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THERMOGRAPHY AS AN ADJUNCTIVE RISK ASSESSMENT TOOL FOR BREAST CANCER

An independent review paper for both clinicians and the public to outline scientific evidence relevant to the cases for and against the use of breast thermal imaging and its appropriate application within clinical settings

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with an

EXECUTIVE SUMMARY

PLACING THE REVIEW PAPER IN A CONTEMPORARY PUBLIC POLICY CONTEXT

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1. BACKGROUND TO A POLICY ISSUE

1.1 Arguably, the Ministry of Health (MoH) has for decades now presided over a New Zealand public policy on breast health that has been focussed upon and primarily limited to screening for and detecting cancer in womens' breasts using radiographic tools.

1.2 It is perhaps reasonable to state that the general policy picture has changed little over more than three decades.

1.3 By way of assessment and comment there are three observations that seem to be particularly relevant:-

1.3.1 Breast cancer data collected does not seem to feed back into policy formulation and review processes therefore there appears to have been no sensible bases for evaluating the success or otherwise of the long-established policies and approach to womens' breast health.

1.3.2 The established policies might reasonably be argued to focus on finding out whether or not a women 'is possibly falling down a cliff (showing evidence of a possible cancer) - or is 'at the bottom of the cliff' requiring early intervention to deal to a significant cancer.

1.3.3 Established policies have been translated into a segmented organisational structure for their delivery. Policy reviews have tended to be 'delivery policy reviews' commissioned from within that organisational structure - i.e. 'delivery' measuring 'delivery' but without the benefit of one of the most important key performance indicators (referred to in 1.3.1).

1.3.4 In addition, reviews have tended to focus regressively upon reviews of literature based primarily on overseas radiographic approaches to 'delivering' radiographic detection of breast cancer. That approach is arguably a sensible and prudent source of 'fine-tuning' for NZ delivery agencies that predominantly form components of the 'secondary' health delivery system. However, such an approach is also arguably not going to address or fill the 'preventative' breast health needs in the primary system at the top of the cliff where there appears to be a policy vacuum.

1.4 Yet the purpose of the New Zealand Health and Disability Act 2000 at Section 3 (1) (a) requires its administration -

"to achieve for New Zealanders (i) the improvement, promotion, and protection of their health" and

(4) …the Crown and DHBs must endeavour to promote the integration of all health services, especially primary and secondary services."

1.5 A group of New Zealand clinicians and some prominent citizens has begun to work together to draw attention to developing clinical approaches that comprise of a cluster of primary risk-factor assessment tools (including latest advances in thermography) that enable a reasonable 'breast health focus' upon women who are identified as being at particular risk of developing breast cancer or for women in their 40s for whom early detection of breast abnormalities can be important.

1.6 In addition, that group of clinicians and citizens is working collaboratively with other experienced clinicians and authorities[1] on identifying early interventions appropriate to particular patient circumstances so as to pursue patient clinical assessments likely to be more conducive to patient wellness.

2. THE CELLULAR CASE FOR BREAST HEALTH MONITORING

2.1 "*Grouping dysfunction on the basis of altered cellular communication may be much more useful for understanding the predisposition to disease than is the categorization of disease from a taxonomic perspective. By understanding the triggers that influence elaboration of intracellular mediators and how these mediators influence signs and symptoms, the clinician may be better able to identify and treat the causes of disease, rather than just the symptoms.*"[2]

2.2 Altered nitric oxide elaboration, physiology and concentration is associated with some chronic-inflammatory-cascade conditions that are linked to cancer.

2.3 Breast cancer cells can over-regulate production of nitric oxide to help facilitate the delivery of higher levels (than normal) of oxygen and nutrient delivery to the mutated tissue.[3]

2.4 Such inflammation can characteristically lead to vasodilation and the infiltration of red and white blood cells that together cause a local rise in temperature.[4]

2.5 Such sustained temperature characteristics measured by thermography to appropriate standards can be indicative of developing pathology and therefore suggest close clinical monitoring and adjunctive investigations.

2.6 It is arguable therefore that such an approach can reasonably form part of a breast care programme at the primary level.

2.7 The particular benefits of such a programme include primary care monitoring of:-

2.7.1 Women in their 40s who account for approximately 18 per cent of breast cancers; such younger-aged women tend to have breast cancers that are more rapidly growing and that are more likely to metastasize.[5] [Many cancer organisations, for screening women between the ages of 40 to 49, have conflicting recommendations as

to whether screening with mammography is appropriate in terms of weighing radiation risks against possible detection benefits.][6]

2.7.2 Women taking synthetic hormone replacement therapy who have a significant increased risk of invasive breast cancer.[7]

2.7.3 Forty per cent of women with fibrocystic disease and an abnormal thermogram develop cancer within five years. Conversely, women with fibrocystic disease and a normal thermogram have a less than 3 per cent likelihood of developing breast cancer.[8]

2.7.4 A repeated abnormal thermogram in the absence of a palpable cancer or abnormal mammogram has been associated with a greater than 30 per cent risk of developing breast cancer within 10 years.[9, 10]

3. QUESTIONABLE BASES FOR PRESENT NSU 'POSITION STATEMENT'

3.1 A present NSU 'Position Statement'[11] declares that its position is based upon a New Zealand Health Technology Assessment (NZTHA) Technical Brief produced by Jane Kerr of the University of Otago in July 2004.

3.2 That Position Statement claims that the Technical Brief was a systematic review - when, on examination, it is patently not such a review.

3.3 The title of that review enquired as to whether or not thermal imaging was both effective for population screening and diagnostic testing of breast cancer.

3.4 That chosen title, which presumably also reflected terms of reference for the work, was arguably a 'straw man' because thermal imaging was bound to fail such an assessment. The reason being that earlier studies, for example, in 1972[12] and a study in 2000[10] addressed that topic and concluded that thermograms were not a screening tool *per se* but had an effective role as a risk marker:

a) a preliminary procedure that can produce results indicative of a need for a mammogram; and/or

b) a procedure for asymptomatic women which can produce indications that pin-point risks.

3.5 The author of the NZHTA chose to record that she had chosen to exclude consideration of thermography as a risk-marker. Therefore her Technical Brief is arguably of no value for determining whether or not public policy should support or not support thermography as an adjunctive clinical risk marker for monitoring breast health within the primary care clinical system.

3.6 The NZHTA paper was quoted as the basis of the Position Statement on thermography - and that Position Statement had a banner that indicated that it represented the position of the MoH and the main non-governmental agencies involved in breast health in New Zealand. Those organisations were apparently

therefore content to rely upon a straw man wearing a thermography hat for the formulation of their policy positions.

