

Technology Review



THERMOGRAPHY

(INFRARED THERMAL
IMAGING)

HEALTH TECHNOLOGY ASSESSMENT UNIT
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1. INTRODUCTION

Medical infrared imaging has been used for applications where physiological information is needed for a comprehensive diagnosis. The primary areas of clinical use include breast health and identification of primary causes of undiagnosed pain. The first use of thermobiological diagnostics is attributed to Hippocrates who in 480 B.C. applied wet mud to the body and picked up the areas that dried first as indicating underlying organ pathology. In 1957 Dr. Ray Lawson discovered and published that the skin temperature over a cancer in the breast was higher than that of normal tissue.

Thermography indicates the temperature pattern to identify an abnormality. Hence, there is no radiation risk as it captures the infrared radiation from the skin and is totally painless.

Thermography, although used as a breast cancer detection tool, has not been accepted on par with mammography, which is the 'gold standard' in breast cancer detection. One of the reasons is the incidence of false positive cases. Since a thermogram only detects superficial abnormalities, there is a high incidence of false positive. Thermal imaging systems have been claimed to be used in detection of other medical conditions such as musculo-skeletal syndromes, nerve disorders, wound healing, stroke, skin cancer, deep vein thrombosis, carpal tunnel syndrome, cardiovascular & stroke risk appraisal.

2. TECHNICAL FEATURES

Thermography is a map of the heat coming from the body using specialized infrared cameras that measure temperature. It does not use radiation or compression and is a non-invasive test. Thermography measures 5 to 6 mm below the dermal level of the skin. Mammography, x-ray, ultrasound and MRI are anatomical tests that provide information on structure and depth.

Thermal imaging provides information on the functioning of the sympathetic nervous system including neurological or vascular dysfunction, myofascial trauma and local inflammatory process. Infrared imaging records temperature changes in blood flow as thermal patterns that display a unique design called thermal signatures. The thermal signatures display patterns of temperature as either hyperthermic (hot) or hypothermic (cold).

The diagnosis of neurological, musculoskeletal or breast abnormalities by thermal imaging is based on comparative temperature asymmetry between normal and abnormal sites. A change in normal temperature contralaterally- outside the known standard range of temperature- is a signal of abnormal function.

It is important that proper protocols are used when performing breast or pain thermograms. A baseline thermogram of the breast is first performed. The patients' hands or feet are then immersed in ice water for 1 minute or until tolerance and then an additional scan of the breast is carried out. This challenges the autonomic nervous system and creates a 'fight or flight' response under sympathetic control.

The current infrared thermal imaging cameras are capable of one part in 4096 resolution, while previous cameras had 8-bit (one part 256) resolution. Thus the results of recent clinical trials are not comparable with the previous ones.

3. METHODOLOGY

Retrieval of evidence-

1. Literature search was done using the MEDLINE and COCHRANE database. The search includes studies in all languages, and limitation was only applied to human subjects.

The keywords used in the search were:

-thermography, infrared thermal imaging, infrared thermal scan, thermal texture map, effectiveness, efficacy, safe*, cost-effectiveness, cost implication, and legal or law, in various combinations.

2. HTA databases were also searched- AHFMR, AHRQ, HTA database
3. Related links were also searched-ECRI, UHMS, TRIP database, Journal websites
4. General search using Google.

4. RESULTS

4.1 Effectiveness

Two systematic reviews were found regarding the effectiveness of thermography in a general context. CETS (1998) reported that large studies showed that thermography, as a screening test for breast cancer, had low accuracy in comparison with other techniques, especially mammography. Its role as a prognostic tool in breast cancer has not been confirmed. There was also no proven effectiveness in detecting spinal and peripheral nerve compression, diagnosis of regional pain syndromes and myofascial pain/ fibromyalgia syndromes, vascular conditions, and dental and maxillofacial practice.

The other systematic review by Hendelsman (1989) failed to support claims of efficacy of thermography as a useful diagnostic modality for non-breast indications. Rather, it is suggested that thermography lacks sensitivity, specificity, or predictive value. Data are lacking to indicate that thermography provides a useful guide to monitor the effect of treatment of any disease entity. The evidence suggest that thermography may only confirm the presence of a temperature difference, that other procedures are needed to reach to a specific diagnosis, and that thermography may

add little to what physicians already know based on history, physical examination, and other studies.

a. Breast cancer

A health technology assessment report in 2004 by Kerr, reviewed the effectiveness of infrared thermography for population screening and diagnostic testing of breast cancer. This assessment reported the evidence that is currently available does not provide enough support for the role of infrared thermography for either population screening or adjuvant diagnostic testing of breast cancer.

Parisky et al (2003) conducted a multi-center 4-year clinical trial at five institutions using infrared imaging of patients for whom breast biopsy had been recommended. He reported that in the 875 biopsied lesions, the index of suspicion resulted in 97% sensitivity, 14% specificity, 95% negative predictive value and 24% positive predictive value. Lesions that were assessed as false negative by infrared analysis were microcalcifications, so an additional analysis was performed in a subset excluding lesions described only as microcalcification. In this restricted subset of 448 subjects with 479 lesions and 110 malignancies, the index of suspicion resulted in 99% sensitivity, 18% specificity, 99% negative predictive value, and 27% positive predictive value. Analysis of infrared imaging performance in all 875 biopsied lesions revealed that specificity was statistically improved in dense breast tissue compared with fatty breast tissue.

