

Objective Measurement of the Physical Exam Using a New Device: Reproducible Triage of Palpable Masses

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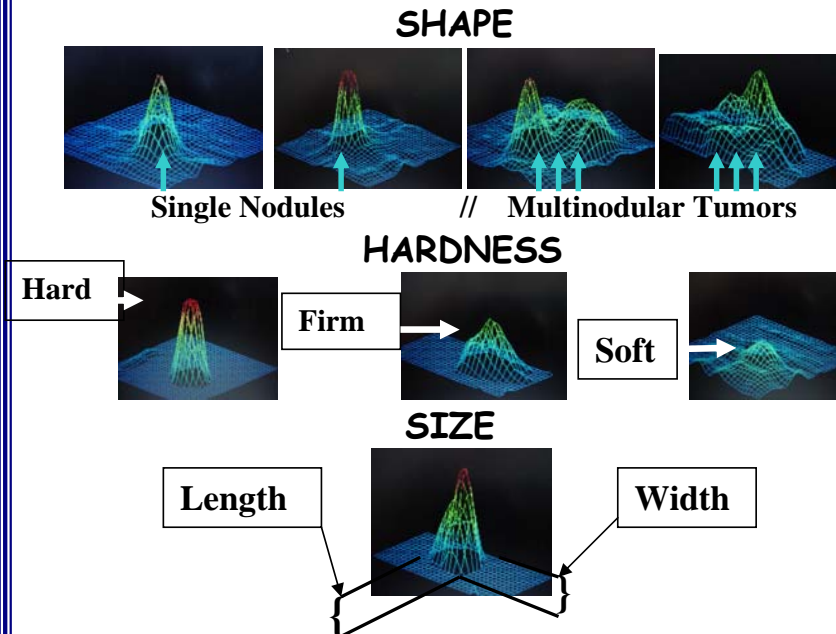
OBJECTIVE: Despite availability of screening mammography, more than half of new breast cancers initially present with a clinical breast mass. Palpable findings are observer dependent and are recorded in stick-figure format. This method adequately identifies location within the breast but relies heavily on subjective opinion as to lesion hardness and nodularity. We have developed a unique device which objectively measures the shape and hardness of breast masses and creates a reproducible record which can be compared to archived standard masses. This device will triage between a palpable mass vs. palpable fibrocystic change. Of those identified palpable masses, it may distinguish between benign and suspicious palpable masses.

METHODS: Seventy-three patients who were referred to our breast clinic with a complaint of a breast mass were examined. In addition to clinical physical examination, ultrasound, and mammograms, each patient underwent a mechanical imaging scan (MIS). This table top device uses a broad-based transducer that measures variable degrees of hardness (elasticity) within the breast. As the transducer scans the area of interest, a real-time display of the palpable area is digitally recorded. Scan measurements include size of the lesion, distribution of firmness within the lesion, maximum hardness and assessment of nearby normal tissue. Final histologic and/or follow-up data (minimum 6 months) was correlated with preoperative hardness/elasticity data.

RESULTS: MIS evaluation separated patients into two groups; those with truly palpable masses and those without. Of the entire group, 59/65 patients were identified as a dominant mass according to MIS data (55/65 for physical exam), while 55/60 areas of normal glandular tissue was confirmed normal by MIS. Sensitivity and specificity of MIS to identify a true mass was 91% and 90% respectively. Using the MIS data, further triage was performed of the truly palpable masses into suspicious (cancers) and probably benign masses.

CONCLUSION: We describe the use of a unique table-top mechanical imaging scan that documents palpable breast masses with high sensitivity and specificity. Patients with truly palpable masses (cancers, benign tumors and firm cysts) were found to have increased firmness (decreased elasticity) while those with nodular breast tissue (fibrocystic change) had less firmness. The use of MIS allowed initial separation between benign and suspicious truly palpable masses. A reproducible record of the breast physical exam is created that allows objective review by multiple examiners at varied times. Further work is necessary to optimize examination methods, improve real-time software interpretation and define the array of diagnostic capabilities.

PHYSICAL EXAM = SHAPE + HARDNESS + SIZE



Value of an objective physical exam (medical imaging scan):

- Provide image documentation of the physical exam.
- Characterize physical attributes of a breast lesion, specifically SHAPE, HARDNESS and SIZE.
- Triage firm and hard lesions from normal tissue.
- Allow delayed review of a breast physical examination.
- Image is reproducible among clinicians.

Study: Seventy-three symptomatic women were examined with the mechanical imaging scan (MIS) along with physical exam, mammogram, ultrasound and many had tissue pathology.

	Patients Examined	
Carcinoma	25	Fibrocystic change 8
Fibroadenoma (like)	22	Breast Cysts 12
Lipoma	3	Seroma 3

APPARATUS: The examining probe is similar to an ultrasound transducer with a slightly larger footprint. Using gel, the transducer is swept over the mass, recording each passage.

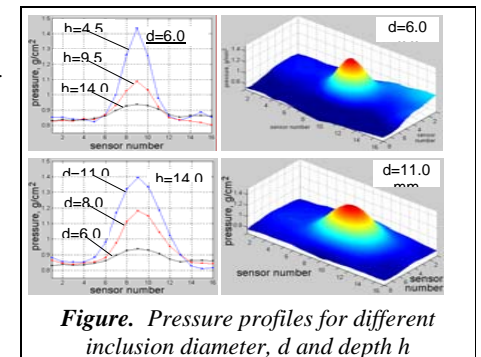


Figure. Pressure profiles for different inclusion diameter, *d* and depth *h*

MIS scores better than Physical Exam for both cancers and masses.

Identification of Masses			
	Sensitivity(%)	Specificity(%)	False Negative (%)
Physical Exam	85	--	15
Mechanical Imaging	91	90	9
Identification of Cancer			
Identify cancer when present (%) False Negative (%)			
Physical Exam	80		20
Mechanical Imaging	92		8