Advances in Breast Cancer Research, 2023, 12, 129-141
https://www.scirp.org/journal/abcr
ISSN Online: 2168-1597
ISSN Print: 2168-1589

Breast Thermography: A 20-Year Retrospective Review of Infra-Red Breast Thermal Imaging in New Zealand and Its Potential Role in Breast Health Management

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How to cite this paper: Godfrey, M. and Godfrey, P. (2023) Breast Thermography: A 20-Year Retrospective Review of Infra-Red Breast Thermal Imaging in New Zealand and Its Potential Role in Breast Health Management. *Advances in Breast Cancer Research*, **12**, 129-141.
https://doi.org/10.4236/abcr.2023.124010

Received: May 25, 2023
Accepted: August 27, 2023
Published: August 30, 2023

Abstract

Cases are presented to reveal how modern computerised infra-red thermal imaging has the potential to assist in early breast cancer detection. The history of thermography and some recent controversies surrounding mammography are discussed. Examples of thermal imaging combined with naturopathic interventions are described. Since 2002, more than 8000 women in New Zealand have chosen to include thermal imaging as a part of their breast health management. Breast thermal imaging combined with relevant health advice, resulted in a perceived worthwhile benefit to patients in managing overall health.

Keywords

Breast Screening, Mammography, Infra-Red Thermography

1. Introduction

The prevention of cancer and the development of more effective strategies to detect cancer precursors and early-stage cancers, when treatment may be most effective, remain critical goals for healthcare services. An international debate concerning potential mammography inadequacies started with the Nordic Cochrane review in 2000 [1]. Esserman, the senior editor of the *J. Nat. Cancer Institute*, then pointed out in 2002: "*The controversy over mammography is often focused on whether or not it should be used as a screening tool. But another equally important issue, given its widespread use, is the optimization of mammography. Considerable effort should, therefore, be devoted to determining how* *to make mammography as effective as it can be and to reduce the tremendous variation in interpretation and biopsy rates*." [2] Four principles regarding mammography were outlined in the *Journal of Women's Health*: "*The final principle is that accounting for tumor biology is important for accurate estimates of lead time, and the potential benefit from screening. Since 'early detection' is actually late in a tumor's lifetime, the time window when screen detection might extend a woman's life is narrow, as many tumors that can form metastases will already have done so. Instead of encouraging screening mammography, physicians should help women make an informed decision as with any medical intervention.*" [3]

The question then arises as to what can be done to improve this situation. While infra-red thermography (IRT) is still being generally dismissed as a valid breast investigation, devices are being widely used in hospital and private gynaecological clinic settings, including in Europe, North America, Canada, Scandinavia, Korea, Taiwan region and Japan. IRT has been privately available in New Zealand since 2002 and over 8000 women in this country have chosen to include this modality in breast-health monitoring, either on its own or alternating with ultrasound and mammography. Even at the earliest stage of cancer development, it is possible to predict its onset by temperature changes that indicate increased metabolic activity caused by developing tumours.

The objective of this review was to determine the possible value of thermography in the long-term management of breast health and the potential improvement in earlier breast cancer detection including women with dense breasts where mammograms are known to be less accurate.

2. Rationale

Can thermography combined with mammography turn around the limitations of:

1) Over-diagnosis, false negatives, false positives.

2) Failure to bring to diagnosis cancers of a life-threatening nature early enough to make a significant difference to the mortality rate?

3. Method

Initial instrumentation used an imported American Mikron infra-red camera with MicroHealth System software which required manual analysis, followed in 2009 by EU-registered InfraMedic MammoVision™ software enabling automated analysis, with a Jenoptik VarioCAM camera. The InfraMedic MammoVision™ system comprised a medically calibrated camera and clinically validated software developed in Germany by Professor Reinhold Berz in 2002 at Frankfurt University with a €750,000 German Government grant. The software included an adjustable grid where temperatures in 24 segments (**Figure 1(a)**) were automatically compared contralaterally to 0.10˚C. The patented system was subsequently EU registered as a medical device (CE2274 by TUV) and is, to date, the only medically registered IRT device. Based on a physiological precept that neo-angiogenic blood vessels may not constrict equally compared to normal breast vascularity the 24 zones are analysed from before and after a physiological challenge of 10 minutes of controlled cooling (**Figure 1(b)**). The camera, stand and laptop computer being sufficiently portable as carry-on airplane luggage, enable the female technician to travel to more distant towns for regular sessions in air-conditioned rooms in health clinics or motels in 15 towns or cities in both the North and South Islands.

