Thermography and Temperature Gradient Studies

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DESCRIPTION

Thermography is intended to measure temperature variations of various organs and tissues by producing brightly colored patterns on a liquid crystal display. Interpretation of the color pattern is thought to contribute to the diagnosis of many disorders including breast cancer. Claims by those that provide thermography services state that various injuries and pathologies cause dilation of blood vessels, angiogenesis, and/or other sympathetic nervous system involvements resulting in temperature differences that can be mapped via thermography. Thermography has been proposed as a diagnostic tool for treatment planning and for evaluation of treatment effects for a variety of conditions. Providers claim thermography can:

- Graphically display the subjective feeling of pain
- Show combined effect of the autonomic nervous system and the vascular system, down to capillary dysfunctions
- Monitor the effectiveness of therapies

- And can present opportunity for early intervention

Available testing in the thermography field includes full body and half body scans as well as scans to specific regions including but not limited to the breast, head, dental, thyroid, half body. Two types of thermal studies are temperature gradient studies and thermography.

- T**emperature Gradient Studies** - In contrast to the skin surface thermography techniques used by some chiropractors and other providers, a newer invasive test called a temperature gradient study involves an intravenous catheter. The catheter is threaded into the coronary arteries to directly measure temperature differences on the inner artery walls. Researchers believe this information may be related to the presence of unstable coronary artery plaques and could be useful in diagnosing vulnerable patients.
- **Thermography** - Thermography is a noninvasive imaging technique that is intended to measure temperature distribution in organs and tissues. The visual display of this temperature information is known as a thermogram. Thermography has been proposed to use with a variety of conditions as a diagnostic tool, for treatment planning and to evaluate the effects of treatment.

Clinical Context and Test Purpose
The purpose of using thermography and temperature gradient studies in individuals undergoing screening or treatment is to inform decisions on diagnosis and treatment for a variety of indications to include but not limited to dermal/skin conditions, treatment of cancer, bone, vascular, ocular, and cardiac conditions.

The question addressed in this portion of the evidence review is: Does thermography and temperature gradient studies when used to screen or diagnose improve the net health outcome compared with standard screening and treatments?

The following PICO was used to select literature to inform this review.

Populations
The relevant populations of interest are individuals being screened or tested for variety of indications to include but not limited to dermal/skin conditions, treatment of cancer, bone, vascular, ocular, and cardiac conditions using thermography and temperature gradient studies

Interventions
The intervention of interest is thermography and temperature gradient studies.

Comparators
The following tests are currently being used to make decisions about screening and diagnosis for a variety of indications to include but not limited to dermal/skin conditions, treatment of cancer, bone, vascular, ocular, and cardiac conditions.: mammography, radiography, magnetic resonance imaging, standard care without imaging.

Outcomes
The outcome of interest for diagnostic accuracy is test validity (i.e., sensitivity, specificity), symptoms, and functional outcomes.

Study Selection Criteria
For the evaluation of clinical validity of thermography for breast cancer, studies that meet the following eligibility criteria were considered:

Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)

Included a suitable reference standard

Patient/sample clinical characteristics were described

Patient/sample selection criteria were described.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Arthritis
(2018) Jones et al noted rheumatoid arthritis is a common inflammatory disease that causes destruction of joints. Accurate recognition of active disease has significant implications in determining appropriate treatment; however, there is significant inter-rater variability in clinical joint assessment. This study aimed to assess the utility of thermographic imaging in the evaluation of inflammatory arthritis activity as an adjunct to clinical assessment. This was a cross-sectional study of 79 subjects recruited from the University of Alberta Outpatient Rheumatology clinic comparing the hand joints of 49 patients with rheumatoid arthritis (RA) diagnosed by American College of Rheumatology (ACR) criteria to 30 healthy volunteers. Convenience sampling of consecutive RA patients was undertaken. The effect of clinical assessment (HAQ and DAS-28) on joint temperature was evaluated using a linear mixed effect model. A thermography camera, FLIR T300 model, 30 Hz, was used to obtain both thermographic and digital images on subjects. Pearson's correlation coefficient was used to assess the correlation of clinical assessments and average joint temperature averaged over all joints. Thermographic analysis did not associate with clinical measures of disease activity. In RA patients, there was no statistically significant relationship between joint temperature and clinical

assessment of disease activity including Health Assessment Questionnaire (coefficient estimate - 0.54, p = 0.056), swollen joints (coefficient estimate - 0.09, p = 0.238), or serologic markers of inflammation such as CRP (coefficient estimate - 0.006, p = 0.602) and ESR (coefficient estimate - 0.01, p = 0.503). Evaluation of disease activity requires a multifaceted approach that includes clinical assessment and appropriate imaging. There may be a role for thermography in assessment of larger joints; however, it does not appear to be an effective modality for the small joints of the hand.

Breast Cancer
(2020; Reviewed through December 2021) UpToDate considers an investigational screening technique as the use of thermography to detect occult breast cancer was based on the observation that patients have elevated breast skin temperatures over their breast cancers. It was first investigated for screening in the Breast Cancer Detection Demonstration Project in the 1970s and was found to have poor test characteristics, with a false-positive rate of 25 percent and a false-negative rate of more than 60 percent.

In 2004, a breast thermography device received approval from the FDA on the basis of prior approval for infrared imaging technology because of demonstrated safety but not necessarily efficacy. The specificity of thermography remains very low, even with modern equipment.

No major organization making screening recommendations recommends thermography. Of those commenting on it, the American Cancer Society states, "No study has ever shown that it is an effective screening tool for finding breast cancer early", and the American College of Radiology specifically states it does not endorse thermography for detecting clinically occult breast cancer. The FDA issued a safety communication in June 2011 notifying consumers that thermography is not a replacement for screening mammography and that thermography on its own is not an effective screening tool. (*Accessed January 2022*)

(2018) Moralez-Cervantes et al reported a classification of thermographic images for breast cancer detection was performed by an automated program. 206 patients were considered for test screening with clinical evidence of a tumor risk factors for breast cancer, BI-RADS classification of mammography, clinical diagnosis, and pathology results of the biopsy. The analyzed thermograms were classified as healthy (< 2.5 thermal score) or with an abnormality (≥ 2.5 thermal score). The findings reveal from 206 patients, 8 true positives and 62 false positives were found. Moreover, 136 were classified as true negatives and there were not any false negatives. Obtaining a sensitivity of 100 % with a specificity of 68.68 %, a positive predictive value of 11.42 % and a negative predictive value of 100 %. It is worthy to mention that the same thermographic images were analyzed qualitatively by an oncologist in a double-blind study, his findings were 7 true positives and 87 false positives, while 111 were classified as true negatives and 1 false negative showing a significant improvement over a manual procedure. Furthermore, an automated method to analyze thermograms was implemented, increasing the sensitivity and specificity of the test under study. The main goal of it will be to help

experts by assisting them with a better screening tool or even gives the possibility that someone without experience may benefit from the test results. The authors emphasize that infrared thermography is not intended to replace mammography.

