

Tomosynthesis Fundamental Techniques and Basic Reading Protocol

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Disclosures

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Consultant: Hologic Inc.



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- Linda Greer, MD
- Stephen Rose, MD
- Kathy Willison
- Rosa O'Brien



Overview

- Benefits and limitations of mammography
- Basics of digital breast tomosynthesis
 - Acquisition of images
 - Image tools
 - Dose
- Benefits of digital breast tomosynthesis
 - Increased cancer detection
 - Decreased recall

Benefits/Limitations of Screening Mammography

Benefits of Mammography

- The most lives are saved when women are screened annually beginning at age 40
- 7 RCT's demonstrate a reduction in mortality when patients are screened
- Mammography is a low cost, accessible imaging modality

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ACR and SBI Continue to Recommend Regular Mammography Starting at Age 40

Both Agree With ACS That Mammography Screening Saves Lives and That Women Ages 40+ Should Have Access to Mammograms

October 20, 2015

Washington, DC (Oct. 20, 2015) — As our shared goal is to save the most lives possible from breast cancer, the American College of Radiology (ACR) and Society of Breast Imaging (SBI) continue to recommend that women get yearly mammograms starting at age 40. New American Cancer Society (ACS) breast cancer screening [guidelines](#), and previous data used by the United States Preventive Services Task Force (USPSTF) to create their recommendations, state that starting annual mammography at age 40 saves the most lives.

"The ACS has strongly reaffirmed that mammography screening saves lives. The new ACS guidelines show that if a woman wants to reduce, as much as possible, her risk of dying of breast cancer, she will choose yearly mammography starting at age 40. A recent [study in the British Medical Journal](#) confirms this, showing that early detection of breast cancer is critical for improving breast cancer survival, regardless of therapy advances. Moving away from annual screening of women ages 40 and older puts women's lives at risk," said Debra Monticciolo, MD, FACR, chair of the American College of Radiology Breast Imaging Commission.

The ACR and SBI agree with the ACS [and others](#) that overdiagnosis claims are vastly inflated due to key methodological flaws in many studies. Overdiagnosis is likely 1 to 10 percent — largely due to inclusion of [ductal carcinoma in situ \(DCIS\)](#). Few, if any, invasive cancers are over-diagnosed.

ACR and SBI also agree with the ACS that the vast majority of the 10 percent of women asked to return following an inconclusive mammogram (often termed a "false positive"), simply get another mammogram and/or an ultrasound for clarification. Only 1 to 2 percent of women have a needle biopsy as a result of a screening mammogram ([see risks infographic](#)). Short-term anxiety from test results, though normal, is [shown to have no lasting effects](#) and

MEDIA CONTACTS

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Visual Abstract

Update on Breast Cancer Screening Recommendations Inclusive of All Women at Average Risk

All women, should have a risk assessment by age 30



Especially minority women, to ensure that they are not in a higher risk category.

Annual mammography screening starting at age 40



Greatest breast cancer mortality reduction.



Diagnosis at earlier stage.



Better surgical options and more effective chemotherapy.

Screening should continue past age 74



No upper age limit unless severe comorbidities limit life expectancy.



Benefits should be considered along with the possibility of



Recall for additional imaging



Benign biopsy

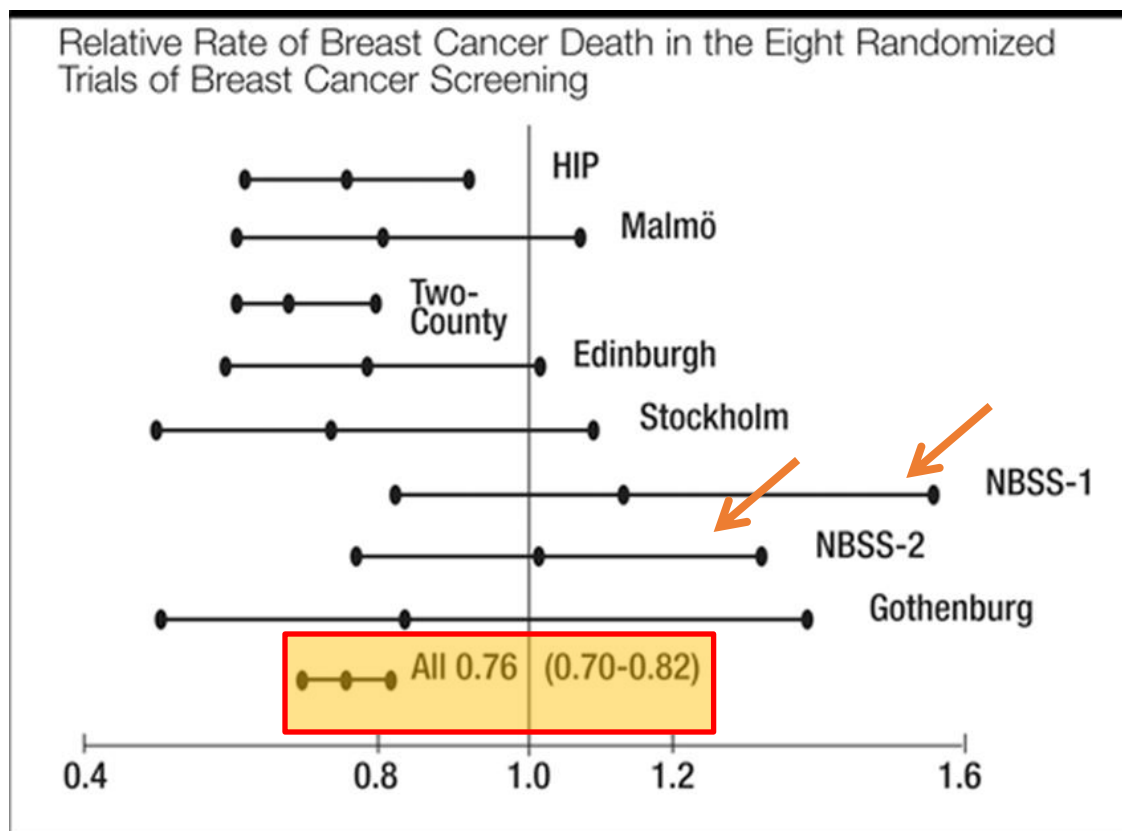


Risks of anxiety and overdiagnosis.

The ACR and SBI affirm that weighing the benefits and risks of mammography should be done by women, not for women.



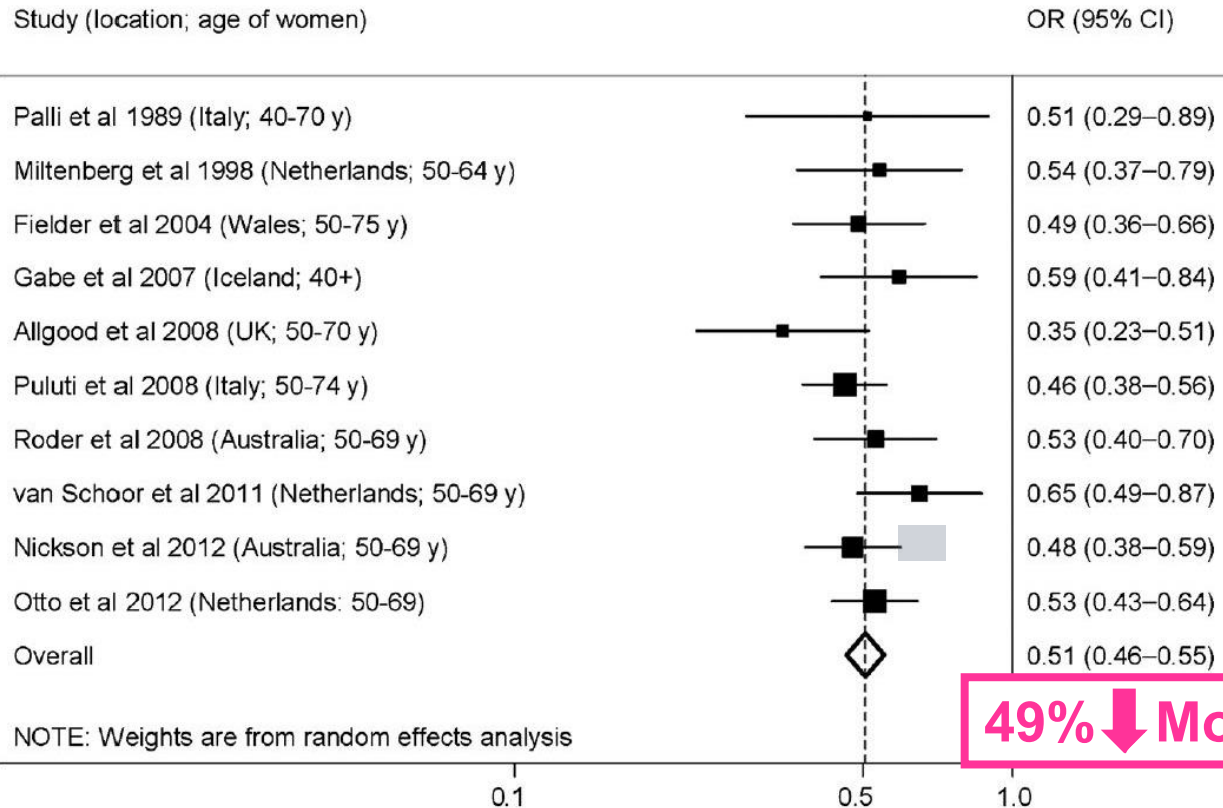
24% mortality reduction



Duffy SW, Tabár L, Smith RA.

CA Cancer J Clin. 2002 Mar-Apr;52(2):68-71.

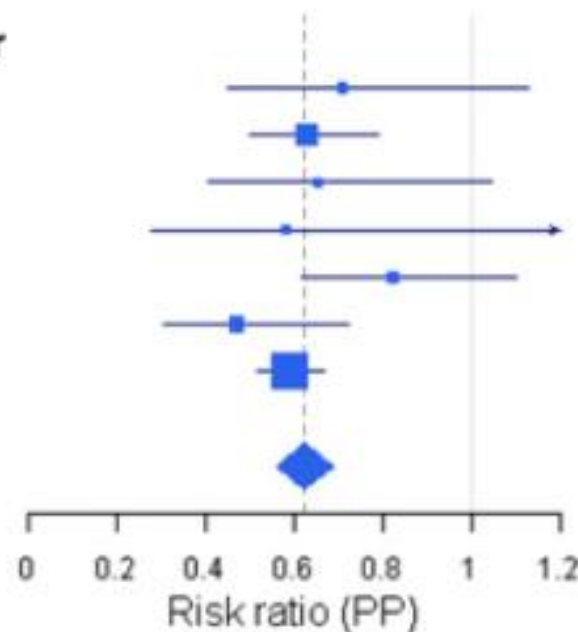
Case-Control Studies (Ages 40–75)



Evidence of Benefit: Observational Trials (Europe)



Study	RR	Lower	Upper
Hakama, (1997) ³⁹	0.71	0.45	1.13
Olsen, (2005) ³²	0.63	0.5	0.79
Sarkeala, (2008) ³⁶	0.65	0.41	1.05
Paci, (2002) ⁴²	0.58	0.28	1.22
Kalager, (2010) ⁵¹	0.82	0.62	1.1
Ascunce, (2007) ⁵³	0.47	0.31	0.73
SOSSEG, (2006) ⁵⁹	0.59	0.52	0.67
Summary (random)	0.62	0.56	0.69



38% mortality reduction

Limitations of Mammography

- Traditional Mammography
 - Sensitivity ranges from approximately 57-93%
 - Most limited in women with dense breasts

Appendix Table 3. Sensitivity of Digital Mammography for Detection of Invasive Breast Cancer, by BI-RADS Breast Density and Age or BCSC 5-y Risk

Variable	Sensitivity (95% CI) (by BI-RADS Breast Density), %*			
	Almost Entirely Fat	Scattered Fibroglandular Densities	Heterogeneously Dense	Extremely Dense
Age				
40-49 y	81.2 (54.4-96.0)	84.3 (76.7-90.1)	68.9 (63.2-74.3)	63.3 (52.5-73.2)
50-59 y	89.6 (77.3-96.5)	87.2 (83.0-90.7)	76.7 (72.2-80.7)	71.3 (60.6-80.5)
60-69 y	92.7 (86.2-96.8)	88.6 (85.3-91.4)	80.9 (76.5-84.8)	65.5 (45.7-82.1)
70-74 y	90.0 (76.2-97.2)	89.8 (84.6-93.8)	81.0 (72.9-87.6)	57.1 (28.9-82.3)
BCSC 5-y risk†				
Low (0%-<1.00%)	90.7 (83.1-95.7)	87.4 (82.3-91.6)	67.6 (59.3-75.1)	40.0 (16.3-67.7)
Average (1.00%-1.66%)	90.4 (81.2-96.1)	87.5 (83.3-90.9)	78.0 (72.2-83.0)	71.0 (58.8-81.3)
Intermediate (1.67%-2.49%)	89.7 (75.8-97.1)	90.1 (86.3-93.2)	80.0 (75.8-83.9)	61.4 (45.5-75.6)
High or very high (≥2.50%)	100 (47.8-100)	86.1 (81.1-90.2)	75.5 (70.8-79.7)	69.6 (59.1-78.7)

BCSC = Breast Cancer Surveillance Consortium; BI-RADS = Breast Imaging Reporting and Data System.

* Boldface values are below the accepted cut point of 75%.

† Model includes age, race, family history of breast cancer, history of breast biopsy, and BI-RADS breast density.

Digital Breast Tomosynthesis

FDA Approval

Hologic Selenia
Dimensions
2/11/2011



GE SenoClaire
8/26/2014



Siemens Mammomat Inspiration
with Tomosynthesis Option
4/21/15

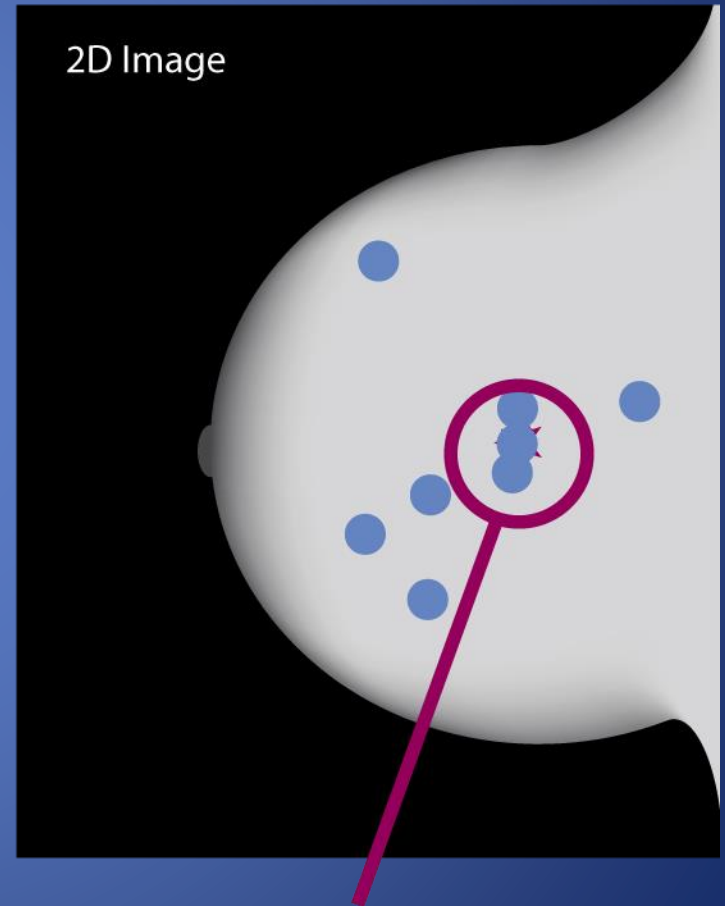
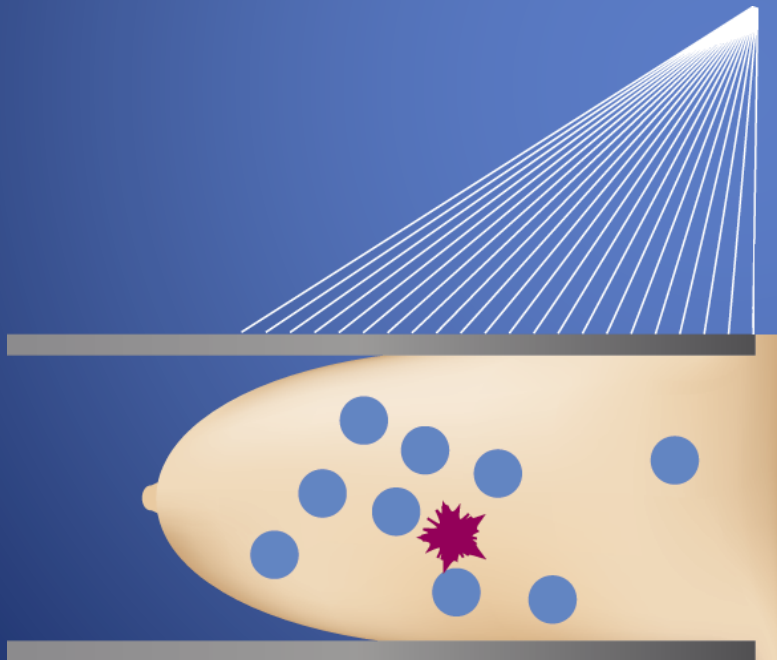


Fujifilm ASPIRE Cristalle with Digital Breast
Tomosynthesis (DBT) Option on 1/10/17



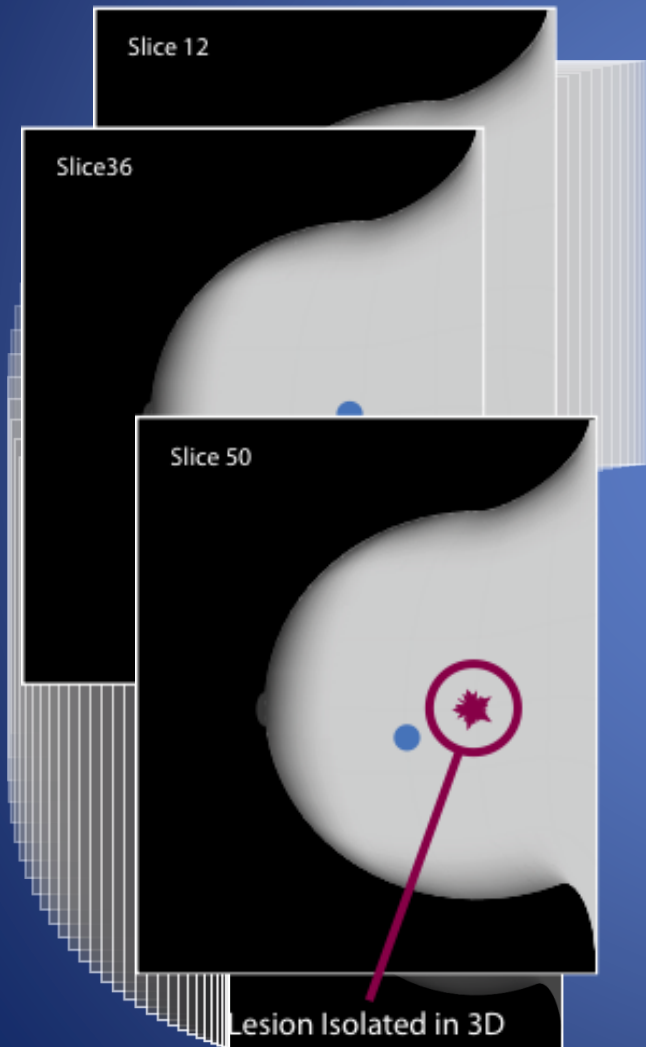
Tissue Superimposition

- Hides pathologies in 2D
- Mimics pathology when doesn't really exist



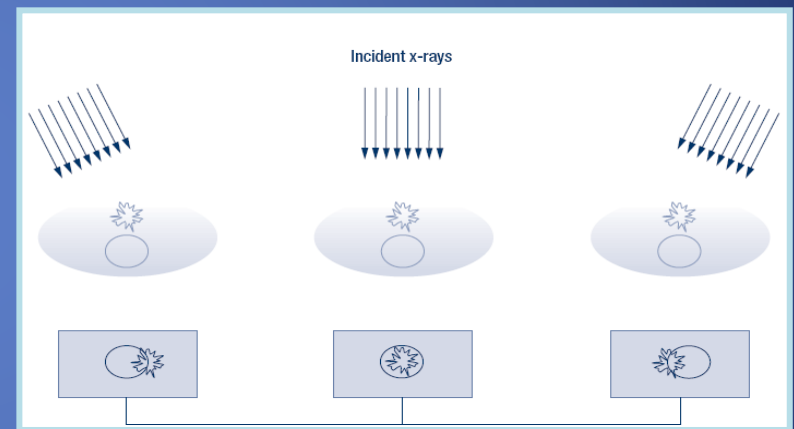
Lesion Superimposed in 2D

Advantages of Tomosynthesis



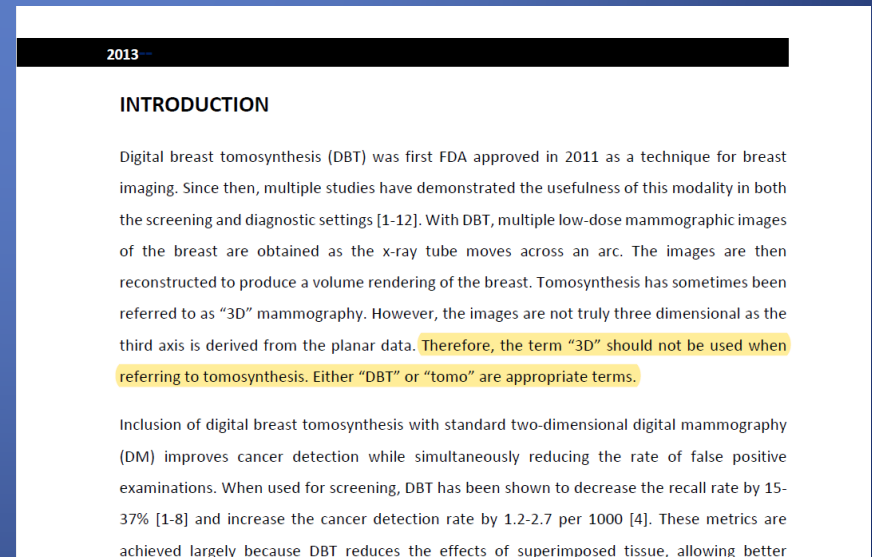
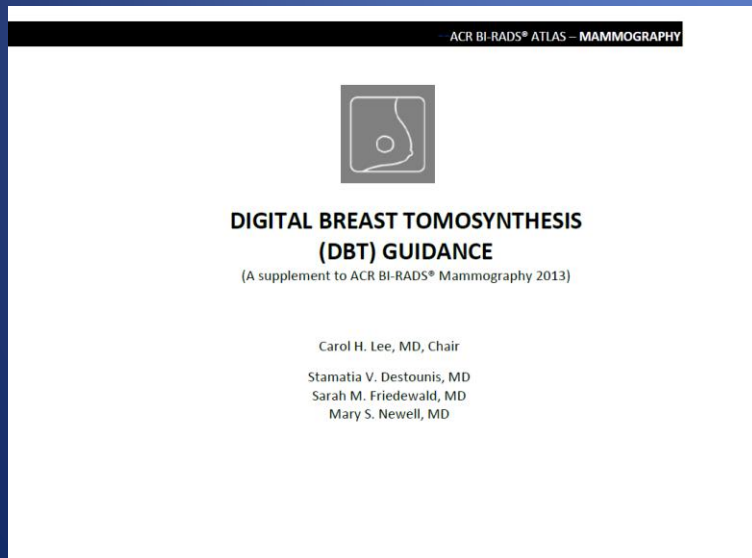
Advantages of Tomosynthesis

- Studies have shown:
 - Decrease in recall rate from screening mammography
 - Improvement in cancer detection
- Results in:
 - Decrease in patient anxiety
 - Decrease downstream costs
 - Increase in positive predictive value



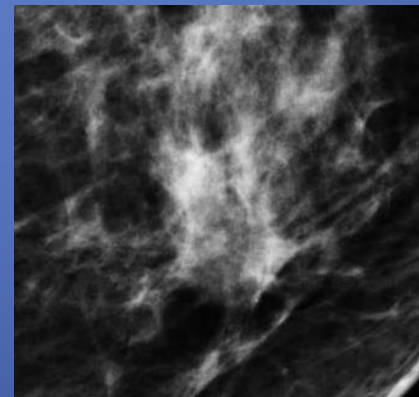
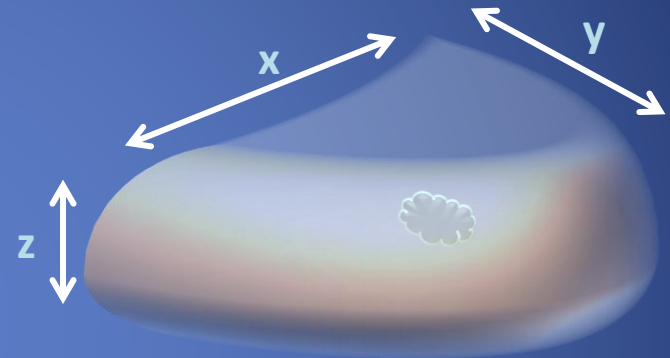
Tomosynthesis Terminology

- **2D mammography** = Conventional digital mammography (DM)
- **3D mammography** = Tomosynthesis or digital breast tomosynthesis (DBT)
- **Combined** = Both DM and DBT image data sets

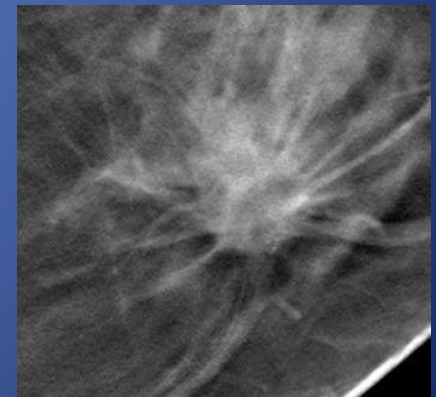


Tomosynthesis

- Information in 3 dimensions (x,y,z)
- Not a true 3D scan
- Not acquired isotropically
- Reconstruction in another plane is possible
 - Very poor fidelity
- Breast is repositioned for each view



2D



DBT Slice

Combined Imaging

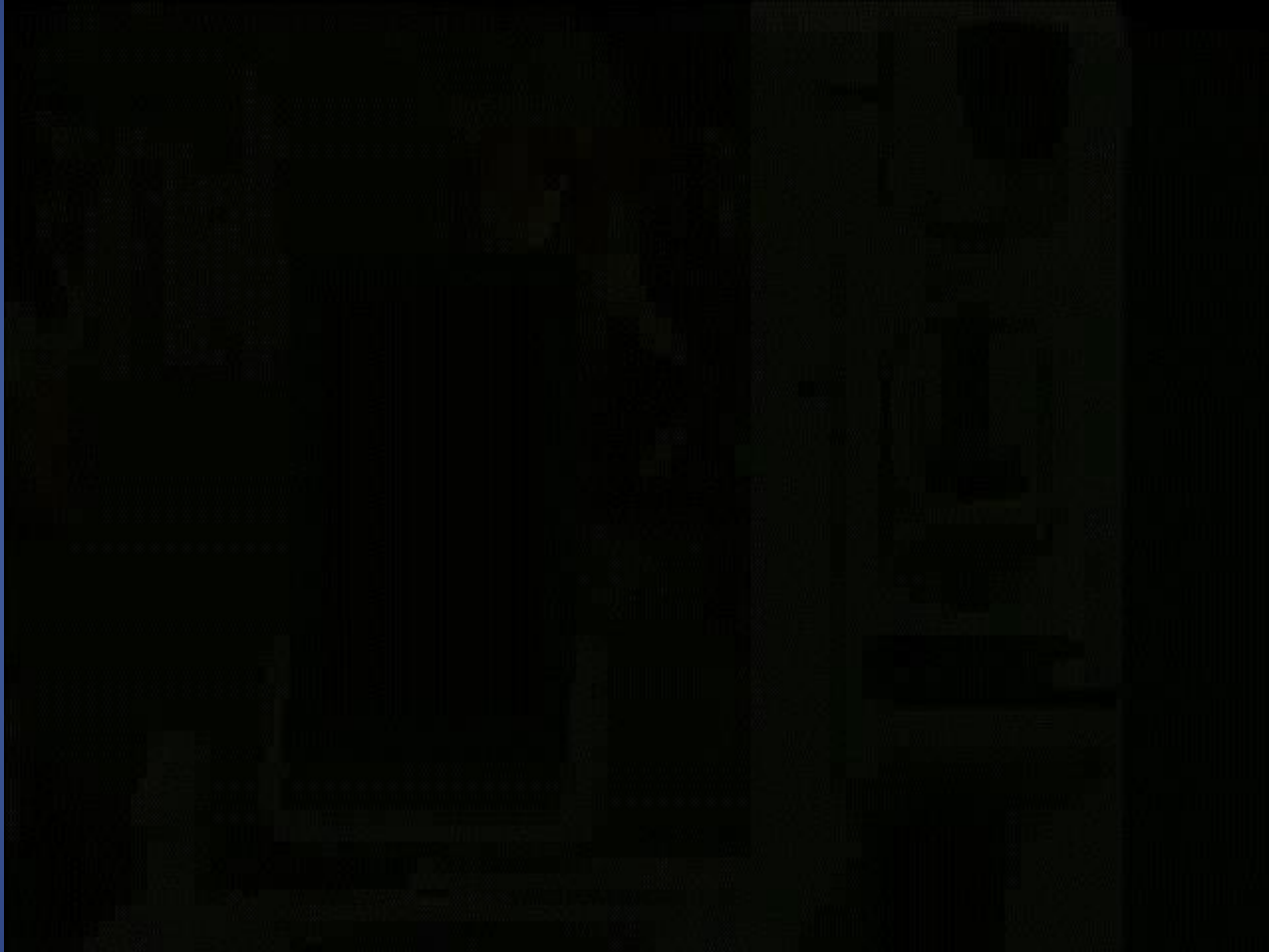
- Why not DBT alone?
 - Overview of the breast
 - Need DM for comparison with prior films
 - Side to side comparisons
 - DM imaging allows for superimposition of grouped calcifications

Acquisition of Images

Tomosynthesis Image Acquisition

- Same patient positioning as standard digital mammogram
 - Compression
 - Stationary breast
- Acquire images of the breast at multiple angles
 - Set number of images (determined by manufacturer),
regardless of breast thickness
- Individual low dose images are reconstructed into thin high resolution images for interpretation
 - The number of reconstructed slices depends on the breast thickness
 - E.g. a 6cm breast in compression will yield 60 slices at 1mm slice thicknesses

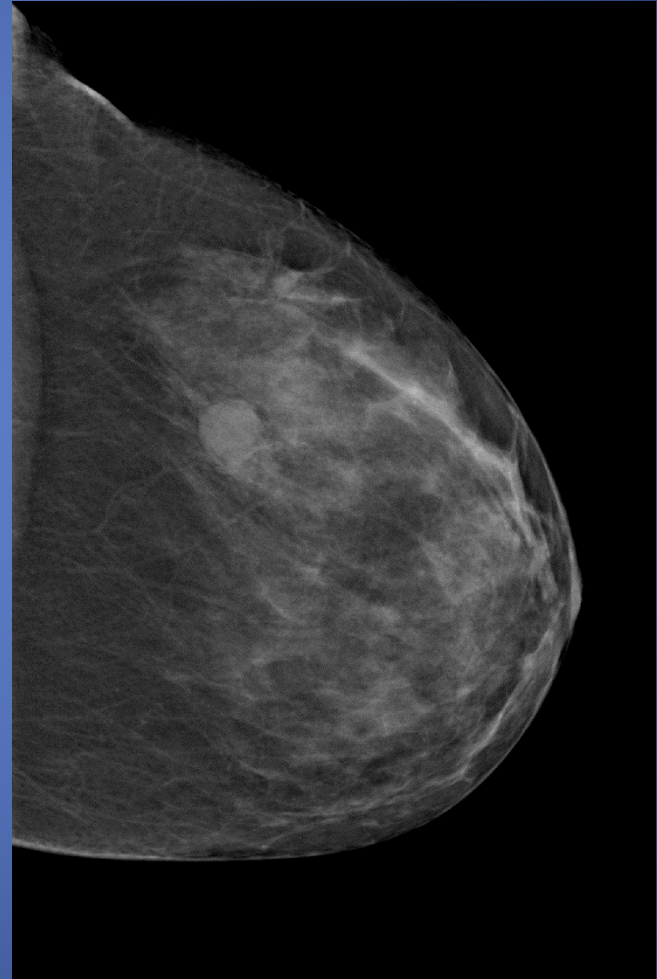
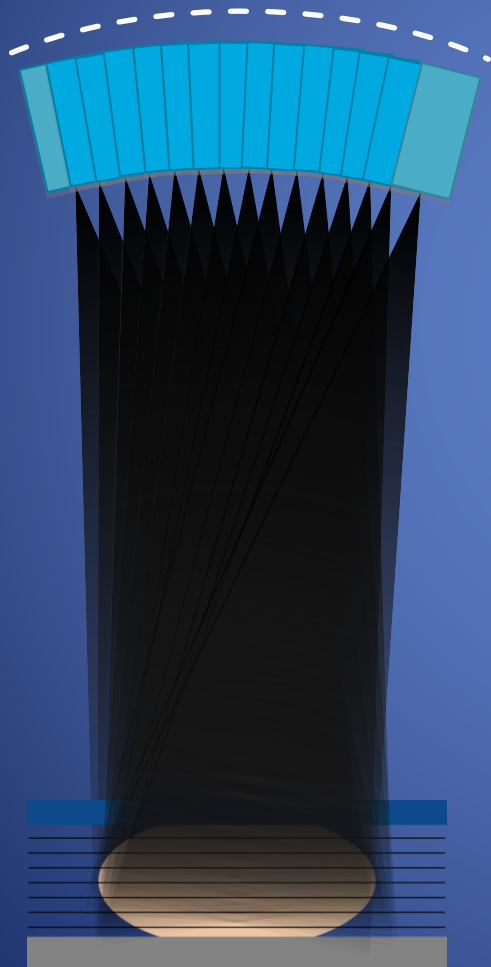
Tomosynthesis Examination



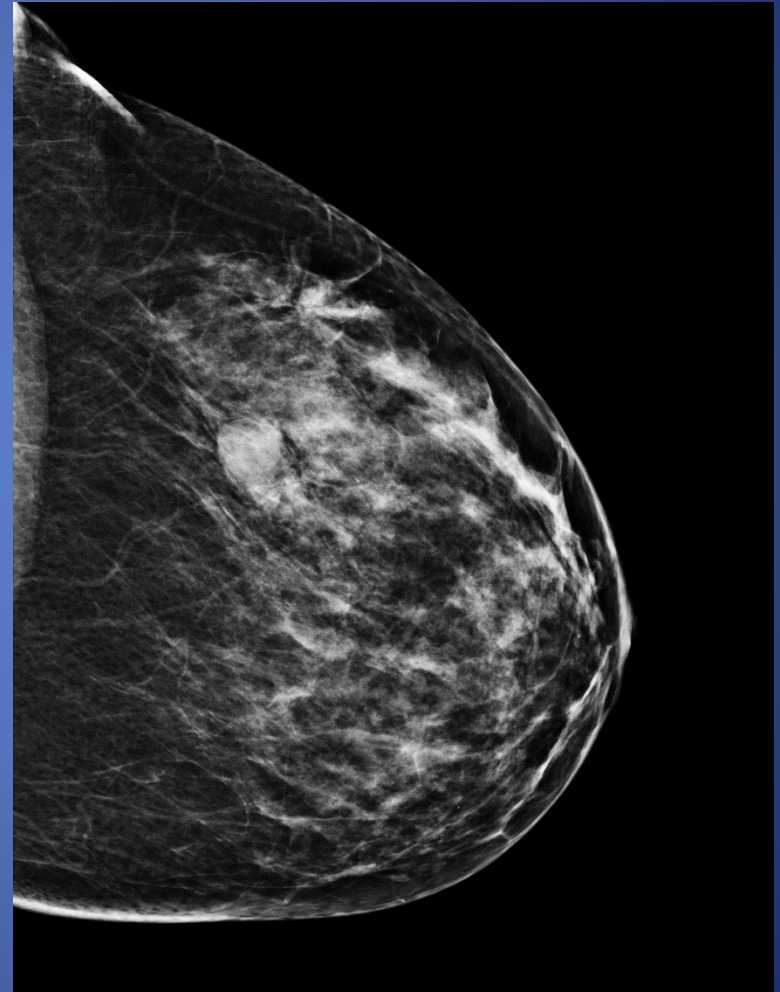
Courtesy of Hologic, Inc.

