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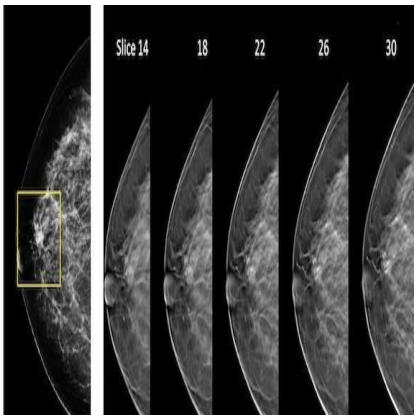
Hologic's Breast Tomosynthesis Reduces Recall Rates and Improves Cancer Detection - U.S. Study



Hologic has announced that the first large-scale observational study in a U.S. clinical practice comparing breast cancer screening with Hologic's 3D mammography technology (breast tomosynthesis) with conventional 2D mammography alone showed a significant reduction in recall rates and a sizeable increase in cancer detection, particularly invasive cancer, across all breast tissue densities. Published in the June issue of the American Journal of Roentgenology (AJR), the study evaluated recall, biopsy, cancer detection and invasive cancer detection rates in a community-based breast imaging practice. The study was issued online in advance of print on May 23, 2013.

The study, "Implementation of Breast Tomosynthesis in a Routine Screening Practice: An Observational Study" was led by Stephen L. Rose, M.D., President and Founder of Rose Imaging, Medical Director of TOPS Comprehensive Breast Center, and Breast Radiologist affiliated with Memorial Hermann Health System in Houston, Texas. The analysis compared the outcomes of 2D mammography screening exams that were interpreted prior to the introduction of Hologic's 3D mammography, with screening exams after the introduction of 3D mammography into the practice.

The Rose study found that the use of Hologic's 3D mammography resulted in:

- A significant 38% drop in recall rates – from 8.7 percent to 5.5 percent ($p < 0.001$)
- An 11 percent drop in biopsy rates - from 15.2 to 13.5 per 1,000 screenings ($p = 0.59$)
- A 35 percent increase in cancer detection rates - from 4.0 to 5.4 per 1,000 screenings ($p = 0.18$)
- A 53 percent increase in invasive cancer detection rates - from 2.8 to 4.3 per 1,000 screening examinations ($p = 0.07$)

The study population included 13,856 women who had received conventional 2D mammography screening exams and 9,499 women who elected to receive a Hologic 3D mammography screening exam. The images were interpreted by one of six radiologists with an average 12 years of reading experience.

"The findings in the Rose paper demonstrate that Hologic 3D mammograms overcome many of the limitations of conventional mammography, namely missed cancers and unnecessary recalls," said Peter Soltani, Hologic Senior Vice President and General Manager, Breast Health. "The use of this groundbreaking technology when performing a screening exam allows radiologists to see distortions of the breast tissue in greater detail than with 2D mammography alone. This results in earlier detection of cancers when they are easier to treat and a reduction in false positives that may look worrisome on conventional digital mammography."

The Rose study is the first large U.S. breast cancer screening trial to report its results in a peer-reviewed journal. The findings are consistent with and supplementary to the Oslo Tomosynthesis Screening Trial which was published in Radiology (online in advance of print January 7, 2013 and in print on April 4, 2013) and the Screening Tomosynthesis or Mammography (STORM) trial in Italy which was published in The Lancet Oncology (online in advance of print April 25, 2013).

Hologic's 3D mammography technology has been approved for use in countries recognizing the CE mark since 2008. It was approved for use in the U.S. for breast cancer screening and diagnosis in February, 2011. Hologic systems are now in use in 48 states in the U.S. and over 50 countries.

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