Tactile Imaging of Breast Masses

First Clinical Report

Parris S. Wellman, PhD; Edward P. Dalton, MD; David Krag, MD; Kenneth A. Kern, MD; Robert D. Howe, PhD

Hypothesis: Tactile imaging can accurately document the palpable extent of breast masses.

Design: Prospective nonrandomized interventional trial, comparing mass size estimates from preoperative physical examination, ultrasound, and tactile imaging with postoperative measurements of the resected masses.

Setting: A community ambulatory surgical center and a university hospital tertiary care center.

Patients: Twenty-three women undergoing surgical excision of breast masses. All subjects had a single, palpable, dominant mass, 0.5 to 3 cm in diameter.

Intervention: Prior to surgery, the size of each mass was estimated from tactile imaging using an array of pressure sensors that is stroked over the mass. Size was also estimated by ultrasound and physical examination. Immediately following resection of the mass, it was bisected, and the palpable extent was measured with a caliper.

Main Outcome Measure: Maximum mass diameter estimates from ultrasound, physical examination, and tactile imaging, compared with the resected measurement.

Results: Tactile imaging estimates were repeatable (7.5% mean SD for multiple estimates of the same mass) and show good agreement with the resected measurements. Mean absolute error was 13%, and linear regression with zero intercept had a slope of 0.94, r^2=0.51. Physical examination and ultrasound estimates had respective mean absolute errors of 46% and 34%, regression slopes of 1.27 and 0.89, and r^2=0.28 and 0.37.

Conclusions: Tactile imaging can provide accurate and reproducible estimates of the size of breast masses. This capability can enhance cancer surveillance for patients with benign masses (eg, due to scarring or fibrocystic changes) because previous work suggests that reliable detection of a difference in mass size by physical examination requires a 40% change in diameter. In contrast, this study suggests tactile imaging requires only a 15% change (95% confidence interval).

Arch Surg. 2001;136:204-208

From the Division of Engineering and Applied Sciences, Harvard University, Cambridge, Mass (Drs Wellman and Howe); New Hampshire Breast Center, Bedford (Dr Dalton); the Department of Surgery, University of Vermont, Burlington (Dr Krag); and the Department of Surgery, Hartford Hospital, Hartford, Conn (Dr Kern). *A portion of salary support for this work was provided by the Whitaker Foundation, Rosslyn, Va (Drs Wellman and Howe), Drs Dalton, Krag, Kern, and Howe have served as consultants to Assurance Medical Inc.*

SURGEONS ARE frequently responsible for diagnosis and surveillance for breast cancer.[1,2] Practice guidelines recommend physical examination of the breasts at frequent intervals, using manual palpation to detect new masses and changes in breast texture.[3,4] Unfortunately, physical examination may be difficult in the considerable fraction of cases that present with benign breast masses. Such masses may be due to normal glandular anatomy, fibrocystic tissue, and surgical or biopsy scars.[5] These conditions make it problematic to detect new nodules or changes in existing masses that might signal malignant transformation. This is especially troublesome because it may be difficult to differentiate these conditions by mammography or ultrasonography.[6-8]

The inability to detect changes in breast architecture across time reflects fundamental human limits in accurately perceiving, verbalizing, and recording tactile sensations.[9] A study of clinical breast examination techniques suggests that reliable detection of a difference in lump size requires a change in diameter of about 40%.[10] Under these limitations, detection of a mass by physical examination may indicate biopsy and other diagnostic procedures, even if the mass is unchanged or was previously proven nonmalignant.

A new medical imaging modality, *tactile imaging*, can address these problems by making objective, quantitative measurements of physical examination results.[11-15] Tactile imaging uses a handheld scan head that the clinician strokes across the tissue of interest. Both the contact pressure distribution and 3-dimensional position of the

PATIENTS, MATERIALS, AND METHODS

EQUIPMENT

The scan head of the tactile imaging system is shown in **Figure 1** (Breast View System; Assurance Medical Corp, Hopkinton, Mass). The contact surface projecting from the handheld instrument is covered by a 16-row × 26-column array of piezoresistive pressure sensors, spaced at 1.5 mm in each direction. The sensors have a pressure range of 0 to 34 kilopascal (kPa). An electromagnetic tracker in the handle senses the relative position and orientation of the scan head with respect to a base receiver located near the patient's shoulder. A computer samples the signals from the tracker and every element in the pressure sensor array at 50-millisecond intervals.

