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DEBI: a New Mechanical Device for Safer Needle Insertions

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INTRODUCTION

Over 1 million core-needle breast biopsies are performed every year in the US alone [1], while gastrointestinal and prostate biopsies are estimated in similar numbers. The cost of core-needle breast biopsies ranges between $500 for manual procedures to $6,000 for image-guided procedures [2]. A retrospective study indicated that approximately 2.5% of breast biopsies fail [3]. Needle bending has been identified as a significant cause of error in biopsies and is particularly likely to occur at the insertion stage [2]. The associated risks include: i) biopsy of the wrong site leading to misdiagnosis; ii) puncture of sensitive areas in proximity of the insertion path; iii) repeated insertions, thus longer procedure duration and increased patient discomfort. Biopsy needles are also prone to buckling, which can damage the needle permanently. Common techniques for correcting needle bending in clinical settings include repeating the insertion (which can be time-consuming) or using a needle guide (which reduces the maximum insertion depth). In research, axial rotation is typically employed for steering bevel-tip needles, but it is less effective for needles with an axial-symmetric tip [4]. Additionally, straight insertions require continuous axial rotation, which can damage soft tissue due to the spinning of the bevel tip [5]. Alternative approaches employ steerable needles, which are not yet part of clinical practice [6].

We have developed a mechanical device that detects needle bending as soon as it occurs and that immediately reduces the insertion force thus helping to avoid deep insertions with deflected needles and the associated risks. Unlike existing solutions, our design does not require actuators or sensors hence it can be made MRI-safe, sterilisable or disposable. Finally, our device can be used with a variety of standard needles, including multi-bevel needles (e.g. diamond tip or conical tip).

MATERIALS AND METHODS

The proposed device resembles a syringe in that it consists of a piston, used to impart the insertion force, and a main body which houses the force-limiting mechanism and supports the needle (see Figure 1). The force-limiting mechanism consists of a spring-loaded relief valve connected to the needle base: when the needle bends, its base moves laterally and tilts the plunger of the relief valve. This reduces the compression of the o-ring mounted on the plunger; thus, the internal pressure

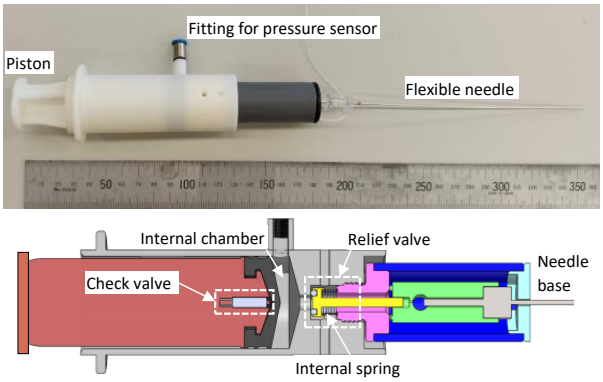

Fig. 1 Photo of the prototype, and section view of the CAD model highlighting the main components of the force-limiting mechanism.

generated by the piston drops, allowing the piston to advance towards the needle base. Consequently, the insertion force and the depth are automatically limited. A check valve is embedded in the piston to refill the internal chamber during retraction. We have manufactured a prototype measuring 172 mm in length and weighing 85 grams by employing standard 3D printing technologies.

We have developed an automated test setup (see Figure 3) to assess the performance of the device with *in-vitro* experiments involving repeated needle insertions in a silicone rubber phantom representative of physiological tissues. The test setup consists of a double-acting plastic pneumatic cylinder (AC111-707-501, IPS Inc.) supplied with digital pressure regulators (Tecno Basic, Hoerbiger, Germany), while a linear encoder (EM1-300, US Digital) has been employed to measure the position of the piston. Each valve regulates the output pressure with an internal pressure sensor and a low-level control loop. A PID algorithm has been employed to control the position of the piston. The bending angle at the needle tip has been measured with an electromagnetic (EM) tracking system (Aurora, NDI Europe) by using an 18G coaxial needle (1.3 mm OD, 0.8 mm ID, 150 mm long) instrumented with an EM sensor (part number 610061, NDI Europe, RMS accuracy 0.2 degrees). The insertion force has been measured with a force sensor mounted on the piston (FSG15N1 A, Honeywell), while the pressure inside the force-limiting mechanism has been measured with an additional sensor

