

Breast Suite

Evidence Book

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Summary of Evidence

1. Categorical AI improves general and specialist radiologist performance

- **Improves general and specialist radiologist performance¹**

ProFound Pro aided all radiologists, including general radiologists, in improving to the level of specialists.

2. Low false negative rate in multi-site deployment

- **Clinically proven sensitivity at scale²**

True positive rate of ProFound Pro was 96% across an evaluation of more than 610,000 patients.

3. Robust and accurate AI algorithm

- **ProFound Pro algorithm showed robust performance³**

In a multinational standalone study, the algorithm showed 14% higher sensitivity compared to breast experts in a reader study.

4. Breast Suite shows excellent clinical performance across population subgroups

- **Equitable benefits for all patients at scale⁴**

ProFound Pro + Safeguard Review improved cancer detection rate by 21% in a study of over 575,000 patients, showing the same benefits across racial subgroups and patients with different breast densities.

5. Breast Suite helps detect aggressive breast cancers

- **Improves diagnosis of aggressive breast cancers⁵**

ProFound Pro + Safeguard Review increased the rate of diagnosing aggressive breast cancers by 49%.

6. Fellowship-trained screening performance for all radiologists with Breast Suite

- **ProFound Pro + Safeguard Review improves CDR and PPV for generalists⁶**

Improved the cancer detection rate of radiologists at scale by 33% and raised generalist radiologists to the performance of fellowship-trained breast imaging specialists.

[1] Kim et al. "[Impact of a Categorical AI System for Digital Breast Tomosynthesis on Breast Cancer Interpretation by Both General Radiologists and Breast Imaging Specialists](https://doi.org/10.1148/ryai.230137)." Radiology Artificial Intelligence. Mar 2024. <https://doi.org/10.1148/ryai.230137>

[2] Kim et al. "Towards Transparency: A Quantitative Evaluation of Mammography AI False Negatives in a Large Scale Multi-Site Clinical Deployment." RSNA, Chicago. 2022.

[3] Lotter et al. "[Robust breast cancer detection in mammography and digital breast tomosynthesis using an annotation-efficient deep learning approach](https://doi.org/10.1038/s41591-020-01174-9)." Nat Med. Feb 2021. <https://doi.org/10.1038/s41591-020-01174-9>

[4] Louis et al. "National Deployment of AI-driven Workflow has Equitable Impact in Breast Cancer Screening in Diverse and Increased Risk Populations". Nature Health. Nov 2025.

[5] Louis et al. "Large-scale deployment of a multistage AI-driven workflow increases detection of deadlier breast cancers" RSNA, Chicago. 2025.

[6] McCabe et al. "Multistage AI-Driven Workflow Improves General Radiologist Screening Mammography Performance to the Level of Fellowship-Trained Breast Imagers: Real-world Evidence in >500,000 Patients" RSNA, Chicago. 2025.

Categorical AI improves general and specialist radiologist performance¹

Intro

We evaluated the performance of general and specialist radiologists reviewing Digital Breast Tomosynthesis (DBTs) with a custom-built artificial intelligence (AI) system.

