CC and lateral C-view images demonstrate expected evolution of the BioZorb® device with focal asymmetry at the superoposterior aspect of the device



Initial postoperative baseline CC and lateral images demonstrate expected postoperative appearance of the BioZorb® device with no suspicious findings

At the time of diagnostic ultrasound examination, the patient reports she has noted the area is becoming more “full” over the years.

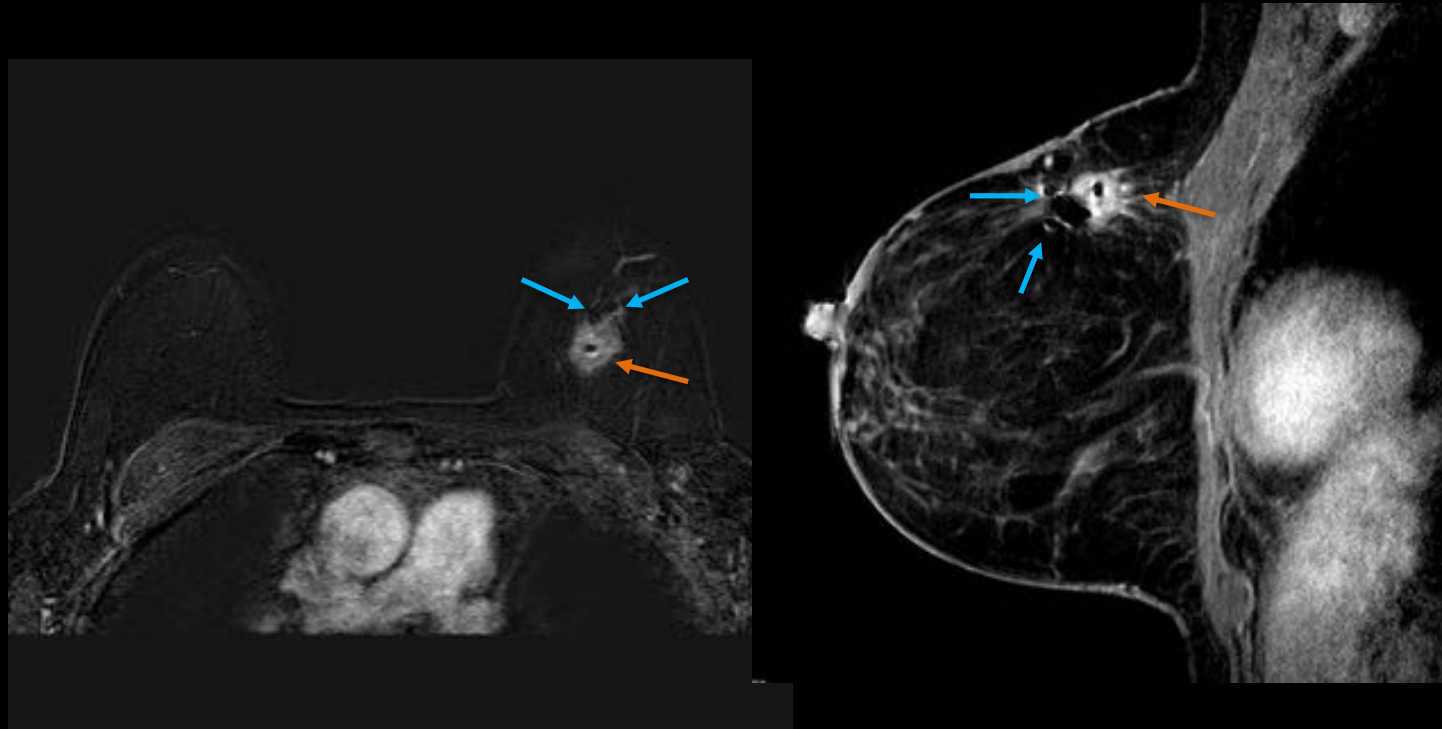
Grayscale longitudinal and transverse images (left and right) along with color Doppler image (center) demonstrate correlating **irregular hypoechoic mass with increased color Doppler flow** in close proximity to the edge of post-surgical change related to the BioZorb®



Biopsy was performed under sonographic guidance at outside facility with marker clip placement. (Below) Pre biopsy lateral view with previously noted **suspicious focal asymmetry** and post biopsy MLO view demonstrates **biopsy marker clip within the mammographic focal asymmetry**.

