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Mechanical Imaging in Medical Applications

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Abstract— **Mechanical Imaging (MI), a.k.a. tactile imaging or stress imaging, is a branch of Elasticity Imaging, a medical diagnostic technique based on the visualization of tissue internal structures in terms of their elasticity modulus. During the last decade, numerous methods and devices have been developed implementing MI technology in various medical applications, such as the visualization and evaluation of prostate conditions, breast cancer screening, the differentiation of benign and malignant lesions, and the characterization of vaginal wall elasticity. This paper presents an overview of MI technology and its applications, strengths and limitations. Results of laboratory and clinical studies clearly indicate that Mechanical Imaging devices have the potential to be used as a cost effective means for cancer screening as well as diagnostics of various diseases accompanied by changes of mechanical properties of soft tissues.**

I. Introduction

MECHANICAL Imaging (MI), a branch of Elasticity Imaging, yields a tissue elasticity map similar to other elastographic techniques. At the same time, MI, a.k.a. "tactile imaging" or "stress imaging", most closely mimics manual palpation. The MI probe has a pressure sensor array mounted on its face that acts like human fingers during clinical examination, slightly compressing soft tissue with the probe and detecting the resulting changes in the pressure pattern.

The physical basis for the mechanical imaging was investigated by Sarvazyan and Skovoroda in the early 1990's [1-4]. Fig. 1 illustrates principal results of that study. Methods for predicting stress patterns in a compressed material with spatially varying elastic properties were designed. A theoretical model has been developed for solving the inverse problem of rebuilding the mechanical structure of an object from the measurements of the surface stress pattern [1, 4]. Theoretical estimates and experimental studies showed that MI may potentially detect hard nodules in the tissue with higher sensitivity than manual palpation [3, 5].

In the period from 1995 to 1999, first prototype of MI device for prostate cancer detection has been developed [6]. Attempts of implementing the theoretical model for solving the inverse problem in the MI device were not very successful because of uncertainties in the boundary conditions. Instead, the concept of knowledge-based (or model-based) imaging has been implemented in this first MI prototype [6, 7]. The computer had in memory a 3-D model of a "normal" prostate and was capable of adjusting (transforming) this model according to the measured data to produce an image that represents the actual examined organ of a particular patient. This approach had certain success in prostate imaging device but appeared to be inapplicable to MI of other organs.

In the following generations MI devices, a different method of 3-D elasticity image formation has been implemented. In this method, the 3-D reconstruction starts with the formation of a seed 3-D structure by stacking the series of 2-D images obtained from the sensor array pressed against the examined tissue. Every 2-D imprint is integrated further by a parallel translation into the 3-D structure by the matching algorithm [8]. The efficiency of this approach in visualizing tissue structures was demonstrated on a variety of phantoms and with clinical data.