Methods

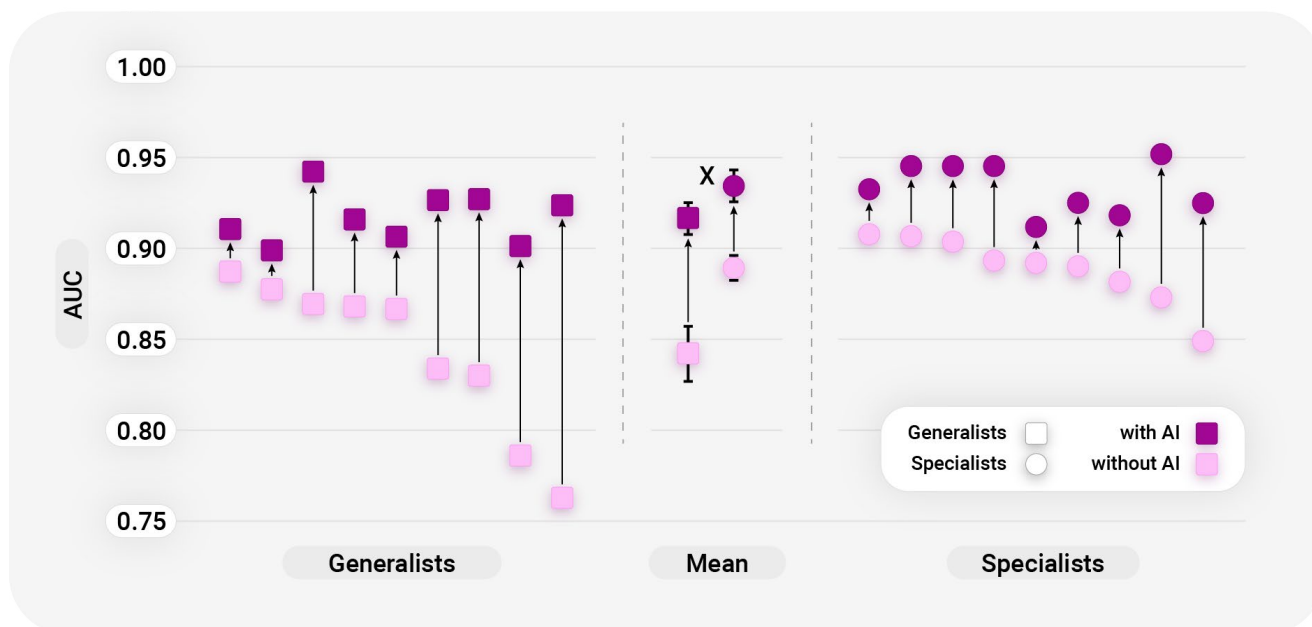
A reader study of 18 radiologists (9g, 9s) involved reading 240 DBT mammograms with and without an AI system.

Results

All radiologists reported improved Area Under the Curve (AUC) performance (avg: 0.93 vs 0.87, $p < 0.001$) with greater improvement for generalists (0.08, $p < 0.001$) than specialists (0.04, $p < 0.001$). Improvements were also observed for all cancer characteristics and patient subgroups.

Conclusion

The AI system improved radiologist performance of DBT screening mammograms for both general and specialist radiologists across patient subgroups and breast cancer characteristics.



[1] Kim et al. "Impact of a Categorical AI System for Digital Breast Tomosynthesis on Breast Cancer Interpretation by Both General Radiologists and Breast Imaging Specialists." Radiology Artificial Intelligence. Mar 2024.
<https://doi.org/10.1148/ryai.230137>

Low false negative rate in multi-site deployment²

Intro

AI-enabled screening of mammograms can improve radiologist performance, but it is unclear how often the AI misses cancers. Here we review the false negative rate of a multi-site deployment of ProFound Pro.

