

WHITE PAPER

DBT and Artificial Intelligence power: New opportunities in breast cancer detection

Performed on Senographe Pristina with ProFound AI® Detection for Digital Breast Tomosynthesis

Abstract

There's growing interest in artificial intelligence and the potential to advance cancer detection while mitigating some of the ongoing burdens on radiologists. To explore this, Boca Institute conducted a study "Real-world breast cancer screening performance with digital breast tomosynthesis before and after implementation of an artificial intelligence detection system" across 103,000 patients with DBT to evaluate clinical performance both with and without AI.³

- This study supports the use of artificial intelligence with a digital breast tomosynthesis program.
- The Lynn Women's Health and Wellness Institute at Boca Raton Regional Hospital Baptist Health in South Florida leveraged iCAD's ProFound AI® Detection for DBT software with GE HealthCare's Senographe Pristina™ Mammography system to help improve its cancer detection rate (CDR) and recall rates.
- Without AI, the CDR per 1,000 screening exams was aligned with the CDR identified in two recently published studies in the U.S.^{6,7}. With AI, the CDR saw a statistically significant increase of 23 percent from 5.77 to 7.08 without a statistically significant change in false positives and recalls.

Introduction

Early diagnosis of breast cancer is crucial for timely treatment and is linked to better outcomes, including a higher survival rate. While screening mammography has reduced breast cancer-associated mortality by 20 to 30 percent through detection of small lesions at early stages, an estimated 15 to 35 percent of cancers are still missed.¹

Digital breast tomosynthesis (DBT) has revolutionized the field and has been shown to deliver superior diagnostic accuracy⁴. However, the downside of DBT is the significant increase in workload, with

examinations shown to require 47 percent longer interpretation time². Staffing shortages are only exacerbating the problem and putting more pressure on radiologists, who are already prone to work-related fatigue.

Optimizing breast imaging

The Lynn Women's Health and Wellness Institute at Boca Raton Regional Hospital Baptist Health in South Florida performs nearly 100,000 breast screenings and diagnostic procedures a year. The Institute, which is led by internationally-recognized radiologist Dr. Kathy Schilling, has a history of high cancer detection rate.

The team utilizes GE HealthCare's Senographe Pristina Mammography system, which delivers superior diagnostic accuracy⁴ at the same low dose as 2D FFDM and has the lowest radiation dose of the major mammography technology on the market⁵.

Establishing a clinical performance reference for DBT without AI

The Institute's CDR and recall rate statistics are highlighted in the reference study table below, while DBT screening performance data in the US recently highlighted in 2023 research are also noted in the adjacent table below, establish a baseline performance measure. These CDR and recall rates align with broadly reported CDR and recall rates across mammography vendors in the United States. One study is based on robust data from the Breast Cancer Surveillance Consortium, which has served as a representative benchmark for mammographic facilities and interpreting radiologists since 2006⁶. An additional study reflects a large cohort of women across the U.S., making it another potential resource for comparisons⁷.

Most recent large studies reporting screening metrics for DBT in the US:

Reference study:

	Lynn Women's Health and Wellness Institute at Boca Raton Regional Hospital Baptist Health South Florida DBT breast screenings (March 1, 2018 to Feb. 29, 2020) ³
CDR/1,000	5.77
Recall Rate %	6.97

	Lee CS, Moy L. et al. "New Screening Performance Metrics for Digital Breast Tomosynthesis in U.S. Community Practice from the Breast Cancer Surveillance Consortium". Radiology, 2023 ⁶	Conant EF, Talley MM, Parghi CR, et al. "Mammographic screening in routine practice: multisite study of digital breast tomosynthesis and digital mammography screenings". Radiology, 2023 ⁷
CDR/1000,	5.8	5.3
Recall Rate %	8.3	8.9

Another step forward

Even though the Institute's CDR of 5.77 and recall rate of 6.97 align with broadly reported CDR and recall rates across mammography vendors in the United States, Dr. Schilling believed there was still a potential to leverage AI to improve cancer detection rates even further at her facility. In 2020, the Institute moved to AI-enhanced digital breast tomosynthesis by integrating iCAD's ProFound AI[®] Detection for DBT with GE HealthCare's Senographe Pristina Mammography system.

ProFound AI[®] Detection for DBT is a high-performing, deep-learning software developed by iCAD that rapidly analyzes 3D images to help detect malignant soft tissue densities and calcifications. Trained with one of the largest available 3D image datasets, ProFound AI[®] Detection for DBT provides radiologists with crucial information, such as lesion Certainty of Finding and Case Scores, which assists in prioritizing caseloads and in clinical decision-making.⁸

Does AI support improved cancer detection?