(2018) Neal et al noted following Institutional Review Board approval, retrospective search identified 38 patients who presented for conventional breast imaging following a thermography-detected abnormality. Study criteria included women who had mammogram and/or breast ultrasound performed for evaluation of a thermography-detected abnormality between January 1, 2000, and December 31, 2015. Patients whose mammograms and ultrasounds were initiated at an outside institution or who did not have imaging at our institution were excluded. Records were reviewed for clinical history, thermography results, mammogram and/or ultrasound findings, and pathology. Mammograms and ultrasounds were prospectively interpreted by one of 14 Mammography Quality Standards Act-certified breast imaging radiologists with 3-30 years of experience. Patient outcomes were determined by biopsy or at least 1 year of follow-up. Patient ages ranged from 23 to 70 years (mean = 50 years). Ninety-five percent (36 of 38) of patients did not have breast cancer. The two patients diagnosed with breast cancer had suspicious clinical symptoms including palpable mass and erythema. No asymptomatic woman had breast cancer. Negative predictive value was 100%. Of 38 patients, 79% (30 of 38) had Breast Imaging Reporting and Data System (BI-RADS) 1 or 2 assessments; 5% (2 of 38) had BI-RADS 3; and 16% (6 of 38) had BI-RADS 4 (n = 5) or BI-RADS 5 (n = 1) assessments. Two of six patients with biopsy recommendations were diagnosed with breast cancer (Positive predictive value 2 = 33.3%). All findings recommended for biopsy were ipsilateral to the reported thermography abnormality. No cancer was diagnosed among asymptomatic women. The 5% of patients diagnosed with cancer had co-existing suspicious clinical findings. Mammogram and/or ultrasound were useful in accurately characterizing patients with abnormal thermography.

(2016) Omranipour et al reported benefits and harms of screening mammography have been disputed in recent years. This fact, along with the limitations of mammography as well as its unavailability in all our medical centers, tempted us to evaluate the accuracy of thermography in detecting breast abnormalities. All patients who were candidates for breast biopsy were examined by both mammography and thermography before tissue sampling in a referral center between January 2013 and January 2014. We defined sensitivities and specificities, and positive predictive values (PPVs) and negative predictive values (NPVs), of the 2 modalities in comparison with histologic results as the gold standard. 132 patients were included. The median age of all patients was 49.5 ± 10.3 years (range 24-75 years). The sensitivity, specificity, PPV, NPV, and accuracy for mammography were 80.5%, 73.3%, 85.4%, 66.0%, and 76.9%, respectively, whereas for thermography the figures were 81.6%, 57.8%, 78.9%, 61.9%, and 69.7%, respectively. The study confirms that, at the present time, thermography cannot substitute for mammography for the early diagnosis of breast cancer.

(2011) Kontos et al determined the sensitivity and specificity of DITI in a series of women who underwent surgical excision or core biopsy of benign and malignant breast

lesions presenting through the symptomatic clinic. Digital infrared thermal imaging was evaluated in 63 symptomatic patients attending a 1-stop diagnostic breast clinic. Thermography had 90 true-negative, 16 false-positive, 15 false-negative and 5 true-positive results. The sensitivity was 25 %, specificity 85 %, positive-predictive value 24 %, and negative-predictive value 86 %. The authors concluded that despite being non-invasive and painless, because of the low sensitivity for breast cancer, DITI is not indicated for the primary evaluation of symptomatic patients, Anor should it be used on a routine basis as a screening test for breast cancer.

Section Summary: Breast Cancer
Thermography has been around for many years, but studies have shown that it's not an effective screening tool for finding breast cancer early. Although it has been promoted as helping detect breast cancer early, a 2012 research review found that thermography was able to detect only a quarter of the breast cancers found by mammography. In other words, it failed to detect 3 out of 4 cancers that were known to be present in the breast. Digital infrared thermal imaging (DITI), which some people believe is a newer and better type of thermography, has the same failure rate. Therefore, thermography should not be used as a substitute for mammograms.

Burns
(2021) Dang et al completed systematic review and meta-analysis of the was performed on the mean sensitivity and specificity of the ability of IR thermography for predicting healing potential. Inclusion criteria were articles investigating the use of infrared (IR) thermography for burn wound assessments in adults and pediatric patients. Reviews and non-English articles were excluded. The results noted a total of 19 articles were included in the final review. Statistically significant correlations were found between IR thermography and laser doppler imaging (LDI) in 4/4 clinical studies. A case report of a single patient found that IR thermography was more accurate than LDI for assessing burn depth. Five articles investigated the ability of IR thermography to predict healing time, with four reporting statistically significant results. Temperature differences between burnt and unburnt skin were found in 2/2 articles. IR thermography was compared to clinical assessment in five articles, with varying results regarding accuracy of clinical assessment compared to thermography. Mean sensitivity and specificity of the ability of IR thermography to determine healing potential <15 days was 44.5 and 98.8 respectively. Mean sensitivity and specificity of the ability of FLIR to determine healing potential <21 days was 51.2 and 77.9 respectively. In conclusion IR thermography is an accurate, simple, and cost-effective method of burn wound assessment. Forward looking infrared has been demonstrated to have significant correlations with other methods of assessing burns such as LDI and can be utilized to accurately assess burn depth and healing potential.

(2018) Martinez-Jimenez et al completed a prospective cohort study Temperature difference (ΔT) between injured and healthy skin were recorded within the first three days after injury in previously healthy burn patients. After discharge, the treatment modality was categorized as re-epithelization, skin graft or amputation. Potential

confounding factors were assessed through multiple linear regression models, and a prediction algorithm based on the ΔT was developed using a predictive model using a recursive partitioning Random Forest machine learning algorithm. Finally, the prediction accuracy of the algorithm was compared in the development cohort and an independent validation cohort. Significant differences were found in the ΔT between treatment modality groups. The developed algorithm correctly predicts into which treatment category the patient will fall with 85.35% accuracy. Agreement between predicted and actual treatment for both cohorts was weighted kappa 90%.

