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Digitally Imaged Elasto Tomography

A unique, new approach to breast cancer screening

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***Abstract*— Breast cancer is a major health problem across the globe. Many incidences in the underdeveloped nations go unreported, due to non-availability or lack of access to breast screening programs. Mammography, the current gold standard for breast screening, comes with several inherent limitations in terms of cost, radiation exposure, and associated discomfort. The cost of equipment and personnel alone puts mammography out of reach for most developing nations. Hence, there is a great and growing need for an adjunct breast screening modality, within reach of general masses, especially in the overpopulated, underdeveloped countries. This research develops a new automated approach for breast cancer screening using Digitally Imaged Elasto Tomography (DIET) clinical prototype. DIET is intended to be a low cost, radiation free, noninvasive and portable breast cancer screening system with a general access to the population and will encourage more women to undergo breast screening. The DIET imaging concept induces mechanical vibrations into a breast and its surface motion is captured with digital cameras and reconstructed in 3D, for elastic characterization of the breast tissues. This paper presents an insight of design development and analysis of the DIET clinical system. Finally, the new DIET technology developed is validated ex-vivo, using two different diagnostic techniques. The trials results are positive and demonstrate viability of this new technology for commercialization.**

Keywords—*Digitally imaged elasto tomography, breast cancer screening, tissue stiffness, motion reconstruction, clinical prototype, modal analysis, elastic characterization*

I. Introduction

The Breast cancer is a major health problem, it is estimated that every year, one million women are diagnosed with breast cancer, and more than 410,000 die from this deadly disease worldwide [1]. Previously, the significance of the disease was not being realized to warrant allocation of health care budget in low and middle income countries [2]. However, more recently, breast cancer has become an urgent public health issue, even in low resource regions [3]. It has now been recognised as most common cancer among women, both in developed and developing nations [4]. Despite extensive characterization of the elastic properties of structural materials, mechanical properties of many biological materials remain unknown or uncertain. This uncertainty is due in part to the technical difficulty of measuring visco-elastic tissues [5], particularly in-vivo, and intersubject variation for a given tissue type.

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However, the stiffness of healthy and cancerous breast tissues have been investigated, and stiffness contrasts of 200-1500% have been reported for carcinomas [6-10]. For breast cancer detection, palpation or clinical breast examination (CBE) remains the most common procedure to date with its inherent limitations of subjectivity and low sensitivity [6, 11]. Manual palpation, often the only available diagnosis, is not recommended for screening in the western world due to poor and variable, performance and its high dependence on operator skill and experience [12]. Other detection modalities include mammography, ultrasound, CT and MRI.

X-Ray mammography is the current gold standard screening method and is widely used in most developed nations, but a high non-compliance rate is observed due to the expected and/or experienced discomfort associated with the required breast compression [13, 14] and limited access to screening in remote or rural areas [15]. More accurate diagnostics, such as MRI are too costly [16].

Thus, there is a great need for an adjunct screening modality to improve screening performance and delivery with a low cost and non-invasive system. A new breast cancer screening system called Digitally Imaged Elasto Tomography (DIET) is being developed that is non-invasive, works well on denser tissues, is less painful, and low cost. The goal is to improve screening performance and compliance. The diagnosis is primarily software based, and thus could be automated, making it objective and systematic, without requiring specialist operator and radiologist skills, further reducing operational costs [17-33].

The DIET concept relies on measuring tissue stiffness instead of radio-density, providing a much higher contrast, as cancerous tissue has been shown to be 200 – 1500% stiffer than the surrounding fibro-glandular or fat tissue [6-10]. The imaging sensor is based on machine vision and motion tracking to measure surface motion on a vibrating breast and analyse this data to identify a stiffer mass within the breast. The initial goal is to detect a 10mm mass, which in a screening application is clinically significant. A tumour size of 10-14mm at first detection has been shown to lead to 15-year survival rates of over 85% [34].

