



High-Resolution Breast PET Improves Breast Cancer Detection

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AT A GLANCE

- Positron emission mammography (PEM) improves breast cancer detection.
- PEM significantly improves ability to differentiate between benign and cancerous lesions.
- Combination of PEM and breast MRI dramatically increased number of suspicious lesions found.

San Diego – An NIH-sponsored, multi-year study of hundreds of women diagnosed with breast cancer found that Positron Emission Mammography (PEM) scanners significantly outperform MRI when differentiating between benign and cancerous lesions. The prospective study also found that the combination of PEM and breast MRI dramatically increases a physician's ability to detect potentially cancerous lesions over MRI alone, presenting a powerful combination for improving care. The findings released today mean that women and their physicians now have a better tool to help cure cancer.

PEM scanners are high-resolution breast PET systems that can show the location as well as the metabolic phase of a lesion. This information is critical in determining whether a lesion is malignant and influences the course of treatment. Other imaging systems, such as mammography and ultrasound, only show the location, not the metabolic phase. PEM scanners, which are about the size of an ultrasound system,

are made in San Diego by Naviscan, Inc. and have been commercially available since 2007.

The NIH study examined 388 women with newly-diagnosed breast cancers, and unlike previous studies on primary lesions, focused on additional or secondary tumors. Understanding the presence of additional tumors is critical to understanding if a lumpectomy or mastectomy is the right surgery. Researchers found that PEM scans accurately distinguished 151 of 189 benign additional lesions, an 80% success rate in what researchers call "specificity." When the same lesions were subject to MRI scans, the specificity dropped to just 66%.

The study also found that the most reliable way to identify lesions was to combine the two technologies. PEM and MRI scanning together saw an additional 31 (out of 116 total) lesions producing a 20% absolute increase in what researchers call "sensitivity" when compared to using MRI alone.

"We looked very carefully for additional cancers and were surprised that barely half of these were shown on MRI," said Wendie Berg, M.D., Ph.D. and Principal Investigator for the trial. "Clearly there is need for better surgical planning information. PEM significantly improved detection of additional disease over MRI alone."

The results validate PEM as an integral imaging tool in the surgical management of breast cancer, and as an alternative for the large number of patients who cannot tolerate breast MRI exams due to claustrophobia, patient comfort, pacemaker, metal implants, or other factors.

"This new technology, available to patients at more than 35 sites throughout the U.S. and internationally, represents a significant advance in the detection and treatment of breast cancer. Comprehensive breast cancer centers and existing imaging centers with MRI capability will benefit from the additional sensitivity and specificity provided by PEM," said Paul J. Mirabella, Chairman and CEO, Naviscan, Inc. "These exciting results, especially during Breast Cancer Awareness Month, will be welcomed news by patients and physicians."

Naviscan will provide additional information at the Radiological Society of North American meeting (RSNA 2009) in Chicago, November 29 – December 3.

This multi-site study (NIH Grant 5R44CA103102) examined women with newly-diagnosed breast cancer. Patients were accrued from six leading clinical centers across the country: ARS Johns Hopkins Green Spring, Boca Raton Community Hospital, Scripps Clinic-Scripps Green Hospital, University of North Carolina, University of Southern California Norris Cancer Center, and Anne Arundel Medical Center.

For more information or to arrange an interview with CEO Paul Mirabella, call 1.858.587.3641 or visit www.naviscan.com.

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About Naviscan, Inc.

Naviscan, founded in 1995, develops and markets compact, high-resolution PET scanners intended to provide organ-specific molecular imaging and guide radiological and surgical procedures. The Naviscan PET scanner is currently installed and available in breast and imaging centers throughout the U.S. and other parts of the world. The Company is headquartered in San Diego, California and is the first company to obtain FDA clearance for a high-resolution PET scanner designed to image small body parts and for breast biopsy image guidance.