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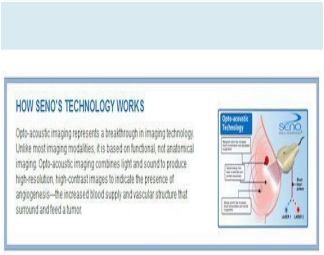
Data: Seno Medical Instruments' Imagio® Might Eliminate Breast Biopsy Need



Two separate analyses of Feasibility Study data presented at the European Congress of Radiology 2014

Seno Medical Instruments, Inc., the company pioneering development of opto-acoustic (OA) imaging as a tool to improve the process of diagnosing breast cancer, has announced that two analyses of outcomes from a US Feasibility Study of its investigational Imagio® breast imaging device were presented at the annual meeting of the European Congress of Radiology 2014.

The first statistical analysis of the Feasibility Study data (Abstract C-0926), suggests that information from Imagio may have the potential to achieve clinically-meaningful sensitivity and specificity for breast cancer beyond those achievable with traditional, standalone diagnostic ultrasound. This will be verified in the ongoing US Pivotal Study, which has already enrolled more than half of the 2,000 subject target.

Imagio may be a useful tool to help physicians reduce the need for biopsy in patients with benign but suspicious appearing breast masses on conventional diagnostic breast ultrasound.

"We are encouraged by these findings, which demonstrate the biopsy-sparing potential of Imagio," said Thomas Stavros, MD, FACR, FSRU, FRANZCR, Medical Director, Seno Medical Instruments. "While surgical and core needle biopsies are considered the gold standard for breast cancer diagnosis, biopsies are the most expensive part of the diagnostic process and over 80% of US biopsies are negative. Imagio has the potential to contribute to the way that breast cancer is diagnosed and to optimise the decision to biopsy."

The second statistical analysis is of pre-defined histopathology findings relative to the specific features of benign and malignant lesions. This information was captured in the Imagio opto-acoustic images during the Feasibility Study. It suggests that Imagio may have the potential to provide additional information that could help clinicians grade the aggressiveness of cancerous breast tumors during the imaging phase of a woman's diagnostic work-up, which will also be verified in the ongoing Pivotal Study.

Separate analysis of the feasibility data showed that OA findings could potentially correlate with molecular subtypes of breast cancer (Abstract C-1528). "If confirmed in a larger series of breast cancer patients, this analysis suggests that OA findings might be useful in differentiating and monitoring early response to medical oncologic treatments," said lead biostatistician Philip Lavin, PhD, FASA, FRAPS, who is a consultant to Seno Medical Instruments. "Our ongoing Pivotal Study will continue to elucidate the potential Imagio may have in both classifying breast masses and determining molecular subtypes."

Imagio fuses an imaging technology based on light-in and sound-out called "opto-acoustics" with traditional ultrasound. The opto-acoustic images provide a unique blood map in and around suspicious breast masses. Unlike other imaging modalities, Imagio does not expose patients to potentially harmful ionizing radiation (x-rays) or injectable contrast agents.
Each year in the US 1.7 million women undergo core needle or surgical breast biopsies after a suspicious mass is found through breast imaging or self-exams. However, more than 80% of these biopsies reveal benign pathology.

Source: Seno Medical

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