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In Vivo Force During Arterial Interventional Radiology Needle Puncture Procedures.

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Abstract. To adequately simulate the forces generated during interventional radiological (IR) procedures, non intrusive in-vivo methods must be used. Using finger tip mounted, non intrusive capacitance force sensor pads (PPS, Los Angeles, California) we have been able to measure the forces involved in interventional radiology without a change in procedure technique. Data acquired during the process of calibration of the capacitance pads in conjunction with extensive in-vitro needle puncture force measurement using a commercially available tensile tester (Nene Industries, UK) are presented here.

1. Introduction

Interventional Radiology is minimal access surgery using manipulation of needles, wires and catheters. IR procedures generally commence with placement of a needle and demand for these procedures is increasing, yet there is a shortage of radiologists both in the UK and worldwide. Apprenticeship training relies on straightforward, invasive diagnostic studies in patients under supervision, but such cases are being replaced by non invasive imaging methods (CT and MR) and alternative training paradigms are required. Models for needle puncture training lack robustness and are destroyed by repeated punctures. Animal models have anatomical differences [1], a lack of pathology and, in the UK, of political acceptability. Virtual reality (VR) simulator models using real CT and MR data have the potential to simulate many procedures, though there is a lack of VR models of arterial needle puncture for interventional radiological procedures. Some models of venepuncture (eg: using the Immersion, Cathsim device [2]) exist, as do lumbar puncture and liver biopsy simulations [3-5] but force feedback in existing virtual reality simulators is typically based on mathematical models and the subjective assessment of experts. Incorporation of empirical data measured during procedures on patients should improve the feel of a simulated procedure and enhance the authenticity of the simulator [6]. Tissue deformation, and cutting and friction forces, during *in vitro* prostate needle placement have been investigated [7] as well as needle forces in cadaveric dog prostate [8] and a soft tissue phantom [9]. In developing realistic simulation of IR needle puncture procedures in virtual environments, it is important to have accurate models of instrument-tissue interaction [10,11], though the complexity of these forces requires direct measurement of tissues *in* *vitro* and, owing to differences of tissue physical properties in life, *in vivo* [12]. Our literature searches have, however, revealed no references to *in vivo*, human vascular needle force measurement and indeed there has been a dearth of unobtrusive devices, which might be used to measure instrument forces in the sterile, *in vivo* environment. Measurement systems for *in vitro* studies [7-9] have allowed a high degree of accuracy but were generally cumbersome and not easily applicable to the *in vivo* scenario. The development of flexible capacitance pads presents a novel opportunity to collect these data *in vivo* [13].

2. Materials and Method

2.1 Calibration

Static testing was initially completed using a laboratory test rig. Fixed masses were used to establish a maximal range of sensor output voltage over the estimated range of in-vivo forces to be measured. Voltages were measured using a digital voltmeter. Masses were applied to the sensors over a range of surface areas to establish that true force, and not pressure, was being measured. The sensors were then subjected to masses increasing by 50g amounts to a maximum of 1050g, the mass was then reduced serially to zero. This process was repeated to establish linear behaviour with increasing force upon the sensor.

Dynamic testing using a test rig consisting of a manufactured finger jig, on which a capacitance sensor could be mounted, was performed using a tensile tester (Nene Industries, UK). A spring was compressed to different forces driven by the tensile tester and held at that force to allow capacitance sensor output to be measured. Output from the capacitance pads was measured using a laptop PC (Dell Computers, USA) via a USB analogue-to-digital converter (Measurement Computing, PMD-1208LS, USA). This testing demonstrated excellent reproducibility in force measurement, the voltage output of the capacitance pads was found not to be linear with respect to applied force but could be modelled accurately using a third order polynomial equation [14].

Further dynamic testing was carried out using tissue substitutes (plasticine, polystyrene, Playdough, cardboard, silastic rubber). Correlation between input force, as measured and applied by the tensile tester, and output voltage from the capacitance sensor pads following translation using the polynomial calibration equation were evaluated and found to be satisfactory.

Dynamic frequency response testing was completed using a high frequency low amplitude bench oscillator with square wave input. This showed responsiveness far in excess of that required to measure physiological systems.

