

Palpation Imaging: Current Status

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Introduction

Before the development of mammography, ultrasound, magnetic resonance imaging and positron emission tomography, we examined the breast with manual palpation. The clinical breast exam is the oldest and most established method of all forms of breast examination. Even today, half of all breast cancers have a palpable mass associated with them. All the newer forms of breast examination record their findings in an accurate and reproducible document for other clinicians to review, and for inclusion to the medical record. The clinical breast exam, however, is recorded in a relatively primitive hand-drawn format.

Typical chart recording of the clinical breast exam includes a verbal description of the findings along with simple hand-drawn figures. These might be a circle with lines on it or a more intricate set of points and lines correlated to a legend explaining each design's meaning. These drawings are quite subjective, observer dependent, and rely heavily on subjective opinion as to hardness and nodularity. Since most of these notes are used by the clinician that drew them, the varied methods of documentation did not seem to be a major problem.

However, attempts to use these drawings by other clinicians have proven difficult. There is no standard lexicon or formal structure expected with these clinic notes. One clinician might use terms such as "fibrous, nodular, and dense" while another might use "firm, thickened and glandular." Hand drawings might show an oval, round or irregular shape, but it wouldn't be clear how true to scale the drawing was. When these same medical records would be used for medico-legal inquiries, hand-drawn pictures left open a variety of interpretations. The lack of a common diagram language and specific-sized drawings made these hand sketches inconsistent. In medico-legal situations, this may work to the detriment of the clinician.

Translating the physical examination into an electronic image

Before considering the creation of a palpation imaging system, one must define the characteristics of the breast physical exam findings. The physical exam involves manual palpation to identify structures that stand out relative to the surrounding breast tissue. These structures have specific components that can be identified. A palpable object within the breast will have a different hardness than the surrounding tissue. Its hardness vary from slightly fibrous to rock hard or be anywhere in the firmness spectrum. Within the palpable object, the distribution of the hardness may be variable, with some areas harder than others. Palpable objects would be either homogeneous or heterogeneous in their hardness. In addition, the physical exam detects the shape of the finding,

from round/oval to irregular and jagged. Finally, the physical exam also evaluates the size of the palpable findings, with length, width, and an estimate of depth.

For palpation imaging to be representative of the clinical examination, the new device would need to identify these same characteristics for a mass; hardness, distribution of hardness within the mass, size, and overall shape. With these guidelines, a new device was created based on technology initially developed at Harvard University.

How palpation imaging works

This unique new device is based on tactile sensor technology. A tabletop device that includes a transducer with a footprint about 3 cm by 4 cm is placed over the targeted location of the breast. On the footplate of the transducer are hundreds of tiny pressure sensors, each of which individually measures the firmness (elasticity) of the breast underneath the transducer. As the patient is examined, a real-time display of the palpable area is digitally recorded. The resulting accumulated image directly relates to the characteristics described above. A digitally created report can then be generated.

To use the device, the breast patients would initially be examined with a clinical breast examination in the supine position. Those areas which were identified as potentially being a palpable mass would then be documented by palpation imaging. The examiner places the transducer over the targeted area and passes the transducer slightly back and forth while recording the findings. The accumulated picture of the mass is captured along with the object's hardness, shape, and size. Firmness of the object is measured relative to the surrounding breast tissue. Due to the spacing of the individual sensors, the readings can be converted to determine the overall size and shape of the object. In addition, the homogeneity of the object can be determined.

For each possible mass within the breast, this device extracts data that can be used to objectively document the findings of hardness (including homogeneity), shape, and size. Repeated palpation imaging examinations of the same lesion by different examiners results in consistent and reproducible findings. Each palpation imaging exam is digitally recorded and transferred into a printed and electronic patient record, available for either paper or electronic medical record.

Why hasn't this been done before, and why do we need this now?

Accuracy in the medical record seems intuitively obvious. But for many years, the physical examination consisted of a description paragraph with a simple drawing. The initial breast exam would usually be performed by a primary care physician who might identify a palpable mass. The patient would be sent to a surgeon to confirm the presence of the palpable findings. Written records of the initial palpable findings would be limited and often not helpful to the surgeon.

With palpation imaging, the primary care physician would be able to obtain a reproducible record of the examination both for the surgeon and for his/her own medical record. Whatever the future course of the patient, the primary care

physician would have an objective record of his/her results. Whether the surgeon agreed or revised the examination, the primary care physician's records would have the substance of objectivity that can be afforded with a mechanical device such as that used for palpation imaging.

This device is not a substitute for a clinical breast examination of a palpable mass by an experienced surgeon. Palpation imaging creates an objective document of the clinical findings. The objective record of the palpable mass is more clear and understandable by all future caregivers.

However, when the palpable findings by the surgeon demonstrate that there is no palpable mass, or that a patient referred with a breast mass actually has fibrocystic breast changes, there is value in palpation imaging. Palpation imaging will identify the area of breast tissue as being similar to the surrounding breast tissue in an objective fashion thereby creating a digital record and validating the surgeon's clinical findings.

