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A sensor for needle puncture force measurement during interventional radiological procedures

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ABSTRACT

Computer-based simulation for interventional radiology training has attracted increasing attention in recent years because of its potential to train remotely from patients and to provide objective assessment of proficiency. Yet developing a high fidelity simulator with realistic tactile feedback requires accurate knowledge of forces exerted on medical devices during interventional radiology procedures. This paper presents the development and validation of a force sensor for the measurement of axial forces generated during needle, and combined cannula/trocar, puncture procedures in patients. In order to assess the performance of this sensor, *in vitro* measurements were obtained using needle penetration of porcine liver, kidney and muscle. The results were compared with forces measured by means of a tensile tester.

Calibration results showed that the force sensor has high sensitivity and linearity. Comparison of the force profiles obtained from the sensor and the tensile tester shows that good agreement was achieved in the *in vitro* studies for all the tissues tested.

Preliminary clinical force measurements during arterial puncture and liver biopsy procedures have been performed in patients. An example of force recording for each procedure type is presented.

1. Introduction

Interventional radiology (IR) medical techniques involve the use of needles, guidewires and catheters to diagnose and treat a range of pathologies in arteries and organs, using imaging technologies such as ultrasound or X-ray to guide the manipulation of these instruments. IR requires a considerable level of proficiency to attain technical success whilst avoiding complications. Traditionally, this expertise is acquired by practising on animals, physical models or patients. However, animal-based training is costly and controversial, with limited relevance of animal anatomy and pathology to humans. An alternative is to use physical models which accurately represent human anatomy, often produced by rapid-prototyping techniques. However, these models are expensive and are easily destroyed by multiple needle punctures. Training on real patients occurs in the traditional apprenticeship method, yet this prolongs procedures and can increase risks to patients.

In recent years, there has been considerable interest in using computer-based simulation for IR training [1–4]. Virtual IR training allows deliberate practice of procedural skills, remote from patients, whilst reducing costs of theatre time for training and avoiding the inevitable risk that this method of learning poses to patients. Not only can this type of simulation offer flexibility for trainees with different skill levels to practise in realistic imaging data sets, but also it brings the added opportunity of precise, objective performance assessments.

Needle access to tissue and organ systems is the essential first step in many IR procedures, such as gaining vascular or visceral catheter access (Seldinger technique), or tissue biopsy for histological diagnosis. Prior to needle puncture, an initial tiny incision is made, through which a needle is inserted into subcutaneous tissues. The location of this skin puncture and guidance of the subsequent needle trajectory to its target, are determined by the operator using either palpation (of bone landmarks and pulse) or ultrasound imaging. Observation of the ultrasound image conveys needle location in real time, allowing the needle tip to be carefully directed towards a suspect soft tissue mass or tumour, abscess, or towards the lumen of a bile duct, renal collecting system or blood vessel. In the last case, where an artery is successfully punctured, pulsatile blood issues from the needle hub, confirming correct needle placement. In the case of an abscess, successful puncture is indicated by the egress of pus from the needle. A guidewire can then be introduced into the punctured vessel or viscus *via* the bore of the needle, feeling carefully for tactile evidence of impending complications. Once the

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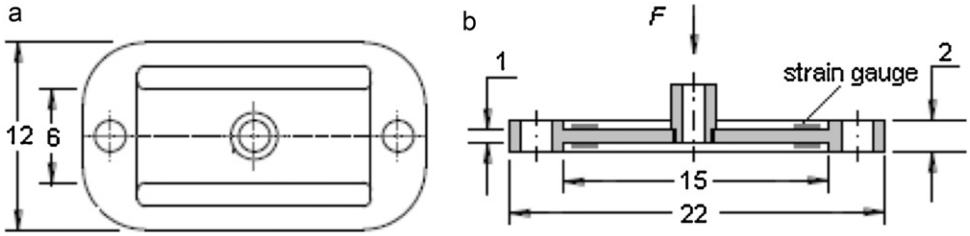

Fig. 1. Thin aluminium beam with integral frame (a) top view and (b) cross-sectional view with strain gauges. All dimensions are in mm.

wire is correctly located in the targeted structure (kidney, bile duct, vessel, *etc.*), the needle is removed leaving the wire in place: a range of diagnostic and therapeutic catheters can then be introduced over the guidewire.

In the real world task, tactile cues are important to safe procedural outcomes. Hence, in an IR training simulator, the fidelity of force feedback during each step of the Seldinger technique, or during the insertion of a cannula/trocar assembly prior to biopsy procedures, should correctly reflect an operator's 'feel' during an actual clinical procedure. To identify this task fidelity, and the forces generated, requires measurements during procedures in patients, a key element of which must be safety, with minimal interference with the clinical procedure being performed.

