

MULTI-MODALITY DATA FUSION AIDS EARLY DETECTION OF BREAST CANCER USING CONVENTIONAL TECHNOLOGY AND ADVANCED DIGITAL INFRARED IMAGING

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ABSTRACT

The fusion of data from the various screening modalities will lead to a cost effective breast cancer detection system that is certain to improve the *early* part of early breast cancer detection methods. We explore the integration of data from mammography, ultrasound, clinical evaluation, and CAD, with non-invasive digital infrared imaging data from the BreastScan IR system, to improve early diagnosis. This will address a new solution to the screening of young women and women with dense breasts.

Key Words: infrared imaging, breast cancer, data fusion

INTRODUCTION

Early detection of breast cancer is largely a concept rather than an established art in today's breast cancer screening environment. Simply, mammography being the only approved modality for screening is only effective in locating sufficiently large cancers in women whose breast parenchyma permits a good quality mammogram. Other familiar modalities, such as ultrasound and MRI are not early detection screening tools, but are primarily used as a diagnostic tool once a suspicious site is identified. Though we hear about early detection being the best defense, the fact remains that most cancer is detected at a late stage with these modalities, and in many cases the women discovers her own cancer. Infrared imaging is the only documented true early detection modality that is proving itself in the breast cancer detection armamentarium.

Infrared imaging was first approved by the FDA as an adjunctive tool for the diagnosis of breast cancer in 1982. There have been many documented studies and literature that shows it is a non-invasive modality that can clearly show the signs developing breast disease [1,2]. If we are to have early detection as a practice and not a concept, we must integrate the best available tools and information,

into a multi-modality information *system* that provides real-time health data to the doctor in an easy to read format. *Fusion* of data from mammograms, clinical information, CAD (computer-aided detection) and advanced infrared imaging, make up the primary tools readily and affordably available. Add to this list, ultrasound and MRI, which are becoming more heavily relied upon assessment tools for those patients whose breasts are dense, and you have a very robust breast health information system.

MATERIALS AND METHODS

Our most recent study involved testing of over 1000 women that presented for their annual screening mammogram at Long Island Diagnostic Imaging, totaling more than 2000 tested during the last four years of clinical evaluation. All of the recent patients were screened with mammography, CAD, and infrared imaging. Ultrasound and clinical examination were provided when indicated.

Without a doubt, mammography, whether film or digital, is the best screening tool for women over 40. In fact, it is the only FDA approved screening tool. For younger women (less than 40 years old) and women with dense breasts this is not an adequate solution. Consider too, that for women younger than 30, the susceptibility to radiation is also a concern. Mammography isn't generally offered to the younger age group unless there is strong family history to justify it. Mammography has a below average performance in those women (of any age) with dense breasts.

Clinical Breast Exam (CBE) is a detection tool but it is hard to say it falls into the *early* category. Young women must rely solely on palpation, and their own observations (BSE). Early detection must occur at the *non-palpable* stage, thus this modality leaves this group with no real means of early detection. The argument that supports CBE

for younger women is the much lower prevalence of the disease in this group. However, many doctors are seeing increasing numbers of early on-set cancers which may indicate a unknown increase in prevalence. Considering that many doctors acknowledge that screening should begin 10 years younger than the primary relative was when her cancer was diagnosed imposes a special challenge to screening increasing amounts of younger women.

Ultrasound is a commonly used diagnostic tool, but it is not FDA approved for screening. However some doctors offer this modality to women with dense breasts. In a recent interview [3], Dr. Thomas Kolb stated that ultrasound could be a useful modality in screening *at-risk* young women, though he cautions that MRI and ultrasound are not widely accepted as breast screening modalities.

Computer-Aided Detection (CAD) is an adjunctive detection tool, aimed at assisting radiologists locate those suspicious abnormalities in mammography. Its sensitivity is limited by the quality of the mammogram and the breast tissue density. The clinical value of CAD is still in debate among doctors because of false-positives. We will demonstrate means of improving CAD's value with *multi-modality data fusion*.

