Spatial Thermographic Imaging©
Improving the Lifesaving Benefit of Breast Cancer Screening

ABSTRACT: Decades of breast cancer screenings have failed to detect tumors early enough to affect metastatic breast cancer and mortality rates. This unacceptable statistic is about to change. Spatial Thermographic Imaging© ushers in vastly improved and earlier thermal breast cancer detection and identification. Using existing thermography equipment to visualize subcutaneous anatomical details, STI reveals small young tumors years before they are detectable with mammography, or indicate high-risk using traditional breast thermography. STI offers the clear possibility of earlier detection and with it potential for reduced metastasis and improved mortality.

INTRODUCTION

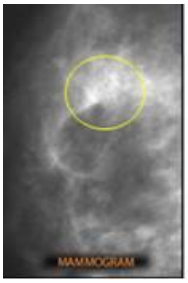
Breast cancer survival has steadily improved, primarily the result of advances in the treatment of the disease. Improvements in medical technology have contributed significantly to the detection and diagnosis of small, non-palpable cancerous lesions; however, these successes have proven inadequate. The incidences of metastatic breast cancer and mortality rate for breast cancer patients have remained essentially unchanged since 1975[1-4].

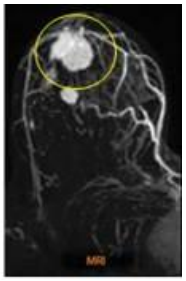
Screening for earlier detection of breast cancer currently remains the best hope for reducing metastasis and improving mortality related to the disease, but the static mortality rate questions whether screening is successful at detecting tumors early enough to affect an appropriate therapeutic response. If the avenue to improved mortality is earlier detection, improved detection and diagnostic techniques must be made available.

X-Ray Mammography is the leading breast cancer-screening tool, but recent studies conclude mammography does not save lives[5,6] and despite its effectivity in detecting sub-palpable lesions, it has not improved mortality nor the incidence of metastasis.

Magnetic Resonance Imaging is safe, noninvasive, significantly more sensitive and provides high resolution, enabling MRI to find small tumors. Excepting its cost, MRI would be an excellent primary screening tool. Current guidelines indicate MRI only for 'high risk' patients.

Figure 1. Mammography and MRI Images of the same afflicted breast hosting a 6cm cluster of three malignant tumors (circled). The cluster and individual tumors are clearly revealed by MRI, but only mildly distinguishable in the mammogram.





Breast Thermography is a non-invasive thermal imaging technique correlating thermal characteristics ("signs") statistically related to breast cancer[7] with the surface thermal patterns resulting from heat transferred from organs and metabolic processes within the breast. The more signs detected, the higher the risk of developed disease. Examination findings are reported as minimal-, low-, and high-risk, with five sub classifications, TH1 - TH5, indicating ascending probability of malignant breast cancer[8, 9].

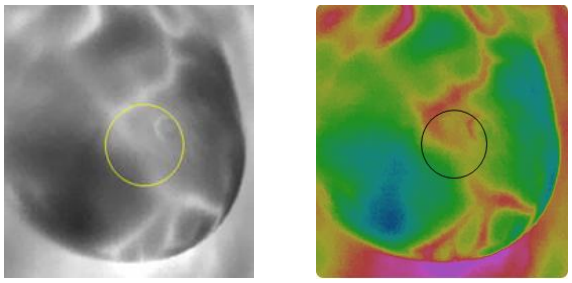


Figure 2. Raw and colorized thermograms
of the breast hosting a cluster of three tumors.

Women and many physicians prefer breast thermography screening, because it is noninvasive, safe, painless, and accurate[10] in detecting signs of breast cancer[11]. In addition, as thermal activity accompanies even nascent metabolic processes, thermography detects early signs of malignancy years before a tumor is detectable with mammography. Notwithstanding the merits associated with breast thermography, is faces obstacles that have served to impact its acceptance as a primary screening tool.

Obstacles Impeding Breast Thermography Acceptance

Breast thermography is an incontrovertibly excellent and unequivocal prognosticator for development of breast cancer, as the abnormal high-risk thermogram in asymptomatic patients is associated with an extraordinarily high risk of cancer. In this regard, breast thermography is superior to mammography, as the abnormal thermogram emerges earlier than the positive mammogram. A low-risk finding, while ruling out advanced cancer, is not the unambiguous prognosticator accompanying high-risk findings.