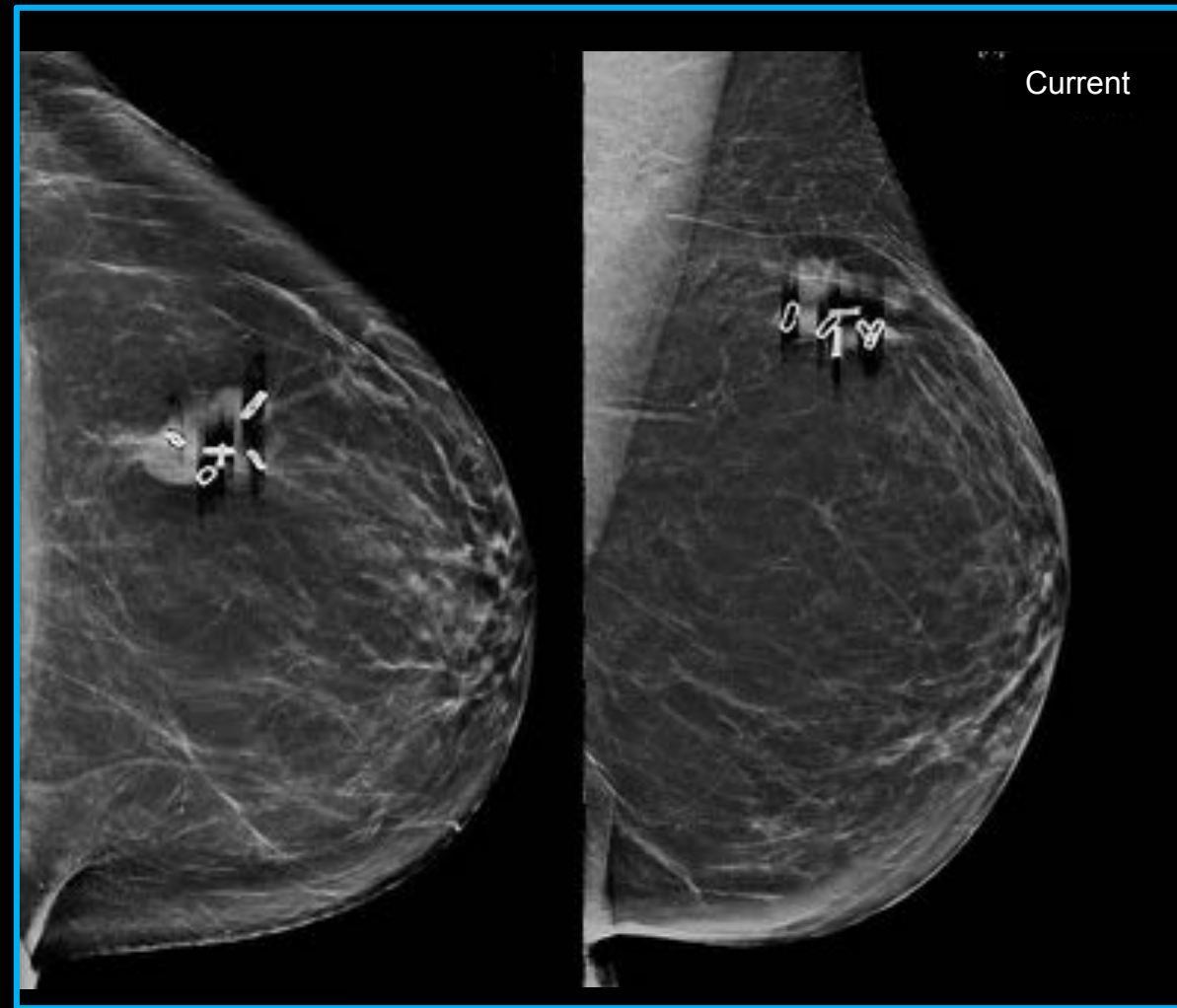


Subsequent breast MRI was performed two months after biopsy. (Below) Axial post contrast subtraction image (left) and delayed sagittal post contrast T1-weighted fat saturated images demonstrate an **irregular enhancing mass with internal clip** located posterior to the **expected susceptibility artifact from the BioZorb® device**.



Same patient reviewing remote priors: Initial CC and MLO (bottom left) mammogram images from original cancer diagnosis 3 years ago demonstrated a **high density, irregular, spiculated mass with associated palpable marker** in a similar location to the area of biopsy proven recurrence.

