Dense Breast Mass Detection by QT imaging

Background

Almost all the clinical trials involving QT imaging have accrued only patients with a “positive mammogram”. This limits the results to “non-inferiority” interpretations. In order to determine if QT has advantages over X-ray mammography the “positive” QT findings need to be compared to the X-ray mammographic findings. This is a pilot analysis of such a comparison.

Methods

Forty QT findings from dense breasts (over 40% quantitative breast density)[1] were selected from a 250-woman case collection study at an academic medical center that was designed to compare X-ray mammography to QT. Patients with dense breasts from the dataset were selected that had findings of a mass on their QT scan. The mammograms of these same cases were read by board-certified breast radiologists, and these interpretative reports were used a basis for the mammographic findings. Co-location of any positive mammographic and QT findings were also confirmed. Two cases were excluded from analysis because they only had hand-held ultrasound examination. Five cases had mammography findings co-located with the QT findings, and the remaining 34 cases were referred to as “Dense Breast Cases with Positive QT and a Negative XRM.”

Results

Following is a chart, Table 1, of 38 masses found on the QTscan in cases with dense breasts which are hard to see on screening XRM.

TABLE 1

PATIENT ID		SIDE	QT FINDING	RADIOLOGIST REPORT	TRUE POS XRM	FALSE NEG XRM
1	002L	LEFT	6 CYSTS THROUGHOUT THE BREAST	UNREMARKABLE		1
2	006R	RIGHT	3MM CYST 9OC COR P37 SOS 156	UNREMARKABLE		1
3	008L	LEFT	1.5X2.5X4MM DUCTAL MASS 10 OC COR P59	UNREMARKABLE		1
4	016R	RIGHT	MASS 11OC COR P42	RT OUTER POSTERIOR MASS	1	
5	016L	LEFT	2 5MM CYSTS 2OC COR P 32	UNREMARKABLE	1	
6	035R	RIGHT	2.5X4CM MASS	UNREMARKABLE		1
7	052L	LEFT	5MM CYST 6OC COR P54	UNREMARKABLE		1
8	055R	RIGHT	5X9 MM OVAL MASS 8OC COR P55	UNREMARKABLE		1
9	059R	RIGHT	2X4X4 MM DUCTAL MASS CENT COR P54	UNREMARKABLE		1
10	060L	LEFT	7X10MM OVAL MASS 5OC COR P53	UNREMARKABLE		1
11	060L	LEFT	7X10MM OVAL MASS 7OC COR P56	UNREMARKABLE		1
12	089R	RIGHT	3X4MM CYST 11OC COR P40	UNREMARKABLE		1
13	089R	RIGHT	10MM CYST 9OC COR P46	UNREMARKABLE		1
14	091R	RIGHT	5X9MM OVOID MASS 5OC COR P45	UNREMARKABLE		1
15	091R	RIGHT	2X3X7 MM DUCTAL MASS 6OC COR P82	UNREMARKABLE		1
16	092R	RIGHT	6MM MASS 630 OC COR P31 SOS 1589	UNREMARKABLE		1
17	106R	RIGHT	MULTIMPLE CYSTS COR P49 CENTRAL	UNREMARKABLE		1
18	106L	LEFT	10MM CYST 40C COR P64	Asymmetries no mass seen		1
19	109R	RIGHT	10X12X15 LOBULAR CYST 9OC COR P72	Masses seen on XRM ARE NOT qt Masses		1
20	109R	RIGHT	7X9 CYST 8OC COR P75	UNREMARKABLE		1
21	109L	LEFT	MULTIPLE CYSTS THROUGHOUT THE BREAST	Rnd masses UL breast	1	
22	111R	RIGHT	9X11X11 MASS 230 OC COR P61	Smooth oval mass UOQ	1	
23	123L	LEFT	12X16MM MULTILOB CYST 2OC COR P38	BiRads 3 vague central shadow		1
24	143R	RIGHT	5MM MASS 10OC COR P64	LUMP UIQ Mammo NEG HHUS Pos		1
25	145R	RIGHT	10MM MASS 9OC COR P37	XRM UNREMARKABLE HHUS shows oval solid mass		1
26	155R	RIGHT	3X9MM DUCTAL MASS 12OC COR P65	MASS OUQ not the QT finding		1
27	157R	RIGHT	17MM CYST 7OC COR P 44	UNREMARKABLE		1
28	157L	LEFT	MULTIPLE CYSTS THROUGHOUT THE BREAST	UNREMARKABLE		1
29	159L	LEFT	10X20MM OVAL MASS 9OC COR P48	ONLY HHUS REPORT		
30	162L	LEFT	MASS 1OC COR P40	Distortion UOQ not in area of QT finding		1
31	167L	LEFT	22MM HIGHLY SUSPICIOUS MASS 530 OC COR P57	ONLY HHUS REPORT		
32	168L	LEFT	7MM CYST 12OC COR P54	UNREMARKABLE		1
33	175L	LEFT	15MMM CYST 2OC COR P53	MASS UOQ	1	
34	177L	LEFT	MASS IUQ	UNREMARKABLE		1
35	178L	LEFT	33MM HIGHLY SUSPICIOUS MASS	UNREMARKABLE		1
36	188L	LEFT	8MM CYST 10OC COR P40	UNREMARKABLE		1
37	188R	RIGHT	12MM CYST 1OC COR P40	Mass UOQ prev cyst on HHUS	1	
38	195L	LEFT	8X10MM CYST 230 OC COR P85	Asymmetry UOQ no mass seen		1
39	197L	LEFT	SUSPICIOUS RETROAREOLAR MASS	UNREMARKABLE		1
40	220R	RIGHT	30MM SUSPICIOUS MASS 12OC COR P48	Breast lump 12OC only Asymmetry on XRM		1
TOTALS					6	32
USABLE CASES		38				

Statistics

There were 38 usable cases and approximately 40 masses (2excluded because of no XRM – only HHUS). Using a denominator of 38, XRM was able to visualize 6 of the 36 abnormalities (16%) and XRM was not able to define 32 abnormalities (84%) – Table 2.

TABLE 2 – STATISTICS OF XRM AND QT SCAN READS

TOTAL USABLE FINDINGS	38	
	NUMBER	PERCENT
TRUE POS XRM CASES	6	15.79%
FALSE POS XRM CASES	0	0.00%
FALSE NEG XRM CASES	32	84.21%
TRUE NEG XRM CASES	0	0.00%
EXCLUDED HHUS ONLY	2	

Discussion

QT is better at seeing certain types of masses in dense breasts than mammography. This corresponds to several studies that have been published[2,3]. QT breast imaging can see into dense breasts with more clarity and is more *sensitive* at detecting certain masses than mammography. QT breast imaging is also more *specific* than x-ray mammography at identifying certain types of masses (cyst vs solid) within breasts[4].

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[1]Natesan R, Wiskin JW, Lee S, Malik B. *Quantitative assessment of breast density: transmission ultrasound is comparable to mammography with tomosynthesis*. Cancer Prevention Research October 23, 2019. Doi: 10.1158/1940-6207.CAPR-19-068 https://cancerpreventionresearch.aacrjournals.org/content/early/2019/10/23/1940-6207.CAPR-19-0268

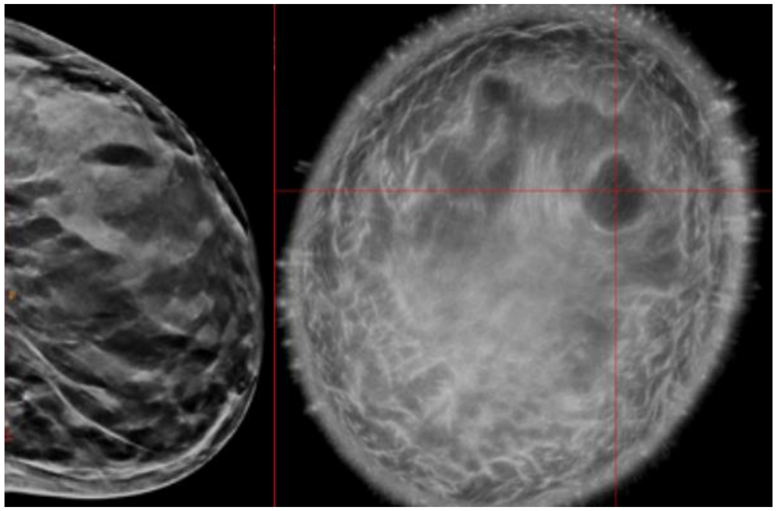
[2]John C Klock, Elaine Iuanow, Kathleen Smith, Nancy A and Obuchowski *Visual Grading Assessment of Quantitative Transmission Ultrasound Compared to Digital X-ray Mammography and Hand-held Ultrasound in Identifying Ten Breast Anatomical Structures*. BAOJ Clinical Trials 3: 015. (2017). https://bioaccent.org/clinical-trials/clinical-trials15.pdf