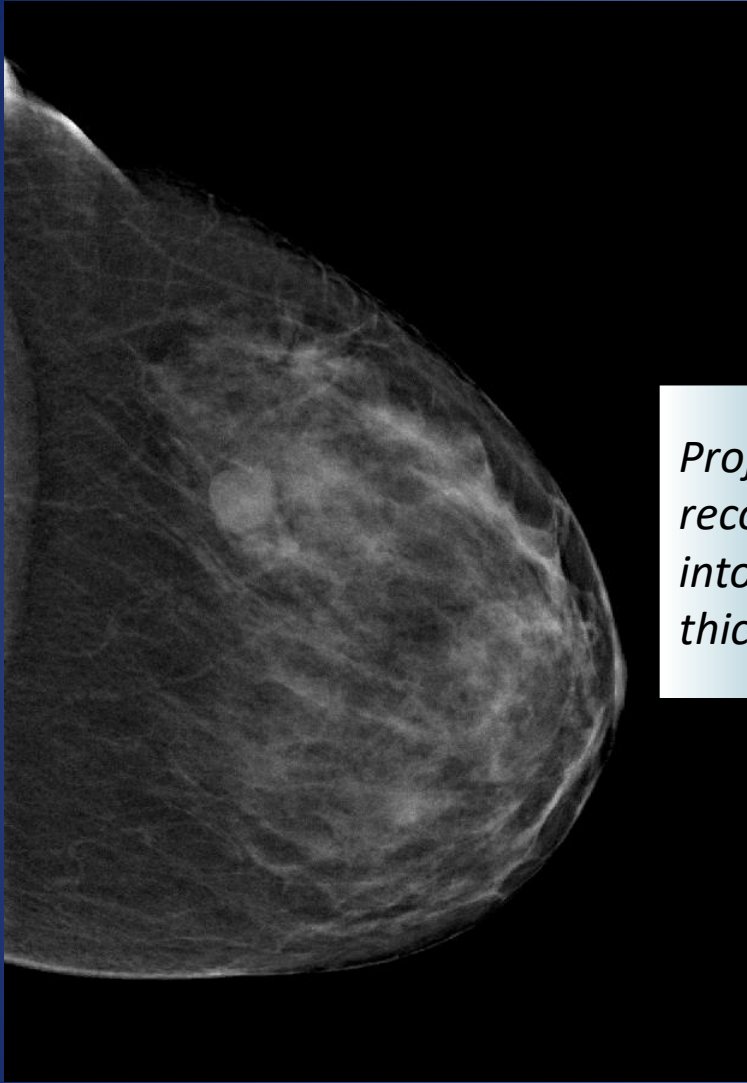
Tomosynthesis Acquisition: Projection Images

Arc of motion of x-ray tube, showing individual exposures



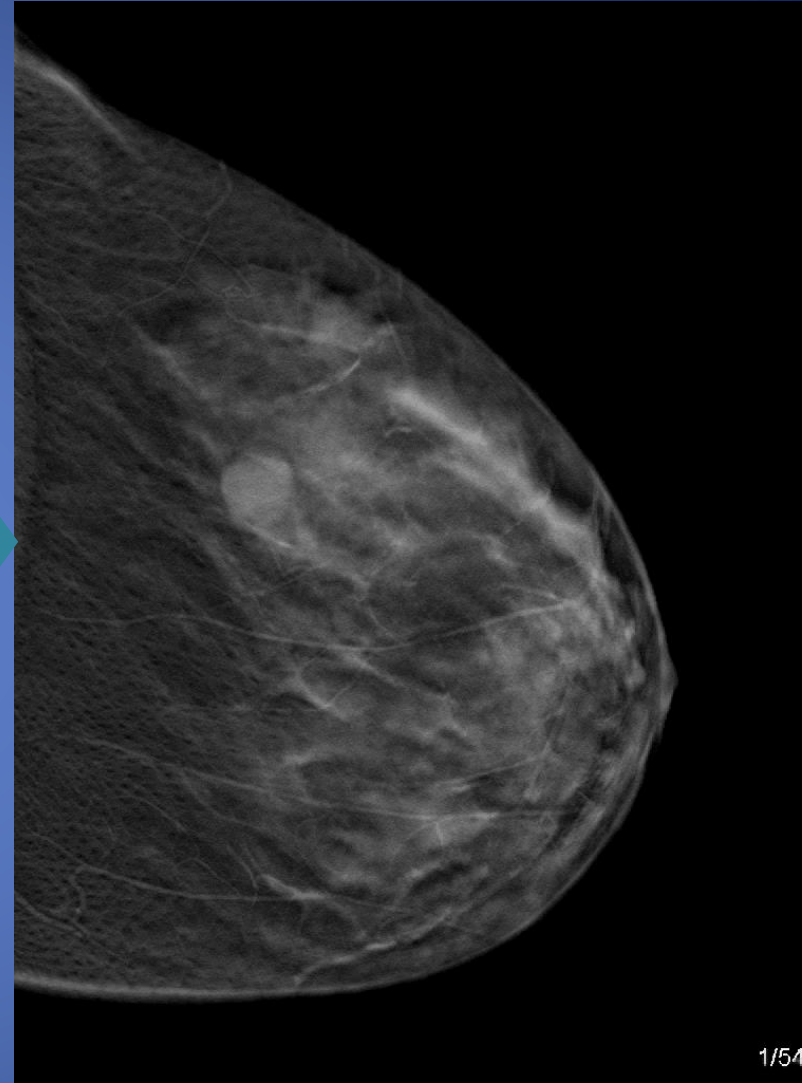
2D image is acquired under the same compression after the projections





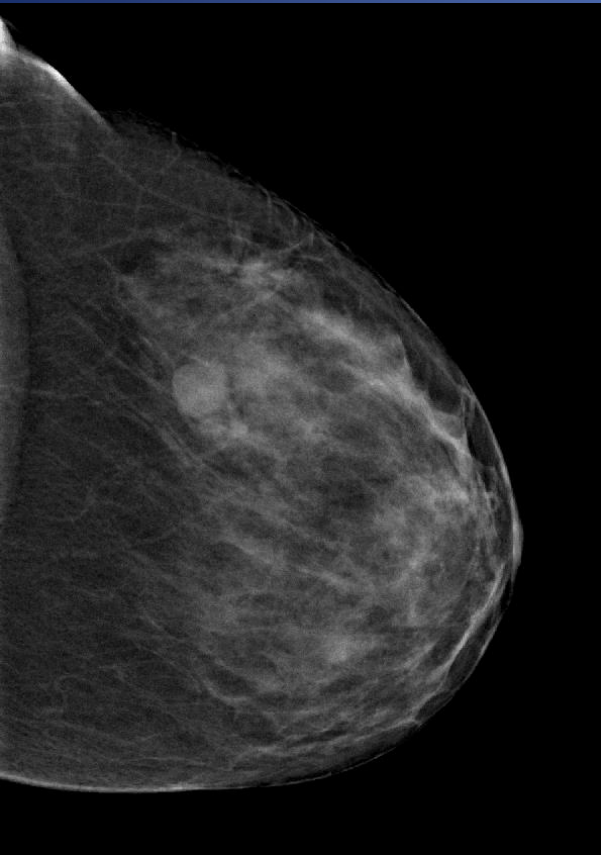
Projection Images
15 images/15° arc

*Projections
reconstructed
into 1 mm
thick slices*

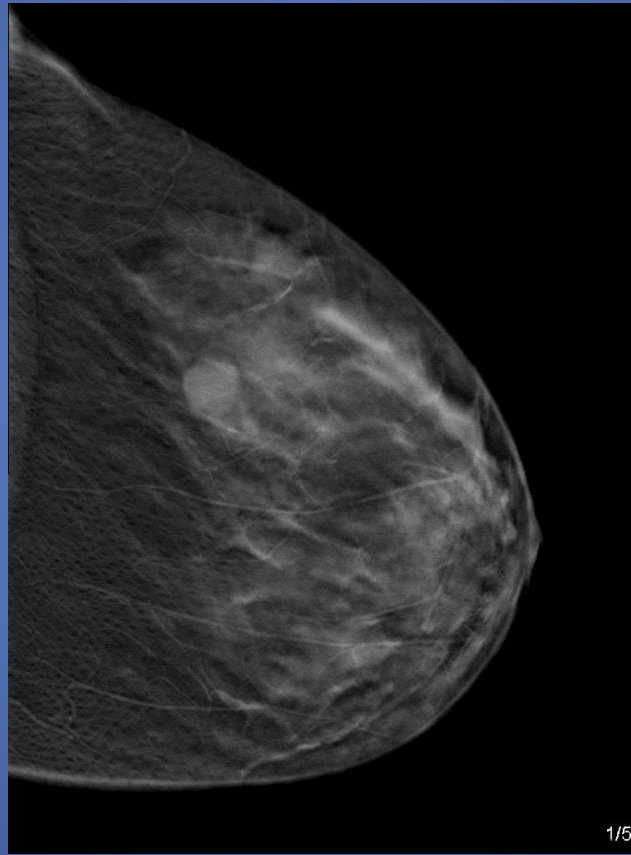


Tomosynthesis
Reconstruction

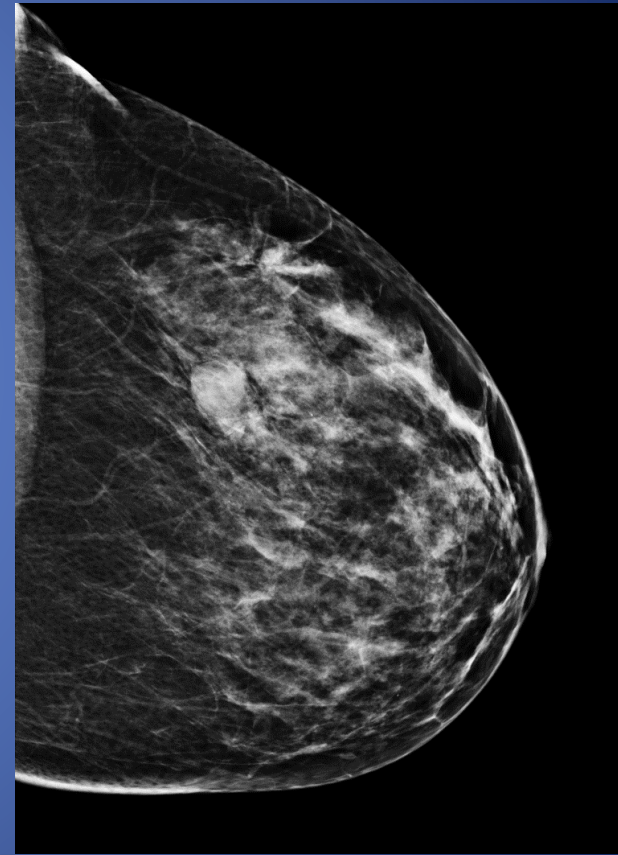
Co-Registered



Projection Images
15 images/15° arc



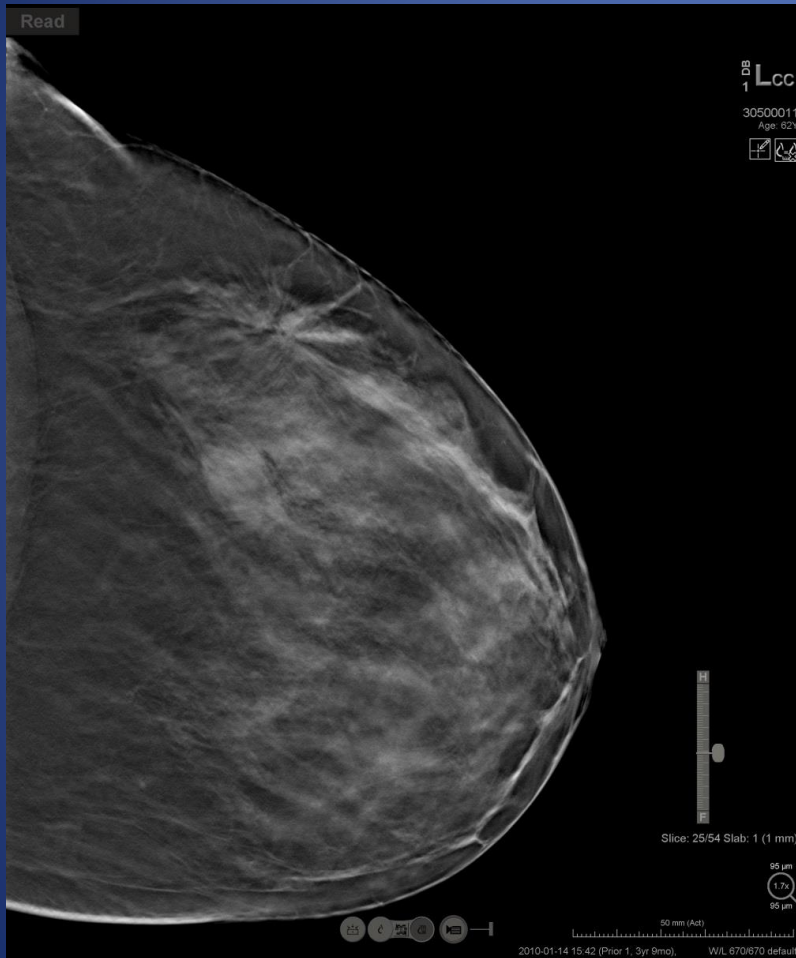
Reconstructed
Tomosynthesis Slices



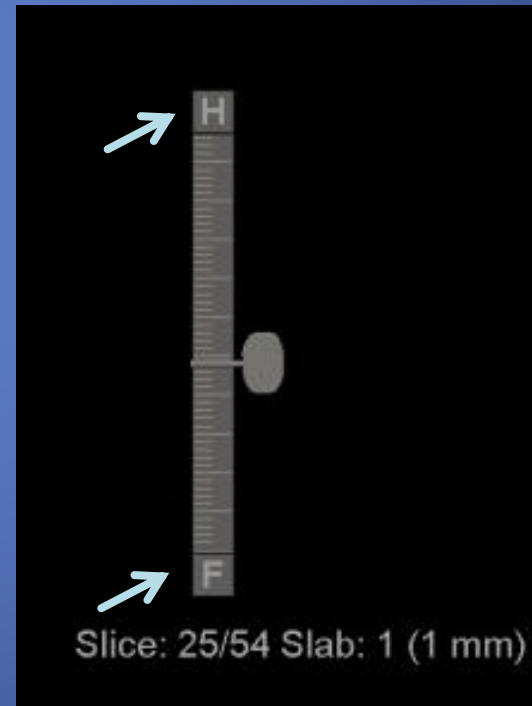
Two Dimensional
Mammogram

Tomosynthesis Specific Tools

Interpretation Tools: CC View

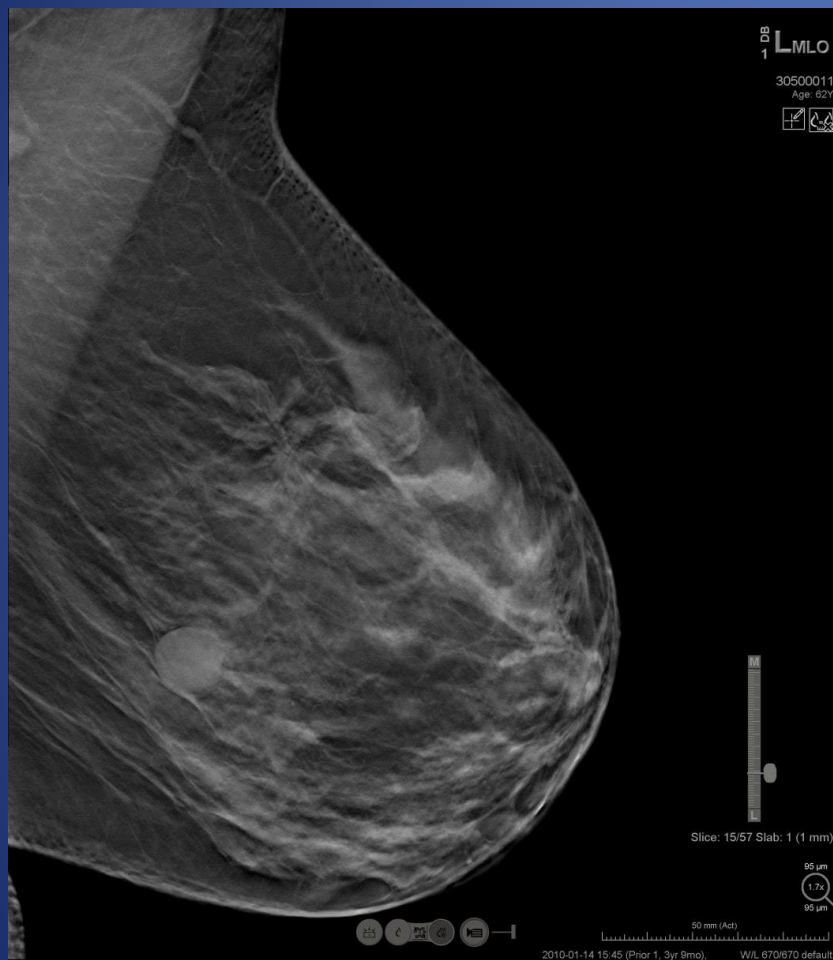


Single slice of a reconstructed tomosynthesis set

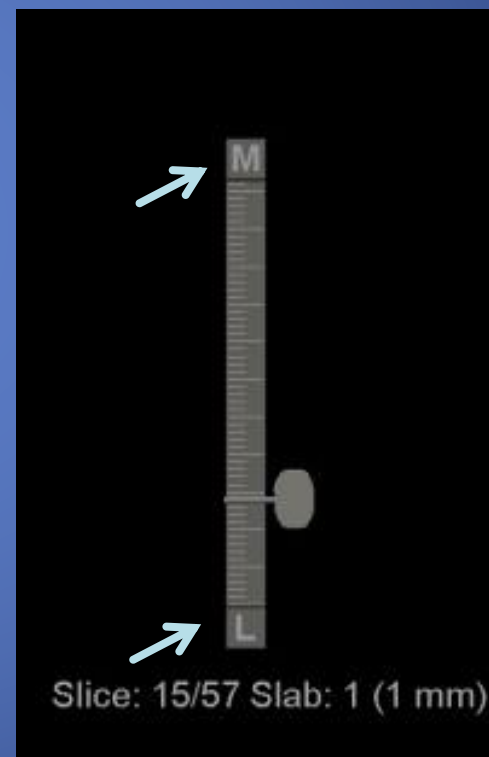


Slice #1 is at the Detector

Interpretation Tools: MLO View

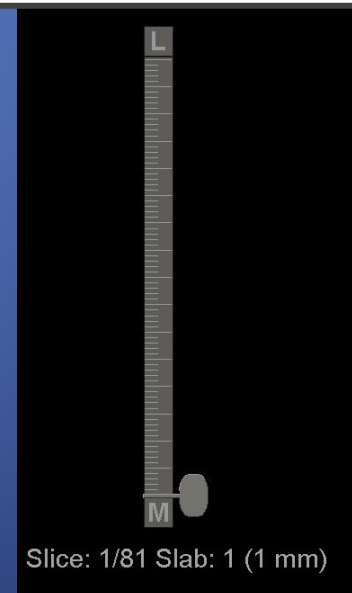
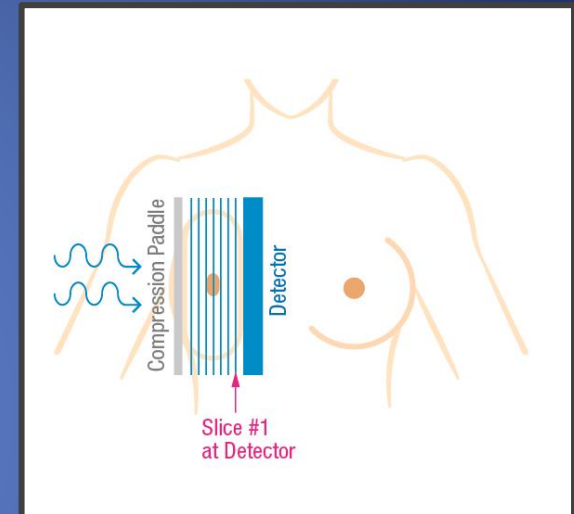
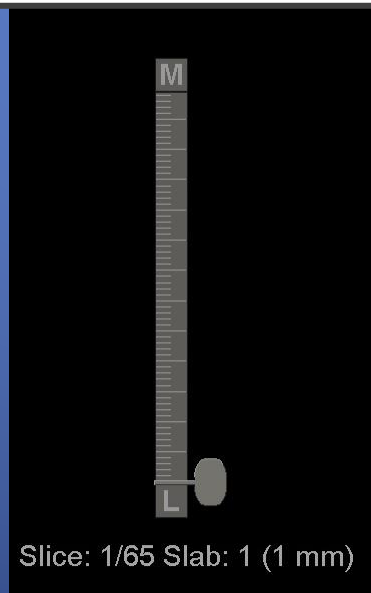
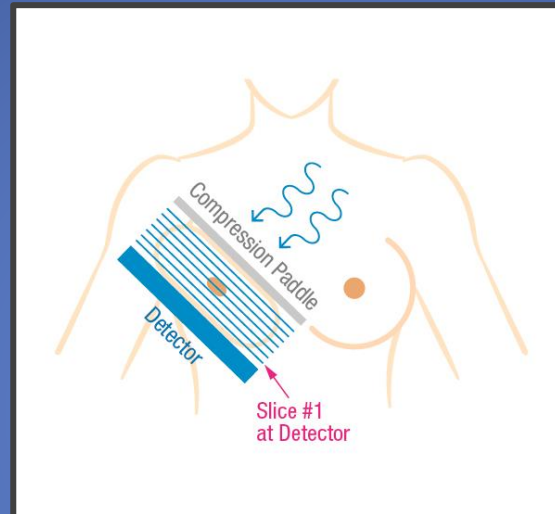
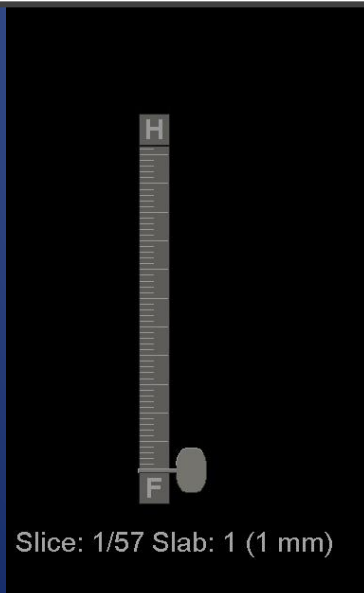
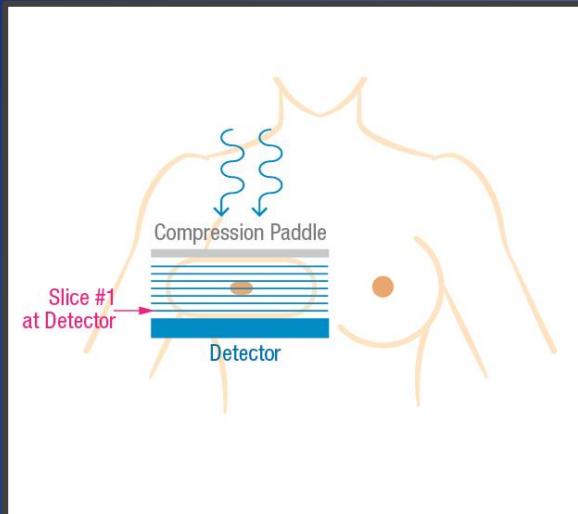


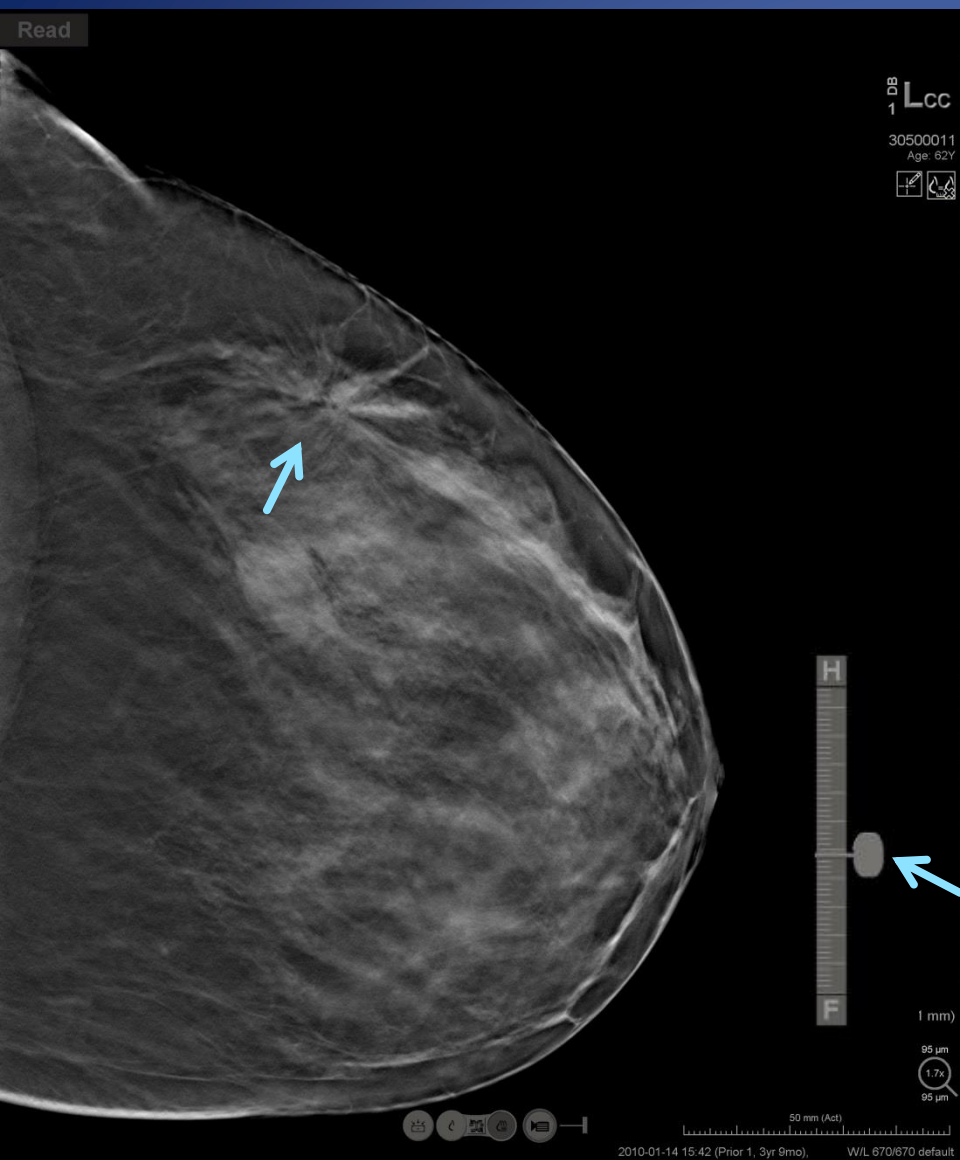
Single slice of a reconstructed tomosynthesis set



