



PRESS RELEASE
April 23rd, 2010

SuperSonic Imagine unveils results of largest breast ultrasound clinical trial ever undertaken

World Wide Breast Trial Results on ShearWave™ Elastography indicate technology could change lesion classification and reduce negative biopsies.

SuperSonic Imagine, the innovative medical imaging company based in Aix-en-Provence, France has unveiled some of the results of the largest clinical breast study ever undertaken in ultrasound imaging. The worldwide multicenter study, involving top clinicians in the breast radiology community, is assessing the clinical benefits of ShearWave™ Elastography in the ultrasonic evaluation of breast lesions.

The study has two objectives: The first is to demonstrate that images obtained using ShearWave™ Elastography are reproducible. The second is to compare ultrasound alone versus the combination of ultrasound and ShearWave™ Elastography for breast lesion diagnosis. The goal of the latter is to improve lesion classification in categories BI-RADS® 3 and BI-RADS® 4ⁱ in order to better direct patients towards clinical follow-up or biopsy.

“This clinical investigation is the largest trial ever undertaken by an ultrasound imaging company as the recruitment will involve a targeted 2300 breast lesion cases”, explains Claude Cohen-Bacrie, co-founder and Scientific Director of SuperSonic Imagine.

“ Today it is essential to obtain additional information on breast lesions to improve diagnosis. In an era of healthcare reform, being able to reduce the number of biopsies by correctly classifying lesions could save resources and spare women the anxiety and difficulty that surrounds invasive procedures. Better lesion classification also means improved diagnosis, which can lead to quicker and better treatment.”

ShearWave Elastography: the technology

Ultrasound imaging plays an important role in breast diagnosis. It is used on palpable masses, as a second intention exam after X-Ray and MRI and as a modality of choice to guide biopsy. ShearWave Elastography is a breakthrough technology that gives additional, important information about tissue elasticity. Unlike conventional elastography methods, which rely on manual compression and measure tissue displacement, ShearWave™ Elastography requires no manual compression and computes true tissue elasticity by measuring the velocity of shear waves as they propagate in tissue. Shear wave propagation speed in tissue is directly related to tissue stiffness. This technology relies upon the generation of a shear wave and its subsequent capture. Shear wave propagation speed is then calculated and a color-coded real time ShearWave™ elastography map is produced showing tissue stiffness. Results are real-time, user-skill independent, reproducible and quantifiable in kilopascals.¹ ShearWave™ Elastography is available only on the Aixplorer® MultiWave™ Ultrasound System.

The multicenter clinical trial

A world wide multicenter breast clinical study was launched in April 2008³ with 17 prestigious American and European sitesⁱⁱ including: the Hammersmith Hospital Imperial College (United Kingdom), the Curie Institute of Paris (France), the DKD Wiesbaden and the academic hospitals Schleswig-Holstein and Greifswald (Germany), Yale Medical Center and the Northwestern Memorial Hospital (USA). The study was conducted under the leadership of Professor David Cosgrove (Imperial College, London).

The first phase of the study was to define a scientific model on 1000 cases, to determine if ShearWave Elastography information can complement ultrasound information in order to improve a diagnosis. To undertake this, it was necessary to identify the criteria of an elastography

¹ Quantification tool is available outside the USA

³ Clinical Trials.gov ID NCT00716482 Protocol ID A00152-53

image that would, when added to ultrasound criteria, improve lesion characterization (in sensitivity and specificity when compared to ultrasound alone) and eventually improve a BI-RADS® score. The ShearWave Elastography criteria or features studied for each lesion were: size, shape, average value of elasticity, homogeneity, orientation and contrast of elasticity between lesion and fatty tissue.

The second phase of the study will consist of testing this scientific model on an independent set of lesions. This phase is currently ongoing.

Clinical Result 1: ShearWave™ Elastography features are reproducible

To determine reproducibility, each clinical investigator was asked to perform and compare features on 3 separate ShearWave Elastography image acquisitions of the same lesion. The clinical results clearly showed that ShearWave™ Elastography is reproducible both qualitatively and quantitatively:

- **Qualitative:** 87% of consecutive repeated ShearWave Elastography exams were 'similar', 'reasonably similar' or 'very similar' in appearance.
- **Quantitative:** Intra-Observer Reproducibility⁴ (IOR) rates for ShearWave Elastography measurements are close to perfect at 0.91.

Reproducibility assures the physician of a reliable and precise evaluation of a lesion, both during an elastography examination and over time, which is key for follow up.