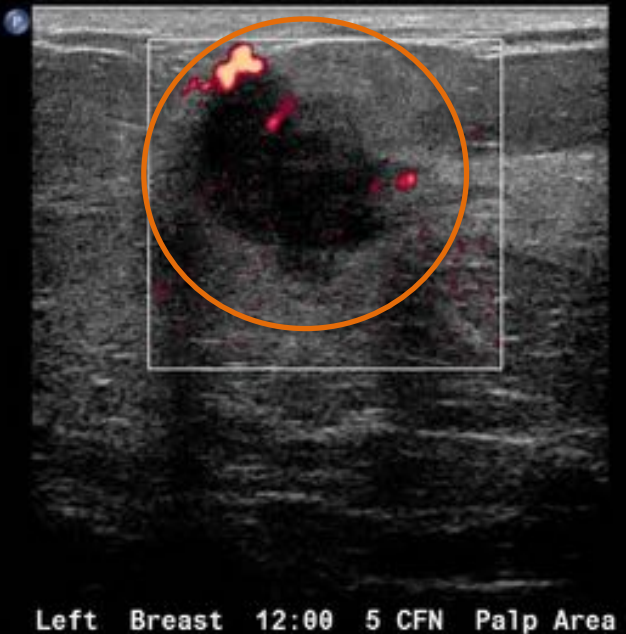
(CC and lateral C-view images of the current mammogram are again presented in the bottom right for comparison)



3 years ago

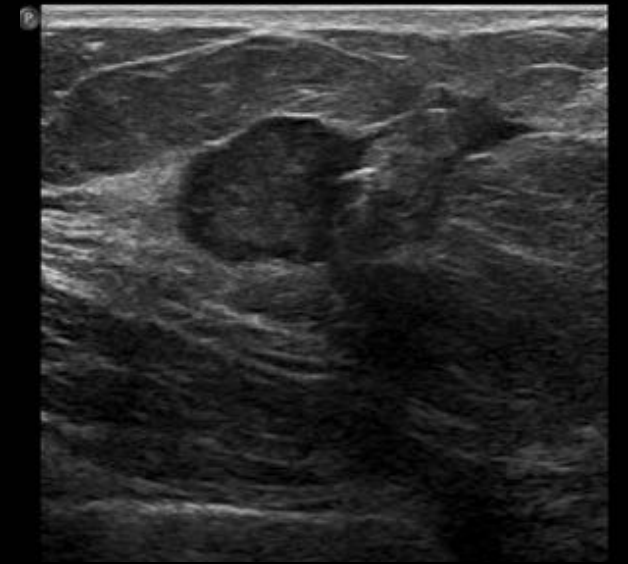


Initial Gray-scale ultrasound images (left) from original cancer diagnosis 3 years ago demonstrate an **irregular, hypoechoic mass with increased power Doppler flow** correlating with the palpable area in a similar location and with similar sonographic appearance to the area of biopsy proven recurrence (right).

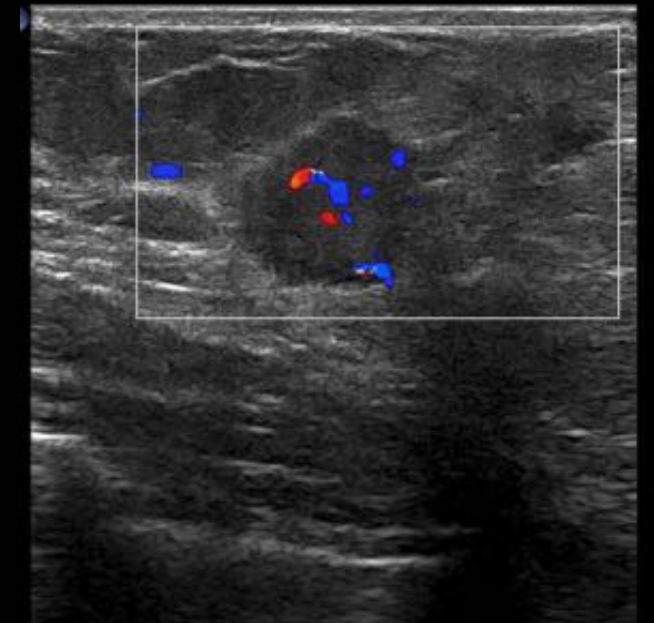


(Gray-scale and color Doppler images of the current ultrasound are again presented on the right for comparison).