Digital infrared imaging has been around a long time, with FDA approval in 1982, as an adjunctive modality for breast cancer diagnosis. Early uses of this technology had some shortcomings, but it also showed its efficacy as a useful and prognostic tool. In one of the large studies, Gautherie [1] demonstrated that about 30-35% of women with an abnormal infrared would develop breast cancer within 2-3 years. Dr. Gamagami, in his Atlas of Mammography comments, "preneoplastic angiogenic alterations can be seen in asymptomatic patients years before clinical or mammographic manifestations of breast cancer appear. These findings in the past were interpreted as false-positive. Now, years later, palpable cancer can be seen developing in the same breast..." [2, p. 232]. This very early warning will allow the doctor to be very diligent with regard to monitoring, and will allow the patient time to improve any lifestyle risks. Our studies utilized the Infrared Sciences Corp., BreastScan IR, digital infrared imaging system. The FDA has recently approved this system, which includes objective, real-time reporting assisted by neural network classification.

This paper will demonstrate the fusion of easily available data into an *information system*, that is not way off in the future, but one that can be utilized today. Because many of the *data fusion* examples are not able to be included here due to space limitations, they will be presented and discussed in detail at the symposium. We include two

representative examples at the end of this paper. Multi-modality strategy is not a new concept for many practitioners, but the inclusion of modern digital infrared imaging to the list of modalities used in the early detection of breast cancer is rare. Our objective is to show how digital infrared imaging fits nicely within the established guidelines for breast cancer screening, and how this data may be presented in a clear and easy to read format for the doctor.

RESULTS AND DISCUSSION

Mammography is often referred to as "the gold standard". This modality is the front line in breast cancer detection. The goal of all screening is to detect cancers before they become palpable or visible to the eye in mammography. The smaller the tumor when detected, the better the prognosis. Screening mammography invariably will lead to detection of invasive cancer but it also leads to many cases of DCIS and benign biopsies. As we progress through the data fusion examples we will demonstrate how the anatomical data from mammography (or ultrasound), fused with the physiological data from infrared imaging can lead to an improved course of action for a particular patient.

The jury is still out on whether digital mammography is as good as film, however once in the digital realm, either technology is applicable to the fusion of data with the other modalities. Coupling mammography with CAD has been done for the last several years, and now at least two FDA approved systems exist. Despite the improved availability of CAD, questions remain about its utility. In a recent publication in Diagnostic Imaging Magazine [4], Dr. A. Malich a radiologist stated that "False-positive rates of CAD markers are still much too high and there are questions whether this causes an increase in patients recalled for further examinations". Clearly CAD adds value to mammography. Elimination of some of the false positive sites can be accomplished if we add another level of modality data to the computer output.

All mammography practices ask patients to fill in a questionnaire prior to the exam, and some provide a CBE before or after the mammogram. They ask the patient if she has anything to report from her own observations (lumps, pain, nipple discharge, etc.) This data may be used in a more effective way if it was available in digital form at the time the mammography is read. Making this handwritten information available for data fusion involves translating clinical data into the digital patient data file, and may be done as part of the patient information being entered prior to the BreastScan IR digital infrared test. Other methods being explored involve direct entry by the patient into a tablet PC while waiting in the waiting room.

The BreastScan IR provides physiological breast health data. A complete discussion of this technology was published and presented in detail, by Thomas DiCicco at IEEE EMBC 2003 [5]. This test is unique among the three aforementioned modalities, as the data is not anatomical and pinpoints unusual metabolic activity in the breasts, which are likely sites of angiogenesis. Direct correlation between the anatomical modalities and the infrared (physiological) modality identifies a site that may need further diagnostic evaluation. Interval cancers may be reduced, as a biopsy may be indicated sooner, rather than later. Uncorrelated data between the two modalities, may lessen the degree of suspicion of a site, and can lead to a reduction in the number of benign biopsies. Either way, the patient benefits from multi-modality data. Dr. John Keyserlingk documents one of the best examples of a current study, in his paper [6] wherein he clearly states the integration of mammography, clinical, and infrared data, led to a 98% detection rate in 100 cases of DCIS. Our own observations have clearly shown those patients that need additional diagnostic evaluation, and those that do not. Our results demonstrate that over 70% of asymptomatic women will have a normal infrared report, while the remainder, show varying degrees of abnormality. It is believed that those patients with the most abnormal infrared report face increased risk of developing breast cancer. We intend to commence long term monitoring of these patients to provide an update to the Gauthrie Study, with modern state-of-the-art infrared technology.

