Clinical NoTouch BREASTSCAN

Breast IR Imaging: Clinical Research

Clinical infrared imaging is a procedure that detects, records, and produces images of skin surface temperatures and thermal patterns. IR imaging of the breast provides information on the normal and abnormal physiologic functioning of the sensory and sympathetic nervous systems, vascular system, and local inflammatory processes.

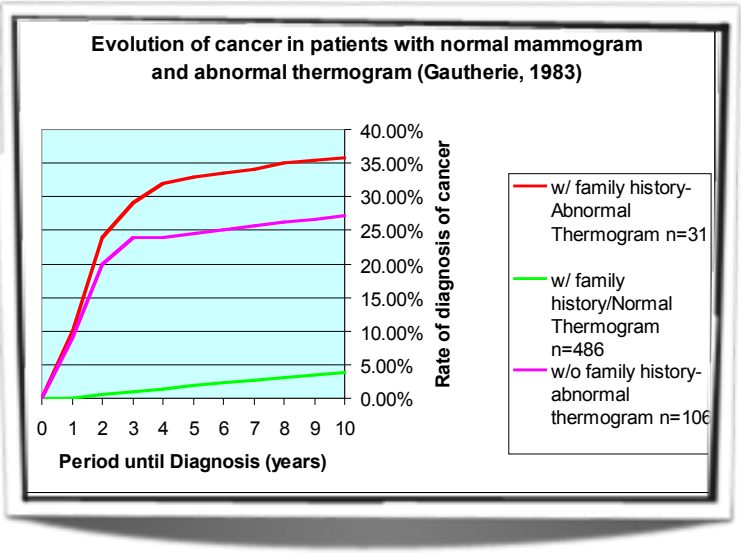
Thermal Imaging for the purposes of adjunctive breast cancer screening is not a new concept. Spanning a period of several decades since the 60s, we have available a plethora of clinical information based on this platform, its advantages and shortcomings. While the commercial use of thermal imaging has declined over the years leading up to present, the global burden of breast cancer has risen to unimaginable proportions, giving us an opportunity to reconsider a novel approach to thermal imaging (NoTouch BreastScan™) and to maximize its clinical potential while minimizing the shortfalls.

In 1965, Gershon-Cohen et al, a radiologist and researcher from the Albert Einstein Medical Center, introduced infrared imaging to the United States. Using a Barnes thermograph, he reported on 4000 cases with a sensitivity of 94%. This data was included in a review of the then current status of infrared imaging published in 1968 in CA - A Cancer Journal for Clinicians.

(Ref: Gershen-Cohen, J., Haberman, J. and Brueschke, E., Medical thermography: A summary of current status. Radiol. Clin. North Am., 3, 403, 1965. Haberman, J., The present status of mammary thermography. CA: A Cancer Journal for Clinicians, 18, 314,1968)

Gautherie and associates screened over 600 women over a period of 10 years. 3.9% of the Control Group (w/ family history and normal thermogram) patients were diagnosed with breast cancer, contrasted with 36% and 27% for Study Group 1 (w/ family history and abnormal thermogram) and Study Group 2 (w/o family history and abnormal thermogram), respectively.

(Ref: Gautherie, M.,Thermobiological assessment of benign and malignant breast diseases.Am. J. Obstet. Gynecol., 147, 861, 1983. Louis, K., Walter, J. and Gautherie, M., Long-term assessment of breast cancer risk by thermal imaging, in Biomedical Thermology, Alan R. Liss Inc., pp. 279–301, 1982)