Methods

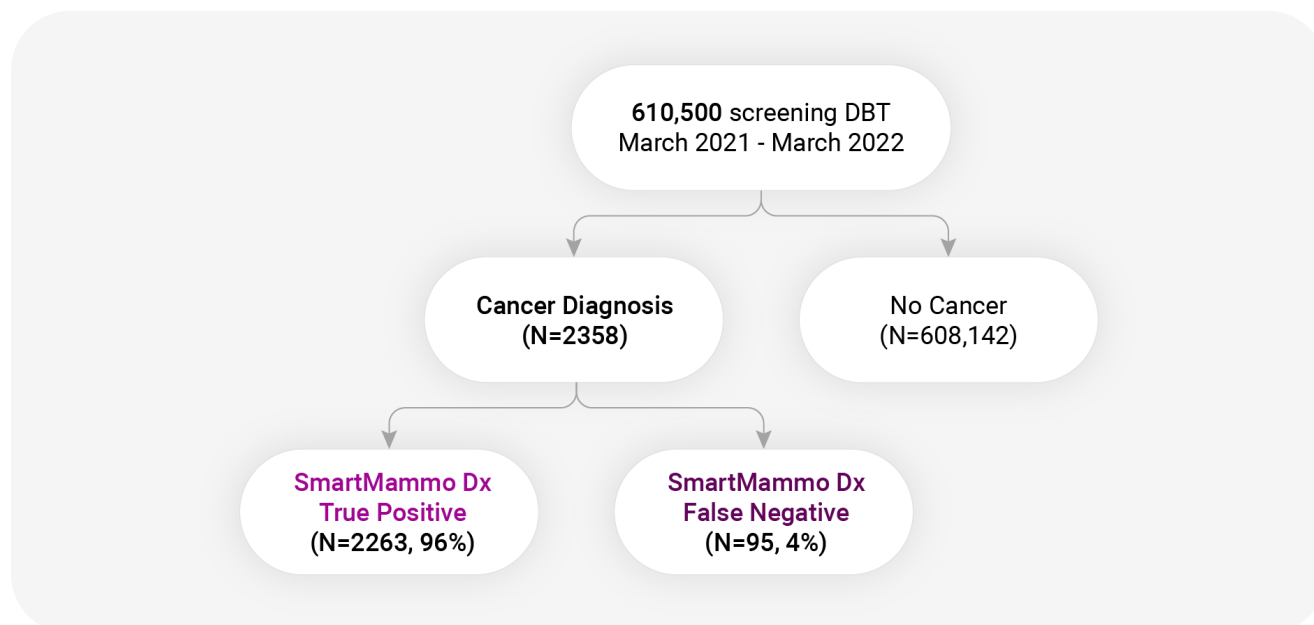
610,500 exams were obtained over a 12-month period from over 190 clinical sites. In this cohort 2,358 exams were confirmed cancers. The cancerous exams and demographics were extracted, and the AI predictions were reviewed against clinical diagnosis.

Results

96% (n = 2,264) of cancers were correctly flagged by the AI as suspicious. Race and ethnicity were similar between false positives and true positives. The top 3 reasons identified for false negatives were: 'Subtle lesion' (27%), 'Not seen on mammogram' (18%) and 'Need priors' (16%).

Conclusion

In a large prospective study, ProFound Pro reported a low false negative rate.



[2] Kim et al. "Towards Transparency: A Quantitative Evaluation of Mammography AI False Negatives in a Large Scale Multi-Site Clinical Deployment." RSNA, Chicago. 2022.

Robust and accurate AI algorithm³

Intro

We developed a deep-learning algorithm that achieves state of the art performance in mammogram classification.

