What's New in BIRADS: Digital Breast Tomosynthesis

Sarah M. Friedewald, MD
Associate Professor of Radiology
Division Chief of Breast and Women's Imaging
Northwestern University, Feinberg School of Medicine
Chicago, Illinois

Disclosure

- Served as a PI in research for Hologic and Guerbet and as a consultant for Bard and Siemens.

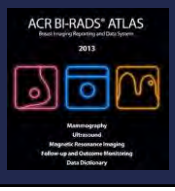
Agenda

- Review different guidance documents produced by ACR
- DBT BIRADS
- FAQs

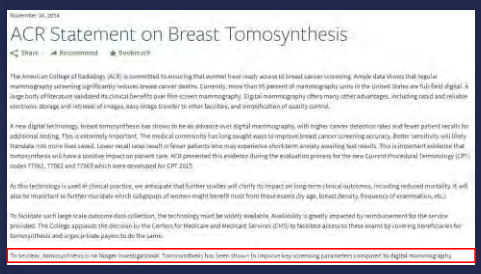
ACR Documents

- Position Statements
- Appropriateness Criteria
- Practice Parameters
- BIRADS

ACR | Appropriateness Criteria



Position Statement on DBT



November 14, 2014

ACR Statement on Breast Tomosynthesis

Share Recommend Bookmark

The American College of Radiology (ACR) is committed to ensuring that women have ready access to breast cancer screening. Ample data shows that regular mammography screening significantly reduces breast cancer deaths. Currently, more than 95 percent of mammography units in the United States are full-field digital. A large body of literature validated its clinical benefits over film-screen mammography. Digital mammography offers many other advantages, including rapid and reliable electronic storage and retrieval of images, easy image transfer to other facilities, and simplification of quality control.

A new digital technology, breast tomosynthesis has shown to be an advance over digital mammography, with higher cancer detection rates and fewer patient recalls for additional testing. This is extremely important. The medical community has long sought ways to improve breast cancer screening accuracy. Better sensitivity will likely translate into more lives saved. Lower recall rates result in fewer patients who may experience short-term anxiety awaiting test results. This is important evidence that tomosynthesis will have a positive impact on patient care. ACR presented this evidence during the evaluation process for the new Current Procedural Terminology (CPT) codes 77061, 77062 and 77063 which were developed for CPT 2015.

As this technology is used in clinical practice, we anticipate that further studies will clarify its impact on long-term clinical outcomes, including reduced mortality. It will also be important to further elucidate which subgroups of women might benefit most from these exams (by age, breast density, frequency of examination, etc.).

To facilitate such large-scale outcome data collection, the technology must be widely available. Availability is greatly impacted by reimbursement for the service provided. The College applauds the decision by the Centers for Medicare and Medicaid Services (CMS) to facilitate access to these exams by covering beneficiaries for tomosynthesis and urges private payers to do the same.

To be clear, tomosynthesis is no longer investigational. Tomosynthesis has been shown to improve key screening parameters compared to digital mammography.

ACR Appropriateness Criteria

ACR Appropriateness Criteria

The ACR Appropriateness Criteria® (AC) are evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for a specific clinical condition. Employing these guidelines helps providers enhance quality of care and contribute to the most efficacious use of radiology. Learn more »

The newest ACR AC are listed below.

ACR Appropriateness Criteria (AC)

- Evidence based guidelines or expert opinion
- Assist providers and referring physicians in making the most appropriate imaging decision
- Assess the benefits and harms
- Topics are reviewed and revised every 3 years
- Each AC topic has:
  - Narrative (variance tables, discussion, evidence summary)
    - Population estimates of radiation levels
  - Evidence table
    - Summarizes the citation type
  - Literature search summary
    - Provides the strategy
    - Summarizes the articles

Appropriateness Criteria Ratings

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

Radiation Level Designations

Relative Radiation Level Designations

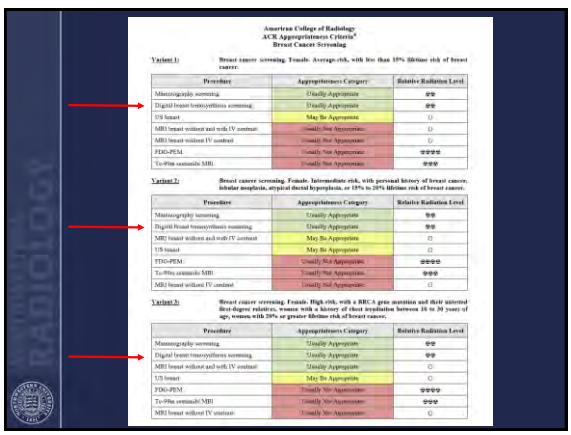
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv
☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv

*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies".