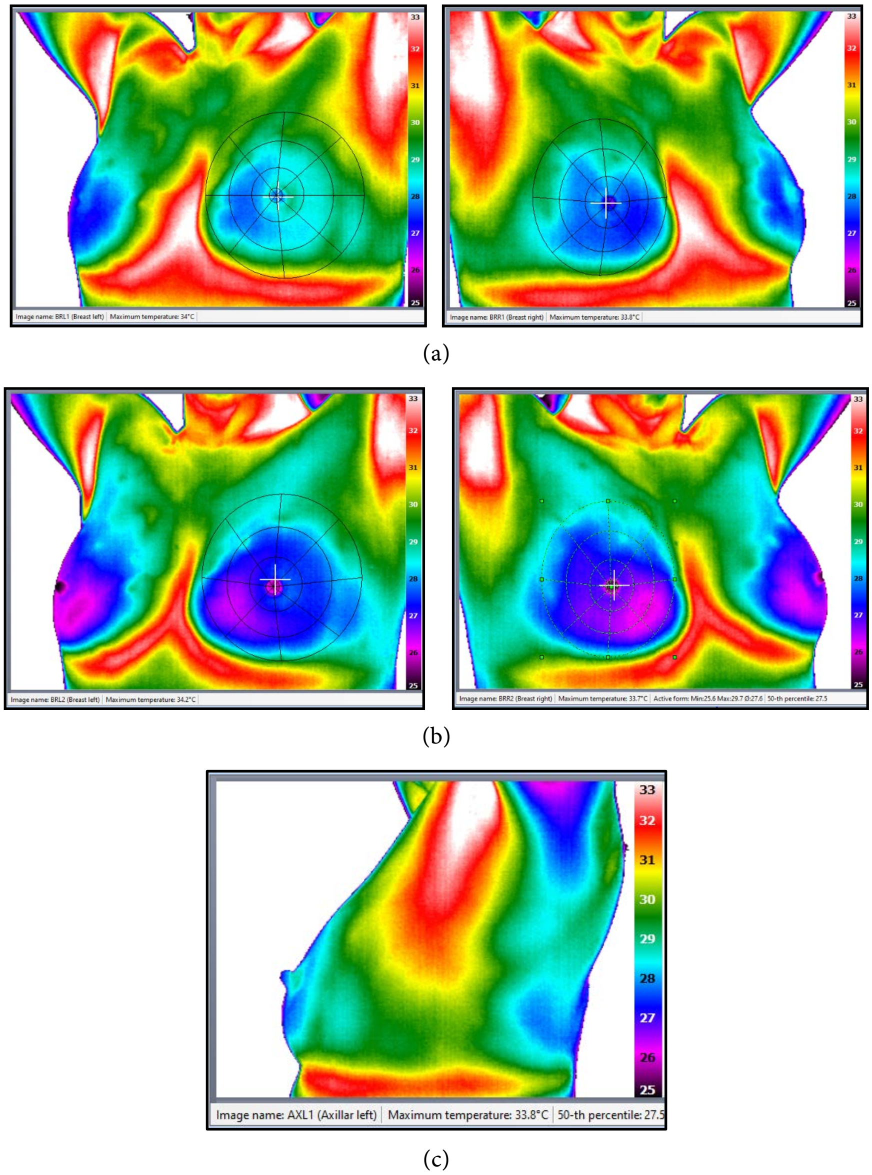


Figure 1. (a) Mammo Visiongrid 12 zones per breast before cooling. Image name: BRL1 (Breast left) Maximum temperature 34˚, Image name: BRR1 (Breast right) Maximum temperature 33.8˚. (b) After cooling. Image name: BRL2 (Breast left) Maximum temperature 43.2˚. Image name: BRR2 (Breast right) Maximum temperature 33.7˚ Active Form: Min 25.6: Max 29.7 - Ø27.6 - 50th percentile 27.5. (c) Axillar view. Image name: AXL1 (Axillar left) Maximum temperature 33.8˚ - 50th percentile 27.5.