Keyserlink et al (2000) observed that when a mammogram was conducted on patients with suspicious clinical examinations the sensitivity was found to be 83%. A combination of mammogram and thermogram increased the sensitivity to 93%. When all three methods (clinical examination, mammogram and thermogram) were considered, the sensitivity was found to be 98%.

In *conclusion*, there is insufficient evidence to support the effectiveness of thermography in this area.

b. Neurology

Tong et al (2003) reported that a thermogram could be used effectively to confirm the success of lumbar sympathetic ganglion block. There is no evidence to support the use of thermography in discogenic disease, spinal or peripheral nerve compression.

In *conclusion*, there is insufficient evidence to support the effectiveness of thermography in this area.

c. Rheumatology

Martini (2002) reported that thermography is a promising diagnostic tool to detect disease activity in localized scleroderma with a sensitivity of 92% and specificity of 68%.

In *conclusion*, there is insufficient evidence to support the effectiveness of thermography in this area.

d. Diagnosis of pain

Thomas (1990) reported that infrared thermography may be useful as a diagnostic tool or as an adjunct to magnetic resonance imaging (MRI), computed tomography (CT) scan or myelography in detecting the cause of low back pain.

In *conclusion*, there is minimal evidence to support the effectiveness of thermography in this area.

e. Surgery

Hamm et al (1986) used thermography in his study to diagnose and evaluate varicoceles in combination with sonography and found that thermography was more sensitive than sonography in detecting persistent varicoceles, with accuracy of 98.4% vs. 92.7%.

In *conclusion*, there is insufficient evidence to support the effectiveness of thermography in this area.

f. Dental and maxillofacial

A 6-year clinical assessment of electronic facial thermography was done by Grant et al (1996) to diagnose the cause of orofacial pain. These include diagnosing sympathetically maintained pain, peripheral nerve mediated pain, TMJ arthropathy, and maxillary sinusitis, cracked tooth syndrome, trigeminal neuralgia, or psychogenic facial pain. The new system of thermal classification resulted in 92% agreement in classification of pain patients and matched controls. This author concluded that thermography has a promising future in aiding the formation of a differential diagnosis of orofacial pain and may help in understanding mechanisms of pain as well as directing therapies.

In *conclusion*, there is insufficient evidence to support the effectiveness of thermography in this area.

g. Vascular

Thermography has been tested for identifying vascular disease in Raynaud's phenomenon, detection of vulnerable plaque and diagnosing venous thrombosis (Herrick, 1998; Briain, 2003) but these literatures are of poor grade.

In *conclusion*, there is insufficient evidence to support the effectiveness of thermography in this area.

4.2 Safety

The literature retrieved were anecdotal, claiming that thermography is harmless based on the fact that its application is rapid, it facilitates the measurement of moving targets, it is a non-contact procedure, it allows measurements of hazardous or physically inaccessible objects, no interference and no energy lost from the target, no risk of contamination, and no mechanical effect on the surface of the object (Katsberger, 2003).

4.3 Cost

There is minimal literature available regarding cost effectiveness or cost implications of thermography. Mooney (1982) identified a British national health survey screening costing study in a particular screening clinic for different regimes: mammography, thermography and clinical examination; thermography and clinical examination; and mammography and clinical examination. Each of these had one or two clinical examinations and the option of single or double reporting of mammograms and thermograms. It then compares the cost-effectiveness of these different regimes where 'costs' are defined widely to include not only screening costs but also biopsy costs, anxiety costs for women biopsied, costs of false negatives etc. The author conclude that mammography with single reporting together with a single clinical examination is the most cost effective option.

Weinstein & Weinstein (1986) suggests that because of its accuracy, low risk, and non-invasive nature, thermography should be employed as a cost effective initial screening procedure to distinguish between patients with substantive radicular disorders and those experiencing minor localized injury.

4.4 Legal aspects

The literatures retrieved regarding legal aspects of thermography use are mainly focused on neurological conditions. There was no other literature available regarding other conditions. Uricchio JV Jr. (1985) believes that practitioners involved in managing clinical situations such as soft-tissue injuries, peripheral nerve insult, reflex sympathetic dystrophy, and nerve root irritation should have knowledge of the test used in their management as well as the indications for the test. He warns that lack of mandated regulatory board guidelines presents the potential for abuse of thermography, both in its application and interpretation.

Finnegan & Koson (1985) examined the medical and value of thermographic picture as legal evidence of spinal conditions and nerve root compression. They concluded that the technical problems of obtaining reproducible test patterns, coupled with the difficulties of interpretation, particularly with respect to spinal conditions, make thermography an unreliable scientific test and thus invalid legal basis for court decisions.

5. CONCLUSION

5.1 Effectiveness

The evidence that is currently available does not provide enough support for the role of infrared thermography for either population screening or adjuvant diagnostic testing of breast cancer. There is also no evidence to support its use in diagnosing discogenic disease, spinal or peripheral nerve compression, detecting disease activity in localized scleroderma, detecting the cause of low back pain, in dental and maxillofacial practice, or vascular disorders.

5.2 Safety

There is insufficient evidence to support that thermography is safe.

5.3 Cost

There is insufficient evidence to support that thermography is cost effective.

5.4 Legal aspects

There is some evidence to conclude that the use of thermography is invalid in a court of law, particularly for spinal and neurological conditions.