DBT Appropriateness Criteria

Digital breast tomosynthesis (DBT) can address some of the limitations encountered with standard mammographic views. In addition to planar images, DBT allows for creation and viewing of thin-section reconstructed images that may decrease the lesion-masking effect of overlapping normal tissue and reveal the true nature of potential false-positive findings without the need for recall. Several studies confirm that in a screening setting, the cancer detection rate is increased with use of DBT compared with 2-D mammography alone [12-27]. Additionally, the rate of recall for benign findings (false-positives) can be decreased [12,14-17,20-25,27-30]. Some authors found these advantages to be especially pronounced in women under age 50 [20,31], in those with dense breasts [31,32], and with lesion types including spiculated masses [33] and asymmetries [28]. Interpretation time for DBT images is greater than for standard mammography [14,34]. Additionally, dose is increased if standard 2-D images are obtained in addition to DBT images. However, synthesized reconstructed images (a virtual planar image created from the tomographic dataset) may replace the need for a 2-D correlative view; current data suggest that these synthetic images perform as well as standard full-field digital images [35,36]. DBT is almost always performed as part of an examination that also includes digital mammography. The digital mammography part of the examination may be in the form of traditional projection mammography or synthesized image from the DBT data.

Revised in 2017



American College of Radiology
ACR Appropriateness Criteria®
Breast Cancer Screening

Variant 1: Breast cancer screening. Female. Average risk, with less than 15% lifetime risk of breast cancer.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
FDG-PEM	Usually Not Appropriate	☢☢☢☢
Tc-99m sestamibi MBI	Usually Not Appropriate	☢☢☢

Variant 2: Breast cancer screening. Female. Intermediate risk, with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15% to 20% lifetime risk of breast cancer.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
MRI breast without and with IV contrast	May Be Appropriate	O
US breast	May Be Appropriate	O
FDG-PEM	Usually Not Appropriate	☢☢☢☢
Tc-99m sestamibi MBI	Usually Not Appropriate	☢☢☢
MRI breast without IV contrast	Usually Not Appropriate	O

Variant 3: Breast cancer screening. Female. High risk, with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between 10 to 30 years of age, women with 20% or greater lifetime risk of breast cancer.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
MRI breast without and with IV contrast	Usually Appropriate	O
US breast	May Be Appropriate	O
FDG-PEM	Usually Not Appropriate	☢☢☢☢
Tc-99m sestamibi MBI	Usually Not Appropriate	☢☢☢
MRI breast without IV contrast	Usually Not Appropriate	O

Adopted 2018 (Resolution 36)*

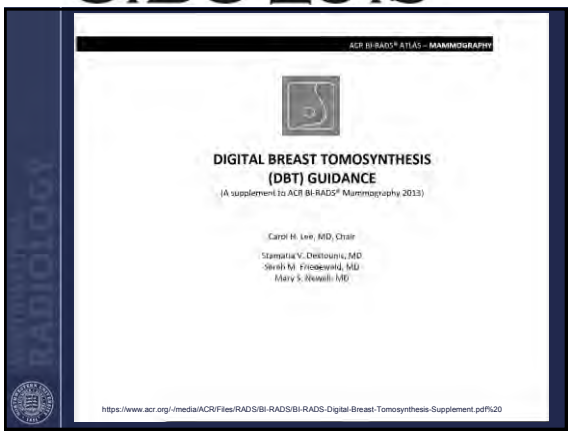
ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF DIGITAL BREAST TOMOSYNTHESIS (DBT)

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care1. For these reasons and those set forth below, the American College of Radiology and our colleagues in medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

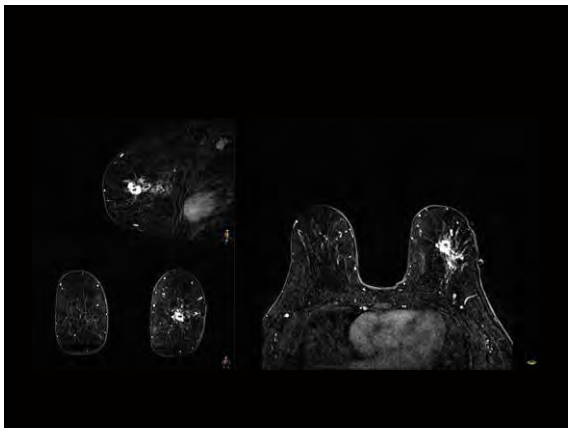
The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

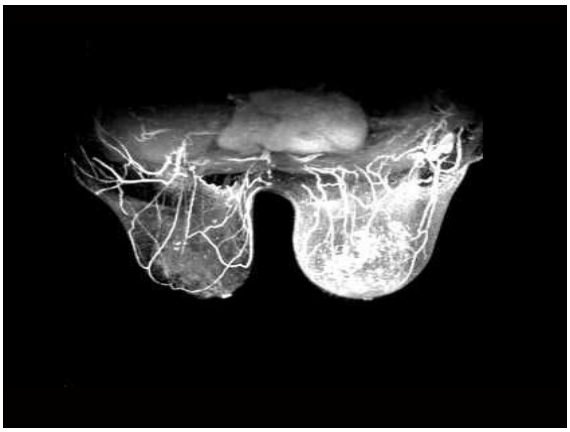
The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to



3D, or not 3D? That is the question…

- Digital breast tomosynthesis is not a true 3D image
  - Images are not acquired isotropically
  - Unlike CT or MRI
  - Cannot reconstruct into multiple different planes (coronal/sagittal/axial)