[3]Klock JC, Lenox MW, Wiskin JW, Malik B, Natesan R. *Transmission Ultrasound Using 3D Inverse Scattering. Open Access E Book on Emerging Trends in Ultrasound*. June 2018 http://openaccessebooks.com/emerging-trends-ultrasound-imaging/transmission-ultrasound-imaging-using-3D-inverse-scattering.pdf; ISBN: 978-93-87500-37-2

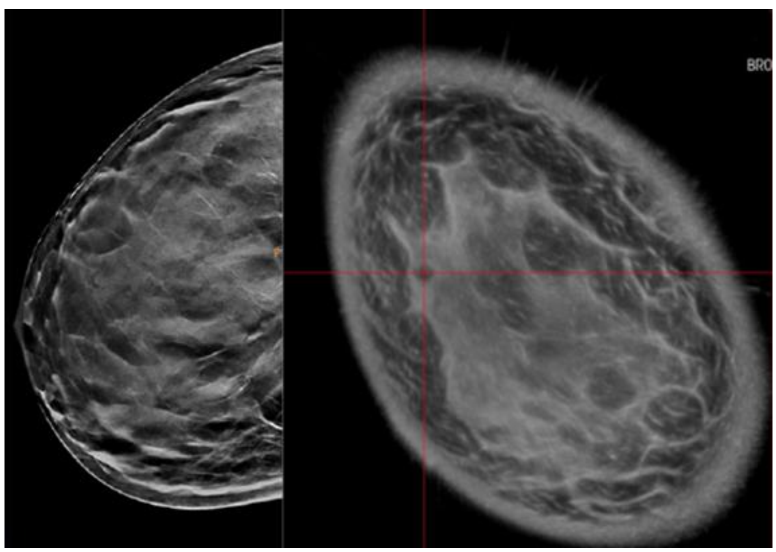
[4]Elaine Iuanow, MD, Kathleen Smith, MBA, Nancy A. Obuchowski PhD[†], Jennifer Bullen MS[†] and John C. Klock, MD. *Accuracy of Cyst vs. Solid Diagnosis in the Breast Using Quantitative Transmission (QT) Ultrasound*. Academic Radiology 2017 Vol 24:1148-1153; doi: 10.1016/j.acra.2017.03.024. Epub 2017 May 23; PubMed ID 28549870. *Academic Radiology* has posted the study in full for free. http://www.healthimaging.com/topics/womens-health/breast-imaging/and-coming-ultrasound-technology-shows-prowess-mammography-adjunct.

Image Review

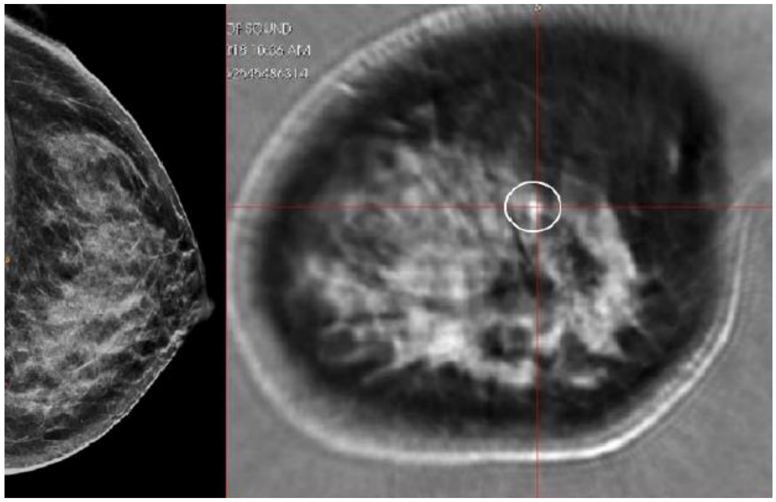
Below are the negative mammograms on the left and the QT masses on the right



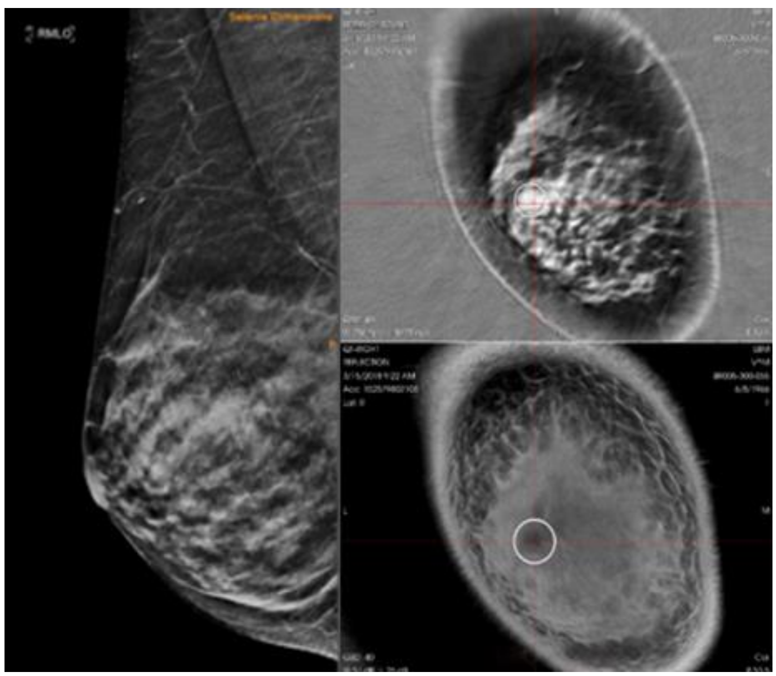
Case 1A - multiple cysts (002L)



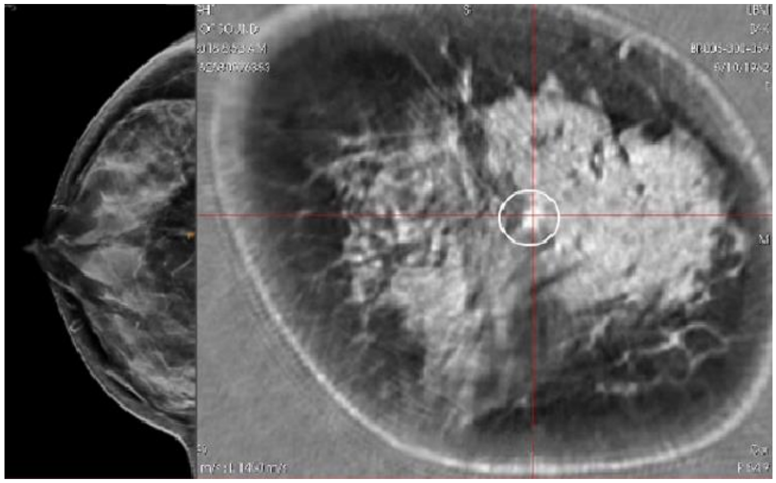
Case 1B - multiple cysts (002L)



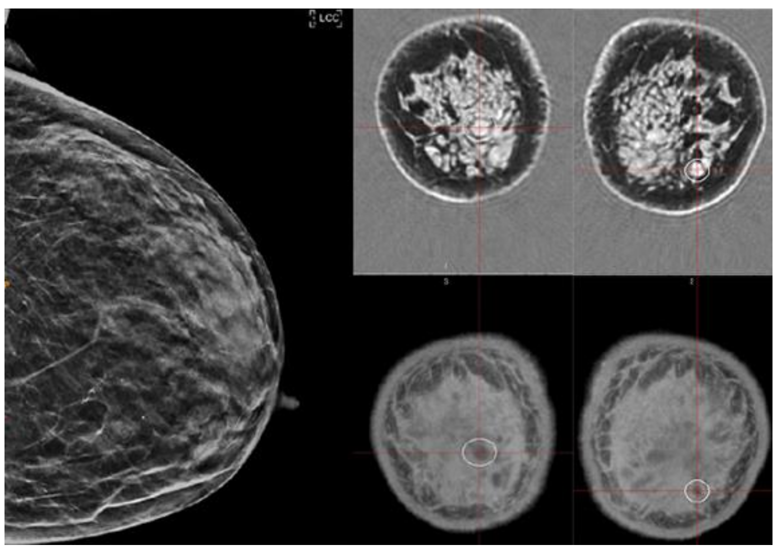
Case 2 – solid mass (008L)



