

Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM-2): a population-based prospective study

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## **Objective**

The goal of this population-based prospective study was to determine if there would be an increase in breast cancer detection with the use of 3D MAMMOGRAPHY™ exams with either a conventional 2D mammogram or with a generated 2D mammogram compared to a 2D mammogram alone. The study also evaluated the reduction of radiation exposure with the combination of 3D MAMMOGRAPHY™ technology and a generated 2D image.

## **Materials and Methods**

The first STORM study, published in 2013, is the basis for the STORM-2 study. The STORM-2 study enrolled asymptomatic women 49 years of age and older. The participants were screened with both 2D and 3D<sup>™</sup> mammographic acquisitions (including 2D and C-View<sup>™</sup> software). Each patient examination was a single breast positioning and compression per view in both cranio-caudal (CC) and mediolateral oblique (MLO) views. Two double-readings were conducted with a review of the 2D only mammogram and then each of the combined 3D<sup>™</sup> exam studies. The Hologic Selenia<sup>®</sup> Dimensions<sup>®</sup> with C-View<sup>™</sup> software was the mammography system utilized.

## **Results**

The combination of  $3D^{\mathbb{M}}$  acquisition with a conventional 2D exposure or a generated 2D image detected more cases of breast cancer than a 2D examination alone. The table represents the results for the 2D alone and the combinations of  $2D+3D^{\mathbb{M}}$  and  $3D^{\mathbb{M}}$  exams with generated 2D images.

	Screening Exams Performed	Cancers/1000	Cancer increase vs. FFDM	Invasive cancers/ 1000	Invasive Cancer Increase vs. FFDM	Recall Positive Predictive Value (PPV1)
FFDM	9672	6.3		4.8		16%
Combo mode	9672	8.5	35%	8.4	76%	18%
TomoHD mode	9672	8.8	40%	8.7	83%	17%

## Conclusion

The study demonstrated significantly improved breast cancer detection with Combo mode and TomoHD mode versus 2D imaging alone. Utilizing a generated 2D image plus 3D MAMMOGRAPHY™ technology offers comparable effectiveness while also reducing the radiation dose when compared to a study that acquires both the conventional 2D and 3D™ mammogram.

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