3D, or not 3D? That is the question…

- Breast is repositioned between the views:
  - E.g. CC and MLO
- Cannot use localizing tools to identify the finding in both views

Terminology: Digital Breast Tomosynthesis

- PLEASE do not use the term "3D" in you reports!
- Acceptable terms for digital breast tomosynthesis:
  - DBT
  - Tomosynthesis
  - Tomo
- Synthetic imaging
  - Please use the abbreviation SM

Report Organization

- Facilities should specify the imaging protocol used
  - DBT-only
  - 1-view DBT with 2-view DM,
  - combination DM/DBT
  - DBT plus synthetic views

Additional Mammographic Work-Up

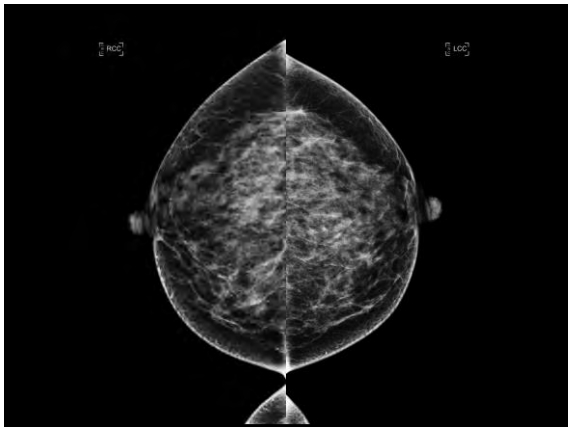
- Traditional work-up protocols may change with DBT
- If the margin and location of a mass are well seen on the tomosynthesis images, additional spot compression or magnification views may not be necessary
- Patient may proceed directly to ultrasound
- Should be specifically stated in the report to avoid confusion

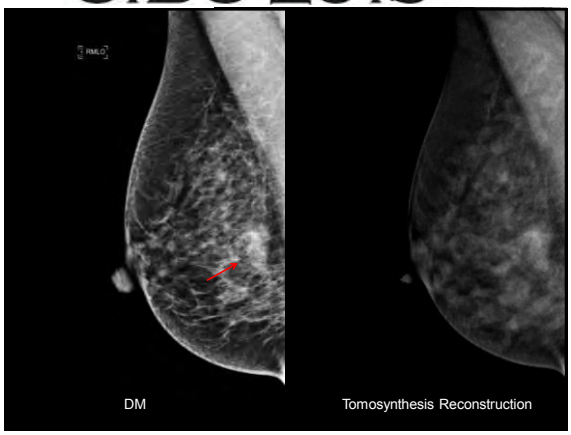
Description of Findings

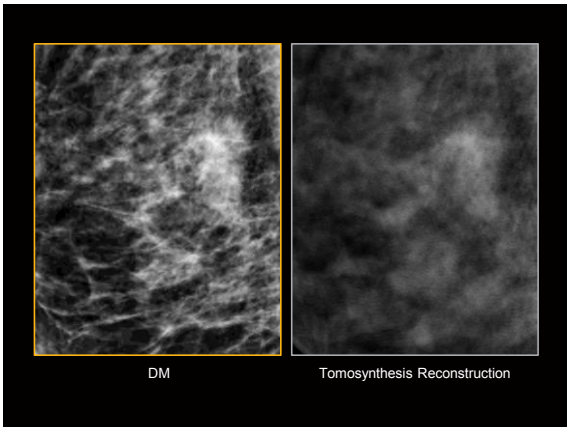
- Suspicious findings identified on DBT slices should be described with standard nomenclature, and indicate the general location in the breast (i.e., laterality, quadrant, and clock-face location; anterior, middle, or posterior depth; distance from nipple).
- However, it is particularly important to specify the slice numbers where the abnormality is in focus.
  - For example: focal asymmetry, left breast, upper outer quadrant, 1:00, posterior depth, 5 cm from the nipple (CC view slice 43/55, MLO view slice 14/50)

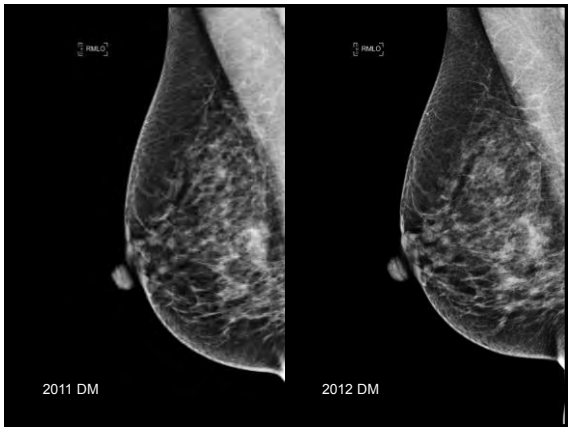
Normal Superimposed Tissue

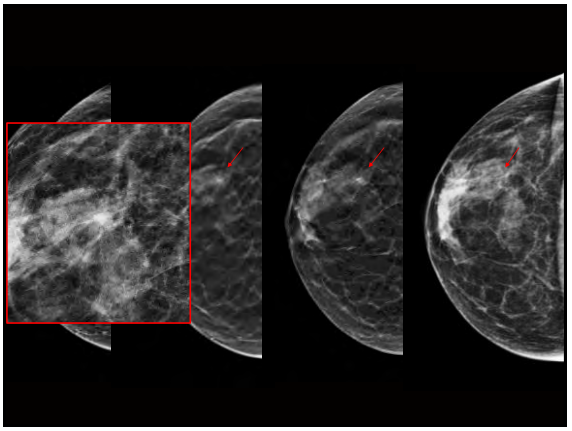
- Asymmetry: visible on only one mammographic projection
- Focal asymmetry: visible on two mammographic projections
- DBT can occasionally help with separation of adjacent breast tissue elements