This study has some limitations: first, it only included patients with burns in extremities, so our results cannot be extrapolated to other areas in the body. Refinement of the algorithm to include burn areas in the head or trunk where no amputation is feasible is currently being explored, along with the search for the optimal time of thermography imaging, even though it did not find a significant association between the time of imaging and the ΔT values. Thermal modelling of injured and healthy tissue warrants further exploration, as it could improve our prediction model and offer information on the time to recovery of different types of wounds and in dynamic changes of the wound temperature, thus providing additional data to better rationalize the appropriate treatment for the patient. Second, the algorithm was trained to make the same treatment decisions as the burn surgeons that treated the patients, therefore, even though that the results shown are supported by the k-means clustering algorithm, they may be applicable only to our burn center. To generalize the results and applicability of the algorithm, further studies in different populations and settings may be required. Third, while it is widely recognized that the depth of burn wounds is not entirely static and that a variety of factors can promote the deepening of a burn in the first few days after sustaining it, not all burns undergo this phenomenon. Ischemia and autophagy of the tissue have been proposed as the leading causes of burn conversion, and as such, it is very likely that infrared thermography can detect it in its early stages. If this is true, wounds with higher ΔT values would probably be associated with burn conversion and deepening of the injury. Nevertheless, in the present study, we did not record burn conversion or dynamic changes in ΔT values, which would have been needed to confirm the hypothesis. It seems that thermography is sensitive enough not to be affected by this factor, but further studies are needed to clarify this point. Finally, a caveat of the method is it measured ΔT of the wounds as an average, yet most wounds will have areas with different temperature values. Indeed, this approach may give further insights to the clinical team and help streamline the treatment of the patients even more.

(2016) Singer et al reported clinical distinction between superficial and deep burns is problematic. The authors determined whether an infrared thermal imaging (IRTI) camera could predict burn depth. Burn depth was assessed by an experienced surgeon, and the burns were imaged with a portable, lightweight IRTI camera that measures heat emission from the skin using long infrared wavelengths (7.5–13 μm). Burns were considered "deep" if they were surgically excised and confirmed to be of full thickness on microscopic evaluation or if they did not heal spontaneously within 21 days of injury. All other burns were considered "nondeep." There were 39 burns that had both days 1 and 2

IRTI measurements and available outcome. Of these, 16 were "deep" burns and 23 were "nondeep." The mean temperatures of "nondeep" burns between days 1 and 2 increased from 30.6 ± 2.7 to 32.1 ± 3.0°C (difference of 1.5 ± 2.3°C). The mean temperatures of "deep" burns decreased from 32.3 ± 2.0 to 30.8 ± 1.3°C (difference of −1.5 ± 2.0°C) between days 1 and 2. Any decrease in temperatures between days 1 and 2 was predictive of a deep wound, and any increase between days 1 and 2 was predictive of a nondeep burn. Using the ultimate burn depth as the criterion standard, the overall accuracy of IRTI was considerably higher than that of clinical assessment; 87.2% (95% CI: 71.8–95.2) vs 54.1% (95% CI: 37.1–70.2). Any decrease in temperatures between days 1 and 2 was predictive of a deep wound. Our results suggest that thermography using IRTI is more accurate than clinical examination in predicting burn depth and could potentially reduce unnecessary surgery as well as reduce delays to surgery when necessary. A limitation of the study is the sample size of 39 participants. The clinical significance of this finding should be confirmed with larger studies.

Cardiac Indications

(2010) Sharif and Murphy noted that critical coronary stenoses have been shown to contribute to only a minority of acute coronary syndromes and sudden cardiac death. Autopsy studies have identified a subgroup of high-risk patients with disrupted vulnerable plaque and modest stenosis. Consequently, a clinical need exists to develop methods to identify these plaques prospectively before disruption and clinical expression of disease. Recent advances in invasive as well as non-invasive imaging techniques have shown the potential to identify these high-risk plaques. The anatomical characteristics of the vulnerable plaque such as thin cap fibro-atheroma and lipid pool can be identified with angioscopy, high frequency intra-vascular ultrasound, intra-vascular magnetic resonance imaging (MRI), and optical coherence tomography. Efforts have also been made to recognize active inflammation in high-risk plaques using intra-vascular thermography. Plaque chemical composition by measuring electro-magnetic radiation using spectroscopy is also an emerging technology to detect vulnerable plaques. Non-invasive imaging with MRI, computed tomography, and positron emission tomography also holds the potential to differentiate between low-risk and high-risk plaques. However, at present none of these imaging modalities can detect vulnerable plaque nor have they been shown to definitively predict outcome. Nevertheless, in contrast, there has been a parallel development in the physiological assessment of advanced athero-sclerotic coronary artery disease. Thus, recent trials using fractional flow reserve in patients with modest non-flow-limiting stenoses have shown that deferral of percutaneous coronary intervention with optimal medical therapy in these patients is superior to coronary intervention. The authors concluded that further trials are needed to provide more information regarding the natural history of high-risk but non-flow-limiting plaque to establish patient-specific targeted therapy and to refine plaque stabilizing strategies in the future.

(2008) García-García and colleagues stated that thin-capped fibroatheroma is the morphology that most resembles plaque rupture. Detection of these vulnerable plaques in-vivo is essential to being able to study their natural history and evaluate potential

treatment modalities and, therefore, may ultimately have an important impact on the prevention of acute myocardial infarction and death. The investigators reported that, currently, conventional grayscale intra-vascular ultrasound, virtual histology and palpography data are being collected with the same catheter during the same pullback. A combination of this catheter with either thermography capability or additional imaging, such as optical coherence tomography or spectroscopy, would be an exciting development. Intra-vascular magnetic resonance imaging also holds much promise. The investigators stated that, to date, none of the techniques described above has been sufficiently validated and, most importantly, their predictive value for adverse cardiac events remains elusive. The investigators concluded that very rigorous and well-designed studies are needed for defining the role of each diagnostic modality. Until researchers are able to detect in-vivo vulnerable plaques accurately, no specific treatment is warranted.

(2007) Schaar and colleagues noted that rupture of vulnerable plaques is the principal cause of acute coronary syndrome and myocardial infarction. Identification of vulnerable plaques is therefore essential to enable the development of treatment modalities to stabilize such plaques. Thermography is one of the several novel methods being examined for detecting vulnerable plaques. It evaluates the temperature heterogeneity as an indicator of the metabolic state of the plaque. The authors concluded that while several invasive and non-invasive techniques are currently under development to assess vulnerable plaques, none has proven its value in an extensive in-vivo validation, and all have a lack of prospective data.

(2006) Madjid et al have shown that inflamed atherosclerotic plaques are hot and their surface temperature correlates with an increased number of macrophages and decreased fibrous-cap thickness. Multiple animal and human experiments have shown that temperature heterogeneity correlates with arterial inflammation in vivo. Several coronary temperature mapping catheters are currently being developed and studied. These thermography methods can be used in the future to detect vulnerable plaques, potentially to determine patients' prognosis, and to study the plaque-stabilizing effects of different medications.