1) Low-risk findings are ambiguous: Traditional breast thermography, although capable of detecting signs of early cancer, does not reveal the underlying cause of an observed errant thermal sign. Low-risk findings document detection of a small number of thermal signs related to breast cancer, but these same signs are ambiguous as they are associated with myriad other causes, e.g., a healthy breast, cysts, in situ carcinomas, etc.

2) Patient dynamics and complacency: To many women, mere suspicion of breast cancer, including suspicious early signs, is synonymous with a doomed prediction. Worry, fear, and denial are common reactions when a woman discovers she may have breast cancer. Reluctance to seek proper medical care is common, even for symptomatic women. Many patients misconstrue low-risk as

no-risk, and dismiss the detection of signs of possible cancer. These patients mistakenly think they are healthy, disregard recommendations, and reject important follow-up.

3) Screening with X-ray mammography remains the gold standard. Despite ample evidence of earlier detection and the outstanding prognostication power of breast thermography, mammography is retained as the gold standard.

Mammography screening revenue is $10 billion per year and the lifeblood for much of the radiological community. Regardless of the caveats, its protagonists resist any effort to supplant or challenge its use. FDA regulations limit breast thermography screening to an adjunctive role subordinate to mammography, i.e., if thermographic evidence of a possible malignancy is not supported with mammography, the patient is presumed healthy.

SPATIAL THERMOGRAPHIC IMAGING© (STI)

Spatial Thermographic Imaging© ('STI') surmounts the obstacles impeding earlier detection, offering the possibility of improved breast cancer survival, reduced metastasis, and improved mortality rates.

STI is a new imaging technique combining the safety, comfort and thermal sensitivity of breast thermography with a proprietary reconstruction algorithm to provide anatomical visualizations of blood vessels, cysts, and tumors, both benign and malignant.

STI processes conventional thermal images captured with currently available IR cameras to reveal anatomical details lying beneath the surface of the breast. These visualizations disclose details that otherwise would remain hidden, offering the opportunity to detect small tumors in their early stages of development, years before they can be diagnosed with conventional methods. Figure 4 - Figure 7 demonstrate STI, its utility, and its power:

Conventional Breast Thermogram STI Processed

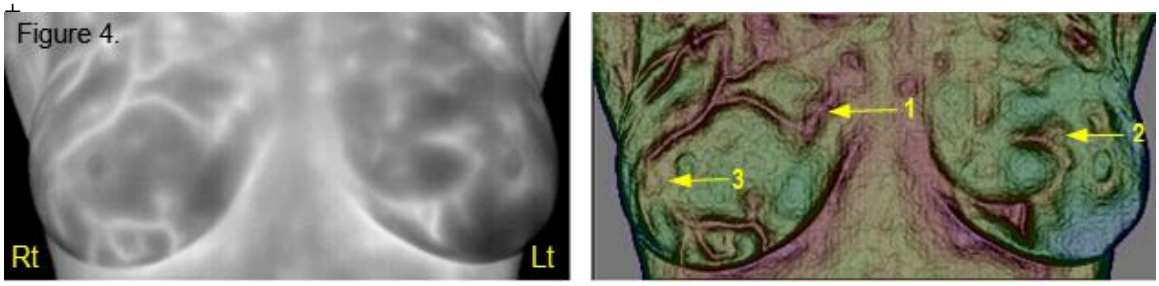
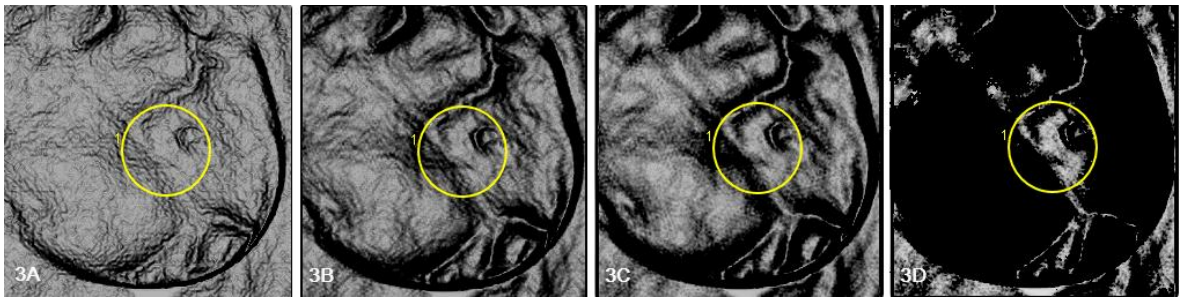


Figure 4. Conventional breast thermogram and with STI processing.