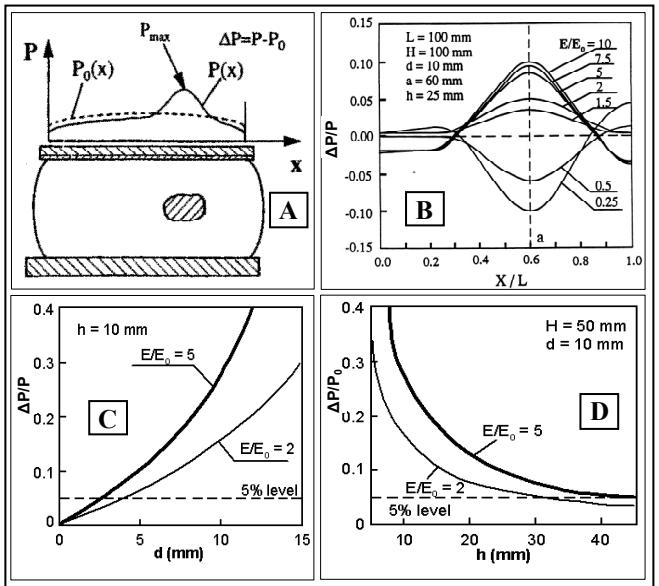

Fig. 1 Dependence of pressure profile data on parameters of a nodule (adapted from [1]). Panel A shows the tissue layer with a nodule pressed by a force sensor array, and the pressure profiles for the tissue with and without a hard nodule. Panel B shows relative changes of pressure profiles as a function of nodule/tissue relative hardness. Here E and E_0 are the Young's moduli of nodule and tissue respectively, H and L are the height and the length of the tissue layer, h and d are the depth and the diameter of a nodule, and $\Delta P=P-P_0$, is the difference between pressure profiles for the tissues with and without a nodule. Panel C illustrates the dependence of the $\Delta P/P_0$ maximum on the diameter d of the nodule located at the depth 10 mm and elasticity moduli ratios 5 and 2. Panel D illustrates the dependence of the $\Delta P/P_0$ maximum on the depth of the nodule.

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During last decade, several devices for soft tissue imaging and elasticity assessment based on the MI technology were developed. These devices include the Prostate Mechanical Imager (PMI) for 3-D prostate visualization highlighting prostate nodularity in terms of tissue elasticity [7-11], the Breast Mechanical Imager (BMI) for breast cancer detection [12-14], and the Vaginal Tactile Imager (VTI) [15]. In all three applications we used the capacitive pressure sensor arrays (Pressure Profile System, CA). Each pressure sensor has sensing area of about 2.0 mm by 2.5 mm, the sensitivity of about 0.05 kPa and hysteresis of 2-4% of the operational range [8, 12]. Probe design, number of sensors in the array (up to 192 sensors) and data processing algorithms were adapted to specific needs of each individual application.

II. Prostate Mechanical Imaging

A. System Overview

The Prostate Mechanical Imaging (PMI) system is shown in Fig. 2. The transrectal probe of the system has two separate pressure sensor arrays and an orientation sensor. The first pressure sensor array (128 sensors) installed on the head of the probe collects a sequence of pressure patterns while the probe is pressed against the prostate. The obtained data are translated into 2-D and 3-D prostate images through temporal and spatial filtering, along with subsequent signal processing [8]. The second sensor array (48 sensors), located on the shaft of the probe, measures the forces applied on the sphincter and tracks the location of the probe head relative to the sphincter. The 3-D orientation sensor, including accelerometers, magnetometers and gyroscopes located in the handle of the probe, provides data on the relationship between acquired stress patterns and the position of the probe. In order to perform the prostate examination, the physician must first place a disposable sheath on the end of the probe and apply a lubricant to the probe. The tip of the probe is then inserted into the patient's rectum and used to palpate the prostate. As the prostate is examined, color images of the prostate are displayed on the computer monitor. The PMI provides a real-time 3-D image of the prostate by capturing its geometrical and elastic characteristics, and reveals the tissue abnormalities within the gland. The PMI examination time is usually within 30 to 60 seconds. The PMI system enables a physician to visually examine and store images of the prostate and palpable abnormalities and to print examination report.

Fig. 2. Prostate Mechanical Imaging system.

B. Clinical Results

In a clinical study conducted in 2004-2006 at the Robert Wood Johnson Medical Center, 168 patients were enrolled to evaluate the ability of PMI technology to provide an objective image of the prostate and detect abnormality [11]. In 84% of cases (141 patients), the PMI provided data sufficient for quantitative assessment and image reconstruction of the prostate. Four potential causes of the 16% failure became apparent: anatomical limitations such as position of the prostate relative to sphincter and/or bladder (5%), insufficient pressure applied (5%), excessive noise from sensors (4%), and inability of the examiner to locate the prostate upon insertion of the probe (2%). Patient age and extended duration of exams did not affect the quality of data or the ability of the system to attain data and produce a prostate image. The receiver operating characteristic analysis demonstrated the ability of the PMI to visualize palpable nodules. The area under the ROC curve was calculated to be 81%, with a 95% confidence interval from 74% to 88% [11]. A subgroup of the study was referred for further transrectal ultrasound (TRUS) guided biopsy testing as a result of patients having an elevated PSA level above 4.0 ng/mL, an abnormal DRE finding, or a combination of age or family prostate cancer history factors. For 13 members of the 21-patient subgroup (PSA levels ranging from 1.0 to 26.7 ng/mL), a biopsy confirmed the presence of cancerous nodules. The PMI examination detected abnormality in 10 of the 13 patients with biopsy confirmed cancer, whereas the digital rectal examination (DRE) identified only 6 of the 13. The 8 remaining cases (PSA levels ranging from 4.4 to 13.6 ng/mL) were defined by the TRUS-guided biopsy as noncancerous in the prostate. The PMI System depicted all 8 as normal images of the prostate,

whereas the DRE detected 7 normal and 1 suspicious reading. These results demonstrated higher sensitivity and specificity for malignancy detection by PMI versus DRE for limited number of patients.