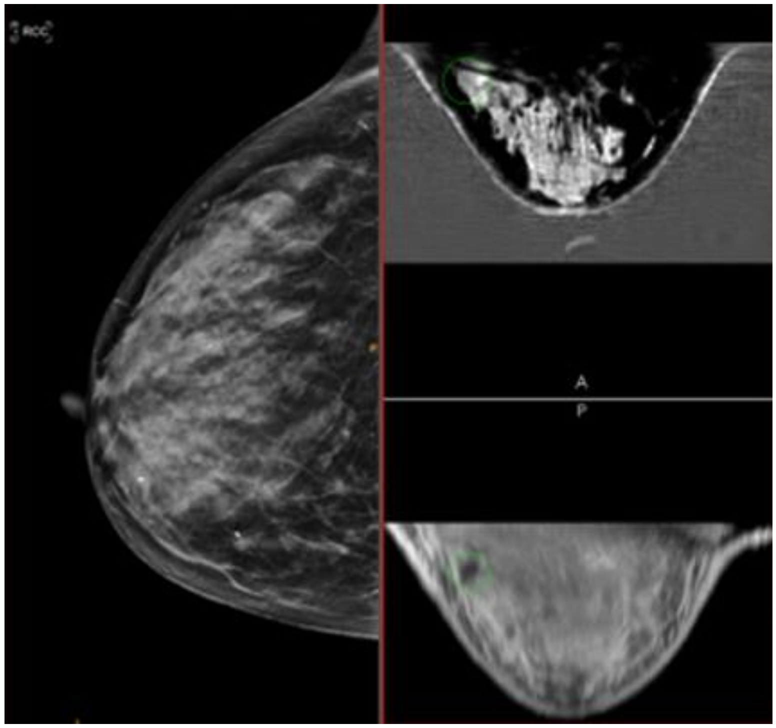
Case 3 solid mass (052L)



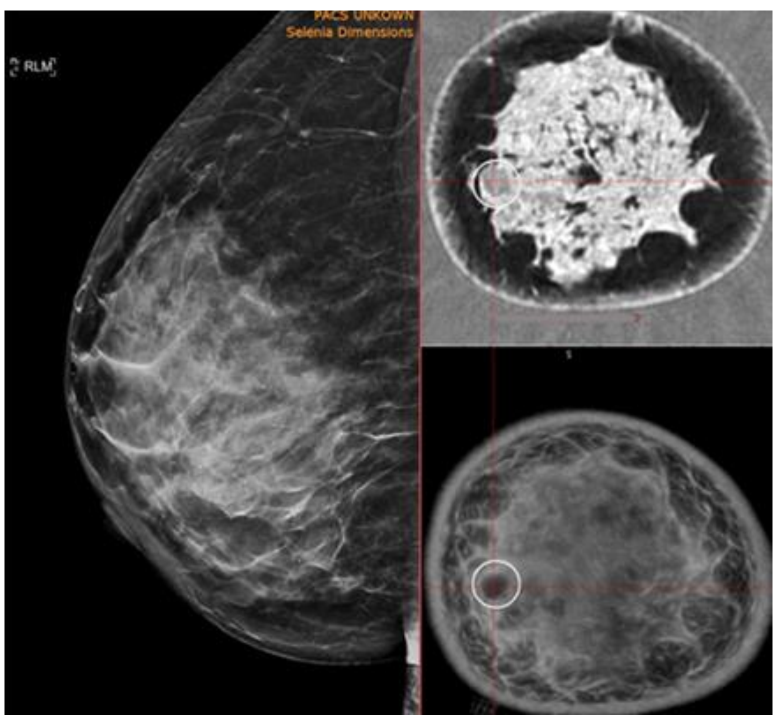
Case 4 – solid mass (059R)



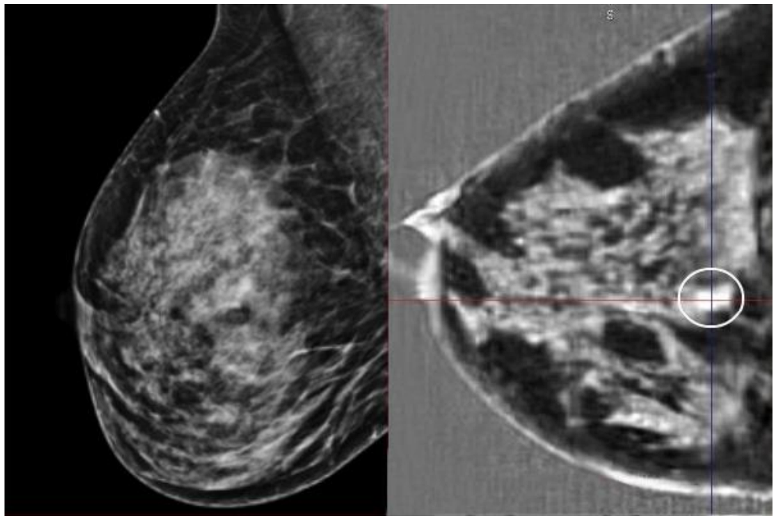
Case 5 – 2 cysts (060L)



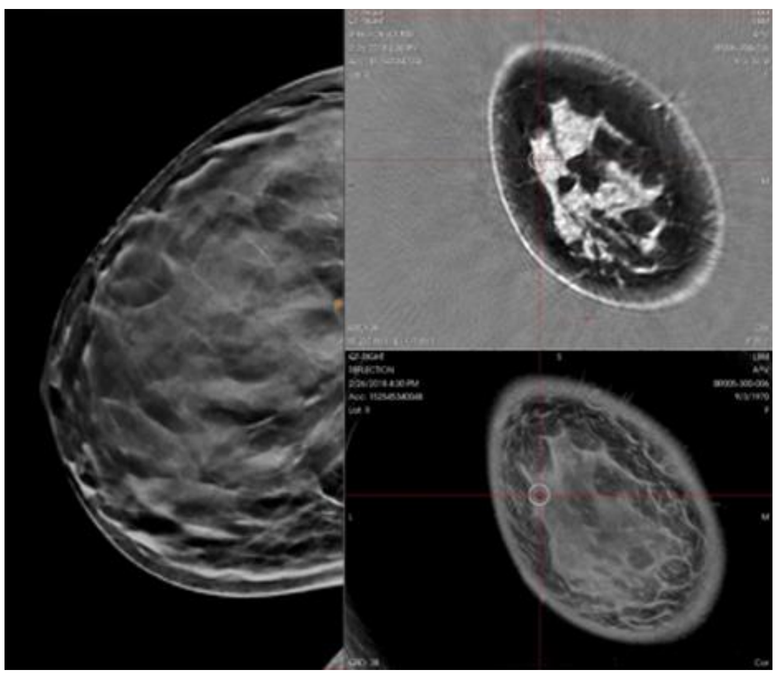
Case 6 Cyst (109R)



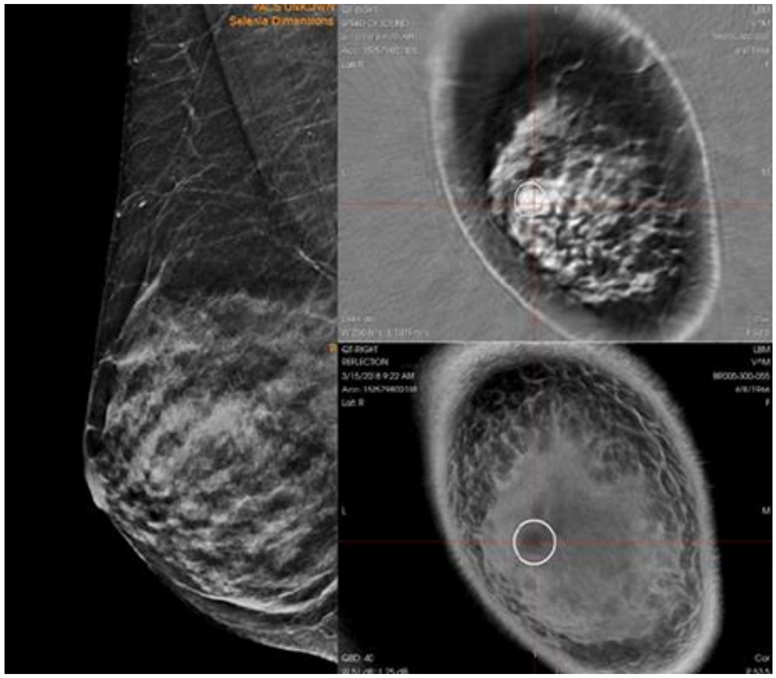
Case 7 Cyst (089R)