Breast IR Imaging Publications: 1998 - 2011

Year	Purpose/Location	Sensitivity	NPV
2011	Accuracy of digital infrared imaging for breast cancer detection in women undergoing breast biopsy (USA, dual camera)	87%	90%
2010	The accuracy of digital infrared imaging for breast cancer detection in women undergoing breast biopsy (single camera)	78%	82%
2009	Comparison of IR results in Biopsy proven cancers / India	88%	87%
2009	Comparison of IR results in Biopsy proven cancers for women younger than 50 years of age / UK	78%	n/a
2008	Effectiveness of a noninvasive digital infrared thermal imaging system in the detection of breast cancer / USA (The American Journal of Surgery (2008) 196, 523–526)	97%	82%
2003	Use of IR imaging in enhanced breast cancer detection and monitoring of the clinical response to treatment / USA (Ref: 25a Annual International Conference of the IEEE Engineering in Medicine & Biology Society. IEEE EMBS 1129-1132. ISBN: 0-7803-7790-7)	98%	n/a
2003	IR's ability to distinguish between benign and malignant lesions / USA (Ref: Parisky, Y. R., Sardi, A., Hamm, R., Hughes, K., Esserman, L., Rust, S., & Callahan, K. (2003). Efficacy of computerized infrared imaging analysis to evaluate mammographically suspicious lesions. American Journal of Roentgenology, 180, 263-269)	97%	95%
2001	Develop a single diagnostic parameter that distinguishes benign from malignant breast lesions. (Ref: Anbar, M., Milescu, L., Naumov, A., Brown, C., Button, T., Carty, C., & Al Dulaimi, K. (2001). Detection of cancerous breasts by dynamic area telethermometry. IEEE Engineering in Medicine & Biology Magazine, 20, 80-91)		
2000	The important role of infrared imaging in breast cancer - New technology improves applications in risk assessment, detection, diagnosis, and prognosis. (Ref: Head, J. F., Wang, F., Lipari, C. A., & Elliott, R. L. (2000). IEEE EMBC Magazine, 19, 52-57)		
1998	Combined efficacy of IR with Mammogram and CBE / Canada (Ref: Keyserlingk, J. R., Ahlgren, P. D., Yu, E., & Belliveau, N. (1998). Infrared imaging of the breast: Initial reappraisal using high- resolution digital technology in 100 successive cases of stage I and II breast cancer. Breast Journal, 4, 245-251)	83%	83%

Breast IR Imaging Publications: 1967 - 1983 (summary with references)

Hoffman first reported on thermography in a gynecologic practice. He detected 23 carcinomas in 1924 patients (a detection rate of 12.5 per 1000), with an 8.4% false-negative (91.6% sensitivity) and a 7.4% false-positive (92.6% specificity) rate. Ref: Hoffman,R.,Thermography in the detection of breast malignancy. Am. J. Obstet. Gynecol., 98,681, 1967
Stark and Way screened 4621 asymptomatic women, 35% of whom were under 35 years of age, and detected 24 cancers (detection rate of 7.6 per 1000), with a sensitivity and specificity of 98.3 and 93.5%, respectively. Ref: Stark, A. and Way, S., The screening of well women for the early detection of breast cancer using clinical examination with thermography and mammography. Cancer, 33, 1671, 1974
In a study comprising 25,000 patients screened and 1,878 histologically proven breast cancers, Amalric and Spitalier reported on their results with infrared imaging. From this group a false-negative and false- positive rate of 9% (91% sensitivity and specificity) was found. Ref: Amalric, D., et al., Value and interest of dynamic telethermography in detection of breast cancer. Acta Thermographica, 1, 89–96
In a mobile unit examination of rural Wisconsin, Hobbins screened 37,506 women using thermography. He reported the detection of 5.7 cancers per 1,000 women screened with a 12% false-negative and 14% false-positive rate. His findings also corroborated with others that thermography is the sole early initial signal in 10% of breast cancers. Ref: Hobbins,W.,Mass breast cancer screening. Proceedings, Third International Symposium on Detection and Prevention of Breast Cancer, New York, NY, 637, 1976 Ref: Hobbins, W.B., Abnormal Thermogram — Significance in Breast Cancer. Interamer. J. of Rad., 12, 337, 1987
Spitalier and associates screened 61,000 women using thermography over a 10-year period. The false- negative and positive rate was found to be 11% (89% sensitivity and specificity). Thermography also detected 91% of the non-palpable cancers. The authors noted that of all the patients with cancer, thermography alone was the first alarm in 60% of the cases. Ref: Spitalier, H., Giraud, D., et al., Does infrared thermography truly have a role in present-day breast cancer management? Biomedical Thermology, Alan R. Liss, New York, NY, 269–278, 1982.

Reporting his Radiology division's experience with 10,000 thermographic studies done concomitantly with mammography over a 3-year period, Isard reiterated a number of important concepts including the remarkable thermal and vascular stability of the infrared image from year to year in the otherwise healthy patient and the importance of recognizing any significant change. In his experience, combining these modalities increased the sensitivity rate of detection by approximately 10%; thus, underlining the complementarity of these procedures since each one did not always suspect the same lesion. It was Isard's conclusion that, had there been a preliminary selection of his group of 4393 asymptomatic patients by infrared imaging, mammographic examination would have been restricted to the 1028 patients with abnormal infrared imaging, or 23% of this cohort. This would have resulted in a cancer detection rate of 24.1 per 1000 combined infrared and mammographic examinations as contrasted to the expected 7 per 1000 by mammographic screening alone. He concluded that since infrared imaging is an innocuous examination, it could be utilized to focus attention upon asymptomatic women who should be examined more intensely. Isard emphasized that, like mammography and other breast imaging techniques, infrared imaging does not diagnose cancer, but merely indicates the presence of an abnormality.