3.7 Public policy is a species of legislation.[13] Its formulation therefore carries with it all of those principles that apply to other layers of legislation. A useful synthesis of relevant principles is contained in the Legislative Committee Guidelines adopted by our Parliament. More specifically, the relevant principles derive from statutory interpretation and administrative law which apply to all Acts.

3.8 However, some principles of administrative law are particularly relevant to the issue here: these principles do not allow legitimate public policy to be formulated:

3.8.1 without an appropriate duty of care;

3.8.2 without due regard to relevant considerations (including appropriate weight being given to those considerations); and

3.8.3 without due focus upon the purpose of the Act that is purported to require administration.

3.9 Another feature is that administrative policies should be approached with a focus upon being 'enabling' and not 'disabling' unless there is a particular mischief that needs to be controlled in the public interest.

3.10 Recently, the evidence indicates that an early New Zealand initiative to invest in and develop thermography as an adjunctive clinical risk marker for breast health at the primary level of clinical services was effectively disabled by an arguably inappropriate public-sector-commissioned Technical Brief that was adopted by a public agency to form a Position Statement that has been adopted as an effective public policy statement. And that policy statement has effectively (and, arguably, inappropriately) unduly influenced breast health service agencies and their staffs as well as setting the scene for a general public cynicism about thermography as an adjunctive risk marker for breast health monitoring.

4. REVIEW PAPER ATTACHED

4.1 The group of clinicians and concerned citizens commissioned a medical researcher to assess thermography as an adjunctive risk assessment tool for breast cancer; to produce an independent review paper for both clinicians and the public to outline scientific evidence relevant to the cases for and against the use of breast thermal imaging and its appropriate application within clinical settings; and to produce an Executive Summary placing the review paper in a contemporary public policy context.

4.2 Only very limited funds were available to apply to this work; it is not therefore by any means to be considered 'definitive' of the clinical potential of thermal imaging as an adjunctive tool in breast health risk assessments and risk management at the primary care level.

4.3 However, it is arguable that there is sufficient evidence advanced to show that there is a *prima facie* case for some public policy research that explores properly the

'opportunity space' for appropriate utilisation of thermography as an adjunctive risk marker tool for appropriate integration with other primary-care level risk markers and risk-management protocols.

4.4 There does seem to be a particularly strong case for such a primary care approach 'capturing' women in their 40s who are presenting with sufficient early risk markers to warrant referral for secondary radiographic investigations - thus reducing the probability of post-radiographic negative findings.

4.5 In that regard the group responsible for this initiative would welcome an opportunity to discuss this topic and also to perhaps enter into a partnering relationship with the Ministry to advance policy research to explore properly how thermal imaging might play a valuable adjunctive role in breast health risk identification at the primary care level.

4.6 Such a primary level initiative, when fully operational and operating with appropriate transferrable and repeatable standards would, collaterally, offer an important line of communication of key breast health messages to be conveyed to the public: effectively, that could become a significant conveyor of key health messages to the public at risk - therefore an initiative at the preventative 'top of the cliff'.

5. GRATITUDE

5.1 We are grateful for the opportunity that you have given to us to submit this summary and its accompanying research.

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1. BACKGROUND

1.1 Breast cancer is now estimated to affect approximately 1 in 9 women during their lifetime. In a number of countries, breast screening programs have been implemented in the hope that early detection of breast cancer can help save lives. A number of cancer associations and patient organizations no longer recommend clinical breast exam or breast self-examination given large randomised controlled trials have not demonstrated a reduction in breast cancer mortality with these modalities, rather an increase in benign biopsies. While mammography is thought to reduce breast cancer mortality, it comes with a price of over diagnosis (diagnosis of a cancer that would have never caused symptoms or death in a patient's lifetime) and increased mastectomies and tumourectomies. As such, many women are left confused about what screening and assessment tools are most appropriate.

1.2 This paper serves to provide an objective overview of the use of clinical breast thermography so that combined with their health practitioner and loved ones, women can make informed and educated choices that best serve them as an individual.

2. THE HISTORY OF THERMAL IMAGING

2.1 Heat production and the exchange of heat are constant unconscious phenomena occurring in a person's life.[1] For centuries, body temperature has been an important indicator of health or disease in man. A classic example is the use of the mercury thermometer which became mainstream protocol in the 1870's and 1880's and is still widely used today as an important medical device to assess illness.[2]

2.2 Infrared radiation is another means by which temperature changes in the skin and subcutaneous tissue can be measured. In 1956, infrared (IR) imaging was introduced by the Canadian surgeon Ray Lawson, MD, who discovered that skin temperature over cancerous breast tissue was higher than that of normal skin tissue.[3] Seven years later, Lawson and his colleague Chughtai, MD from McGill University published their research which showed that the change in skin temperature associated with breast cancer was related to increased venous blood flow and increased metabolism.[4]

2.3 In 1965, IR imaging was introduced to America by Gershen-Cohen, MD, a radiologist from the Albert Einstein Medical Centre. Initially this new modality was considered a key competitor to mammography and a technology that could help reduce breast cancer mortality.[5] In examining 4,000 thermal images, Gershen-Cohen found this modality to be a highly accurate of breast cancer with a true positive rate of 94% and a false positive rate of 6%.[6] JoAnn Haberman, MD, another radiologist from the Temple University School of Medicine reported an 87% true positive rate for thermography and a 13% false negative rate following a review of over 16,000 thermal imaging cases between 1964 and 1968.[7]

2.4 In 1972 Isard et al published a paper in the American Journal of Roentgenology that put a halt to the notion that thermal imaging could detect breast cancer. The authors stated that IR imaging does not diagnose cancer; rather it can only indicate the presence of an abnormality. What Isard and his colleagues found was that thermograms are remarkably stable over time in healthy patients and changes in thermal images can therefore be of great significance.[8]

2.5 The same year this paper was published, Gerald Dodd, MD a radiologist from the University of Texas provided an update on thermography at the 7th National Cancer Conference. This event was sponsored by the National Cancer Institute and the National Cancer Society. Dodd proposed that IR imaging be utilized as a screening agent for mammography given 15-20% of women over the age of 40 had abnormal thermograms. Of this percentage of women with abnormal infrared images that went on to have a mammogram, 5% would be referred for biopsy. Given these findings, he concluded that pre-screening with thermography could significantly reduce the need for a mammogram by an estimated 80-85%. From his work at the university, Dodd determined thermography to be approximately 85% sensitive in detecting breast cancer. Undeterred by the false positive rate of 15-20% he maintained that an abnormal thermogram even in the absence of any other abnormalities helped identify a high risk population.[6]