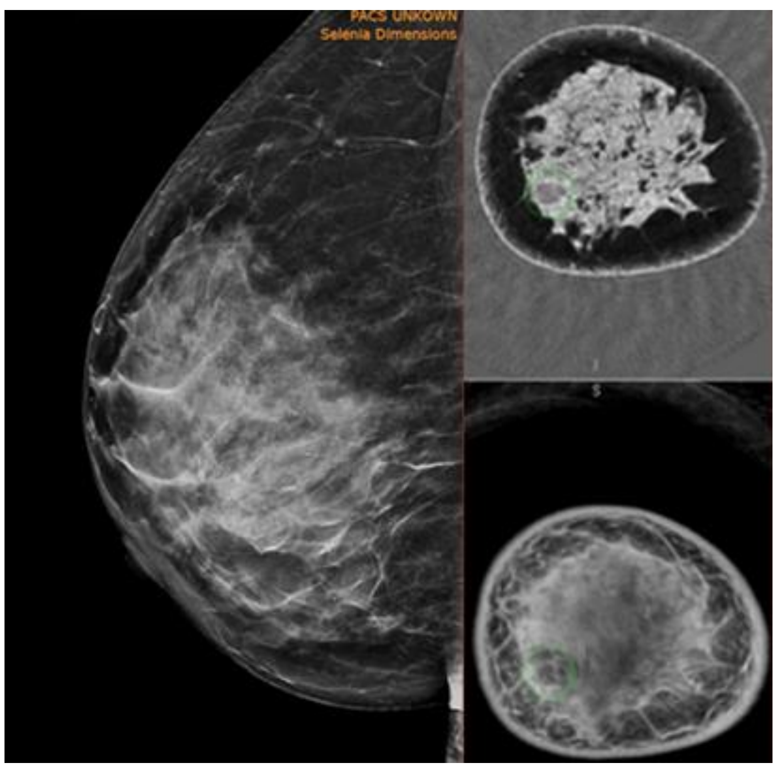
Case 8 Mass (091R)



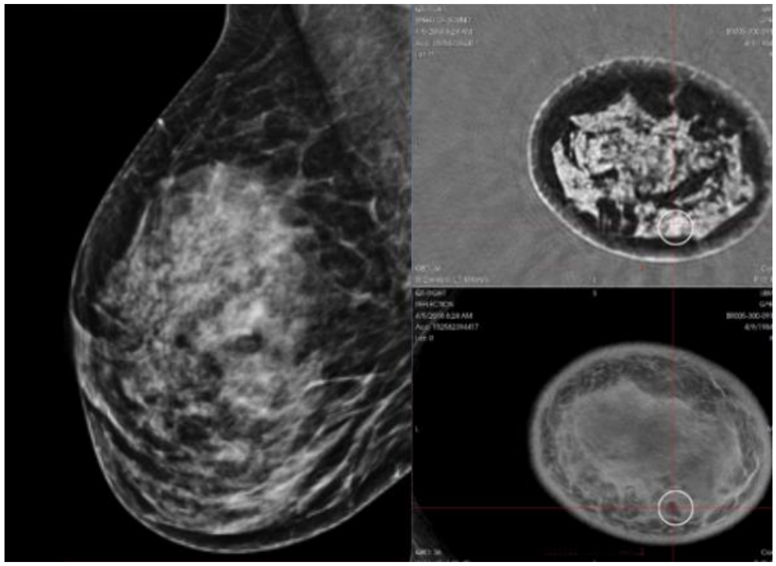
Case 9 (006R)



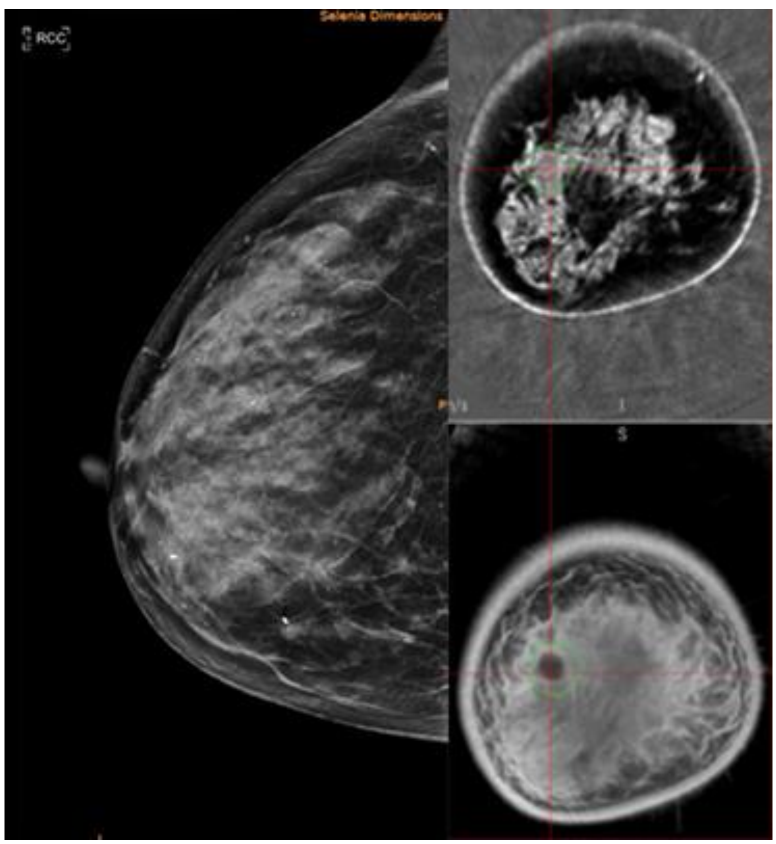
Case 10 (055R)



Case 11 Cyst 2 (089R)

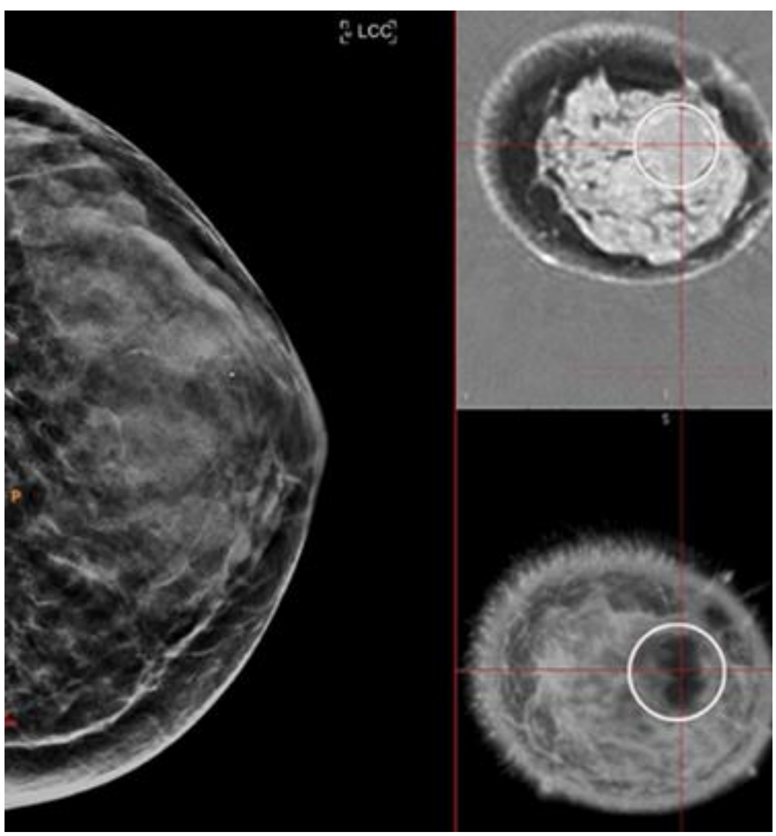


Case 12 (091Rb)