6. APPENDIX

A- Evidence table:

- effectiveness
- safety
- cost effectiveness
- legal aspects

B- Levels of evidence scale

**EVIDENCE TABLE: THERMAL TEXTURE MAPS
ASPECT: EFFECTIVENESS**

No	Author, title, Journal, Year, Volume, Page Number	Study Design, Sample Size, Follow up	Outcomes & Characteristics	Grade	Comment
1	Report CETS 98-5 NE Thermography. Technology Brief. Montreal: CETS, 1998. Vi-16 P. (ISBN 2-550-34381-6).	HTA	<p>-Thermography was first proposed as a screening test for breast cancer but large studies showed that it had low accuracy in comparison with other techniques, especially mammography. In more recent studies, its role as a prognostic tool has not been confirmed.</p> <p>-Its use in the detection of spinal and peripheral nerve compression appeared promising, but this was not substantiated by later studies and, in the case of spinal nerve compression, by a meta-analysis.</p> <p>-Thermography has no current role in diagnosis of regional pain syndromes and myofascial pain/fibromyalgia syndromes.</p> <p>-Vascular conditions can be diagnosed more accurately by ultrasound techniques and although the possible utility of thermography in dental and maxillofacial practice has been raised in recent studies, there is no definite role for thermography in mainstream clinical practice at present.</p>	Good	

			-The most recent report by the Council on Scientific Affairs of the American Medical Association (AMA) in 1993 concluded that 'in view of the lack of sufficient proof of effectiveness, it is the policy of the AMA that use of thermography for diagnostic purposes cannot be recommended at this time'. Review of the most current literature shows no reason to change this conclusion.		
2	Handelsman H. Thermography for indications other than breast lesions. Health Technol Assess Rep 1989;Rockville MD. National Center for Health Services Research and health Care Technology Assessment, no.2. Accession no. 16526	HTA	This HTA failed to support claims of efficacy of thermography as a useful diagnostic modality for non-breast indications. Rather, it is suggested that thermography lacks sensitivity, specificity, or predictive value. Data are lacking to indicate that thermography provides a useful guide to monitor the effect of treatment of any disease entity. The evidence suggest that thermography may only confirm the presence of a temperature difference, that other procedures are needed to reach a specific diagnosis, and that thermography may add little to what physicians already know based on history, physical examination , and other studies.		

BREAST CANCER					
3	<p>Kerr J. Review of the effectiveness of infrared thermal imaging (thermography) for population screening and diagnostic testing of breast cancer. Christchurch: New Zealand Health Technology Assessment (NZHTA), 2004:49.</p>	<p>Systematic review (HTA) To review the evidence for the effectiveness of infrared thermography for population screening and diagnostic testing of breast cancer?</p>	<p>CONCLUSION: The evidence that is currently available does not provide enough support for the role of infrared thermography for either population screening or adjuvant diagnostic testing of breast cancer. The major gaps in knowledge at this time can only be addressed by large-scale, prospective randomised trials. More robust research on the effectiveness and costs of technologically advanced infrared thermography devices for population screening and diagnostic testing of breast cancer is needed, and the conclusions of this review should be revisited in the face of additional reliable evidence.</p>	Good	

4	Parisky YR et al. Efficacy of computerized infrared imaging analysis to evaluate mammographically suspicious lesions. AJR Am J Roentgenol. 2003 Jan;180(1):263-9.	Multi-center 4-year clinical trial, conducted at five institutions using infrared imaging of patients for whom breast biopsy had been recommended. The data from a blinded subject set were obtained in 769 subjects with 875 biopsied lesions resulting in 187 malignant and 688 benign findings.	<p>In the 875 biopsied lesions, the index of suspicion resulted in a 97% sensitivity, a 14% specificity, a 95% negative predictive value, and a 24% positive predictive value. Lesions that were assessed as false-negative by infrared analysis were microcalcifications, so an additional analysis was performed in a subset excluding lesions described only as microcalcification. In this restricted subset of 448 subjects with 479 lesions and 110 malignancies, the index of suspicion resulted in a 99% sensitivity, an 18% specificity, a 99% negative predictive value, and a 27% positive predictive value. Analysis of infrared imaging performance in all 875 biopsied lesions revealed that specificity was statistically improved in dense breast tissue compared with fatty breast tissue.</p> <p>CONCLUSION: Infrared imaging offers a safe noninvasive procedure that would be valuable as an adjunct to mammography in determining whether a lesion is benign or malignant.</p>	Fair	No mention about the study sampling whether it was randomized
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5	<p>J.R. Keyserlink. Functional Infrared Imaging of the Breast. Journal of IEEE Engineering in Medecine and Biology, pp 30-41, May/June 2000</p>	<p>Clinical trial using a new high-resolution, computerized IR station and software program acquired by the Ville Marie Breast Center. Objective (1) to assess IR imaging's ability to complement clinical exam and mammography in the early detection of breast cancer.(2) to show that high- resolution IR imaging provides additional safe, practical, and objective information when produced and interpreted by sufficiently trained breast physicians. Our integrated IR station consisted of a scanning-mirror optical system containing a mercurycadmium- telleride detector (Bales Scientific, CA) with a spatial resolution of 600 optical lines</p>	<p>-Infrared imaging revealed minor variations (IR- 1 or IR-2) in 17% of our patients while the remaining 83% had at least one (34%), two (37%), or three (12%) abnormal IR signs. Of the 39 patients with either a nonspecific or equivocal clinical exam, 31 had at least one abnormal IR sign, with this modality providing pertinent indication of a potential abnormality in 14 of these patients who, in addition, had an equivocal or nonspecific mammography - The mean histologically measured tumor size for those cases undetected by mammography was 1.66 cm, while those undetected by IR imaging averaged 1.28 cm. In a concurrent series of 100 consecutive eligible patients who had an open biopsy that produced benign histology, 19% had an abnormal IR image and 30% had an abnormal preoperative mammography that was the only indication for surgery in 16 cases. The 83% sensitivity of IR imaging in this series is higher than the 70% rate for similar Stage I and 11 patients tested from the Royal Marsden Hospital two decades earlier -Infrared imaging's most tangible contribution in this series was to signal an abnormality in a younger cohort of breast cancer patients who had noncontributory mammograms and also nonspecific clinical exams who conceivably would not have been passed on for second-line evaluation. -17% of these tumors were undetected by IR imaging. -19% false positive rate in histologically proven benign conditions, in part a reflection of our current grading system,</p>	<p>This study uses current cameras which is capable of one part in 4096 resolution, while previous IR cameras had 8- bit (one part in 256) resolution</p>
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6	<p>Health Devices Alerts™ Abstracts 1984-01-20 Abstract 07373. Radiologists adopt anti-thermography policy for breast cancer screening. Med World News 24:10; 1983 Dec 12. Accession No: 07373</p>	Policy statement	<p>A policy statement issued by the American College of Radiology states that thermography to detect breast cancer, because of its low rates of accuracy, is a waste of time and money, and is not recommended except as an ancillary test. SA Feig, M.D., professor of radiology at Jefferson Medical College in Philadelphia, expresses concern that women who have negative thermograms may mistakenly believe they don't need follow-up mammography.</p>	Poor	
8	<p>Richardson JD. Imaging of the breast. Med Clin North Am. 1984 Nov;68(6):1481-514</p>	? systematic review	<p>Based upon current evidence, thermography does not appear to have any established clinical indications. Computed tomography, ultrasonography, lightscanning, and NMR may be useful as adjuncts to mammography, and further research seems warranted. Mammography remains the "gold standard" in breast imaging.</p>	Poor	Abstract