In addition to equivocal intense and asymmetric vascularity, there are important aberrant thermal signs subtly revealed in the raw thermogram. The cause of the revelations is unknown, whereas the STI processed image clearly reveals atypical appendages to a

blood (feeder) vessels as the underlying causes for the atypical signs. Site-1, a mild hyperthermia, easily interpreted as vascular, is a benign cyst; Site-2, a mild hyperthermia, is benign DCIS, and Site-3, remarkably a mild hypothermia, is a cluster of three malignant tumors.

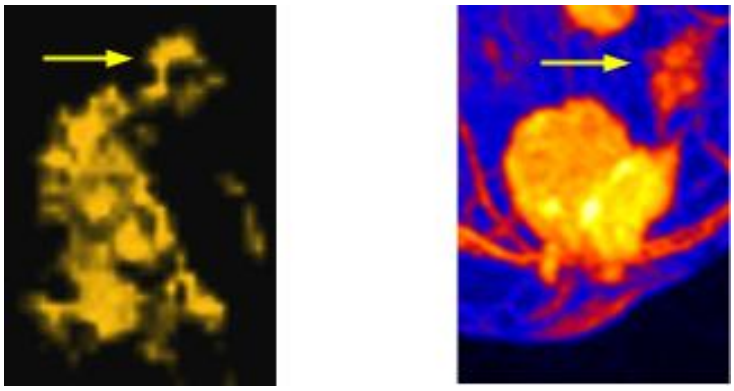
Figure 4, above, is a shallow-depth, macroscopic view of the subcutaneous breast. STI is able to penetrate deep into the breast to better visualize the identified suspicious neoplasms, as Figure 5 demonstrates.



5A 5B 5C 5D

Figure 5. STI traversing through the breast hosting the three tumor cluster from shallow depth (3A), descending through medium depths (3B and 3C), and visualizing the three individual tumors at deep depth (3D).

Figure 6 is a close-up view of the cluster. The arrows point to the smallest of the three tumors, which measures about 2mm across.



STI MRI

Figure 6. Close-up view of three-tumor cluster imaged with STI and with MRI.

Figure 7 evidences the superior imaging capability of STI by way of comparison with mammography and breast thermography, and demonstrates it approaches MRI resolution.

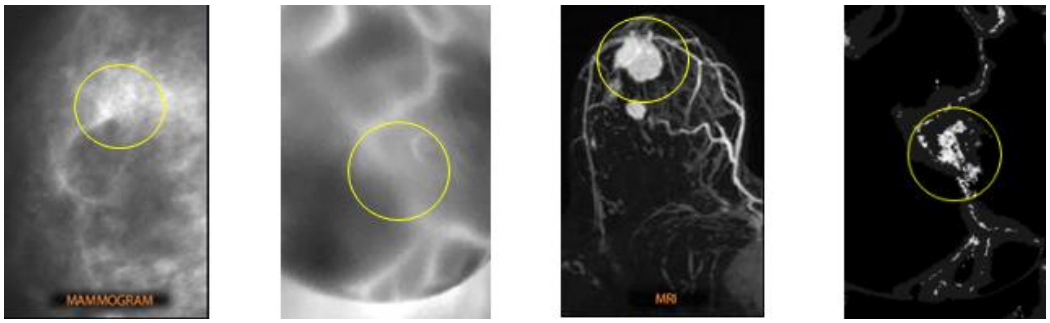


Figure 7. Comparing Mammography, Conventional Thermography, MRI, and STI

Reading Service STI Test Results

More than 1,000 breast thermography examinations interpreted by the TAS reading service have undergone evaluation with STI, with gratifying results. Malignancies have been identified in approximately 25% of low-risk borderline normal (TH2) and borderline abnormal (TH3) patients. STI demonstrates remarkable efficacy in revealing young malignant tumors, while at the same time, ruling out cancer when the low-risk outcomes are caused by benign causes, e.g., cysts, fibroadenomas, etc.