2.6 In 1983 Jones published his findings from over 70,000 imaging cases and found a true positive rate of 85% and exact false positive rate of 13%. He also assessed over 20,000 images between 1967 and 1972 and found that approximately 90% of Stage III and Stage IV cancers and 70% of Stage I and II cancers had accompanying abnormal thermograms. It was this research that gave credibility to thermography as a front-line detection modality for breast cancer.[9]

2.7 In the 1970's, studies on thermography were also underway in Europe. One of the great pioneers of breast thermography is Michel Gautherie, PhD, a French scientist from the Louis Pasteur University. His research in the 1980's further advanced Lawson's findings whereby he found a correlation between temperature changes in a thermogram and cancer growth rates. He noted that fast growing tumours can result in significant changes in thermograms which can occur 6-12 months prior to changes in morphology. Slow growing cancers on the other hand demonstrated very small or even non-detectable changes in temperature in thermograms. Having reviewed over 58,000 thermal images, Gautherie felt that thermography would be a valuable prognostic tool to help identify faster growing cancers at an earlier stage before any palpable or radiographic abnormalities could be detected.[1], [2]

2.8 On the whole, thermography failed to take off in the 1980's due to the low degree of sensitivity and a high level of subjectivity in thermographic interpretation. Studies during this time that compared thermography with mammography had many methodological flaws, leading to the erroneous conclusion that thermograms are ineffective screening tools.[10] The trial that was most damaging to thermography's reputation was the Breast Cancer Detection and Determination Project (BCDDP). Despite the many short comings of the BCDDP including technical limitations, poor image resolution and a lack of standardization of interpretation protocols, some 30 years later critics intent on discrediting thermography are still leveraging from this paper.

3. THE BREAST CANCER DETECTION AND DETERMINATION PROJECT (BCDDP)

3.1 Thermography lost acceptance in the medical arena following the results of BCDDP undertaken by the American Cancer Society and the National Cancer Institute.[11] The BCDDP was a 5 year screening program that became operational in 1973 and was completed in March of 1981. Asymptomatic females between the ages of 35 and 74 underwent a breast examination, mammogram and thermogram along with a detailed family history. Participants were recruited from 29 registered screening centres throughout the U.S. and in total; there were over 280,000 participants.[11],[12]

3.2 When thermography was hastily added to the BCDDP, it was with the thought it could have the potential to replace mammograms and clinical breast exam. The Working Group of the BCDDP had six objectives, one of which was to determine if a negative thermogram would be sufficient to waiver the use of mammograms and clinical breast exam in the detection of breast cancer. Their reasoning was based on the fact that previous studies had indicated a comparable sensitivity and specificity between mammography and thermography. Stringent quality control parameters were put in place for the radiographic component of the BCDDP and screening centres had to first prove their expertise in mammography before being awarded a contract. Throughout the program, ongoing reviews of mammography were conducted by project radiologists and there were also on-site visits by consultants to address procedural challenges and image quality. Thermal imaging protocols were not subject to the same rigorous standards, rather the protocol was summarised in one paragraph which stated that image interpretation be conducted by a BCDDP trained technician. Of the 29 centres involved in the BCDDP, only 5 had prior infrared imaging experience. A year and a half into the project, attempts were made to up skill both radiologists and technicians in thermography with the offer of additional training. Less than half the centres (11 out of 29) sent their staff fortraining. As such, there was no consistent quality control or standardization with many centres neglecting to cool their patients prior to thermographic examination. And, unlike the more comprehensive grading scales currently used to interpret thermal images, results in the BCDDP trial were merely reported as 'normal' or 'abnormal'.[6], [11] All three modalities (clinical breast exam, mammography and thermography) were supposed to be reported independently, however the Working Group was unable to assess if this protocol was consistently followed nor were they able to evaluate the quality of the examinations.6

3.3 Thermography was dropped from the BCDDP in 1977 given its 41% detection rate of breast cancer in the first screening round. The low sensitivity of thermography in the BCDDP was not reflective of the many trials performed between 1969 and 1976 that yielded an average sensitivity of 72%.[14]

3.4 What is seldom captured in the literature is the Working Group's comments in their report that their decision to drop thermography from the BCDDP should not be taken as a determination of the future of infrared imaging, rather they recommended future research of IR imaging be given high priority in carefully controlled conditions with experienced staff given its value as a radiation-free technique.[11]

3.5 The 1977 Consensus Development Meeting held by the National Institutes of Health and the National Cancer Institute were also of the opinion that future research on breast cancer should focus on non-invasive techniques such as thermography, ultrasound and biologic markers.[15]

3.6 While the BCDDP Working Group concluded that thermography did not appear to be a suitable substitute to mammography for routine screening, they were unable to comment on the role of infrared imaging as a complementary modality.[11]Because thermography was prematurely withdrawn and no comparative data were collected, no conclusions could be made about the possible value of thermal imaging as a risk indicator for breast cancer or a prognostic marker in women with abnormal thermograms who ended up being diagnosed with breast cancer.[16] Additionally, it was not possible to determine if an abnormal infrared image could be predictive of interval cancers (those that develop between screenings) given this information was also not collected.[6]

3.7 Despite the fact that the BCDDP deemed thermography an unacceptable stand alone modality for breast cancer detection, in 1982 the Food and Drug Association of America (FDA) approved the use of thermal imaging as an adjunctive screening tool for breast cancer.[17]Today, nearly 30 years later, breast thermography still has FDA approval as an adjunct tool and there are numerous clinics throughout the U.S. and Europe utilizing thermal imaging in this capacity.