A tactile mapping algorithm assembles all of the individual pressure frames, or tactile images, to form a composite *tactile map* of the tissue.[14,15] The tactile map consists of a single image that is readily interpreted by the clinician. By averaging multiple images, the tactile map reduces artifacts due to transducer noise, variations in user technique, and small motions of the tissue. To compute the tactile map, a best-fit plane is determined from the position tracker data in the neighborhood of the map (**Figure 2**). Each image is normalized by its average pressure to reduce the pressure variation between images. All images are then spatially registered using the position tracker data and projected onto the best-fit plane, where they are averaged.

The map is displayed to the clinician on the system's monitor using false-color contour plots; a typical example is shown in **Figure 3**. This image is used directly for comparison with subsequent examinations, and in addition, the system estimates the maximum diameter of the lump. In laboratory testing using rubber models with mechanical properties closely comparable to breast tissue and masses, maps converge to within a 2.5% root mean squared difference from the final values within 6 strokes. The accuracy of lump size estimates was approximately 7.1% mean absolute error (MAE), including the effects of system noise and interuser and intrauser variability.[14,15]

CLINICAL TECHNIQUE

In the clinic, the patient is placed supine with the ipsilateral arm over the head to constrain and flatten the breast tissue. Because the initial application of tactile imaging is measuring lump parameters rather than searching for lumps, the breast mass of interest is first located by the clinician, and precise absolute position measurements are not required. If the breast is highly mobile, the tissue adjacent to the mass is restrained by the clinician's contralateral hand to eliminate gross motion during examination.

At the start of the imaging process, the clinician provides an anatomical orientation reference by positioning

Continued on next page

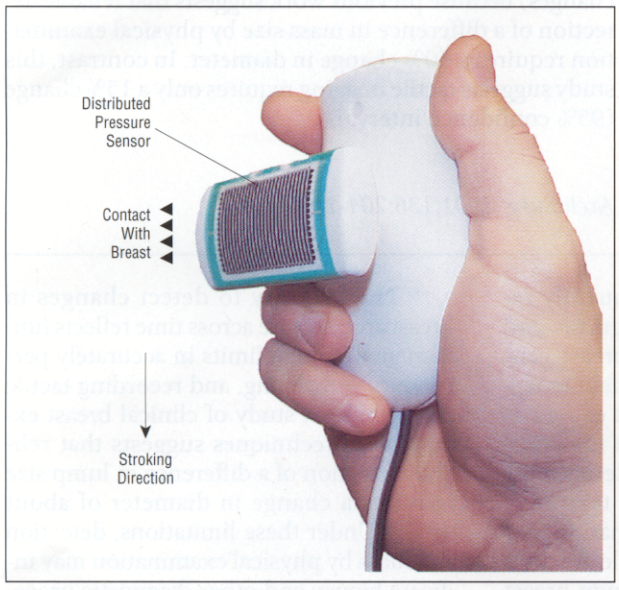

Figure 1. *Tactile imaging system scan head.*

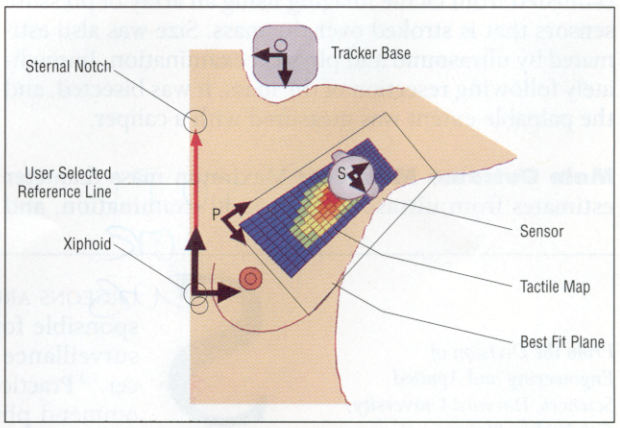

Figure 2. *Patient chest with tactile map plane and landmarks for orientation reference.*

