Determining Efficacy of Concurrent CAD for Digital Breast Tomosynthesis (DBT)

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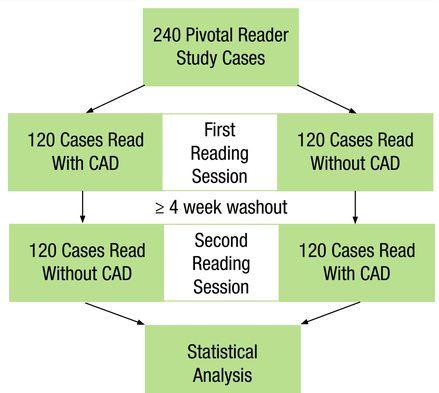
INTRODUCTION

- DBT has been shown to improve tissue visualization and cancer detection compared to 2D FFDM, but interpretation time may be twice as long [(1-4)].
- DBT concurrent read CAD (iCAD Inc., NH USA) is used at the beginning of the interpretation session and used throughout, unlike traditional 2D second read CAD.
- Co-primary objectives:
  - To assess radiologist performance in reading DBT, with and without CAD.
  - To evaluate influence of CAD on DBT interpretation time.

MATERIALS AND METHOD

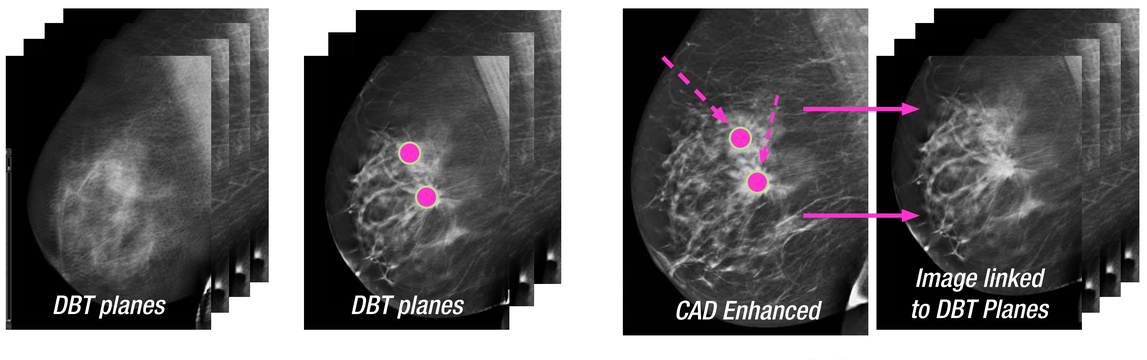
- 2 retrospectives studies :
  - PILOT study : 6 radiologists and 80 cases.
  - PIVOTAL study : 20 radiologists and 240 cases.
- Multi reader – multi case (MRMC) cross-over design reader studies.
- With CAD, the radiologist initially views the lesion on 2D projection then navigates directly to the DBT plane for characterization.



Cross over design for the pivotal study

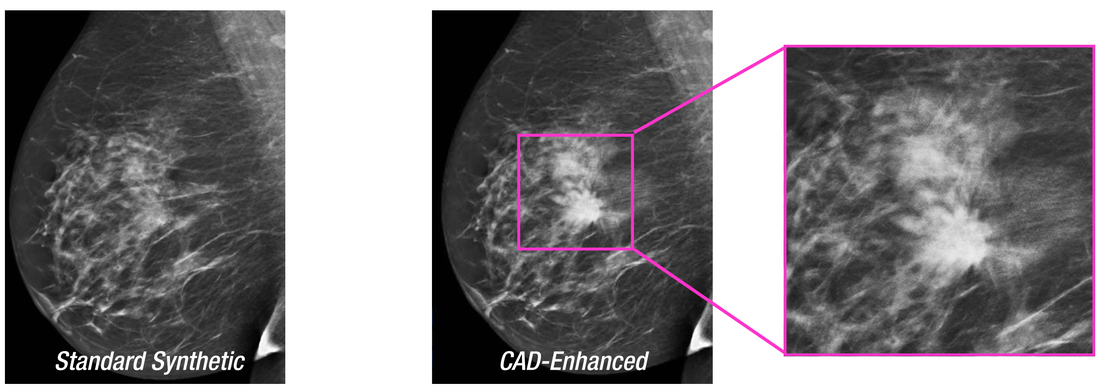
HOW DOES TOMO CAD WORK?

- The CAD system detects and extracts suspicious masses, architectural distortions and asymmetries from 3D DBT planes and blends them into the corresponding 2D synthetic image. (Calcification detection and analysis are excluded.)