4. ADVANCES IN THERMOGRAPHIC TECHNOLOGY

4.1 In the early days, thermography was limited to techniques such as infrared thermograms, plate thermograms and liquid crystal imaging all of which failed to demonstrate a high degree of sensitivity and specificity. Since the 1990's there have been significant improvements in infrared systems with an accompanying increase in accuracy.[18] For example, in the 2008 prospective trial by Arora et al, modern digital thermography was able to detect 97% of biopsy confirmed malignancies.[17]

4.2 Historically, IR cameras lacked the sensitivity to detect subtle temperature changes necessary to identify and monitor disease. The sensitivity of the new infrared technology is so much more sophisticated that these instruments can detect temperature changes within 0.025°C, making it easy to detect skin surface changes of 0.05-0.1°C. Modern day focal plane staring array digital imagers can now assign temperatures to every point in the array which can then be transferred to computerized software tools to further enhance image analysis and interpretation.[19], [20]

4.3 As with mammography, it is imperative that thermograms are accurately interpreted by highly trained thermographers. The BCDDP is testimony to this with many of the individuals interpreting the images void of any formal training and results varying vastly between the screening centres.[2] Nowadays, there is rigorous training for interpreters which is provided by thermography-specific medical associations and institutes. Accredited members receive standardized procedures for patient preparation and testing along with well defined protocols to ensure objective and accurate interpretation of the images.[21] Interpretation protocols are a culmination of the clinical and scientific work from elite thermography researchers. These include recognition of diffuse heat patterns involving parts, half or the entire breast, hotspots with asymmetry along with an increase in areolar, periareolar heat, blood vessel discrepancy and an overall diffuse heat pattern.[18]

5. THERMOGRAPHY AS A FUNCTIONAL TOOL VS AN ANATOMICAL TOOL

5.1 Thermography is a physiological test that provides information on temperature and infrared heat patterns of the breast.[22] Because the skin emits thermal radiation, it is well suited to infrared imaging.[23] As a functional test, thermography captures metabolic images. This technique differs from mammography which is a structural test that captures anatomical changes.[5]

5.2 Thermography records the temperature distribution of the body by using infrared radiation emitted from the surface of the skin at wavelengths between 0.8μm and 1.0μm. A special infrared camera detects this heat from the skin. The amount of radiated energy recorded by the camera is converted into an energy signal which in conjunction with other parameters calculates the temperature of the skin. A visual map (thermogram) of the distribution of temperatures on the surface of the skin is created which is recorded electronically.[19]

5.3 Just as a finger print is unique to an individual, so are breast thermal images. In a healthy woman, the symmetry between the two breasts while never identical is very similar. Likewise, vascularity between breasts in an otherwise healthy woman should also be consistent. In other words, a woman may exhibit minimal vascularity (cold breasts) or high

levels of vascularity (warmer breasts), but the overall symmetry, heat emission and contours of the breasts should be comparable.[24] Because thermograms in a healthy woman remain remarkably constant, serial thermograms can assess tissue changes over time. A healthy initial thermogram can therefore serve as a baseline to compare future thermograms against.[18]

5.4 Blood is the main heat exchange fluid of the body. When significant differences occur between the blood temperature and the surrounding tissue through which the blood travels, convective heat transport occurs changing the temperature of both blood and tissue (this is known as a perfusion based heat transfer interaction). An increase in temperature detected by thermography invariably relates to changes in perfusion.[19] Changes in breast contour, vascular patterns or differences in regional or global heat are all signs of an abnormal thermal image.[24]

5.5 Alterations in temperature and vascularisation of breast tissue can be influenced by a number of factors including:

5.5.1 **Angiogenesis** – the growth of a tumour relies on the recruitment of blood vessels both in and around the cancerous cells, a process known as angiogenesis. The blood supply provides oxygen and nutrients to support tumour growth. These blood vessels differ in that they don't contain smooth muscle fibres and therefore are not regulated by the hormone adrenaline (epinephrine) that is involved in normal vasoconstriction. This physiological difference means there is a more constant blood supply to the site of the tumour with a corresponding rise in temperature surrounding the tissue.[25]

5.5.2 **Inflammation** – this can result from increases in temperature caused by infection, injury and wound healing as well as cancer. All of these factors can lead to vasodilation and the infiltration of white and red blood cells which can cause a rise in skin temperature.[18]

5.5.3 **Nitric Oxide** – this is a vasodilatory substance that is produced by the vascular and immune system and serves as a natural defence mechanism and a regulatory component of the blood stream. Breast cancer cells can also over-regulate the production of nitric oxide to help facilitate the delivery of oxygen and nutrients to the mutated tissue. The nitric oxide produced by tumours makes the vessels non-flexible and increases dilation which in turn changes the thermal load.[23]

5.5.4 **Oestrogen** – the hormone oestrogen plays a role in vasodilation by increasing the production of nitric oxide. Accordingly, oestrogen imbalances can lead to an increase in temperature in oestrogen sensitive tissue such as breast tissue.[18]

5.6 As a functional test, thermography can detect breast abnormalities that other screening methods cannot identify, namely thermal and vascular changes. These functional changes are thought to take place before the onset of structural changes that can occur in diseased or cancerous states. When functional abnormalities are detected early, there is an opportunity for early intervention.[18]

6. WHO IS THERMOGRAPHY SUITABLE FOR?

6.1 Thermography can be a valuable tool for indicating changes in breast disease or abnormal risks and can be utilized in the following ways [3]:

6.1.1 to trace and evaluate a potential problem
6.1.2 to observe the effectiveness of treatment intervention
6.1.3 to monitor breast health over time

6.2 The increased metabolic activity seen on a breast thermogram can be an indication of mastitis, fibrocystic breast disease or cancer.[26] Other factors that can alter thermal patterns include scars or skin lesions, superficial veins that lead to hyperthermia and anatomical differences in the breasts although the latter is rare.[27]

6.3 Thermography does not diagnose cancer; rather it can detect an abnormality and alert the physician to the need for further investigation and identify women who need to be more closely monitored.[8] IR imaging is not a competitor to, or a replacement for mammography, rather it is an adjunct tool that can identify areas of abnormal thermal symmetry which are often associated with underlying pathology.[28] According to Ng and Kee, when combined with other anatomical procedures thermography "may contribute to the best possible evaluation of breast health".[29]

6.4 One of the key benefits of thermography is its effectiveness in women with dense breasts, making it suitable for those who are young, on oestrogen therapy or those with fibrocystic breasts.[5] Fibrous breasts are very dense and can mask early cancers, particularly if no microcalcifications are present. Infrared imaging when used serially can help identify changes in fibrocystic breasts. This is of key importance given that an estimated 40% of women with fibrocystic disease and an abnormal thermogram go on to develop breast cancer within the following 5 years.[2] Conversely, women with fibrocystic disease who have a normal thermogram have a less than 3% likelihood of developing cancer according to Gautherie's extensive research. Serial thermograms can therefore help monitor the effects of hormone treatment for fibrocystic breasts without the complications of radiation exposure.[2]