4. Examples

4.1. Case 1

A 57-year-old woman with a history of two breastfed children presented with a diffuse, bulky and mobile mass that was discovered in the upper outer right breast in March 2007. A subsequent mammogram reported: "*Both breasts show relatively dense stromal appearance with bilateral benign vascular calcification. In the area of clinical concern, there is a focal area of somewhat increased density with reasonably well-defined margins.*" An ultrasound was performed and reported: "*A* 1 × 1.5 *cm relatively well-defined area which is predominantly hypo to anechoic. Internal echoes are seen with good posterior enhancement suggestive of a probable benign cyst.*" A fine-needle biopsy was performed and reported as benign.

The patient decided to have thermal imaging before deciding whether to request an excision. The thermography findings were significantly abnormal with heat over the mass and abnormal vascularity (**Figure 2**). The patient was therefore advised to either have an MRI or surgical excision with the latter being the better option. The mass was excised in July 2007 with histology confirming an infiltrating ductal carcinoma (T2N0M0) ER positive PR negative, with clear resection margin and a clear sentinel lymph node. The patient has remained well to 2023 with annual comparative imaging.

4.2. Case 2

A 53-year-old woman with a history of fibrocystic breasts and no familial history of breast cancer had her first thermogram in April 2004. Mammography and ultrasound performed two weeks previous had identified fibrocystic changes and indeterminate micro-calcifications that were deemed inconclusive. On thermal imaging, the left nipple was observed to be lying slightly higher with no other obvious distortions. The left breast revealed a more pronounced network of blood vessels crossing the breast with an abnormal "vascular completeness" passing both medially and laterally to the nipple (**Figure 3**). Three months later,

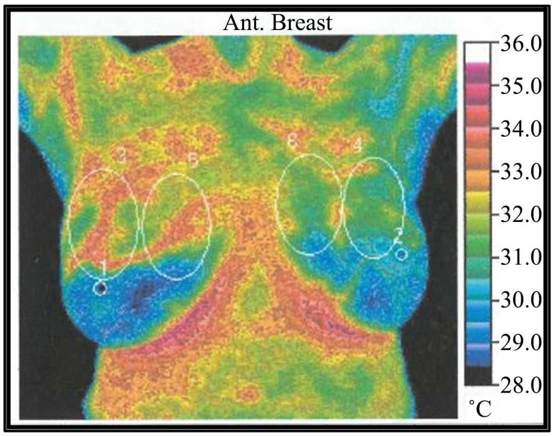


Figure 2. Case study 1 (2007).

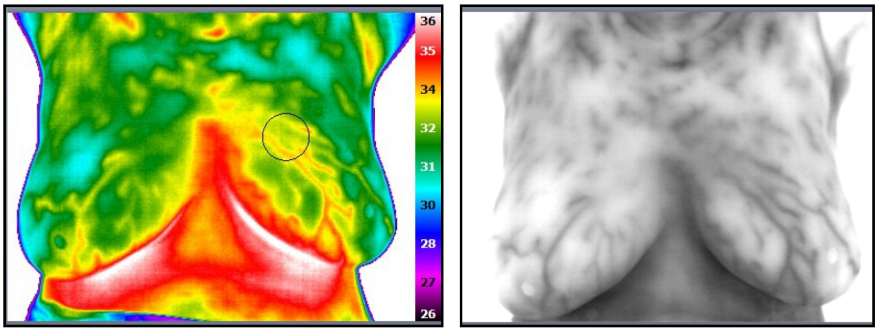


Figure 3. Anterior including inverted grey scale. Case study 2.