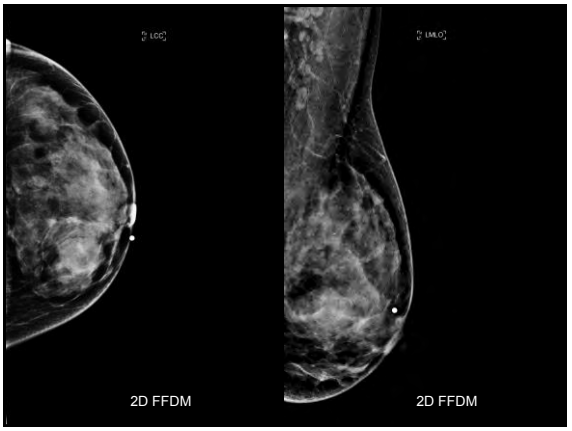


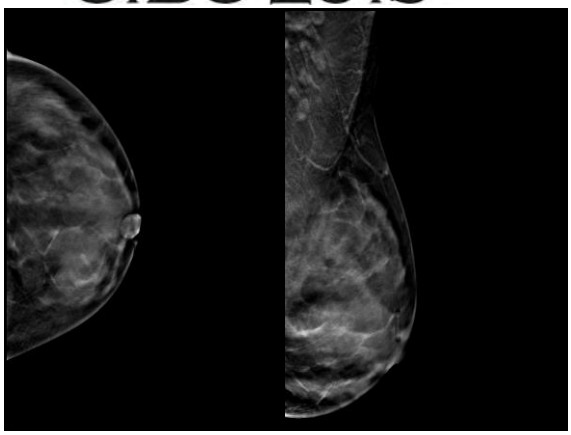


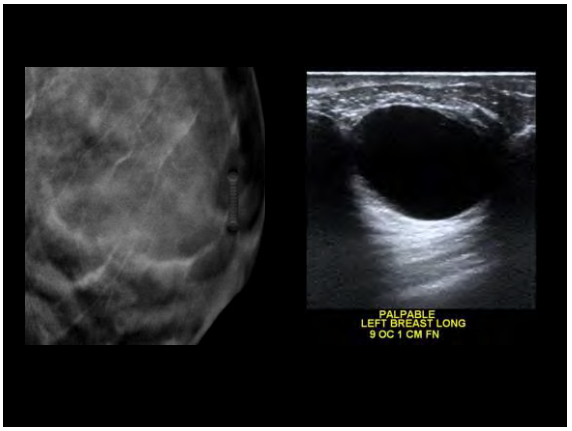


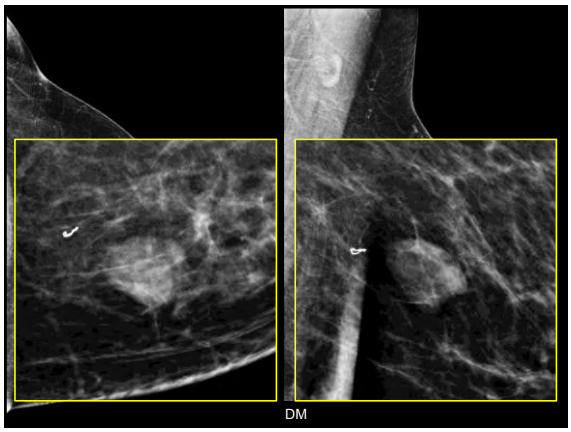
Masses Well Visualized on DBT

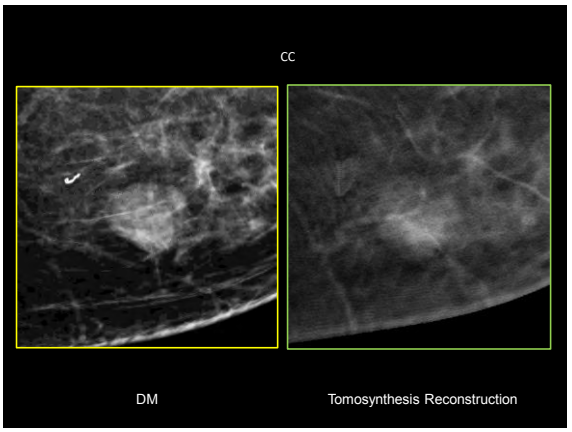
- Masses on DBT have similar appearances as masses on DM
- May be more conspicuous
- Just because it is circumscribed on DBT does not mean it can be dismissed
  - Still need to evaluate with ultrasound
    - New finding
    - Solitary lesion
    - Obscured margins

