Spinal Column Needle With a Force Feedback: Introductory Study

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***Abstract*— Chronic back pain is a well-established health problem, and sufferers should be able to get life-changing medication through safe and accurate injection methods. Although spinal column injections can be performed with imaging support, there is a risk of inaccuracy at a fraction millimetres. Subjective approaches, such as loss of resistance, are difficult to learn and require substantial training. These treatments endanger the patient's life since the needle may be inserted into the wrong tissue, causing nerve damage. The tactile input would assist the surgeon in determining which sort of tissue they had placed the needle into during the touching stage. This study proposes the development of a device capable of sensing the touching point and returning a signal indicating the magnitude of pressing force. In vitro testing of the device was performed using a spinal model. The results demonstrate that the device successfully provides force feedback indicating distinct tissue model types.**

Keywords—embedded sensors, back pain, tactile feedback, sensing needle.

I. INTRODUCTION

The spine is the most prevalent source of back pain and approximately two-thirds of the population will suffer from back pain within their life-time [1]. Treatments are available to relieve the pain but the current approaches to locate the target tissue lack accuracy and can potentially put the life of the patient at risk.

A study revealed that epidural injections in the facet joint play a significant role in providing an effective and responsive joint pain relief [2]. It is also demonstrated that these epidural procedures can restore functionality in patients which verifies the fundamental requirement for such technology [3].

Steroid injections are a common use for epidurals in the treatment of radiculopathy and persistent back pain [4]. But finding the right tissue to treat the pain is essential; these tissues are frequently small and complex, making identification more difficult. While epidural steroid injections are frequently used to relieve pain, there is a significant risk of spinal cord infarction with some techniques, including transforaminal epidural steroid injections [5].

For the purpose of instructing and evaluating spinal anaesthesia, Lovquist et al. [6] created a haptic simulator. It mimics the insertion of a needle while providing feedback as it happens. To reduce training expenses and patient danger, a virtual reality lumbar puncture simulator has been created [7]. Forces that oppose needle insertion and rotation were feedbacked using a six-degree-of-freedom haptic device. Elayaperumal et al. [8] created an instrumented biopsy needle that gives medical professionals the capacity to feel interaction forces right at the inner stylet tip of the needle. Due to the sensors' immunity to electromagnetic fields—optical fibre Bragg gratings, or FBGs—the needle may be used for MR-guided operations. The device features a number of micro-machined holes at the tip in addition to extra sensors. Without appreciably decreasing the stiffness or strength, the perforations heighten the sensitivity of the strain to axial forces.

Facet joint pain is a type of chronic back pain which originates in the spinal column and can lead to motion restriction and eventual physical deconditioning [9].

Fluoroscopy is an imaging technique used to help in the placement of a needle for a facet joint injection to relieve discomfort. However, correct intraarticular needle placement requires clear visualisation of the joint area, yet anatomic obstacles cannot be recognised by fluoroscopy, making safe needle placement challenging [10].

According to Abolhassani et al. [11], an image-guided procedure's lack of accuracy makes real-time imaging and force feedback useful for identifying tissue deformation and target movement. Furthermore, it is mentioned that "tactile sensing alone cannot be used to interpret tissue type," hence it is advised to combine it with another method like medical imaging. Ultrasounds can also be utilised to help locate the target tissue. Xia et al. [12] have reported that using ultrasounds to visualise the needle tip can be difficult. When the insertion angles are steep, the needles are difficult to see, and occasionally the needle shaft can be mistaken for the needle tip.

The loss of resistance (LOR) method is another technique used for spinal epidurals. It entails manually losing air while the needle is inserted into the desired epidural area [13]. Patients with diseases like spinal stenosis are the target audience for this treatment [14]. However, it has been demonstrated that improper needle tip placement accounts for 10% of failure LOR epidural procedures [15]. Failure to place an epidural needle can have serious repercussions for patients, including headaches, paralysis, and even death [16]. Additionally, Lin et al. point out that the operator's experience has a major role in the success rate of epidural surgeries. Because of this, doctors need extensive training, which can be costly and time-consuming. The challenge of mastering needle placement for physicians was also highlighted by Vaira et al., who found that most physicians needed to practise for 60–90 times before they were proficient enough.