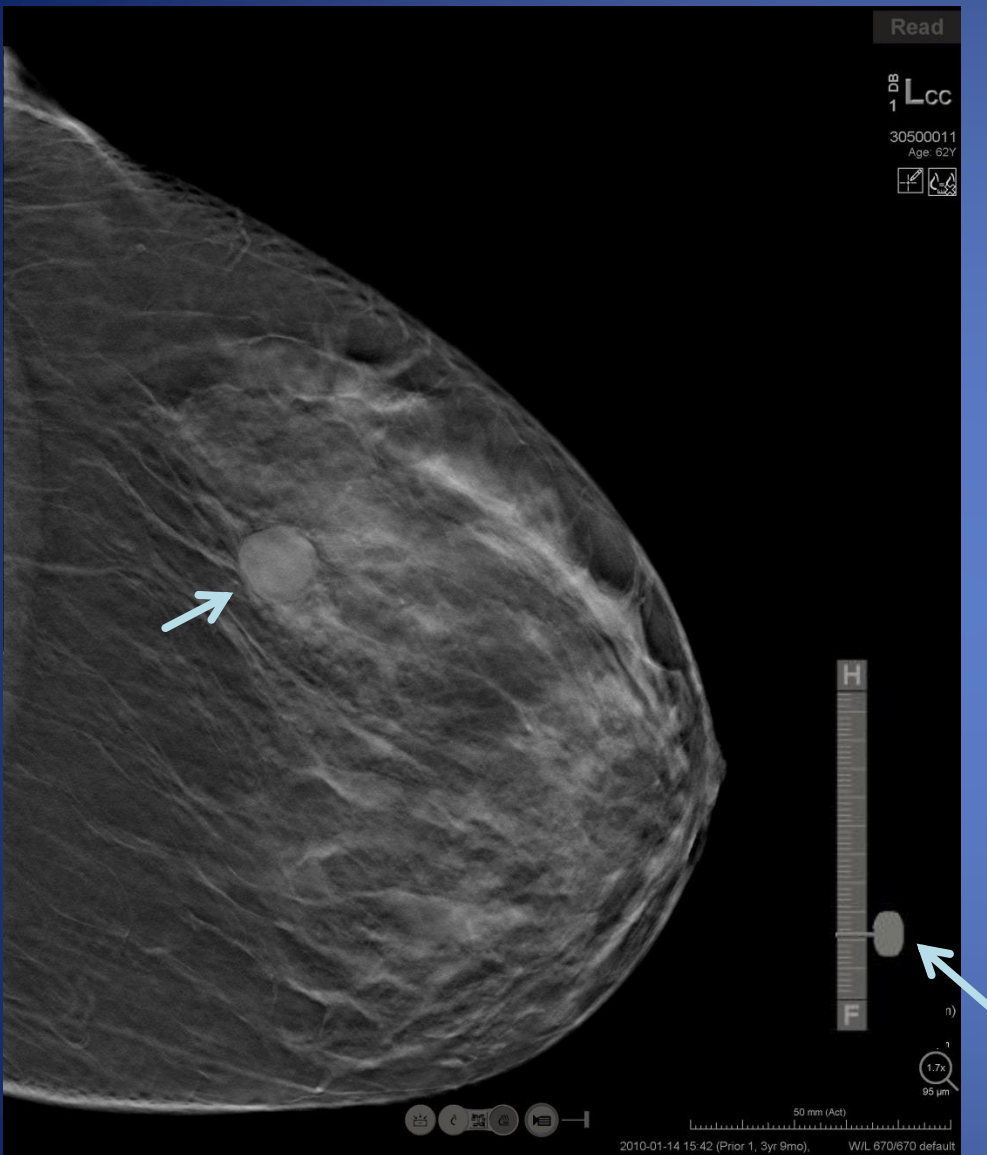
Slice #1 is at the Detector

Understanding the Scroll Bar

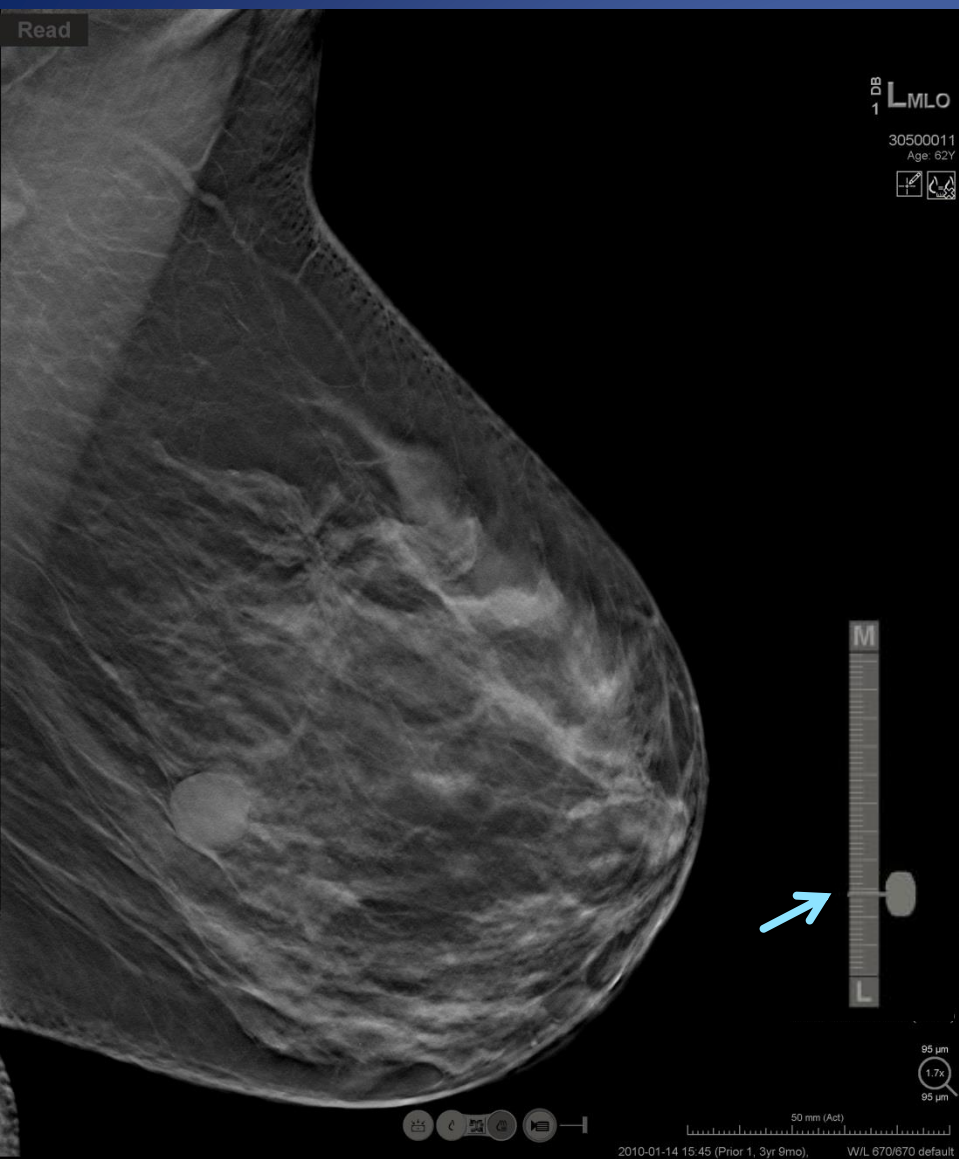




Scroll bar localizes to mid-breast



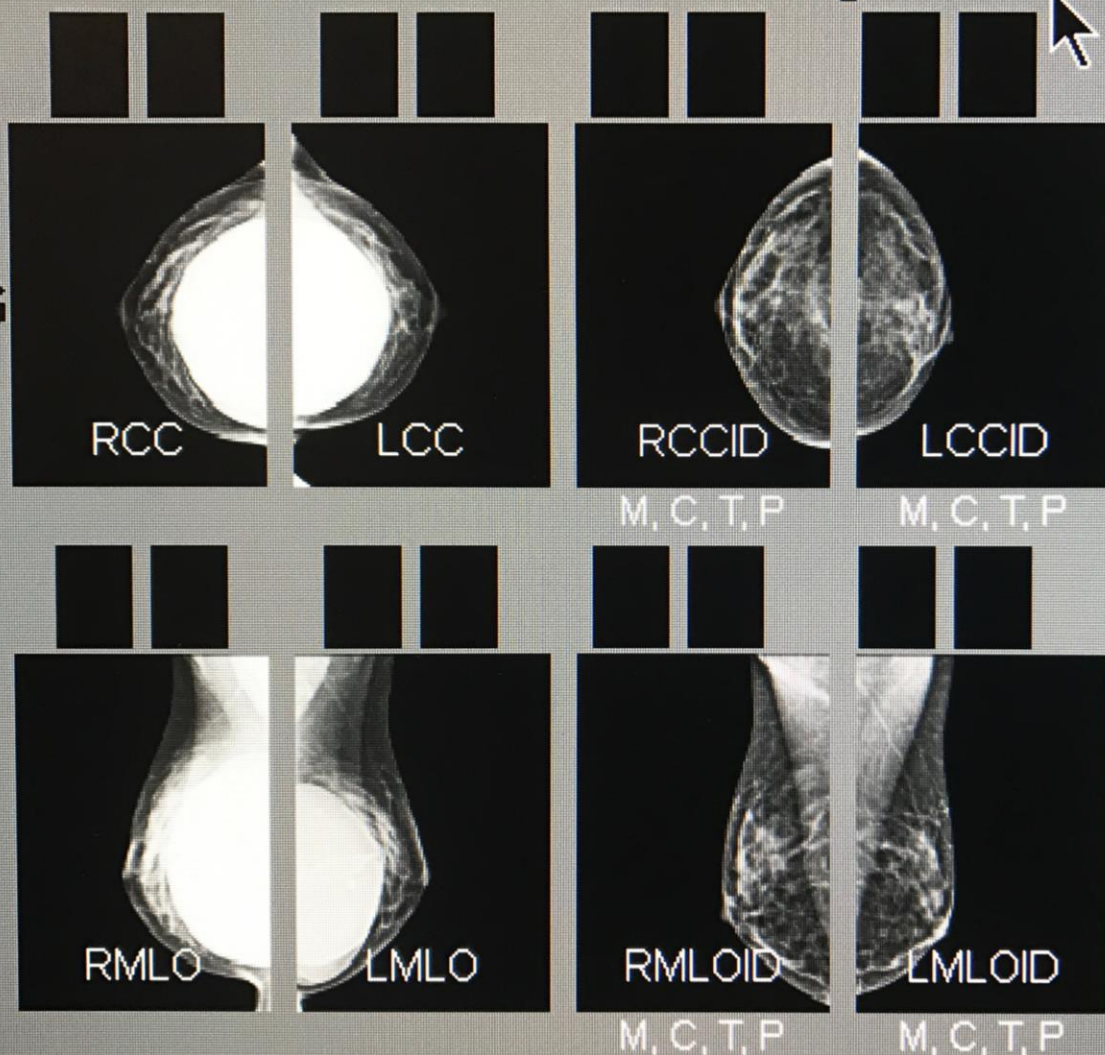
Scroll bar localizes to
inferior breast



Scroll bar localizes
both lesions to the
lateral breast

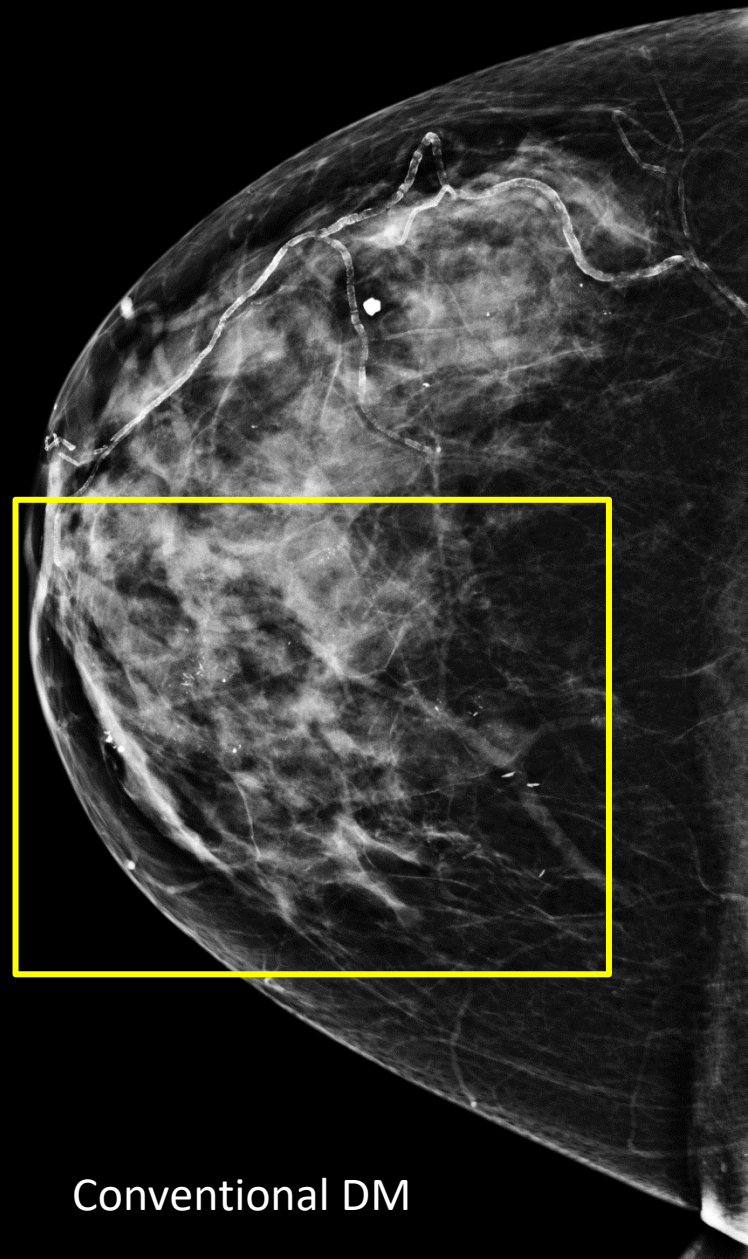
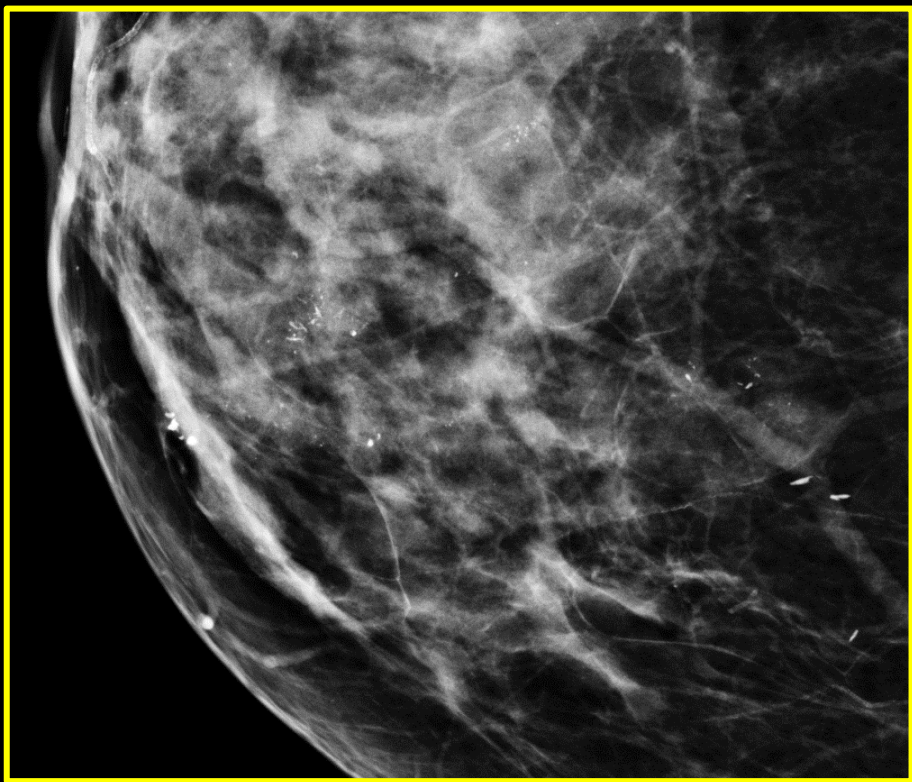
01-04-2017 BR DBT Screening Mammography-Digital

MG



Slab Viewing

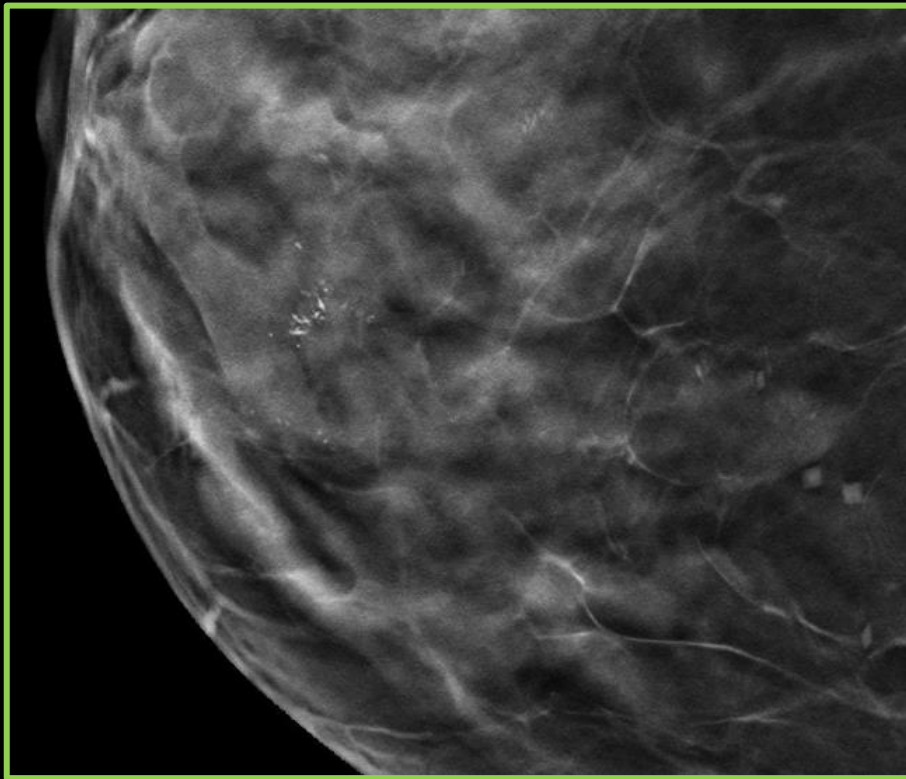
- Option of increasing the slab thickness
 - As the slab thickness increases, the advantages of tomosynthesis decreases
- Useful in understanding relationship of calcifications



Conventional DM

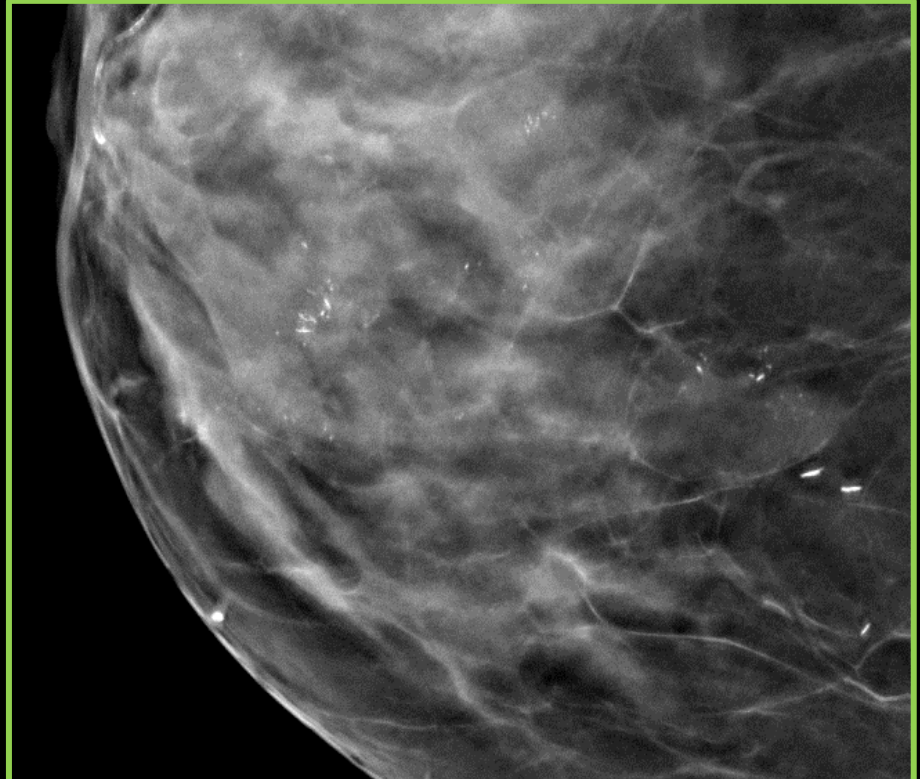
1 mm slice

Slice: 9/55 Slab: 1 (1 mm)



13 mm Slab

Slice: 11/55 Slab: 13 (13 mm)

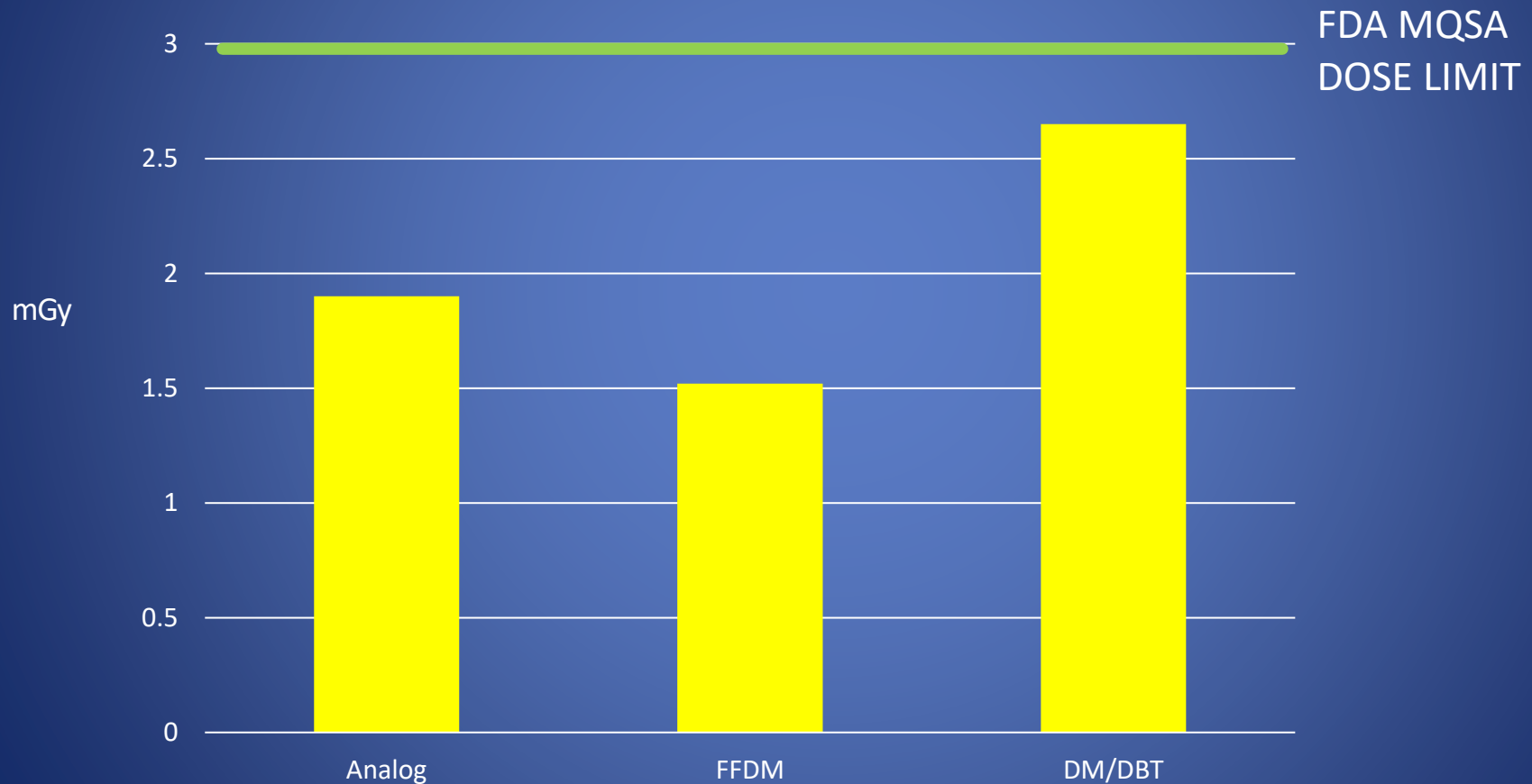


Tomosynthesis Dose

Tomosynthesis Dose

- Current mammography units operate at
 - 1-2mGy for the phantom dose
- USFDA sets dose for screening at 3mGy/view
- 2D + 3D mammography image is
 - Approximately 2.65mGy for the phantom

Comparison of Doses (ACR Phantom)

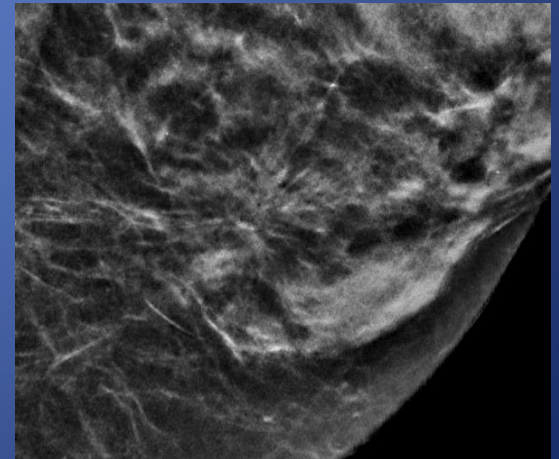
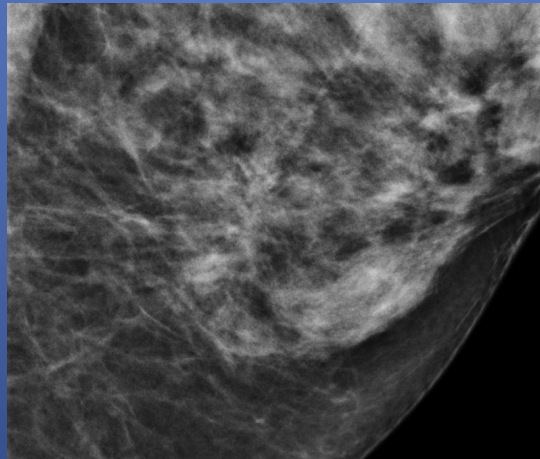


Dose to the Breasts

- Breast elements are mature at approximately 30 years of age
- Or, at the time of pregnancy, whichever comes first
- Breasts are extremely sensitive to radiation prior to complete development of tissue
 - Radiation to the chest between ages 10-30
- After complete maturation, sensitivity to radiation is minimal

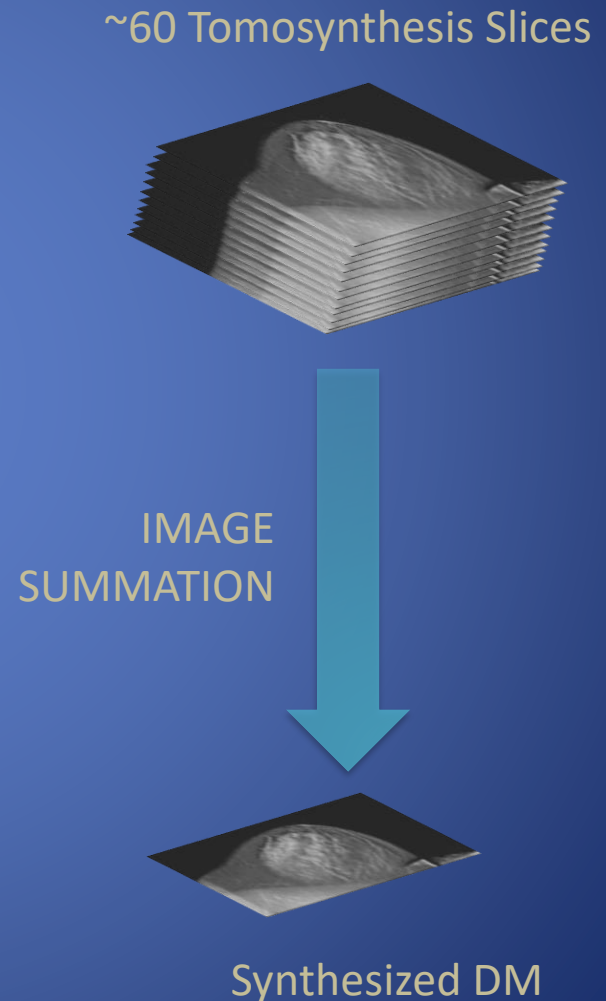
Opportunity for Dose Reduction

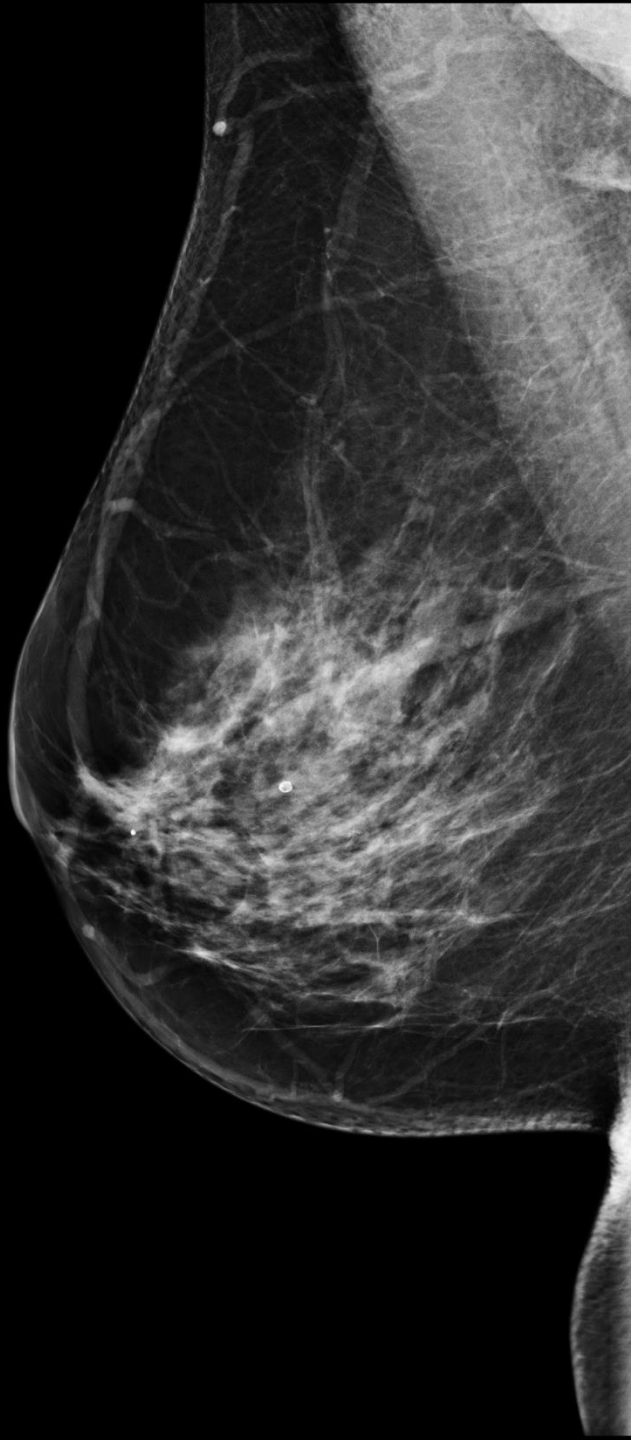
- Synthesized images
 - Looks similar to standard DM images but eliminates the need for the DM acquisition
 - Provides all the benefits of a DM image without the dose
 - Eliminates dose concerns: implants; breasts larger than detector