6.5 Thermography can also provide early warnings of breast abnormalities and highlight potentially suspicious cases particularly when mammographic and clinical exams are equivocal or non-specific.[6] An abnormal thermogram in the absence of any other findings can serve as an alarm signal and these women should be monitored more regularly.[1] Research has shown that approximately 10% of breast cancers can be detected at an earlier stage with the combined use of thermal imaging. Gautherie and Gros closely monitored a subset of women whose only finding was an abnormal thermal image. With further examinations and follow up mammography testing and biopsies, they were able to identify an additional 35 to 50 cancers each year.[27]

7. UNDERSTANDING THE THERMOGRAPHY PROCEDURE

7.1 Patient preparation is an important part of the thermographic procedure. To help increase the accuracy of the thermal image, a detailed list of instructions are provided prior to the appointment. Women are advised to avoid topical creams and lotions along with exercise, smoking and hot fluids as all these factors can affect the emissivity of the skin and interfere with the thermographic pattern.[30]

7.2 The actual procedure itself requires the patient to undress from the waist up and sit in a private procedure room for approximately 15 minutes. This allows the surface of the breasts to acclimate to the temperature of the room. A controlled environment for thermal imaging is of critical importance. Both temperature and humidity need to be constant. While the temperature can range from 18-22°C, the variance can not exceed 1°C during the actual procedure. Ensuring a stable room temperature removes the variable of physiological stress that can otherwise have an adverse impact on the results. During the procedure itself, patients are seated approximately 1-2 metres in front of the infrared camera with their arms raised above their head while a number of images of the lateral and anterior breasts are captured. Some clinics elect to perform an additional procedure known as the cold water challenge (or autonomic challenge) which involves placing both hands in cold water (at approximately 10°C) for 1 minute, after which the images are then repeated.[18]

7.3 Cold water emersion is the most common method for the autonomic challenge during a thermographic procedure. This technique elicits a neurovascular survival response triggered by peripheral neural receptors which is then conveyed to the central nervous system. In order to prevent hypothermia, the blood vessels are constricted in the peripheries. The cold water challenge can help identify non-responding blood vessels which can be involved in early angiogenesis.[31] This is because blood vessels from a cancerous tumour in the early phases of growth do not have a smooth muscle layer and consequently are without neural regulation. When faced with a cold water challenge these abnormal blood vessels do not constrict in response to sympathetic stimulation. Adding this technique to thermography screening may therefore help reduce both false positive and false negative rates.[31]

7.4 Thermal images are then interpreted by a board certified thermographer who evaluates a number of different features including[22]:

7.4.1 Graphic criteria – to evaluate vascular patterns and symmetry
7.4.2 Thermal criteria – to assess vascular temperature and non-vascular surface temperature
7.4.3 The presence of localized or focal areas of increased non-vascular surface temperature with changes of 1°C or greater (including the areola region) are also taken into account.

8. THERMOGRAPHY ADVANTAGES AND DISADVANTAGES

8.1 Thermography as previously mentioned differs from mammography in that it provides information on the biological activity of the breast vs. the gross internal anatomy.[24] Some researchers believe that thermography hasn't been widely embraced by physicians because tests of a biological base are not familiar to them and were not part of their medical training as is the case for anatomical tests such as radiology and other screening modalities. It is also thought that education on thermophysics and thermophysiology to clinicians would help encourage the acceptance of this modality in mainstream medicine.[1]

8.2 One key advantage of thermography is that it is a totally non-invasive procedure. It is a contact-free assessment that doesn't require compression of the breasts which is often associated with pain.[32]Unlike mammograms, there is no exposure to radiation which also means repeat tests are safe and without risk.[18] This is very important for women with suspicious findings or equivocal results who need to be more closely monitored.[33]

8.3 The disadvantages of thermal imaging speak to its limitations as a diagnostic marker or stand alone screening tool for breast cancer. When thermography emerged in the 1960's it was considered a key competitor to mammography and throughout the seventies and eighties, scientists continued to explore IR imaging as a screening test and diagnostic marker for breast cancer.[5] Some researchers such as Amalric, Spitalier and Gros thought thermal imaging held great promise as a diagnostic tool for breast cancer whereas other scientists such as Nathan and Moskowitz and their respective colleagues thought it held no value as a screening modality.[30]

8.4 One of the reasons there was so much controversy around thermography as a diagnostic marker for breast cancer was due to questions around its accuracy in relation to sensitivity and specificity.[5] Sensitivity relates to the ability to accurately identify those who have a disease or condition, whereas specificity is the ability to accurately identify those without a disease or condition. Early studies revealed a high degree of variation in sensitivity for the use of thermography as a diagnostic test.[6] The quality of the trials along with the use of older infrared technology and broad interpretation guidelines were thought to be some of the reasons for the observed variances. An example where interpretation protocols significantly

affected the thermographic results is captured in the research by Feig and colleagues. In 1977 they published their findings from 16,000 self selected women who had undergone clinical breast exam, mammography and thermography for the detection of breast cancer. In the initial series, only 39% of women with known breast cancer had an abnormal thermogram. This percentage increased to 75% in the last screening round based upon more objective criteria for image interpretation.[34]

8.5 Research from Japan in the late 1980's and early 1990s demonstrated sensitivities of 82 and 88% and specificities ranging from 68 and 84% for the use of thermal imaging in the diagnosis of breast cancer. Because of its low degree of accuracy, thermography was considered more suited as a prognostic marker, rather than a diagnostic tool.[35] As technology improved over time, so did the accuracy of thermography. In 1996, Gamagami's research was published in the book titled "Atlas of Mammography". He investigated the presence of angiogenesis through thermography and found that 86% of non-palpable breast cancers demonstrated hypervascularity and hyperthermia in thermographic images. He also reported that thermal imaging was able to detect 15% of cancers that were not identifiable through mammographic assessment.[6]

8.6 Thermography has been found to have a high false positive rate when used as a tool for breast cancer detection. However, research by Gautherie and others have discovered that a high percentage (>30%) of abnormal thermograms in the absence of a palpable cancer or radiographic abnormality eventually manifest at a later stage as cancer.[27]

8.7 Just like mammograms, infrared imaging is also subject to false negative results, that is both technologies can miss a lesion. False negative thermograms tend to occur with very slow growing cancers, ductal carcinoma *in situ* (DCIS) or when the heat distribution between the skin and the tumour is challenged as can be the case with cancers deep within fat tissue or diffuse cancers with oedema and skin thickening.[1]

8.8 In June of 2010, the National Screening Unit, the Cancer Society of New Zealand and the New Zealand Breast Cancer Foundation released a position paper recommending against thermography as a screening or diagnostic tool for breast cancer. Their evidence was largely based on the 2003 Tech Brief commissioned by the National Screening Unit of the New Zealand Ministry of Health. This report assessed the efficacy of thermography for population screening and as a diagnostic test for breast cancer. As such, all scientific evidence for the use of thermography as a risk indicator or monitoring tool was excluded from the selection criteria.[36]