9	Mazurin Via et al. [Thermography in ambulatory care of patients with breast cancer]. Vopr Onkol. 1983;29(8):22-5. [Article in Russian]	5-year dynamic thermographic study carried out in 78 out-patients with breast cancer	Thermographic procedure offers a means of timely detection of recurrences and metastases (those into bones included). Its diagnostic value consists in that symptoms, recurrences and metastases detectable by its application develop at an earlier stage than those detected by X-ray techniques and before clinical manifestations of the disease. Thermographic procedure is used for monitoring application of chemotherapy and its timely modification. Since it is not time-consuming and is absolutely harmless it should be used on a large scale for monitoring the condition of breast cancer patients and the efficacy of their treatment.		
10	Moskowitz M. Screening for breast cancer: how effective are our tests? A critical review. CA Cancer J Clin. 1983 Jan-Feb;33(1):26-39.	Review	Little evidence to indicate that clinical thermography lowers the stage at detection, and neither does a positive thermogram in screening seem to have a strong predictive value.	Good to fair	
11	Rodes ND. Cancer of the breast. Screening. Major Probl Clin Surg. 1979;5:91-112.	Cohort study	The definitive role of thermography in detection of breast disease has yet to be fully determined. The maximal scientific benefit and the true impact of the screening demonstration projects will be realized only after long-term followup of the 280,000 participants.		No results re. this study was available to achieve to a conclusion.

12	Dodd GD. Present status of thermography, ultrasound and mammography in breast cancer detection. Cancer. 1977 Jun;39(6 Suppl):2796-805.	Consensus	-At present thermography finds its greatest use as an adjunct to mammography and physical examination; it should not be used as the sole modality in a screening program -overall true positive rate of 70% to 75% may be anticipated with thermography, the bulk of false negatives would seem to occur in those tumors most amenable to therapy, i.e., subclinical cancers. The "false positive" rate of thermography is also excessive, but would be acceptable for establishing a high risk group if true positive rates could be improved.	Poor	Very back-dated evidence
13	Feig SA Thermography, mammography, and clinical examination in breast cancer screening. Review of 16,000 studies. Radiology. 1977 Jan;122(1):123-7.	Prospective study	Breast cancer screening detected 139 biopsy-proved malignancies in 16,000 self-selected women (8.7/1,000). In these, xeroradiography detected 78% (109), clinical examination 55% (76), and thermography 39% (54). In all 16,000 women, the thermogram was interpreted as positive in 17.9% (2,864). The greatest effectiveness of mammography vs. clinical examination was seen in detection of early breast cancers (small lesions with negative axillary lymph nodes). In this group, thermography was less effective than it was in patients with larger lesions and lymph node metastases.	Fair	

14	Moskowitz M. Lack of efficacy of thermography as a screening tool for minimal and stage I breast cancer. N Engl J Med. 1976 Jul 29;295(5):249-52.	In a study of thermograms of 42 patients with Stage 1 or smaller carcinomas of the breast, 44 confounding cases and 64 randomly selected subjects being screened	The ability of expert thermographers to identify the patients with carcinoma correctly (true positive = 0.238) varied little from the ability of untrained readers (true positive = 0.301). Furthermore, in the expert group, the indexes of suspicion were so high (0.436) and the true-positive levels were so relatively low (0.238, P = 0.0005). CONCLUSION: Thermography may well have a very limited role as a screening or pre-screening modality for the detection of minimal or Stage 1 breast cancers.	Poor	No mention about the study design.
15	Revesz G. Breast thermography as a screening technique. An evaluation of performance data. Cancer. 1975 Dec;36(6):2159-63.	Review	The concepts of relative operating characteristics (ROC-curves) and detectability index (d') are introduced for the purpose of evaluating performance in breast thermography. In assessing published information on the subject the authors have found that much of it is anecdotal and lacks sufficient data to determine performance. It was also found that for those published findings which had sufficient data it was possible to reconcile conflicting conclusions as to the efficacy of thermography, and that performance could be quantitated with the use of the detectability index.	Good	