Methods

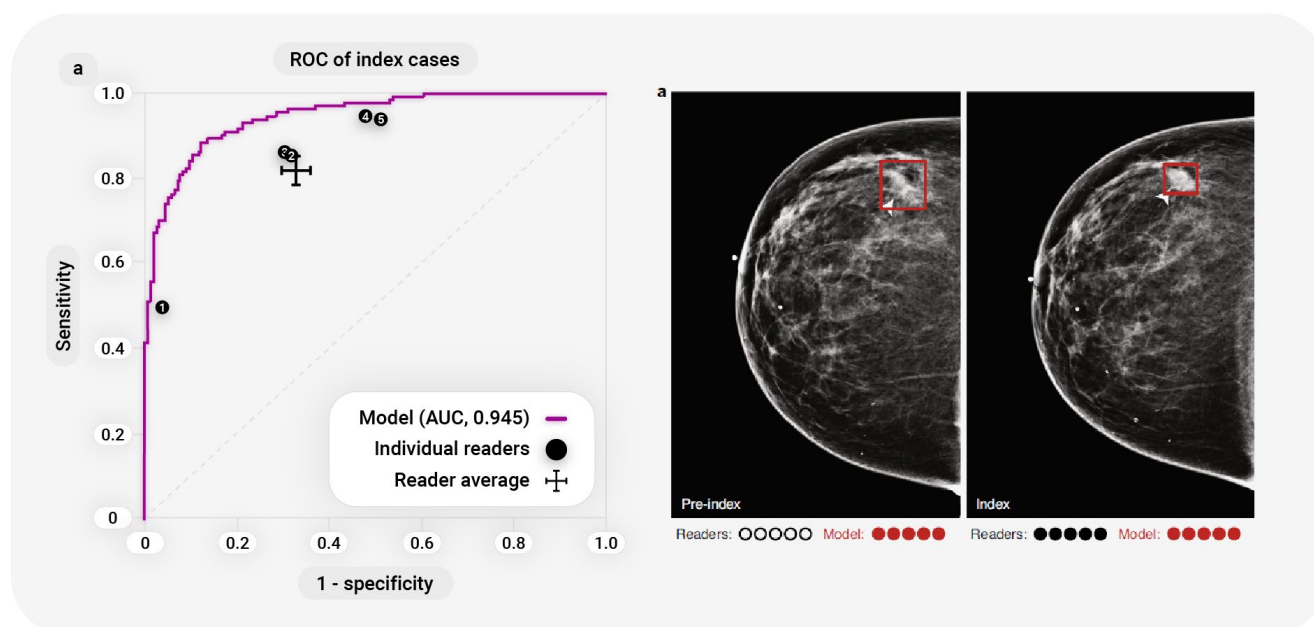
Two public datasets and 6 research sites contributed data to train, validate, and test our AI models. Outputs of the models were suspicion levels and bounding boxes for suspicious lesions (Figure below). The model was compared to 5 readers in a reader study of 131 index cancers and 154 confirmed negatives.

Results

The AI model reported an Area Under the Curve (AUC) of 0.945 and outperformed all radiologists with a sensitivity 14% higher than the average radiologist sensitivity.

Conclusion

The AI algorithm showed robust and generalizable performance often detecting cancer the year before clinical diagnosis, demonstrating that artificial intelligence can improve the diagnostic accuracy of mammography.



3] Lotter et al. "Robust breast cancer detection in mammography and digital breast tomosynthesis using an annotation-efficient deep learning approach." Nat Med. Feb 2021. <https://doi.org/10.1038/s41591-020-01174-9>

Breast Suite shows excellent clinical performance across population subgroups⁴

Intro

Concern remains about efficacy of AI in screening mammography in racial subgroups. Here we investigated the impact of ProFound Pro + Safeguard Review on a large and diverse cohort.

Methods

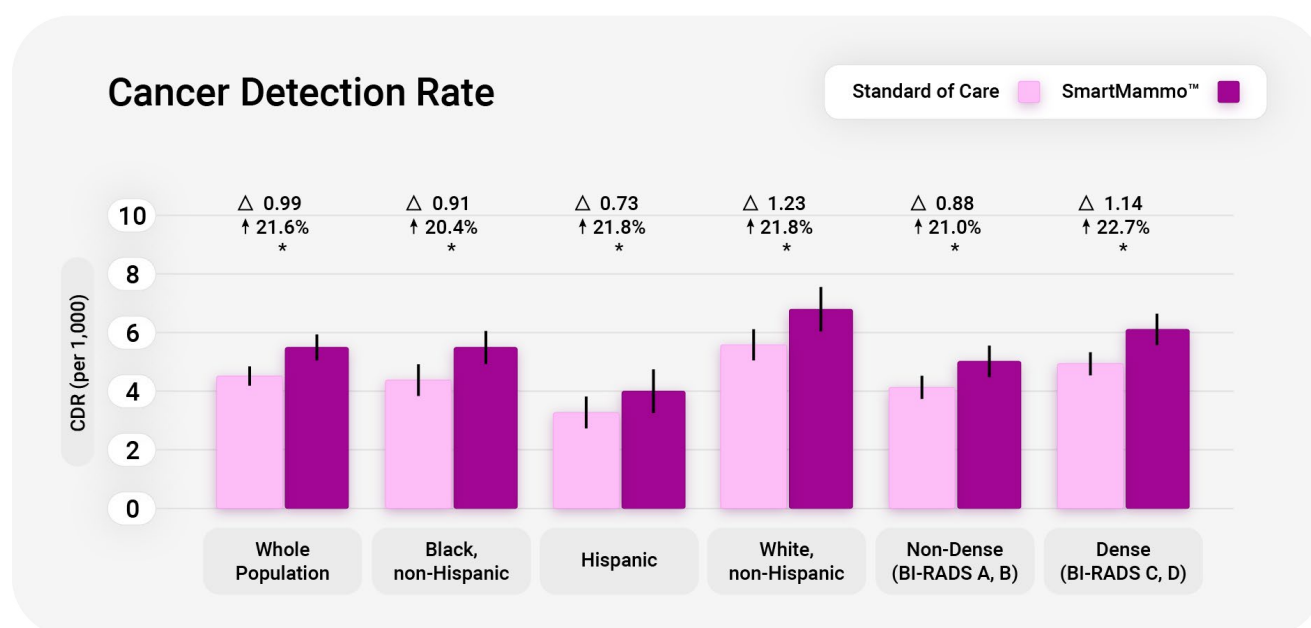
579,883 exams across 109 sites in the US were reviewed (208,891 received EBCD). Demographics and clinical outcomes were recorded. Recall Rate (RR) and Cancer Detection Rate (CDR) were calculated for whole population and racial and ethnicity subgroups.