The inability of any of these techniques to precisely identify the relevant tissue is a common problem. Not only are imaging techniques unable to identify essential tissues, but they also cannot detect the needle point. The LOR is a blind approach that doesn't rely on imaging; yet, because it relies on the physician's skill and knowledge, it takes a lot of training to get the hang of the procedure. These factors alone demonstrate the need for a simple way to shorten medical professionals' training durations while yet giving them access to an accurate method for identifying every tissue layer. It should be mentioned that in order to get higher accuracy, the tactile feedback device should be used in conjunction with another imaging device.

For these reasons, the goal of this project is to develop a more accurate tissue identification technique to alleviate discomfort in the spinal joints. The operator will be informed of the proper position via an LCD and LED system, and a force sensor will provide the tactile feedback of the needle. These enhancements will shorten the time doctors need to teach new physicians and improve patient safety by simplifying the process of identifying the target tissue. .

II. MATERIALS AND METHODS

A. Tactile Needle: Hardware Design

The sensor holder and the sensor lid make up the device's two hardware components. These components were designed in SolidWorks and then 3D printed with an Ultimaker 3. The sensor holder was designed around the geometry of the load cell (Fig. 1).

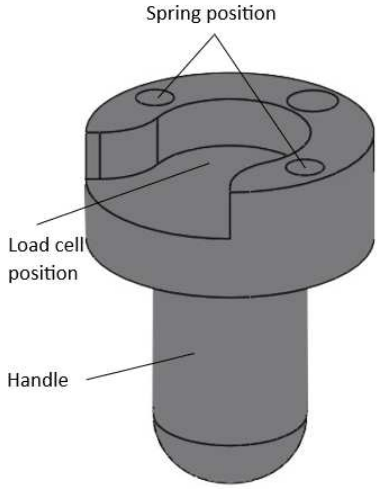

Fig. 1. CAD drawing for the needle sensor holder.

It consists of a half circle with a rounded edge to accommodate the load cell. This allows the main body of the load cell to be placed in the circular cut-out whilst, the elongated section of the load cell can be directed to the exposed end of the circle. This enables the load cell to be easily installed and removed, while also allowing the wires to escape. A handle was also incorporated to provide the user a comfortable way to hold the device. The shell around the cut-out was enlarged to include two shallow holes that can hold the springs that connect the sensor lid to the sensor holder.

The sensor lid (Fig. 2-A) contains an extruded cylinder in the middle which is designed to be the contact point of the load cell. Therefore, when the needle is inserted, the springs compress until the extruded cylinder touches the load cell which provides a reading. Like the sensor holder, there are two shallow holes which are to house the same springs. However, once printed it had the same issue as the sensor holder which was the large size.

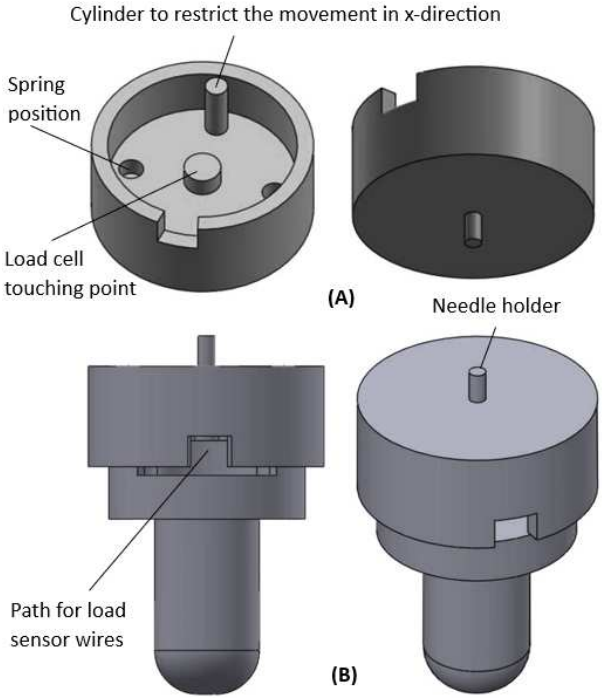

Fig. 2. The tactile needle device: (A) sensor lid, (B) assembly of the sensor holder and lid.