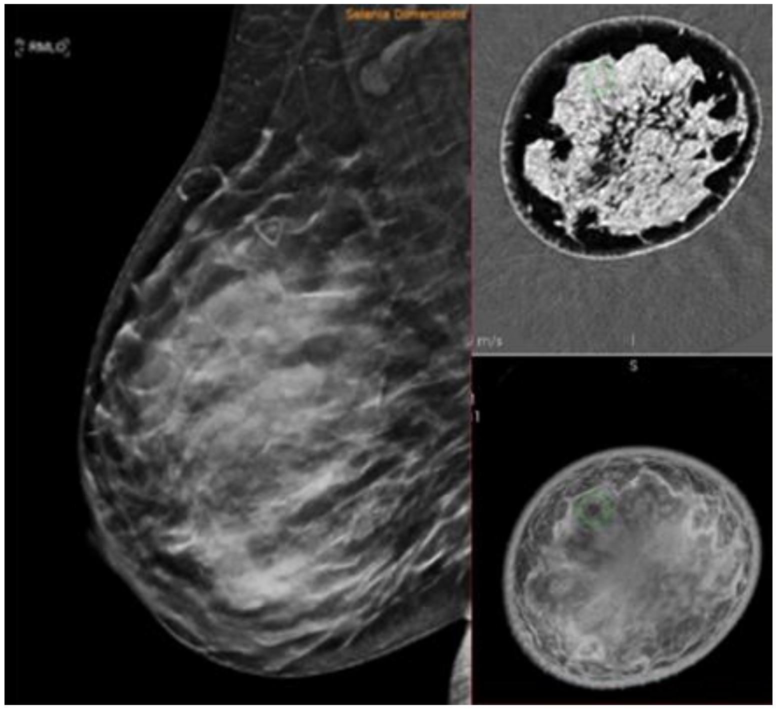


Case 13 (109Rb)

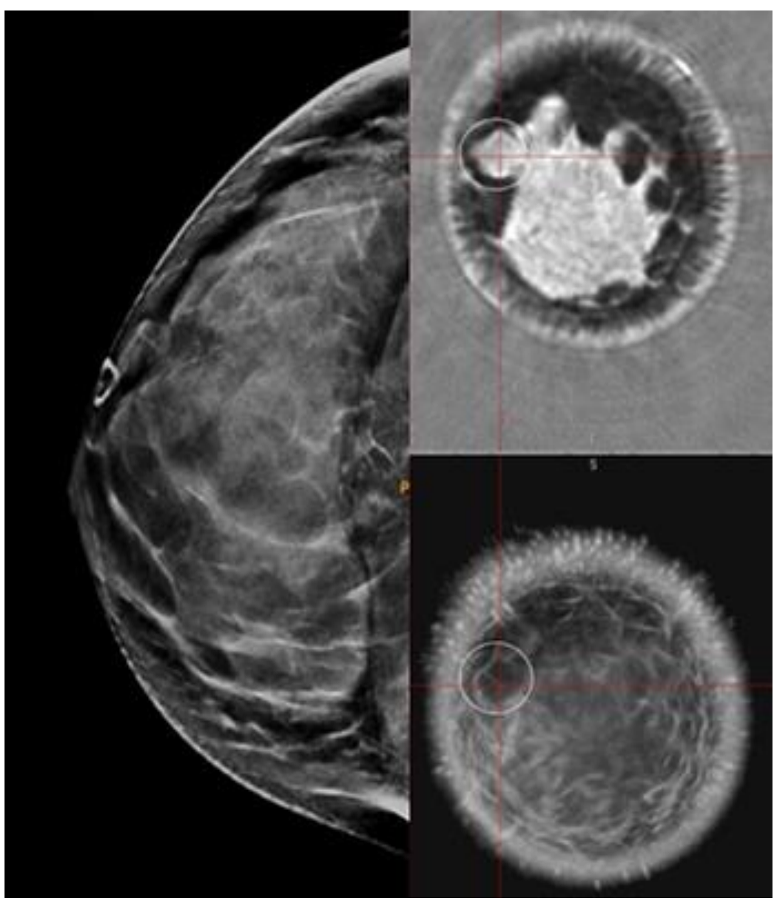
Case 14 (111R)



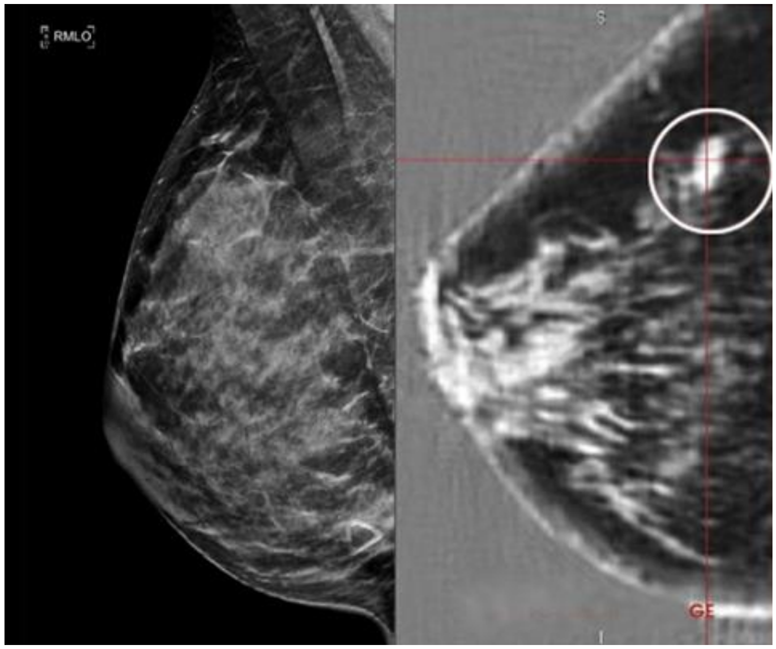
Case 15 (123R)



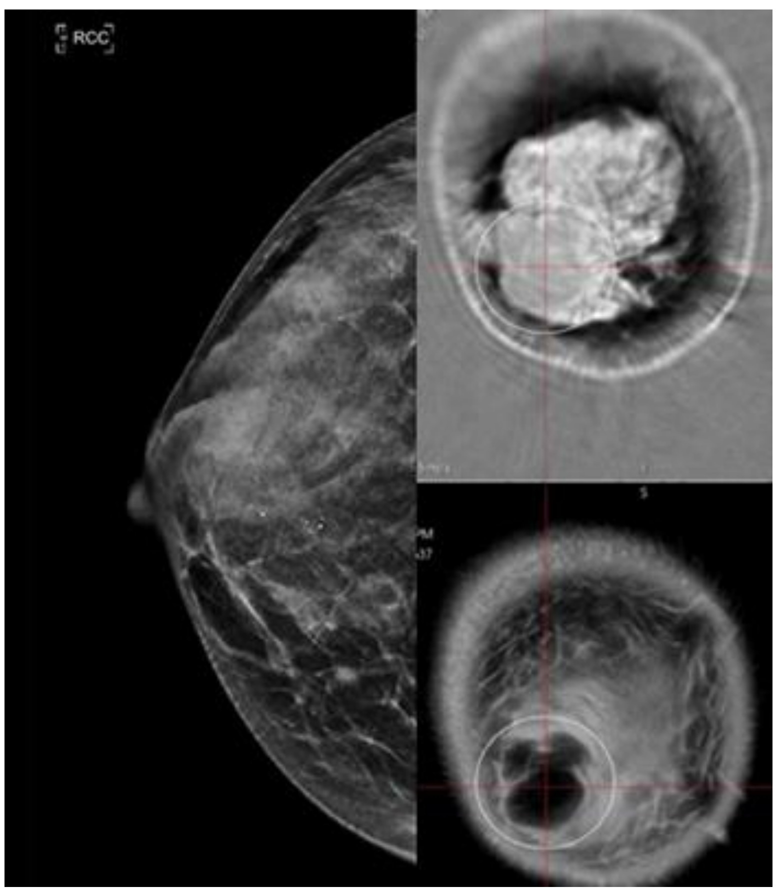
Case 16 (143R)