The following figures show a Data Fusion Case Study, which illustrates the points made in this discussion. The patient is a 60-year-old female that had regular (annual) mammograms. Her breast tissue is ideal (fatty) for a good quality mammogram. In her February 2000 mammogram she was given a “normal” evaluation, and at the same time she had an “equivocal” infrared exam. The infrared exam indicated a suspicion in the UOQ (upper outer quadrant) of the left breast. No abnormality was observed at that time. In February 2001 she returned for her next annual mammogram complaining of a lump in her left breast. The mammogram revealed a mass in the UOQ of the left breast, and at the same time she had an “abnormal” infrared exam. Subsequent biopsy of the site confirmed a malignant mass. Figure 2 shows her February 2000 digitized mammography with CAD markers (simulated for illustration). The three *calc* marks identify three sites of suspicious *microcalcifications*. Figure 1 is the corresponding infrared image from February 2000, clearly pointing to an equivocal area in the UOQ of the left breast. Figure 3 is the layered combination of the three pieces of data, presented in real-time to the doctor. Figure 5 shows the patients February 2001 digitized mammography with CAD markers (again simulated for illustration). This time in addition to the previous *calc* marks an additional *mass*

mark identifies a suspicious mass. Figure 4 is the corresponding infrared image clearly indicating a now “abnormal” area in UOQ of the left breast. Figure 6 shows all modalities in one image (mammography, clinical, CAD, and infrared), clearly showing the new mass. Retrospectively, the now identified cancer can be seen in the earlier mammogram, circled only by the infrared test. Figures 7 and 8 show a patient with a cancer in the left breast UOQ, that also complained of a lump. General Note for figures: CAD—yellow squares and circles, IR—pink or red circles, Clinical—Green circles

CONCLUSION

When we couple any or all of the digital information together, we would be able to formulate a display that has four related (i.e. multi-modality) pieces of breast health information in one display. The data can be color coded and layered such that it indicates the type or level of concern, and the doctor may remove any or all of it from the underlying mammography for observation. Even those offices that do not have a CAD system can benefit coupling in the clinical and infrared observations. This is NOT a future technology. Data Fusion will add *early* back into early detection of breast cancer. Not utilizing all aspects of readily available data to formulate a diagnosis is not in the best interest of early detection. Every piece of what we need to create the displays that are shown in this paper exists and is readily available to the doctor. Everyone benefits when all are presented and utilized in a clear and concise format.

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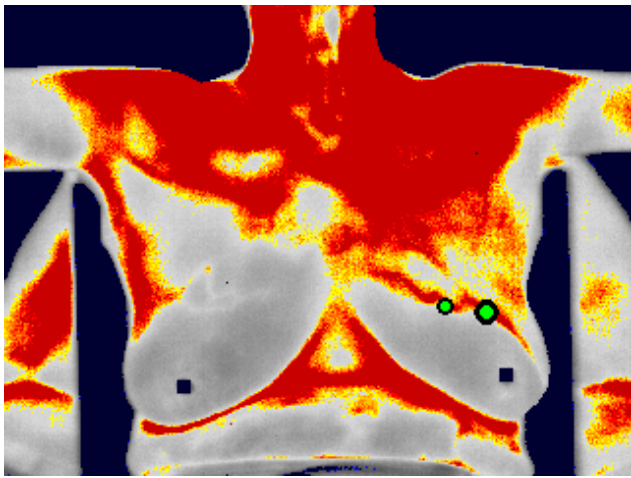