The sensor lid was designed with a 4mm shell with an additional extruded part included which is complementary to the hole in the sensor holder. This was designed to restrict the movement of the device in the x-direction only because the two springs alone would have allowed unnecessary movement in the y-direction. Finally, on the external part of the lid, a small cylinder was extruded out which was designed to fit the epidural needle. This eradicated the need to attach a syringe tip and made the new design appear sleeker. An assembly of the design is illustrated in Fig. 2-B, which demonstrates the overall appearance of the device.

TABLE I. THE LAYERS OF TISSUE IN THE EPIDURAL LUMBAR AREA AND THE FORCE REQUIRED TO PUNCTURE THEM WITH A NEEDLE [17].

Tissue	**Human puncture force (N)**	**Thickness (mm)**
Skin	6.0372	10.8
Fat	1.974	2.8
Muscle	4.354	1.9
Interspinous Ligament	7.467	18
Ligament Flavum	12.1330	7.4
Epidural Space/Subdural Tissue/Dura-mater	2.437	8.6
Bone	8.0265	-

Two stainless-steel compression springs with a 0.08N/mm spring rate were used to allow the sensor lid to push down onto the load cell when a force is applied onto the needle and then to spring back to its original height. A low spring rate was crucial because a stiff spring would interfere with the actual force the needle was exerted to. Lower spring rates were available however, the diameter of the spring also reduced with the spring rate. This cast doubt upon the sturdiness of the spring because only two springs would be

supporting the sensor lid. Therefore, a compromise had to be met by having a low spring rate yet a diameter that can effectively support the sensor lid.

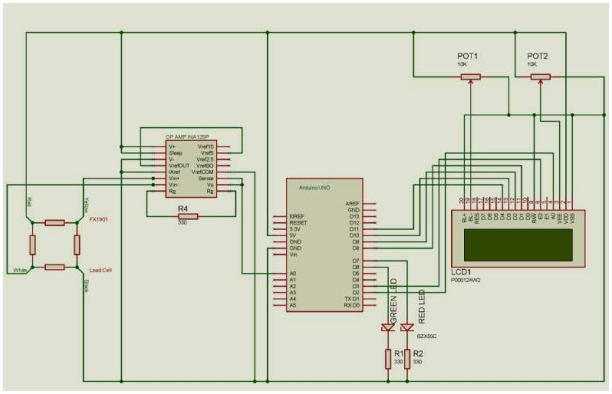

Fig. 3. Tactile sensing and feedback circuit diagram.

B. Tactile Needle: Electronics for Sensing Design

A load cell is the primary sensor to conduct the tactile feedback of the needle. Several load cell types were evaluated, with the FX1901-111N being the recommended sensor. This is because, for this application, a compressive force is being applied so the load cell must record compression and not tension. The force detected by the load cell must be adequate to withstand the force necessary to penetrate and cut through human skin and tissues. Table I depicts the layers of tissue in the epidural lumbar area and the force required to puncture them with a needle. The highest force required is 12.133 N, while the minimum is 1.974 N, for the ligamentum flavum and fat, respectively. Furthermore, the size of the sensor was critical since the total device had to be small and compact.

Fig. 3 depicts the circuit diagram, which describes how all of the components were linked. A microcontroller board (Arduino Uno) was used to process the load cell signals, establish a threshold to activate the required LEDs, and show the force reading on an LCD module. An operational amplifier (INA125P) was added to raise the voltage differential between the load cell's inputs while suppressing the common voltage.

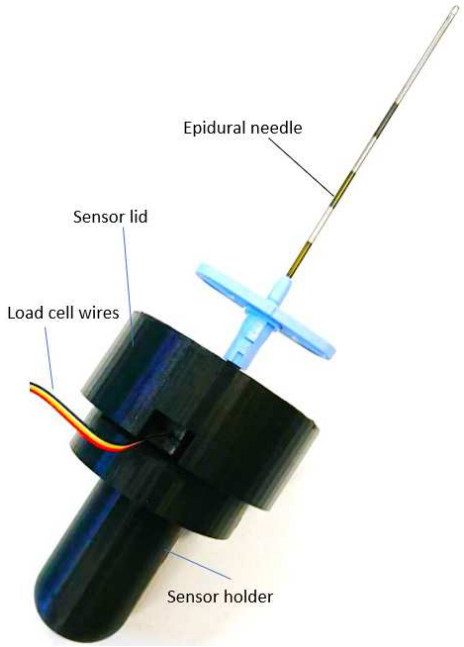

Fig. 4. A complete assembly of the tactile sensing device including the Tuohy epidural needle.