scan head are continuously recorded, providing a spatially coherent set of tactile measurements of the tissue of interest. These data may be used for several applications. One function is detecting new masses, which are revealed as pressure concentrations in the tactile images; this screening application is presently under development. The second application is documenting existing masses to enable detection of changes in these tissue structures that might signal malignancy. In this report, we present the first assessment, to our knowledge, of tactile imaging as a practical method for documenting the size of palpable breast masses. This clinical evaluation compares mass size estimates from tactile imaging, ultrasonography, and physical examination.

RESULTS

The tactile maps required 20 to 40 seconds to generate, with a mean scanning time of 25 seconds. **Figure 4** shows illustrative tactile maps of the most common mass type seen in the subjects: infiltrating ductal carcinoma. Subjectively, the surgeons and patients noted

the scan head over readily palpable landmarks, the sternal notch and the xiphoid (Figure 2A). The clinician then strokes the sensor over the skin in the region of interest, using lubricant to minimize friction. An audible tone assists the clinician maintaining the desired average pressure range (5-14 kPa), and images outside this range are not averaged into the tactile map. The clinician continues stroking until the tactile map, continuously updated on the monitor, satisfactorily reflects the palpable contour of the tissue of interest; this typically occurs with the first few strokes.

At the start of the imaging process, the clinician provides an anatomical orientation reference by positioning the scan head over readily palpable landmarks, the sternal notch and the xiphoid (Figure 2A). The clinician then strokes the sensor over the skin in the region of interest, using lubricant to minimize friction. An audible tone assists the clinician in maintaining the desired average pressure range (5-14 kPa), and images outside this range are not averaged into the tactile map. The clinician continues stroking until the tactile map, continuously updated on the monitor, satisfactorily reflects the palpable contour of the tissue of interest; this typically occurs with the first few strokes.

CLINICAL ASSESSMENT PROTOCOL

Although tactile imaging is a promising method for documenting benign breast masses, this study involved breast malignancies. Surgical resection of the lump permitted direct measurement of lump size for comparison with presurgical tactile imaging size estimates, following the protocol approved by our institutional review boards. Unpaid volunteers were recruited from patients with a single, palpable, dominant mass, 0.5 to 3 cm in diameter, scheduled for surgical resection. One African American and 21 white women participated in the study. Ages ranged from 43 to 83 years (mean age, 62 years). Patients had a total of 17 infiltrating ductal carcinomas, 3 fibroadenomas (including 2 distinct masses in 1 breast), 1 lobular carcinoma, 1 phyllodes tumor, and 1 fibrocystic mass, all as determined by postoperative histologic examination reports. Two surgeons who were experienced in the clinical use of the tactile imaging system participated in the study.

Patients followed the usual treatment course for their diagnosis, with the addition of tactile imaging examination prior to surgery. Ultrasound examination of each subject was performed, and the maximum diameter was estimated from images of the mass. The surgeon performed a physical examination and estimated the maximum size of the mass. In addition, the surgeon made 3 to 5 tactile maps of each breast mass, using different stroking techniques for each map (strokes in a single direction, strokes in all directions, etc). This diversity was used to assess variation in size estimates due to clinical technique. Maximum diameter was computed from each map as we have described.

Immediately after resection, the ex vivo mass was bisected parallel to the adjacent skin plane, and the palpable size of the mass was measured. Because the mass margin was not typically visible, its extent was determined by palpating the excised specimen with a gloved finger. The maximum diameter was then measured using a caliper.