Complex Regional Pain Syndrome

(2021; Last updated 01/14/2022) UpToDate noted the following information regarding imaging in CRPS in children:

- Radiographs and other imaging modalities (i.e., magnetic resonance imaging [MRI], bilateral thermography, and bone scans) do not reliably differentiate CRPS from other disease processes, such as trauma.
- Thermography is not helpful in the diagnosis of pediatric CRPS.
  (*Accessed January 2022).*

Foot Ulcers

(2020) Petrova et at completed a study to date to investigate the clinical utility of thermography compared with no thermography assessed diabetic foot ulcer incidence in 110 participants with a history of diabetic neuropathy and foot ulcers. After 12 months

follow up, the study found no significant difference between use of monthly thermography versus no thermography and foot ulcer incidence (62% versus 56%; adjusted OR 0.55, 95% CI 0.21 to 1.40) or time to ulcer recurrence (adjusted HR 0.67, 95% CI 0.34 to1.3).

(2016) Staffa et al stated that foot complications in persons with diabetes mellitus (DM) are associated with substantial costs and loss of quality of life. Increasing evidence suggests changes in skin temperature, measured using an IRT system, may be a predictor of foot ulcer development in patients with DM. In a case study, these researchers described the long-term IRT findings and overall clinical outcomes of a patient with DM and peripheral vascular disease (PVD). Foot temperature measurements using IRT were obtained slightly more than 1 year before and immediately following endovascular treatment of a 76-year-old man, a non-smoker with type 2 DM, hypertension, and ischemic heart disease with cardiac arrhythmia. Although he was otherwise asymptomatic, the infrared measurement showed an average temperature difference of 2.3˚ C between the left and right foot until he developed a small, trauma-induced wound on the left foot, at which time left foot temperature increased. He was diagnosed with recto-sigmoid adenocarcinoma, underwent surgery and chemotherapy, and subsequently was evaluated for PVD. Before undergoing peripheral angiography and percutaneous transluminal angioplasty, IRT evaluation showed a hot spot on the left heel. Immediately following endovascular treatment, the mean temperature difference between the right and left foot was low (0.2˚ C), but a Stage I pressure ulcer was visible on the left heel. Skin breakdown in that area was observed 2 months later, and the wound continued to increase in size and depth. The patient died shortly thereafter due to complications of cancer. In this case study, a series of infrared images of foot skin temperatures appeared to show a relationship with blood circulation and wound/ulcer development and presentation. The authors concluded that IRT has the ability to instantaneously measure the absolute temperature of the skin surface over a large area without direct skin contact. However, they stated that these devices are very sensitive; and prospective clinical studies are needed to determine the validity, reliability, sensitivity, and specificity of these measurements for routine use in patients who are at risk for vascular disease and/or foot ulcers.

Musculoskeletal Injuries

(2019) Corte et al completed a longitudinal prospective study with 28 professional soccer players that composed a first division of Brazilian's soccer team between 2015 and 2016. In both seasons (2015 and 2016), muscle injuries were documented and classified in grade of severity, by ultrasound. During the following season (2016), infrared medical thermography was applied twice a week (48 hours after game) and if a difference of temperature was detected higher than 0.4°C, a prevention protocol was initiated. Muscle injuries in 2016 were documented. The results noted in 2015, the total number of muscle injuries was 11. In 2016, the total number of muscle injuries was 4 (p=0.04). It represents an incidence/player of 78% in 2015 and 28% in 2016, corresponding to a decrease of 64% in 2016. Seven players played in the first team in both seasons. Among these seven players, muscle injuries were reduced from 8 (in 2015) to 3 (in 2016)—a decrease of 63%

in the season we used thermographic monitoring (p=0.06). In conclusion the pilot data provides a promising catalyst for a rigorous RCT that could examine whether thermography can contribute to a muscle injury prevention program.

(2014) Sanchis-Sanchez et al completed a systematic and meta-analysis review noting musculoskeletal injuries occur frequently. Diagnostic tests using ionizing radiation can lead to problems for patients, and infrared thermal imaging could be useful when diagnosing these injuries. In conclusion, a systematic review was performed to determine the diagnostic accuracy of infrared thermal imaging in patients with musculoskeletal injuries. A meta-analysis of three studies evaluating stress fractures was performed and found a lack of support for the usefulness of infrared thermal imaging (including thermography) in musculoskeletal injuries diagnosis.

Miscellaneous

(2010) Han and associates examined the usefulness of infrared thermography as a predictor of post-herpetic neuralgia (PHN). Infrared thermography was performed on the affected body regions of 110 patients who had been diagnosed with acute herpes zoster (HZ). Demographical data collected included age, gender, time of skin lesions onset, development of PHN, and co-morbidities. The temperature differences between the unaffected and affected dermatome were calculated. Differences greater than 0.6 degrees C for the mean temperature across the face and trunk were considered abnormal. The affected side was warmer in 35 patients and cooler in 33 patients than the contralateral side. A patient's age and disease duration affected treatment outcomes. However, the temperature differences were not correlated with pain severity, disease duration, allodynia, development of PHN, and use of anti-viral agents ($p > 0.05$). The authors concluded that a patient's age and disease duration are the most important factors predicting PHN progression, irrespective of thermal findings, and PHN cannot be predicted by infrared thermal imaging. There is insufficient evidence to support the use of thermography in post-herpetic neuralgia.

Miscellaneous: Dermal Conditions

(2019) Magalhaes et al reported the incidence rates of melanoma have risen to worrying levels over the last decade. Delayed diagnosis, due to faults on the detection stage, indicates the necessity of new aiding diagnosis techniques. Since metabolic activity is highly connected to neoplasia formation, a detection technique that focuses its results on vascular responses, as Infrared thermal (IRT), seems to be a viable option. Static and dynamic (cooling) thermal images of melanoma and melanocytic nevi lesions were collected and analyzed to retrieve thermal parameters characteristic of this skin lesion types. The steady-state and dynamic variables were tested separately with different machine learning classifiers to verify whether the distinction of melanoma and nevi lesions was achievable. Their results noted the differentiation of both types of skin tumors was doable, achieving an accuracy of 84.2% and a sensitivity of 91.3% with the implementation of a learner based on support vector machines and an input vector composed by static variables. In conclusion the use of IRT for skin tumor classification is achievable, but some improvement is needed to raise the metrics of sensitivity and

specificity. For future work, it is recommended the study of dynamic parameters for the classification of other types of skin neoplasia.