Current

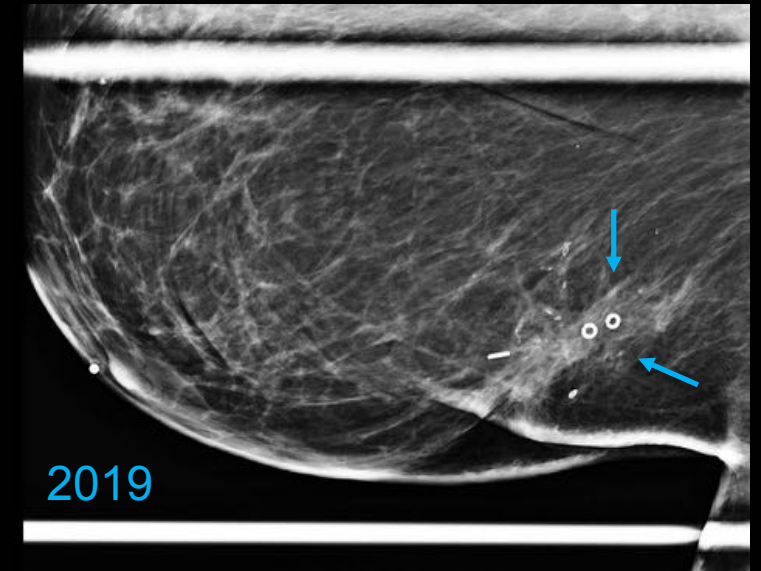
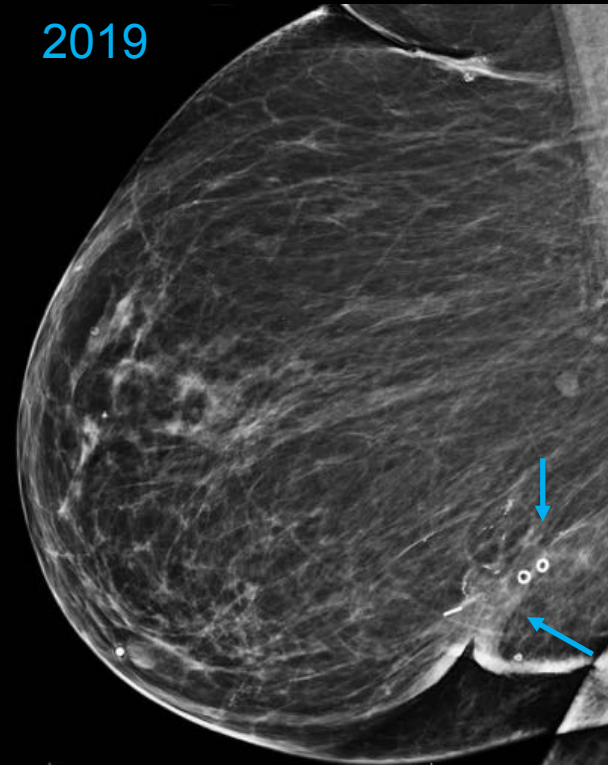
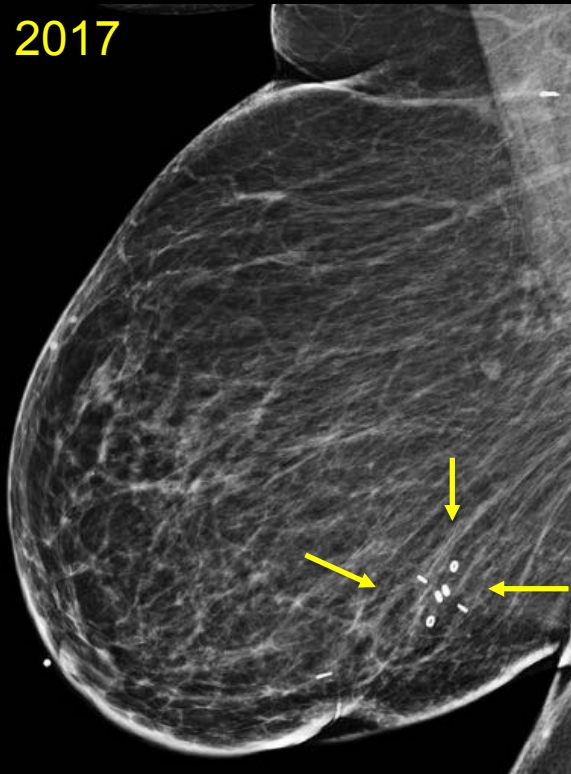