2.2 In-Vitro

2.2.1 Liver

Ox liver with time minimised from slaughter to laboratory use was used for in-vitro estimation of liver needle puncture force. Liver was chosen as the initial test substrate because it has a homogenous tissue structure lacking macroscopic anatomical variation in its peripheral parenchyma. Ox liver was chosen as the specific test medium to provide sufficient depth of tissue in the organs homogeneous periphery during needle puncture. A range of needles were mounted on the tensile tester finger jig and were driven into the tissue at a fixed rate, 500mm per minute, an approximation of the speed of needle insertion during interventional radiological procedures. Needle orientation was normal to the liver surface being punctured, depth of puncture was 6cm. Output force data from the tensile tester and the capacitance pad output voltage were continuously measured. Punctures were repeated to obtain an average and a range of forces involved. Output from the capacitance pads was measured using a laptop PC via a USB analogue-to-digital converter.

Needles used for puncture included Chiba needle (Cook, Europe), co-axial biopsy trocar needle (Temno, Allegiance Heathcare Corp, USA), uni-axial biopsy needle (Temno, Allegiance Heathcare Corp, USA), Kellett needle (Rocket Medical, UK), Kimal needle (Kimal, UK), Rita radiofrequency ablation needle (Rita, UK), Radionics radiofrequency needle (Radionics, UK), spinal needle (Steriseal, UK), vascular access one part needle (Cook Europe, Denmark) and vascular access two part needle (Cook Europe, Denmark).

2.2.2.Kidney

Pig kidneys with time minimised from slaughter to laboratory use, were used for in-vitro estimation of kidney needle puncture force. Kidneys do have macroscopic variation in their structure but this variation has conformity across the specimen where the needle puncture path is normal to the capsule of the organ. Pig kidney was chosen as the specific test medium because of the similarity between porcine and human anatomy. A range of needles (see above in the liver in-vitro methodology) were mounted on the tensile tester finger jig and were driven into the tissue at a fixed rate, 500mm per minute, an approximation of the speed of needle insertion during interventional radiological procedures. Needle orientation was normal to the surface of the kidney being punctured; a depth of puncture of 6cm was used. Output force data from the tensile tester and the capacitance pad output voltage were continuously measured. Punctures were repeated to obtain an average and a range of forces involved.

2.3 In-Vivo arterial needle puncture

Following Local Research Ethics Committee approval, measurement was made of forces generated during arterial needle puncture during vascular interventions in ten adult patients (8 male, 2 female, mean age 69 yrs, range 42 to 83 yrs). Following a surgical hand scrub a single sensor pad was mounted on the operator's right thumb, the sensor pad was lightly taped to the operator's thumb, beneath a sterile surgical glove. During the needle puncture procedure, the operator's thumb was positioned such that the sensor pad was centred over the needle hub, allowing normal forces to be measured. Static and dynamic forces were then measured throughout the arterial needle puncture procedures. Patients undergoing evaluation were routine listed patients undergoing standard investigation for peripheral vascular disease. Vascular access was obtained by puncture of the common femoral artery. Ultrasound guidance was used to determine the anatomical location of the needle tip while a sensor generated force profile was obtained. The needle advancement was effected under ultrasound guidance with the needle hub normal to and centred on the force pad, allowing forces to be measured throughout arterial needle puncture. Data were sampled at a rate of 100Hz and saved to a PC. The whole procedure was video taped to establish a time line to correlate force fluctuations to physical manoeuvres.

3. Results

3.1 Calibration

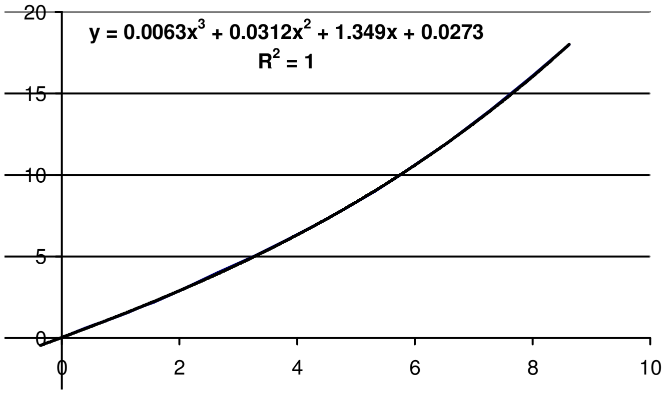


Fig 1. Calibration curve with the calibration equation to convert from capacitance pad voltage output to force in Newtons. X axis is Volts and Y axis is force (Newtons).

3.2 In-Vitro

Our data demonstrates the influence on force of needle gauge, needle design and the tissue being punctured.

