Tactile Imaging: The Requirements to Transition from Screening to Diagnosis of Breast Cancer - A Concise Review of Current Capabilities and Strategic Direction

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***Abstract*—This paper presents a review of Tactile Imaging, a developing technology for breast cancer screening finding traction in the marketplace. The paper identifies the necessary steps required to develop the technology from a screening method to the point where stand-alone diagnosis of suspected breast lesions can be performed without the need for a secondary care referral for a mammogram or biopsy. The relevant literature on Tactile Imaging is reviewed and current capabilities in academia are compared with those implemented in industry before being cross referenced with the metrics for breast cancer diagnosis. Tactile Imaging in academia has been shown to be capable of binary lesion classification and has seen extensive development, to where benign biopsy rates could be reduced by 23%. This has not been mirrored in the marketplace however, where market inertia relegates such systems to early warning screening only as an adjunct to mammography. Additionally, for detailed subclass diagnosis of breast conditions, more metrics are required than is currently available from Tactile Imaging at present. A detailed scheme of work is provided to achieve this. The additional metrics required for stand-alone diagnostics using Tactile Imaging are: background breast elasticity, lesion position on the breast, and lesion depth. These can estimate the lesion constituents and thus the histological diagnosis.**

***Clinical Relevance*— By analyzing the limitations of the current technology, and the direction that research is following, policy makers and researchers alike can focus on the appropriate areas for the ultimate goal of reducing the burden on secondary care centres and providing comfort to patients.**

I. Introduction on Tactile Imaging

THE process of Tactile Imaging, also called Mechanical Imaging [1], is a method of elasticity imaging most commonly used for breast cancer screening but has seen increasing academic development to become a self-contained diagnostic tool in the clinical environment [2]. Though many implementations of Tactile Imaging exist, based on mobile piezo-resistive sensing elements [3] or optical hyperspectral imaging [4], the most common in industry and most advanced in terms of academic development is fixed array imaging embodied by SureTouch™ (Sure Inc., US-CA). This technology uses a 12x16 capacitive pressure transducer array to measure the reaction stress from breast tissue at a given level of compression. In doing so, the technology is able to differentiate a breast lesion from the surrounding healthy tissue with better accuracy and sensitivity to size and hardness than the clinical breast exam (CBE) and shear wave ultrasound [5] [6] [7].

The key driving force behind the development of tactile imaging to this day is the reduction of patient stress during the process of cancer diagnosis, culminating in reducing the need for uncomfortable and stressful mammography, and eliminating the need for benign biopsies by providing accurate diagnosis of a lesion at the primary care centre or patients home.

To achieve this goal and develop Tactile Imaging beyond a simple screening tool, more diagnostic metrics are required than are currently available. This paper analyses the current technological capabilities, and requirements for diagnostic development and aims to recommend a strategic direction to achieve this end goal.

II. Capabilities of Tactile Imaging

A. Commercially Available Capabilities

The three primary commercially available technologies: SureTouch™, iBreastExam™ (UELifeSciences, IN), and MicroMedi® optical sensor (MicroMedi Inc., KR) are by and large capable of delivering the same diagnostic metrics but to differing accuracy and resolution.

Optical methods are very good at discerning size and planar area due to their high image resolution [4] compared with tactile array methods, but cannot detect multi-nodule tumors as the plastic waveguide cannot conform to geometry with convex and concave features in close proximity. Tactile arrays do not suffer this as each element is independent from its neighbors.

Mobile sensing arrays, in the form of the iBreastExam™, are highly capable of providing lesion elasticity and location but fall short of the higher spatial resolution fixed array imaging technique of SureTouch™ as it possesses only a 4x4 element array compared with 12x16 in a similar scan area.

