

# ABUS shown to improve cancer detection in women with dense breasts

The addition of Automated Breast Ultrasound (ABUS) to screening mammography showed a significant increase in cancer detection with a nominal insignificant decrease in specificity, according to a study that has been published in the *American Journal of Roentgenology* (DOI:10.2214/AJR.15.15367).

The objective of the study, titled “Automated Breast Ultrasound in Breast Cancer Screening of Women with Dense Breasts: Reader Study of Mammography-Negative and Mammography-Positive Cancers,” was to assess and compare radiologists’ performance in the detection of breast cancer using full-field digital mammography (FFDM) alone and using FFDM with 3D ABUS. Reader performance was compared in terms of area under the ROC curve, sensitivity, and specificity.



“This was a clinical reader study conducted on women with dense breasts, and it showed that readers were able to statistically detect more cancers with the addition of ABUS than with conventional mammography alone. The results are particularly important in that the study showed a significant

increase in detection performance (in terms of AUC) in both mammography-negative cases and a significant increase in the mammography-positive cancers,” said Maryellen Giger, Ph.D., Professor of Radiology at the University of Chicago.

Results showed that for cancers originally missed with mammography in women with dense breasts, the addition of ABUS demonstrated a relative increase in sensitivity of 62 percent. For cancers originally missed by mammography that had no prior breast interventions, the addition of ABUS demonstrated a relative increase in sensitivity of 110 percent. Results showed a modest decline in specificity with the addition of ABUS.

“Our results suggest that for women with dense breasts who undergo screening mammography and are told that no abnormality is found, they may want to undergo supplemental imaging, such as ABUS,” Dr Giger added.

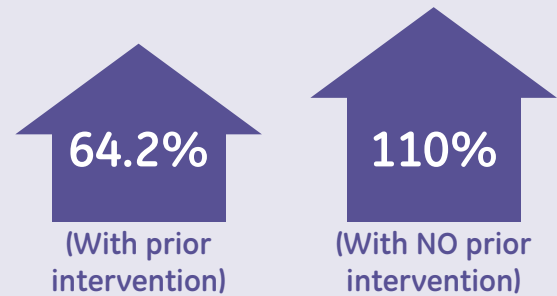
A robust reader training program was instituted with this study, highlighting the importance of quality assurance and quality control efforts and multiplanar interpretation to help minimize false-positives. Based on the results of the study, authors conclude that the ABUS technique allows standardization and reduces operator dependence, which may result in a more efficient integration of ultrasound into the screening workflow environment.



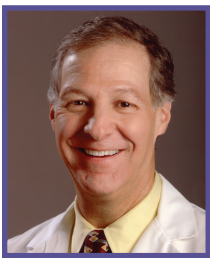
## Cancer Detection Summary

	FFDM	FFDM + ABUS	Change with ABUS	Relative change
AUC	0.72	0.82	0.10	14%
Sensitivity	57.5%	74.1%	16.6%	29%
Specificity	78.1	76.2	-1.9	-2.4%

## Mammographically Occult Cancer Detection Relative Sensitivity Increase



Minor decrease in specificity was not statistically significant



“With disruptive technologies like ABUS, training is very important. Not as it relates to sensitivity, as clinicians generally know what a cancer looks like on ultrasound, but as a means of reducing callbacks and getting comfortable with identifying normal results on an ABUS exam. We have to expect some increase in callbacks when we add imaging tools to the screening process, but it is also reasonable to expect the increase to be proportional to the increase in cancer detection,” said Marc Inciardi, MD, Section Head, Breast Imaging, University of Kansas Medical Center, Kansas City.

## Increased Detection of Invasive Cancers

This multi-reader, multi-case Reader Study was used as the basis for the GE Healthcare ABUS system’s Pre-Market Application (PMA) approval from the FDA. ABUS technology from GE Healthcare is the only ultrasound device approved by the U.S. FDA for screening women with dense breasts. This system was developed specifically for dense breast imaging to help find cancer that may be missed by mammography, and is also approved for diagnostic use.

Data for the Reader Study was generated through the sub-analysis of cases accumulated during the prospective Somolnsight study, which showed a 55% relative increase in invasive cancers over mammography alone in dense breasted women when Invenia™ ABUS is used in conjunction with mammography (in patients with no prior breast interventions). This, according to the study authors, suggests positive implications for potential detection, treatment and prognosis in patients with dense breasts.

Results of the study, “Assessing Improvement in Detection of Breast Cancer with Three-Dimensional Automated Breast Ultrasound in Women with Dense Breast Tissue: The Somolnsight Study,” were published in Radiology (DOI: 10:1148/radiol.14132832).



# Multi-Modality Screening Protocol for Women with Dense Breasts

As the healthcare system in the United States moves closer to achieving personalized medicine, there is a clear need for customizing breast care based on a woman's individual risk factors. One size does not fit all as evidenced by the limitations of mammography, particularly among women with dense breasts. It is prudent to suggest that clinicians employ an evidence-based approach to navigating through the supplemental imaging tools available for screening mammography.



"It used to be that 2D mammography was the only breast cancer screening game in town. Now that breast imagers have alternatives, it's incumbent on us to tailor screening regimens in order to maximize our chance of finding clinically significant cancers." This was the key take-away message from Dr. Joseph Russo, section

chief of women's imaging at St. Luke's University Health Network in Bethlehem, PA, when presenting a new algorithm for personalized breast cancer screening at the recent National Consortium of Breast Centers meeting (NCoBC 2016), as reported in a recent article in AuntMinnie.

Designed to help imagers decide how to personalize their approach, the screening protocol helps determine which women need what kind of screening, while also providing

patients and referring physicians with clear guidelines. According to Dr. Russo, personalized screening means taking a multimodality approach. In addition to 2D mammography, St. Luke's uses tools such as automated breast ultrasound (ABUS), digital breast tomosynthesis (DBT), and other modalities as adjuncts to screening.

Performing risk assessment on every patient, St Luke's screening protocol takes both patient risk and breast density into account. "The biggest difference in our protocol is a more liberal use of automated breast ultrasound. I find ABUS to be especially useful, not only in dense breast patients, but in patients who are both dense and cystic. ABUS allows the radiologist to discount a background of complicated cysts and focus on suspicious findings such as architectural distortion and potentially solid masses," he said.

The recent publication of the ABUS Reader Study bolsters a growing body of research that suggests that use of ABUS as a supplemental screening tool may provide optimization of sensitivity while reducing false positives. As a result, this combined approach may be an advantageous screening choice for the majority of women with dense breast tissue. "Personalized breast cancer screening isn't just a fanciful idea, but rather an imperative," concludes Dr. Russo.

## Sustained Cancer Detection Results with ABUS

"The clinical benefit of ABUS is finding the cancers that mammograms miss," noted Dr. Inciardi. The Somolnsight study cohort at the University of Kansas included some 1,700 patients and Dr Inciardi estimates that the UKMC local results demonstrated a 60% increase in the detection of additional cancers that were mammographically occult. Since subsequently incorporating ABUS breast screening into UKMC clinical practice, Dr Inciardi estimates they have done more than 1,200 exams since 2013. Despite a transition to 3D mammography, he reports that his practice's cancer detection rate of mammographic occult cancers has held steady between 2-3/1000.





## Imagination at work

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