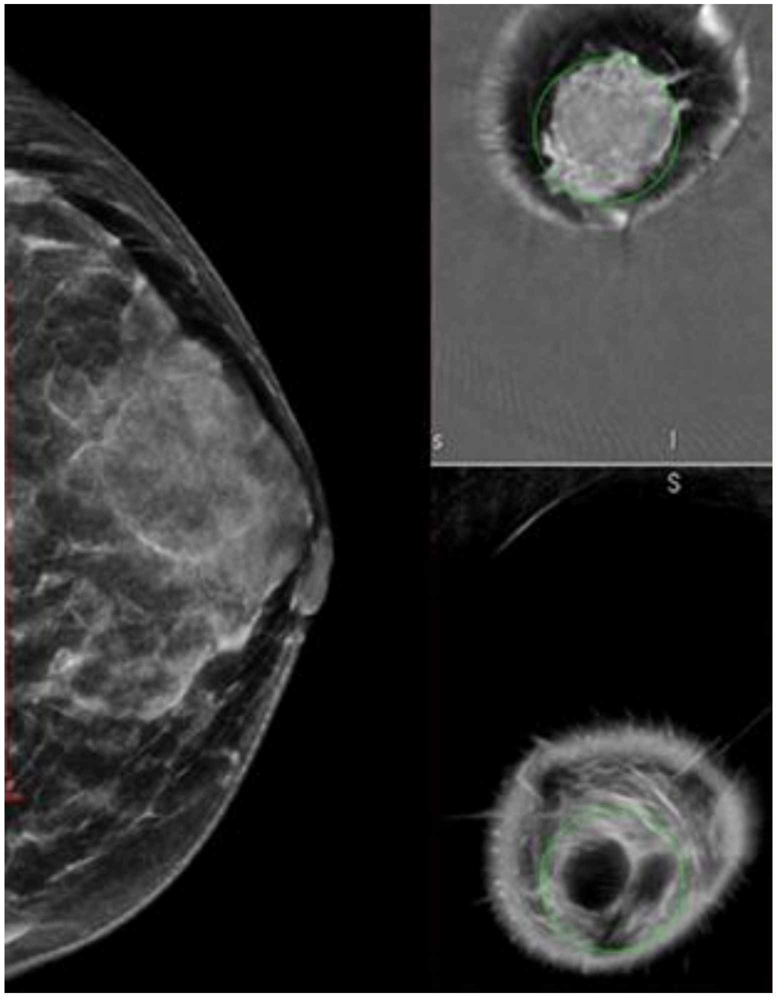
Case 16 (145R)



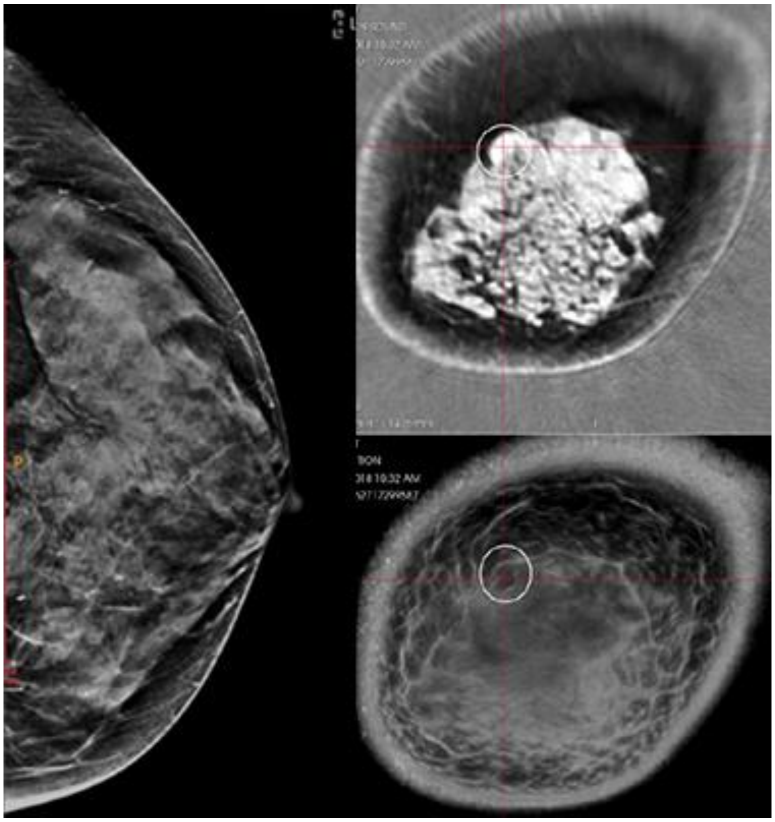
Case 17 (155R)

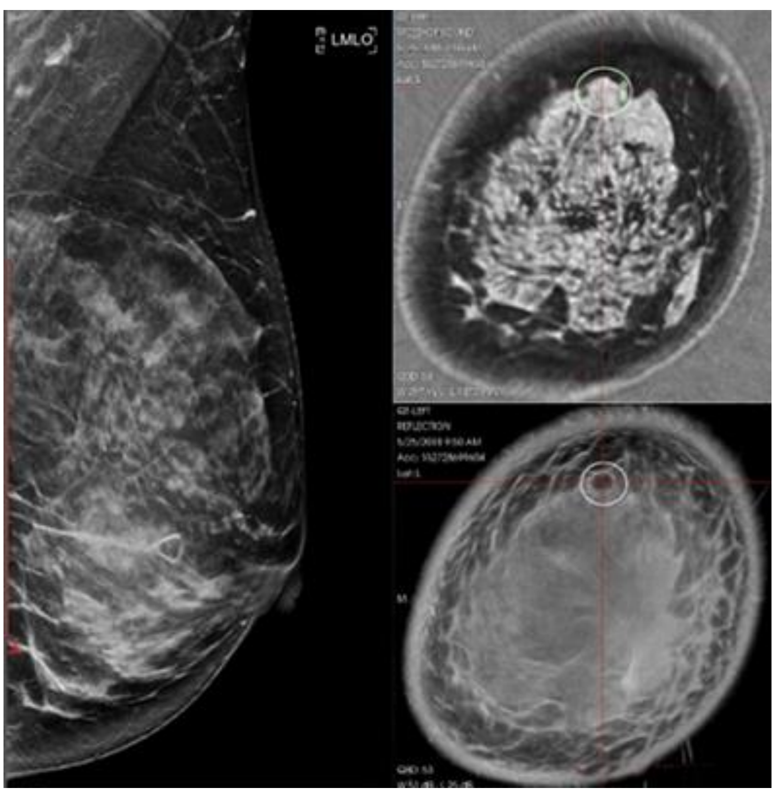


Case 18 (157R)

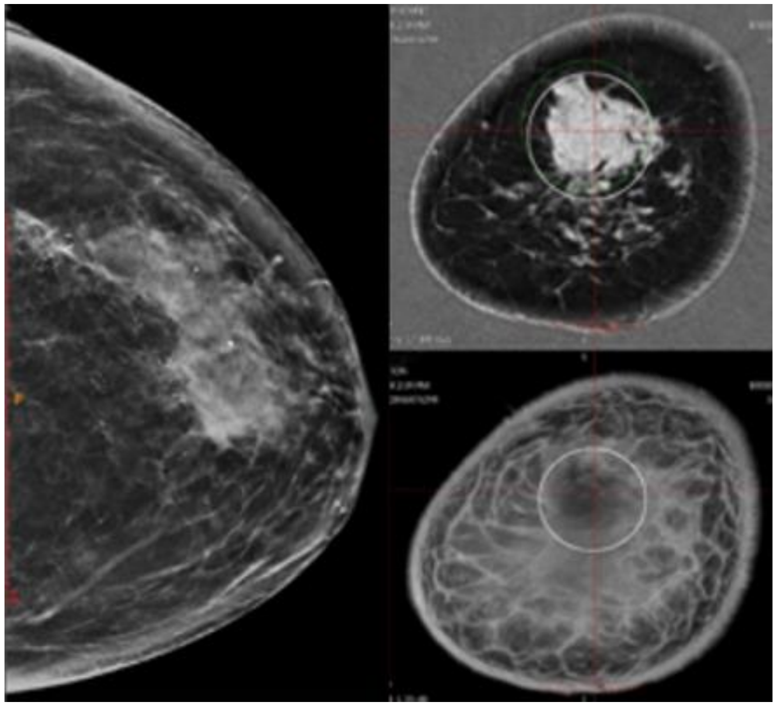


Case 19 (157L)