Left Breast 1 o'clock 6 CMFN Long Palp

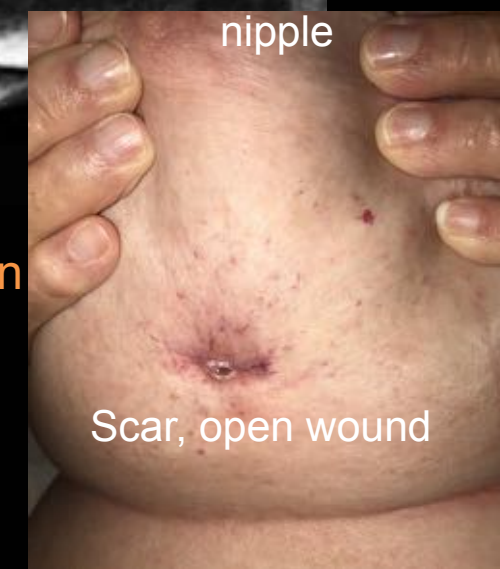
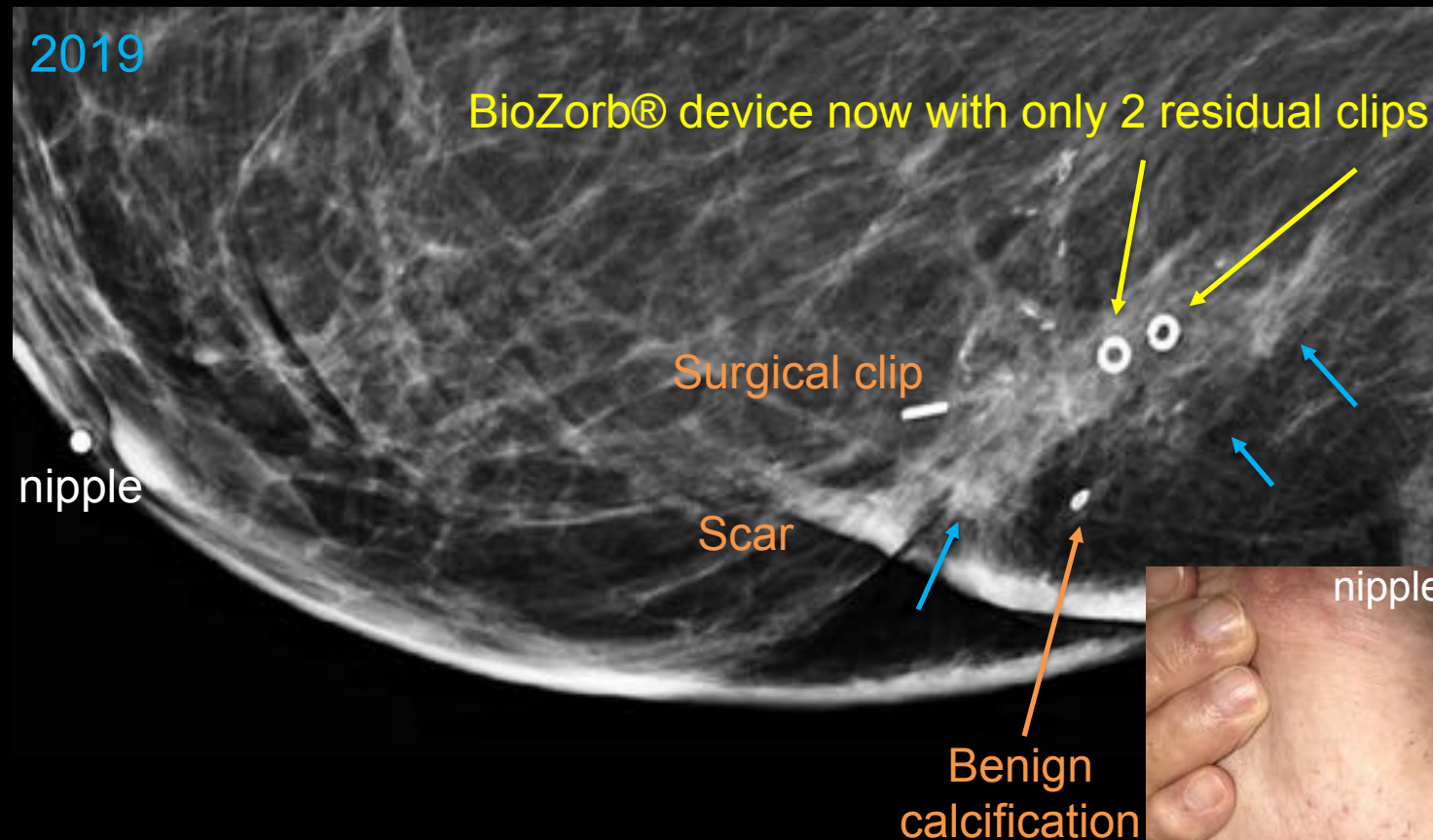
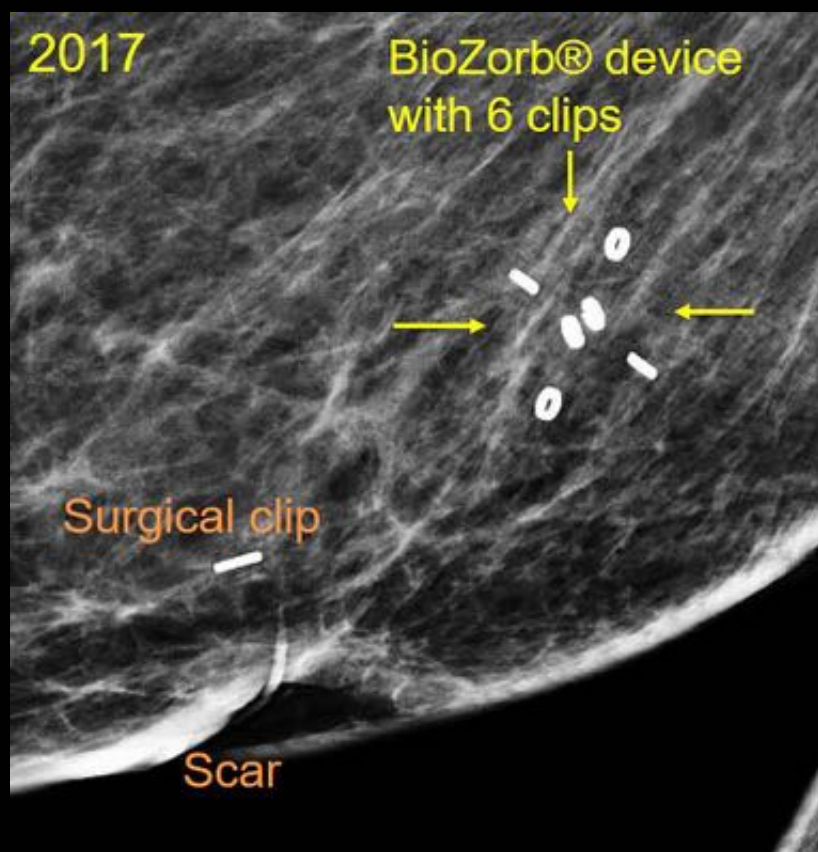