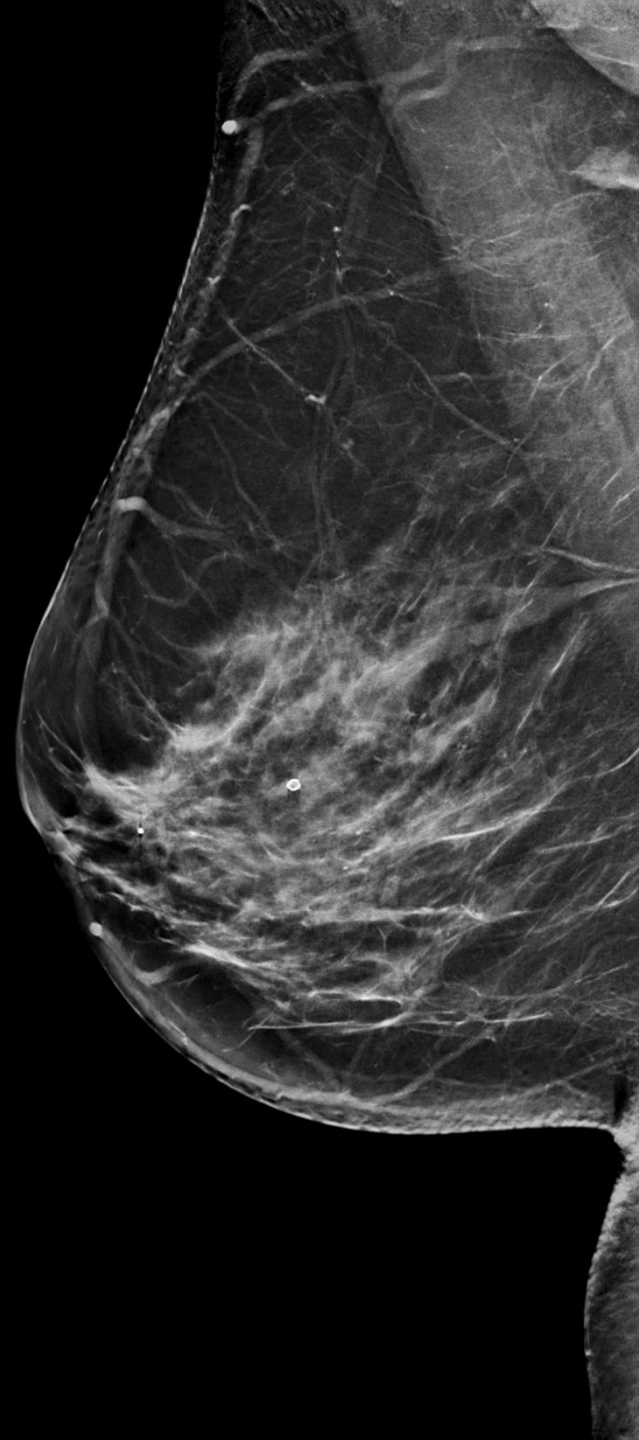
Generated “Synthesized” DM Image

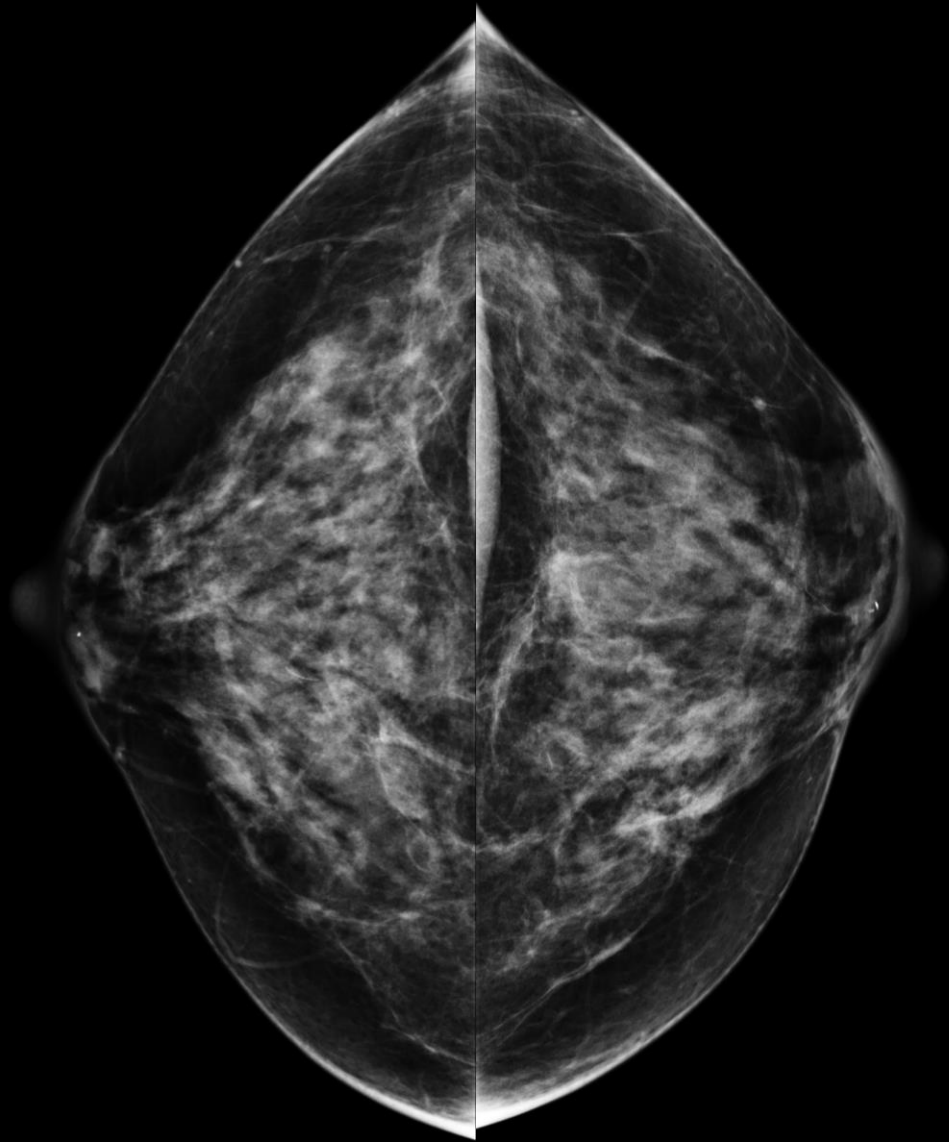
- Perform a standard tomosynthesis scan
- Computer software program creates a DM image
 - Similar to Maximum Intensity Projection (MIP) as done with MR images





→ C-View

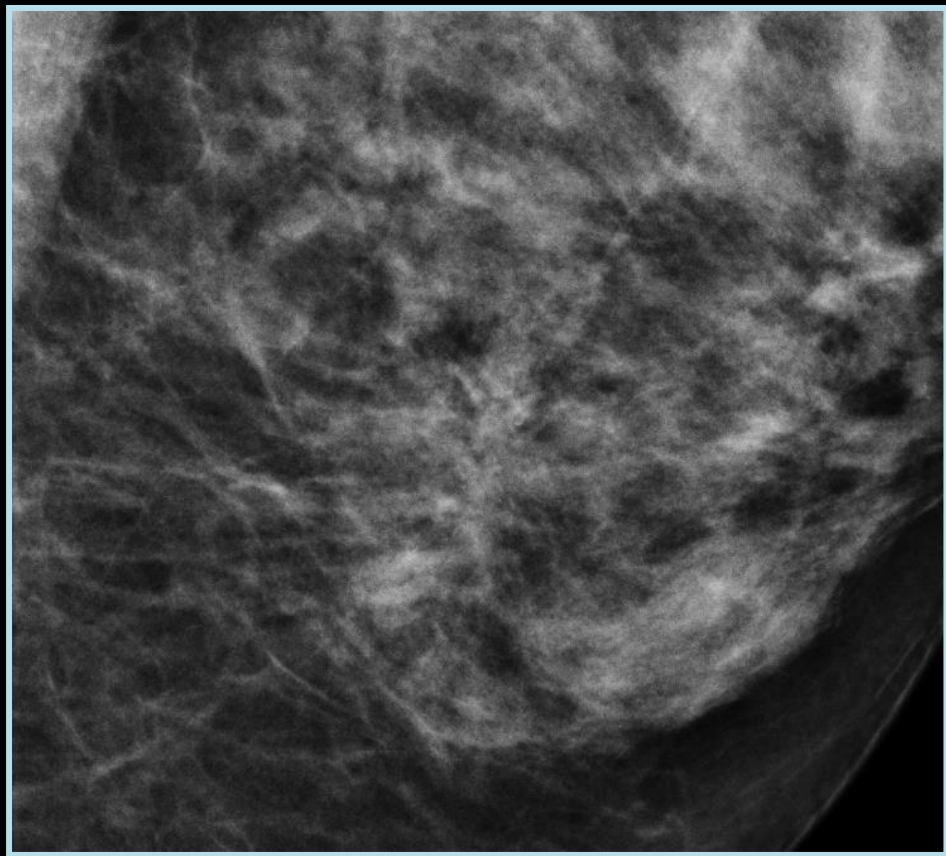




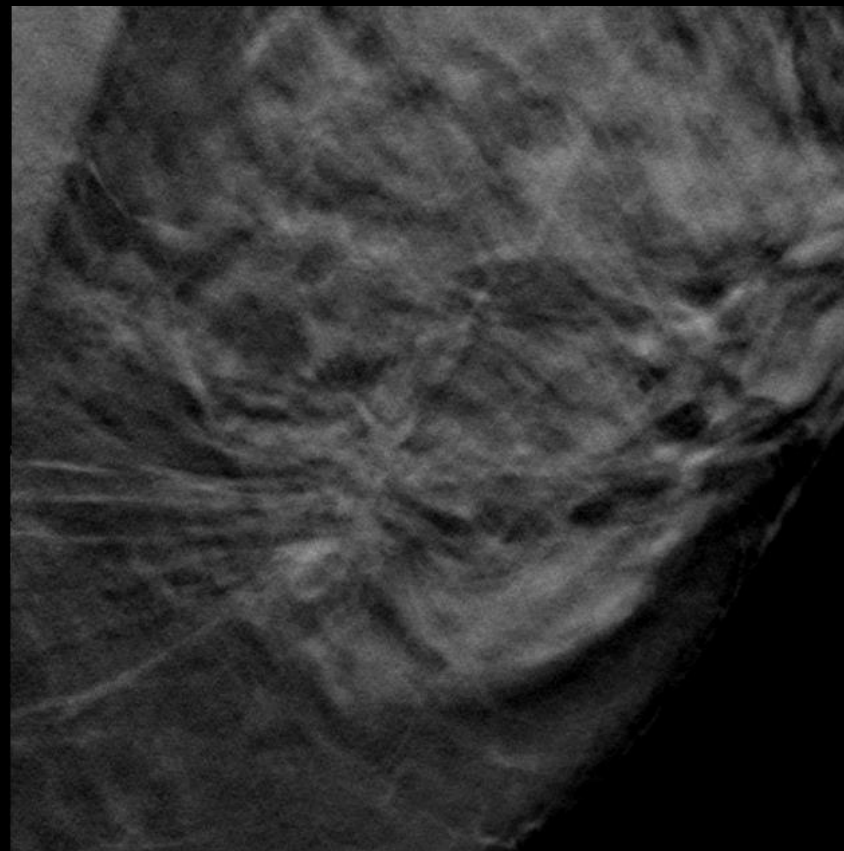
RMLO

LMLO



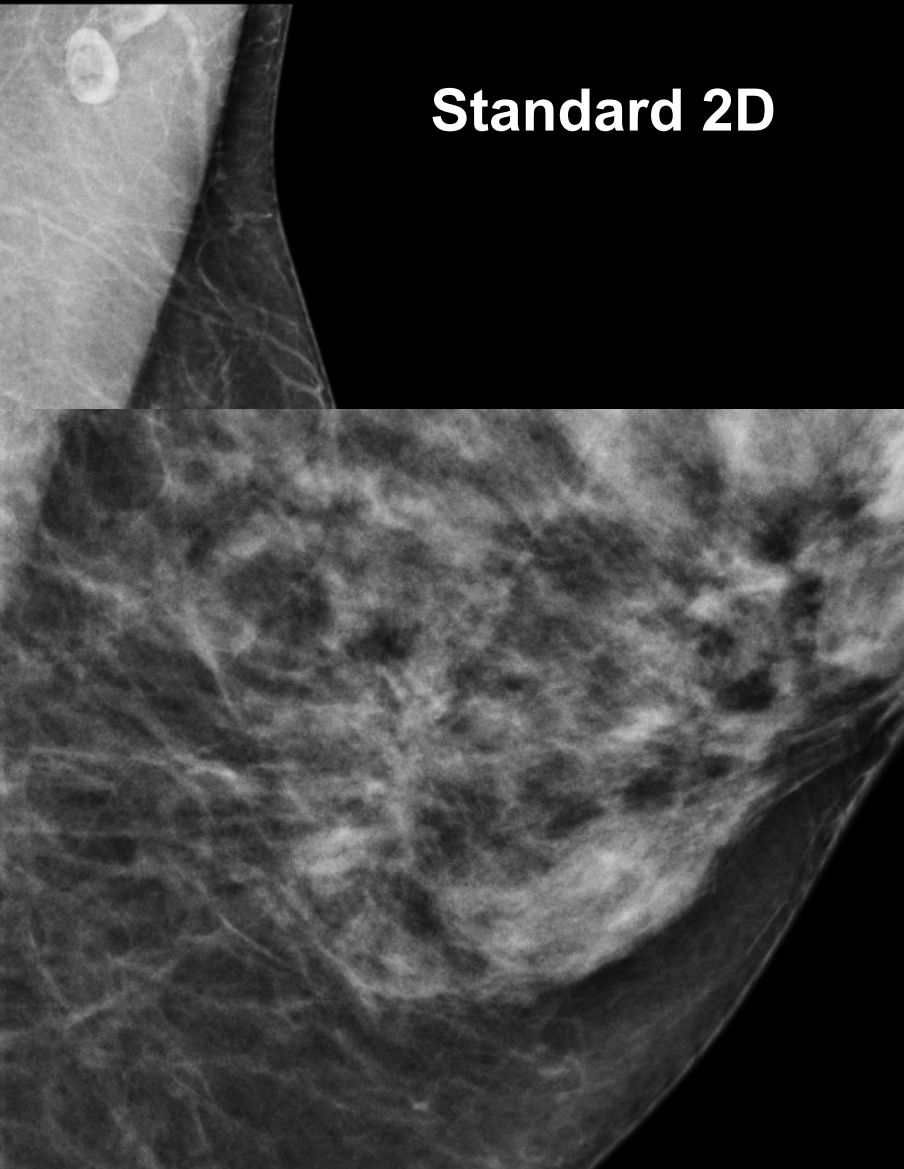


Standard 2D Image

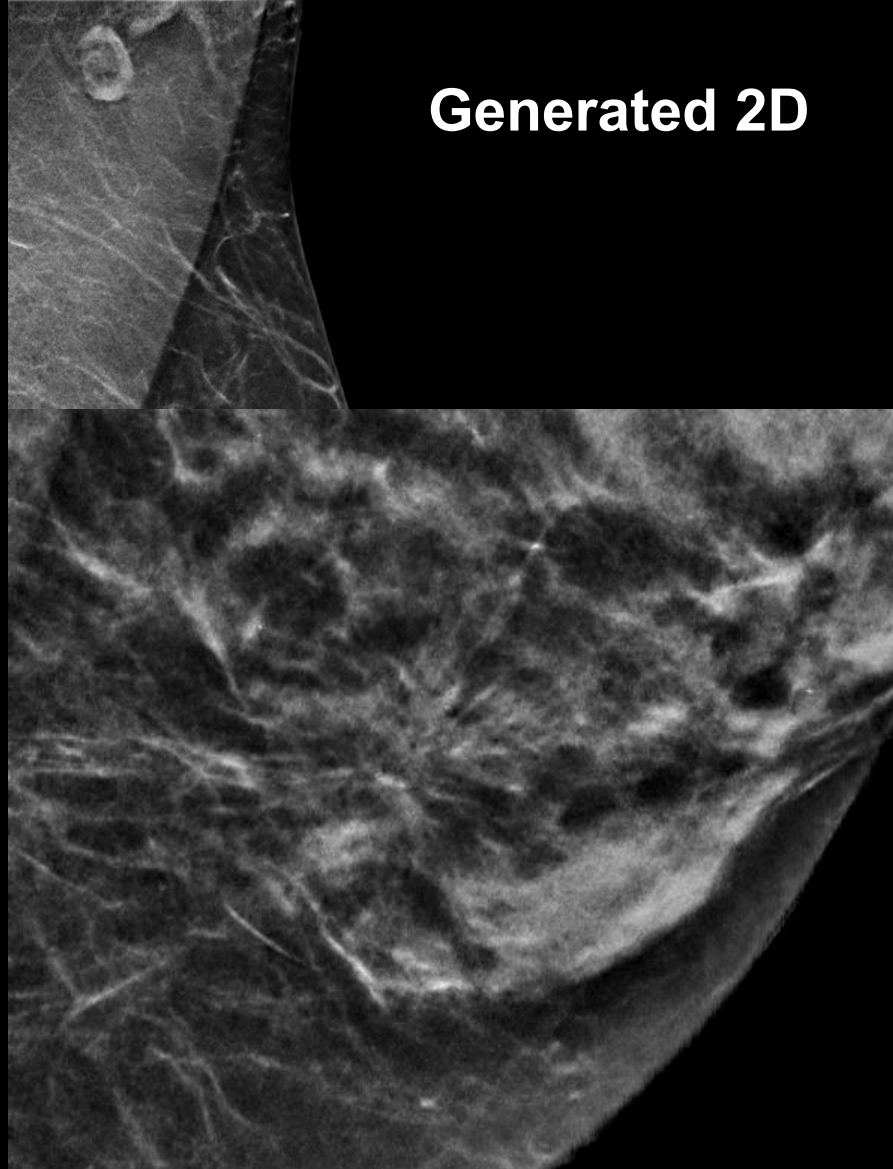


Tomosynthesis Slice
Invasive Ductal Carcinoma

Standard 2D



Generated 2D



Synthesized Imaging

- Limit dose, maximizing information if still performing DM
 - Implants:
 - DM with implant
 - DM + DBT for implant displaced views
 - Breasts larger than detector
 - Consider imaging bulk of breast in DM + DBT with remaining breast in DM only
- Synthesized DM has changed paradigm
 - DBT + synthesized DM on all patients

Benefits of DBT

Increase in Cancer Detection

- Improves lesion conspicuity
 - Distortion
- Removes tissue superimposition
 - Margin evaluation
 - Localization

Breast Cancer Screening Using Tomosynthesis in Combination with Digital Mammography

Friedewald, SM, Rafferty, EA, Rose, SL, et al. *JAMA*
2014;311(24):2499-2507

JAMA The Journal of the
American Medical Association

Site Characteristics

Site	# Radiologists	Academic or Non-Academic	Duration of Time Period 1 (months)	DM Cases Period 1	Duration Time Period 2 (months)	DM+Tomo Cases Period 2	Total Cases used for Primary Analysis	Transition to DM+Tomo	DM Cases ^a Imaged Period 2
1	7	A	12	10746	16	4366	15112	Hybrid	16098
2	10	N	12	19830	19	7909	27739	Hybrid	26105
3	6	A	12	10753	16	14014	24767	Complete	0
4	7	A	12	12533	17	8607	21140	Hybrid	10,022
5	13	N	12	26502	13	3640	30142	Hybrid	33112
6	18	N	12	25488	3	5868	31356	Complete	0
7	20	N	12	22606	18	2613	25219	Hybrid	29112
8	6	N	12	16694	18	16149	32843	Hybrid	16098
9	3	N	12	4801	21	16269	21070	Hybrid	2178
10	5	A	12	17623	22	5880	23503	Hybrid	6416
11	20	N	12	53181	17	24281	77462	Hybrid	56803
12	12	A	12	40382	22	34119	74501	Hybrid	45473
13	12	N	12	20048	20	29948	49996	Hybrid	4568
Total	139			281187		173663	454850		245985

Abbreviations: DM, digital mammography; DM+Tomo, digital mammography plus tomosynthesis

^a DM cases imaged during period 2 were used in analysis to address potential selection bias

Site Characteristics

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1	7	A	12	10746	16	4366	15112	Hybrid	16098
2	10	N	12	19830	19	7909	27739	Hybrid	26105
3	6	A	12	10753	16	14014	24767	Complete	0
4	7	A	12	12533	17	8607	21140	Hybrid	10,022
5	13	N	12	26502	13	3640	30142	Hybrid	33112
6	18	N	12	25488	3	5868	31356	Complete	0
7	20	N	12	22606	18	2613	25219	Hybrid	29112
8	6	N	12	16694	18	16149	32843	Hybrid	16098
9	3	N	12	4801	21	16269	21070	Hybrid	2178
10	5	A	12	17623	22	5880	23503	Hybrid	6416
11	20	N	12	53181	17	24281	77462	Hybrid	56803
12	12	A	12	40382	22	34119	74501	Hybrid	45473
13	12	N	12	20048	20	29948	49996	Hybrid	4568
Total	139			281187		173663	454850		245985

Abbreviations: DM, digital mammography; DM+Tomo, digital mammography plus tomosynthesis

^a DM cases imaged during period 2 were used in analysis to address potential selection bias

Results

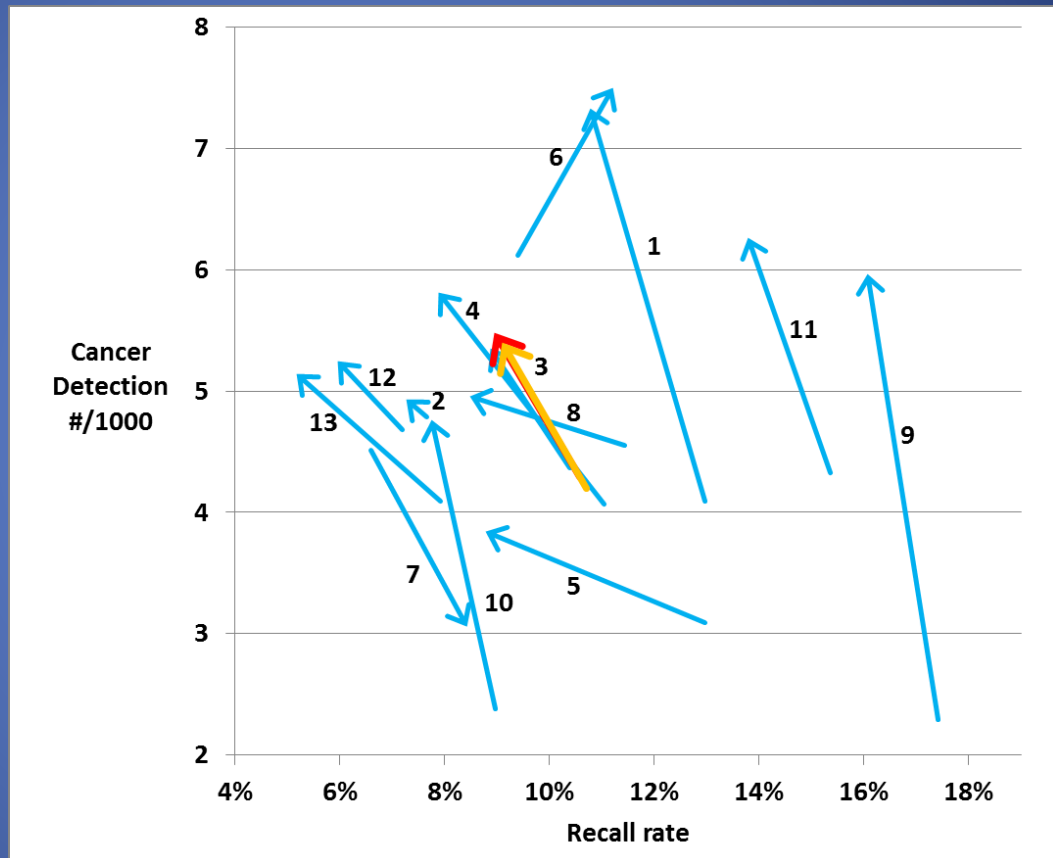
	DM	DM+Tomo	Absolute Difference	Relative change	P-Value
Recall Rate	10.7%	9.1%	16/1000	-15%	P<.001
Cancer Detection Rate	4.2/1000	5.4/1000	1.2/1000	+29%	P<.001
Invasive Cancer Detection Rate	2.9/1000	4.1/1000	1.2/1000	+41%	P<.001
PPV1	4.3%	6.4%	2.1%	+49%	P<.001
PPV3	24.2%	29.2%	5.0%	+21%	P<.001

Results

Blue Arrows:
Numbers represent
each site

Yellow Arrow:
Represents model
estimate

Red Arrow:
Represents pooled
performance



Site Characteristics

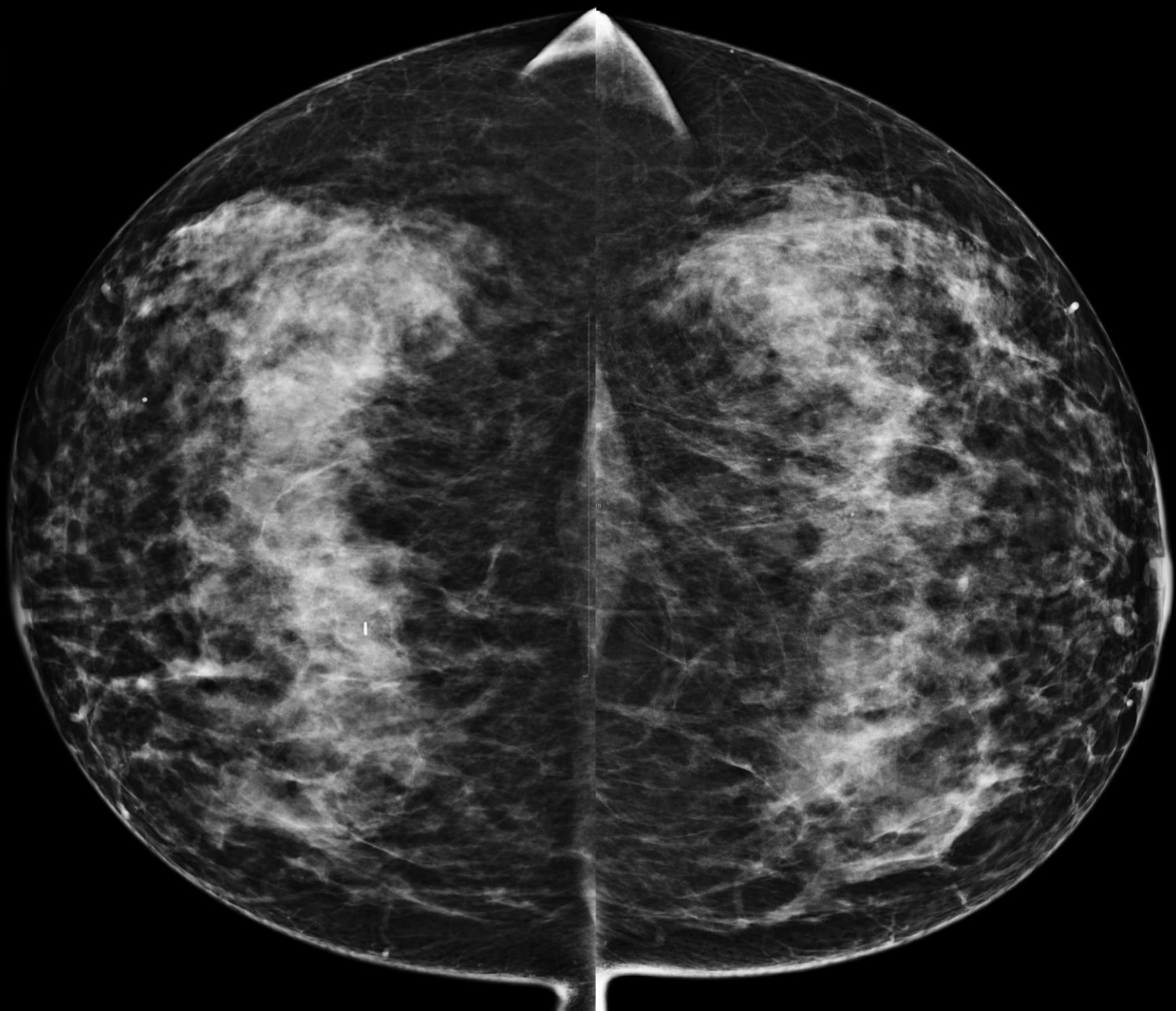
Site	# Radiologists	Academic or Non-Academic	Duration of Time Period 1 (months)	DM Cases Period 1	Duration Time Period 2 (months)	DM+Tomo Cases Period 2	Total Cases used for Primary Analysis	Transition to DM+Tomo	DM Cases ^a Imaged Period 2
1	7	A	12	10746	16	4366	15112	Hybrid	16098
2	10	N	12	19830	19	7909	27739	Hybrid	26105
3	6	A	12	10753	16	14014	24767	Complete	0
4	7	A	12	12533	17	8607	21140	Hybrid	10,022
5	13	N	12	26502	13	3640	30142	Hybrid	33112
6	18	N	12	25488	3	5868	31356	Complete	0
7	20	N	12	22606	18	2613	25219	Hybrid	29112
8	6	N	12	16694	18	16149	32843	Hybrid	16098
9	3	N	12	4801	21	16269	21070	Hybrid	2178
10	5	A	12	17623	22	5880	23503	Hybrid	6416
11	20	N	12	53181	17	24281	77462	Hybrid	56803
12	12	A	12	40382	22	34119	74501	Hybrid	45473
13	12	N	12	20048	20	29948	49996	Hybrid	4568
Total	139			281187		173663	454850		245985

Abbreviations: DM, digital mammography; DM+Tomo, digital mammography plus tomosynthesis

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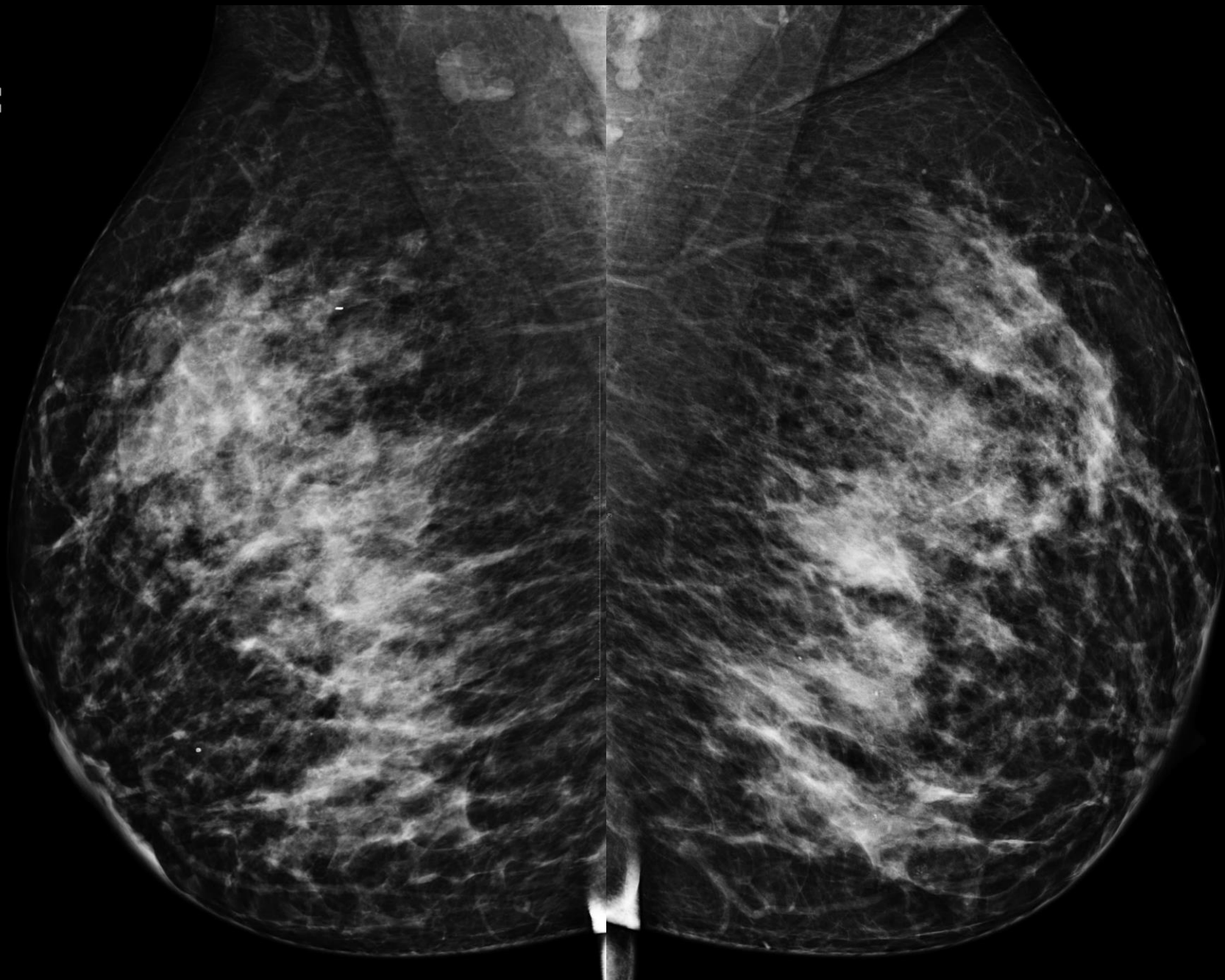
RCC