(2018) Maillot and associates stated that radiotherapy is a common adjuvant treatment of breast cancer. Acute radiation-induced dermatitis is a frequent side effect. These researchers hypothesized whether it is possible to capture the increase of local temperature as a surrogate of the inflammatory state induced by radiotherapy. They designed a prospective, observational, single-center study to acquire data on temperature rise in the treated breast during the course of radiotherapy, establish a possible association with the occurrence of dermatitis and examine the predictive value of temperature increase in future occurrences of radiation-induced dermatitis. All patients presenting for neoadjuvant or adjuvant radiotherapy during the course of breast cancer treatment at the university hospital of Martinique were considered for inclusion. Every week, patients were examined by 2 trained investigators for the occurrence of radiation-induced dermatitis, graded based on Radiotherapy Oncology Group, Common Terminology Criteria for Adverse Events v.4.0 and Wright scales. A frontal thermal image of torso was taken in strictly controlled conditions, with a calibrated TE-Q1 camera (Thermal Expert, i3systems, Daejeon, Korea). These investigators studied temperature differences between the irradiated breast or thoracic wall and the contralateral area. For each thermal picture, these researchers measured the difference in maximum temperature as well as the difference in minimum temperature and the difference in the average temperature in the considered area. They studied the evolution of these parameters over time (week after week), measuring the maximum recorded difference and its correlation to acute radiation dermatitis intensity. A total of 64 consecutive patients were included. For all patients, these investigators noticed an increase of temperature during the course of radiotherapy. Difference in maximum, minimum and average temperature was higher between the 2 breasts of patients with a radiation-induced dermatitis grade 2 or above compared to patients with no or mild dermatitis. Higher temperatures were also significantly associated with an increased sensation of discomfort, as recorded by questionnaire ($p < 0.05$). The authors concluded that as expected from the inflammatory phenomena involved in radiation-induced dermatitis, a noticeable increase in temperature during the course of radiotherapy was observed in all patients. Furthermore, high-grade radiation-induced dermatitis was strongly associated with an additional increase in local temperature, which was probably linked to the intense inflammatory reaction. Lastly, with a 1.4°C threshold set beforehand, it was possible to anticipate the occurrence of radiation-induced dermatitis, with interesting positive and negative predictive values (PPV and NPV) of 70 % and 77 %, respectively in this population. Moreover, these researchers stated that these findings need to be confirmed in a dedicated study.

Miscellaneous: Vascular Conditions

(2019) Cruz-Segura et al reported microsurgical reconstruction, vascular obstruction occurs in approximately 20% of patients. Close monitoring is central to their care. Clinical/Doppler detection of vascular obstruction could be enhanced by thermography. A diagnostic test design included consecutive cases of hospitalized patients, ≥18 years

old, who underwent surgery with free flaps. Two researchers separately evaluated patients with clinical/Doppler methods and thermographic camera hourly for 24 hours, every 2 hours for the next 24 hours, and then every 3 hours until discharge. The gold standard was visualization of thrombus or vascular obstruction during surgical reintervention. Sensitivity, specificity, positive/negative predictive value (PPV/NPV), and a delta temperature receiver operating characteristic (ROC) curve were calculated. Their results noted a total of 2,364 tests were performed with a thermographic camera in 40 patients (31 females, 9 males) aged 50.12 ± 9.7 years. There were 28 deep inferior epigastric perforator, 5 anterolateral thigh, 3 radial, 2 scapular, 1 fibular, and 1 anteromedial thigh flaps included. Six (15%) had postoperative vascular obstruction (5 venous and 1 arterial). One flap developed partial necrosis and one total necrosis (overall survival 97.5%). ROC curve (area 0.97) showed the best results at ≥ 1.8° C of difference to the surrounding skin. Considering two consecutive positive evaluations, the sensitivity was 93%, specificity 96%, PPV 57%, and NPV 99%. The thermal imaging camera allows to identify the obstruction between 2 and 12 hours before the clinical method. In conclusion, utilizing a thermographic camera can reduce detection time of vascular obstruction by several hours in microvascular free flaps that include the cutaneous island. This method proves useful for early diagnosis of postoperative vascular obstruction.

(2019) Chen et al completed a study on the value of a smartphone-compatible thermal imaging camera in the detection of peroneal artery perforators: Comparative study with computed tomography angiography. The aim of this study was to investigate the value of a smartphone-compatible thermal imaging camera in the mapping of the peroneal artery perforators. Twelve consecutive patients scheduled for fibular flap reconstruction were enrolled. The lower limbs were first studied using smartphone-based dynamic infrared thermography (DIRT). During the rewarming, the hotspots were marked, small rubber markers were taped to the registered sites, and then the patients were sent for a CT scan. The diagnostic performance of smartphone-based DIRT was evaluated by comparing the DIRT findings with CT angiography and intraoperative findings. The reported results were DIRT detected 42 of the 57 dominant perforators in 24 limbs and resulted in a sensitivity of 73.7% and a positive predictive value of 65.6%. They reported the sensitivity and positive predictive value of the smartphone-based DIRT are low.

(2019) Unger et al reported knowing the location of the blood vessels supplying the skin and subcutaneous tissue is a requirement during the planning of tissue transfer in reconstructive surgery. Commonly used imaging techniques such as computed tomography angiography and indocyanine green angiography expose the patient to radiation or a contrast agent, respectively. Infrared thermal imaging was evaluated with success as a non-invasive alternative. To support the interpretation of thermograms, a method to automatically detect the perforators was developed and evaluated. A system consisting of a thermal camera, a PC and custom software was developed. The temperature variations of the skin surface were analyzed to extract the perforator locations. A study was conducted to assess the performance of the algorithm by comparing the detection results of the algorithm with manually labelled thermal images by two clinicians of the deep inferior epigastric perforator flap of 20 healthy volunteers.

In conclusion the results of this study showed that it is possible to automatically and reliably detect the skin perforators in thermograms despite their weak temperature signature. Infrared thermal imaging is a non-invasive and contactless approach suitable for intraoperative use. Combined with a computer-assisted tool for the automatic detection of perforator vessels, it is a relevant alternative intraoperative imaging method to the standard indocyanine green angiography. A limitation of the study is the sample size of 20 participants. The clinical significance of this finding should be confirmed with larger studies.