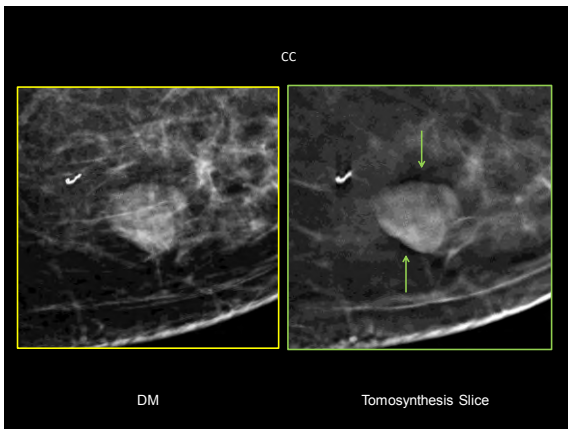


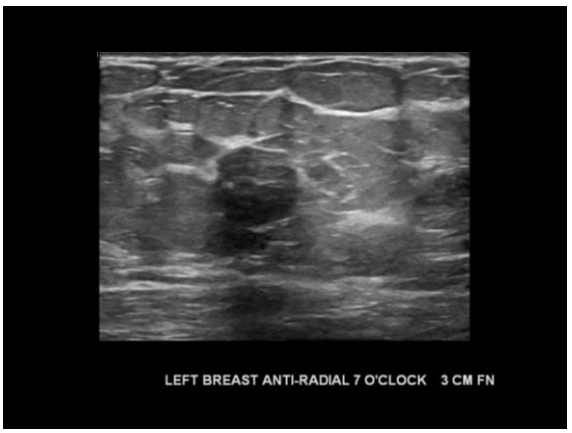


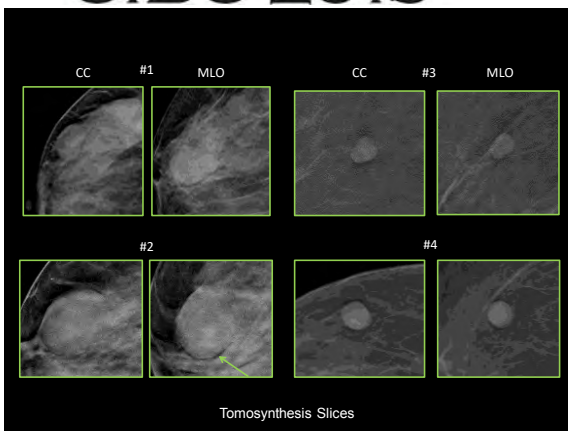






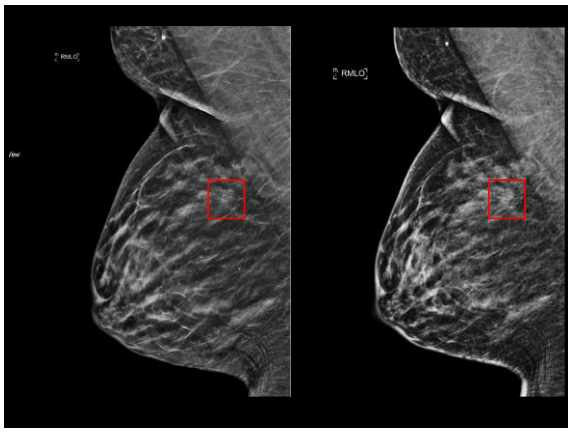


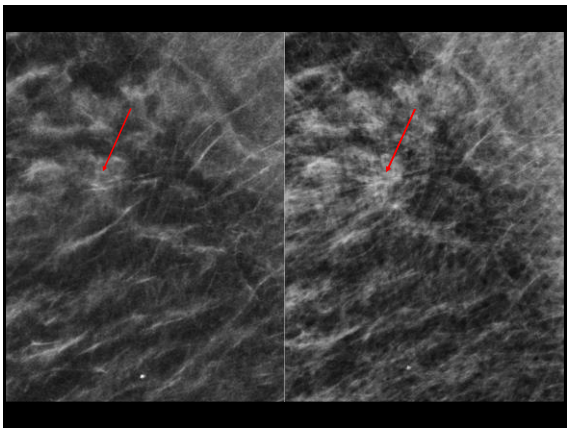




True Calcifications on SM Versus Pseudocalcifications

- Back-projection algorithm used in generation of the synthetic images from the DBT images
  - Designed to preserve the high-attenuating voxels
  - Calcifications may appear enhanced
  - May also contain artifacts that may be interpreted as calcifications "psuedocalcifications"
  - Or, calcifications mayappear less well defined because the x-ray tube moves in an arc
    - Voxels are shifted very slightly perpendicular to the movement of the tube causing blurring
    - Motion