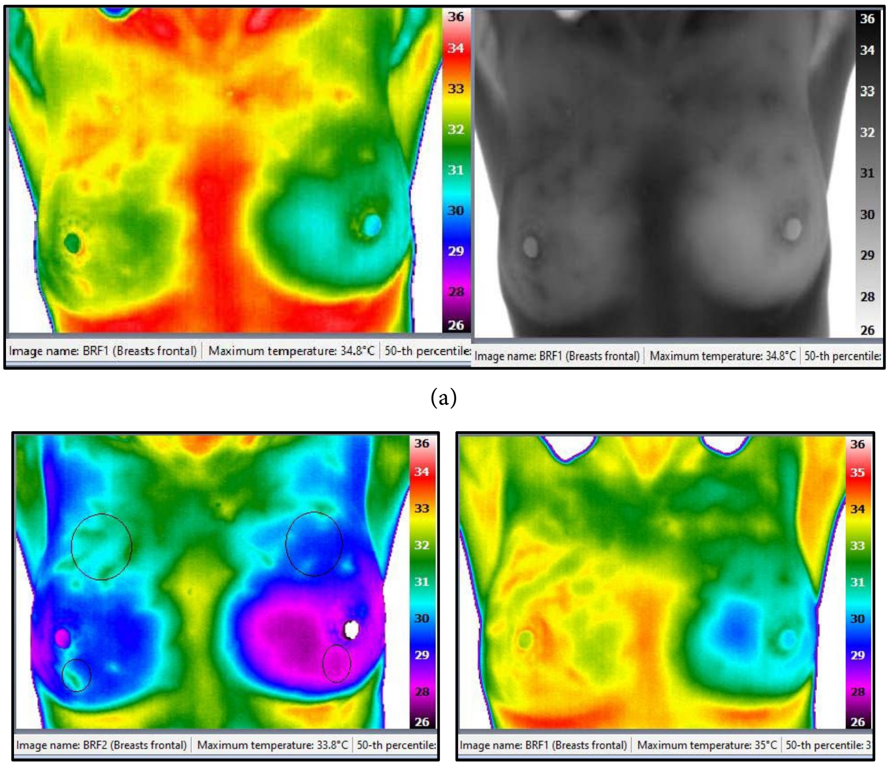
and after an unchanged ultrasound, the breast had thermally deteriorated with an increase in the inter-nipple temperature to 2.0˚C (previously 0.5˚C) and 3.0˚C between lower medial breast temperatures. A repeated mammography and ultrasound again reported findings as only consistent with fibrocystic changes and reportedly less obvious micro-calcifications. The thermal abnormality persisted with comparative imaging in October 2004 and February 2005. After further discussion with the radiologist, the patient was advised to have an MRI and an 8 mm tumour was identified and subsequently confirmed after excision as an infiltrating ductal carcinoma.

4.3. Case 3

A 48-year-old mother with one breast-fed child and a normal mammogram the previous year had her first thermogram in May 2016 (**Figure 4(a)**). The global right breast temperature was 1.0˚C higher than the other side. A subsequent ultrasound was reportedly normal. However, a further thermography confirmed an increased contralateral temperature at 1.3˚C. Additional imaging was done in May 2017 and the contralateral temperature was measured at 1.6˚C with specific contralateral areas exceeding the 2.0˚C upper limit. A repeated mammogram was normal, and an ultrasound was considered indeterminate. However, after her GP detected a possible mass, the patient was referred to a breast specialist and a subsequent biopsy and "lumpectomy" confirmed a 22 mm stage II Grade 3 invasive ductal carcinoma ER/PR positive HER2 negative N0T0 (**Figure 4(b)**) and following this underwent radiotherapy (**Figure 4(c)**).

5. Discussion

Infra-red thermal thermography (IRT) identifies a heat signal from the upper 5 mm of the skin. Typically in health, contralateral temperature variance remains below 1.0˚C including that of the breasts that, being superficial, are thus eminently suitable for thermal imaging. The MammoVision software uniquely permits sequential monitoring of both ipse- and contra-lateral heat differences to reveal otherwise undetectable progressive changes in localised heat, and/or vascularity. It is thus suitable for not only identifying the heat from trauma or inflammation, but, in theory, also the heat generated by any neo-angiogenesis



(a)

(b) (c)

Figure 4. (a) Anterior including inverted grey scale. Case study 3. Image name: BRF1 (Breasts frontal) - Maximum temperature 34.8˚ - 50th percentile; Image name: BRF1 (Breasts frontal) - Maximum temperature 34.8˚ - 50th percentile. (b) Anterior after 10 minutes of cooling. Case study 3. Image name: BRF2 (Breasts frontal) - Maximum temperature 33.8˚ - 50th percentile. (c) 8 months after radiotherapy. Case study 3. Image name: BRF1 (Breasts frontal) - Maximum temperature 35˚ - 50th percentile.

supplying a developing cancer. The latter lacking normal innervation, would in theory, fail to constrict after a cooling period of 10 minutes in the MammoVision protocol, and thus potentially differentiate from inflammation or hormonal heat.