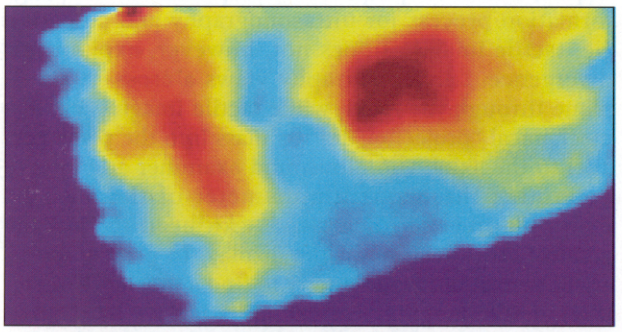

Figure 3. *Typical clinical tactile map, showing biopsy scar on left and benign mass of normal glandular tissue on right (5× 9-cm area).*

that the tactile maps reproduced the palpable shape of the masses.

Figure 5A compares the maximum diameter estimates from tactile imaging with the ex vivo size measurements. To provide a consistent number of data points, 3 tactile maps were analyzed in each case. The mean size estimate for each mass is plotted with error bars showing SD. Overall, the mean SD was 7.5%. The MAE of the tactile imaging estimates with respect to the ex vivo measurements was 12% for the maximum diameter and 19% for the minimum. For the ex vivo size measurements, the repeatability as determined for multiple examiners measuring the same masses was 5% (1 SD), which is indicated by error bars in the abscissa on the plots.

Figure 5B and 5C presents a comparison of the maximum size estimates from physical examination and ultrasonography, respectively, to the ex vivo size measurements. As only one ultrasonography and physical examination was performed in each case, no estimate of variance is shown. Of 23 masses in the study, 1 was not visible in ultrasound images and is plotted as zero diameter in Figure 5C. This mass was palpable in preoperative physical examination (7.5 mm estimate) and ex vivo size measurement (12.0 mm) and was visible in the tactile map (17.5 mm). In another patient, a distinct fibroadenoma mass was discovered during tactile mapping of a nearby fibroadenoma mass, although it was not detected during preoperative physical examination. Following discovery, it was marginally discernible by palpation. Its size was successfully measured by ultrasonography (10.0 mm), tactile imaging (15.0 mm), and ex vivo palpation (17.0 mm). It is plotted in Figure 5B as zero diameter.

The **Table** presents the MAE for each modality and the slope and coefficient of determination for the linear regression with zero intercept. The regression for tactile imaging is based on all 3 estimates of each mass. Tactile imaging shows lower error than physical examination and ultrasound estimates (13% vs 46% and 34%). The variance accounted for by the linear regression was also higher for tactile imaging estimates (r^2=0.51 vs 0.28 and 0.37).

COMMENT

These results suggest that tactile imaging may be a useful tool for documenting the size of breast masses. It