To evaluate the impact of AI-assisted technologies, the Institute conducted its own retrospective evaluation: "Real-world breast cancer screening performance with digital breast tomosynthesis before and after implementation of an artificial intelligence detection system."⁹

The observational study represents more than 103,000 DBT screenings from March 2018 to February 2022. The exams were performed with 11 GE HealthCare Senographe Pristina Mammography systems at three hospital-based ambulatory outpatient centers and with a mobile mammography van. Readings and interpretations were completed by nine Mammography Quality Standards Act (MQSA) certified, dedicated breast radiologists

with an average of 22 years of experience. The study compared approximately 54,000 screenings before the implementation of AI with 48,000 screenings after the adoption of ProFound AI[®] Detection for DBT.

	Date	Volume	Cancers
Pre-AI	3/1/2018 - 2/29/2020	54,440	383
Post-AI	3/1/2020 - 2/28/2022	48,742	399

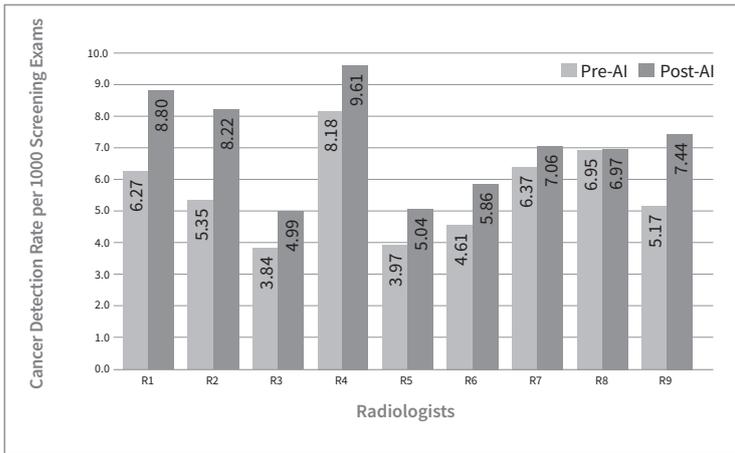
Results: Real-world breast cancer screening performance with digital breast tomosynthesis before and after implementation of an artificial intelligence detection system.

Performance measure	Pre-AI	Post-AI	Difference relative	p Value
CDR/1000	5.77	7.08	↑ 23%	0.0047
Recall rate %	6.97	6.96	↓ <1%	0.4696
PPV1 %	8.28	10.17	↑ 23%	0.0031
Sensitivity %	81.98	86.47	↑ 5%	0.0523
Specificity %	93.56	93.70	↑ <1%	0.1854

AI has a strong impact on cancer detection rates

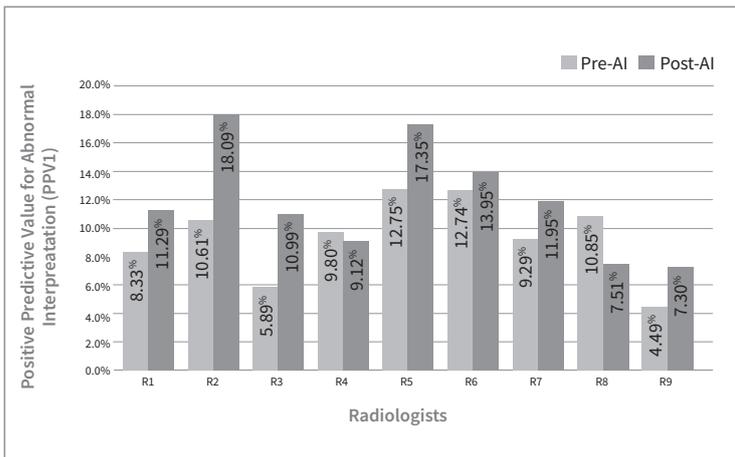
The CDR increased for all radiologists when utilizing AI. There was a statistically significant increase of 23 percent in the pooled cancer detection rate when utilizing AI, and it was achieved without a rise in false positives or unnecessary recalls.

Cancer detection rate: Pre-AI and Post-AI for each radiologist



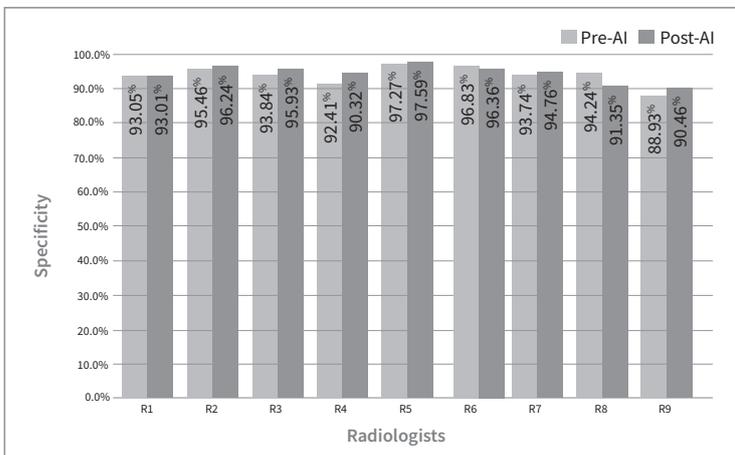
The study indicates that the Institute's pooled cancer detection rate of 5.77 saw a statistically significant increase of 23% ($p=0.0047$).