8.9 Because thermography doesn't provide information on the exact anatomic detail of the breast, it needs to be combined with an anatomical test such as mammography.[37] For example, thermal images are unable to define a specific area that needs to be biopsied, whereas mammograms can identify the location of a lesion or tumour.[18]

8.10 As with all screening modalities, there is no perfect test that can accurately identify everyone with the disease or unequivocally confirm the absence of pathology. Given thermography cannot provide information on the specific cause of physiological changes, the role of thermal imaging lies as a complementary modality that can serve as a risk indicator and monitoring tool.[16], [38]

9. THERMOGRAPHY AS A RISK INDICATOR

9.1 Over the last four decades, there have been a number of peer-reviewed articles that support the use of thermography as a risk marker. In fact, according to a number of researchers, a persistent abnormal thermogram is thought to be "the single greatest indicator of breast cancer risk" and is considered 10 times more important than a positive family history for the

disease.[2], [10], [31] While thermography has been criticized for having a high false positive rate, these so called 'false' positives are often found in women with tumours that are not yet palpable through clinical breast exam or detectable through conventional mammograms. Because physiological changes over time are known to precede morphological changes, an abnormal thermogram can often be the first warning sign of an increased risk for breast cancer.[20], [27], [38], [39]

9.2 Perhaps one of the most impressive earlier papers on thermography was the seminal study by French researchers Gautherie and Gros. In 1980 they published their findings after assessing approximately 58,000 women with clinical breast exam, mammography and thermography to determine the value of thermal imaging as a relative long term predictive indicator of cancer development. 1,527 women aged between 32 and 53 with TH-3 (equivocal) thermograms were followed for a total of 12 years. 784 (51%) of these women had no abnormalities detected by clinical breast exam, mammogram or ultrasound, 461 (30%) were diagnosed with benign conditions (predominately fibrocystic processes) and 282 (18%) were diagnosed with breast cancer confirmed by biopsy. Of the 784 'normal' women, 177 went on to develop breast cancer within 2 years of the initial equivocal thermogram and in the following 2 years another 121 women were diagnosed with malignancies, yielding an overall detection rate of 38%. Of the 461 women initially diagnosed with benign conditions, 9% went on to develop breast cancer in the first 2 years and a further 34% developed cancer in the following 2 years making the combined detection rate 44%. It is worth noting that in a general population, normally only 1-2% of women would be diagnosed with breast cancer over a 4 year time frame. In this same study, 90% of the women who had an abnormal thermogram (TH-4 and TH-5 grade), had a diagnosis of breast cancer established in their first visit. In those with a TH-1 or TH-2 (normal) thermography score, 0.4% had a histologically confirmed diagnosis of breast cancer. In light of these findings, Gautherie and Gros considered thermography to be an independent risk marker for breast cancer.[27] Through his long standing research, Gautherie has also discovered that thermography can provide an indication of tumours that have a more rapid growth rate.[1]

9.3 Thermographic research was also being conducted at the Elliott Mastology Centre in Louisiana, U.S.A. in the 1970s and 1980s. The retrospective analysis by Head, PhD and colleagues also found thermography to be an invaluable modality to assess a women's risk for breast cancer. Their study was divided into 2 parts with the first consisting of results from 126 deceased breast cancer patients, 100 randomly selected living breast cancer patients and 100 randomly selected non-cancer patients. All women had undergone a clinical breast exam, mammogram and thermogram. The authors found that a significantly higher percentage of the deceased group (88%) had abnormal infrared images when compared with living cancer patients (65%) and normal patients (28%). Because abnormal thermograms were not related to other known risk factors (see Table 1), they like Gautherie considered thermography to be an independent risk indicator of breast cancer.[40]

9.4 In the early 1970s Harold Isard, MD, another U.S. researcher, assessed the thermographic examinations from approximately 10,000 women over a four year period. Abnormal thermal images were found in 72% of women with diagnostically confirmed breast cancer. While he and his colleagues were quick to point out that thermography "cannot and does not diagnose cancer" they did conclude that this modality can help identify women who should be examined more regularly due to an increased risk of breast cancer.[8]

9.5 The 1985 paper by Agnes Stark, PhD, also found a high incidence of breast cancer following an abnormal thermogram. Set in England, this study was a prospective trial which included 11,240 asymptomatic self-selected women over the age of 40 who were screened for breast cancer. Screening included a detailed history, clinical exam, mammogram and thermogram. Women were separated into two groups, those with one or more risk factors and those

without any risk factors. For the purposes of the study, risk factors included conventionally recognised risks (refer Table) and a positive thermogram. Women with one or more risk factors were invited to attend annual follow up screening over the next 10 years. Of the 11,240 women screened, the incidence of cancer in the no risk group was 0.4% (24/5825), 3.3% (127/3881) in those with one risk factor and 17.1% (263/1534) for women with more than one risk factor. For 494 women, the only risk factor was a positive thermogram and the incidence of cancer in this group was 20%. The inclusion of thermography meant that an additional 99 women were kept under annual surveillance and diagnosed with cancer at an earlier stage. Stark concluded that thermography was of value as a risk factor and an early warning tool and felt it had potential as an initial screening test to identify women who needed to be monitored more regularly.[30]

9.6 Long-term follow-up studies have shown that abnormal thermograms often result in a cancer diagnosis 4-5 years following the initial thermal image with many also being detected between years 5 and 10. Medical texts authored by the Strasbourg group have documented a 33% incidence of breast cancer in women with an initial abnormal thermogram and no other indication of breast disease. This equates to a rate of breast cancer 6 times higher than what would ordinarily be expected from a normal population.[10] Similarly, Head and Elliott who have researched thermal imaging for decades have found that women with an abnormal thermogram in the absence of any other pathology have an estimated 30% increased risk of developing breast cancer.[16] By monitoring these women more regularly with the aid of other screening modalities and repeat thermograms, there is a greater opportunity for cancers to be detected earlier when the probability of cure is higher.[16]

