



Breast Thermal Imaging, The Paradigm Shift

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Summary

Infrared thermal imaging of the breast, a non-invasive adjunctive diagnostic methodology has become all but non-existent in the United States. This is in large part due to extensive debate concerning thermography in the trial courts, related to spinal injury cases and also due to the model or basis used for breast thermal imaging. This paper attempts to identify possible factors which will bring thermal breast imaging back into serious mainstream consideration as a valid adjunct to overall breast pathology diagnosis.

Key Words

Breast thermal imaging, protocol, technology, quantification, paradigm shift, prevention, risk assessment.

Introduction

For purposes of this paper, I define the word "paradigm" to mean "model". The paradigm, or model for breast thermal imaging must change.

The initial use of thermography was for breast cancer screening and diagnosis. This was error. Thermography as a test of physiology is not capable of, and will never be capable of detecting breast cancer.

Anatomical testing such as mammography can also not detect breast cancer. This is a paradox. Both procedures, thermography and mammography, demonstrate abnormalities indicating the possibility of the presence of cancer, as well as a host of other breast conditions. These clinical findings require differential diagnosis.

ONLY laboratory confirmation of abnormal cell morphology can make the correct diagnosis of cancer.

Thermography's role in breast cancer and other breast disorders is one of early detection and monitoring of aberrant (abnormal) physiology and the establishment of risk factors for the development or existence of cancer. This is breast thermography's only role at the current time in history.

After large scale clinical trial under appropriate protocols and further development of the procedure, equipment, protocol and certification it is hoped that certain thermal "markers" may become more generally accepted and pathognomonic of various breast disorders, including types and location of cancer.

Appropriate Training

Since thermography is a non-invasive (no radiation) procedure there is no specific legislation or regulatory act under which thermography can be scrutinized in the United States. Early thermographic pioneers created entrepreneurial training and certification programs for both physicians and technicians.

These programs cultivated a host of new course instructors and a variety of organizations and certifications became available.

Some courses offered thermographic certification to people with no medical background or formal medical education. For example, injured workers in California could under vocational rehabilitation laws to become certified as thermographic technicians and open their own labs.

These individuals needed an interpreting physician, so they found doctors who were willing to review and "read" the examinations performed, although few of those physicians themselves had training or certification in the field of thermography.

To avoid a deluge of poor quality and inadequate thermographic study as well as faulty interpretation of the studies, university based training programs must be established. With the electronic super highway in existence, a global network can be aimed at creating such standards and uniformity of study, worldwide.

Appropriate Equipment

There are essentially two types of thermographic equipment utilized in medical practice.

One is LCT (liquid crystal thermography). These are essentially latex plates embedded with liquid crystals which react to surface heat of the body by giving off visible color. The mix of crystals used in the detector determines the detectors ability to differentiate heat ranges.

The other is Electronic Thermography also known as telethermography. The latter are camera\computer based systems which are highly accurate and function in real time with no contact to the subjects skin.

Many manufacturers modified thermographic equipment utilized for night vision or military applications. Some of these detectors were not

of adequate quality to read heat patterns emitted from human skin. For example, a system with a sensitivity above 0.5 degrees C, did not provide consistent quantification (numeric measurement).

Systems which sensitivity of 1.0 degrees centigrade provide for errors ranging between 0.1 and 1.9 degrees. With pathology found at the .4 to 1.0 C range, it is obvious that such equipment is not appropriate for utilization, but none the less, these inappropriate systems were heavily utilized in the 70's and 80's for this purpose.

Early electronic thermographic systems utilized detectors made from indium antimonide which had a spectral range of 2-5 millimicrons. As heat patterns detectable from breast tissue fall into the 8-13 millimicron range the 2-5 millimicron detectors were not adequate and the more expensive mercury cadmium telluride detectors should have been used(1). These detectors were much more costly to the average clinician or research facility and so they were not used. (Focal plane array cameras in the modern era are aiding in the correction of this divergence.

Unaware physicians, who desired to use thermography in their practices purchased the less expensive systems and thus the basis for many of the false positive findings reported in the literature. Had they used the appropriate systems with the correct optical wave band, these false positives would have been eliminated or significantly reduced.

Many of the manufacturers of computer based systems designed software that caused the images to look fantastic, but these images were displaying information that was not necessarily complete and thus, the unwary physician found inconsistency in his studies as well as a high false positive rate which would not have occurred had the appropriate systems been utilized in breast cancer screening.

As with any medical device the appropriate technology, performed according to a consistent and established protocol by board certified individuals will result in more accurate studies and satisfactory scientific yields.

Regulation

Though medicine as a whole cries out for less governmental control, the lack of regulation within the field of thermography is a significant problem. For example, in the United States, medical, chiropractic and podiatric licensing boards have adopted position statements regarding clinical utility of thermography and some have "accepted" various protocols for implementation, but that is all.