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As SureTouch™ is a suitable compromise between spatial resolution, elasticity measurement, and geometry discrimination, and already boasts a range of academic publications on it principle, fixed array tactile imaging; it shall be the focus of this review and the target of future recommendations. A graphical representation of the outputs from a fixed array tactile imaging system, namely SureTouch™, imaging an embedded lesion in a breast is shown in Fig. 1. As can be seen in Fig. 1, Tactile Imaging is able to detect simple and complex lesions, determine their size in the scanner imaging plane, estimate their hardness relative to the surrounding tissues and locate the lesion on a 2D representation of the breast.

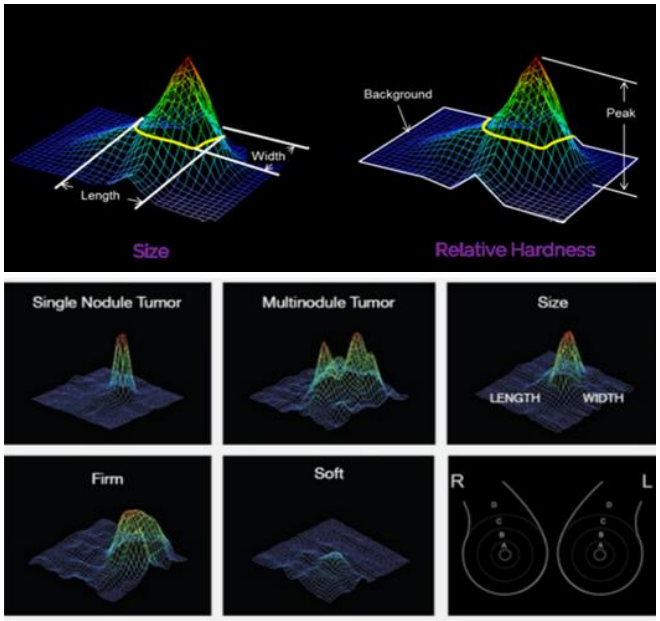

Fig. 1 – Representative lesion images from SureTouch™ [8]. Currently available metrics are: Size, Relative Hardness, Complexity, and Location on the Surface, with multi-nodal lesions discernable.

At present, Tactile imaging serves as a primary care screening tool [9] providing clinicians with information to advise the patient on appropriate actions. However, it has been known for over a decade that the technology is capable of more, perhaps even of replacing mammography [10].

B. *Academic Capabilities*

In academia the capabilities of tactile imaging are yet more impressive, having been shown to perform basic binary lesion classification in clinical trials [2] with 91.4% sensitivity and 86.8% specificity. In this case the effect on the reduction of benign biopsy rates was considered to be 23% with no missed cancers increasing to 50% reduction with only 4.6% missed cancers. Naturally, missed cancers are unacceptable, but it has been consistently shown in literature on machine learning in breast cancer diagnostics that sensitivity can be improved to 98% with 97% specificity when large supervised data sets are considered in conjunction with additional patient parameters not obtainable from imaging technology [11] [12] [13] [14].

Additionally, when global images of the breast are created through image mosaicking similar resolution and capabilities as mammography can be achieved [15]. With these capabilities, the benign biopsy rate can be reduced to 50% with no missed cancers although this remains to be shown in the literature.

C. *Reasons for Disparity*

There are several key reasons for the disparity between tactile imaging in current clinical practice and that in academia, namely: the lack of comprehensive clinical trials. Published clinical trials on diagnosis using tactile imaging have typically involved 150 patients, and encompass no more than 1000 in total which pales in comparison to the breadth of radiology studies which total over 100000 patients. The diagnostic works using machine learning typically use populations in this range.

Consequently, tactile imaging does inspire the same confidence as mammography in industry and the clinical environment and faces pushback despite the public demand for such a technique and the continuous development in academia. This has an additional implication, in that tactile imaging has been under continuous development since its inception in 1997, but mammography has seen no procedural development since 1980, indicating that it is the established and mature technology.