9.7 Risk Factors Associated with Breast Cancer [41]

Risk Factor	Explanation
Gender	Breast cancer is found predominately in women.
Age	Increasing age – the incidence of breast cancer is extremely low in women under 25 years and increases up to a 100-fold by the age of 45. After menopause, the age-related risk varies between continents. In the U.S. and Sweden, there is a continued risk for breast cancer up to the age of 75. In Japan, the incidence of breast cancer plateaus after age 45 and then slowly declines.
Geographic Location	5-10 fold differences in the incidence of beast cancer have been noted in different countries with the Far East, Asia and South America exhibiting the lowest incidence and North America and Northern Europe the highest incidence. Genetic, lifestyle and environmental factors are thought to play a role in such differences.
Genetic Factors	Family history of breast cancer (mother, sister, daughter). Mutations in the breast cancer susceptibility genes (eg BRCA1, BRCA2, p53, ATM or PTEN) are associated with a high individual risk for developing hereditary breast cancer. BCRA1 and BCRA2 mutations are thought to be the cause of 80-90% of all hereditary breast cancers.
Reproductive Factors	Having the first menstrual period before the age of 12 can increase breast cancer risk by 10-20%. In women who undergo menopause after the age of 54 there is an estimated 3% increased risk of developing breast cancer for every 1-year increase in menopausal age. There is also an increased risk of breast cancer in women who have never been pregnant and women whose first pregnancy is after the age of 35.
Medical	Medical factors that increase breast cancer risk include a previous history of breast cancer and previous biopsy results that indicate atypical hyperplasia or radial scar formation. Previous exposure of breast tissue to high-dose radiation is associated with a dose-dependant increase in breast cancer risk.
Oestrogen Exposure	Prolonged use of conjugated equine oestrogens has been found to increase the risk of breast cancer by 2.2% for each additional year of use. The use of exogenous oestrogen and progestin can increase breast cancer risk by up to 30% after 5 years. Current use of oral contraceptives is also associated with a 24% increase in breast cancer risk.

Lifestyle Factors	Drinking more than one alcoholic beverage per day increases breast cancer risk. Every 10 g increment in alcohol consumption (approximately 1 drink) is associated with a 9% increase in risk. Well done meat intake increases breast cancer risk (most likely due to the production of heterocyclic aromatic amines). Obesity has been shown to increase breast cancer risk but only in postmenopausal women. For every 5kg of weight gained since the lowest adult weight, there is an 8% increase in breast cancer risk.

9.8 Does early detection of breast cancer with thermography improve survival rates? Gautherie and colleagues followed the survival rates of 106 women whose diagnosis of breast cancer was initiated by an abnormal thermogram. In other words, all other modalities including breast exam, mammography and biopsy when necessary were initially negative. These women were compared with 372 patients who were diagnosed with breast cancer during their initial assessment. They were then divided into 2 groups based upon their treatment I ntervention (radiotherapy or surgery) and followed for a period of 5 to 10 years. Women who underwent radiotherapy secondary to follow up of an abnormal thermogram had a much higher survival rate after 10 years when compared with women who had radiotherapy following a cancer diagnosis on the first medical visit (36% vs. 24% respectively). In the group of women who had surgery, there was also a significant improved 5-year survival rate in those who had surgery after follow up from a thermographic abnormality compared to those who had surgery following an initial diagnosis of cancer (44% vs. 33% respectively). These findings indicate that the early detection of breast cancer in women at high risk significantly increases their survival rate.[2]

10. THERMOGRAPHY AS A PROGNOSTIC MARKER

10.1 While there have been many studies on the use of thermal imaging as a prognostic marker, its use in this capacity is still considered controversial.[13], [20], [28], [40], [42-47] For example, some researchers have found a correlation between the grading of thermal images and cancer survival rates, while others have not. In 1988 Isard et al published their findings on the survival rates of 70 women with breast cancer who were followed for a minimum of 6 and a maximum of 13 years. They applied a thermographic scoring system which categorized thermal images into three different prognostic groups; favourable (PFI), equivocal (PFII) and poor (PFIII) and compared the results with the tumour-node-metastasis (TNM) classification system. They found that women with abnormal thermograms had a 30% survival rate after 5 years vs. an 80% survival rate in subjects with normal infrared images. After 10 years, the survival rate reduced to 20% in those with abnormal thermograms and 70% in women with normal thermal images. From this research, the authors concluded that thermography could be a useful prognostic indicator for survival in women with breast cancer.13 Conversely, the 1991 paper by Sterns and Zee found no significant difference in 5-year survival rates and 5-year disease-free survival in patients who did not have an abnormal thermogram.[47] Head and Elliott formally questioned the significance of these findings given their use of outdated liquid crystal technology and the incorrect classification of TH-3 thermography scores as normal images.[48]

10.2 Some of the earlier papers using older technology however did support the use of thermography as a prognostic tool. One such example is the 1975 paper from the Royal Marsden Hospital and Institute of Cancer Research in England. Jones et al found a statistically significant association between thermograms, the clinical stage of the disease and survival rates. In their research they performed over 12,000 thermograms between July of 1967 and January of 1972 and documented the mean 3 year survival rates of 172 women with Stage I, Stage II and Stage III breast cancer. While no statistical difference was found in the three year survival rates of women with Stage I tumours, those with Stage II and III tumours with a normal thermogram result had a better survival rate than those with abnormal thermal images (84% and 61% respectively).[28] During the same year in Europe, Gros et al assessed 779 women with breast cancer and found a correlation between the thermographic score and

the staging of cancer according to the tumour-node metastases classification. Women with normal thermographic results had better 3-year survival rates in each of the stages (T0-T4) when compared with women who had an abnormal thermogram.[13]

10.3 In 1980, von Fournier and colleagues published a paper in Germany that assessed 147 cases of breast cancer. They found a relationship between breast cancer growth rates and thermographic abnormalities. Women who had fast growing tumours were more likely to demonstrate pathological signs on an infrared image. From their research, they estimated that a 2 centimetre tumour takes on average 20 years to grow and found that most breast cancers start their invasive growth when women are between the ages of 30 and 40. Given their findings, they concluded that serial thermograms could provide clues about the biological activity of the lesion and patient prognosis. They also thought thermograms could be of value in indentifying women with interval cancers (cancers that develop between screenings).[49]

10.4 Further research by Head and Elliott in the 1990s continued to explore the use of thermography as a prognostic tool for breast cancer. Their findings revealed that women with abnormal thermograms at the time of breast cancer diagnosis had a poorer prognosis when compared to women with normal thermal images.[20] Head and Elliott also discovered that abnormal thermograms in women with breast cancer were associated with faster growing tumours and correlated with tumour ferritin concentrations. Given tumour growth rate is both a documented and accepted prognostic indicator of breast cancer, the authors felt this finding further supported the use of thermography as a prognostic marker.[40] Additional research published in 2000 by Head and colleagues proposed that thermography in conjunction with other clinical and biochemical assessments could help select patients more suited to adjuvant chemotherapy.[16]