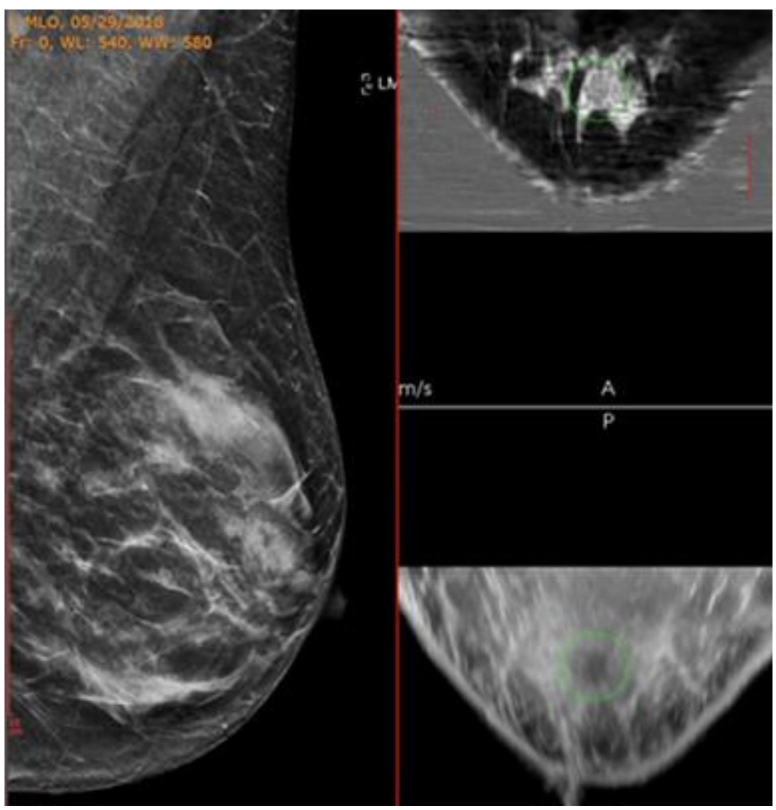

Case 20 (162L)



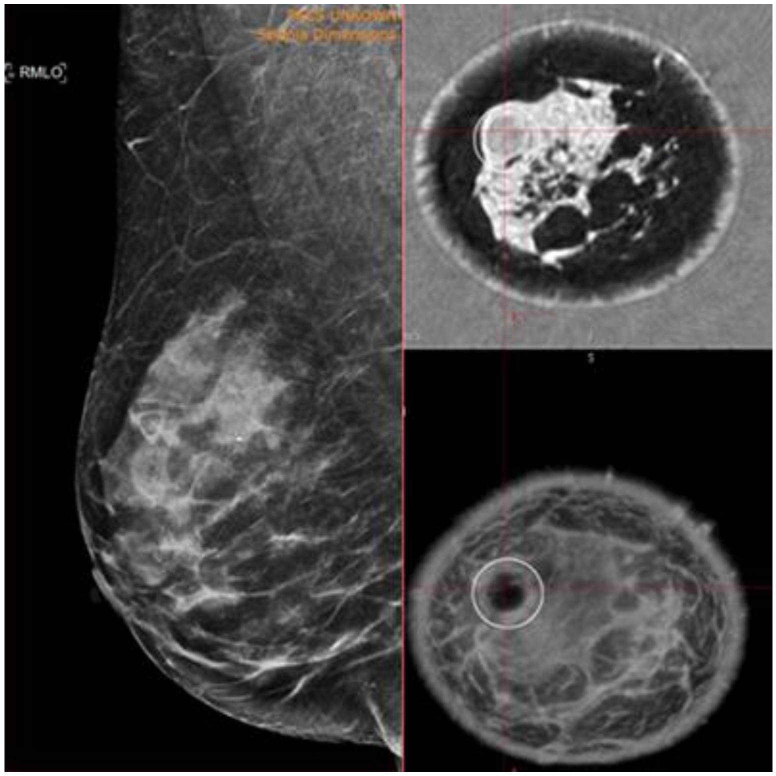
Case 21 (168L)



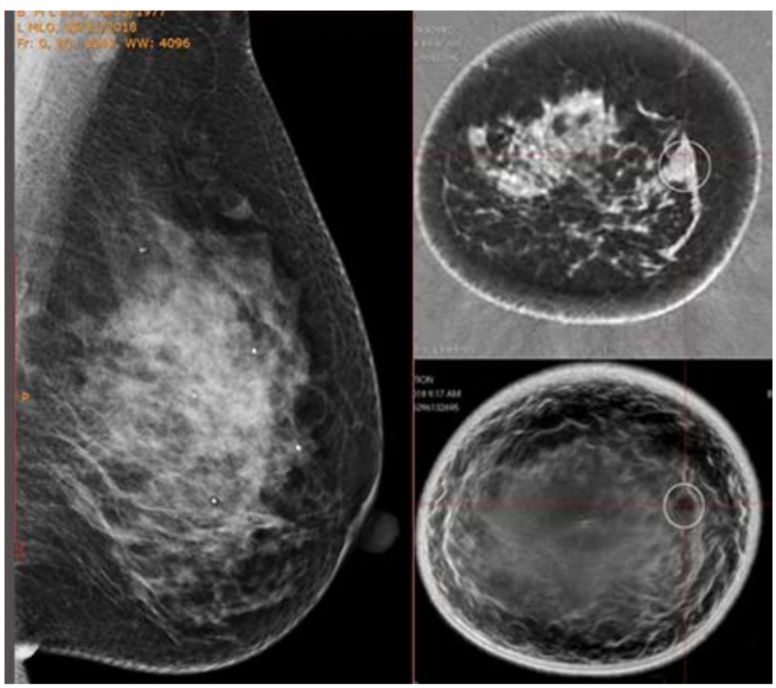
Case 22 (178L)



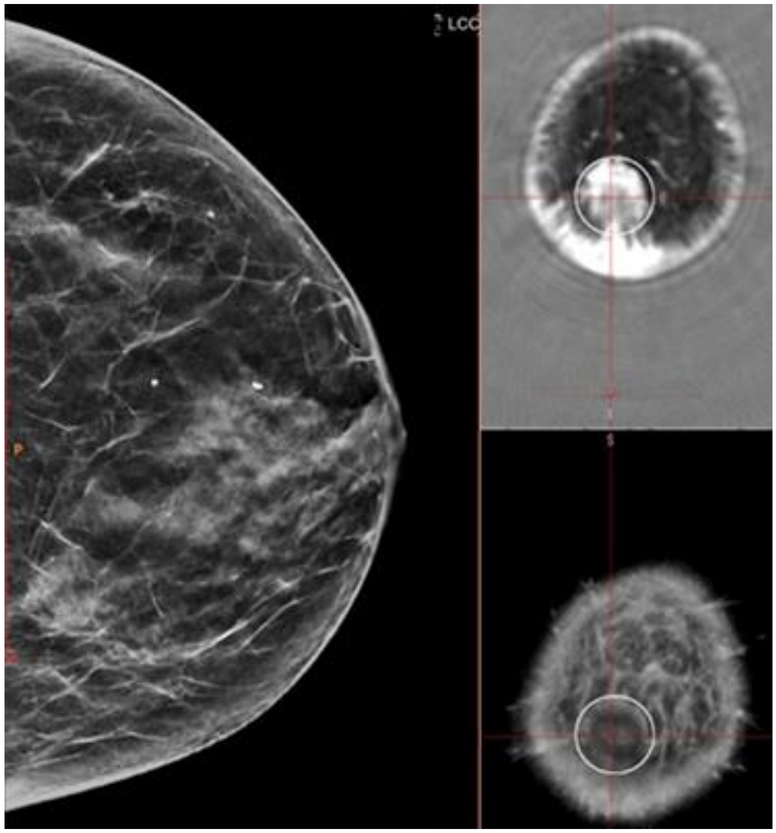
Case 23 (188L)