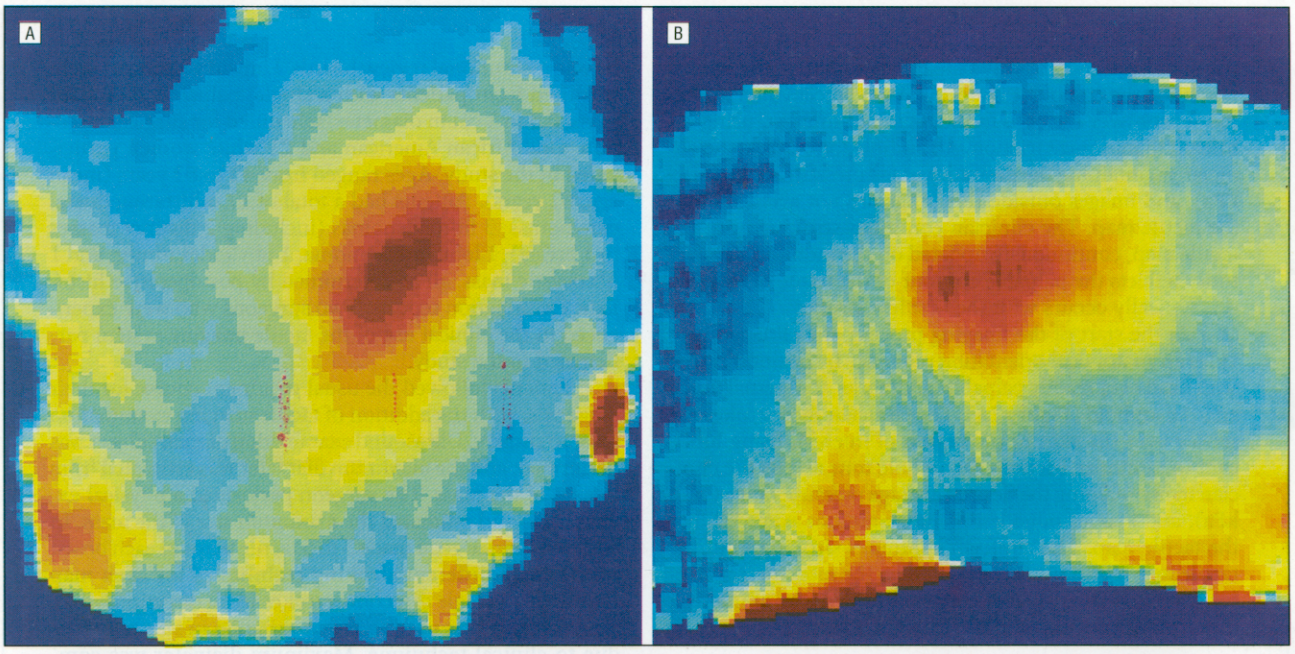

Figure 4. *Tactile maps of 2 infiltrating ductal carcinomas (5× 5-cm area).*

proved easy to use in a clinical setting, requiring less than 1 minute to produce each map. Compared with the criterion standard of ex vivo measurement, tactile imaging estimates showed good accuracy, with an MAE of 13%, regression slope near unity, and r^2=0.51. Although the examiners in the study used a variety of stroking techniques to make multiple maps of the same lump, the measurements were repeatable, with a mean SD of 7.5%.

This measurement capability enables convenient and accurate comparative examinations. This may permit clinicians to monitor suspicious structures across time so that changes may be easily detected. If the statistics estimated here for multiple maps made during the same examination can be generalized to examinations separated in time, the results imply that a 15% change in diameter will be detected as a significant difference in size (95% confidence interval of 2 SDs). For example, if the size of a mass on first tactile imaging examination is 10 mm and on a subsequent examination it is larger than 11.5 mm, then the size has significantly changed, and further diagnostic procedures are indicated.

In contrast, previous work suggests that the 95% confidence interval for conventional physical examination requires approximately a 40% change in diameter.[10] This correlates with the observed spread of manual size estimates seen in Figure 5B and is probably largely due to human limitations in quantifying tactile sensations.[9] Both of the surgeons who performed the physical examinations in this study are breast specialists who routinely perform many examinations; therefore, lack of training is unlikely to be a major factor.

The observed discrepancy between mass size estimates by ultrasonography and palpation (both physical examination and tactile imaging) accords with frequent anecdotal reports by clinicians. Figure 5C quantifies this difference by comparing ultrasound estimates with the ex vivo palpation measurements; linear regression with zero intercept has a slope of 0.89 and r^2=0.28. The data show even lower correlation between physical examination and ultrasound estimates, with a regression slope of 1.29 and r^2=0.11.

This difference might be explained by a number of factors, including the imaging process, clinical techniques, and tissue properties. Comparison of the image formation process for ultrasonography and palpation (ie, tactile imaging) does not, however, explain this divergence. Ultrasonography views a cross-sectional plane through the mass, while tactile imaging views a mechanical "projection" of the mass into the plane parallel to the skin. The ultrasound examiner attempts to determine the maximum diameter of the mass by manipulating the ultrasound scan head to find the greatest cross-section on the display. In principle, this could permit ultrasonography to find a greater diameter than tactile imaging. For example, if a well-anchored mass is larger in the direction perpendicular to the skin than in the parallel direction, this larger diameter would be visible in the ultrasound image, while the tactile map would show the smaller diameter in the transverse plane. However, the data in this study does not show such an overestimation bias: the linear regression slope for ultrasound estimates is 0.89, while overestimation should produce a value greater than 1. There are also essentially equal numbers of ultrasonography estimates that are larger and smaller than the ex vivo measured size (12 above vs 11 below).