III. Metrics for Diagnosis

In order to diagnose a suspicious lesion, certain attributes and properties of the lesion must be known. However, exact quantified metrics are rare in the academic literature, with the majority of metrics being qualitative.

One of the most valuable metrics for breast cancer diagnostics is lesion density, or more appropriately the relative density of a lesion compared with background tissue, indicating the proportion of breast fat [16] which has been standardized in the breast imaging reporting and data system (BIRADS).

The lesion size and shape is another important metric when examining for breast cancer [17] although it is still noted that these are difficult to quantize using manual palpation. More advanced screening methods such as mammography, ultrasound, and tactile imaging provide this information [6].

Additionally, acutance, that is the nature of the lesion boundary conditions, is related to malignancy [18]. It is observed that benign tumors generally are well defined with sharp boundaries between them and the surrounding tissues, as opposed to malignant tumors which are generally blended with the surrounding tissues due to the tumors need for nutrients and blood flow. Verma et al. furthered the discussion by showing that 4 discrete measures of shape – Round, oval, lobulated, and irregular; with 5 classes of acutance – circumscribed, micro-lobulated, obscured, ill defined, and spiculated; can be used for the classification of malignancy or benign lesions [13].

The importance of lesion mobility is well known, as well as the difficulties in measuring lesion mobility [1]. Malignant lesions typically exhibit restricted mobility due to lesion bonding with local tissues and blood vessels. This indicates that a highly mobile lesion is likely to be benign.

As benign lesions are far more common than malignant lesions in western countries, it is important that physicians recognize benign lesions confidently to reduce the need for surgical biopsy [19]. This will reduce the unnecessary surgical biopsy rate, reducing the suffering and rate of complications amongst screening patients.

The primary metrics presented above that are used for clinical diagnostics are: *breast density, lesion density and elasticity, growth / fluctuation rate, lesion size, shape, and boundary conditions, and lesion mobility*. There are other, secondary metrics that are publicly considered to be 'risk factors' but are not considered to be diagnostic features in the literature. these include: *previous history, patient weight / body fat percentage, ethnicity, breast or other related pain, whether the patient smokes or uses narcotics, early beginning to periods, and late menopause* [20]. Combining these secondary risk factors with primary diagnostic metrics obtained through tactile imaging or other means can lead to a better estimation of the confidence in a classification of lesion malignancy. The example is a diagnosis of benign from primary metrics, combined with an absence of risk factors, leads to a higher confidence in the diagnosis.

IV. Comparison of Capability and Requirement

It has been shown in this paper that the current capabilities of tactile imaging, though capable of basic binary classification, fall short of detailed histological diagnosis of suspected lesions. Although it has also been shown that if large datasets are available, then tactile imaging will be capable of more detailed diagnosis without technological development. From the analysis of the metrics used in breast cancer diagnosis, both in current practice and in academic literature, tactile imaging comes close to ticking all of the necessary boxes.

The missing metrics from tactile imaging are: *Absolute elasticity of the lesion, the lesions position within the breast, an estimation of the surrounding tissue, the estimation of lesion acutance, and quantification of lesion mobility*. These are in some ways addressed by current commercial implementations of tactile imaging as shown in Fig. 1, but requires additional technological development to fully meet the requirements for diagnosis in situ. This is a task that requires clinical, commercial, and academic cooperation in order to produce a practical solution, or range thereof.

V. Current work developing tactile imaging

Work has already begun on developing tactile imaging to deliver the desired additional diagnostic metrics. Recent works by this author have shown that measurement of the elasticity of the background breast tissue is possible within 4% using tactile imaging combined with some measure of breast strain in compression [21], in this case using displacement measured from an integrated accelerometer. Additionally, this author has shown that by combining tactile sensors with an illuminated infra-red (IR) camera, the dermal elasticity and lesion position relative to the vascular tree map can be determined [15].