An example of a prostate mechanical image from on-going clinical study is shown in Fig.3.

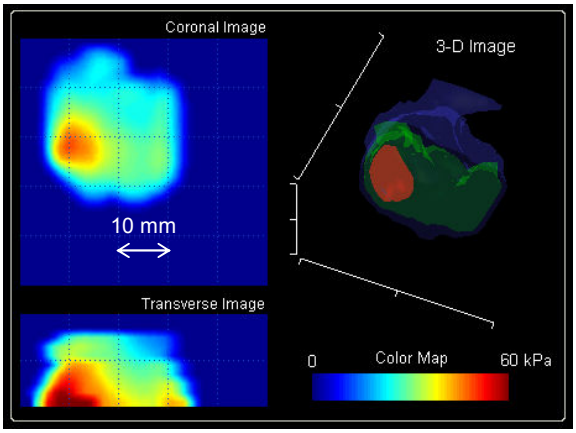

Fig. 3. An example of the PMI examination result. Both PMI and DRE detected nodule in the left lobe. TRUS-guided biopsy identified adenocarcinoma with Gleason score of 7 in the left base.

III. Breast Mechanical Imaging

A. System Overview

The Breast Mechanical Imager (BMI) includes a probe with a pressure sensor array, an electronic unit, and a laptop computer [12]. The pressure sensor array (192 sensors) is installed on the probe head surface. Fig. 4 shows general view of the BMI probe. During the examination, the sensor array contacts breast skin through a disposable elastic protective cover. Real time images are displayed to help examiner evaluate findings in real time and avoid excess data collection. The data management tab allows data saving and retrieval, as well as a printout of the examination report for the patient's chart. The breast examination procedure includes two modes: mode 1 - total breast examination to detect suspicious sites and mode 2 - local scan at the suspicious sites to characterize detected nodules. A thin layer of lubricant (ultrasound gel) is applied to breast before the examination. After a suspicious site is detected in mode 1, the manipulation of the probe is switched to mode 2. The local scan in mode 2 is accomplished by two procedure variations: probe pressings against the breast over the detected abnormality, and circular motion of the probe. The examiner observes in real time accumulated cross-sectional images of a mass/lesion in orthogonal projections [12]. The breast examination in mode 1 takes 1-2 minutes; a single local scan in mode 2 takes 20-40 seconds. Collected data with a geometrical localization of findings on a breast map are instantly saved in digital format. The three-dimensional image composition and features calculations are accomplished in real time.

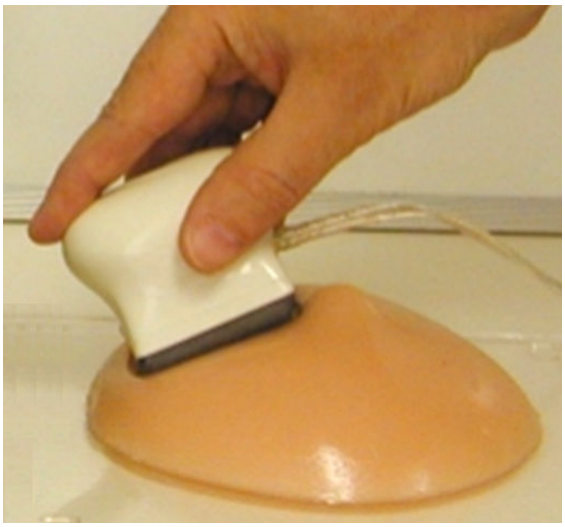

Fig. 4. Hand held probe of the Breast Mechanical Imager.

Currently, the BMI is used in two modifications. The first is a visual mapping system for documentation of the findings during clinical breast examination. It is produced by Medical Tactile, Inc. (California, USA) under the trade name of SureTouch™. The second is a research BMI for differentiation of benign and malignant breast lesions [14]. The basic distinctions between the two modifications are the indication for use and data processing software.