Ref: Isard, H. J., Becker, W., Shilo, R., et al., Breast thermography after four years and 10,000 studies. Am. J. Roentgenol., 115, 811, 1972

In a unique study comprising 39,802 women screened over a 3-year period, Haberman and associates used thermography and physical examination to determine if mammography was recommended. They reported an 85% sensitivity and 70% specificity for thermography. Haberman cautioned that the findings of thermographic specificity could not be extrapolated from this study as it was well documented that long- term observation (8 to 10 years or more) is necessary to determine a true false-positive rate. The authors noted that 30% of the cancers found would not have been detected if it were not for thermography.

Ref: Haberman, J., Francis, J. and Love, T., Screening a rural population for breast cancer using thermography and physical examination techniques. Ann. N.Y. Acad. Sci. , 335, 492, 1980.

Gros and Gautherie reported on a large scale study comprising 85,000 patients screened. Culmination of the data resulted in a 90% sensitivity and 88% specificity for thermography.

Ref: Sciarra, J., Breast cancer: Strategies for early detection, in Thermal Assessment of Breast Health (Proceedings of the International Conference on Thermal Assessment of Breast Health), MTP Press LTD, pp. 117–129, 1983.

Ref: Gautherie,M.,Thermo biological assessment of benign and malignant breast diseases. Am. J. Obstet. Gynecol., 147, 861, 1983.

Ref: Louis, K., Walter, J. and Gautherie, M., Long-term assessment of breast cancer risk by thermal imaging, in Biomedical Thermology, Alan R. Liss Inc., pp. 279–301, 1982.

Ref: Gros, C. and Gautherie, M., Breast thermography and cancer risk prediction. Cancer , 45, 51, 1980.

In a large-scale multi center review of nearly 70,000 women screened, Jones reported a false-negative and false-positive rate of 13% (87% sensitivity) and 15% (85% sensitivity) respectively for thermography.

Ref: Jones, C.H., Thermography of the female breast, in Diagnosis of Breast Disease, C.A. Parsons (Ed.), University Park Press, Baltimore, pp. 214–234, 1983.

In a study performed in 1986, Usuki reported on the relation of thermographic findings in breast cancer diagnosis. He noted an 88% sensitivity for thermography in the detection of breast cancers.

Ref: Useki, H., Evaluation of the thermographic diagnosis of breast disease: Relation of thermographic findings and pathologic findings of cancer growth. Nippon Gan Chiryo Gakkai Shi, 23, 2687, 1988.

In a study comparing clinical examination, mammography, and thermography in the diagnosis of breast cancer, three groups of patients were used: 4,716 patients with confirmed carcinoma, 3,305 patients with histologically diagnosed benign breast disease, and 8,757 general patients (16,778 total participants). This paper also compared clinical examination and mammography to other well-known studies in the literature including the National Cancer Institute (NCI)-sponsored Breast Cancer Detection and Demonstration Projects. In this study, clinical examination had an average sensitivity of 75% in detecting all tumors and 50% in cancers less than 2 cm in size. This rate is exceptionally good when compared to many other studies at between 35 and 66% sensitivity. Mammography was found to have an average 80% sensitivity and 73% specificity. Thermography had an average sensitivity of 88% (85% in tumors less than 1 cm in size) and a specificity of 85%. An abnormal thermogram was found to have a 94% predictive value.

Ref: Nyirjesy, I., Ayme, Y., et al., Clinical evaluation, mammography, and thermography in the diagnosis of breast carcinoma. Thermology, 1, 170, 1986

In a series of 4,000 confirmed breast cancers, Thomassin and associates observed 130 subclinical carcinomas ranging in diameter of 3 to 5 mm. Both mammography and thermography were used alone and in combination. Of the 130 cancers, 10% were detected by mammography only, 50% by thermography alone, and 40% by both techniques. Thus, there was a thermal alarm in 90% of the patients and the only sign in 50% of the cases.

Ref: Thomassin, L., Giraud, D., et al., Detection of subclinical breast cancers by infrared thermography, in Recent Advances in Medical Thermology (Proceedings of the Third International Congress of Thermology), Plenum Press, New York, NY, pp. 575–579, 1984.

Parisky and associates published a study from a multi center 4-year clinical trial using infrared imaging to evaluate mammographically suspicious lesions. Data from a blinded subject set was obtained in 769 women with 875 biopsied lesions resulting in 187 malignant and 688 benign findings. The index of suspicion resulted in a 97% sensitivity in the detection of breast cancers.

Ref: Parisky, Y.R., Sardi, A., et al., Efficacy of computerized infrared imaging analysis to evaluate mammographically suspicious lesions. AJR, 180, 263, 2003

As early as 1976, at the third International Symposium on Detection and Prevention of Cancer held in NewYork, thermal imaging was established by consensus as the highest risk marker for the possibility of the presence of an undetected breast cancer

Ref: Amalric, R., Gautherie, M., Hobbins, W. and Stark, A., The future of women with an isolated abnormal infrared thermogram. La Nouvelle Presse Medicale, 10, 3153, 1981.