A. Determining Background Tissue Elasticity

Determining the background breast elasticity, or the average elasticity of the breast, is a precursor to measuring the elasticity of an embedded lesion. With the idea of making minimal hardware changes to existing technology in mind, the elasticity can be determined within 4% using a tactile element and a displacement sensor developed from a double integrated accelerometer. This means that absolute elasticity measurement capability can be added to existing tactile imaging systems with minimal effort in design [21].

It is important to note however, that the practicality of the developed technique is limited to ex-vivo measurements. Whilst the technique does work well on inanimate materials, its use on live patients can prove problematic as the measurement instrument must be repeatedly gently bounced off of the test material to guarantee reliability. Its usefulness in the laboratory is not affected by this, but for clinical use another method must be considered for integration into a full in-vivo diagnostic system.

B. Estimating Lesion Position within the Breast

Estimating the lesion position in the breast using tactile imaging was previously achieved by controlling how the breast scanner is moved over the breast. By utilizing an IR camera it has been shown that the vascular network can be imaged [22] [23], and can be mapped to allow for position on the breast to be determined without the need for a controlled scanning regime [15].

This system is able to map the vascular network accurately as it is able to estimate the deformation of the vascular network during the tactile measurement process, and undo it in the mapping process. To calculate deformation, the elasticity of the tissue must be known, and is determined during the calibration process by observing vascular deformation during controlled system motion into the breast.

The developed system is ultimately capable of determining the position of a lesion, or any other feature, using a vascular tree map and is also capable of estimating the elasticity of the background tissue simultaneously. As such it is a step closer to a fully integrated diagnostic tactile imaging system. Unfortunately, the system currently does not have the ability to measure the elasticity of an embedded lesion directly. By combining it with a tactile array [1] or a hyperspectral elasticity measurement system, capable of measuring lesion elasticity but not the background tissue [4], the system can deliver 3 of the 4 missing diagnostic metrics required for a fully integrated solution.

C. Summary of Developed Technology and Future Work

These works have shown that it is already possible to obtain most of the desired metrics individually, however it is currently not possible to determine the full range of diagnostic metrics simultaneously. Further work must be done to combine the recent developments with traditional tactile imaging systems [1] [3] and prepare the developed technology for clinical validation to achieve the diagnostic capability that was predicted over a decade ago. This will largely focus on miniaturizing the technology to make it practical for implementation in a hand held tactile imaging

system that will be more comfortable to use than existing elastography technologies [24]. Clinical validation will naturally follow on from the novel technology.

Measuring the acutance and shape of a lesion, other than simply circular or oblong, using tactile imaging is the final major technical challenge once the previous technologies are miniaturized. The measures of acutance and shape are known [25] and it is likely that a camera based tactile imaging system will have sufficient resolution to characterize such features.

Finally, once methods for measuring each of the missing metrics have been developed and combined into a single solution, the lesion can be diagnosed automatically using machine learning. This is considered a trivial task, as it is known that, with these metrics, high sensitivity and specificity classifications can be made.

VI. Conclusion and Strategic Direction

Due to the relative weighting of each diagnostic metric and risk factor [17] [18] it is possible to prioritize the required metrics for classification of breast lesions. In this regard, the top 3 priority metrics are: Absolute Elasticity, Lesion location, and Lesion Acutance. These metrics will provide information on the lesion component materials, its surrounding tissues, and its virility in terms of connection to the surrounding tissues.

This author aims to address these issues, by developing tactile imaging sensor technology and processing algorithms. The journey has already begun but, despite the path being long, the steps required are clear. The end goal will be to present a device capable of delivering all necessary diagnostic metrics, presented in this paper, that can then be applied in expansive clinical trials to prove the capabilities of tactile imaging in breast cancer diagnosis and subsequently begin building public confidence in the technology that will see widespread public usage in the near future. It is believed, and known, that by validating such technology, and deploying in the clinical environment, the lives of millions can be improved by reducing patient stress during the difficult process of cancer diagnosis.

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