This suggests that other factors cause the observed divergence of ultrasonography and ex vivo estimates. Clinical technique may play a role, and masses may have indefinite margins, making it difficult to determine the boundaries from noisy images. A more important factor is probably the difference in mechanical properties of some tissues at palpation and ultrasound frequencies ($\approx 10^0$ Hz vs 10^6 Hz). Some portion of the masses with relatively

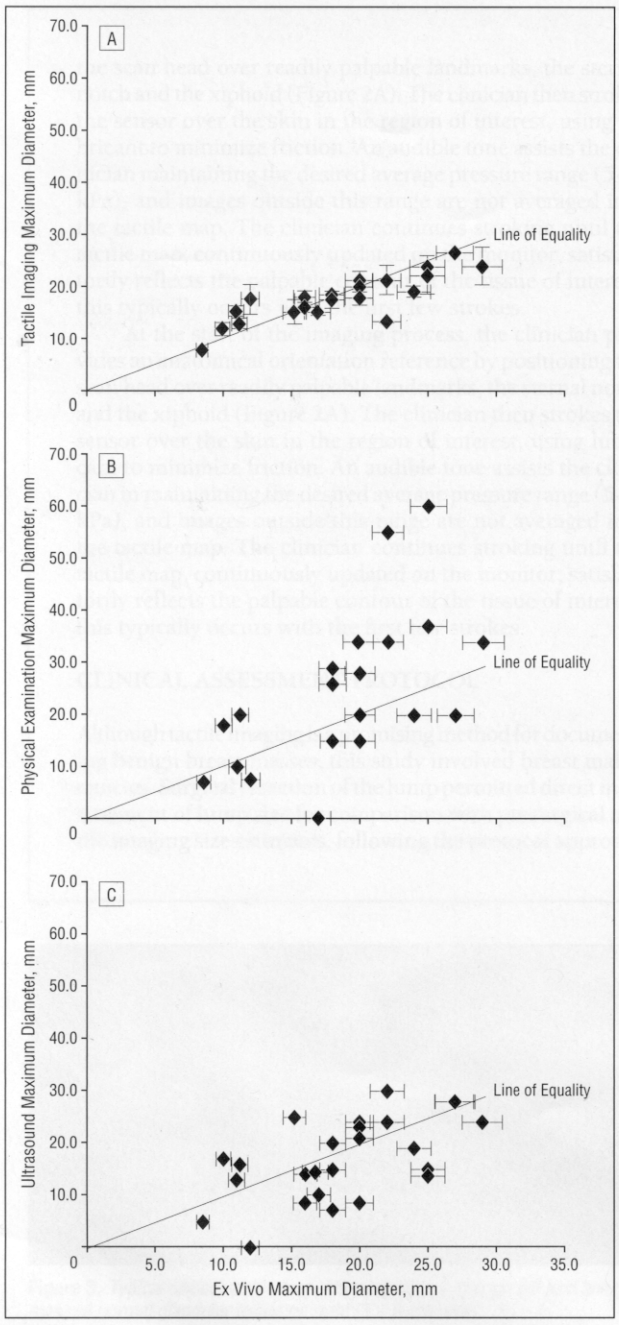

Figure 5. *Estimates of maximum diameter compared with ex vivo measurements: A, tactile imaging; B, physical examination; and C, ultrasonography.*

high stiffness in palpation may not show sufficient contrast in high-frequency impedance to be discernible in ultrasound images.