Ref: Gautherie, M. and Gros, C., Contribution of infrared thermography to early diagnosis, pre-therapeutic prognosis, and post-irradiation follow-up of breast carcinomas. Laboratory of Electroradiology, Faculty of Medicine, Louis Pasteur University, Strasbourg, France, 1976.

Ref: Hobbins, W., Significance of an "isolated" abnormal thermogram. La Nouvelle Presse Medicale, 10, 3155, 1981.

The Wisconsin Breast Cancer Detection Foundation presented a summary of its findings in this area, which has remained undisputed. This, combined with other reports, has confirmed that an abnormal infrared image is the highest risk indicator for the future development of breast cancer and is 10 times as significant as a first order family history of the disease.

Ref: Hobbins, W., Thermography, highest risk marker in breast cancer. Proceedings of the Gynecological Society for the Study of Breast Disease, 267–282, 1977.

Ref: Louis, K., Walter, J. and Gautherie, M., Long-term assessment of breast cancer risk by thermal imaging, in Biomedical Thermology, Alan R. Liss Inc., pp. 279–301, 1982.

In a study of 10,000 women screened, Gautherie found that, when applied to asymptomatic women, thermography was very useful in assessing the risk of cancer by dividing patients into low and high risk categories. This was based on an objective evaluation of each patient's thermograms using an improved reading protocol that incorporated 20 thermo-pathological factors.

Ref: Gauthrie, M., Improved system for the objective evaluation of breast thermograms, in Biomedical Thermology. Alan R. Liss, Inc., New York, NY, pp. 897–905, 1982.

A screening of 61,000 women using thermography was performed by Spitalier over a 10-year period. The authors concluded that "in patients having no clinical or radiographic suspicion of malignancy, a persistently abnormal breast thermogram represents the highest known risk factor for the future development of breast cancer".

Ref: Spitalier, H., Giraud, D., et al., Does infrared thermography truly have a role in present-day breast cancer management? Biomedical Thermology, Alan R. Liss, New York, NY, 269–278, 1982.

From a patient base of 58,000 women screened with thermography, Gros and associates followed 1527 patients with initially healthy breasts and abnormal thermograms for 12 years. Of this group, 44% developed malignancies within 5 years. The study concluded that “an abnormal thermogram is the single most important marker of high risk for the future development of breast cancer”.

Ref: Gros, C. and Gautherie, M., Breast thermography and cancer risk prediction. Cancer , 45, 51, 1980.

Spitalier and associates followed 1416 patients with isolated abnormal breast thermograms. It was found that a persistently abnormal thermogram, as an isolated phenomenon, is associated with an actuarial breast cancer risk of 26% at 5 years. Within this study, 165 patients with non-palpable cancers were observed. In 53% of these patients, thermography was the only test which was positive at the time of initial evaluation. It was concluded that (1) A persistently abnormal thermogram, even in the absence of any other sign of malignancy, is associated with a high risk of developing cancer, (2) This isolated abnormal also carries with it a high risk of developing interval cancer, and as such the patient should be examined more frequently than the customary 12 months, (3) Most patients diagnosed as having minimal breast cancer have abnormal thermograms as the first warning sign.

Ref: Amalric, R., Giraud, D., et al., Combined diagnosis of small breast cancer. Acta Thermographica, 1984.

Ref: Spitalier, J., Amalric, D., et al., The Importance of infrared thermography in the early suspicion and detection of minimal breast cancer, in Thermal Assessment of Breast Health, MTP Press Ltd. pp. 173–179, 1983.

In a study by Gautherie and associates, the effectiveness of thermography in terms of survival benefit was discussed. The authors analyzed the survival rates of 106 patients in whom the diagnosis of breast cancer was established as a result of the follow-up of thermographic abnormalities found on the initial examination when the breasts were apparently healthy (negative physical and mammographic findings). The control group consisted of 372 breast cancer patients. The patients in both groups were subjected to identical treatment and followed for 5 years. A 61% increase in survival was noted in the patients who were followed-up due to initial thermographic abnormalities. The authors summarized the study by stating that “the findings clearly establish that the early identification of women at high risk of breast cancer based on the objective thermal assessment of breast health results in a dramatic survival benefit”.

Ref: Gautherie, M., et al., Thermobiological assessment of benign and malignant breast diseases. Am. J. Obstet. Gynecol., 147, 861, 1983.

Ref: Jay, E. and Karpman, H., Computerized breast thermography, in Thermal Assessment of Breast Health, MTP Press Ltd., pp. 98–109, 1983.