16	Edell & Eisen . Current imaging modalities for the diagnosis of breast cancer. Del Med J. 1999 Sep;71(9):377-82.	Anecdotes. This article is an overview of imaging modalities that have emerged to augment mammography and improve the accuracy of non-invasive breast cancer diagnosis.	Ultrasound is currently used to differentiate breast masses and guide aspirations and biopsies. Magnetic resonance imaging has excellent sensitivity in demonstrating breast cancer but a low specificity. Nuclear medicine studies have recently emerged that detect the increased metabolic rate and vascularity of breast cancers. Other modalities, such as thermography and computed tomography, have a more limited utility for breast cancer diagnosis. Digital mammography is among other emerging technological advancements that will continue to develop and improve the accuracy of breast cancer diagnosis in the future.	Poor	
17	Kaiser WA. [MR mammography]. Radiologe. 1993 May;33(5):292-9. [Article in German]	Anecdotes	-Among the available imaging modalities (mammography, sonography, DSA, thermography, CT) only mammography has been able to demonstrate a significant reduction in mortality, but unfortunately only for women above 50 years of age. -"dynamic magnetic resonance mammography (MRM)," i.e., repetitive imaging of the same slices before and at short time intervals after the injection of a contrast medium, high sensitivity (98.9%) and specificity (97.2%) was found in detecting breast cancers of different histologies.	Poor	

18	Heywang-Kobrunner SH. Non-mammographic breast imaging techniques. Curr Opin Radiol. 1992 Oct;4(5):146-54.	Evaluation of techniques that image other physical tissue properties (sonography, thermography, trans-illumination, CT, non-contrast-enhanced MR imaging, biomagnetism, biostereometry, and ductoscopy)	Among these techniques, digital luminescence radiography and contrast-enhanced MR imaging are the most developed and the most promising. They are at the threshold of becoming clinically important. Doppler ultrasound could be useful for certain indications. Whereas MR spectroscopy, positron-emission tomography, the search for appropriate antibodies, and possibly transillumination, ductoscopy, and biomagnetism offer interesting new aspects for research, the value of CT, thermography, and biostereometry is not yet established.	Poor	
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19	<p>Ciatto S. Diagnostic and prognostic role of infrared thermography. Radiol Med (Torino). 1987 Oct;74(4):312-5.</p>	<p>Cohort study. A series of 469 breast cancer studied by physical examination (PE), mammography (M) and infrared thermography (TH) is discussed. Follow-up was performed up to 5 years later.</p>	<p>-The poor diagnostic role of TH is proven for the low sensitivity in the total series (0.47) and, particularly, in T1 cancers (0.26). -TH does not increase significantly the cumulative sensitivity (0.98 vs. 0.97 in the total series). Its limited advantage is offset by the great number of useless biopsies due to TH false positive. -A correlation between TH pattern and prognosis is evident only when TH is considered independently from other reliable prognostic indicators such as the T or N categories. -If survival curves are stratified by T or N or if a multivariate analysis based on TH, T and N variables is performed, all correlations between TH pattern and prognosis disappear; for this reason the use of TH as a prognostic indicator in the clinical practice is disregarded.</p>	Fair	
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20	Liszka G. Diagnostic value of infrared thermography in breast cancer, and in proliferative and non proliferative mastopathies. Arch Geschwulstforsch. 1987;57(6):487-91.	Results of breast examinations in 201 female patients controlled by cytology and histology.	Based on the results obtained by an AGA 680 type infrared thermography, the author concluded that the method is primarily suitable for the examination of biological thermogenesis, one of the functional characteristics of tumours. Some T1 breast cancer of the same histological type are thermographically "silent", i.e. display no pathological alterations. Thermographical signs characteristic of carcinomas are to be found only in 60-70% of the cases. It is explained by the biological heterogeneity of tumours, i.e. the amount of heat generated by the metabolic processes of the different carcinomas is not equal, as well as they are different in vascularization and as a consequence of it in their heat conduction parameters. Similar reasons explain the appearance of different thermographic patterns--negative or characteristic of cancerous alterations--in proliferative mastopathies.	Fair	No mention about study design
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21	Lapayowker MS. Thermography and ultrasound in detection and diagnosis of breast cancer. Cancer. 1980 Aug 15;46(4 Suppl):933-8.	Anecdotes	Although thermography has not proven to be of significant value in detecting early breast cancer as used in the National Breast Cancer Detection Program, it can represent a high risk indicator and can be useful in combination with other factors in reducing the number of women who should receive routine mammograms for screening purposes. In breast cancer patients, thermography has been shown to have prognostic value. "Cold" breast cancers have an increased survival as compared to those with increased infrared emission in some series.	Poor	
21	PA van Dam, ML Van Goethem, E Kersschot, J Vervliet, IB Van den Veyver, A De Schepper, and P Buytaert. Palpable solid breast masses: retrospective single- and multimodality evaluation of 201 lesions. Radiology 1988 166: 435-439.	Blinded, retrospective study. 201 consecutive patients who had a solid palpable breast mass and who underwent biopsy between September 1982 and July 1986 were included.	Benign breast disease was diagnosed histologically in 106 women, while carcinoma was established in 95. The sensitivities of physical examination, mammography, US, and thermography were 0.88, 0.94, 0.78, and 0.49, respectively. US alone had the highest sensitivity in correct diagnosis of a benign solid breast mass and had the highest accuracy (0.84). Use of four modalities increased the preoperative diagnostic true-positive rate to 0.97, with some decline in specificity. Multimodality testing seems particularly beneficial in pre- and perimenopausal patients.	Fair	
NEUROLOGICAL DISORDERS					