Similar issues apply in mammographic imaging of breast masses, where tissue properties that cause mechanical contrast are not necessarily correlated with properties that cause radiological contrast. In this study, patients underwent mammography prior to surgery, but because mass size is often not stated in radiology reports and is poorly correlated with the other modalities when it is reported, it was not analyzed here. This does not imply that comparative mammography is not a valuable surveillance method for cancer. Mammography, ultrasonography, and tactile imaging are all useful and often complementary methods of detecting changes in breast masses. The main result of this study is that tactile imaging enables quantitative measurements of the palpable size of breast masses and may meaningfully decrease the magnitude of the size change that can be reliably detected compared with conventional physical examination.

Comparison of Maximum Mass Diameter Estimates to Ex Vivo Measurement

Technique	Mean Absolute Error, %	Regression	
		Slope	r^2
Tactile imaging	13	0.94	0.51
Physical examination	46	1.27	0.36
Ultrasonography	34	0.89	0.28

Corresponding author and reprints: Robert D. Howe, MD, Harvard University Division of Engineering and Applied Sciences, 29 Oxford St, Cambridge, MA 02138 (e-mail: howe@deas.harvard.edu).

REFERENCES

1. Loomer L, Brockschmidt JK, Muss HB, Saylor G. Postoperative follow-up of patient with early breast cancer: patterns of care among clinical oncologists and a review of the literature. *Cancer.* 1991;167:55-60.
2. Stark MR, Crowe JP Jr. Breast cancer evaluation and follow-up: a survey of the Ohio Chapter of the American College of Surgeons. *Am Surg.* 1996;62:458-460.
3. Smith TJ, Davidson NE, Schapira DV, et al. American Society of Clinical Oncology 1998 update of recommended breast cancer surveillance guidelines. *J Clin Oncol.* 1999;17:1080-1082.
4. National Comprehensive Cancer Network. Update: NCCN practice guidelines for the treatment of breast cancer. *Oncology (Huntingt).* 1999;13:41-66.
5. Haagensen CD. *Diseases of the Breast.* 3rd ed. Philadelphia, Pa: WB Saunders Co; 1986.
6. Dershaw DD. Evaluation of the breast undergoing lumpectomy and radiation therapy. *Radiol Clin North Am.* 1995;33:1147-1160.
7. Mendelson EB. Evaluation of the postoperative breast. *Radiol Clin North Am.* 1992; 30:107-138.
8. Balu-Maestro C, Bruneton JN, Geoffray A, Chauvel C, Rogopoulos A, Bittman O. Ultrasonographic posttreatment follow-up of breast cancer patients. *J Ultrasound Med.* 1991;10:1-7.
9. Bloom HS, Criswell EL, Pennypacker HS, Catania AC, Adams CK. Major stimulus dimensions determining detection of simulated breast lesion. *Percept Psychophys.* 1982;32:251-260.
10. Lavin PT, Flowerdew G. Studies in variation associated with the measurement of solid tumors. *Cancer.* 1980;46:1286-1290.
11. Dario P, Bergamasco M, Sabatini A. Sensing body structures by an advanced robot system. In: *Proceedings of the 1988 IEEE International Conference on Robotics and Automation.* Los Alamitos, Calif: IEEE Computer Society Press; 1988: 1758-1763.
12. Sarvazyan AP, Spector AA. Compterized palpation of the prostate: experimental and mathematical modeling of the stress-strain fields. In: *Proceedings of the 11th IEEE Symposium on Computer-Based Medical Systems.* Los Alamitos, Calif: IEEE Computer Society Press; 1998:110-112.
13. Wang Y, Nguyen C, Srikanchana R, Geng Z, Freedman MT. Tactile mapping of palpable abnormalities for breast cancer diagnosis. In: *Proceedings of the 1999 IEEE International Conference on Robotics and Automation.* Piscataway, NJ: IEEE Computer Society Press; 1999:1305-1309.
14. Wellman PS, Howe RD, Dewagan N, Cundari MA, Dalton E, Kern KA. Tactile imaging: a method for documenting breast masses. In: *Proceedings of the First Joint BMES/EMBS Conference.* Piscataway, NJ: IEEE Computer Society Press; 1999:1131-1132.
15. Wellman PS. *Tactile Imaging* [doctoral thesis]. Cambridge, Mass: Harvard University; 1999.