Left Breast 1 o'clock 6 CMFN Long Palp

Case 2: 72 year old with history of right segmental mastectomy in August 2017 for invasive and in situ ductal carcinoma, completed radiation therapy in October 2017, noting open wound and drainage of pus and blood near the post-surgical site for approximately 2 months

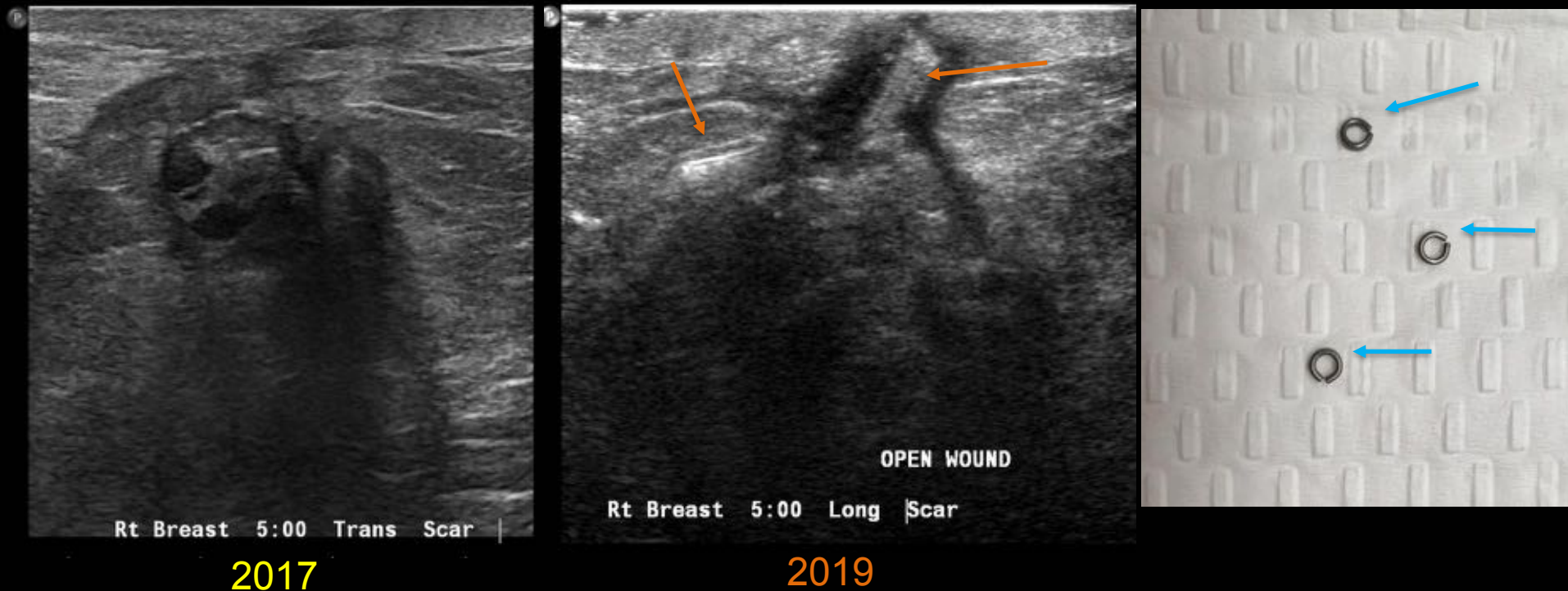


Initial 2017 lateral-medial (LM) view demonstrates expected postoperative change with BioZorb® device. Current LM full field and spot compression mammography images demonstrate new asymmetry associated with the BioZorb® device.



Initial 2017 zoomed in LM mammogram view (top left) demonstrates expected postoperative change with BioZorb® device. Current zoomed in LM spot compression mammography image (top right) again demonstrates new asymmetry (blue arrows) with four of six BioZorb® clips missing. The photograph (right) demonstrates the open wound noted along the inferior breast at the time of current diagnostic examination.

US images from 2017 (normal expected postoperative change associated with the BioZorb®) and currently demonstrating the change in the patient's scar and associated BioZorb® device which is now extruding through the open wound in the skin. Patient collected several of the clips from the BioZorb® that were extruding through her breast.



The patient was evaluated by surgery and findings were felt to be infected seroma or fat necrosis which drained through the scar. Patient was monitored with subsequent healing of the wound on clinical examination.

Summary

- The treatment of breast cancer requires a multi-team approach and it is important to stay well-versed in normal and abnormal imaging findings associated with the latest devices being implanted in patients undergoing breast conservation surgery.
- The BioZorb® device is being increasingly used by surgeons and radiation oncologists to assist in the treatment of breast cancer due to evolution of surgical technique and radiation therapy.
- The expected appearance of the device on initial post treatment mammogram is that of six equally spaced titanium clips within an oval mass which is represented as an area of shadowing on sonography.
- The “spokewheel” configuration of the device can also be recognized on postoperative CT and MR images which should demonstrate no abnormal enhancement.
- As the device is expected to slowly absorb, the normal evolution on imaging demonstrates decreased space between the six radiopaque markers and a gradual shift to a more isoechoic appearance on sonography without associated increased vascularity.
- Increased eccentric density on mammography with correlating solid and hypervascular mass on sonography and abnormal enhancement on MRI are expected findings in the setting of local recurrence.

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**Author contact:
Miral Patel, MD
mpatel6@mdanderson.org**

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