In this regard, Guidi and Schnitt in 1996, observed that angiogenesis is an early event in the development of breast cancer and may occur before there is structural evidence of in-situ carcinoma [4]. Gamagami in his *Atlas of Mammography* showed that IRT could reveal hypervascularity and hyperthermia in 86% of non-palpable breast cancers and, in 15% of these, infra-red imaging helped detect cancers that were invisible on mammography [5]. Spitalier and associates followed 1416 patients with isolated abnormal breast thermograms for eight years and found that a persistently abnormal thermogram was associated with an actuarial breast cancer risk of 26% at five years [6]. Notably, the mean age when diagnosed was 51 years for IRT and 63 for mammography with peaks at 45 and 65, respectively. In the 165 patients with non-palpable cancer, thermography was the only test that was positive when compared to mammography and ultrasound in 53% of these patients at the time of initial evaluation. They concluded that a persistently abnormal thermogram, even in the absence of any other sign of malignancy, was associated with a high risk of developing interval cancer, and as such the patient should be examined more frequently than every 12 months [6].

Gautherie also revealed that when breast cancer was detected in 106 patients using thermal imaging, despite other screening methods being negative, there was a 61% improvement in the five-year survival when compared to 375 controls with both groups having identical treatment [7]. This was a controlled outcome study, albeit not randomised. Notably, all these earlier results came from using far more primitive equipment and lacked the stable thermal imaging cameras and computerisation as in the InfraMedic MammoVision™ system (**Figure 5**).

Difficulties have arisen with clinicians and radiologists when presented with abnormal thermograms while conventional investigations have repeatedly remained normal. However, earlier investigators who followed up patients with abnormal thermograms and other investigations reportedly normal, were able to confirm an eventual malignancy several years later. Gautherie and Gros followed 1527 patients with apparently healthy breasts but abnormal thermograms for 12 years and 40% developed malignancies within five years. Subsequent to Spitalier's findings, they concluded "*an abnormal thermogram is the single most important marker of high risk for the future development of breast cancer with a 94% predictive value*" [8]. These apparent "false" positives should not therefore be dismissed as such and require not only close monitoring but also interventions aimed at improving overall and breast health. Gøtzsche pointed out that by the time breast cancer tumours were large enough to be imaged, they had gone through approximately 30 doublings [9]. Gøtzsche's findings were corroborated and refined when Keen and Jørgensen found the "*Time difference between screen-detected* (21.4 *years old*) *and clinically detected* (22.8 *years old*) *tumors* (*or two doublings*) *would be at most* 520 *days.*" [3]

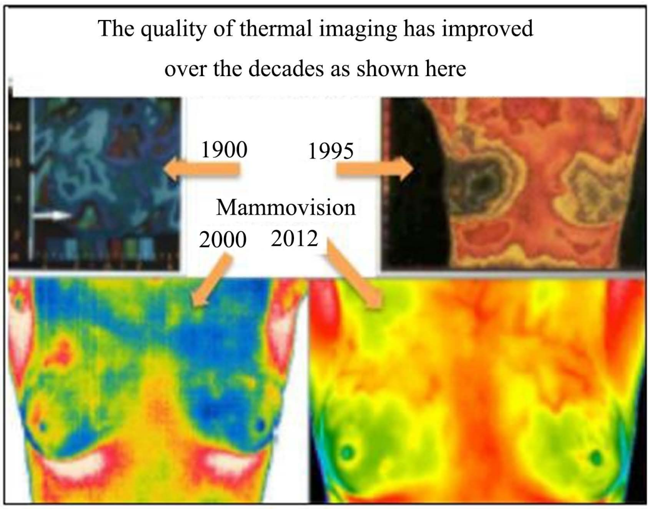


Figure 5. Comparative IRT. The quality of thermal imaging has improved over the decades as shown here 1990, 1995, 2000, 2012.

Even more rapidly growing tumours could be at least five years old before they are large enough to be detectable by structural imaging, whereas the increased metabolic and angiogenic activity they induce is potentially detectable much earlier by thermography [5]. This fact gains further significance as it has been shown that an abnormal thermogram tends to be associated with more rapidly growing tumours that are more likely to have metastasised with a shorter disease-free interval [10]. Ohsumi also concluded that patients with hot tumours had significantly lower disease-free and specific survival than those with cold tumours [11].