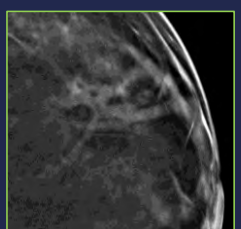
Ectatic Ducts

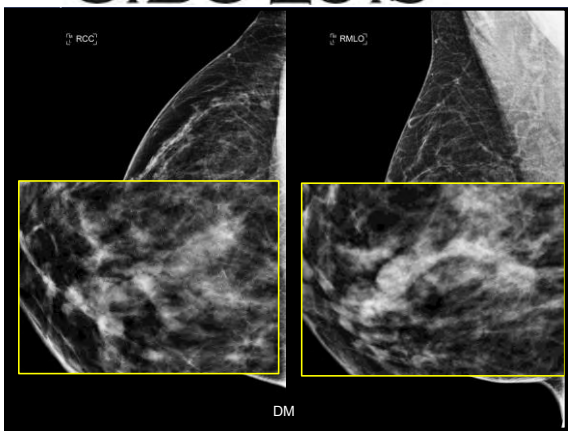
- May be more conspicuous on DBT
- Should not be the sole indication for recalling patient
- Prior mammograms may show stability
- If unilateral ductal ectasia is new
  - Needs evaluation

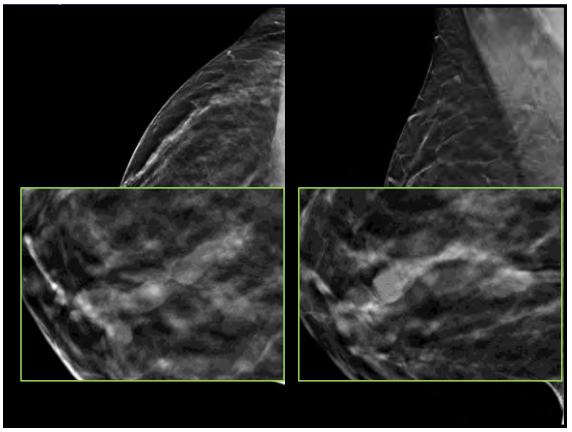
- 235,209 sequential cases
  - 9 screening
    - 1/9 was DCIS
  - 12 diagnostic
    - 1/12 was DCIS

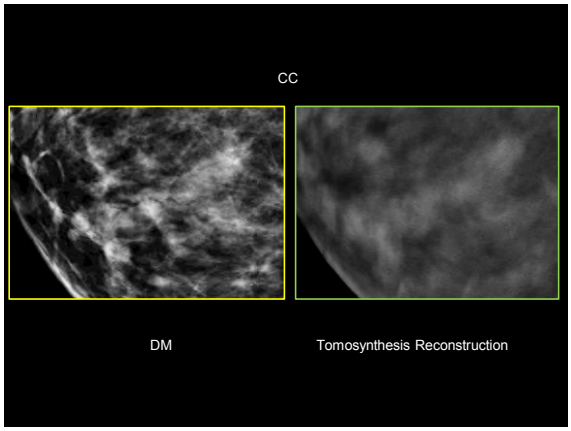
Ductal Ectasia

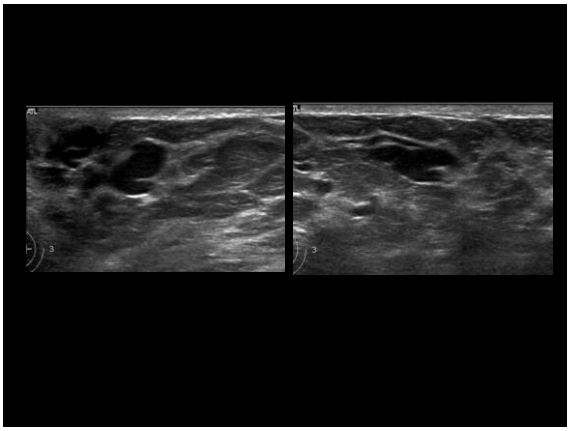
- Duct ectasia is occasionally more prominent on tomosynthesis
- Does not necessarily indicate a malignant process and should be evaluated at radiologist's discretion