Results

All subgroups experienced a CDR increase (20–23%) with the whole population CDR increasing by 21%. RR also increased by a modest amount of 5-9%. No difference was observed between subgroups.

Conclusion

Use of ProFound Pro + Safeguard Review resulted in improved clinical outcomes for whole population and all density, race, and ethnicity subgroups. There was no evidence of differences in performance for population subgroups.



[4] Louis et al. "National Deployment of AI-driven Workflow has Equitable Impact in Breast Cancer Screening in Diverse and Increased Risk Populations". Nature Health. Nov 2025.

Breast Suite helps detect aggressive breast cancers⁵

Intro

Concerns remain over the types of cancer identified by AI algorithms in screening mammograms. Here we reviewed cancers identified by the AI-enabled review process, ProFound Pro + Safeguard Review.

Methods

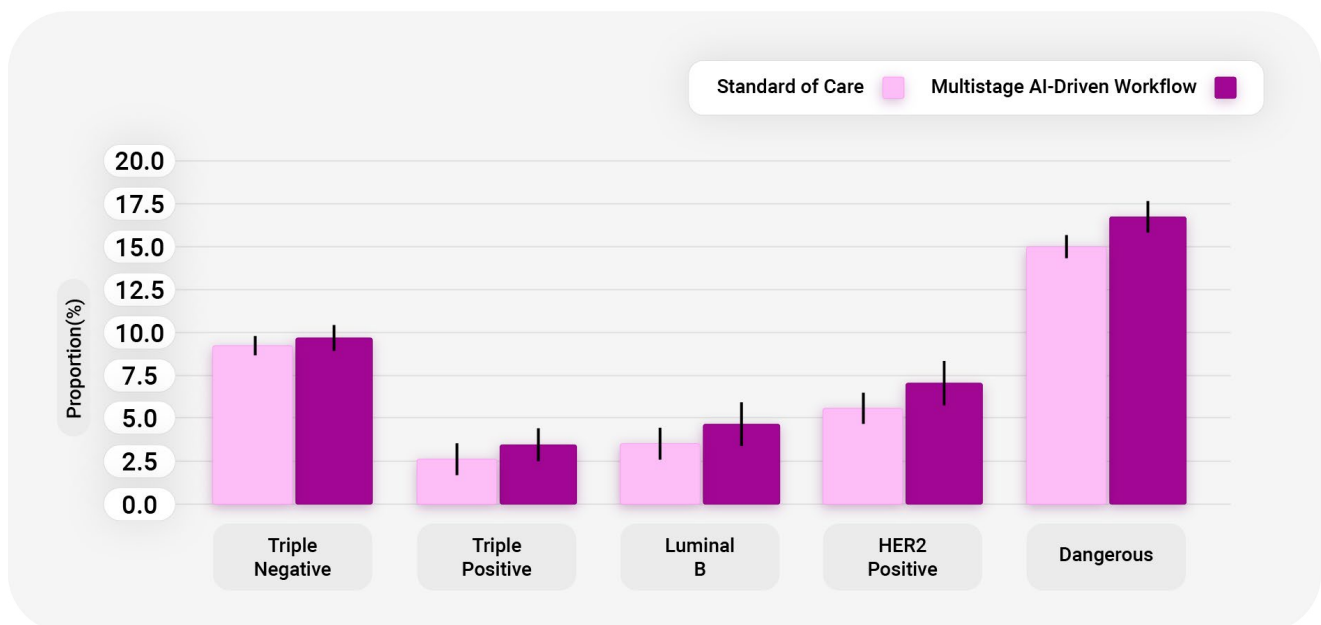
In a review of 2,454 cancers found during standard of care (SOC) (n=1491) and with the AI workflow (n=963), the distribution of grade and subtypes (ER, PR, HER2, triple negative, and Luminal B) were compared between the groups.