Positive predictive value for recall (PPV1): Pre-AI and Post-AI for each radiologist



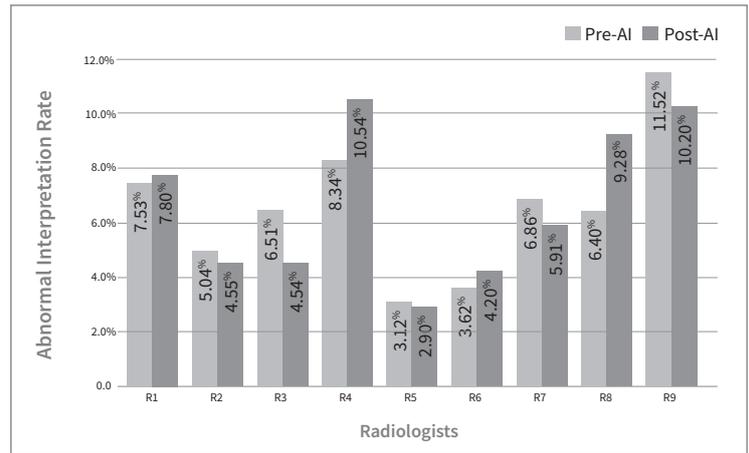
The study indicates that the Institute's pooled PPV1 of 8.28 saw a statistically significant increase of 23% ($p=0.0031$).

Specificity: Pre-AI and Post-AI for each radiologist



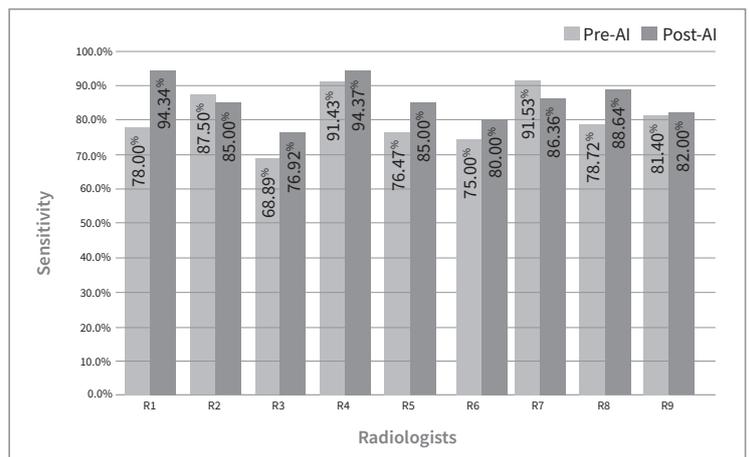
The study indicates that the Institute's pooled specificity showed no statistically significant change ($p=0.1854$).

Abnormal interpretation rate (recall): Pre-AI and Post-AI for each radiologist



The study indicates that the Institute's recall rate increased for 4 radiologists and decreased for 5, and there was no statistically significant change in the pooled recall rate ($p=0.4696$).

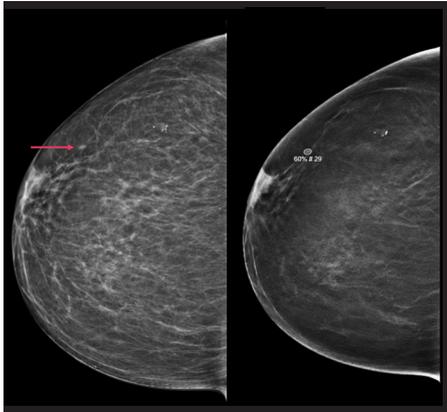
Sensitivity: Pre-AI and Post-AI for each radiologist



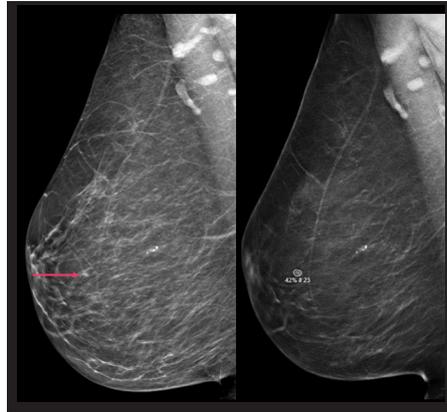
Although the Institute's pooled sensitivity of 81.98% increased by 5%, this increase was not statistically significant, with $p=0.0523$ slightly larger than $p=0.05$. Along with a statistically significant 23% increase in pooled cancer detection rate ($p=0.0047$), this 5% increase in pooled sensitivity is likely to be clinically significant.