3.2.1 Liver.

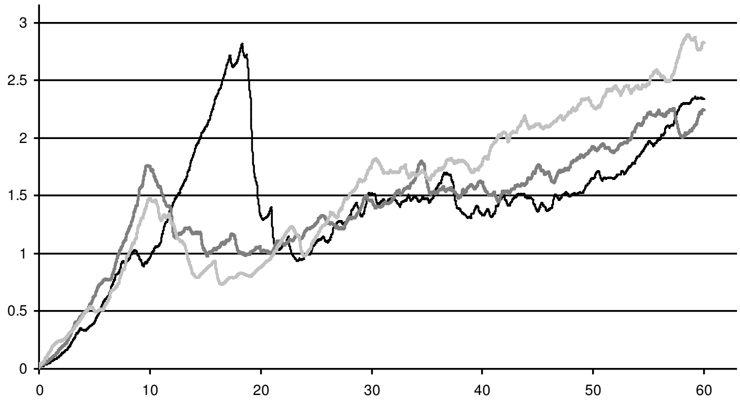


Fig 2. Comparison of force required for in-vitro liver puncture all needles are 18 gauge, light grey trace biopsy needle, dark grey trace, spinal needle, black trace, Kimal needle. X axis is displacement (mm) and Y Axis is force (Newtons).

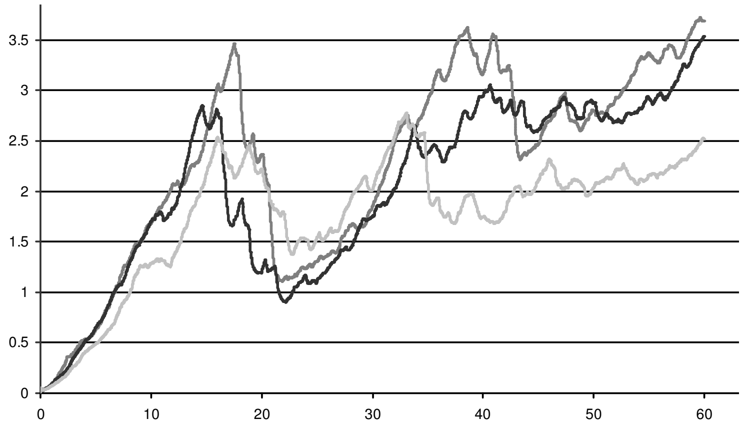


Fig 3 Comparison of force required for in-vitro liver puncture. All needles are coaxial biopsy trocar needles, the light grey trace is a 19 gauge needle (thinnest calibre), the dark grey a 15 gauge needle (thickest calibre) and the black a 17 gauge needle (mid calibre). The X axis is displacement (mm) the Y axis is force (Newtons).

3.2.2 Kidney.

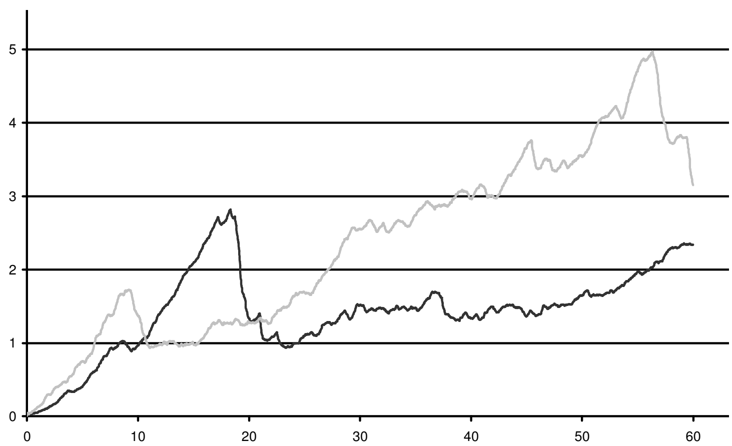


Fig 4. Comparison of force required for in-vitro puncture of liver, black trace and kidney, grey trace using a Kimal needle. X axis is displacement (mm) and Y axis is force (Newtons).

3.3 In-Vivo arterial needle puncture

The capacitance sensors were found to be unobtrusive during *in vivo* studies with no adverse clinical events recorded. Voltage output range 0.066 to 2.706 Volts, was equivalent to 0.13 to 8.89 Newtons (mean 3.76, SD: 3.32) required to puncture the arterial wall. Fig 5 shows sensor output over a 55 second period during ultrasound guided needle puncture. The elevated baseline is due to the compressive force of the surgical gloves. There is a low amplitude periodic waveform recorded during needle / vessel wall contact (commencing at black arrow in fig 1) with periodicity correlating to the patient's pulse rate (72 beats / min). Just prior to vessel lumen entry there are two peaks of sensor output, the second being the maximum at 3.9 V which is equivalent to 5.1 Newtons. The final reduction in sensor output corresponds to the observation of vessel wall penetration by ultrasound imaging with an arterial blood jet from the needle (white arrow in fig. 5).