For diagnostic BMI we have developed algorithms to provide assessment of breast lesion features such as hardness related parameters, mobility, and shape. A statistical Bayesian classifier was constructed to distinguish between benign and malignant lesions by utilizing all the listed features as the input. A detailed description of developed algorithms to provide assessment of breast lesion characterization is presented in [12, 14].

B. Clinical Results

Clinical results for 179 cases, collected at four different clinical sites, have demonstrated that the BMI provides a reliable image formation of breast tissue abnormalities and calculation of lesion features. Malignant breast lesions (histologically confirmed) demonstrated increased hardness and strain hardening, as well as decreased mobility and longer boundary length in comparison with benign lesions. Statistical analysis of differentiation capability for 147 benign and 32 malignant lesions revealed an average sensitivity of 91.4% and specificity of 86.8% with a standard deviation of ±6.1%. The area under the receiver operating characteristic curve characterizing benign and malignant lesion discrimination is 86.1%, with the confidence interval ranging from 80.3% to 90.9% and with a significance level of P = 0.0001 (area = 50%). This study demonstrated the capability of mechanical imaging for characterization and

differentiation of benign and malignant breast lesions. We hypothesize that the breast mechanical imager has the potential to be used as a cost effective device for cancer diagnostics that could reduce the benign biopsy rate, serve as an adjunct to mammography, and to be utilized as a screening device for breast cancer detection [13, 14].

IV. Vaginal Tactile Imager

We designed and built a proof-of-concept prototype of the Vaginal Tactile Imager (VTI) which includes a transvaginal probe, an electronic unit, and a laptop computer. The vaginal probe comprises a pressure sensor array (120 sensors) and a simple orientation sensor (two-axis tilt sensor). The objective of a pilot clinical study with 13 patients was to assess the VTI capability in vaginal wall elasticity characterization. We found that the VTI can clearly visualize the increased rigidity at the mesh graft site after reconstructive surgery with the use of adjuvant materials for vaginal support [16]. The tactile image shown in Fig. 5 may be considered as a documentation of the vaginal wall state after such surgery. Any significant

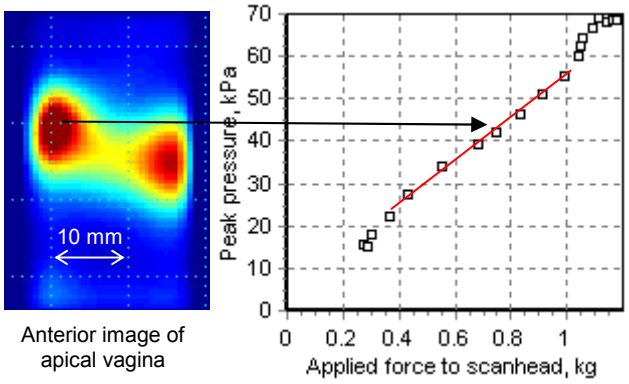

Fig. 5. Tactile image (left) and calculated loading curves (right) for peak value corresponding to increased rigidity for 59 y.o. women after pelvic reconstructive surgery using a mesh graft behind the anterior vaginal wall.

changes in the elasticity pattern of vaginal walls in time (months or years) might be observed by repetitive VTI scanning after establishing confidence intervals for quantitative values. The collected VTI data for sites with increased hardness allowed elasticity assessment of these sites by calculating the slope of the peak value inside the pressure pattern versus total applied force to the scanhead. We have also received the preliminary data demonstrating that VTI might be used for pelvic organ prolapse characterization [15].

V. Conclusions

Mechanical Imaging technology has already established a distinct niche among other methods of elasticity imaging. Results of clinical studies have proven the feasibility of MI and portend the creation of a simple and inexpensive device for detecting tissue abnormalities, which utilizes physical principles and measured parameters similar to those associated with manual palpation. Data obtained in the clinical testing of the MI devices suggest that Mechanical Imaging technology meets basic requirements for the mass cancer screening and for an affordable method of day-to-day monitoring of cancer in its advanced stages: it is simple, fast, inexpensive and safe. However, the MI method is general and may have much broader implications in diagnostics and treatment monitoring. The full extent of its medical application has yet to be explored.

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