22	Yong Chul Kim et al. Infrared thermal imaging in the assessment of successful block on lumbar sympathetic ganglion. Yonsei medical Jurnal. Vol.44, no.1 pp 119-124,2003	Clinical study. Examined the net changes in temperature at various regions of the lower extremities in an attempt to identify the regions demonstrating the most significant temperature chnages following a lumbar sympathetic ganglion block (LSGB)	A thermogram can be used effectively to confirm the success of LSGB, regardless of the disease involved with the exception of peripheral vascular disease cases.The evaluation of the temperature changes following a LSGB at the feet particularly at the plantar surface, using thermographic imaging representes an effective, simple and safe method for determining the success of LSGB.	Good to fair	There was an absence of a control group in this study due to ethical reason.
23	Weinstein SA, Weinstein G. A clinical comparison of cervical thermography with EMG, CT scanning, myelography and surgical procedures in 500 patients. Postgrad Med: Custom Communications 1986; (Mar):44-6. Accession No: 11312		The relative merits of cervical thermography were compared to EMG, CT scanning, myelography, and direct surgical visualization. Cervical thermograms were performed in 500 patients with complaints of pain in the neck or upper extremities. Trigger point disorders represent difficult clinical problems to properly document without the application of thermography, which appears to be a safe and effective diagnostic procedure, disclosing, in this series, no false negatives.	Poor	

24	Weinstein SA, Weinstein G. A review of 500 patients with low back complaints: Comparison of five clinically-accepted diagnostic modalities. Postgrad Med: Custom Communications 1986; (Mar):40-3. Accession No: 11313	Thermographic evaluations conducted in a large series of patients with complaints of lumbar spine region pain were compared to the evaluations obtained in these same patients with 4 alternative diagnostic modalities: EMG, CT scanning, myelography, and surgical exploration	As a primary indicator of pathology, thermography was 10 to 20% more accurate than the alternatives studied. A negative thermogram was almost 100% accurate in demonstrating no nerve root irritation. Because of its accuracy, low risk, and noninvasive nature, thermography should be employed as a cost-effective initial screening procedure to distinguish between patients with substantive radicular disorders and those experiencing minor localized injury.	Fair	
25	Richard A. Deyo. Back Pain Patient Outcomes Assessment Team (BOAT)	The back pain PORT, supported by AHCPR, analyzes back surgery practice variations and examines the relative effectiveness of alternate ways of diagnosing and treating low back pain.	Spinal thermography, a test advocated by some physicians and chiropractors for diagnosing disk abnormalities, is inaccurate and poorly validated. The PORT researchers recommend that its use be limited to research settings.	Fair	

26	MM Raskin, M Martinez-Lopez, and JJ Sheldon. Lumbar thermography in discogenic disease Radiology 1976 119: 149-152.	Anecdotes	Thermography is a simple, noninvasive outpatient procedure which can be performed on patients with clinical symptoms of a herniated disk. A positive thermogram usually indicates that an abnormality will be found by myelography. However, the myelographic findings cannot be predicted by a negative lumbar thermogram.	Poor	Very backdated article
RHEUMATOLOGY					

27	G. Martini. Juvenile-onset localized scleroderma activity detection by infrared thermography. <i>Rheumatology</i> 2002; 41: 1178-1182	Retrospective study, to define the clinical utility of infrared thermography in disease activity detection in localized scleroderma (LS). 130 thermal images of 40 children with LS were reviewed and the sensitivity and specificity of thermography were calculated	The sensitivity of thermography was 92% and specificity was 68%. Full concordance between the two clinicians was observed in 91% of lesions, with a kappa score of 0.82, implying very high reproducibility of this technique. CONCLUSION: Thermography is a promising diagnostic tool when associated with clinical examination in discriminating disease activity, as long as it is applied to lesions without severe atrophy of the skin and subcutaneous fat. Further evaluation is needed to determine whether thermography can predict the future progression of lesions.	Good to fair	No mention of study design
PAIN					

28	Thomas D. Infrared thermographic imaging, magnetic resonance imaging, CT scan and myelography in low back pain. Br J Rheumatol. 1990 Aug;29(4):268-73.	Sixty-five cases of chronic low back pain were studied	. Infrared thermography (IRT) was abnormal in 92%, magnetic resonance imaging (MRI) in 89%, computerized tomography (CT) in 87% and myelography in 80%. IRT correlated with MRI in 94% of cases, and with CT in 87% of cases. Of 22 MRI positive disc and root cases, 21 (95%) had significant leg abnormalities on IRT. All 19 cases with radicular involvement on CT and all 18 with radicular involvement on myelography demonstrated significant leg changes on IRT. CONCLUSION: IRT maybe useful as a diagnostic tool or an adjunct to MRI, CT scan or myelography in detecting cause of low back pain.	Fair	No mention of study design
SURGERY					