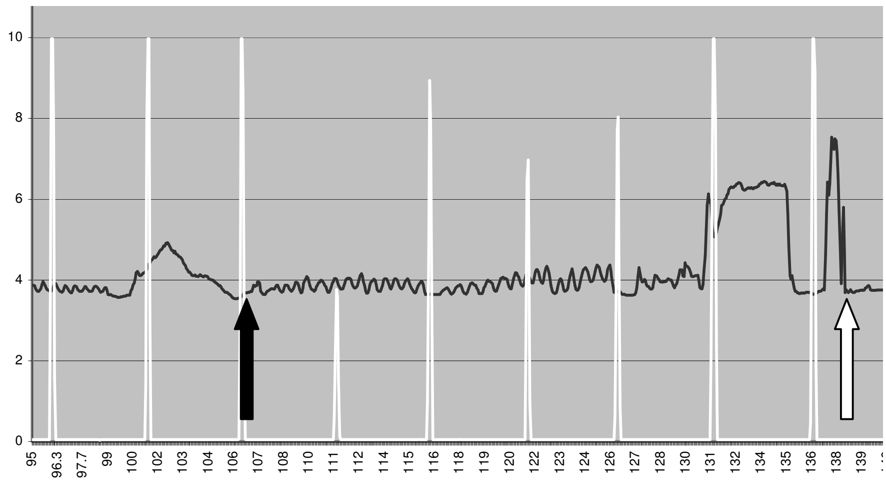
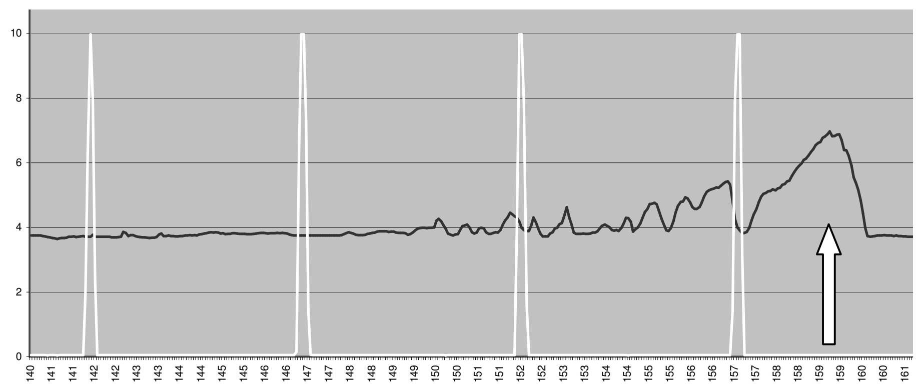


Fig 5: Sensor output shown in Volts (black trace). Baseline as time (seconds) with 5 second time points (white trace). Wall contact at black arrow. White arrow indicates vessel entry

Fig 6 shows a 24 second period of sensor output during arterial puncture in this case. This again shows a periodic waveform during needle / vessel wall contact, followed by progressive increase in sensor output, up to 2.9 V (equivalent to 3.8 Newtons) immediately preceding entry into the vessel lumen. The final reduction in sensor output corresponds to the observation of vessel wall penetration during ultrasound imaging, with a simultaneous arterial blood jet from the needle.

Fig 6. Sensor output shown in Volts (black trace). Baseline as time (seconds) with 5 second time points (white trace). White arrow indicates vessel entry.



4. Conclusions.

Using the capacitance force sensor pads single degree of freedom force measurement can be performed in-vivo in the sterile clinical environment and without significant interference with the operator's 'feel' encountered during the procedure. These preliminary data show feasibility of using these unobtrusive sensors during any IR invasive procedure in order to model instrument-tissue forces intra-operatively. The sensor responses are reproducible, with the output being related to force rather than pressure. During arterial puncture, a periodic waveform during needle–wall contact was equivalent in rate to the observed pulse, and is likely to represent force transmitted by the needle due to arterial pulsation. This method does not distinguish cutting from friction / clamping effects [9], and cannot capture rotational and lateral forces. Nonetheless such techniques should provide a suitable method of authenticating haptic output forces in simulator models.

5. Future Work.

We are continuing to acquire data on the needle force involved during IR procedures. In-vitro and *in vivo* puncture force data is being incorporated into new simulations and we are exploring and developing novel techniques for measurement of the forces involved in IR [14].

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