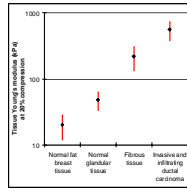
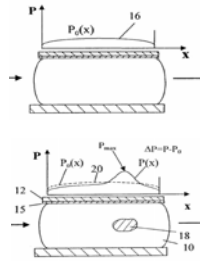


Background

Clinicians have long depended on their sense of touch to assess tissue abnormalities, both benign and malignant. For the evaluation of the breast, this has been formalized into the clinical breast exam (CBE), where an examiner uses his/her sense of touch to detect breast masses. Despite the ubiquitous use of the CBE, the sense of touch is a subjective tool, leading to concerns about repeatability and interpretation. During the last decade several objective techniques for assessing tissue hardness, or elasticity modulus, have emerged, with Ultrasonic Elastography and Magnetic Resonance Elastography being the most promising. The wealth of data obtained by these techniques during the last few years has clearly demonstrated that measurements of elastic properties of tissue could be used to detect and differentiate benign and malignant breast lesions and have a potential for dramatically reducing the number of unnecessary breast biopsies.³ If the CBE were more quantitative and objective, it may then yield diagnostic benefits.



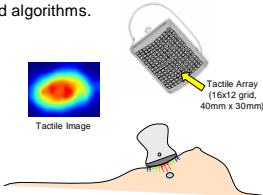
Good correlation is found between tissue hardness and type.¹



Variations in hardness produce differing reaction pressures when tissue is compressed.²

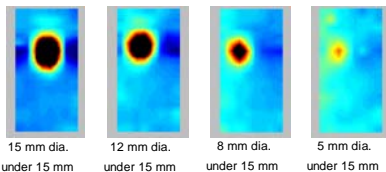
Electronic Palpation Imaging

An innovative technology called electronic palpation imaging (EPI) uses an array of tactile sensors mounted on a handheld probe. As opposed to ultrasound or mammography, which emit and measure ultrasonic waves and x-rays, respectively, a tactile sensor records a mechanical measurement of pressure. As the probe is pressed against the breast, the sensor array captures varying reaction pressures caused by differences in tissue hardness. Salient feature data such as lesion size, shape, and hardness are quantified using sensitive electronics and advanced algorithms.



The stiffer tissue in a lesion causes different reaction pressure signatures.

In addition to being more objective and repeatable, tactile array sensors can be more sensitive than the human sense of touch, capable of clearly imaging sub-palpable lesions as shown in the figure below:



Palpable ← || → Sub-Palpable

EPI Device Design History

An early EPI device was developed based on a piezoresistive tactile array sensor design. However, sensor performance and other concerns required the use of a magnetic position tracking system, resulting in a large, complex, and expensive cart-based system. A new design was required with improved sensor performance and a smaller form factor.



Original EPI Device Required a Large, Bulky Cart

EPI Device Current Design

As part of a general redesign effort, the piezoresistive array was replaced with a capacitive-based tactile array sensor to improve performance and the entire system was shrunk down to a small notebook form factor.

Using the capacitive tactile sensor, the performance was significantly improved, thus eliminating the need for the 3D positioning system, and the small, portable unit was simpler and easier to use. The user interface also underwent extensive changes based on feedback from physicians and users.

Continued development is underway to improve the device performance, as well as miniaturizing the electronics to allow for an eventual prescription handheld device for use in the home.



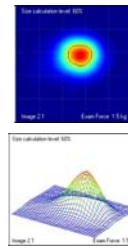
Commercially-available EPI Device



Physician Using EPI Device in a Clinical Breast Exam

Materials & Methods

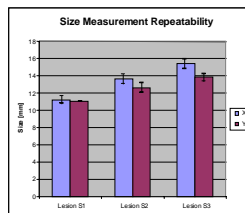
We performed two studies using an EP device currently FDA cleared for documentation purposes. In the first study, EP was used to examine two sets of 3 phantoms. One set differed only in size, ranging from 11-19 mm in diameter, while the second differed only in hardness, ranging from 30-500 kPa. All six phantoms were examined five times. In the second study, 6 different users examined the same phantom in order to evaluate repeatability and precision across different users. This was repeated with a total of four different phantoms differing in both size and hardness for a total of 24 sets of measurements. Users were given only basic instruction on how to use the device and were asked to use an exam force of 1.2-1.3 kg to remain consistent with one another.