One of the most difficult issues in breast care occurs when one tries to document that a patient, who later develops breast cancer, did not have any palpable findings at a past examination by a surgeon. A large number of breast-cancer related lawsuits have been initiated because the patient felt that she had a lump at a time when the surgeon said no lump existed. There is great value to surgeons of an objective record of palpable findings when no true mass exists. This adds further credibility to the surgeon's record if any medico-legal issue arises.

Limitations of the device, cross training with ultrasound

With any mechanical device, there are limitations, most notably due to operator issues. Clinicians require training to properly use palpation imaging. Since the transducer looks similar to an ultrasound transducer (but somewhat larger), the maneuvers of examining the breast are relatively simple for someone experienced in sonography. Like ultrasound, the exam is a targeted exam, with the transducer placed over the suspected area and slightly passed back and forth over the target. The image is recorded on the device, along with the location within the breast. Repeated examinations may be performed to obtain an optimal record. The complete exam takes about 10 minutes or less. Each new area must be examined separately, as in ultrasound.

Limitations beyond proper training are relatively few. Some women have very tender breasts. When that occurs, one may reset the pressure sensitivity to a lower level for patient comfort. There are minor setting adjustments necessary to be made when the device is initially used. Finally, with any new device, a baseline period of experience is necessary before one uses the device routinely.

Current identified Value to Doctors, Nurses, Breast Health Professionals, Rural health providers, Primary or GYN care

There are several ways in which palpation imaging may be useful to a variety of clinicians. The accurate documentation of the breast clinical exam is useful for all those who examine the breast for palpable findings. For the primary care physician, the gynecologist, the nurse practitioner, and the breast health

specialist the accurate and reproducible documentation of their findings is valuable. The value is both for the medical record and its use as a referral document, as well as the medico-legal documentation of the findings in an objective fashion.

As mentioned, breast surgeons might use this device to create a precise document of their physical findings, especially for use to supplement their medical record. The printed palpation imaging report is a very presentable document to send to referring physicians. The report can be individualized for each surgeon's practice, and can reflect personal observations for each patient. It can also be utilized as a "second examiner" if a medico-legal dispute arises regarding the presence or absence of a palpable mass. Since about 5% of breast cancers have only palpable findings without mammographic or sonographic abnormalities, this device can support and document the surgeon's examination.

Another group of physicians that might utilize palpation imaging is breast radiologists. In the past, radiologists have refrained from performing breast clinical exams for a variety of reasons, including lack of physical examination training. Many of these barriers will vanish when utilizing palpation imaging. The transducer of this device is used similarly to an ultrasound transducer. The examination is very similar to sonography, and the image on the device is very readable by most radiologists. As with sonography, the radiologist can examine a portion of the breast which has been identified by the referring clinician as a possible mass. In addition to mammography and sonography, the radiologist can examine the targeted area with palpation imaging. In a short time, an objective document can be created representing the palpable area. Further clinical workup can then be performed by the referring clinician utilizing three imaging examination reports.

In countries outside the U.S. with limited resources and personnel, this device can be used by health care professionals in an outreach or screening center. Many women find fibrocystic nodularity within their breast and are concerned they have a palpable mass. This device may give the local health care professionals aid to triage those with a palpable mass and those without. Women who are identified as having a palpable lump may then be referred into the centralized healthcare facility to further workup the palpable findings.

Existing data and current trials

Palpation imaging has been studied on patients with a variety of breast disorders. The key goal has been to document the physical findings of the breast disorder. Correlation of the presence of a palpable mass has been demonstrated in initial studies. In a study of 73 patients with palpable masses, palpation imaging compared favorably to physical exam of the breast in both sensitivity (91%) and specificity (90%) with fewer false negative exams (9%)¹. Also in that study, during the examination of 60 patients with normal tissue, palpation imaging correctly identified 92% of normal glandular tissue¹. This limited study is being repeated in a multi-center fashion to confirm the consistency and reproducibility of palpation imaging.

Future potential value

In the near future, algorithms will be developed to go beyond simple documentation of palpable findings. The device will be modified to correlate palpation imaging with specific disorders of the breast. For example, it is known that many breast cancers are more firm, irregular and heterogeneous than benign masses. Preliminary studies using a small subset of patients with breast cancer were also studied with palpation imaging. In this small study, palpation imaging was slightly better than physical exam in cancer identification (92% vs. 80%) with fewer false negatives than physical examination (8% vs. 20%). Further studies and algorithm modifications must occur before palpation imaging can be used in this fashion.

Summary

Prior to the development of palpation imaging, no method existed to create uniform objective measurements of the clinical breast examination. Now, using a specialized transducer, the characteristics of the clinical breast exam, hardness, heterogeneity, size and shape can be measured in real-time and objectively recorded in a reproducible manner. Many clinicians may find use for this device in the regular care for the breast patient to accurately document the breast physical examination. Potential future uses will depend on improvements in the interpretive algorithm.

References:

1. Kaufman CS, Jacobson L, Bachman BA, Kaufman LB. "Objective measurement of the physical exam using a new device: reproducible triage of palpable masses," *Breast Cancer Research and Treatment*, 2004; 88; supp 1:S223-4.
2. Kearney TJ, Airapetian S, Sarvazyan A. "Tactile breast imaging to increase the sensitivity of breast examination," *J Clin Oncol*, 2004; 22; July 15 supp: 1037.