STI Surmounts Breast Thermography Obstacles

1) Overcoming low-risk ambiguities. Breast thermography detects signs of cancer, but those signs also accompany myriad other causes. In addition, unlike mammography and MRI, which reveal anatomical characteristics, breast thermography correlates observed thermal signs with the most frequent and statistically significant thermal characteristics associated with breast cancer. Correlation is not causation; hence, additional uncertainty.

   STI virtually peels away tissue to reveal subcutaneous anatomical details, and these visualizations disclose causes that otherwise would remain hidden. Seeing those details brings clearer understanding of the cause of the underlying sign, because seeing more means knowing more. STI significantly reduces the ambiguities and uncertainties brings causation to the aberrant sign.

2) Combating patient reluctance to follow-up. Low-risk (TH2/TH3) indicates identified signs of cancer, but not advanced cancer, but patients often misinterpret low-risk as no-risk. The issue of patient complacency and the reluctance to seek indicated additional study is driven by misunderstanding, fear, and economics, which, along with potential economic impact provides the fear-motivated excuses for not seeking additional studies that might confirm pathology.

Trying to convince the patient they are at risk of a future catastrophic disease by reviewing conventional thermal images is generally without merit, as the images are confusing and difficult to understand by patients. STI images are complex, but provide an anatomical visualization of the cause underlying the errant sign. If a picture is worth a thousand words, and seeing is believing, on seeing the signs in the raw image enhanced by STI to provide a clear view of the cause, the patient becomes highly motivated to seek further study, regardless of the cost.

3) Mammography remains an obstacle. Overcoming the obstacles presented by the industry promises to be difficult: The acceptance of any other primary screening technology faces significant adversarial resistance. Future clinical trials of STI are expected to duplicate the gratifying results experienced in the TAS reading service.

STI Equipment Requirements

STI processes conventional 255-level grayscale thermographic images captured by all currently used medical grade infrared cameras. While 'high-resolution' (600px x 400px) cameras are available, STI does not require high-resolution cameras to achieve successful results.

The preceding thermal images were recorded with a medium-resolution (320px x 240px), entry-level, medical- grade, infrared-sensitive camera (FLIR sc325).

Figure 8 and Figure 9 were recorded with a low-resolution (160px x 120px) and high-resolution (640px x 400px) cameras, respectively.

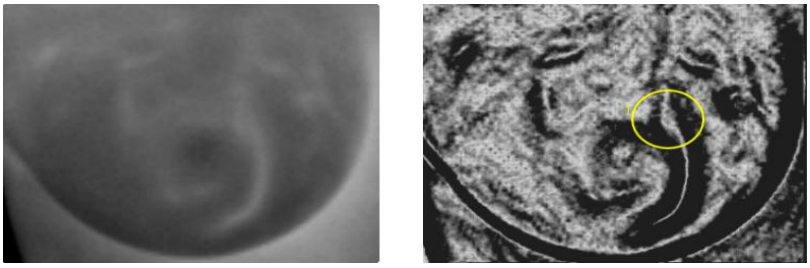


Figure 8. Low-resolution thermal image and same image STI-processed.

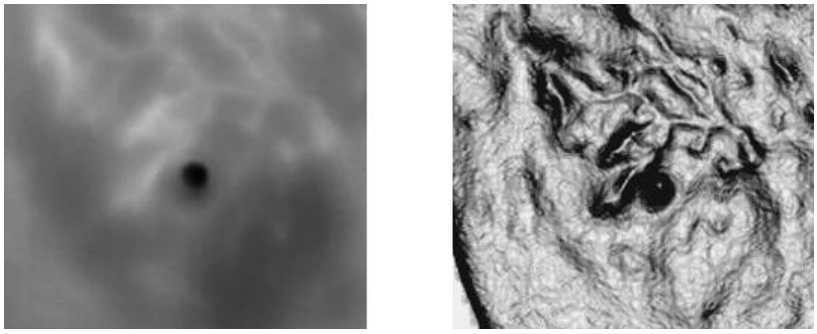


Figure 9. High-resolution thermal image and same image STI-processed.

SUMMARY AND CONCLUSIONS

Mammography, the leading screening modality for decades, detects advanced breast cancer; however, studies irrefutably demonstrate screening for early breast cancer with X-ray mammography is without merit insofar as metastasis and mortality rates are concerned. Breast thermography detects advanced cancer earlier than mammography, is uniquely capable of detecting very early malignancies, and is thus a suitable replacement. Obstacles and imposed restrictions have prevented breast thermography from affecting metastasis and mortality.