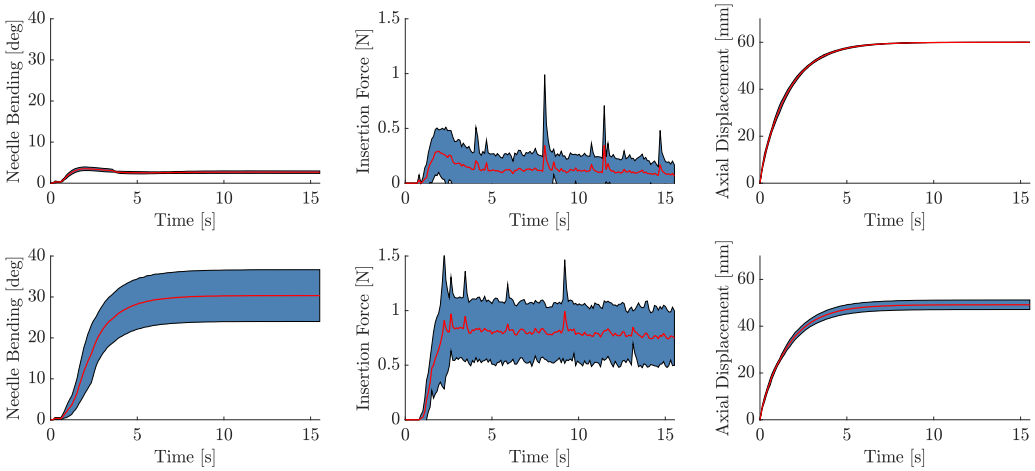

Fig. 2 Test results: Top row with force-limiting mechanism, Bottom row without force-limiting mechanism.

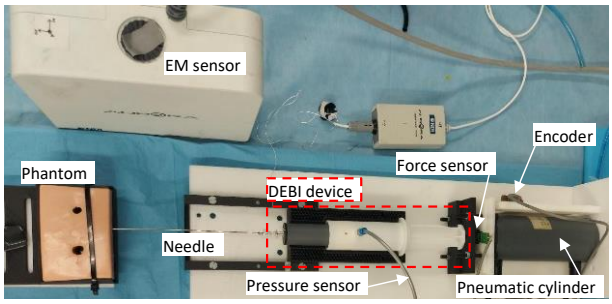

Fig. 3 Test setup for automated needle insertions.

(4525DO-DS3AS005GPF, Measurement Specialties). A micro-controller (mbed NXP LPC1768) communicates the pressure set-point to the proportional valves and collects the measurements from the linear encoder, the force sensor, and the pressure sensor. A Matlab script retrieves the sensor measurements using a serial link.

RESULTS

A set of needle insertions have been conducted with a silicone-rubber phantom (PlatSil GEL-10, Polytek), shore A = 10, representative of liver tissue [7], setting the needle perpendicular to the surface of the phantom. Each needle insertion has been repeated five times, and for each measurement we have computed the mean value (displayed in red) and the standard deviation (displayed in shaded blue) of axial displacement, bending angle, and insertion force. The test results (see Figure 2) show that the needle bending angle remains below 5°, while the insertion force remains below 0.5 N. The insertion speed is approximately 8 mm/s, which is representative of percutaneous interventions of the liver (see [8]). In comparison, removing the force-limiting mechanism yields needle bending angles above 30° and insertion forces above 1 N. Thus, the proposed mechanism reduces the needle bending by over 80%, which is similar to the results achieved with our controller [9] in automated closed-loop insertions.

DISCUSSION

The experimental results indicate that our device can effectively limit needle bending, thus reducing the associated risks. Since the device is completely mechanical (i.e., sensors have only been used for data collection), it can be produced in low-resource settings to suit various manual and robotic-assisted percutaneous procedures.

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