The DIET imaging procedure consists of three fundamental steps, as shown in Fig.1:

- **Excitation** of the breast at low frequencies (10-100Hz)
- **Motion tracking** of breast surface motion by digital images of the breast surface
- **Software analysis** of this motion to detect disturbances caused by a stiffer inclusion

The DIET system has been tested in vitro on silicone phantom breasts with comparable elastic properties to human tissue [31, 35].

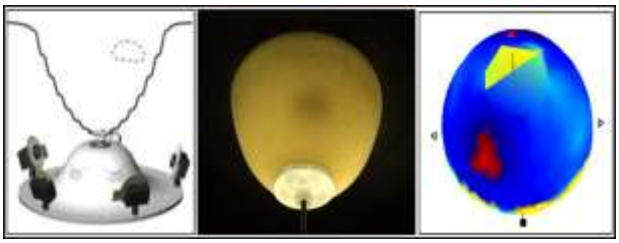

Figure 1. . Key steps of the DIET Imaging procedure: (1) Excite the breast at low frequencies [left], (2) Image surface motion with digital cameras [middle] and (3) Calculate motion disturbance for diagnostic analysis [right]. Embedded in this breast phantom is 20 mm stiffer inclusion at 6-7 o'clock which can be easily identified.

II. Clinical Prototype

Previous work during DIET concept validation, system showed promising results [17-28, 31]. A DIET stage-1 prototype was developed and tested *in-vitro* on silicone breast phantoms with limited *in-vivo* trials to establish requirements for the clinical prototype [31]. The initial trials revealed a number of limitations, restricting the employment of DIET system in a large scale clinical trial. These limitations needed to be addressed to better establish the sensitivity and specificity of DIET breast cancer screening technology based on results from larger clinical trials. Development of a DIET clinical prototype thus required major improvements in image quality, imaging speed, robust vibration actuation, ergonomics, imaging procedures and diagnostic software, all of which would improve performance as well as adding robustness. The main aim of this research was to develop a DIET clinical prototype system suitable for large scale clinical trials with main focus on safety, speed of the imaging procedure, robustness of the electronics, ergonomic design for patient comfort, control integration, and more robust diagnostic software. The compactness of the system, portability and cost effectiveness also remained priority objectives. All sub-systems were designed, built, programmed and tested in the lab, before final integration into the DIET clinical prototype [36].

A. *Imaging technology*

An array of five robust (industrial), high speed (USB-2) CCD cameras with 2MP resolution was developed, programmed and integrated with high powered strobe illumination system to eliminate the requirement of very high frame rate cameras (fps=50-100). The overall objective was to develop an optical imaging system for clinical DIET prototype with reduced imaging time while improving its performance.

The imaging array consisting of five IDS UI 2250 SE-C cameras synchronized with strobe illumination system was designed to capture breast surface motion with high accuracy and in a shortest possible time (Fig. 2). Adequate lenses were selected and integrated. Cameras were programmed for the DIET imaging session and to provide a real time video to facilitate the operator in positioning the breast actuator. The cameras were integrated into the system synchronised with strobe illumination to avoid the requirement of high cost cameras with high frame rate. The overall imaging time for acquisition of images at one frequency was reduced from over 4 minutes to 17 seconds, which would enable a screening of 10-20 frequencies in 3-6 minutes far faster than 30 minutes as in DIET stage-1 prototype [35].

To avoid very high cost CCD industrial cameras with high frame rates in the range of 50-100 fps, a novel strobe flash system was implemented using 6 high power LEDs, which provided approximately 10x more illumination, as in Fig. 2(C). A circular polarizer was applied, which eliminated the glare. The overall objective of 4-5 times higher illumination compared to stage-1 prototype was achieved and the duty cycle for pulse generation was reduced from 2% to 0.5%. These changes removed the blurriness from images at lower frequencies and also helped in optimizing the total imaging time. The imaging time to capture 10 phases at a particular frequency using the previous cameras and the strobe illumination system was reduced to 17.4 s from 252, a factor of ~15x [36].