Leveraging AI to identify small, clinically-relevant, breast cancers

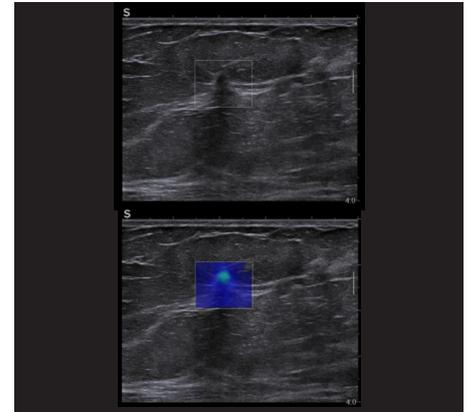
Dr. Schilling explains that the AI-powered software refocuses radiologists to detecting smaller cancers that may have otherwise gone undetected.



Case Score: 78%
Lesion Score: 60%

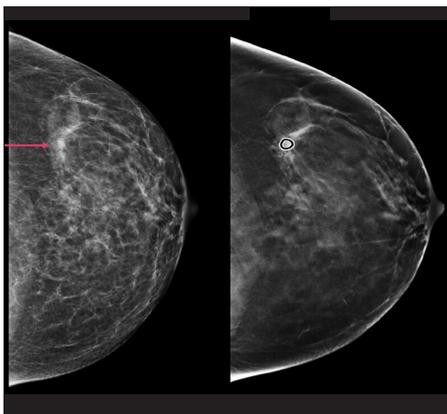


Case Score: 78%
Lesion Score: 42%

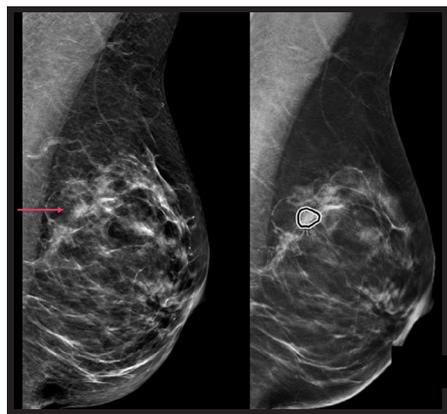


3mm Invasive Lobular Carcinoma ER+,
PR+, Her2-

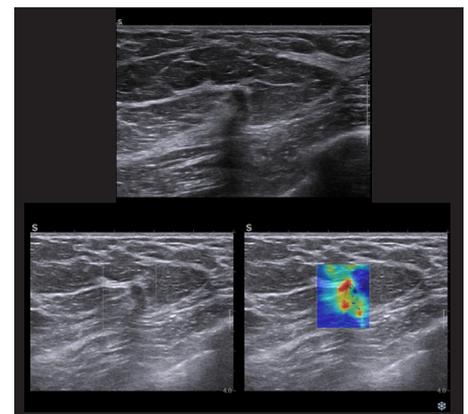
ProFound AI® Detection for DBT helped radiologists at Lynn Women's Health and Wellness Institute diagnose an invasive lobular carcinoma as small as 3 millimeters in size. The software flagged a suspicious area that later presented as a small, solid mass with a malignant appearance during targeted ultrasound.



Case Score: 88%
Lesion Score: 31%



Case Score: 88%
Lesion Score: 71%



IDC and DCIS grade 2

ProFound AI® Detection for DBT highlighted suspicious areas in these DBT mammograms. The patient subsequently had a targeted ultrasound exam, which identified a small, solid mass with epigenic rim and edge shadowing. It was later identified as an IDC and DCIS.

Conclusion

The study: "Real-world breast cancer screening performance with digital breast tomosynthesis before and after implementation of an artificial intelligence detection system" supports the use of AI in a DBT screening program. The Lynn Women's Health and Wellness Institute's clinical performance with Senographe Pristina and without AI, was in line with the most recently published studies in the U.S. When using Senographe Pristina in conjunction with ProFound AI® Detection for DBT the Institute was able to increase

their CDR from 5.77 to 7.08 without a statistically significant change in false positives and recall. The Institute was also able to increase PPV1 without a rise in false positives or unnecessary recalls. As a result, artificial intelligence offers new opportunities to enhance accuracy and increase efficiencies. This could reduce some of the daily burdens impacting breast radiologists, while providing certainty and peace of mind and improving patient outcomes.

References

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