29	B Hamm et al. Varicoceles: combined sonography and thermography in diagnosis and posttherapeutic evaluation. Radiology 1986, Vol 160, 419-424	One hundred eighteen patients with clinically suspected varicocele were examined with thermography and sonography before phlebography of the internal spermatic vein (ISV).	The combination of sonography and thermography led to an exact differentiation among eight patients with normal findings (6.8%), 103 with left-sided varicoceles (87.3%), six with bilateral varicoceles (5.1%), and one with a right-sided varicocele (0.85%). The accuracy of thermography was 98.4% and of sonography, 92.7%. Thermography was more sensitive than sonography in detecting persistent varicocele in 63 patients reexamined after sclerotherapy.	Fair	No mention of study design
VASCULAR DISEASE					
30	Ariane L Herrick, Stuart Clark. Quantifying digital vascular disease in patients with primary Raynaud's phenomenon and systemic sclerosis. Ann Rheum Dis 1998;57:70-78 (February)	Review-to identify objective measures of digital vascular disease that are helpful in predicting those patients with Raynaud's who have underlying connective tissue disease, and to measure reliably digital vascular disease progression, and responses to treatment.	Thermography measures blood flow indirectly, by measuring skin surface temperature. Most studies of primary and secondary Raynaud's incorporate dynamic testing in response to a standard cold challenge. The patterns of rewarming differ between control, primary and secondary Raynaud's, but the use of thermography for monitoring disease progression/response to treatment is less well established, especially as studies examining the reproducibility of the technique are lacking.	Poor	

31	<p>Brian D. MacNeill; Harry C. Lowe; Masamichi Takano; Valentin Fuster; Ik-Kyung Jang. Intravascular Modalities for Detection of Vulnerable Plaque. Arteriosclerosis, Thrombosis, and Vascular Biology. 2003;23:1333</p>	Brief reviews	<p>Without the structural definition obtained from high-resolution imaging modalities, the independent role of thermography seems limited. Furthermore, the immediate evaluation of local mechanical therapy and the selection of an appropriate site for background measurement are confounded. However, combining thermography with the structural detail of other imaging modalities theoretically produces an attractive synergy of anatomic and physiologic predictors of plaque vulnerability.</p>	Poor	
32	<p>WG Ritchie, RL Soulen, and MS Lapayowker. Thermographic diagnosis of deep venous thrombosis Radiology 1979 131: 341-344.</p>	Clinical trial.	<p>Two hundred patients with suspected deep venous thrombosis had thermography performed prior to ascending phlebography. Diagnostic agreement was obtained in 79%. Published diagnostic thermographic criteria were used; it was not possible to diagnose consistently limited or early thrombosis, especially in the calf muscle veins. Venous insufficiency produced the majority of false positives.</p>	Fair to poor	No mention of study design.

DENTISTRY					
33	B. M. Gratt, S. B. Graff-Radford, V. Shetty, W. K. Solberg, and E. A. Sickles A 6-year clinical assessment of electronic facial thermography Dentomaxillofac Radiol 25: 247-255. (1996)	Objective: To report the findings a 6-year clinical application of ET on patients with orofacial pain. Methods: ET was conducted (in a blinded manner) using an Agema 870 unit at 0.1 degree C thermal accuracy. 164 dental patients mainly with diagnostic problems and 164 matched (control)	Subjects with 'hot' thermograms had the clinical diagnoses of sympathetically maintained pain, peripheral nerve mediated pain, TMJ arthropathy, and maxillary sinusitis. Subjects with 'cold' thermograms were found to have the clinical diagnoses of peripheral nerve-mediated pain and sympathetically independent pain. Subjects with 'normal' thermograms were found to have the clinical diagnosis of cracked tooth syndrome, trigeminal neuralgia, pretrigeminal neuralgia, or psychogenic facial pain. The new system of thermal classification resulted in 92% (301 of 328) agreement in classification of pain patients and matched controls. CONCLUSION: These studies suggest that ET has promise in aiding the formation of a differential diagnosis of orofacial pain and may help in understanding mechanisms of pain as well as directing therapies.	Good to fair	Blinded, controlled study, but was it randomized?

34	<p>P. A. Biagioni, R. B. Longmore, J. G. McGimpsey, and P. J. Lamey Infrared thermography. Its role in dental research with particular reference to craniomandibular disorders Dentomaxillofac Radiol 25: 119-124. (1996)</p>	Anecdotes	<p>The use of infrared thermography in dentistry has been minimal, principally due to technological inadequacies of previous thermal imaging systems. However, with the ever-developing advancement in technology, current systems are capable of producing real-time, highly sensitive digitized thermal images. This development has led to an increased use of infrared imaging within both medical and dental research. The present paper describes these techniques and their previous applications within dentistry, and, through the use of a pilot study, highlights possible future applications in the assessment of craniomandibular disorders.</p>	Poor	
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35	B. M. Gratt, and M. Anbar Thermology and facial telethermography: Part II. Current and future clinical applications in dentistry Dentomaxillofac Radiol 27: 68-74. 1998	Anecdotes	<p>Static area telethermography (SAT) has recently been shown to be of help to the dentist in (1) the diagnosis of chronic orofacial pain, (2) as a unique tool in assessment of TMJ disorders, (3) as an aid in assessment of inferior alveolar nerve deficit, and (4) as a promising research tool. DAT, recently made possible by advances in computing technology combined with advanced infrared sensor technology, extracts quantitative information about hemodynamic processes from hundreds to thousands of digital thermal images of the affected facial areas, measured and collected within less than 3 min.</p> <p>Dynamic area telethermography (DAT) has promise of offering a better insight into aberrations of the neuronal control of facial skin perfusion and aiding our understanding of the correlation between orofacial pain and facial thermal abnormalities. This promising new insight may help in the management of orofacial pain.</p>	Poor	
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BONE METASTASES					
36	IM Freundlich, R O'Mara, and MJ Pitt. Thermographic, radionuclide, and radiographic detection of bone metastases Radiology 1977 122: 665-668.	The sensitivity of thermography to osseous metastases is compared to 99mTc bone scanning using the specificity of radiographic skeletal survey as proof of metastases. Thirty-five patients with suspected disease were selected for study.	Bone scans detected 94.4% while thermograms detected 22.2%. Thermography proved quite insensitive to osseous metastases. Radionuclide bone scanning is the method of choice for the present.	Fair to poor	No mention of study design