B. *Vibration actuation*

Steady state sinusoidal actuation of the breast is a very important process of DIET imaging. Typical frequency range of this actuation is between 10-70 Hz and at amplitudes between 1-2 mm peak to peak. Surface motion reconstruction of this applied actuation indicates the presence of a stiffer inclusion inside the healthy breast tissue.

The mechanical response of the breast was modelled, and the actuation stroke and force requirements were estimated. To obtain precise and accurate linear motion and to minimise overall size, 3-voice coils were integrated in actuation system, Fig. 3. A real-time controller was programmed to communicate with an external machine (Host-PC) through TCP/IP, using an LVDT sensor for feedback. To optimise linear motion and a sustained output over time, two concentric springs were integrated in the overall design. Vibration analysis was conducted and damping feet were implemented to provide vibration isolation to the cameras. Calibration of LVDT position sensor was done for precise feedback.

Figure 2. (A) Evolution process of digital cameras for DIET, starting from left Canon G5, Canon G9, IDS UI 1465 LE-C, IDS UI-2250 SE-C with C mount lens (B) Exploded view of the camera mount and heat sink (C) Assembled camera with strobe light and PCB ready to be mounted on the main frame Programming IDS UI 2250 SE-C

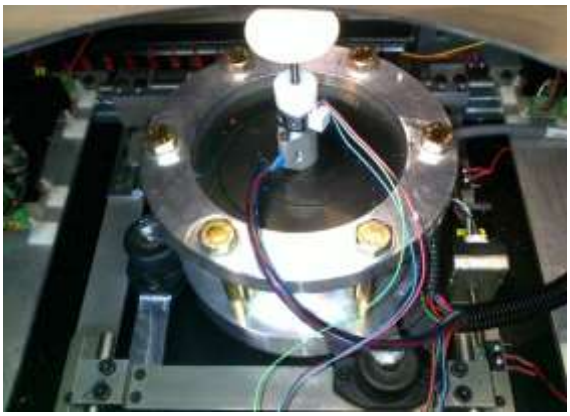

Figure 3. Inside view of the DIET clinical prototype, showing the actuator installed on the 2 – axis positioning system, while the breast interface mounted on the z-axis positioning motor can also be seen

C. Actuator positioning

A 3-axis positioning system was designed to remotely control the automatic positioning of the breast actuator, according to the size of the breast. The positioning system was subdivided into two components providing motion in XY stack and in the Z-axis independently. Two stepper motors with limit switches were implemented for positioning in X and Y direction. For positioning along the Z-axis, the design changes were implemented in the actuation unit to accommodate the a chopper motor, two limit switches and the main shaft through which the lead screw moved the breast interface in up and down direction. The motors providing motion in 3-axis were programmed to be controlled remotely using a Field Programmable Gate Array (FPGA).

D. Ergonomics

The clinical DIET prototype was ergonomically designed to provide comfort for patients during imaging and to ensure better mobility for multi-site trials. The physical dimensions of the prototype are (700 L x 650 W x 300 H) mm^3 in transportation mode and the device weighs 45Kgs. A comparatively heavier MAYTEC frame was chosen for the prototype with a view to achieve the flexibility in positioning of various DIET subsystems. The frame material promises flexibility for future add-ons and modifications. Now, once the size specifications and the installations/positioning of various subsystems have been finalized a further reduction in the overall weight can be achieved by choosing a lighter material for the frame.

Before finalizing the design, a low risk ethical approval was obtained and the ergonomic trial was conducted on 23 female subjects with various ethnic backgrounds. Based on their observations certain changes were implemented. Installation/integration of the hardware required for DIET imaging was successfully carried out in the specified space and the system is operational. The system is covered by acrylic housing panels from all sides to protect the imaging environment from outside light.

