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Development of a novel actuator for the dynamic palpation of soft tissue for use in the assessment of prostate tissue quality☆

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ABSTRACT

This paper reports on a novel device suitable for the *in vivo* assessment of prostate tissue quality. One of the first steps in the assessment of a patient who may have prostate cancer is a digital rectal examination (DRE). Our aim is to instrument this procedure to allow us to quantify results and add a dimension of assessment in that a dynamic stiffness measurement is made. The device is finger mounted and comprises a pneumatically actuated membrane which applies modulated force to the tissue to which it is applied. A strain gauge embedded in the membrane measures the response (*i.e.* the modulated displacement) and allows the dynamic stiffness of the tissue to be measured. Changes in dynamic stiffness with location allow a mechanical assessment of tissue quality.

As a proof of concept, a prototype device has been fabricated and its performance assessed through a series of measurements on both cadavers and excised prostate glands for *ex vivo* assessment. Measurements have been compared to results obtained by non-instrumented palpation and traditional DRE. Although part of a wider study aimed at identifying correlations between tissue morphology and its mechanical characteristics, this paper demonstrates that the probe can sense qualitative differences between parts of a prostate with and without tumours. Ultimately, scanning the prostate with the device allows stiffness maps of the gland to be built which can then be used for diagnostic purposes to identify diseased prostatic tissue.

1. Introduction

Studies have shown that changes in the mechanical characteristics of biological tissue, such as viscosity and elasticity, can be related to changes in the condition of the tissue [1]. Although some changes in condition are due to normal factors such as hydration or ageing, mechanical characteristics can often be used to detect the presence of disease. Indeed, tactile assessment of tissue quality through palpation has been routinely carried out for many years now as a way of detecting tumours or abnormalities, predominantly in the breasts or testes [2]. The quantitative measurement of these properties however, could allow for a more accurate, and recordable, medical diagnosis at an early stage. It can also provide information about the tissue, identifying the presence and location of disease over time, and help to classify tumours and detail the size, depth and progression of such growths.

Methods of quantifying and correlating the mechanical characteristics of tissue to its morphology have been demonstrated previously. Phipps et al. found differences in the dynamic behaviour of benign and malignant prostate samples using an electromechanical shaker to induce a cyclic load on samples using a ball-end probe attached to a load cell [3]. Krouskop et al. carried out a similar study on breast and prostate tissue, using a mechanical indenter and comparing results with sono and elastogram images [4]. Jalkanen et al. used an indentation-controlled resonant sensor system which was able to distinguish between cancerous and healthy prostate tissue through changes in resonant frequency [5]. These approaches were only intended for application to excised tissue and the findings may or may not transfer to living tissue which has a fluid tension. Ahn et al. have demonstrated the mechanical palpation of prostate tissue using a robotic probe which could be deployed *in vivo* [6]. However controlling the probe is relatively expensive and complex, training in operating the device would be required and, in its current state, without direct feedback from the user, it would be difficult to pinpoint the location of

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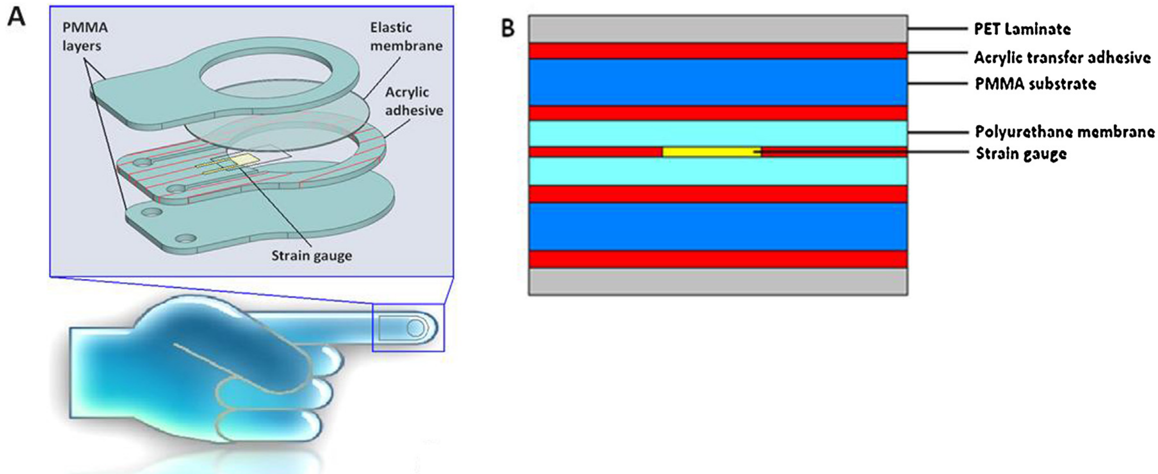