Figure 1 February 2000 Equivocal Infrared

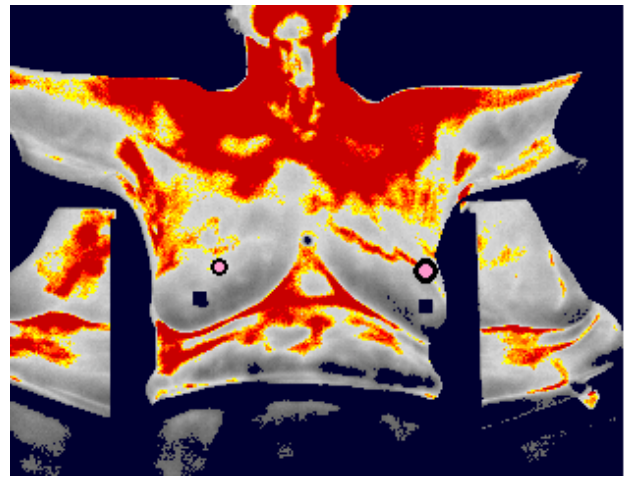


Figure 4 February 2001 Abnormal Infrared

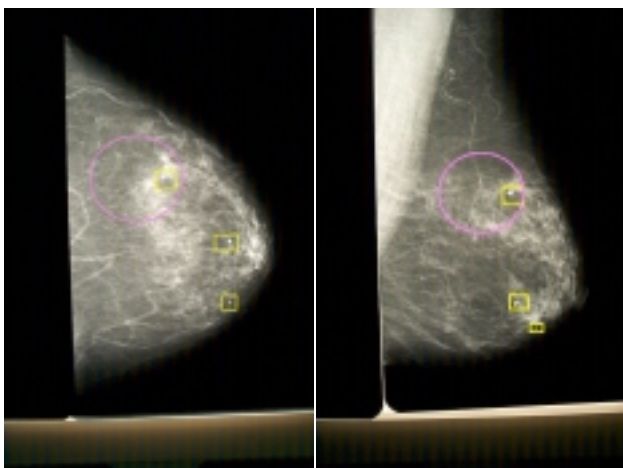


Figure 2 LCC
IR and CAD Marks Shown on both figures

Figure 3 LMLO
IR and CAD Marks Shown on both figures

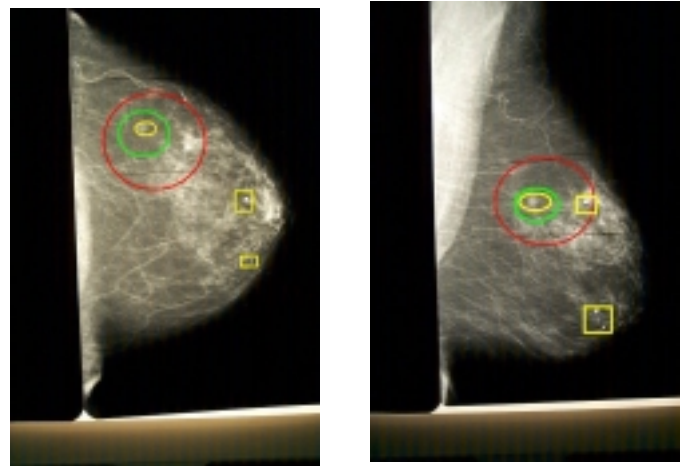


Figure 5 LCC
IR, CAD and Clinical on both figures

Figure 6 LMLO
IR, CAD and Clinical on both figures

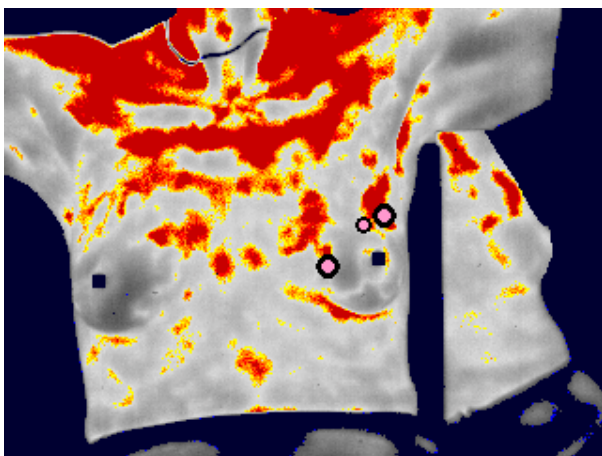


Figure 7 Abnormal Infrared

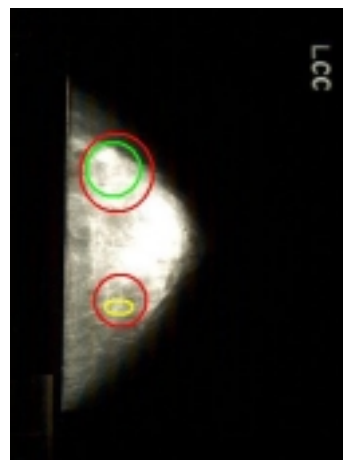


Figure 8 IR, CAD, Clinical