DIET clinical prototype ensures comfort to the subject under examination. In addition to the main breast hole, it carries two cavities to hold the inactive breast in a comfortable position. It contains a head-rest, arm-support and leg-support to ensure ease to the patient during examination. The top surface was ergonomically designed keeping the anthropomorphic dimensions of women of 50^{th} percentile in view. The memory foam can be applied on the top surface to ensure comfort to sternum area. The system is wheeled to ensure easy portability (Fig. 4 (a)) and has height adjustable feet to ensure levelled positioning during examination (Fig. 4 (B)).

E. Graphical user interface

The array of 5 CCD cameras, strobe lights, the motion actuation unit and 3-axis positioning system were programmed in C# using visual studio. The FPGA (cRIO NI 9012) was programmed in LabVIEW and various motion input subsystems were controlled using a client-server environment. The TCP/IP connection was established to provide client-server environment which communicated through sockets. A real-time video from two different cameras (installed at 72^o apart) was incorporated to facilitate positioning of the breast interface according size dimensions of breast, under screening. A windows based graphical user interface (GUI) was designed enabling an operator to run the system, without significant operational training. Finally, a testing mode was provided to monitor performance of different DIET systems employed in large scale screening programmes.

III. Diagnostic Approach

This research presented a concept to detect stiffer inclusions in the healthy breast tissues by using principles of modal analysis theory. Hypothesis testing was used to detect significant changes in the second natural frequencies, indicating presence of tumour. The objective was to detect at least a 10 mm tumour, which is a clinically significant size, in screening applications. This goal was successfully achieved [36, 37]. The approach presented is capable of detecting tumours of 10 mm in diameter or larger in silicone phantoms in an objective way, by only analysing surface motion of the oscillating breast, as shown in Fig 5. The approach is computationally inexpensive and well-conditioned, especially when compared to inverse finite element analysis. If in-vivo validation yields similar results, the method presented could be used to detect the existence and approximate location of a stiffer inclusion in clinical real time within moments of testing. This method provides software based diagnosis and does not require any human intervention.

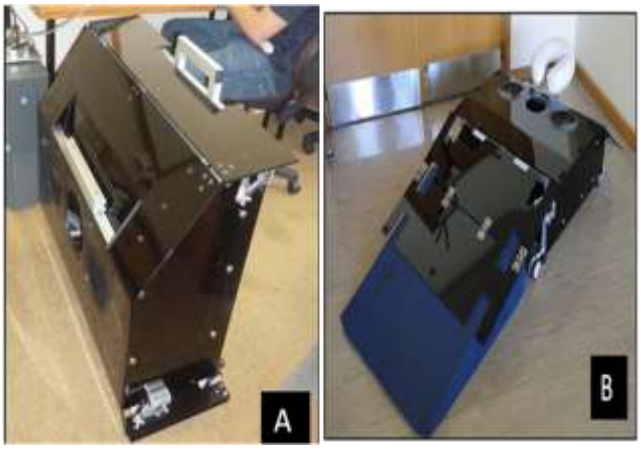

Figure 4. DIET clinical prototype (A) transportation mode, (B) extended mode

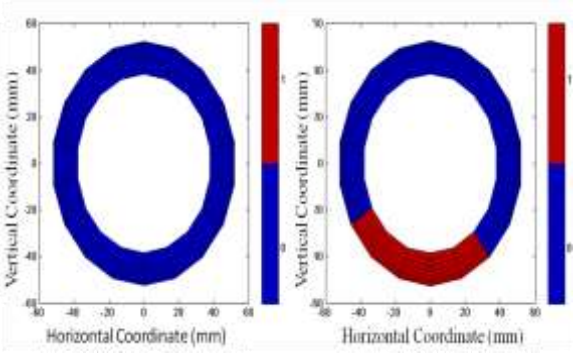

Figure 5. Result of *t*-test for phantoms (A) healthy (left) and (B) having a 10mm tumour at 6 o' clock (right). The thresholded outcome 1-*p* [hypothesis rejected (red) or accepted (blue)) is shown in each case, indicating a (lower) second natural frequency and thus a stiffer inclusion at the red area.