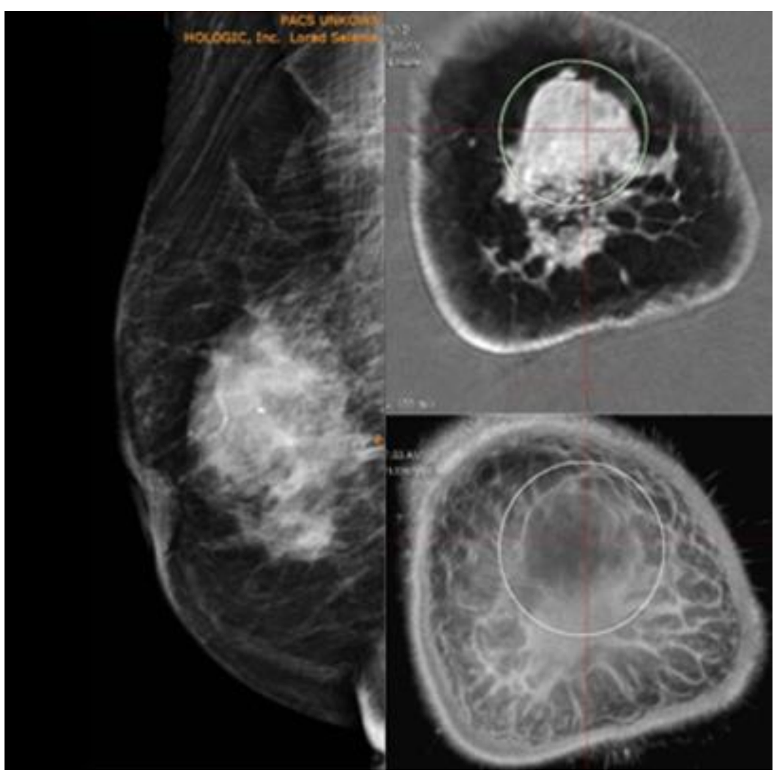
Case 24 (188R)



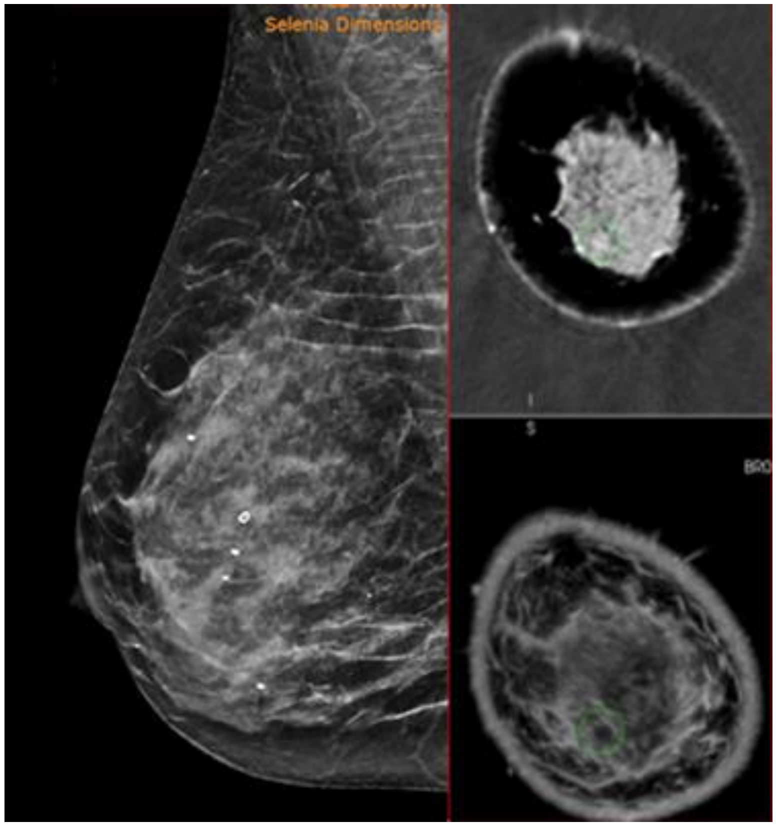
Case 25 (195L)



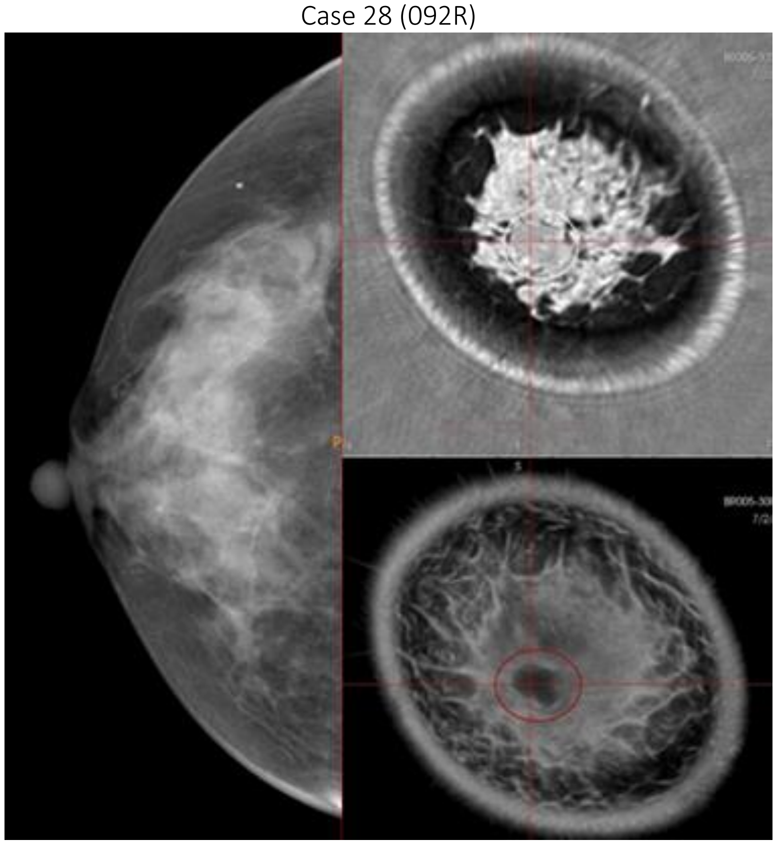
Case 26 (197L)



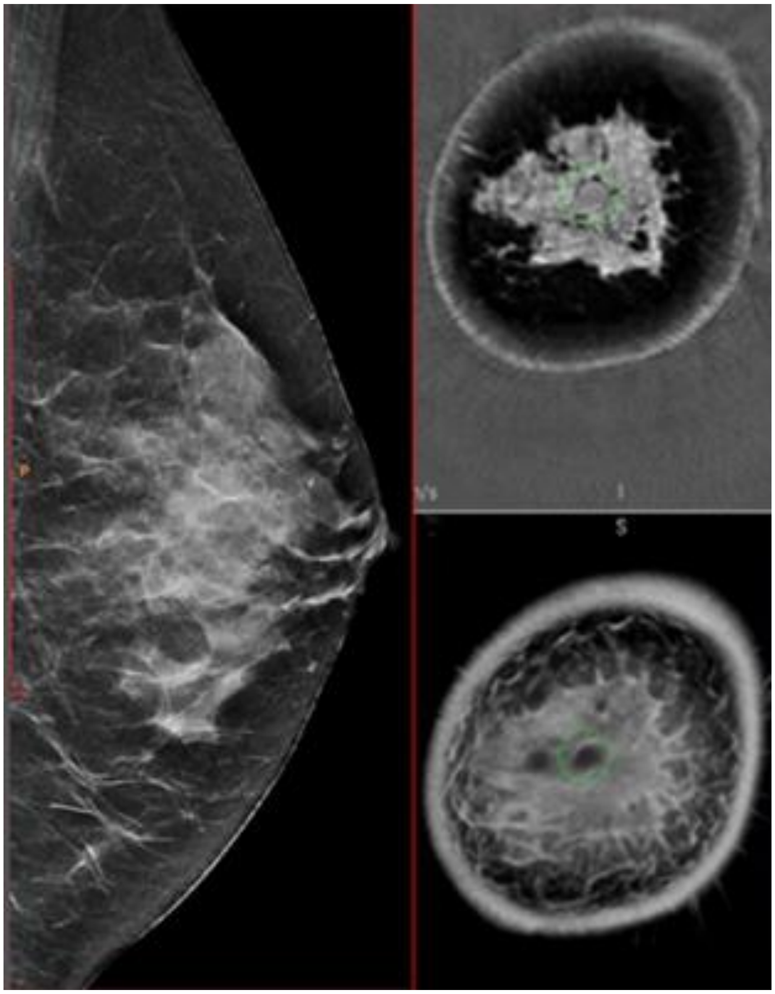
Case 27 (220R)



Case 28 (092R)



Case 29 (106R)



Case 30 (106L