Results

The majority of cancers detected with the SOC and AI-driven workflow were intermediate or high grade (80.6% SOC, 80.7% AI). No differences were found in the distribution of cancer type, grade or invasiveness ($p>0.05$) between cohorts. Accounting for the 21.6% CDR increase from prior work, an estimated 20 additional dangerous cancers were found.

Conclusion

More clinically relevant cancers were detected without increasing the proportion of DCIS diagnoses. This shows that the AI-driven workflow investigated here increases the benefits of screening mammography without increasing potential harms.



[5] Louis et al. "Large-scale deployment of a multistage AI-driven workflow increases detection of deadlier breast cancers." RSNA, Chicago. 2025.

Fellowship-trained screening performance for all radiologists with Breast Suite⁶

Intro

Up to 70% of screening mammograms are read by generalist radiologists. Although training is expensive and time consuming, AI may be leveraged to assist radiologists immediately. We investigated the impact of ProFound Pro + Safeguard Review on screening performance for both generalist and fellowship-trained breast imaging specialist radiologists.

Methods

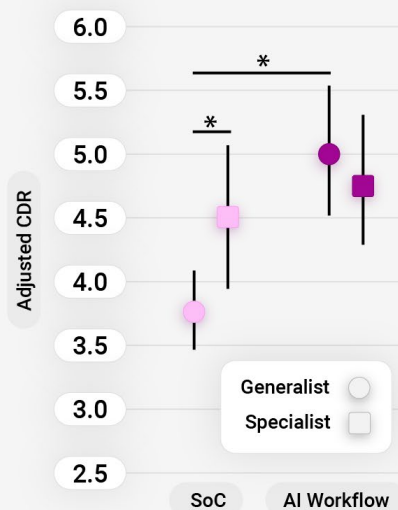
In a review of 579,583 exams (365,811 standard interpretation, 211,931 with Breast Suite) and 96 radiologists (60 generalists, 35 specialists), the cancer detection rate (CDR), recall rate (RR), and positive predictive value of recalls (PPV) were compared between groups.

Results

On average, radiologists improved CDR by 33%. The generalists showed a greater improvement, reaching the level of specialists. PPV also increased in generalists by 15% to the level of specialists, and absolute RR increased by 1.3%. PPV and RR in specialists did not change.

Conclusion

The ProFound Pro + Safeguard Review multistage AI-driven workflow substantially improved CDR and PPV for generalists, allowing them to perform on par with breast imaging specialists.



[6] McCabe et al. "Multistage AI-Driven Workflow Improves General Radiologist Screening Mammography Performance to the Level of Fellowship-Trained Breast Imagers: Real-world Evidence in >500,000 Patients" RSNA, Chicago. 2025.

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