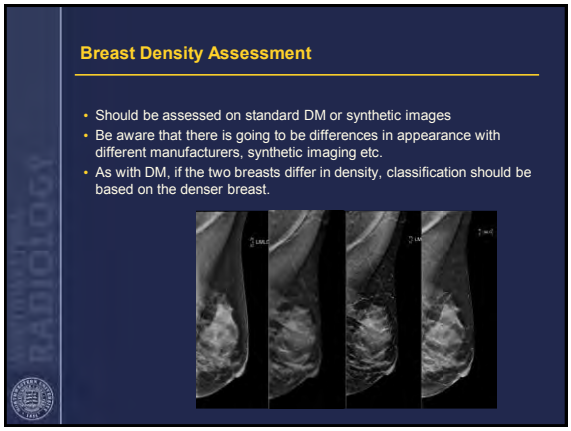

Tomosynthesis Slice

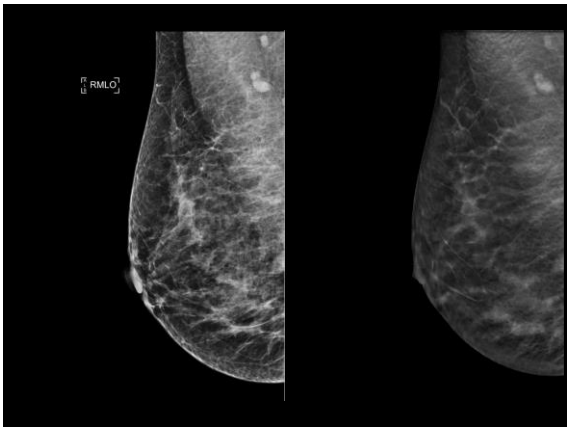












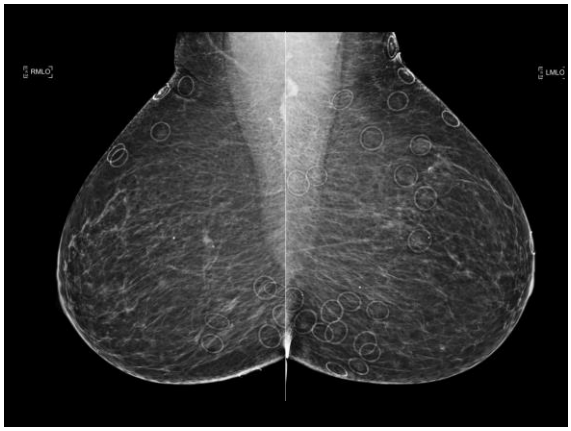
Use of Radiomarkers for Skin Lesions

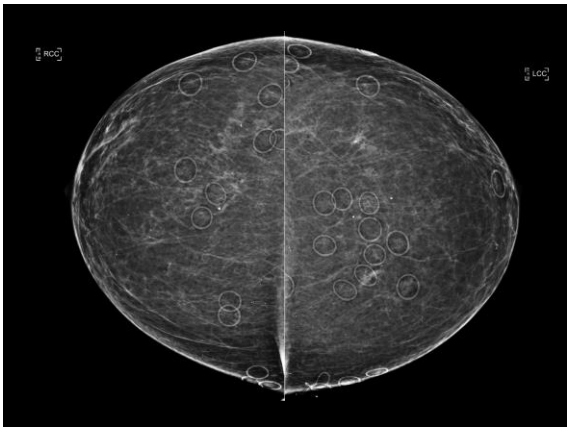
- Reasons not to place markers on skin:
  - Results in reconstruction artifacts on the DBT images (in the same plane as the gantry motion)
  - May block findings on mammogram
  - Expensive and time consuming
  - Sometimes skin findings can be determined at the time of screening due to slice location

Alternative: accompanying diagram marking location of moles and scars

Use of Radiomarkers for Skin Lesions

- Reasons to place markers on the skin:
  - There are several scenarios in which the skin lesions appear to be deeper in the breast based on the slice indicator.
  - It eliminates time spent determining whether a lesion is in the skin.





FAQs

- Since DBT can enable improved lesion characterization and visualization, can we give a BI-RADS® category 3 assessment at screening if the lesion appears to have typically benign characteristics?

A) Yes
B) No

FAQs

- Since DBT can enable improved lesion characterization and visualization, can we give a BI-RADS® category 3 assessment at screening if the lesion appears to have typically benign characteristics?

A) Yes
B) No

- BI-RADS® category 3 should NOT be rendered at screening
- Same as BI-RADS® category 3 assessment for DM

- DBT can improve assessment of lesion characteristics
- Help to determine the likelihood of malignancy
- BUT, further work-up is needed to adequately assess the lesion to determine if biopsy is necessary

FAQs

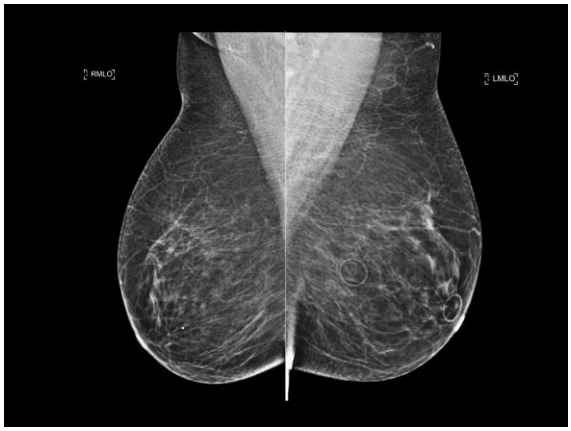
- Is it appropriate to assign a BI-RADS® category 4 at screening for a clearly suspicious lesion, such as a spiculated mass on DBT, for which additional mammographic views would not add important information?