LCC

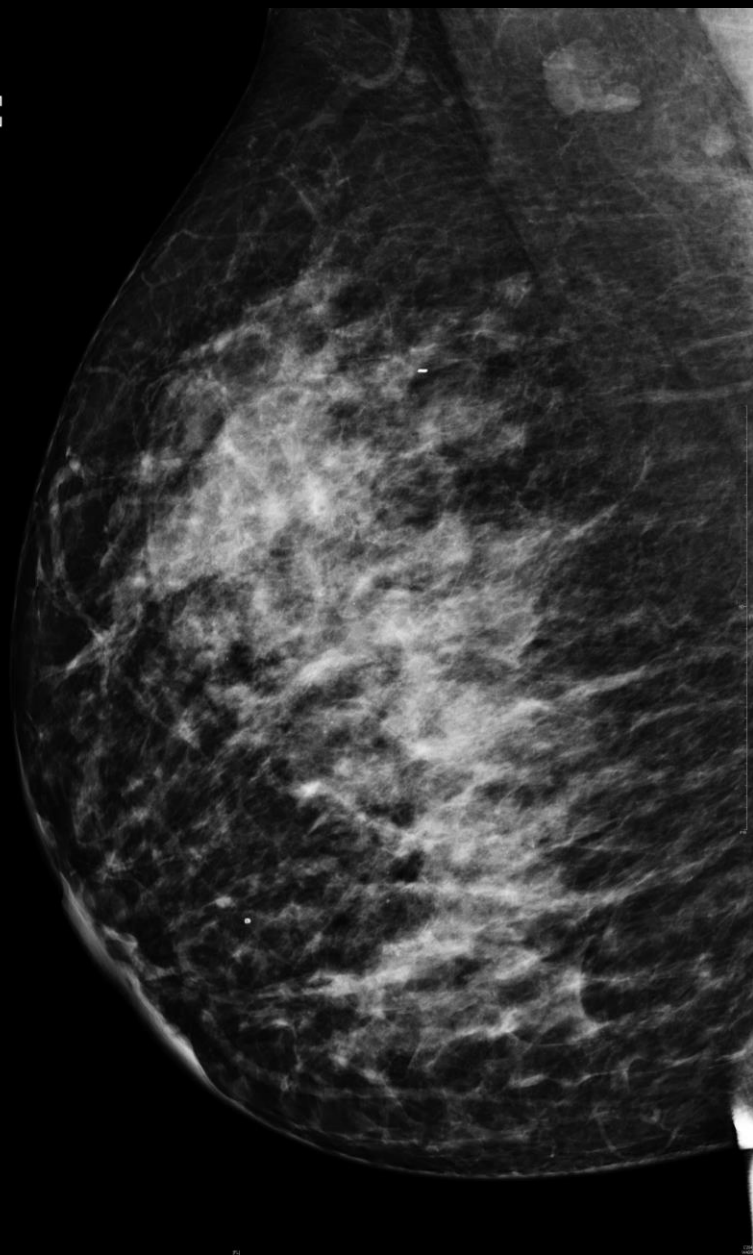


RMLO

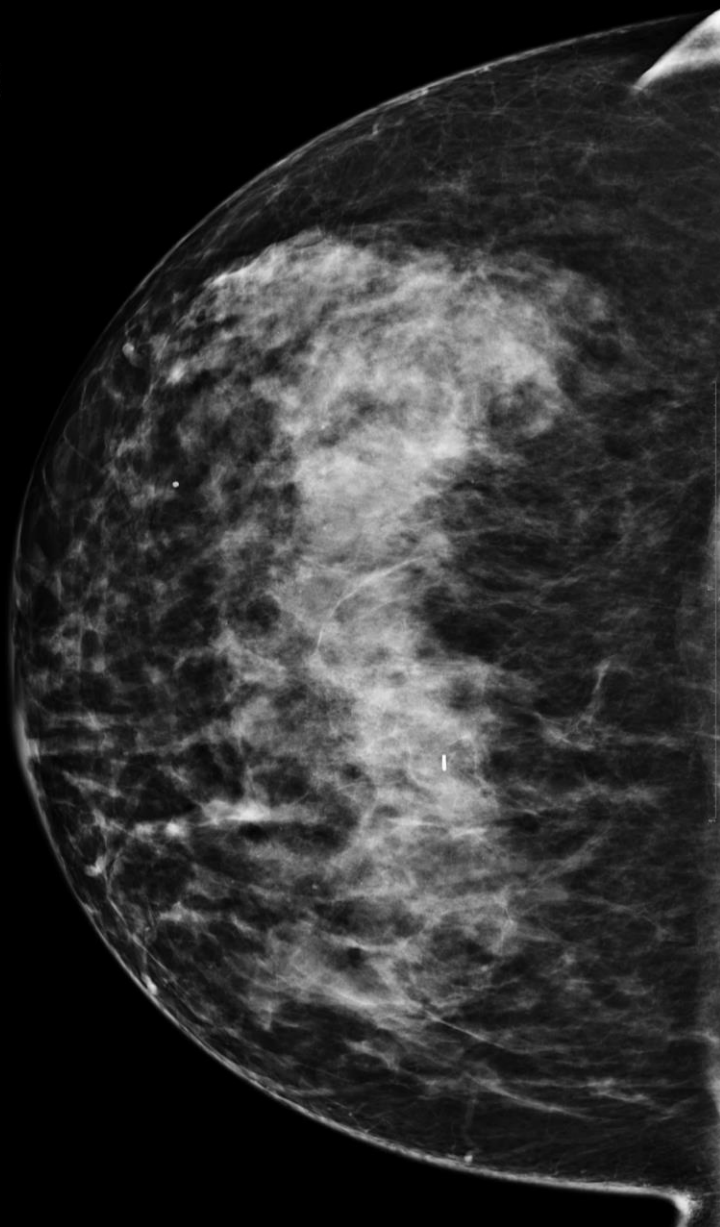
LMLO

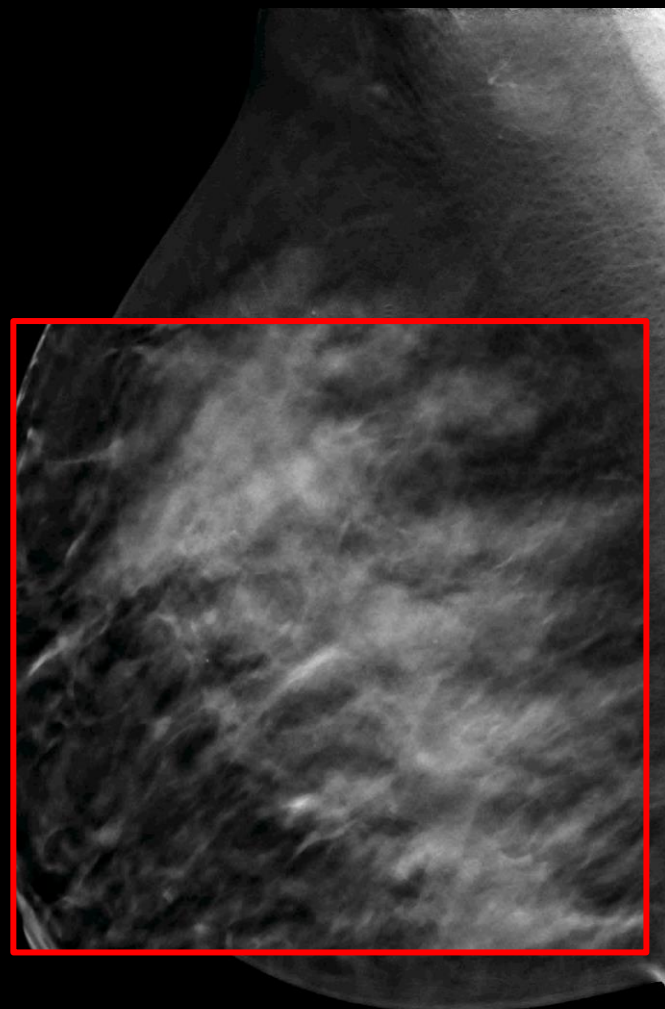
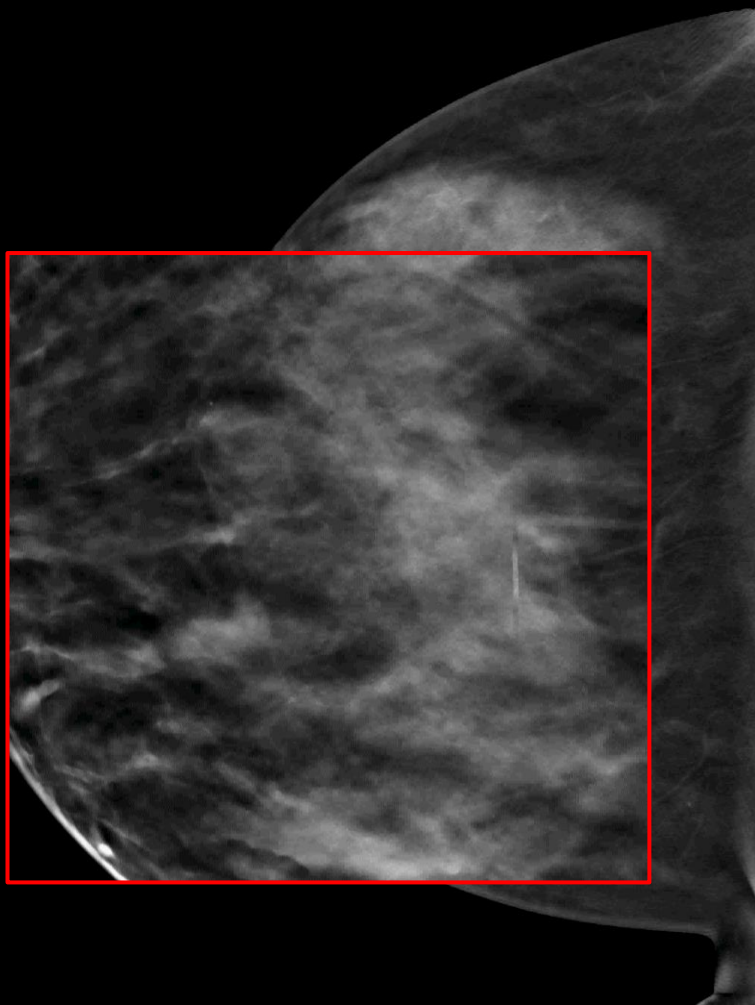


RMLO

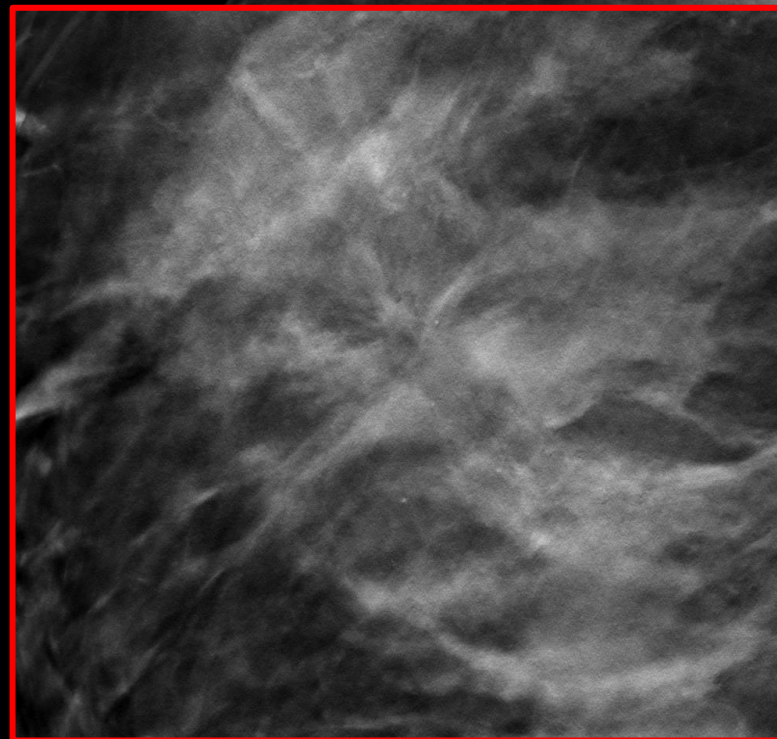
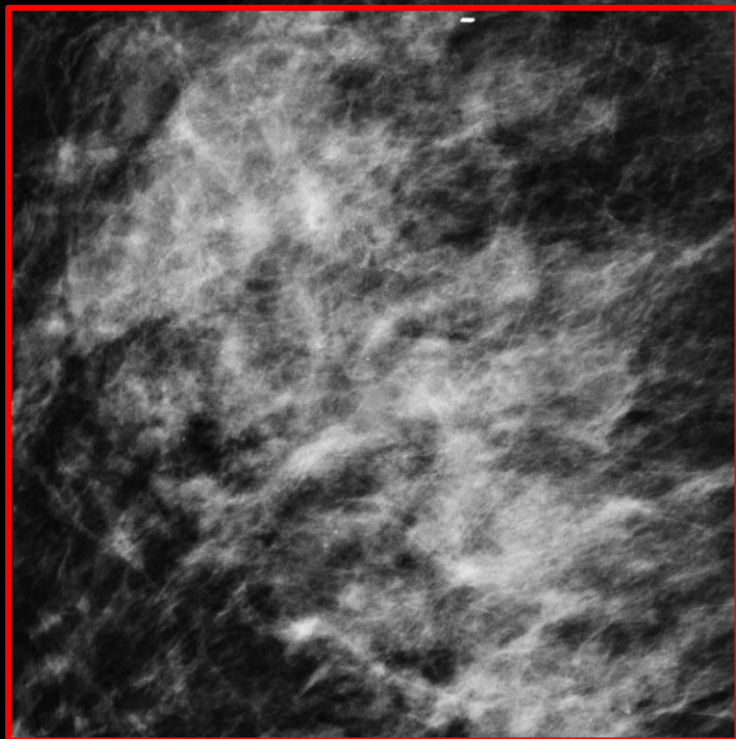


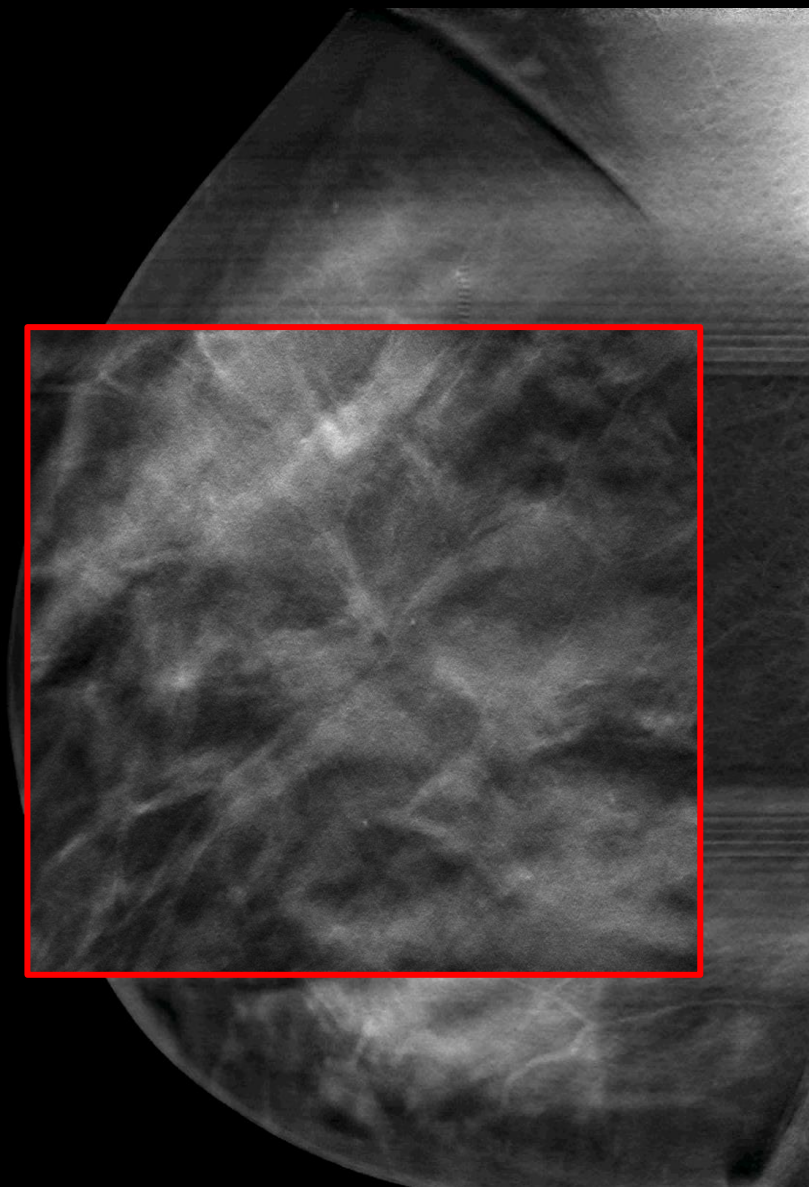
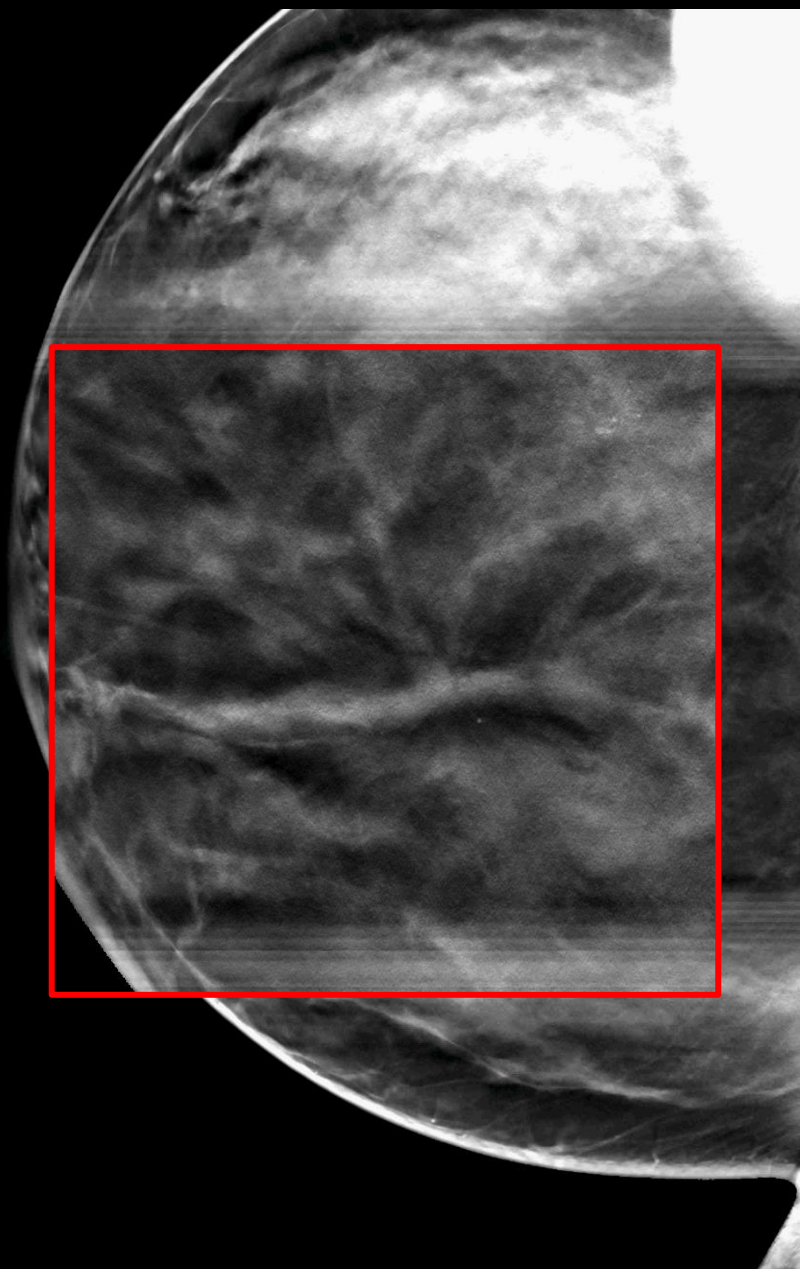
RCC





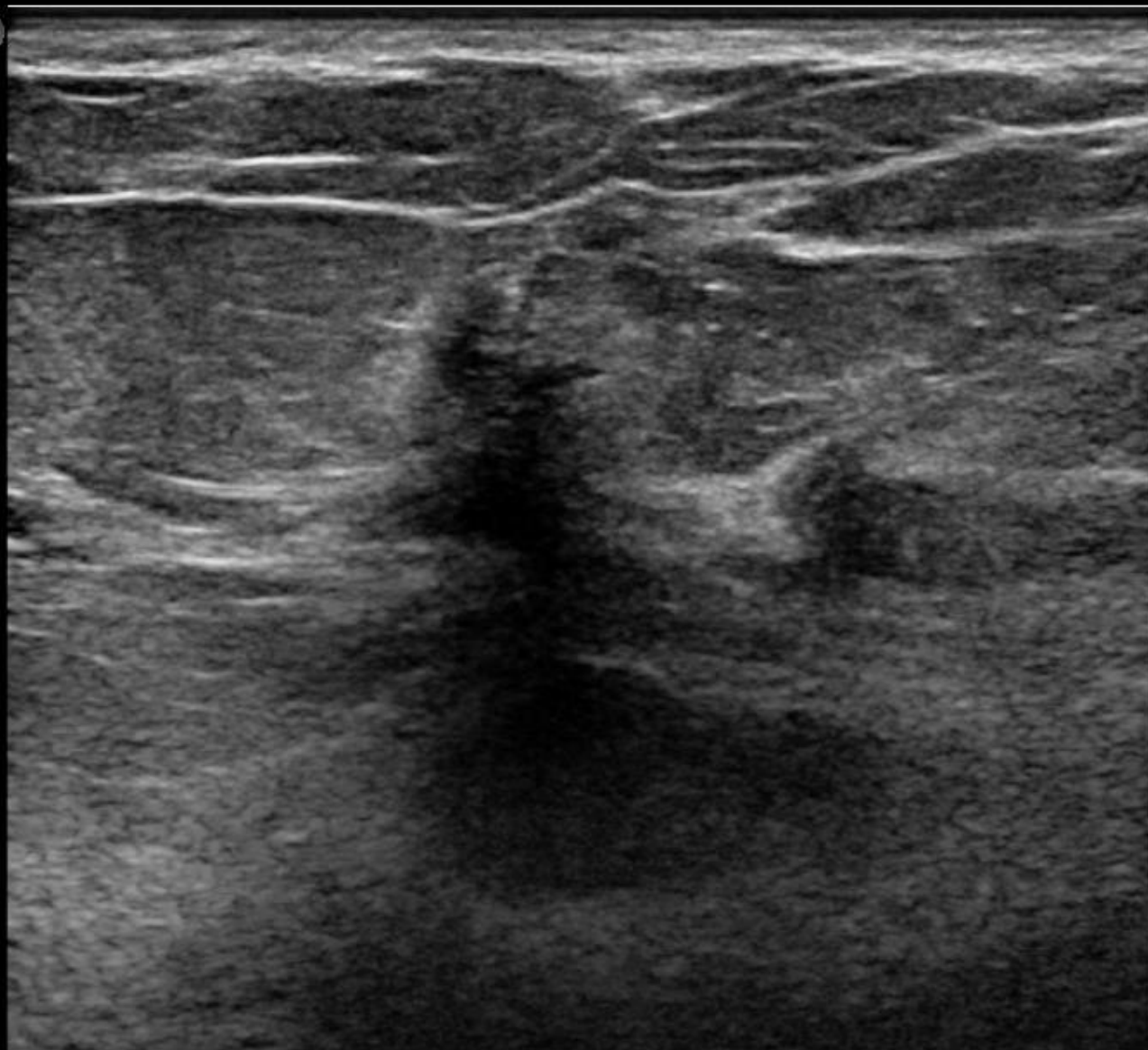
RA
K RMLO





F/54

P



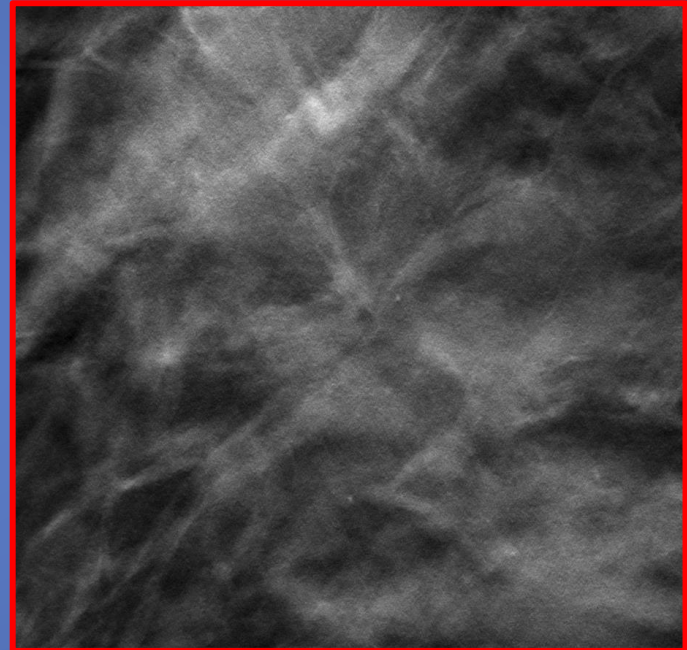
X

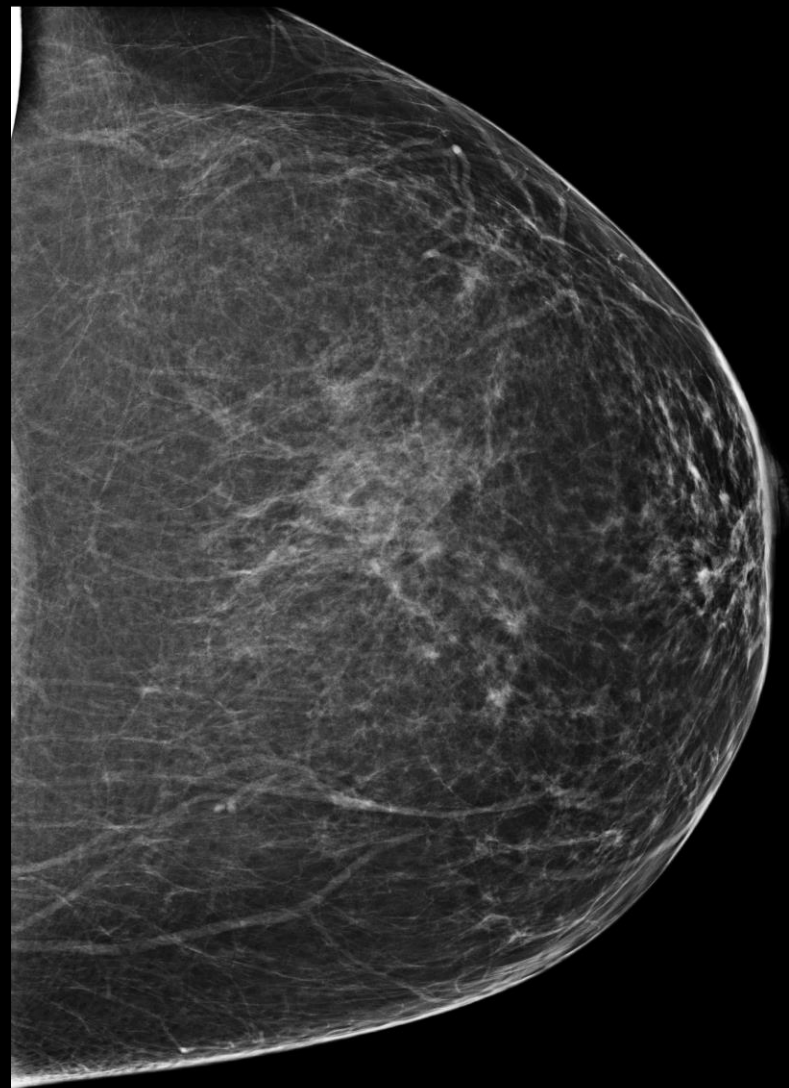
3.5

Rt Brst 12:30 6cm Rad

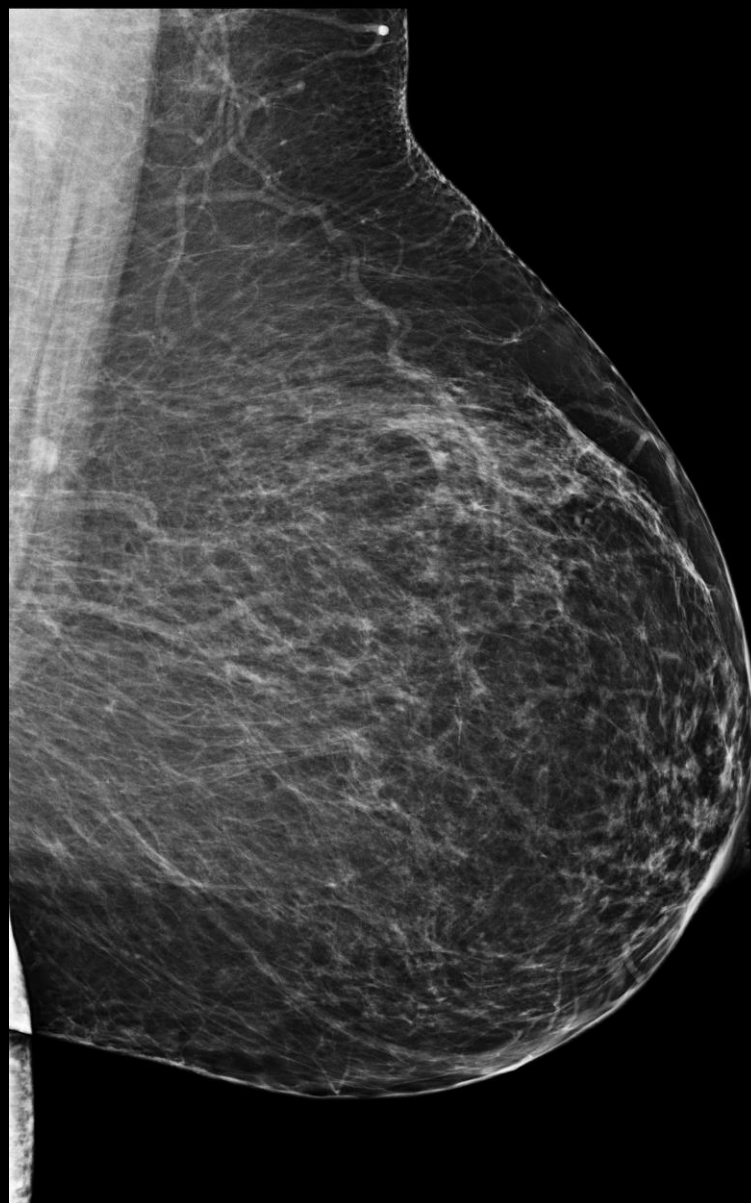
Pathology

- Right breast: 12:30, 6 cm from the nipple, ultrasound-guided core needle biopsy (BI-RADS 5):
 - Invasive ductal carcinoma, grade 1 (2+1+1)
- Tomosynthesis only, DM occult