Ocular Conditions

(2014) Wu et al completed an evaluation to assess ocular surface temperature and the efficacy of anti-allergic eye drops. Thirteen asymptomatic patients (24.7 ± 2.8 years) with proven seasonal allergic conjunctivitis due to cedar pollen were studied. A 0.025% levocabastine ophthalmic suspension was instilled in one eye (levocabastine eye) and artificial tears in the other eye (artificial tear eye) in a masked fashion 10 min prior to a conjunctival allergen challenge (CAC). Then, a drop of cedar pollen solution was dropped into the conjunctival sac to induce the allergic reaction. The surface temperature of the inferior bulbar conjunctiva was measured before and 30 min after the CAC with a newly developed non-contact ocular surface thermographer (OST). The degree of conjunctival injection and chemosis was also determined by slit lamp biomicroscopy. The changes in the symptoms were evaluated by a questionnaire. Results noted after the CAC, the temperature increased by 0.67 ± 0.10°C in the artificial tear eyes but by only 0.21 ± 0.06°C in the levocabastine eyes ($p < 0.05$). The score for conjunctival injection was 1.38 ± 0.24 and the chemosis score was 0.85 ± 0.25 for the artificial tear eyes and 0.62 ± 0.27 and 0.08 ± 0.08 in the levocabastine eyes ($p < 0.01$). The temperature increase was significantly correlated with the conjunctival injection scores ($r = 0.63$; $p < 0.001$). In conclusion the significant correlation of the conjunctival surface temperature with the severity of the conjunctival allergic reaction indicates that the temperature measured by the OST can be used to objectively evaluate the efficacy of topical anti-allergic agents A limitation of the study is the sample size for this of 13 participants. The clinical significance of this finding should be confirmed with larger studies.

Oral Conditions

(2018) Dong et al completed a prospective pilot study to evaluate the diagnostic performance of a non-radiating, noninvasive infrared (IR) thermal imaging system in the detection of cervical lymph node metastasis from oral cavity cancer. In this prospective clinical trial, a total of 90 oral cavity cancer patients suspected of having cervical lymph node metastasis underwent IR imaging of the neck prior to neck dissection. Analysis of the IR images was performed by two methods: manual qualitative analysis and automatic analysis by an entropy-gradient support vector machine (EGSVM). The efficacies of the EGSVM-based infrared thermal imaging system and contrast-enhanced computed tomography (CT) were compared by using the Noninferiority Testing. Compared with manual qualitative analysis, the EGSVM-based automatic analysis had a higher sensitivity (84.8% vs. 71.7%), specificity (77.3% vs. 72.7%), accuracy (81.1% vs. 72.2%), positive predictive value (79.6% vs. 73.3%) and negative predictive value

(82.9% vs. 71.1%). The EGSVM-based infrared thermal imaging system was noninferior to contrast-enhanced CT ($P < 0.05$). The EGSVM-based infrared thermal imaging system showed a trend of higher sensitivity, whereas contrast-enhanced CT showed a trend of higher specificity. The EGSVM-based infrared thermal imaging system is a promising non-radiating, noninvasive tool for the detection of lymph node metastasis from oral cavity cancer.

It was noted there are still limitations. First, this is a patient-based diagnosis of cervical lymph node metastasis from oral cavity cancer. Metastatic lymph nodes and the vascular abnormalities they cause can both result in deviations in heat, which provides the basis for the use of infrared imaging. While we can locate the abnormal area in two-dimensional space, it is difficult to precisely identify the lymph nodes within this area. Due to its limitations in identifying the exact anatomical localization of lesions, this method is currently more suitable for use as a screening tool. We anticipate that the EGSVM-based infrared thermal imaging system will play a role as a fast-screening tool for detecting of cervical lymph node metastasis from oral cavity cancer in resource-limited environments. Second, in this study, we extracted only one feature for automatic classification; the performance of the model can be improved with additional useful features. Additionally, more patients are needed to evaluate the diagnostic performance of this method in a multi-center clinical trial before it can be widely used for the detection of cervical lymph node metastasis from oral cavity cancer.

Pressure Ulcer

(2020) Bilska et al completed a comparative study to assess the usefulness of skin surface infrared thermography (SSIT) as a prognostic tool in the treatment of stages III and IV pressure ulcers (PU), with hydrocolloid/hydrogel dressings plus 20 exposures to low-level laser therapy (LLLT), compared with hydrocolloid dressings alone, in a group of long-term bedbound care patients. Participants were randomly assigned to group I: PUs treated with specialist wound dressings and laser therapy, or to group II: PUs treated with specialist wound dressings without laser therapy. Thermal imaging sessions were carried out at the beginning of the study, and after two and four weeks of treatment. Thermal imaging processing was applied to compare percentage differences in the temperature distribution between the groups within selected regions of interest (ROIs). The correlation between the temperature distribution and PU healing was evaluated.

The results noted a total of 43 patients took part. In the study, three variants of PU healing were observed: pure healing (H) with minimal granulation; healing with hypergranulation (H+G); and non-healing (NH). Analyses of SSIT-related thermographic patterns revealed their dependence on the course of healing. The percentage of successful PU healing reached 79.2% in group I compared with 73.7% in group II ($p<0.05$) The dominant variant of healing in Group I was H, while in group II the variants H and H+G were present with equal frequency. In conclusion thermal imaging processing allowed comparison of differences in the temperature distribution between the groups within ROIs. Application of LLLT significantly improved the healing process ($p<0.05$). The clinical significance of this finding should be confirmed with larger studies; however,

SSIT may be useful as a prognostic tool during the treatment of PUs, with the ability to predict the course of healing initially, that is independent of LLLT treatment.
(2013) Nakagami et al completed a prospective cohort study to investigate whether thermography can be used to detect latent inflammation in pressure ulcers and predict pressure ulcer prognosis in a clinical setting. For this cohort study, they recruited 35 patients with stage II-IV pressure ulcers on the torso, who underwent thermographic assessment on discovery of their pressure ulcer. The patients were followed up for at least 3 weeks. Thermography was performed immediately after dressing removal. Pressure ulcers were classified into two groups depending on whether the wound site temperature was lower or higher than the peri wound skin: the low temperature group and the high temperature group respectively. A generalized estimation equation was used to estimate the relative risk of delayed healing of pressure ulcers, comparing wounds with high temperatures and low temperatures. The results noted of the 35 patients, 21 had 'low temperature' wounds and 14 had 'high temperature' wounds at baseline. Two patients in the high temperature group presented with overt infection and were excluded from further analysis. Twenty-two pressure ulcers were considered to heal 'normally' (that is, the wound area reduced by 30% or more within 3 weeks) and 16 did not heal. The baseline DESIGN score (a measure of gross wound status) did not differ in any subscales between the high and low temperature groups. The relative risk for delayed healing in high temperature cases was 2.25 (95% confidence intervals: 1.13-4.47, p=0.021). Sensitivity was 0.56, specificity was 0.82, positive predictive value was 0.75, and negative predictive value was 0.67. In conclusion the results indicate that using thermography to classify pressure ulcers according to temperature could be a useful predictor of healing at 3 weeks, even though wound appearances may not differ at the point of thermographical assessment. The higher temperature in the wound site, when compared with peri wound skin, may imply the presence of critical colonization, or other factors which disturb the wound healing. It should be noted the sample size for this cohort study was limited to 35 patients. The clinical significance of this finding should be confirmed with larger studies.