STI combines the ability of breast thermography to detect tumors in their infancy with a proprietary algorithm to deliver anatomical visualizations of subcutaneous tissue. These visualizations serve to reveal anatomical details of malignancies years earlier than can be done with current conventional means, while overcoming obstacles associated with traditional breast thermography. More than 1,000 low-risk breast thermography examinations have undergone evaluation with STI, with approximately 25% confirmed malignancies in asymptomatic patients.

With the exception of expensive MRI, STI demonstrates unchallenged efficacy in detecting early breast cancer tumors, and it shows substantial promise of improving metastasis, survival, and mortality rates.

If earlier detection is the answer to improved metastasis and mortality rates, STI is the needed replacement for mammography as the primary breast cancer screening modality.

References and Comments

1. Effect of Screening Mammography on Cancer Incidence and Mortality
JAMA Intern Med. 2015;175(9):1490-1491.
<http://archinte.jamanetwork.com/article.aspx?articleid=2363022>

2. Annual screening does not reduce risk of death from breast cancer
http://www.medicalnewstoday.com/articles/272433.php

3. Mammograms Are Not Effective In Lowering Breast Cancer Death Rates
<http://www.medicalnewstoday.com/articles/253163.php?trendmd-shared=0>

4. Trends in Metastatic Breast and Prostate Cancer — Lessons in Cancer Dynamics
H. Gilbert Welch, M.D., M.P.H., David H. Gorski, M.D., Ph.D., and Peter C. Albertsen, M.D., N Engl J Med 2015; 373:1685-1687
<http://www.nejm.org/doi/full/10.1056/NEJMp1510443>

5. Benefits and harms of mammography screening, Breast Cancer Res. 2015; 17(1): 63.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4415291/>

6. National Cancer Institute Fact Sheet - "Mammograms", Published on-line: <https://www.cancer.gov/types/breast/mammograms-fact-sheet>

7. Accurate and objective evaluation of breast thermograms; basic principles..., M. Gautherie, A. Kotewicz and P. Gueblez, , Thermal Assessment of Breast Health (Proceedings of an International Conference), MTP Press Ltd., 1983, pp72-97

8. A breast absent thermal signs associated with cancer is minimal-risk (normal:TH1). A low-risk finding (borderline-normal:TH2 or equivocal:TH3) indicates a small number of thermal signs known to be associated with cancer have been observed. A high-risk

9. Categories, Classifications, and Associated Risk:

- **TH1 - Normal (Minimal-risk)**: The breast is absent thermal signs associated with malignant breast disease.
- **TH2 - Borderline Normal (Low-risk)**: The breasts are thermally symmetrical, with non-complex vascular patterns and only minor, yet observable changes in tissue. This classification is associated with a 10% risk of confirming malignant breast cancer.
- **TH3 - Equivocal (Low-risk)**: The breast evidences a suspicious atypical metabolic or vascular process. This classification is associated with a 25% risk of confirming malignant breast cancer.
- **TH4 - Abnormal (High-risk)**: The breast exhibits multiple thermal signs correlated with malignant breast cancer. This classification indicates a 60% - 80% risk for development of cancer.
- **TH5 - Severely Abnormal (High-risk)**: The breast exhibits several thermal signs correlated with malignant breast cancer. This category indicates a 96% probability for confirming malignant breast cancer.

10. http://www.americanjournalofsurgery.com/article/S0002-9610(08)00475-3/abstract Effectiveness of a noninvasive digital infrared thermal imaging system in the detection of breast cancer, Nimmi Arora, M.D. et al, Department of Surgery, New York Presbyterian Hospital–Cornell, New York, NY, USA

11. Twenty principal signs of breast cancer are the result of examining 110,000 symptomatic women to identify the most frequent and significant thermal characteristics associated with the disease. Each identified sign derives a weighted score based on its statistical frequency of occurrence and pathological significance. Example signs include local or regional hyperthermia, atypical vascular characteristics, etc., Gautherie, M.; Kotewicz, A.; Gueblez P.: Accurate and objective evaluation of breast thermograms..., Thermal Assessment of Breast Health (Proceedings of an International Conference), MTP Press Ltd., 1983, pp72-97.