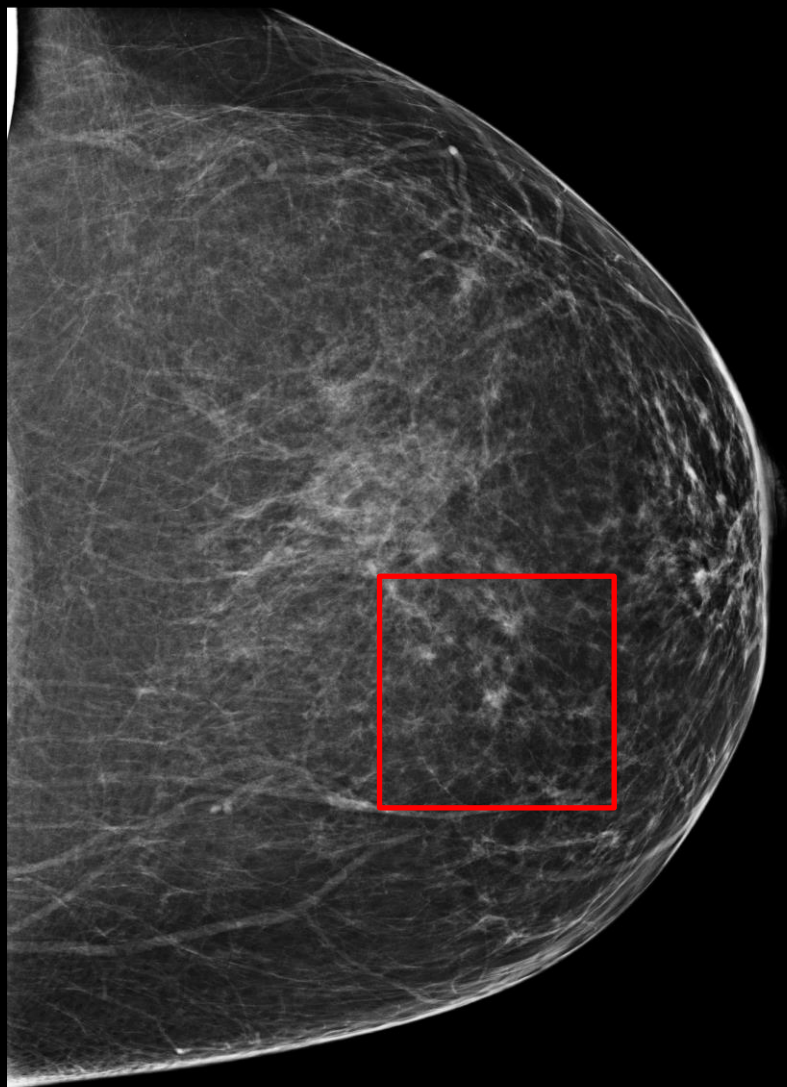




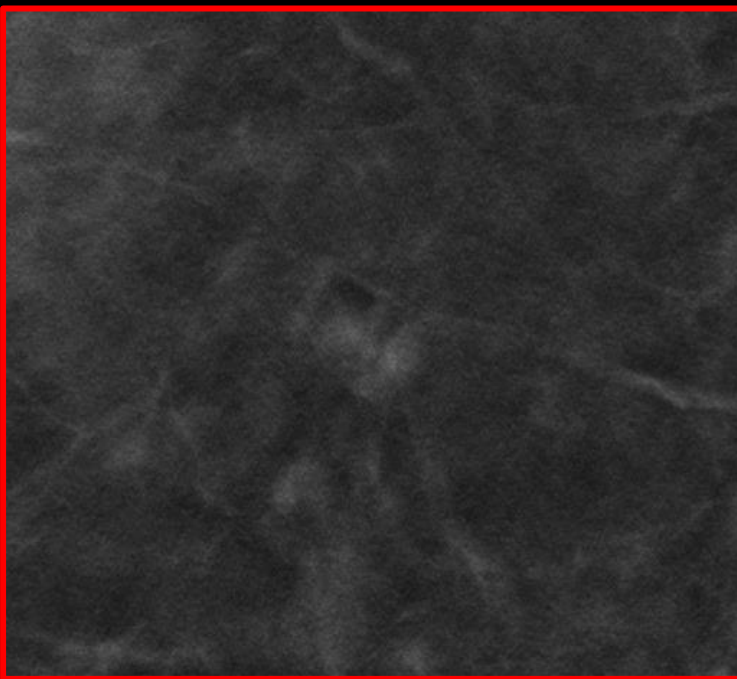
LCC

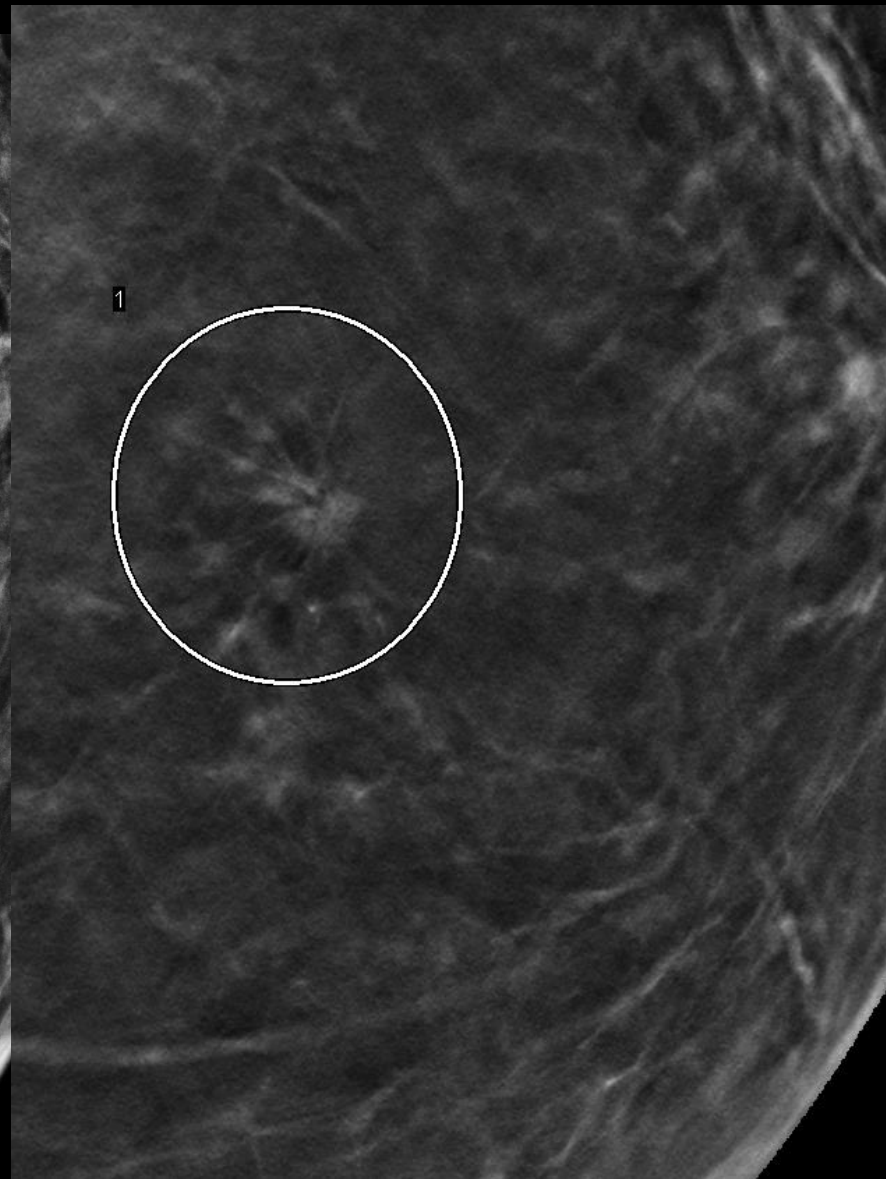
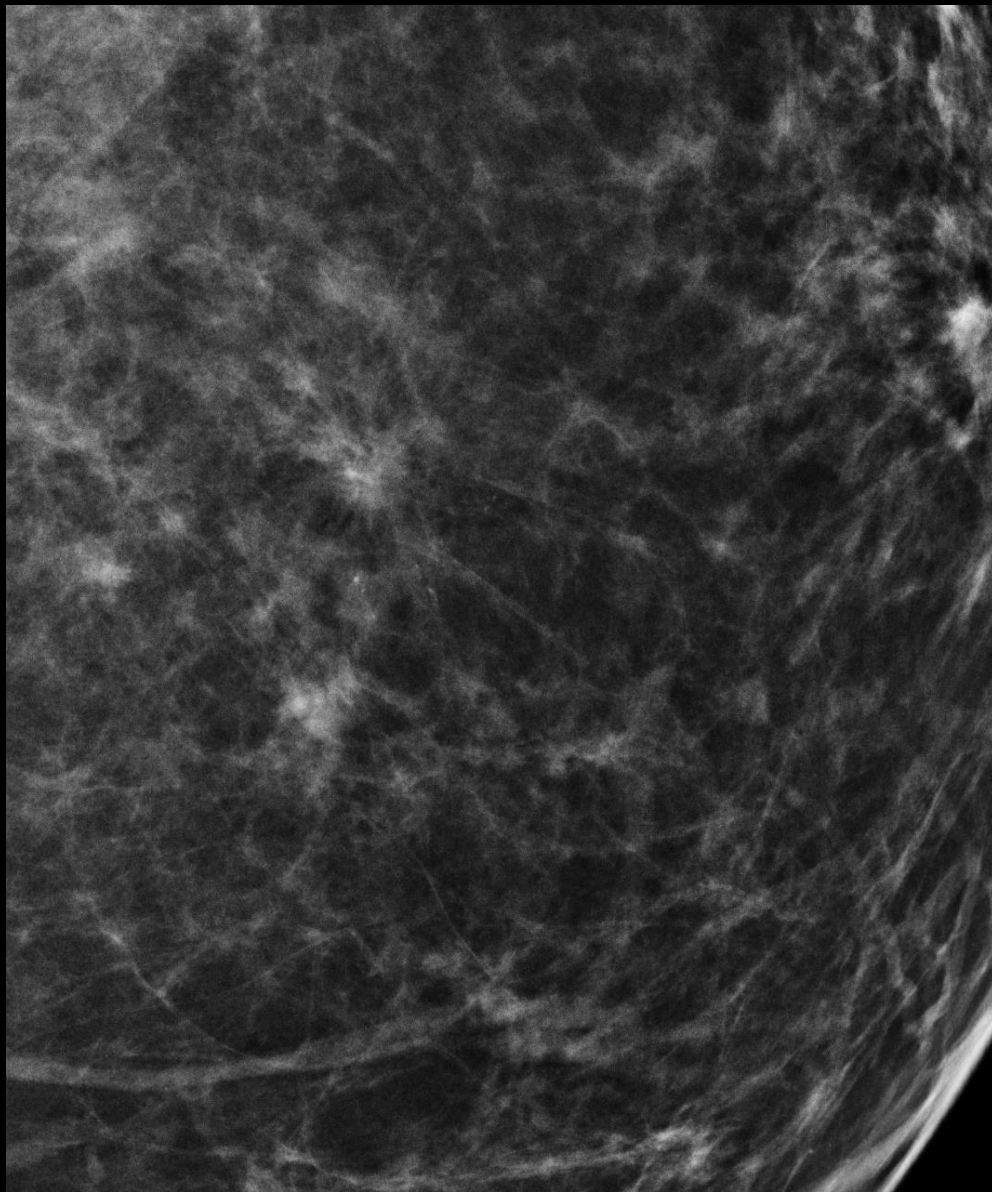


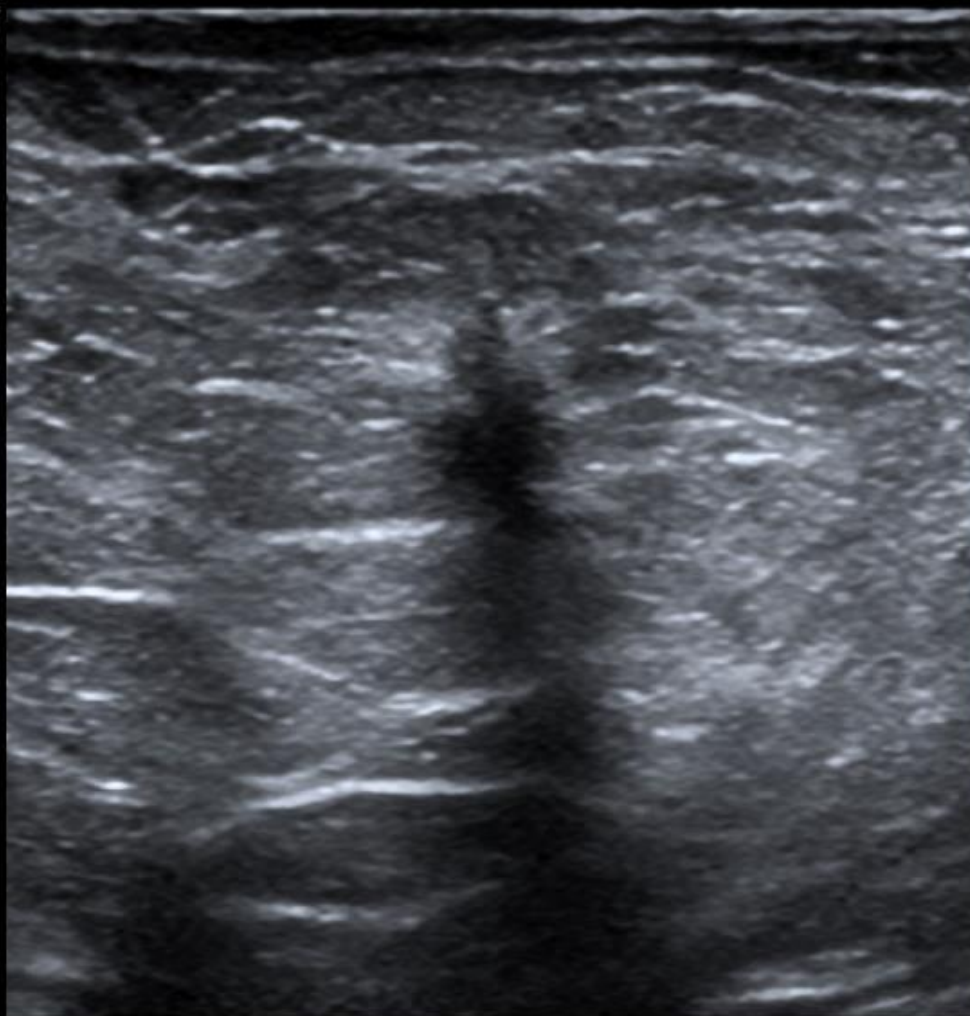
LMLO



LCC







- B CHI
- Frq 10.0 MHz
- Gn 60
- S/A 1/1
- Map H/0/0
- D 4.0 cm
- DR 66
1- FR 15 Hz
- AO 100 %



3-

4-

LEFT BREAST
7 O'CLOCK 3CMFN

CP

Pathology

- Left breast 7:00, 3 CMFN
 - Invasive ductal carcinoma, grade 2
- Fatty breast
- Tomosynthesis only (occult on DM)



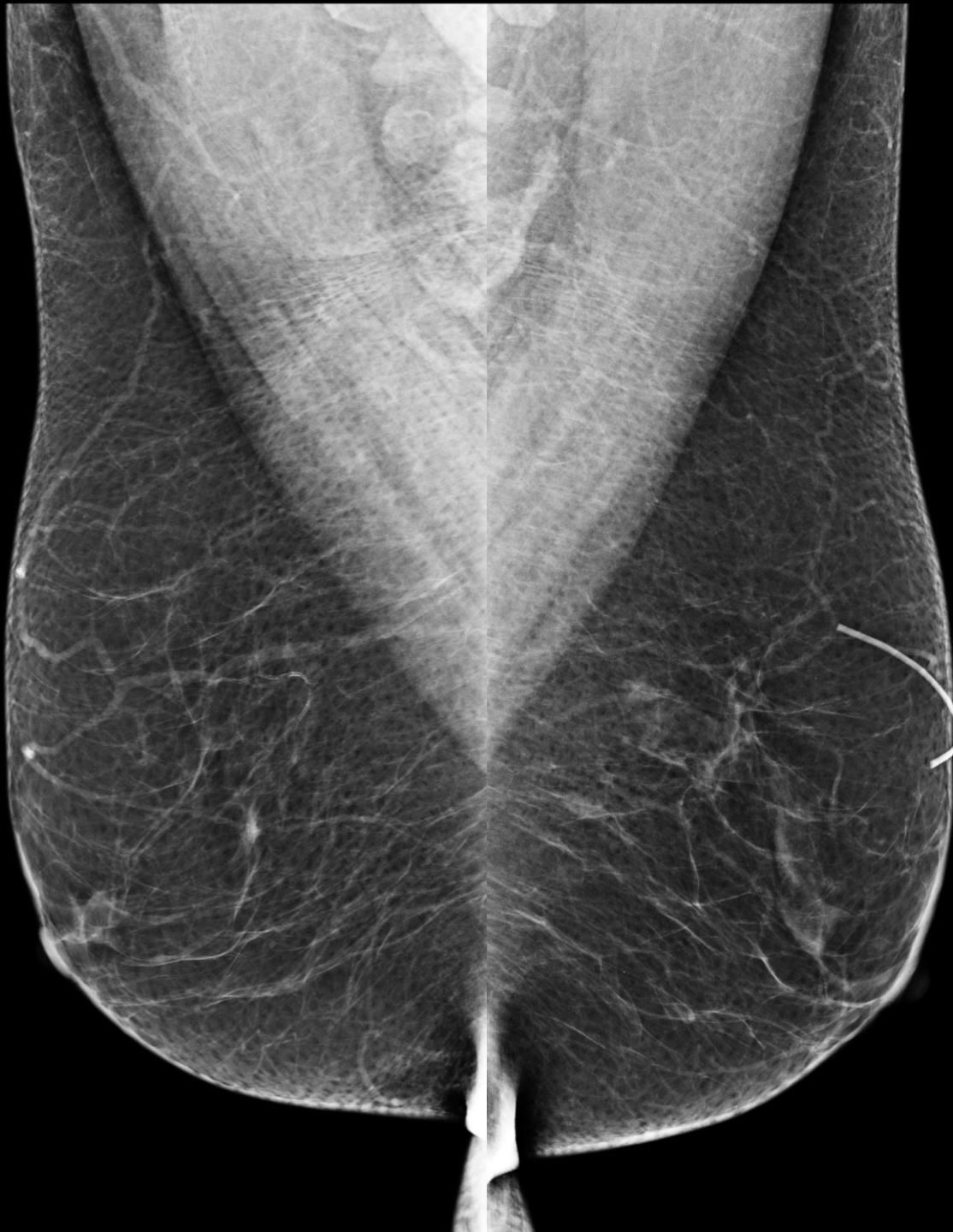
R
L
S
RCC

R
L
S
LCC

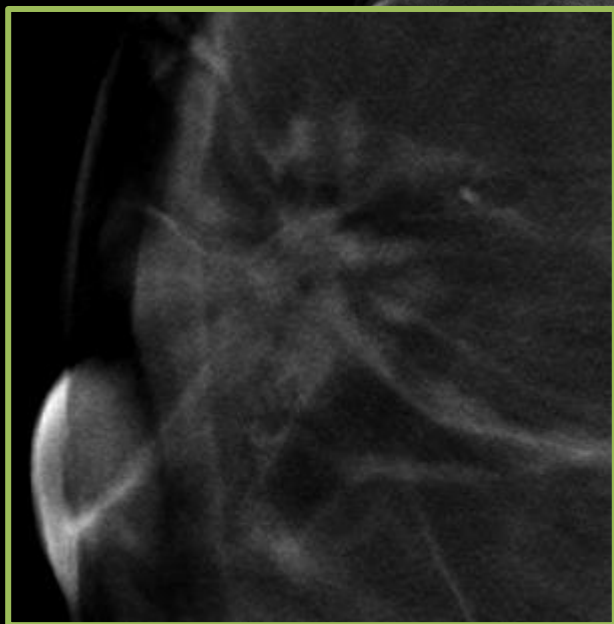


[R
L
S] RMLO]

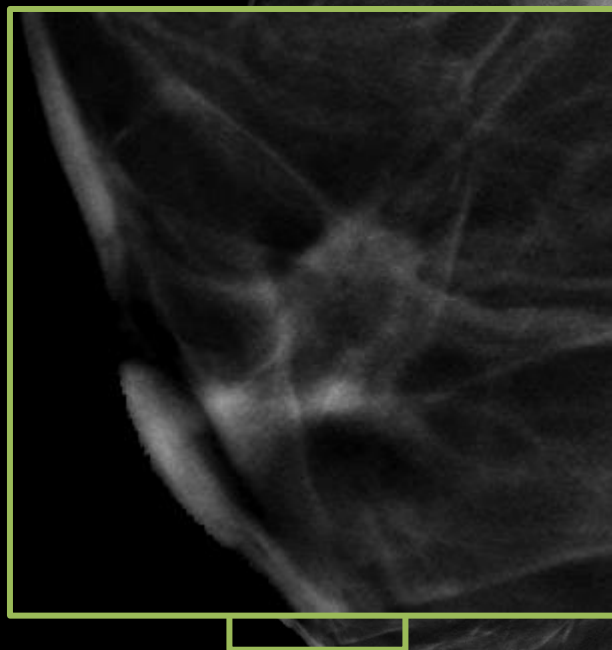
[R
L
S] LMLO]



RCC

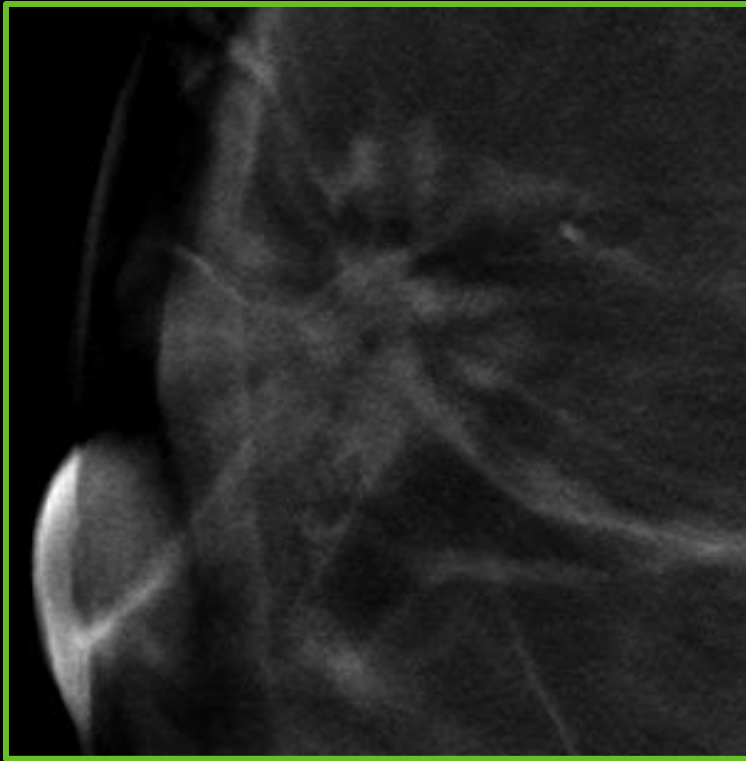


RMLO

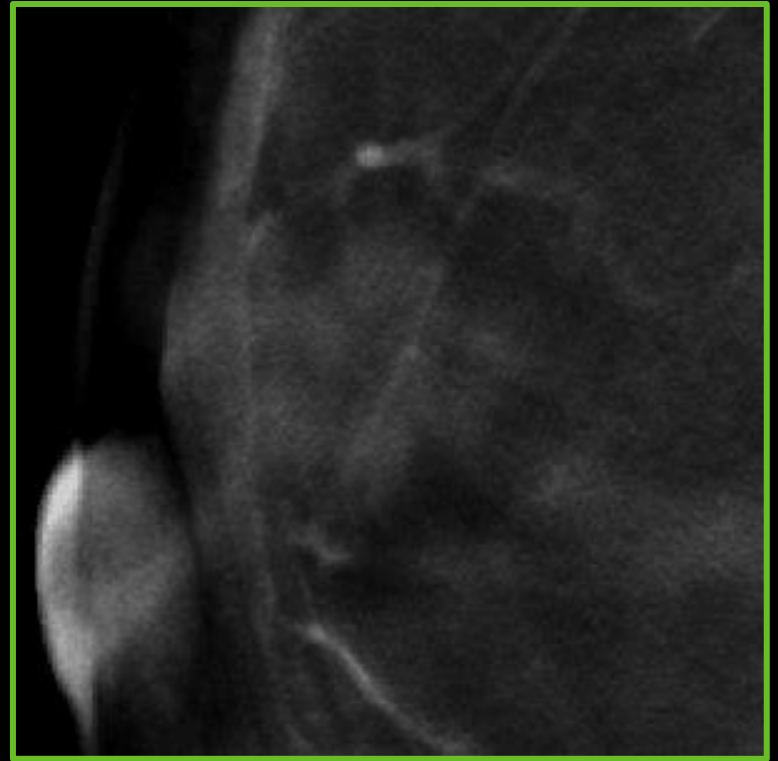


Tomosynthesis Slices

CC

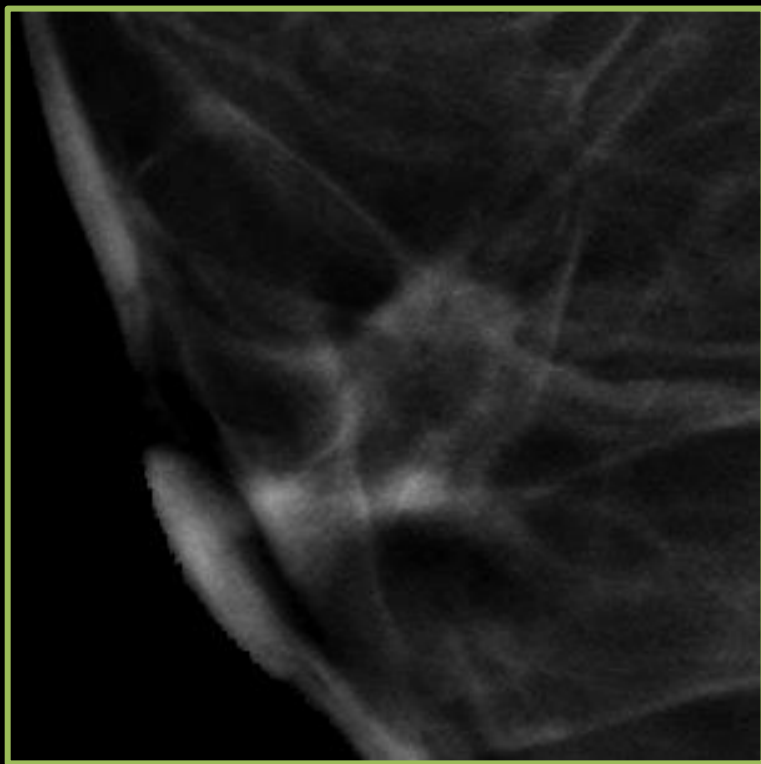


Tomosynthesis Slice

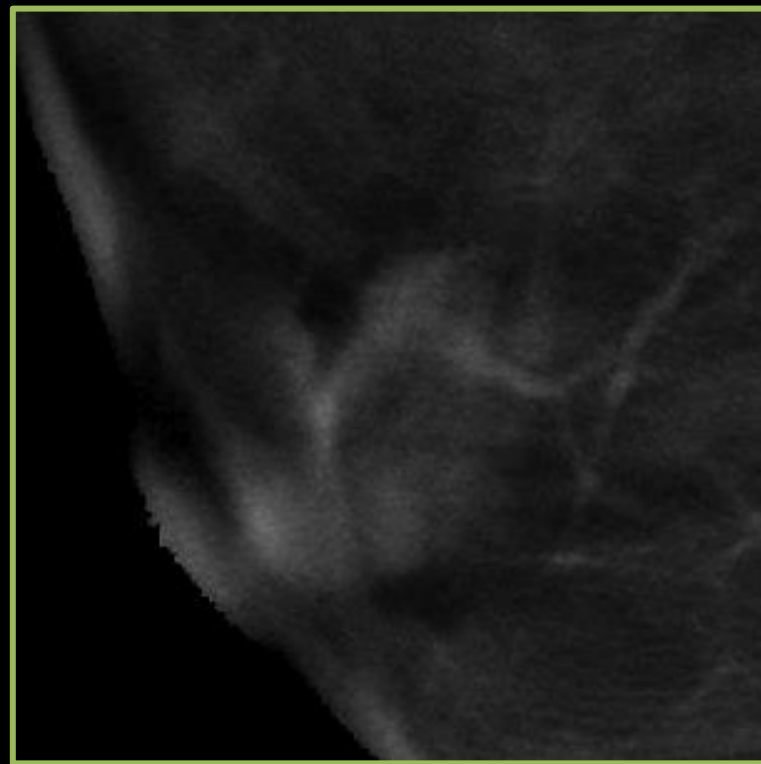


Tomosynthesis Reconstruction

MLO

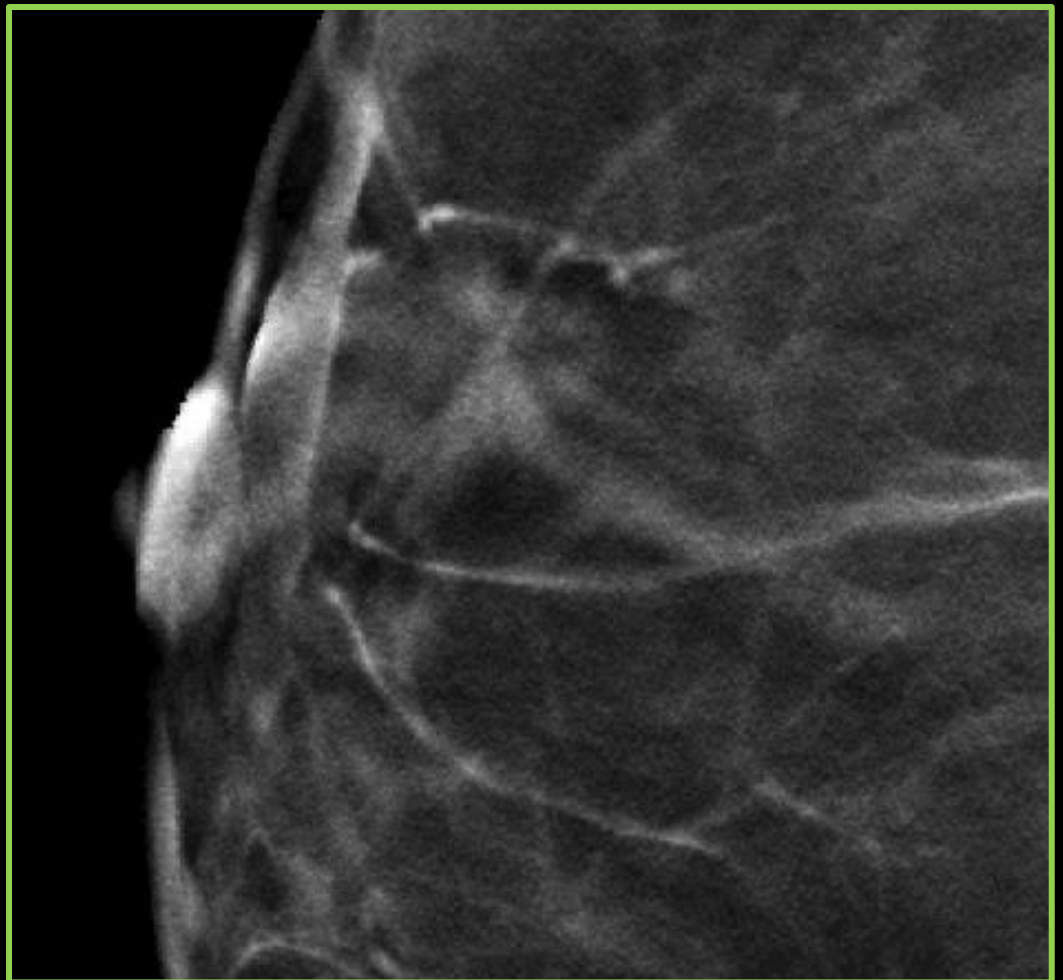
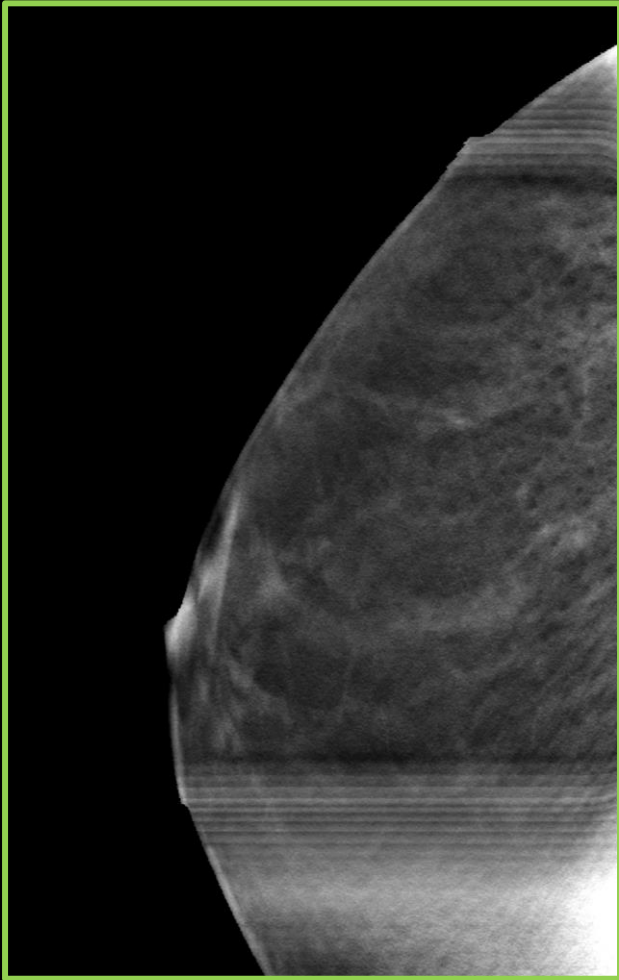