Fig. 1. (A) Schematic principle of probe; (B) cross sectional schematic of prototype.

the probe when inside the human body. The current gold standard for sensing tissue elasticity/stiffness of the prostate gland comes from ultrasound elastography and a good evaluation of the principles and various applications of this technique are covered by Cosgrove et al. [7]. These methods apply a compression force to the tissue being imaged while producing ultrasound images before and after the compression. Areas which show the most deformation are the softest while areas with less deformation are stiffer. This allows for a relative stiffness maps but only through more expensive and complex set ups such as shear wave elastography are quantitative measurements possible. Here acoustic forces act upon the tissue and the time taken for the shear waves to travel through the tissue help determine a stiffness value as a Young's modulus.

This paper describes the design, fabrication, testing and *ex vivo* demonstration on human prostate of a novel device for the instrumented palpation of soft tissue. The design is scalable for different types of intervention and the embodiment reported here is specifically configured to be incorporated into a standard digital rectal examination (DRE). It is intended to be cheaper, simpler and quicker to implement than current ultrasound elastography techniques and used at an earlier stage of diagnosis.

Despite the fact that most biological materials are known to exhibit time-dependent mechanical behaviour and are often nonlinear, many probes and reported results in tissue mechanics assume their response to be linear elastic obeying Hooke's law where the force required to extend or compress the material by a given amount is defined by the spring constant or stiffness of the material [8]. In such a case static measurements are sufficient as the response of the material is assumed to be immediate. A probe tip is usually pressed into the material while the displacement and the force experienced by the tip are recorded. Examples of this type of measurement can be seen from micro and nano-indenters [9] and in atomic force microscopy [10]. Biological materials are sometimes assumed to be viscoelastic, displaying both elastic and viscous characteristics and commonly modelled using various combinations of springs and dashpots, such as the Maxwell, Kelvin-Voigt and standard solid models, where both elastic and viscous parameters are taken into account. Many different models have been used in the literature for particular materials, but all have the common requirement that any test needs to include an assessment of the time of tissue response as well as its magnitude [11,12]. Any measurements made on biological materials should take this into account if the best assessment of tissue quality is to be made. The approach taken in this work is to modulate the applied force so that the relationship between dynamic force and dynamic displacement gives a complex stiffness. The approach has the advantage that varying the frequency of modulation provides an additional tool with which to probe tissue morphology. Taking the (highly simplified) view that the viscous behaviour is related to fluid movement within the tissue, it might be expected that short-range movements in small volumes of tissue will be revealed by modulating at relatively high frequency and vice versa. It has previously been demonstrated by Yang et al. that, for the scale of measurements in the current embodiment (*i.e.* a few mm), frequencies of 1–20 Hz reveal dynamic behaviour in excised prostate tissue [13].

Tactile sensors are widely used in in robotics, biomedical instruments and many industrial applications where force and/or pressure need to be controlled or directed [14,15]. A tactile sensor can be defined as *"a device that can measure a given property of an object through physical contact between sensor and object"* [16]. For example, a simple MEMS tactile sensor can measure force or

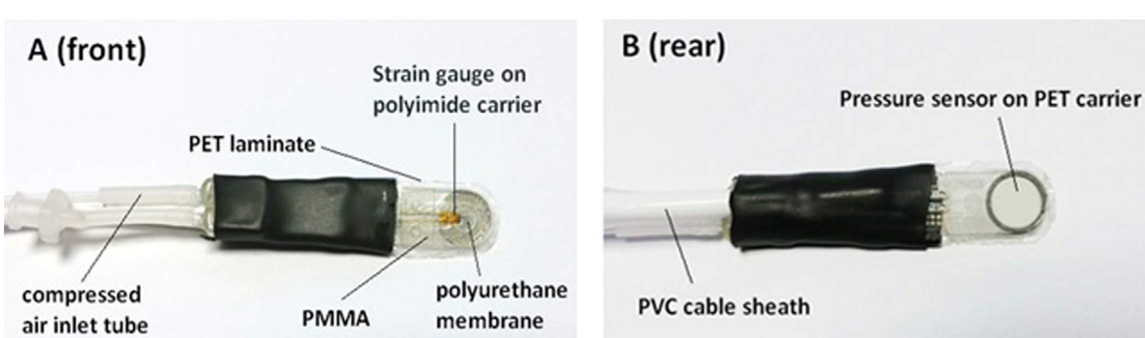

Fig. 2. (A) Proximal (patient-facing) view of prototype probe; (B) distal (finger-facing) view of prototype probe.