**EVIDENCE TABLE : THERMAL TEXTURE MAPS
ASPECT : SAFETY**

No	Author, title, Journal, Year, Volume, Page Number	Study Design, Sample Size, Follow up	Outcomes & Characteristics	Grade	Comment
1	Kastberger G. Infrared imaging technology and biological applications. Behav Res Methods Instrum Comput. 2003 Aug;35(3):429-39.	Personal review	The advantages of using IR imaging are (1) rapidity in the millisecond range, facilitating measurement of moving targets, (2) non-contact procedures, allowing measurements of hazardous or physically inaccessible objects, (3) no interference and no energy lost from the target, (4) no risk of contamination, and (5) no mechanical effect on the surface of the object.	Poor	
2	Mazurin Via et al. [Thermography in ambulatory care of patients with breast cancer]. Vopr Onkol. 1983;29(8):22-5. [Article in Russian]	5-year dynamic thermographic study carried out in 78 out-patients with breast cancer	Thermographic procedure is not time-consuming and is absolutely harmless it should be used on a large scale for monitoring the condition of breast cancer patients and the efficacy of their treatment.	Fair	(abstract)

**EVIDENCE TABLE : THERMAL TEXTURE MAPS
ASPECT : COST EFFECTIVENESS**

No	Author, title, Journal, Year, Volume, Page Number	Study Design, Sample Size, Follow up	Outcomes & Characteristics	Grade	Comment
1	Mooney G. Breast cancer screening. A study in cost-effectiveness analysis. Soc Sci Med. 1982;16(13):1277-83.		This paper identifies the long run average British National Health Service screening costs in one particular screening clinic for various different regimes: mammography, thermography and clinical examination; thermography and clinical examination; and mammography and clinical examination; each of these having one or two clinical examinations and the option of single or double reporting of mammograms and thermograms. It then compares the cost-effectiveness of these different regimes where 'costs' are defined widely to include not only screening costs but also biopsy costs, anxiety costs for women biopsied, costs of false negatives, etc. By defining costs in this way, it was possible (if somewhat tentatively because of the small numbers involved) to identify mammography with single reporting together with a single clinical examination as 'the best buy'.	Good	

2	<p>Weinstein SA, Weinstein G. A review of 500 patients with low back complaints: Comparison of five clinically-accepted diagnostic modalities. Postgrad Med: Custom Communications 1986; (Mar):40-3. Accession No: 11313</p>		<p>Thermographic evaluations conducted in a large series of patients with complaints of lumbar spine region pain were compared to the evaluations obtained in these same patients with 4 alternative diagnostic modalities: EMG, CT scanning, myelography, and surgical exploration. As a primary indicator of pathology, thermography was 10 to 20% more accurate than the alternatives studied. A negative thermogram was almost 100% accurate in demonstrating no nerve root irritation. Because of its accuracy, low risk, and noninvasive nature, thermography should be employed as a cost-effective initial screening procedure to distinguish between patients with substantive radicular disorders and those experiencing minor localized injury.</p>	Poor	<p>Author made an assumption of cost-effective due to its accuracy, low risk, and noninvasive nature.</p>
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**EVIDENCE TABLE : THERMAL TEXTURE MAPS
ASPECT : LEGAL ASPECTS**

No	Author, title, Journal, Year, Volume, Page Number	Study Design, Sample Size, Follow up	Outcomes & Characteristics	Grade	Comment
1	Uricchio JV Jr. Electronic thermography in medical practice. Legal Aspects Med Pract 1985; 13(Apr):1-2, 8. Accession No: 09273		The author believes that practitioners involved with clinical situations such as soft-tissue injuries, peripheral nerve insult, reflex sympathetic dystrophy, and nerve root irritation should have knowledge of the test and its indications. He warns that lack of mandated regulatory board guidelines presents the potential for abuse of thermography, both in its application and interpretation. He believes that a considerable amount of clinical information can be obtained from thermography if there is professional medical control and appropriate regard for the basic physiological mechanisms involved.	Fair	
2	Finnegan WJ, Koson DF. Jumping from the Frye Plan into State Farm Fire: An analysis of spinal thermography as scientific test evidence. Law Med Health Care 1985; 13(5):205-12. Accession No: 11314	The authors examine the medical and legal use and value of thermographic pictures as legal evidence of spinal conditions and nerve root compression.	The technical problems of obtaining reproducible test patterns, coupled with the difficulties of interpretation, particularly with respect to spinal conditions, make thermography an unreliable scientific test. This unreliability leaves spinal thermography an invalid legal basis for court decisions	Fair	

LEVELS OF EVIDENCE SCALE

Level	Strength of evidence	Study design
1	Good	Meta-analysis of RCT, Systematic review
2	Good	Large sample RCT
3	Good to fair	Small sample RCT
4		Non-randomised controlled prospective trial
5	Fair	Non randomised controlled prospective trial with historical control
6	Fair	Cohort studies
7	Fair	Case-control studies
8	Poor	Non-controlled clinical series, descriptive studies multi-centre
9	Poor	Expert committees, consensus, case reports, anecdotes

Adapted from Catalonian Agency For Health Technology Assessment (CAHTA)
Spain