Tomosynthesis Slice

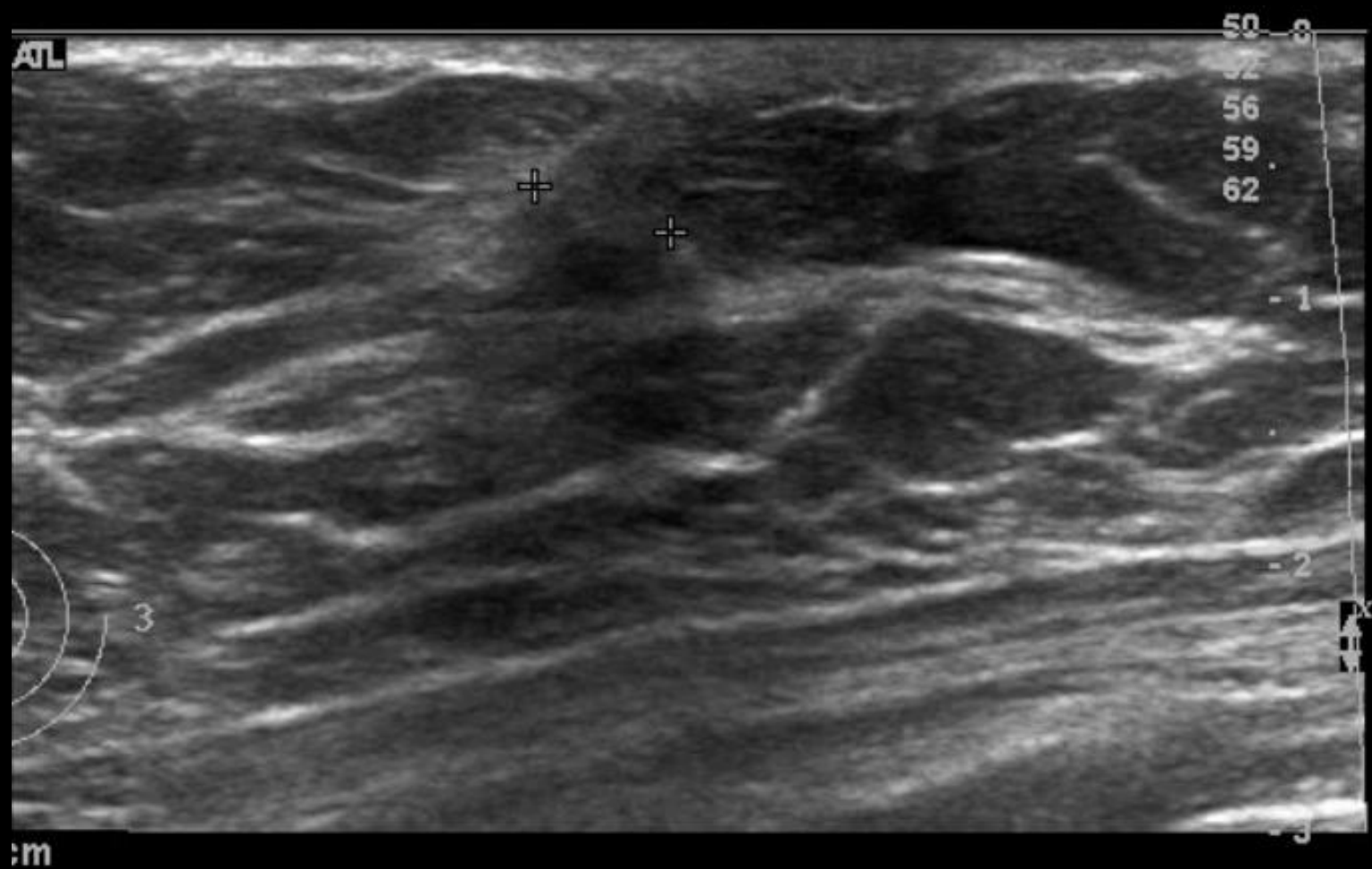


Tomosynthesis Reconstruction

RSCC



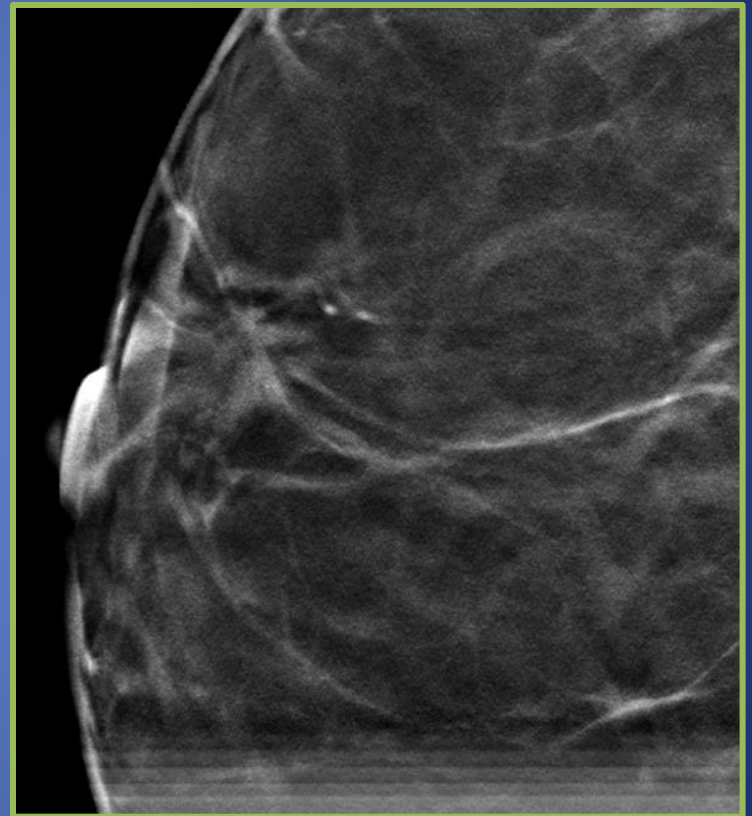
Tomosynthesis Reconstruction



RIGHT BREAST RETROAREOLAR

Pathology

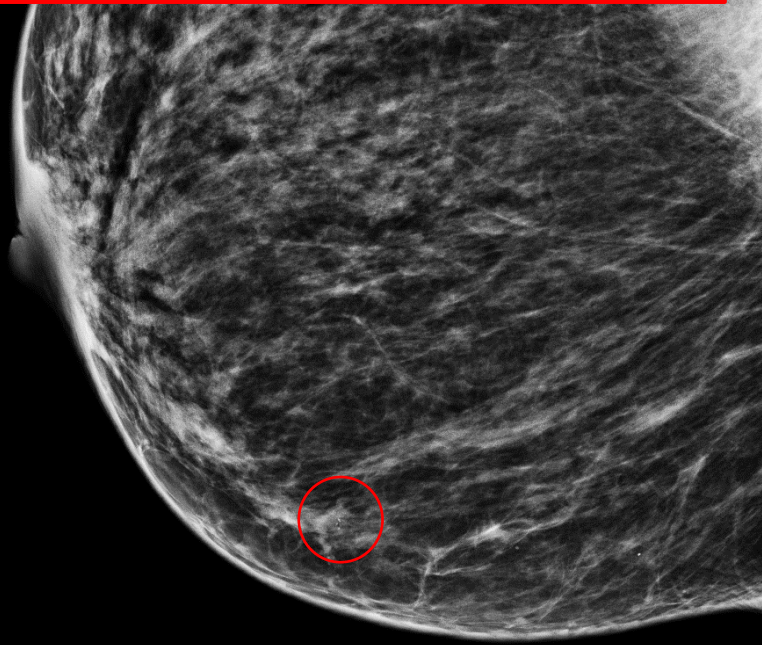
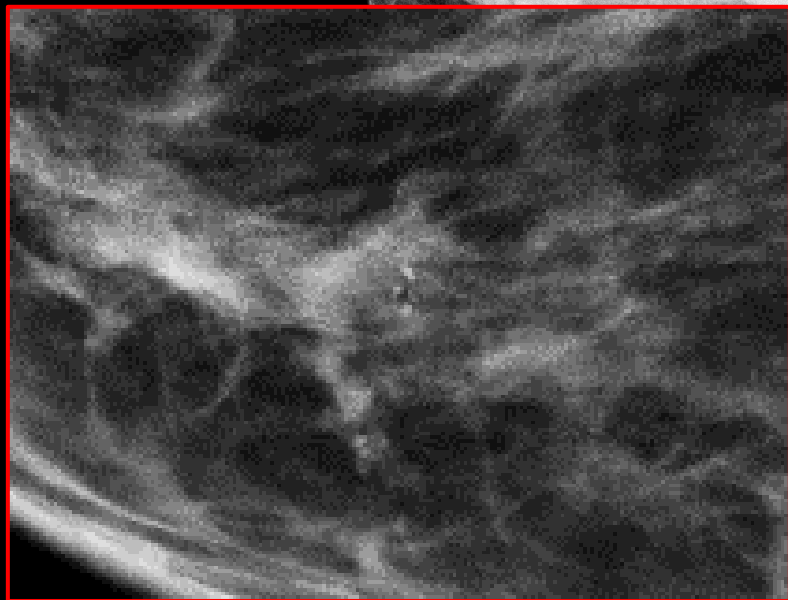
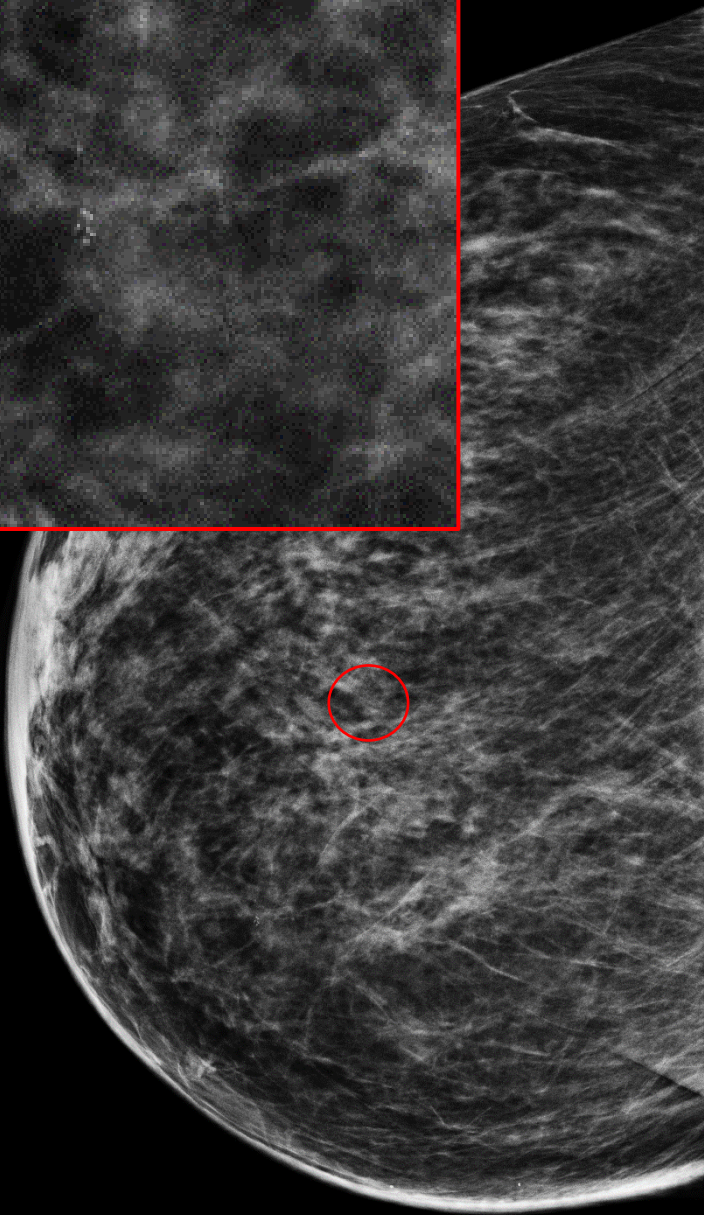
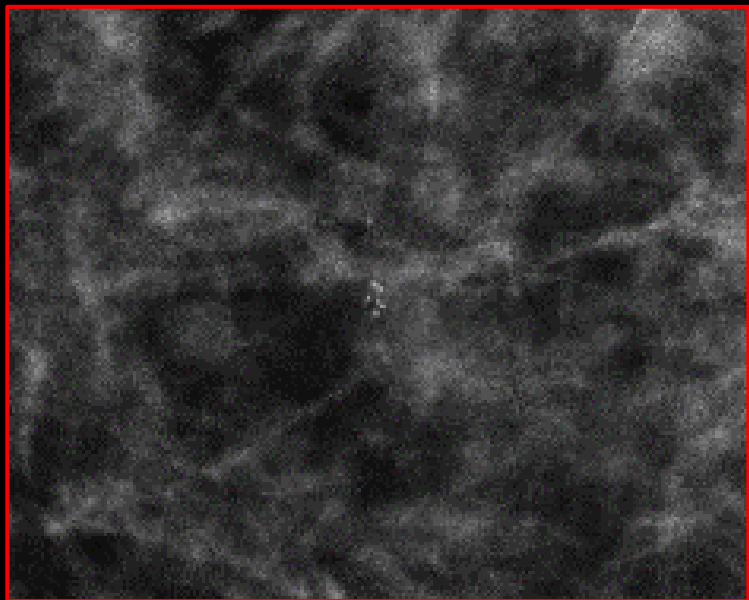
- *Invasive lobular carcinoma*
- *Fatty Breast*
- *Spot Tomosynthesis confirms*



Decrease Recall Rate

Decrease Recall Rate

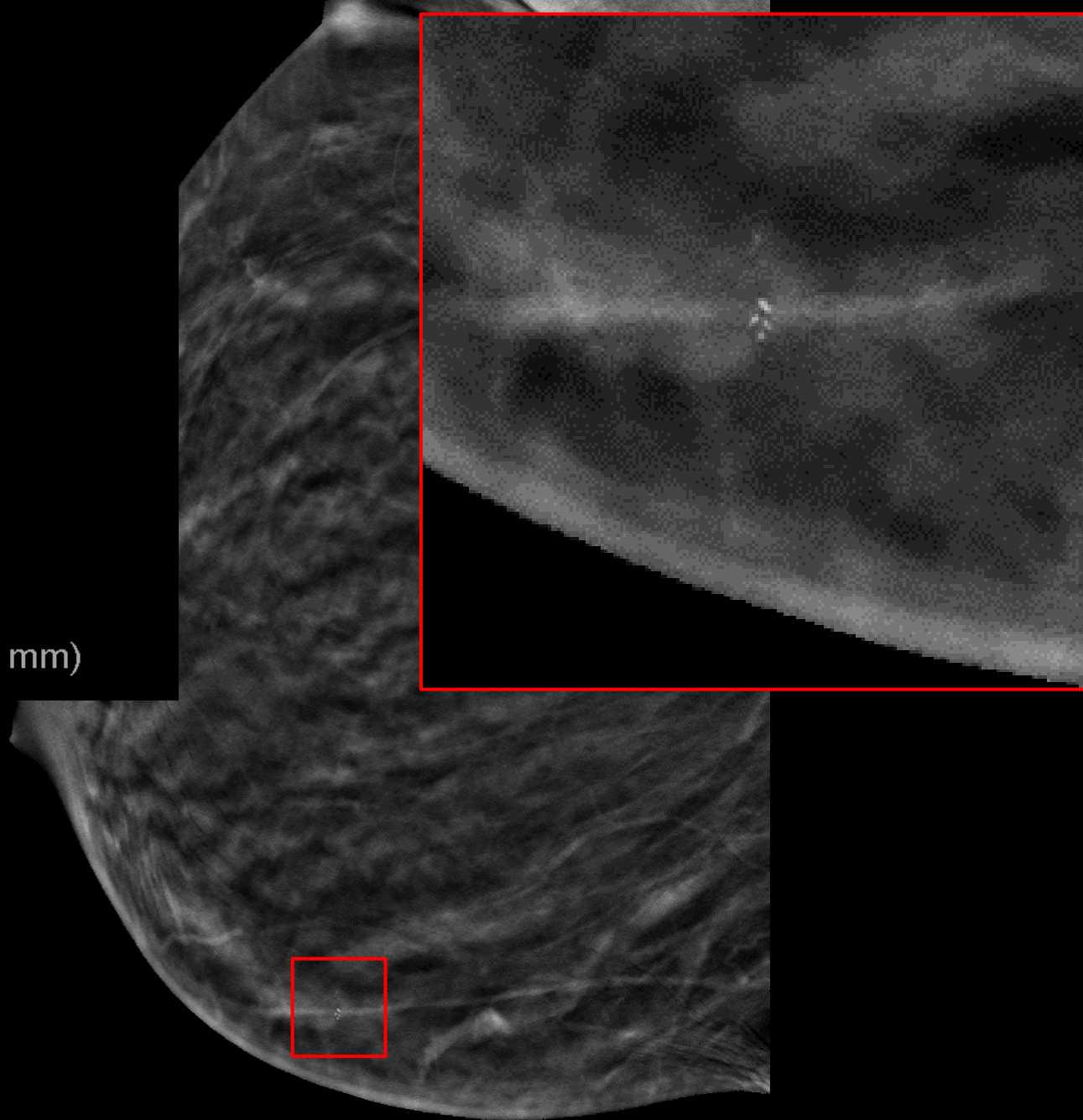
- Superimposed tissue
- Skin calcifications/lesions
- Nipple not in profile
- Tortuous vessels
- Lymph nodes





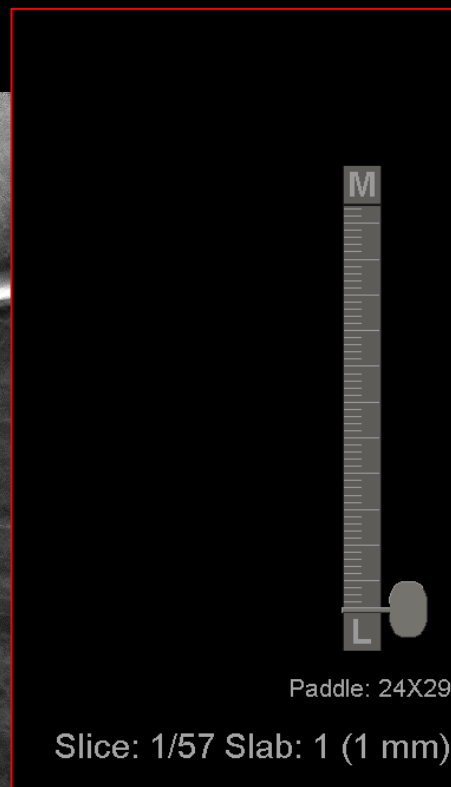
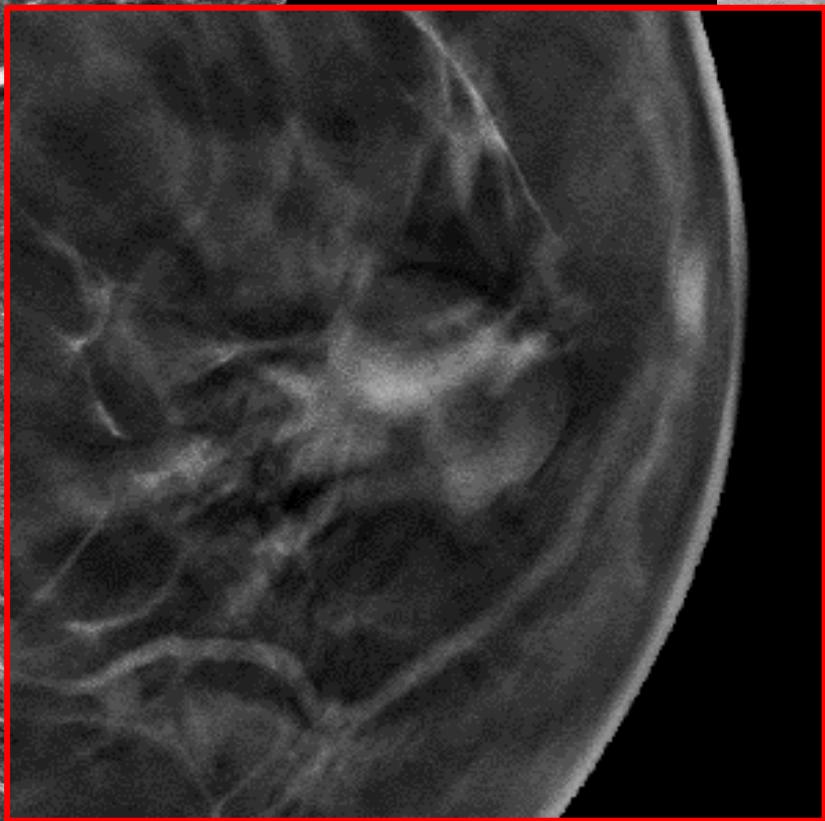
Paddle: 18X24

Slice: 1/50 Slab: 1 (1 mm)



Decrease in Recall

- Skin calcifications
- Don't need to be recalled
- Don't have to do skin localizations

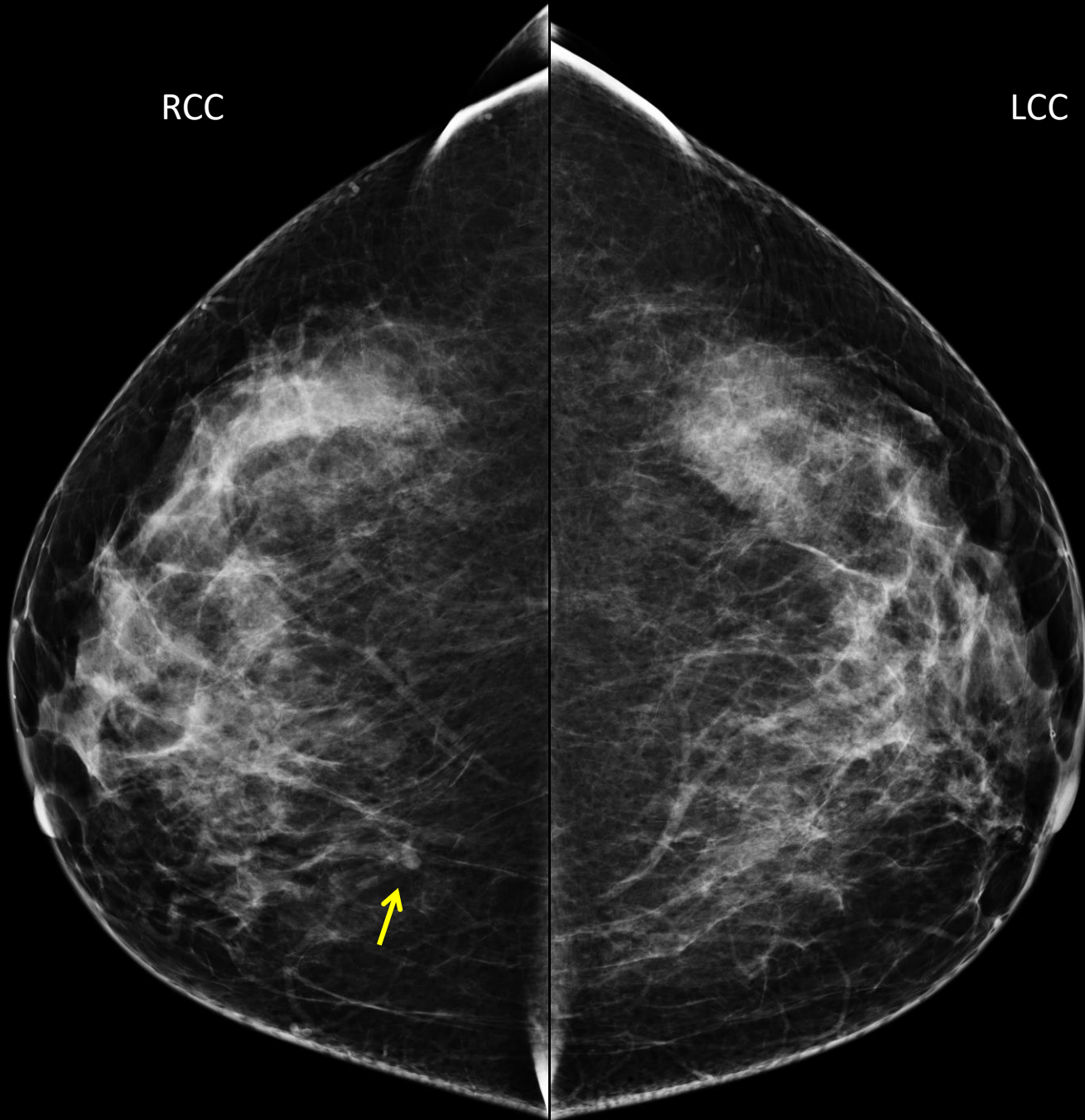


Decrease Recall Rate

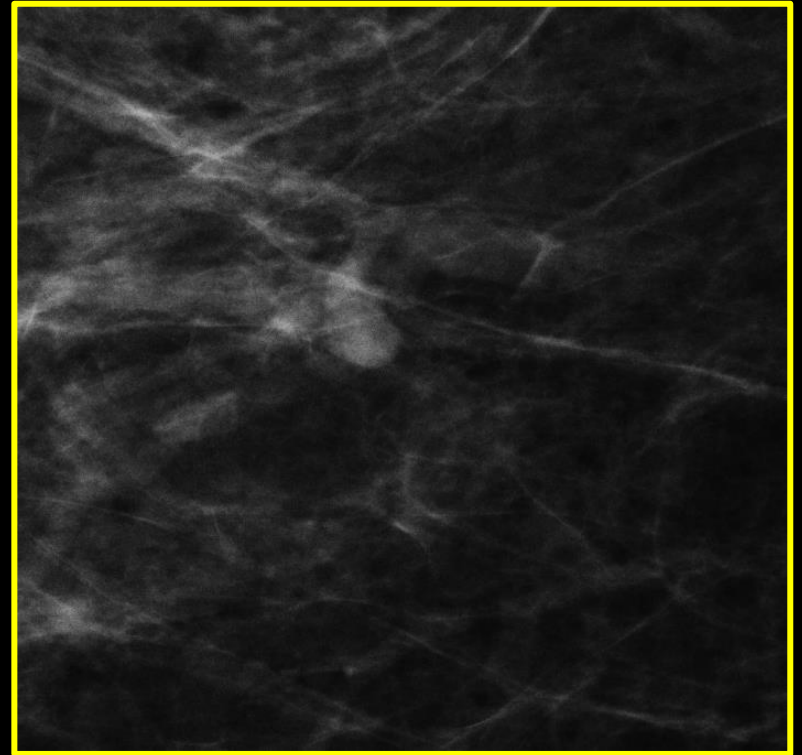
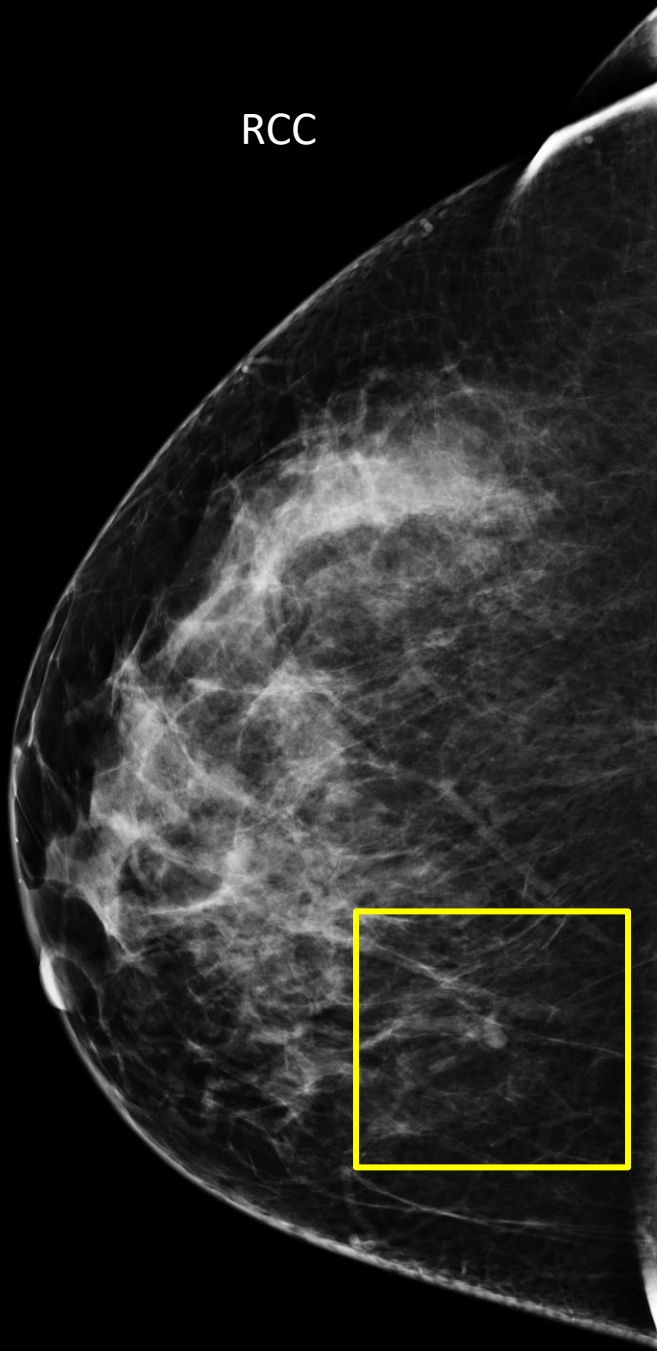
- Nipple not in profile
- Doesn't need to be recalled

RCC

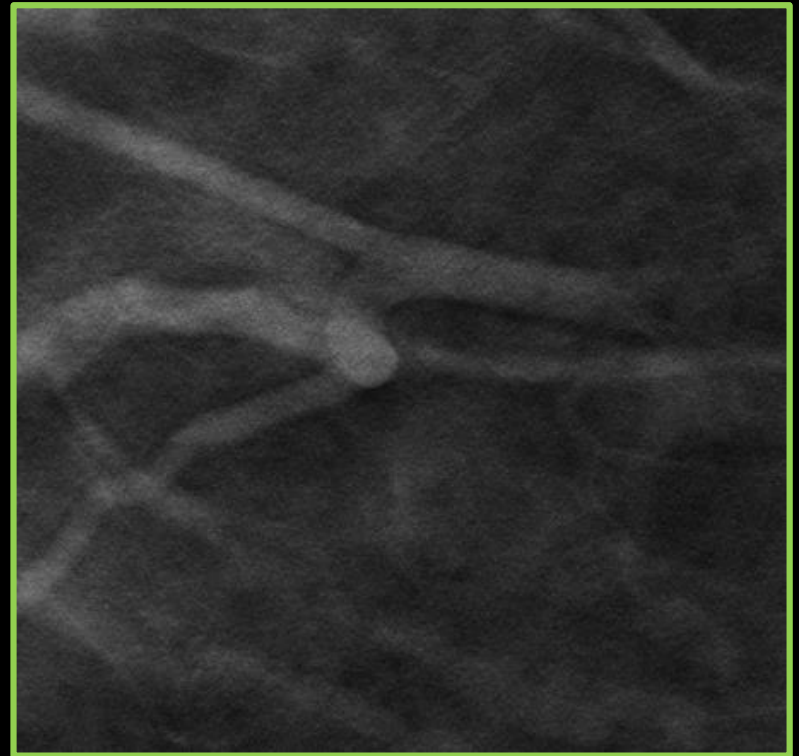
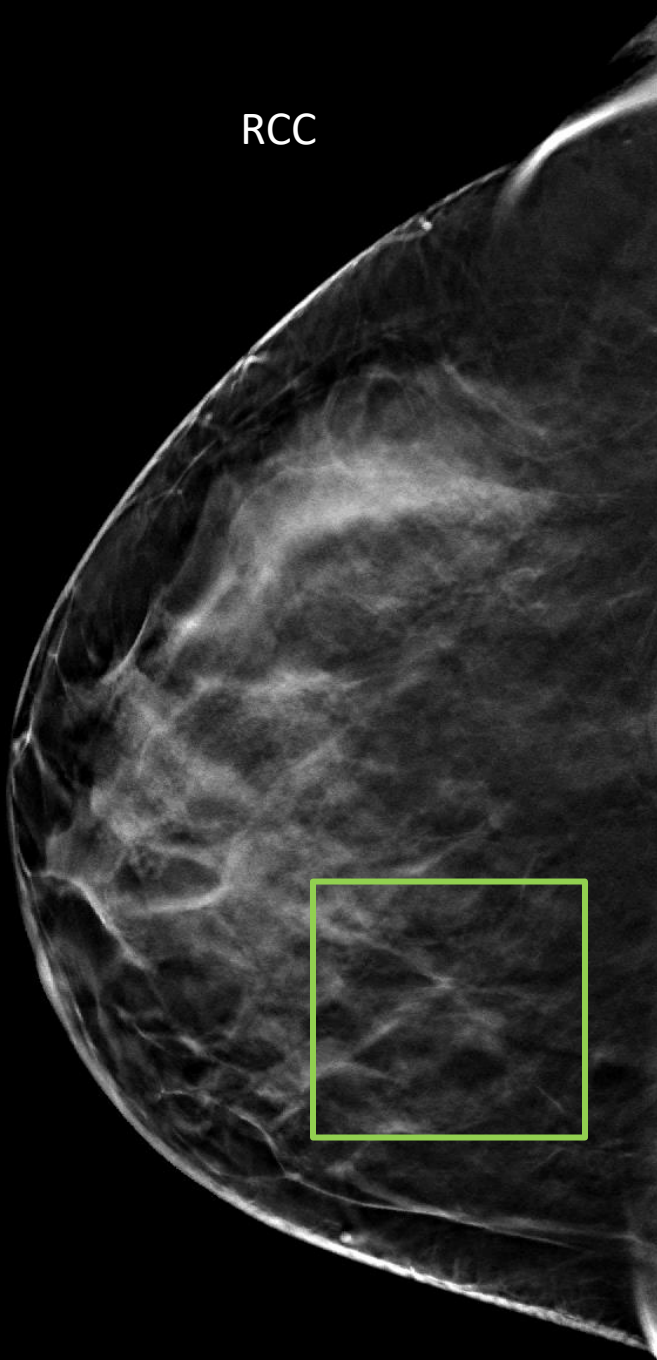
LCC