10.5 One of the more recent and well conducted studies on the use of thermography as a prognostic indicator was the 2002 paper by Oshumi et al. This was a retrospective study that assessed 340 women with unilateral invasive breast cancer without distant metastases. The median follow up period for living women was 8 years. They assessed the difference in temperature between the two breasts (ΔT) rather than vascular changes as they felt this was a more objective way to assess thermograms. Women with 'hot' tumours (as evidenced by a change in ΔT of >/= 0.9°C) had a significantly lower disease free and specific survival period when compared with women who had 'cold' tumours (reflected by a change in ΔT of <0.9°C). The researchers found a ΔT in thermographic images to be an independent prognostic factor in women with primary breast cancer. The paper concluded by saying thermography may be "a useful prognostic factor in node positive breast cancer, especially in patients who plan to be treated preoperatively with systemic therapy".[35]

10.6 Given the prognostic utility of thermography has not been fully determined, its use in this capacity is still considered experimental.[16]

11. THERMOGRAPHY AS A MULTIMODAL APPROACH

11.1 The use of thermal imaging as a complementary modality has been researched by a number of scientists and physicians. One of the earlier papers that evaluated thermography in the multimodal setting was the 1971 report by Isard et al. They documented their findings from 10,000 combined thermography and mammography studies in symptomatic and asymptomatic women which were performed between 1967 and 1970. Mammography alone identified 85% of cancerous lesions in symptomatic women and thermography identified 72% of the breast cancers. When clinical breast exam and thermography were combined, the sensitivity increased to 88%. The combination of mammography and thermography further increased the accuracy to 92%. This was because each technique did not always detect the same lesion. These findings were similar to the results of the 1970 paper by Furnival et al

who demonstrated a 90% sensitivity in breast cancer detection with the combined use of clinical breast exam and thermal imaging and a 95% sensitivity with the addition of mammography.[8]

11.2 In 1974, Stark and Way published their research on the adjunct use of thermography as a screening tool in well women considered to be at higher risk of developing breast cancer. 2,684 women were examined between January of 1970 and July of 1972. All women underwent clinical breast exam, mammography and thermography. The combined use of all 3 modalities significantly improved the detection rate of preclinical breast cancer. Of the 66 women diagnosed with breast cancer, 52 were in the preclinical stage, thus in total, the pick up rate was 24.5 per 1000 well women.[50]

11.3 Gautherie's 1980 paper published in the Cancer Journal also noted a higher detection rate of breast cancer with the combined use of thermography. By continuing to monitor women whose only abnormality was a questionable thermogram, an additional 35-50 cancers were detected each year from his patient population. This equated to an approximate 10% improvement in the early detection rate of breast cancer.[27]

11.4 The prospective study from Nyirjesy, MD and Billingsley, MD was another paper that demonstrated an increased breast cancer detection rate with the additional use of thermal imaging. Between 1974 and 1983, 8,757 patients who underwent routine clinical breast exam and breast self-exam training were offered a breast thermogram. Women with abnormal thermal images (TH-3, TH-4 TH-5) were then assessed with mammography irrespective of breast examination findings. In total, 45 cases of breast cancer were detected of which 28 were established in the initial visit and the remaining 17 were detected during the follow up examinations. The addition of thermography resulted in an earlier diagnosis of breast cancer in 12 (26.7%) patients. Based on the short comings of current breast screening techniques and the clinical findings of the study, the authors recommended a multimodal approach to improve early detection breast cancer.[51]

11.5 In 1987 Gautherie et al released a report from a four year prospective study between 1981 and 1984 that assessed over 25,000 symptomatic and asymptomatic women to determine the value of breast thermography in the early stages of malignancy. All subjects underwent clinical breast examination, mammography and thermography with the latter being interpreted without any knowledge of the results from the other modalities. Women were followed for a period of 4 to 41 months. Both types of thermographic methods were used in 76% of the subjects; contact or liquid crystal thermography and infrared thermography. A computerized thermography protocol was utilized that comprised of 20 questions (divided equally between qualitative and quantitative signs) to assist with objective interpretation of temperature and vascular differences. Thermograms were then assigned a numerical score and classified into 5 groups (TH-1 to TH-5). Of the symptomatic women, 70% had an abnormal thermogram (TH-3, TH-4 or TH-5). For 8 of the 49 women diagnosed with *in situ* cancers and 6 of the 31 women diagnosed with minimally invasive cancers, the only initial abnormality was an equivocal or abnormal thermal image. Thus in total, 14 women had an earlier diagnosis of cancer because they underwent further investigation and closer monitoring based on the abnormal thermal image. The overall rate of positive thermograms in patients with minimal cancer was much higher than that found in previous studies which ranged from 20% to 30%. The authors attributed this finding to the more sophisticated high resolution thermal imaging systems employed in the study.[39]

11.6 In 2000, Keyserlingk and colleagues published their findings on 100 successive cases of breast cancer that included thermal imaging with fully integrated, high resolution, computerized technology. The minimum evaluation for all cases included clinical exam, mammography, and thermography. The sensitivity of thermal imaging as a stand alone modality for breast cancer detection was 83%. In women with an abnormal thermogram, or positive mammogram and positive clinical breast exam, the sensitivity rose to 98%. Half the

tumours identified with thermography were under 2 cm in size suggesting that the newer IR technology is more sensitive to early vascular and metabolic changes in breast tissue.[6]

12. CLOSURE

12.1 A significant number of breast cancers are found in women between the ages of 40 and 50. Many associations, charities and independent organisations are now advising against mammographic screening for this age group. Given clinical breast exam and breast self-exam have also been discredited in peer-reviewed papers, the very women who stand to lose the greatest number of years of life if diagnosed with breast cancer are left with very few assessment options.

12.2 For nearly 30 years, researchers have been advocating that young women be regularly assessed "by the most effective means available" so breast lesions can be detected and treated early to reduce mortality. In recognising the fact that no current breast screening modality is without its limitations, a multimodal approach has been proposed by a number of researchers. Such an approach would comprise of 'breast awareness', clinical breast exam, mammography screening and thermography.

Because thermography is a functional test that has peer-reviewed evidence to support its use as an independent risk marker for breast cancer, it serves to complement current conventional screening tools. As a non-invasive and radiation-free procedure, thermography can be safely used without risk to identify breast abnormalities and monitor breast heath over time.

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