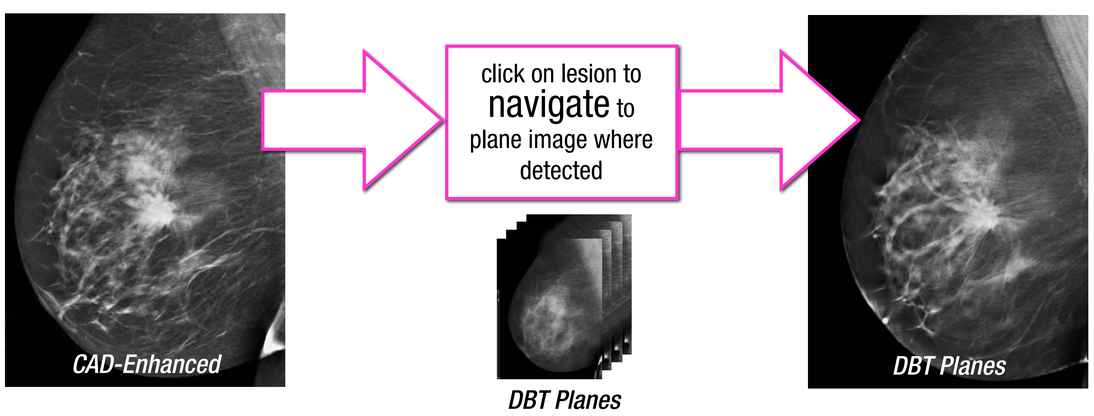


Input images | Suspicious regions detected on the DBT planes | Creation of CAD-Enhanced Synthetic Image

1. DETECT



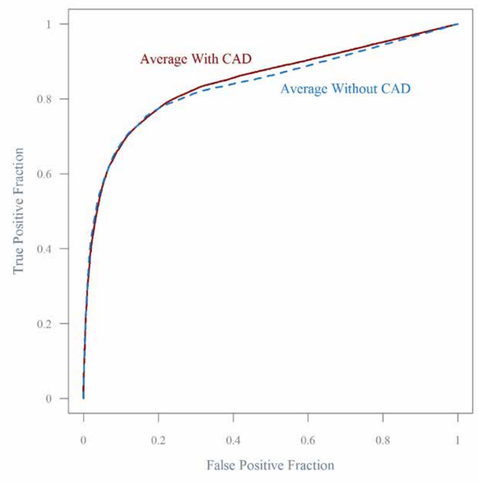
2. NAVIGATE



DBT Concurrent CAD does not use “marks” to highlight regions of interest.

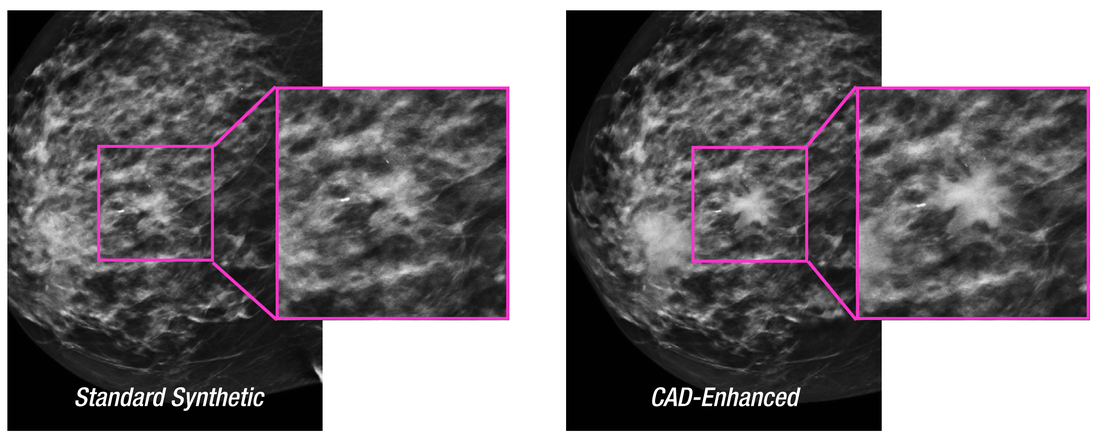
RESULTS FOR PILOT AND PIVOTAL STUDIES

STUDY RESULTS		
CATEGORY	PILOT	PIVOTAL
Total Number of Cases	80	240
# Malignancies / cancer patients	23 / 21	67 / 60
Total Number of Readers	6	20
# Breast Imaging Radiologists	5	9
Performance with vs without CAD	Non-inferior	Non-inferior
Reading time improvement	23.5%	29.2%



Average of Empirical ROC Plots without and with CAD for pivotal study

- 50% of malignant soft tissue densities visible on standard synthetic image.
- >90% of malignant soft tissue densities visible on CAD-enhanced synthetic image.



- No change in radiologist performance for detection of cancers by measurement of AUC.
  - Average AUC increased by 0.007 (95% CI: -0.013, 0.028; non-inferiority $p < 0.01$ for non-inferiority margin 0.05), from 0.839 without CAD to 0.846 with CAD.
- Slight non-statistically significant changes in radiologist sensitivity and specificity with CAD.
  - 2.3% increase in sensitivity (95% CI: -0.6%, 5.3%), from 84.7% without CAD to 87.0% with CAD.
  - 1.8% decrease in specificity (95% CI: -4.1%, 0.5%).
- 29.2% statistically significant reduction in radiologist reading time (95% CI: 21.1%, 36.5%; $p < 0.01$).

CONCLUSION

- > 90% sensitivity in detecting malignant soft tissue densities.
- 40% more malignant soft tissue densities visible on synthetic image enhanced with CAD vs without CAD.
- Average 29.2% reduction in DBT reading time while maintaining high DBT reader sensitivity, specificity, and AUC.

Concurrent use of CAD maintains performance of DBT with significant reduction in reading time.

(1) McDonald et al. 2016; (2) Bernardi et al. 2012; (3) Skaane et al. 2013; (4) Dang et al. 2014