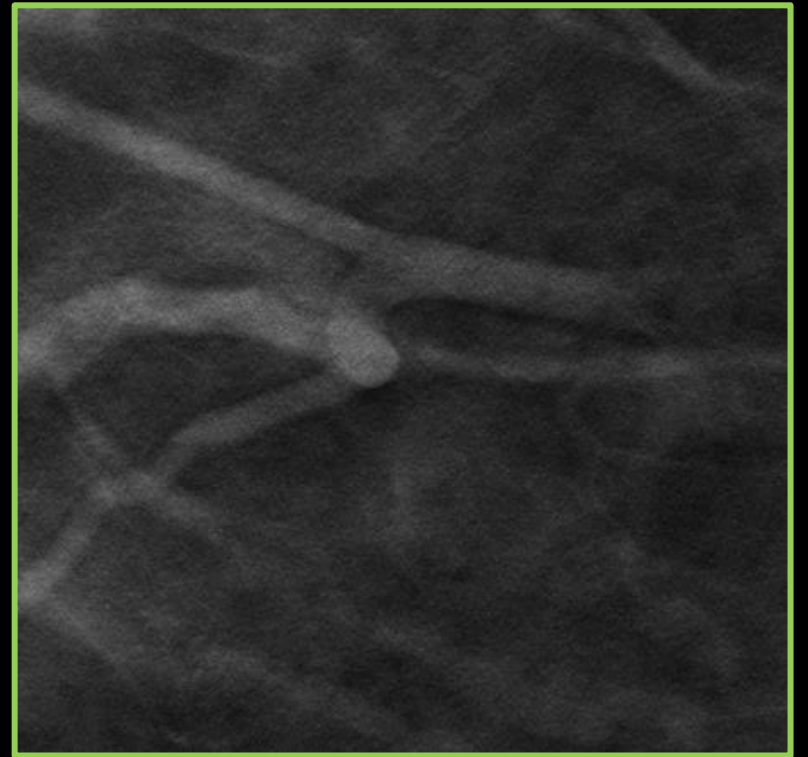
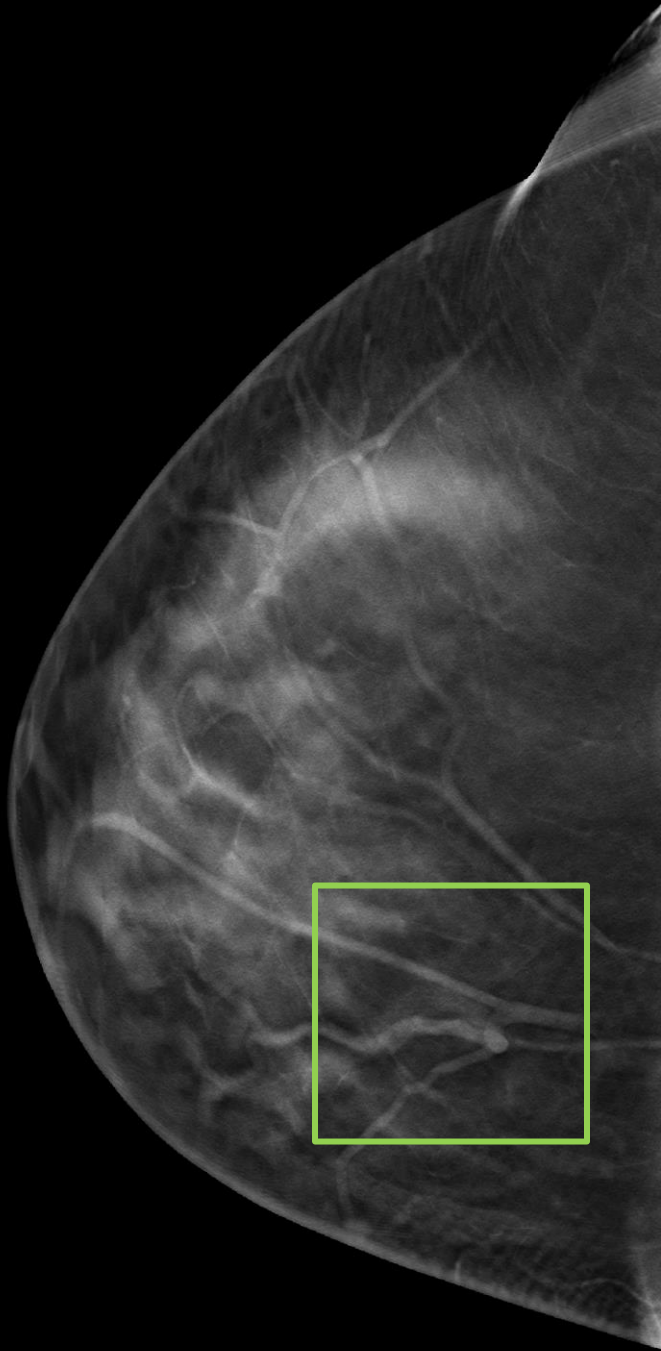


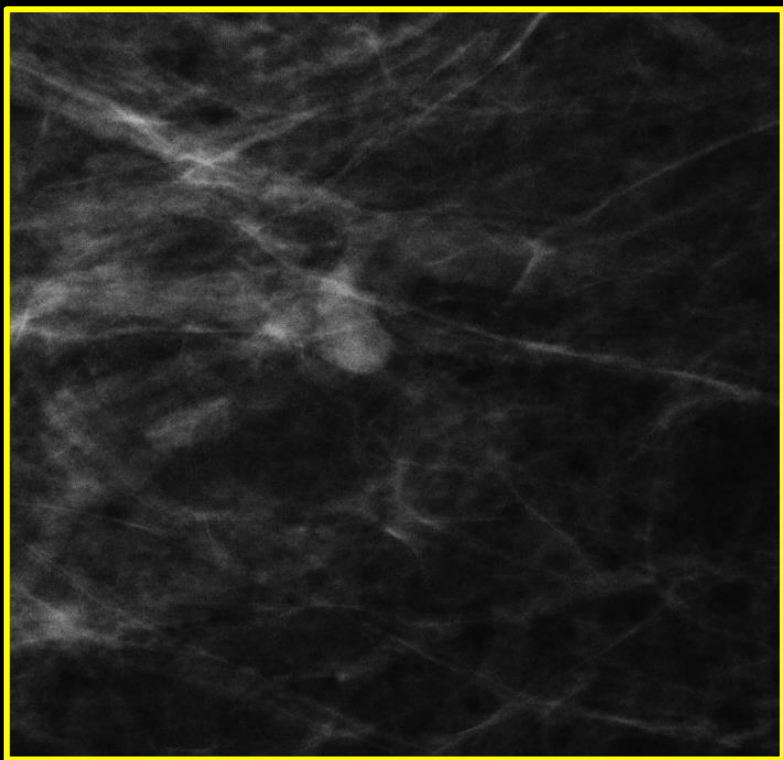
RCC



RCC



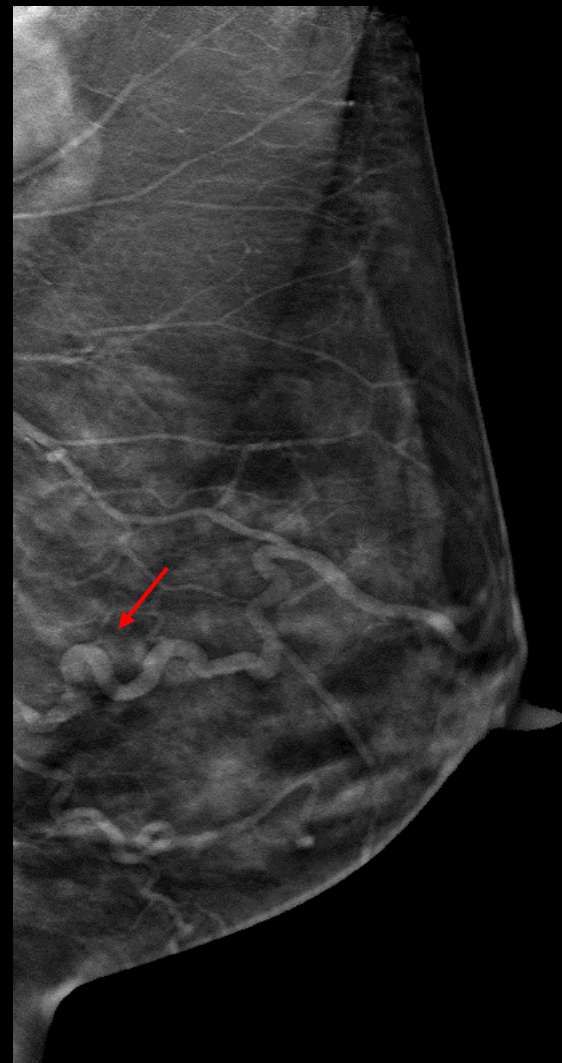
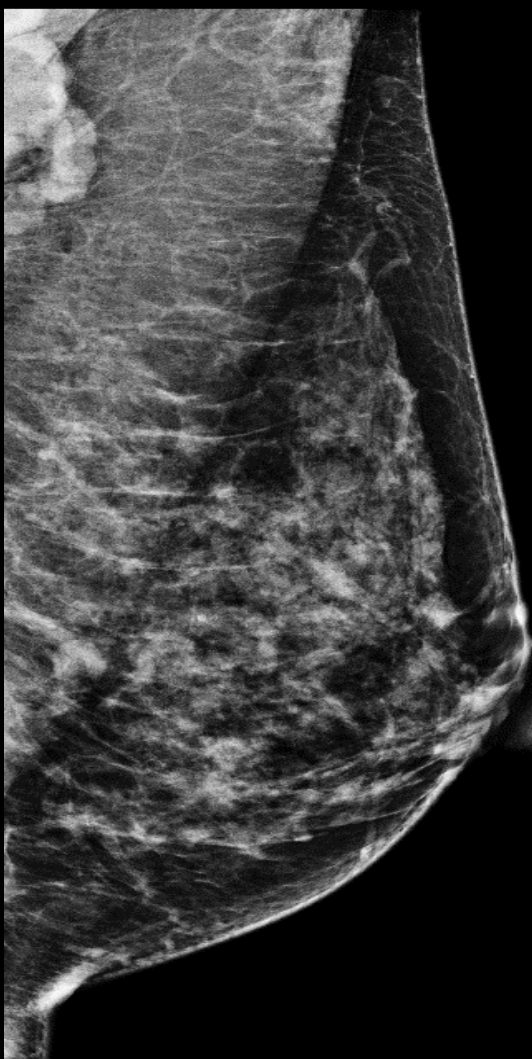




2D FFDM

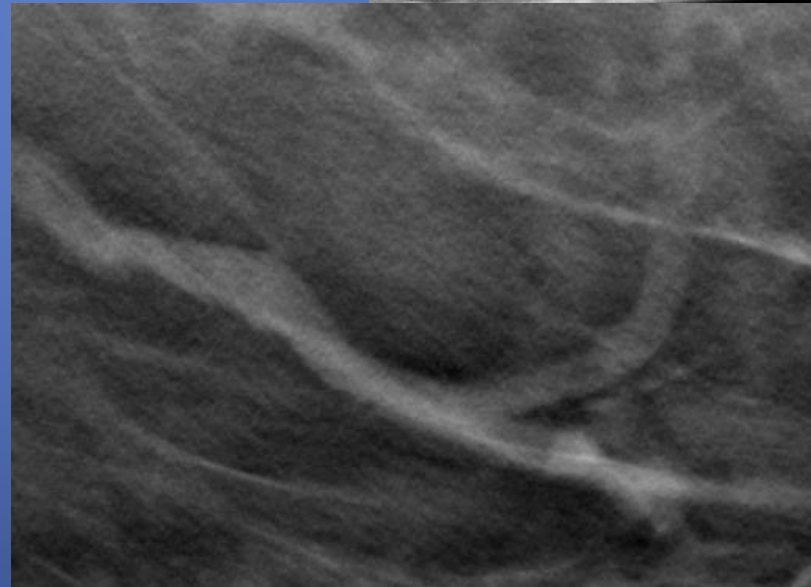


Tomosynthesis Slice



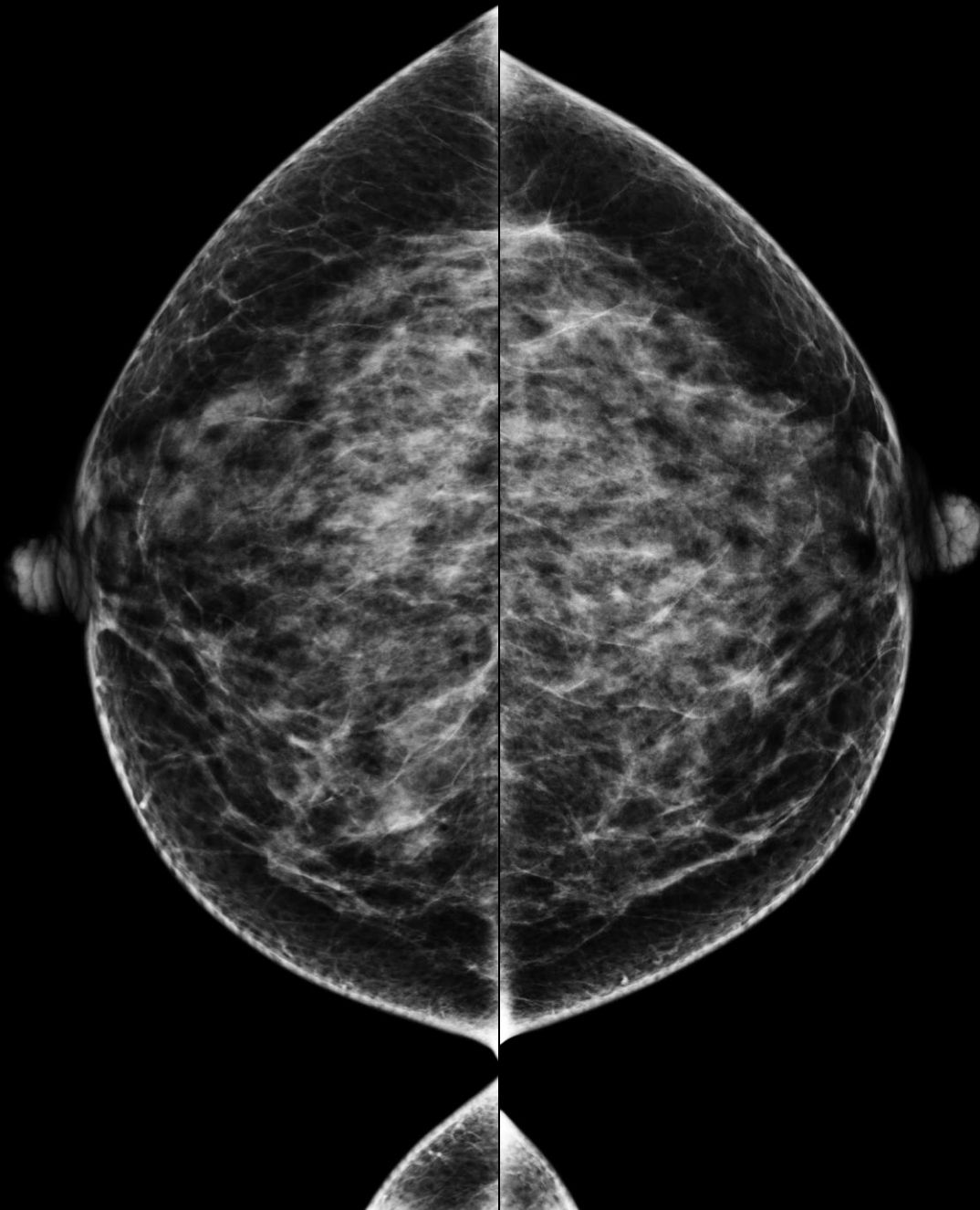
Tortuous Vessels

- Overlapping components of tortuous vessels may imitate mass lesions
- Tomosynthesis enables the radiologist to confidently assess true etiology



[C.M.] RCC

[C.M.] LCC



[CR] RMLO



[CR] LMLO

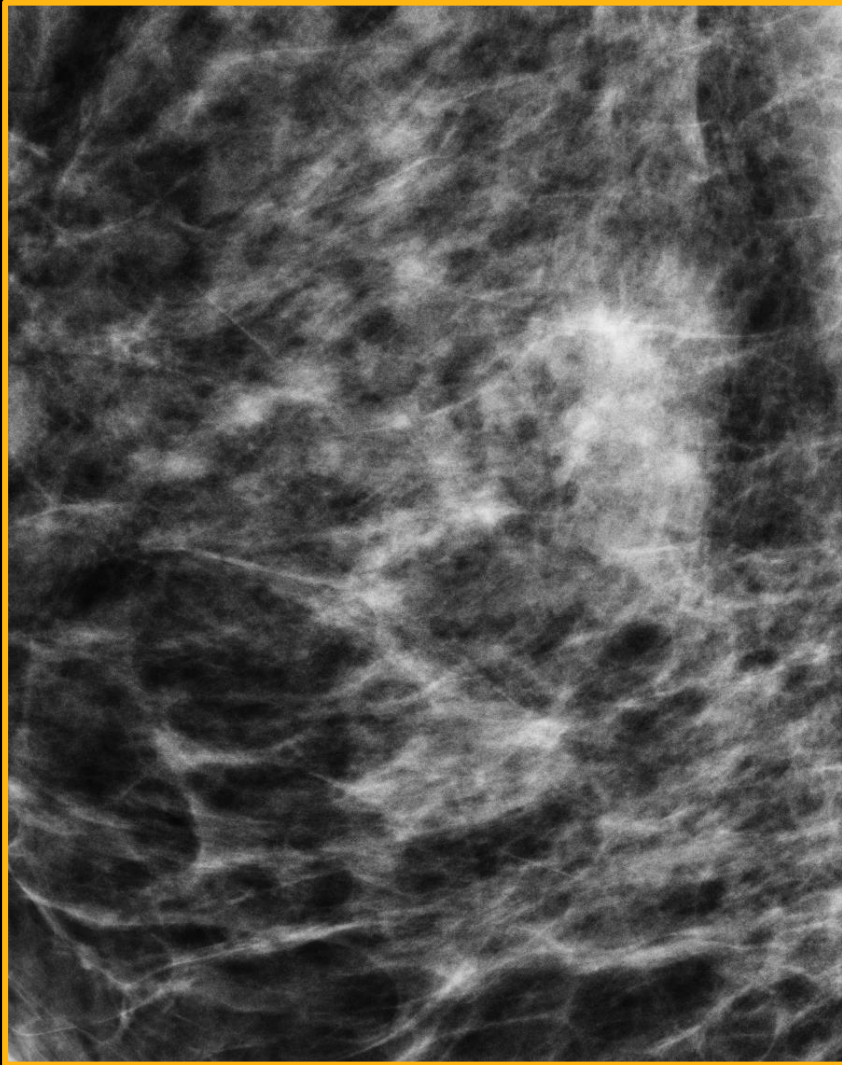
[C.R.C.] RMLO



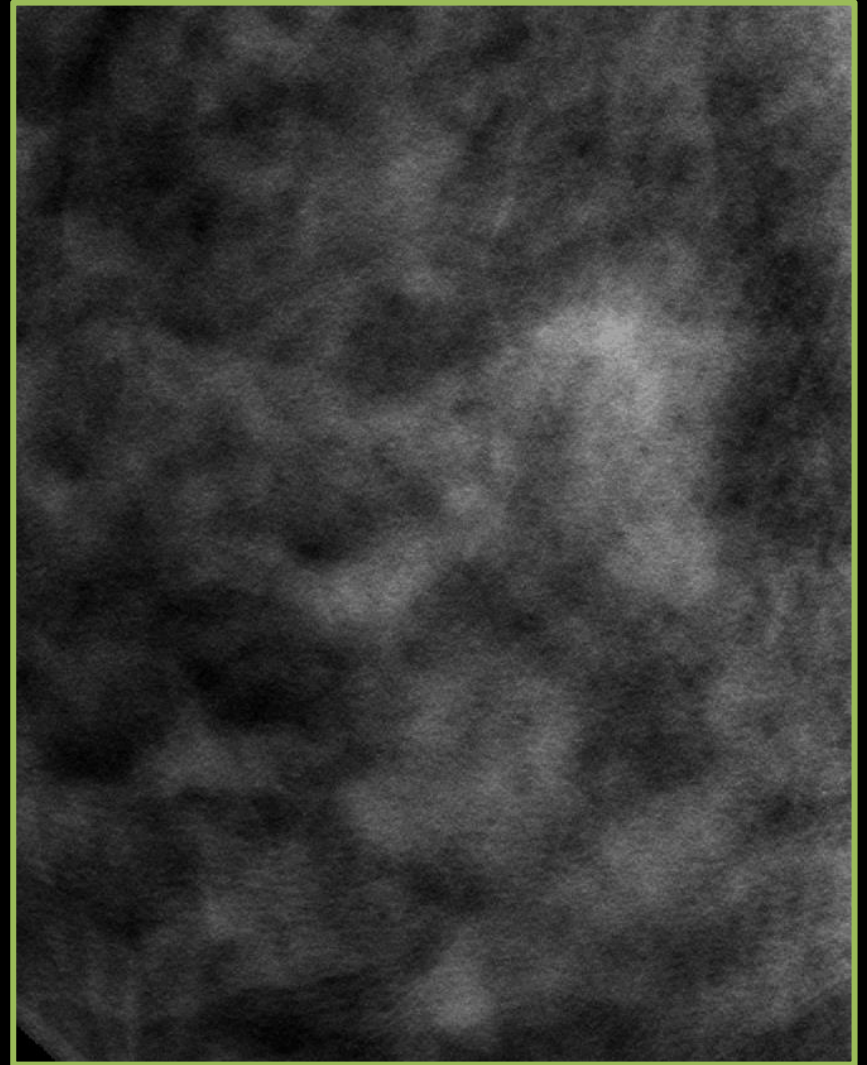
2D FFDM



Tomosynthesis Reconstruction

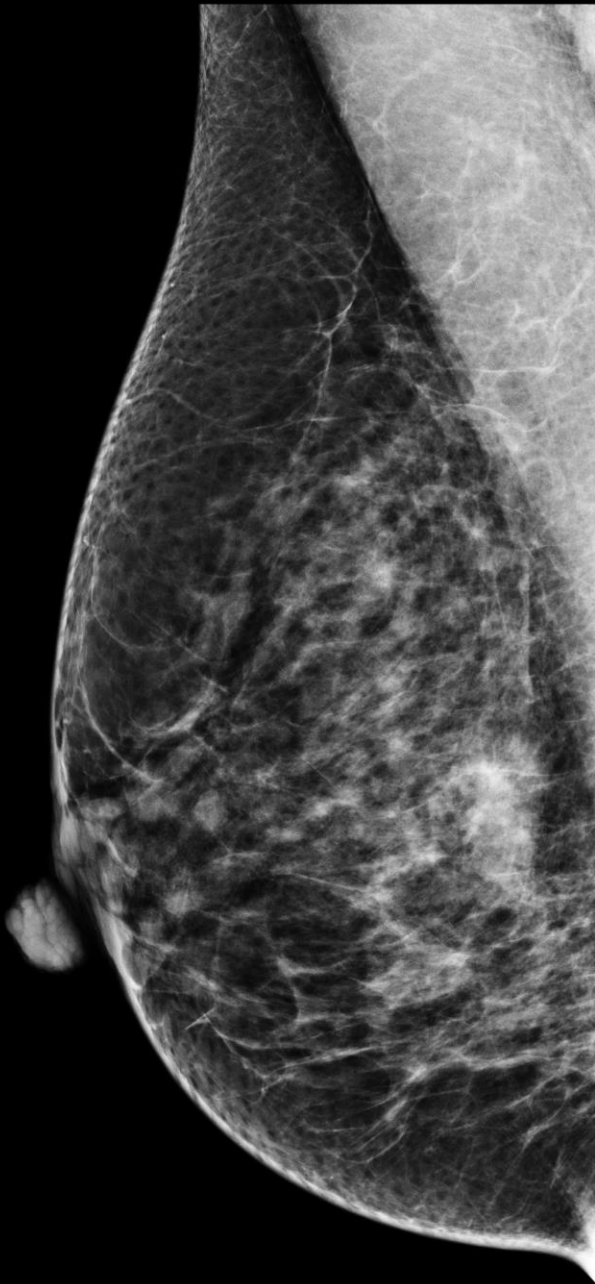


2D FFDM



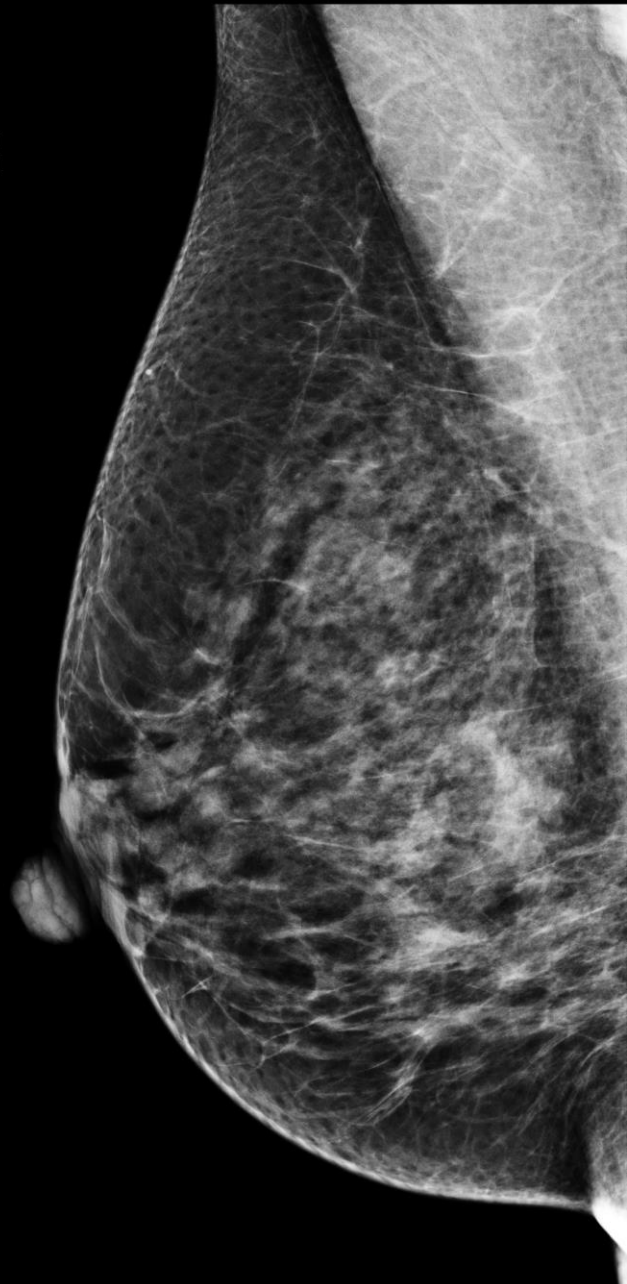
Tomosynthesis Reconstruction

[C R C] RMLO



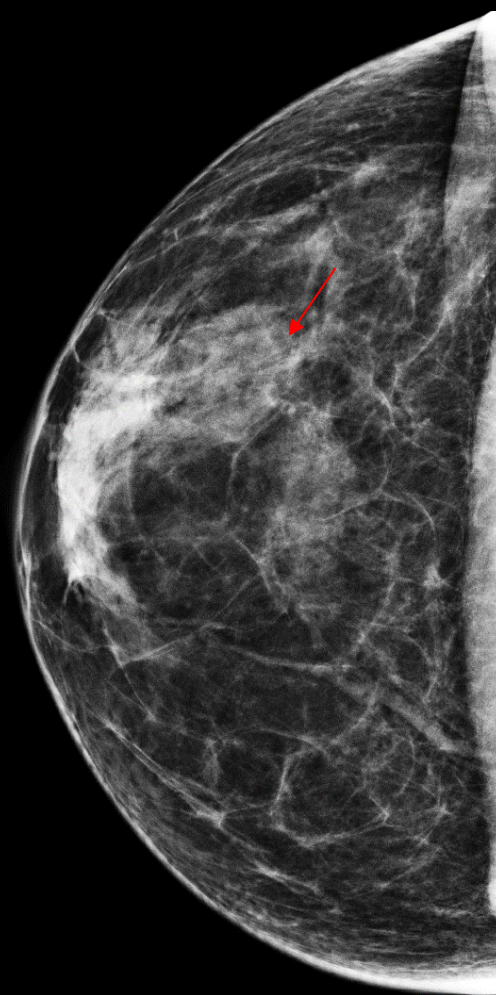
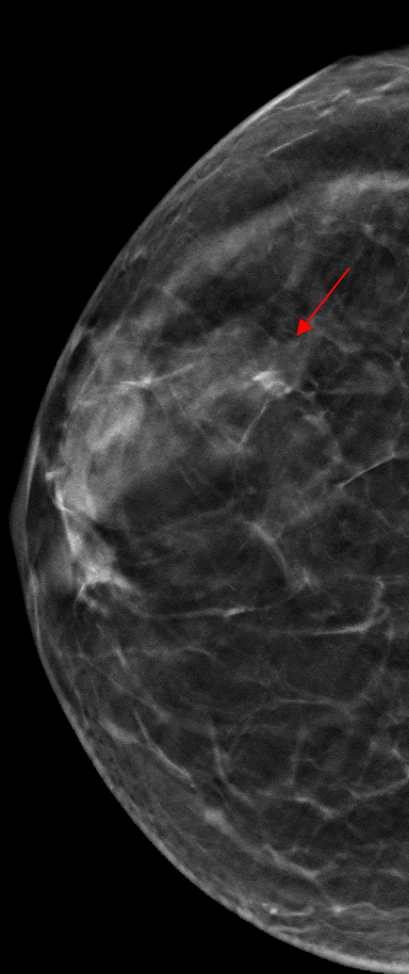
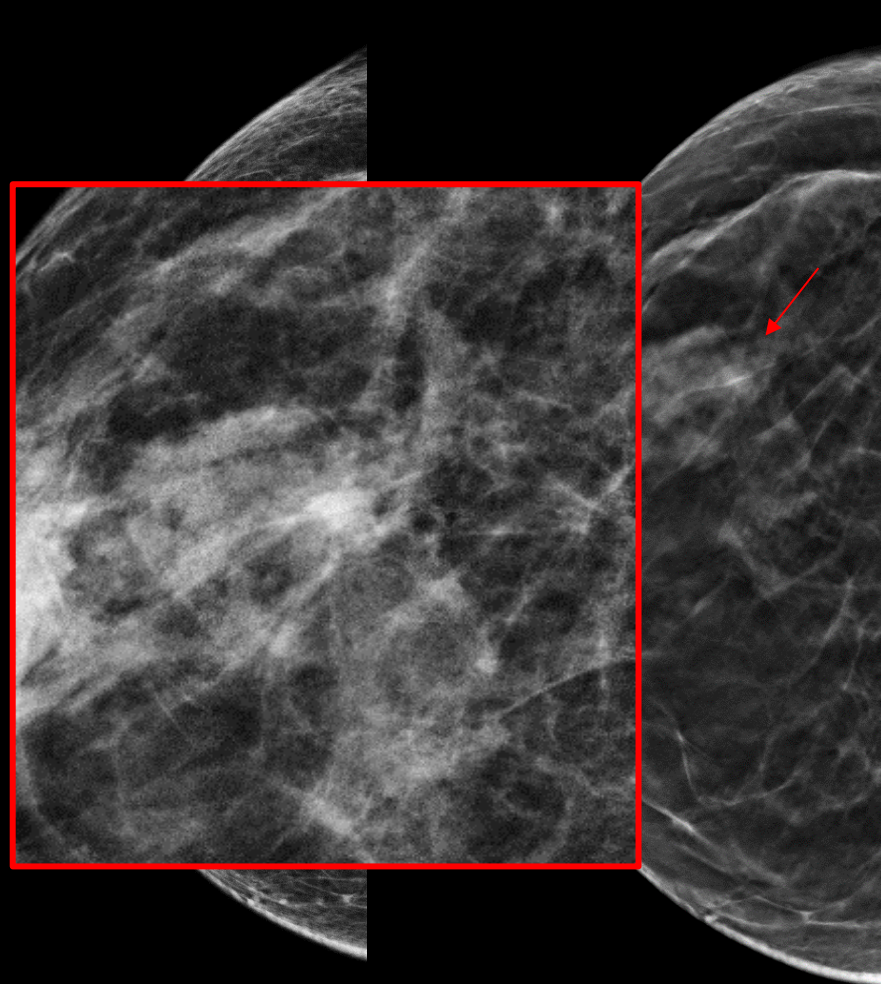
2011

[D M G] RMLO



2012

2D FFDM



Decrease Recall Rates

- Superimposed breast tissue
- Simulates a lesion
- No convex margins
- Will not see mass or discrete distortion on either view
- No need for call back for spot views or ultrasound

Summary

- The scientific evidence supporting the use of tomosynthesis is abundant
 - Increased lesion conspicuity/cancer detection
 - Decreased false positives
 - Yields a higher positive predictive value
 - Helps the radiologist in the diagnostic setting
 - Improved lesion localization
 - Increases pre-test probability of a lesion's benign or malignant status

Thank You

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