However, anyone can own and operate thermographic equipment. Only a licensed health care providers with portal of entry status, (MD, DC, DPM, etc.) can interpret or render a diagnostic opinion of the examination.

In addition, this also relates to the ability to bill an insurance carrier and receive payment for services. Thus entrepreneurs with no formal medical training often submitted studies to insurance companies which were of very poor quality. This resulted in not only denial of payment, but a doubt was rightfully cast on the legitimacy and quality of thermographic studies as they were being performed by inadequate personnel.

With this lack of regulation, a great many poorly performed studies found their way into the medical literature and the court system. (see personal injury model below).

Proper Protocol

A major factor related to the inconsistency of published works in the thermographic imaging field is the various protocols under which the procedures is performed. Although not difficult, the protocol of the examination, a with x-ray or any other diagnostic device, is essential to accurate and reliable outcome.

Some examples of thermographic protocols would be :

Factors Affecting Examination

the ambient room temperature at which the examination is performed

the length of time allowed for patient equilibration to the ambient temperature

the type of equipment utilized

the type of floor covering

the presence or absence of windows which can alter room temperature

the type of heating or air conditioning for thermal regulation of the room.

the usage of lotions, deodorants and cosmetics on the skin

the ingestion of vasodilator and vasoconstrictor substances (ie:caffeine)

the medications taken by the patient

While the scope of this paper can not devote a great deal of space to protocol, it is important to note that most non-thermographic clinicians that the author has had opportunity to oppose in the legal system, have had no idea that such protocol exists or is important.

When I taught the diplomate course for thermography in California, physicians were asked to submit thermographic studies as part of their completion requirements. The vast majority of unacceptable studies (which incidentally, were used for diagnosis of patients in these clinicians practices) were found to contain errors created simply by poor protocol which would have been very easy and inexpensive to correct. For example, performing the procedure on tile flooring which by its cold temperature, caused abnormal sympathetic heating responses in the subject under evaluation. A carpeted floor is required.

Protocol is everything. Without an internationally accepted protocol, no comparison of accuracy, double blinded study, or evaluation of the technology and its effectiveness can be made. With the wide ranging opinion of thermographers and pseudo-thermographers concerning appropriate protocol, it is no wonder that many studies performed worldwide do not correlate, while other studies performed to a stringent protocol are so very consistent.

Anecdotal vs Scientific Evidence

It is very important to differentiate scientific fact from anecdotal evidence. For purposes of this paper I define anecdotal to mean a myth or a fable not supported by fact, but accepted because of a common belief or usage.

Many physicians and investigative journalists use anecdotal data to support their point of view. An example of this is the often published article in a medical journal that uses 20-30 references by other authors who all have just rewritten an original thesis or premise in order to get published without contributing any new data.

Now the materia medica has a number of consistent articles or studies which appear to be powerful when used as an argument for or against a given procedure or point of view. In reality, anecdotal evidence is disastrous when not recognized.

Thermal imaging is pure science. While prone to misinterpretation by "untrained" clinicians, its diagnostic accuracy and yield are unparalleled. With respect to breast thermal imaging, a great number of studies by researchers in different parts of the world, utilizing different technology have still demonstrated the usefulness and clinical utility of the procedure. (when utilized appropriately).

In the United States, William Hobbins, MD(2) demonstrated in a sample of 37,050 patients, a yield of 56 cancers per 1,000 abnormal thermograms as compared to the 5.6 per 1,000 in the BCDDP studies utilizing mammography. In France, Gauthrie et al(3) utilizing thermography determined 73% correct diagnosis in 486 breast cancer patients.

In worldwide retrospective studies, thermograms were positive in a minimum of 71% to a maximum of 93% in patients with breast cancer as reported by Nyirjesy(4).

There are literally thousands of pages of discussion in print regarding the benefits of thermography as it relates to breast cancer. The interesting observation to this author is the wide variety of protocols and equipment utilized and yet a tremendously high statistical correlation of accuracy prevails. Think of what might happen if the technology and training were more standardized.

Comparison of Thermal Imaging to Other Diagnostic Procedures

Comparing anatomic (mammography) to physiologic (thermography) is a great irony and source of confusion in medicine. Many radiologists I have spoken to fear that their investment in mammographic equipment will be wasted because they view thermography as competitive with mammography or that stereo-tactic biopsy is better than thermography.

This is a classic example of the lack of training and anecdotal arguments I have previously described. Mammography is anatomical. So are other beneficial procedures such as ultrasound, diaphenoscropy and CT scanning.