Clinical Result 2: ShearWave™ Elastography feature(s) increase diagnostic accuracy and improve lesion classification

Regression models based on 1000 cases were statistically evaluated by Caroline Doré, an independent biostatistician from the Hammersmith Hospital and show that each individual ShearWave elastographic feature, when added to the ultrasound evaluation, improved the

⁴Intra-Observer Reproducibility Landis & Koch

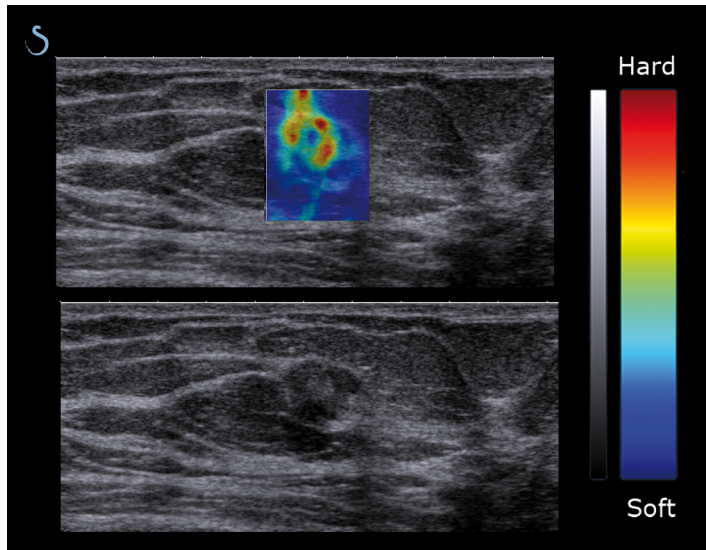
classification of the BI-RADS® score of a lesion. The global evaluation is calculated on an analysis of the area under the ROC curve (Receiver Operating Characteristic). The larger the area under the curve, the better the BI-RADS® score classification.

The clinical results demonstrated that when two ShearWave Elastography features are added to the ultrasound evaluation, correct breast lesion classification rates soar to 87%, thus leading to more accurate results.

Scientifically evaluated, the results of this clinical study therefore demonstrate that ShearWave™ Elastography features, when added to the BI-RADS® score significantly improve the specificity and sensitivity of the diagnosis of the lesion. Associated with the BI-RADS® score, these features increase the percentage of correctly classified lesions and improve lesion diagnosis.

“Historically, ultrasound imaging was considered as an efficient method to differentiate solid lesions from liquid lesions. As a result of research over the last 15 years, ultrasound has become an important technique, with a very high negative predictive value, in the classification of lesions on the BI-RADS® scale: 2(benign) to 5 (highly suggestive of malignancy). Today, the results of this multicenter study show that ShearWave™ Elastography combined with ultrasound, further improves lesion classification by significantly raising the percentage of lesions that are correctly classified and increases the specificity in the diagnosis while keeping a high negative predictive value and sensitivity”.

« Our clinical objective is to confirm if ShearWave™ Elastography, combined with ultrasound, leads to a more refined lesion classification of BI-RADS® 3 and 4 and in turn leads to a better direct patients towards follow-up or biopsy”, concludes Claude Cohen-Bacrie.



Aixplorer® MultiWave Ultrasound System *

Malignant breast lesion with hard shell: Color-Coded ShearWave Elastography map shows stiff tissue indicated in red, and soft tissue indicated in blue.

i

BI-RADS® is the acronym for Breast Imaging-Reporting and Data System, a quality control system developed by the ACR (American College of Radiology) to assess breast lesions according to their degree of malignancy.

<p>BI-RADS® classification BI-RADS® 1 = Negative BI-RADS® 2 = Benign findings BI-RADS® 3 = Probably benign findings BI-RADS® 4 = Suspicious abnormality BI-RADS® 5 = Highly suggestive of malignancy</p>	<p>Statistical reality of the BI-RADS® scores The probability for BI-RADS® lesions 3 to be malignant is less than 2% high The probability for BI-RADS® lesions 4 to be malignant is between 2 and 94% high The probability for BI-RADS® lesions 5 to be malignant is more than 94% high</p>
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ii

Clinical sites:

- United States: Denver, Philadelphia, Los Angeles, Boston, Baltimore, Chicago, New Haven ,
- Great Britain: London,
- Italy: Gorizia,
- France: Paris, Marseille, Nice, Lyon
- Germany: Wiesbaden, Osnabrück, Kiel, Greifswald

About SuperSonic Imagine:

SuperSonic Imagine is a young, innovative company that was founded in 2005 by Jacques Souquet, Claude Cohen-Bacrie and a team of experts from the ultrasound medical imaging field. SuperSonic Imagine has created, developed and launched the AIXPLORER® innovative MultiWave™ Ultrasound system with dedicated breast, thyroid and abdomen applications. The unique technology developed by the company relies upon the combination of two waves: an ultrasound wave that offers an exceptional quality of B-Mode image, and a shear wave (ShearWave™ Elastography). SuperSonic Imagine holds the exclusive rights to 25 patents and submissions and this ensures the company is at the forefront of the medical imaging market. In addition



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to diagnostic applications researchers at SuperSonic Imagine are currently developing ultrasound applications to be used in non-invasive therapy. This method is based on the Time Reversal Mirror technology, set up by Mathias Fink, a co-founder of SuperSonic Imagine.

The company, based in Aix-en-Provence, France, has almost 120 employees located at its headquarters and at its other offices located in Seattle, London and Munich.

For more information about SuperSonic Imagine please visit our website: <http://www.supersonicimagine.fr>

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