The investigation of interventional needle puncture forces has been investigated previously by custom-made or commercially available force measuring products [5–12]. Washio and Chinzei [5] described a coaxial force sensor which can measure both the cut force and the friction force during a needle insertion of different tissues. Podder et al. [6] used a six-axis force sensor (Nano17®, ATI Industrial Automation, America) to perform the force measurement during a prostate brachytherapy. A MRI compatible 3DOF optical force/torque sensor was also built for the same purpose [10]. It has a force measurement range from 0 to 20 N with resolution of 0.1 N. Peirs et al. presented the design of a 3-axial force sensor which measures of 5 mm in diameter to provide force feedback during minimally invasive robotic surgery [13]. It uses a flexible titanium structure as the sensing element and three optical fibres to detect the deformation when subjected forces from different directions. To our knowledge, none of the previous sensors allows the free passage of the jet of blood, an essential step in the Seldinger technique, to confirm that the needle tip is within the vessel lumen. For this reason, we previously used a capacitive force sensor (Contacts®, Pressure Profile Systems, Inc., Los Angeles, America) which was mounted on the operator's thumb using a finger glove for *in vivo* force measurement during an arterial puncture procedure [12]. However, the commercial or home-made force sensors used previously are bulky: some are designed for use with robotic systems and are unsuitable for use during clinical procedures. The Contacts® sensor used in our previous study was found sensitive to position changes between the sensor and the needle hub. In addition, the placing of the sensor between the operator's thumb and the needle hub significantly reduces the tactile feeling of the operator which is essential to perform the Seldinger technique.

This paper describes the development of a coaxial force sensor for unobtrusive measurement of the insertion force during arterial puncture and liver biopsy. Studies were carried out to measure forces on needle puncture of porcine liver, kidney and muscle using this force sensor, and the results were compared with those recorded simultaneously using a tensile tester. Clinical measurement of forces during arterial puncture and biopsy procedures are currently being performed. Preliminary data obtained from one case of arterial puncture during cardiac catheterisation and one liver biopsy procedure are presented.

2. Methods

2.1. Sensor design

The vascular access needle (Cook Europe, Cork, Ireland) used in our institution consists of a 19G steel needle component to which is attached to a moulded plastic Luer assembly (holder) which incorporates wings, designed to facilitate holding by an operator during puncture procedures. An important requirement for the sensor is that it should be small and light so that any interference with the procedure and the normal method of use of the needle can be minimised. The sensor design is based on the use of a thin beam with an integral frame machined from one piece of aluminium bar. The beam is 15 mm in length, 1.0 mm thickness and 6.0 mm width and has a circular hole of diameter 2.8 mm in the centre (Fig. 1a). An aluminium tube that fits into this hole is securely bonded onto the beam. Force applied to the middle of the beam induces strains in

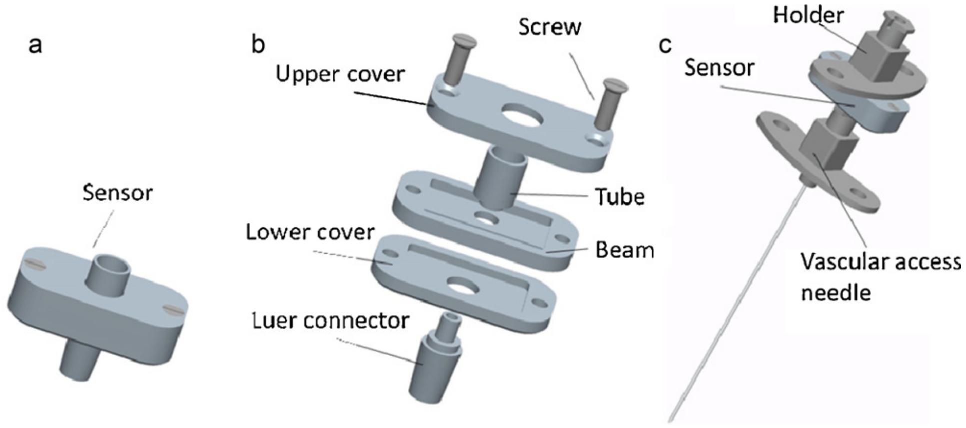

Fig. 2. Needle force sensor structure (a) sensor assembly; (b) exploded view of the sensor and (c) sensor inserted in an arterial puncture needle.