Thermography is a test of physiology (function), and not of anatomy. One can not compare apples to oranges. The procedures are most definitely correlative and complimentary and not competitive. The view that thermography is competitive is error, and one of the most significant detractors from its effective utilization today.

When used adjunctively with other laboratory and outcome assessment tools, the best possible evaluation of breast health is made.

Radiologists need to understand the tremendous potential of thermography to detect the physiologic manifestation of disease that

so often predate the anatomical analysis of the condition. In my first paper on this subject(5) I point out the danger in "over reading" thermograms and state that we should utilize the data obtained from thermal imaging from a "screening" standpoint only, not from a diagnostic one. (1987)

This "complimentary" nature of thermal imaging is of unparalleled significance to this issue.

Quantification

Technology, especially in light of the desk top PC and the Pentium processor, has at last reached a stage of development and cost effectiveness that makes the availability of dynamic quantitative and reliable thermography a definitive reality.

In the past, the quantitative (or numbers) measurement of actual spot temperatures was difficult. Many thermographer s' used liquid crystal imaging (much like the temperature strips we use on our children's foreheads). While bright, colorful and reliable images could be obtained, no precise measurement could be made. This is called qualitative imaging (quality of image).

While the quality of a properly performed thermogram can provide immediate thermal imaging information to the unaided eye, (excluding the estimated 15% of the population who are color blind), errors can be made in the interpretation by assuming that a color change is significant when in fact it may not be.

(authors note: due to the email capabilities of this type of correspondence, the original text and illustration presented below have been modified to meet the standards available for download)

Qualitative thermography uses color or gray scale images for comparison of left to right, as in the right nipple as compared to the left, or the full breast, right compared to left. With qualitative imaging, a color scale is presented as a crude marker for comparison to the patients actual temperatures. It was assumed that a color change indicated a pathology as illustrated below. This was based on a ten

color scale, 1 degree centigrade between colors. So as represented in the diagram, a shift from yellow to orange was assumed to be a 1 degree centigrade increase in heat, left compared to right.

Sample Color Scale Representation .1 degree increments

Pink	Red	Orange	Yellow	Olive	Lime	Dk Blue	Blue	Lavender	Black
31.0*	30.0*	29.0*	28*	27*	26*	25*	24*	23*	22*

X X X-X = 1.0 degree centigrade difference
 Y Y Y-Y = 1.9 degree centigrade difference
 Z Z Z-Z = 0.1 degree centigrade difference

* degrees centigrade

So, if the right breast were orange on the qualitative image, and the left breast were red, a pathology was assumed to exist as a 1 degree centigrade increase in heat had occurred thus shifting the color scale.

WRONG! Please notice that the beginning of each color block has a temperature selected. They increase in 1 degree centigrade increments. Also notice that there is a "0" in the tenths position. This means the system is measuring unit values of 1/10th degree centigrade. Because the color "scale" is assigning only one color to a block of temperature, all temperatures falling within that "block" are assigned by the computer, the same color.

Therefore, a difference as little as .1 degree centigrade or as much as 1.9 degrees centigrade could shift the color assignment. Obviously a .1 degree centigrade shift is minimal and non diagnostic. A 1.9 degree centigrade shift is quite severe and indicative of pathology. Both however, would assign with these outdated systems, the same relative color shift and thus the reason for misdiagnosis and the reporting of the so-called false positives.

In my thermography lecture series, I devote one hour with graphic slides explaining this phenomenon, which is so easily corrected once the "concept" is grasped

I have now designed software that differentially measures the actual spot temperatures in the contralateral tissues so that this error can no longer occur, yet many clinicians still utilize, and rely upon the outdated and dangerous qualitative imaging techniques.

Conclusion

I would like to restate, that thermography of the human breast is not a stand alone tool as some have suggested in the screening and diagnosis of breast cancer. It is adjunctive. We can not ignore thermographys' tremendous role as an early risk indicator or as a monitor for treatment.

When a thermogram is positive, a closer look at the patient's diet, exposure to environmental toxins and pollution and lifestyle is in order. Clinical blood work in addition to mammography is essential.

When mammography and blood work are negative or equivocal, thermographic monitoring on a quarterly to semi-annual basis should be performed in those patients with suspicious thermograms.

In this way changes in tumor angiogenesis can be evaluated and other procedures can be ordered to aid in the earliest possible diagnosis. The procedure is non-ionizing and safe and there is no reason to simply "wait and see" any longer.

It is here that the paradigm needs to shift. We can no longer accept the "wait and see" attitude just because a mammogram is negative. Perhaps some day with a more universal and a-political approach, thermal imaging markers can be even further classified into more effective and even pathognomonic categories. This will require a team approach, worldwide.

Until that time, one thing is certain. In the presence of cancer or not, an abnormal thermogram is indicative of abnormal physiology, and this can not be ignored any longer.

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