(2017) Oliveira et al completed a systematic review and examined the clinical significance of ultrasound (US), thermography, photography and sub-epidermal moisture (SEM) measurement in detecting skin/tissue damage and thus predicting the presence of pressure ulcers (PUs); determined the relative accuracy of one of these assessment methods over another; and made recommendations for practice pertaining to assessment of early skin/tissue damage. The following databases, Cochrane Wounds Group Specialized Register, the Cochrane Central Register of Controlled Trials, Ovid Medline, Ovid Embase, Elsevier version, Ebsco CINAHL, ClinicalTrials.gov, WHO International Clinical Trials Registry (ICTR) and The EU Clinical Trials Register were searched for terms including thermography, ultrasound, sub-epidermal moisture, photograph and pressure ulcer. These investigators identified 4 SEM, 1 thermography and 5 ultrasound studies for inclusion in this review. Data analysis indicated that photography was not a method that allowed for the early prediction of PU presence; SEM values increased with increasing tissue damage, with the sacrum and the heels being the most common anatomical locations for the development of erythema and stage I PUs. Thermography identified temperature changes in tissues and skin that may give an indication of early PU

development; however, the data were not sufficiently robust; US detected pockets of fluid/edema at different levels of the skin that were comparable with tissue damage. Thus, SEM and US were the best methods for allowing a more accurate assessment of early skin/tissue damage. Using the EBL Critical Appraisal Tool, the validities of the studies varied between 33.3 to 55.6 %, meaning that there is potential for bias within all the included studies. All of the studies were situated at level IV, V and VII of the evidence pyramids. These researchers noted that although the methodological quality of the studies warrants consideration, these studies showed the potential that SEM and US have in early PU detection. The authors concluded that SEM and US are promising in the detection and prediction of early tissue damage and PU presence. However, they stated that these methods should be further studied to clarify their potential for use more widely in PU prevention strategies.

Scleroderma

(2018) Agazzi et al completed a cohort study of patients with juvenile localized scleroderma (JLS) to assess reliability of the two indexes of Localized Scleroderma Cutaneous Assessment Tool (LoSCAT), the modified Localized Scleroderma Skin Severity Index (mLoSSI) and the Localized Scleroderma Skin Damage Index (LoSDI), when applied by clinicians with different experience in scoring and managing patients with JLS. Secondary aim was to compare LoSCAT and infrared thermography (IRT) in monitoring lesions over time. Forty-seven patients (129 lesions) entered the study, and 26 (79 lesions) were re-evaluated with same modality after 4.5 (SD 1.5) months. mLoSSI showed excellent inter-rater reliability expressed by ICC 0.965 confirmed by ANOVA. Similarly, inter-rater reliability for LoSDI was good (ICC = 0.774) but worse concordance among examiners was observed. A comparable improvement of mLoSSI in all anatomic sites was noted by all examiners in 79 lesions examined in two subsequent visits and was consistent with thermography.

In conclusion different clinical experience in JLS did not influence clinical judgement in modified Localized Scleroderma Skin Severity Index (mLoSSI) which showed excellent concordance, whereas Localized Scleroderma Skin Damage Index (LoSDI) is less precise in damage assessment and not completely reliable in monitoring skin changes. Infrared thermography confirms to be a helpful tool for detecting disease activity and reliable in monitoring lesions over time. A limitation of the study is the sample size of 47 participants. The clinical significance of this finding should be confirmed with larger studies.

(2018) Ranosz-Janicka et al completed a review with one hundred and four LoS lesions were examined in 40 adults. Thirty-one lesions were erythematous, 26 were sclerotic, 35 presented as atrophy of the dermis and 11 as atrophy of the subcutaneous tissue. The sensitivity and specificity of IRT for detecting activity/inflammation were 80.7% and 86.3%, respectively. The positive predictive value was 71%, negative predictive value 91%. Statistically significant positive correlation was found between the ΔTavg and the clinical ER and DAT scores. Their conclusion reported IRT may be a useful method for assessing erythematous LoS lesions and quantifying the degree of activity/inflammation.

Knowing the patient, false positive results attributable to more severe degree of skin and subcutaneous fat atrophy can be easily recognized. A limitation of the study is the sample size of 40 participants. The clinical significance of this finding should be confirmed with larger studies.

Temporomandibular Joint Disorder

(2019) de Melo completed a systematic review on the scientific efficacy of infrared thermography (IT) on the diagnosis of temporomandibular joint disorders (TMDs). An electronic search was performed in 8 databases for publications up to May 2018. Additionally, a hand search of the reference lists was conducted. There were no restrictions on language or on year of publication. Two independent reviewers selected the studies, reviewed the abstract information, and assessed the quality. The methodology of the included articles was evaluated by using the QUADAS-2 tool. The results noted nine studies fulfilled the eligibility criteria and were included in the systematic review. Four studies concluded that IT presents low accuracy or is not an accurate instrument for TMD diagnosis, but there was substantial variation in sensitivity, specificity, and receiver operating characteristic curve values. Five studies concluded that IT appears to be promising or may be a complementary diagnostic aid in the evaluation of TMDs. These studies presented sensitivity values ranging from 70% to 90% and specificity values ranging from 62% to 92%. All studies were judged as being "at risk of bias" and as having "concerns regarding applicability." In conclusion the literature is still lacking in sufficient number of studies regarding the reliability of IT for the diagnosis of TMDs.

Summary of Evidence

No published studies demonstrate how the results of thermography and temperature gradient studies can be used to enhance patient management and improve patient health outcomes. The limited available studies address the use of thermography and temperature gradient studies in patients with a variety of clinical conditions. They are primarily identified for arthritis, breast cancer, burns, cardiac indications, ulcers, musculoskeletal injuries, post-herpetic neuralgia, melanoma, scleroderma, temporomandibular joint disorder, vascular, ocular, and oral conditions and tend to be in the form of case series, retrospective reviews, or narrative reviews with small patient populations, lacking control groups and/or comparison to proven diagnostic studies.

There is insufficient evidence to support the use of thermography and temperature gradient studies for screening, diagnosis, and treatment. Studies are lacking that thermography and temperature gradient studies can accurately diagnosis any condition or improve the accuracy of another diagnostic tool. Moreover, there are no published studies evaluating whether use of thermography and temperature gradient studies in patient management, such as to select a treatment or determine treatment effectiveness, improves net health outcomes. Further randomized controlled trials are warranted to include comparison to other diagnostic tools to determine safety and efficacy of this technology. The evidence is insufficient to determine the technology improves net health outcomes.