A concern with mammography is over-diagnosing invasive breast cancers, *i.e.*, those that could have been ultimately self-limiting if not detected with mammography. The variation in lead time between the first detectable thermographic abnormality and the presentation of breast cancer as a detectable tumour, on mammography or ultrasound, appears likely to indicate the relative rapidity of growth of breast cancer. This information about tumour growth pattern is not available with mammography alone, but when combined with thermographic monitoring provides the foundation of the information needed to differentiate slow-growing over-diagnosed tumours from relatively rapidly growing and potentially life-threatening cancers.

Mammography combined with ultrasound has been the gold standard for breast screening. The exclusive clinical reliability has been challenged [12] [13] [14]. Duffy and associates concluded in a study of women aged 39 - 40 that the overall long-term benefit was a 12% reduction in mortality after an average of 23 years or 1:1000 screened [15]. Notwithstanding this, mammography is still an important well-established valid tool, which, unlike IRT, also permits localisation for subsequent biopsies, the last part of the standard triple test. However, given that there is an acknowledged approximately 20% failure rate for even diagnostic mammography [16], there is indeed a need for an additional easily performed and cost-effective screening modality in the wider community. MRI is too expensive or impracticable in many areas.

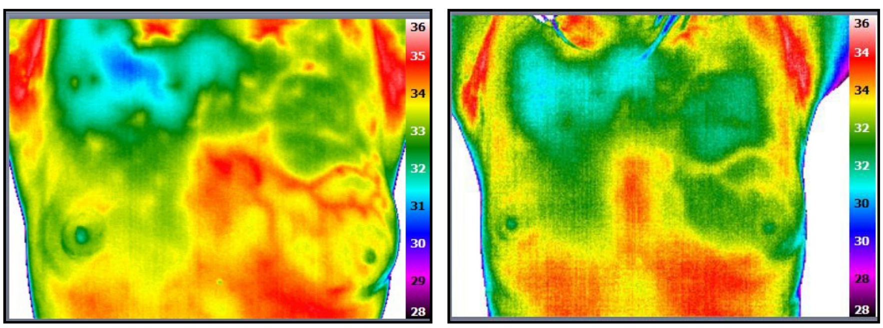
It is therefore unfortunate that IRT has tended to be used by physicians and technicians in relative isolation from radiology departments, with the latter tending to ignore the thermographic findings. However, the two screening methods are complementary and not competitive. Structural screening in some form will always be necessary, although the research indicates that primary screening by thermal imaging can be a more sensitive earlier marker.

The 1982 Breast Cancer Detection and Determination Project (BCDDP) [17] was extensively used in a widely distributed 2010 Position Statement co-sponsored by the National Screening Unit, The Cancer Society, the NZ Breast Cancer Foundation and the RANZ College of Radiologists as evidence to dismiss thermography [18] without giving due consideration to some serious BCDDP flaws. The five-year BCDDP started in 1973 and involved over 280,000 participants. IRT was later added to the project, but in only 11 out of the 29 radiology centres were the technicians adequately trained in the use of IRT. The technicians merely reported the findings as normal or abnormal. This contrasted with radiologists' strict training and ongoing supervision with their grading at BI-RAD 1 - 5. There was neither IRT standardisation nor the now-required ambient temperature control. Unfortunately, while the technology has vastly improved, there has yet to be any formal international agreement on standards and protocols.

Logically, cancer cannot develop in a healthy breast. The breast tissue first becomes unhealthy, and this is when IRT can have a unique potential role in monitoring breast health, as abnormalities can lead to the earlier initiation of structural investigations and interventions. Fibrocystic breast disease is a recognised risk factor, and the first two patients above had a history of dense fibrocystic breasts. This inflammation is readily detected with IRT and responds to intervention with iodine, selenium and other antioxidant supplementation, as shown in the following images taken fifteen months apart in a 23-year-old nulliparous woman on oral contraception (**Figure 6(a)** and **Figure 6(b)**). During the same time, her abnormal grade three Pap smear also reverted to normal, with both breast and cervix remaining healthy in subsequent two-yearly monitoring over the next 10 years while also having breastfed two children.