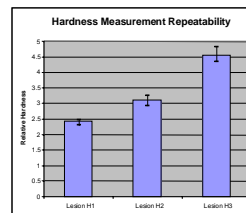
The above two images show 2D and mesh views of the same lesion using the EP device. Higher pressures show up as "warmer" colors in the 2D image and as larger vertical distances in the mesh image. The black outline in the 2D image represents the pressure level used to calculate lesion size characteristics.

Single-User Study

For the single operator study, we found the standard deviation to be less than 0.6 mm in size measurements, while the relative hardness standard deviation was better than 5%. Error bars in graphs represent one standard deviation.



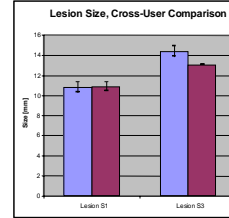
	Lesion S1		Lesion S2		Lesion S3	
	X [mm]	Y [mm]	X [mm]	Y [mm]	X [mm]	Y [mm]
Mean	11.2	11.0	13.6	12.6	15.4	13.8
Sigma	0.45	0.90	0.55	0.55	0.55	0.45



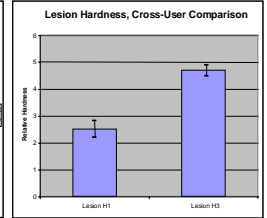
	Lesion H1	Lesion H2	Lesion H3
Mean	2.4	3.1	4.5
Sigma	1.7%	3.2%	4.6%

Multi-User Study

When compared across multiple users, the EP data was found to be statistically similar both to itself and to the single-user data. The standard deviation for size measurements was better than 0.6 mm, and for hardness was better than 6%.



	Lesion S1		Lesion S3	
	X [mm]	Y [mm]	X [mm]	Y [mm]
Mean	10.8	10.8	14.3	13.0
Sigma	0.52	0.41	0.52	0.00



	Lesion H1	Lesion H3
Mean	2.5	4.7
Sigma	5.9%	4.1%

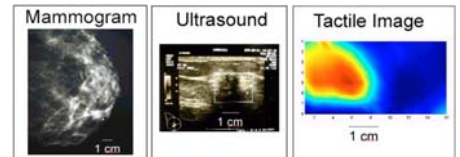
Discussion

The single operator study showed very consistent results when the EP device was handled by an experienced user. As the same procedure is also used as part of the final quality acceptance testing done on each EP device, existing data was reviewed and found to be consistent with these results. When multiple users were involved, the results were very similar to the single user data. Using the single user data as a baseline, multiple users' size data was within 7% and hardness data within 4%. Quantifying absolute accuracy is difficult, as there is no accepted standard for determining the size envelope of a lesion, and hardness measurements were to this point only qualitative in nature. However, the consistency of EP results, both within a battery of tests and across multiple users, suggests that such quantitative standards may now be possible.

	Lesion S1		Lesion S3	
	X [mm]	Y [mm]	X [mm]	Y [mm]
Single	11.2	11.0	15.4	13.8
Multi	10.8	10.8	14.3	13.0
Delta	4.0%	1.5%	6.9%	5.8%

	Lesion H1	Lesion H3
Single	2.4	4.5
Multi	2.5	4.7
Delta	3.3%	3.2%

An ongoing, NIH-funded, clinical study is underway to compare EP data with mammography, ultrasound, and where possible, biopsy data from over 300 patients at multiple institutions for the dual purposes of improving accuracy of salient feature metrics and for establishing a correlation between key EP metrics and pathology. A clinical trial is also being planned in China to assess the screening viability of the device. In addition, FDA-cleared devices are deployed at 8 locations in the United States, Europe, and Asia for additional clinical feedback.



The same cancerous lesion imaged with mammography, ultrasound, and EPI.⁴

Conclusion

The use of EPI allows collection of digital images that accurately and consistently correspond to known breast mass phantoms. EPI is consistent between different examiners studying the same phantom. This may allow the CBE to become an objective and more scientific tool by collecting accurate digital images that correspond to manual palpation.

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