Practice Guidelines and Position Statements

American Cancer Society (ACS)
(2018) The American Cancer Society does not endorse thermography as a method for detecting breast cancer. (*Accessed January 2022*)

American College of Physicians (ACP)
(2019) The American College of Physicians issued a guidance statement for breast cancer screening in average-risk women those reviews existing screening guidelines.

- While the use of thermography was not mentioned in this statement, the authors conclude that evidence is insufficient to understand the benefits and harms of primary or adjunctive screening strategies in women who are found to have dense breasts on screening mammography. (*Accessed January 2022*)

American College of Obstetricians and Gynecologists (ACOG)
(Reaffirmed 2020) ACOG's Committee on Gynecologic Practice finds that current published evidence does not demonstrate meaningful outcome benefits with alternative screening modalities (e.g., breast tomosynthesis or thermography) in women with dense breasts who do not have additional risk factors. Evidence is lacking to advocate for additional testing until there are clinically validated data that indicate improved screening outcomes. (*Accessed January 2022*)

American College of Radiology (ACR)

- ACR Appropriateness Criteria Supplemental Breast Cancer Screening Based on Breast Density
    - (2021) Currently thermography is not listed as a recommended breast cancer screening modality. (*Accessed January 2022*)

- ACR Statement on Imaging for Myelopathy
    - (2021) The use of thermography was not mentioned in this statement. (*Accessed January 2022*)

European Society of Breast Imaging et al
(2017) A position paper by the European Society of Breast Imaging and 30 other national breast radiology bodies on screening for breast cancer stated the following:

- "…screening with thermography or other optical tools as alternatives to mammography is discouraged." (*Accessed January 2022*)

National Comprehensive Cancer Network (NCCN)
(Version 2.2022) Breast Cancer Screening and Diagnosis

- The use of thermography was not mentioned in this document. (*Accessed January 2022*)

Reflex Sympathetic Dystrophy Syndrome Association (RSD) and the International Research Foundation for RSD and Complex Regional Pain Syndrome (CRPS)
The Reflex Sympathetic Dystrophy Syndrome Association (RSD) and the International Research Foundation for RSD and Complex Regional Pain Syndrome (CRPS) issued guidelines for the treatment of RSD and CRPS. Each of these guidelines indicates thermography may be used to assist in the diagnosis of RSD/CRPS. However, neither guideline has supporting evidence for its conclusion. (*Accessed January 2022*)

Society of Breast Imaging (SBI)
(Active as of 2022) The Society of Breast Imaging does not currently support the use of thermography/ infrared imaging of the breast as either a screening tool in the detection of breast cancer or as an adjunctive diagnostic tool. Breast thermography was approved by the FDA in 1982 only as an adjunct to mammography. A detailed background and review of the scientific data follows below. In summary, there are currently no studies supporting the use of thermography alone or thermography as an adjunct to mammography that show clear benefits of the technique. It is also unclear how the abnormal areas detected by thermography were aspirated or biopsied. No method was described to accurately transpose the thermographic location of the lesion to the mammogram and then to the actual location in the breast.

Until there are more encouraging data available, the SBI cannot support the use of thermography/infrared imaging of the breast. (*Accessed January 2022*)

United States Preventive Services Task Force
(2016) The U.S. Preventive Services Task Force recommendations on breast cancer screening do not mention thermography. Additionally, there is insufficient evidence for the use of adjunctive screening methods for breast cancer (ultrasonography, magnetic resonance imaging, digital breast tomosynthesis, or other methods) in women identified to have dense breasts on a negative screening mammogram. (*Accessed January 2022*)

Regulatory Status
(2019) The FDA is alerting women, health care providers, and people getting breast cancer screening, that thermography is not an effective alternative to mammography and should not be used in place of mammography for breast cancer screening or diagnosis.

There is no valid scientific data to demonstrate that thermography devices, when used on their own or with another diagnostic test, are an effective screening tool for any medical condition including the early detection of breast cancer or other diseases and health conditions.

Summary of Problem and Scope
The FDA is aware that health spas, homeopathic clinics, mobile health units, and other health care facilities are using thermography inappropriately as a standalone tool for breast cancer screening or diagnosis.

The FDA has received reports that these types of facilities provide false information that can mislead patients into believing that thermography is an alternative or better option than mammography. Some facilities make inaccurate, unsupported, and misleading claims, such as thermography can find breast cancer years before it would be detected through other methods or thermography improves detection of cancer in dense breasts. (*Accessed January 2022*)

A number of thermographic devices have been cleared for marketing by the Food and Drug The table below is not intended to be an all-inclusive list. Examples of these devices are:

Device Name	Manufacturer	Clearance	510(K) No.
AlfaSight 9000 Thermographic System™	Alfa Thermodiagnostics	2015	K150457
FirstSense Breast Exam®	First Sense Medical	2016	K160573
Infrared Sciences Breastscan IR System	Infrared Sciences	2004	K032350
InTouchThermal Camera	InTouch Technologies	2019	K181716
Notouch Breastscan	UE Lifesciences	2012	K113259
Sentinel BreastScan II System	First Sense Medical	2017	K162767
Telethermographic Camera, Series A, E, S, and P	FLIR Systems	2004	K033967
WoundVision Scout™	WoundVision	2013	K131596

Food and Drug Administration product codes: LHQ, FXN. Devices with product code LHQ may only be marketed for adjunct use. Devices with product code FXN do not provide a diagnosis or therapy.

PRIOR APPROVAL

Not applicable.

POLICY

Thermography (i.e., thermal imaging and temperature gradient studies) is considered **investigational** for all indications, including but not limited to the following due to a lack of evidence demonstrating an impact on improved health outcomes.

- Arthritis
- Atherosclerotic coronary artery disease (CAD) assessment
- Breast cancer screening
- Breast cancer dermal management related to radiotherapy

- Burns
- Complex regional pain syndrome
- Diabetic ulcer management
- Melanoma
- Postherpetic neuralgia
- Temporomandibular joint disease
- Vascular obstruction

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 93740 Temperature gradient studies
- 93799 Unlisted cardiovascular service or procedure *(when utilized for thermography)*

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POLICY HISTORY

Date	Reason	Action
January 2022	Annual Review	Policy Revised
January 2021	Annual Review	Policy Revised
January 2020	Annual Review	Policy Renewed
January 2019	Annual Review	Policy Revised
January 2018	Annual Review	Policy Revised
January 2017	Annual Review	Policy Revised
January 2016	Annual Review	Policy Revised
February 2015	Annual Review	Policy Renewed
March 2014	Annual Review	Policy Revised
April 2013	Annual Review	Policy Renewed
April 2012	Annual Review	Policy Renewed
June 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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