It has been observed that painful breasts can become pain-free within weeks of starting daily iodine supplementation. Endocrinological considerations suggest that low dietary iodine intake may produce a hyper-oestrogenic state, characterised by relatively high production of oestrone and oestradiol and a relatively low oestriol to oestrone and oestradiol ratio with increased risk of breast, endometrial or ovarian cancer. Increased iodine intake is likely to reduce the risk of these cancers [19] [20]. In another paper, objective evidence of remission of fibrocystic disease was confirmed [21]. However, despite life-style changes, vascular progression can still occur, as shown in case 3 above.

IRT can detect a potential pre-cancerous state, thus permitting a cooperative intervention between the woman and her health practitioner. Recently, four cases of breast cancer in young women after keeping cell phones in the bra were reported [22]. **Figure 7** shows the IRT breast appearance after a 60-year-old woman kept her cell phone tucked into her bra on a four-month backpacking holiday. There has been no evidence of progression over the subsequent 10 years following intensified naturopathic assistance with both IRT and ultrasound monitoring.



(a) (b)

Figure 6. Changes after 15 months.

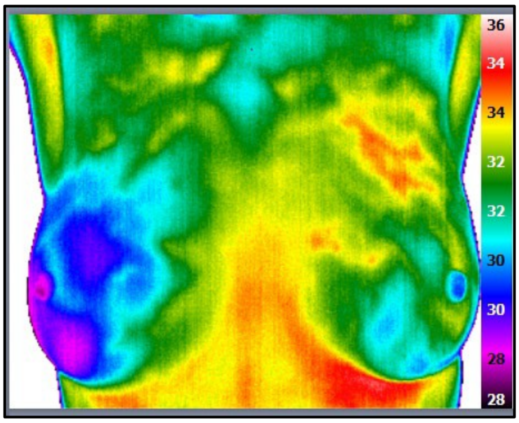


Figure 7. Prolonged exposure to cell phone in left bra cup.

The latest (2013) thermal imaging textbook [23] includes a chapter on breast IRT in which the findings of a small pilot study by Berz and Schulte-Uebbing at a German academic gynaecological clinic are reported [24]. Notably, IRT identified two breast cancers with normal mammographic findings and did not miss any of the mammography identified cancers.

Over-diagnosis is also a problem using mammography, with approximately 25% of mammography screening detected breast cancers being DCIS, rather than invasive breast cancer [14]. Research is also needed to see if IRT can help differentiate between a "hot" DCIS lesion that could warrant surgical intervention and a cold lesion that could justify a wait-and-see program with IRT monitoring the results of naturopathic intervention. The need for this research has become even more relevant with a publication stating that 20% of carcinomas-*in-situ* progressed to life-threatening invasive cancers during a 20-year follow-up in Canada [25].

Furthermore, the most recent 2023 release by the US Preventative Service Task Force (USPSTF) is recommending mammography from age 40 years; however, "*We know that women with dense breasts are at higher risk of breast cancer and, unfortunately, mammograms do not work as well for them,*" says Task Force member John Wong, M.D. "*What we don't know yet, and what we are urgently calling for more research on, is whether and how additional screening for women with dense breasts might be helpful, including through ultrasound, breast MRIs or something else.*" [26]

Recently, several research papers on breast thermography, and especially, the added use of Artificial Intelligence (AI) have appeared [27] [28]. The added use of AI appears to enhance the accuracy of IRT although the algorithms in the MammoVision software appeared adequate for sequential monitoring of any vascular or thermal changes.

In 8000 women (age 17 - 91) using thermal imaging as part of their breast health management, indications of 51 possible developing breast cancers resulted in timely interventions. During this time, eight breast cancers were either self-diagnosed with a breast lump and/or by mammography with half being low-grade DCIS. In these women, isolated thermography failed to reveal any marked vascular or thermal abnormalities. Notwithstanding the cost of privately funded tests compared to State-funded mammograms, this non-touch modality proved popular with many patients continuing long-term.

6. Conclusion

Computerised infra-red thermal imaging is a clinically useful, non-invasive, adjunctive breast investigation. International research has shown that a persistently abnormal and especially a deteriorating thermogram can be associated with a developing cancer even in the absence of other routine screening evidence of malignancy. Thermography has a particular role in those with dense breast tissue, where mammography is less specific, and especially in younger women. Whilst larger randomised investigations have yet to be financed, wider use by physicians and radiologists in combination with standard investigations appears justified.

Conflicts of Interest

The authors provide nationwide private breast thermal imaging.

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