IV. Discussion and Conclusions

The research presented has developed a fully functional clinical prototype of the DIET breast cancer screening system suitable for use in large-scale clinical trials. The major objective of the research was system development of the imaging technology for the DIET system with a particular focus on image quality, imaging speed, robust vibration actuation, ergonomic design and a new imaging procedure. These objectives have been achieved. A clinical prototype on the standards of modern electrographic imaging medical devices has been ergonomically designed. A specific focus has been given to the modularity of all the subsystems to allow any future hardware and software modifications, enabling much of DIET's advantages regarding portability of the method.

More specifically, the time for acquisition of motion images at a single frequency with Stage-1 DIET prototype, was over 4:12 minutes, thus, a sweep of 20 frequencies, required approximately 1:20 Hours. This imaging time was not suitable for a breast cancer screening application. In clinical DIET system, an array of software controlled industrial cameras has been developed and the image capture time has been reduced to 17.4s at one frequency, this would enable a screening of 10-20 frequencies in 3-6 minutes per breast.

The previous system provided 10 kcD illuminations for DIET imaging, which entailed longer exposure times and a higher duty cycle (2%) for pulse generation. The longer exposure increased overall imaging time and also caused blurriness in the resulting images. There was also no mechanism for reduction of glare, which caused loss of information in the motion data. A new strobe flash system with high power LEDs was designed increasing the overall illumination by a factor of ~10x. A circular polarizer has been applied which attenuate the glare twice, once while leaving the light source and again while entering the camera aperture. The pulse generation duty cycle has been reduced from 2% to 0.5% and exposure time from 2s to 250ms. The design and implementation of this new strobe illumination system has eliminated blurriness from motion images, provided a ~100% reduction of glare, and increased the image capture speed by a factor of ~15x. Moreover, with the synchronisation of this strobe system with actuation, the need for high frame rate, expensive, CCD cameras has been eliminated.

The vibration actuation in the stage-1 DIET system showed limitations, particularly in terms of size and positioning. The mechanical response of the breast was modelled, and the actuation stroke and force requirements were estimated to integrate 3-voice coils in the actuation system. For accurate synchronisation, a real-time controller was programmed to communicate with Host-PC through TCP/IP, using an LVDT feedback. Vibration analysis was conducted and damping feet were implemented to provide vibration isolation to the cameras. Overall, a compact and accurate actuation system capable of providing actuation of 1-2 mm peak-to-peak at frequency range of 10-90 Hz was designed and implemented, with a remote and automated 3-axis positioning control providing a much more effective and flexible solution.

All the subsystems were installed and integrated in the ergonomically designed DIET clinical prototype, to ensure patient comfort and ease of operation. The developed imaging procedure is automated and a Windows-based GUI has been developed to ensure system operation without any operational training. A real-time video from two different cameras has been incorporated to facilitate positioning of the breast interface according to breast size and a testing mode has provided to monitor performance of a number of DIET systems employed in large scale screening programmes. All of these changes help this DIET concept reduce cost and time for screening, while increasing its flexibility and compatibility as a potential screening tool.

Finally, a new diagnostic technique using the principles of modal analysis theory has been developed to identify stiffer inclusions in the healthy breast tissues. Hypothesis testing was used to detect significant changes in the second natural frequencies that indicated presence, location and size of the tumours. This approach is computationally inexpensive and well-conditioned, especially when compared to inverse finite element analysis. The approach presented is capable of detecting tumours of 10 mm in diameter or larger in silicone phantoms. If in-vivo validation yields similar results, the method presented can be used to detect the existence and approximate location of a stiffer inclusion in clinical real time within moments of testing.

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