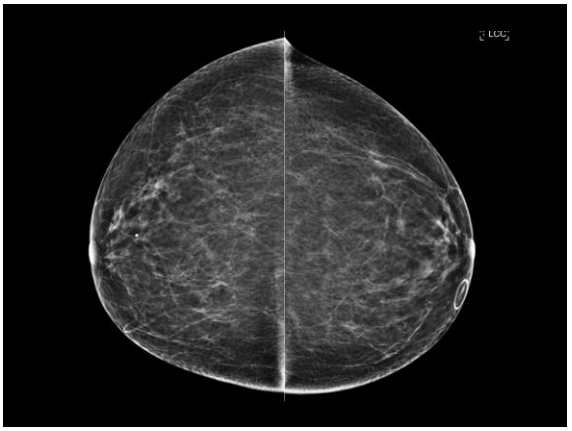
A) Yes
B) No

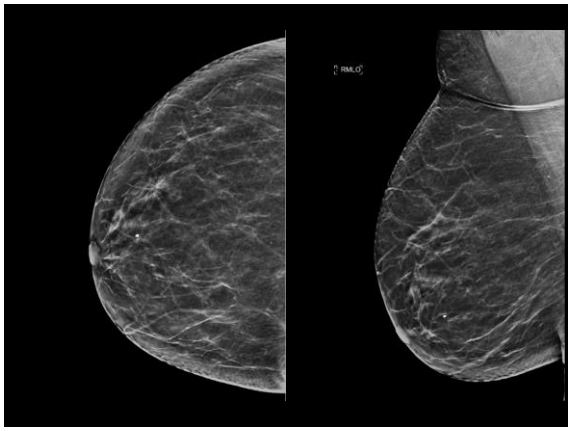
FAQs

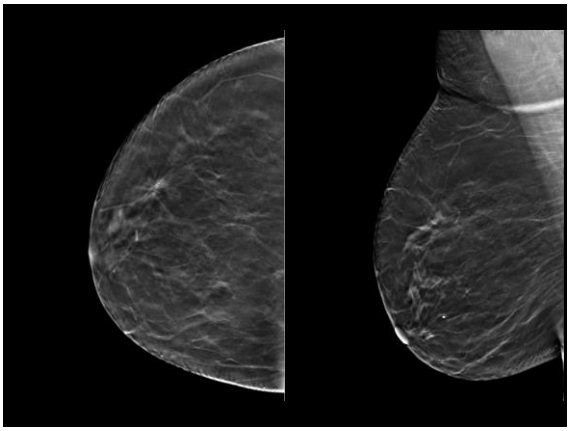
- Is it appropriate to assign a BI-RADS® category 4 at screening for a clearly suspicious lesion, such as a spiculated mass on DBT, for which additional mammographic views would not add important information?

A) Yes
B) No







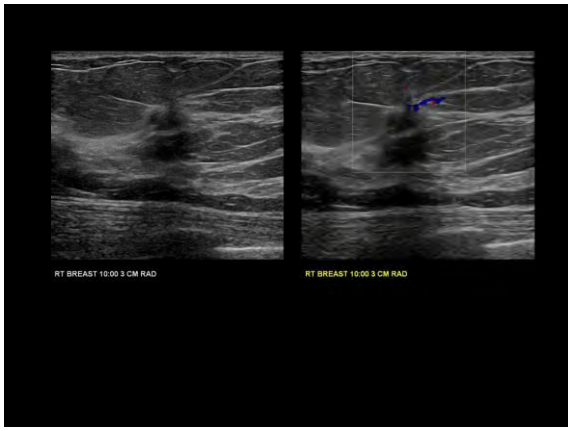


FAQs

- Is it appropriate to assign a BI-RADS® category 4 at screening for a clearly suspicious lesion, such as a spiculated mass on DBT, for which additional mammographic views would not add important information?

  A) Yes
  B) No

- Assigning BI-RADS® category 4 or 5 directly from a tomosynthesis screening examination is discouraged
- Even if a finding is clearly depicted on DBT images
  - Ultrasound for masses or asymmetries a
  - Magnification images for calcifications



FAQs

- We have outreach facilities that do not have DBT-capable units. Patients are being sent to our main facility from the outreach offices with category 4 assessments on their diagnostic mammograms, but the impression on the report recommends a DBT work-up followed by a DBT-guided biopsy if there is a suspicious finding.
- I would like to have the diagnostic mammogram from the outreach facility a category 0 and recommend DBT, then the final assessment could be given following the diagnostic tomosynthesis. Is it permissible to use this method?

  A) Yes
  B) No

FAQs

- We have outreach facilities that do not have DBT-capable units. Patients are being sent to our main facility from the outreach offices with category 4 assessments on their diagnostic mammograms, but the impression on the report recommends a DBT work-up followed by a DBT-guided biopsy if there is a suspicious finding.
- I would like to have the diagnostic mammogram from the outreach facility a category 0 and recommend DBT, then the final assessment could be given following the diagnostic tomosynthesis. Is it permissible to use this method?

  A) Yes
  B) No

FAQs

- Can a lesion seen only on one view of DBT with a well characterized margin and occupying 3D space be called a “mass” rather than an “asymmetry” (due to its presence on only one view?)

  A) Yes
  B) No

FAQs

- Can a lesion seen only on one view of DBT with a well characterized margin and occupying 3D space be called a “mass” rather than an “asymmetry” (due to its presence on only one view?)

  A) Yes
  B) No

The finding should be termed an asymmetry because it is visible on only one mammographic projection.

However, if the finding displays a circumscribed margin and is oval in shape, it may be judged to be a real finding, in which case additional diagnostic mammography may be averted.