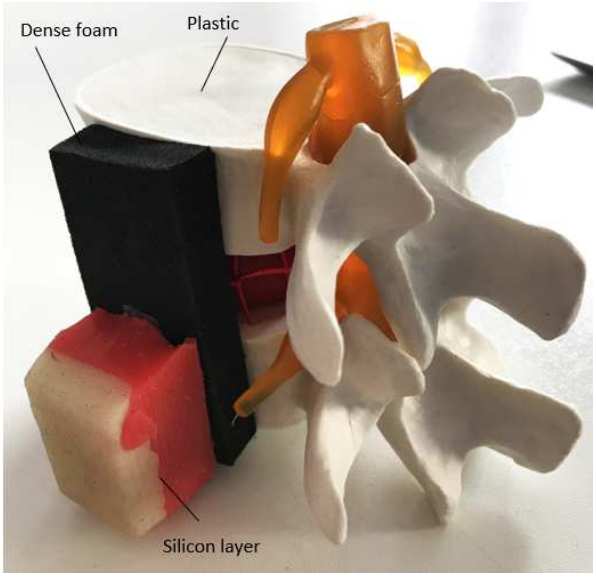

Fig. 5. Spine model with three layers, silicon, dense foam, and plastic.

To let the user know if the needle is in the right tissue, red and green LEDs were employed. To pierce and cut through tissue, a Smiths Medical Tuohy epidural needle size 16G (O.D 1.6 mm, I.D 1.15 mm, length 80 mm) with a bevel tip was utilized (Fig. 4). The power supply for this board was a 9V battery. The suggested input voltage range for an Arduino is between 7 and 12 volts, thus it is appropriate to power one. The load cell values were displayed on an alphanumeric LCD display. Electrical connections were made using a breadboard and a jumper wire kit.

It became clear that calibrating weights were needed as the investigation progressed. When no force was applied, the load cell had a significant offset, therefore the Arduino code needed to be adjusted once a known weight was supplied. The Neewer 1000g Precision Calibration Weight Kit Set, which included a variety of weighted stainless-steel components, was the weight set that was selected. In the end, a lumbar disc herniation model served as the spine model for the device's testing phase.

III. RESULTS AND DISCUSSION

To determine this product's efficacy in a true epidural injection, it would be ideal to do in-vitro testing. It would not be safe to do so at this time, though, as it is still a prototype. Rather, a lumbar spine model was used to test it by placing the needle into it. Three layers were used to make the model of the lumbar spine: silicone for the soft tissue, dense foam for the layer of tougher tissue, and plastic for the bone (Fig. 5).

The needle was inserted into the model at random speeds and angles to mimic the variation of real-life spinal injections. The test was repeated five times to prove intersession reliability, with the average force of each layer recorded along with the corresponding LED colour.

According to Table II, the product was effective in terms of tactile feedback since the forces varied depending on the composition of the layer. Each layer displayed the desired colour; nevertheless, the colours might sometimes fluctuate.

For example, the primary light in the second layer is green, but as the needle approaches the end of that layer, it becomes red before reaching the bone. This margin of error might be the difference between the correct and wrong tissue, which could have serious repercussions. The gadget can only receive feedback when it is going forward since the load cell only detects compression. The device cannot acquire readings while being taken out; so, if the needle is pushed too far, it must be reinserted to obtain precise results.

TABLE II. RESULTS OF THE INSERTION OF THE NEEDLE INTO THE SPINAL MODEL LAYERS

Material (Layers)	Average Force (N)	LED Colour	Desired Colour
Silicone tissue	2.215	Red	Red
Dense Foam	3.887	Green, but towards the end the red light turns on	Green
Spine Model	5.382	Green but when enough force is applied it turns red.	Red

Since the prototype is used to penetrate through tissue models at this stage of the study, it needs to be strong enough to withstand forces from the artificial layers used for testing. For the device, a simulated in-vitro environment was used to conduct a Finite Element Analysis (FEA) (Fig. 6). The needle received a force of 12.13 N, the highest force ever seen during an epidural operation. Because the greatest stress exerted is 1.3 MPa, which is significantly less than PLA's 17.9 MPa compressive strength, the FEA study demonstrates that the material and form of the components are robust for their intended function.

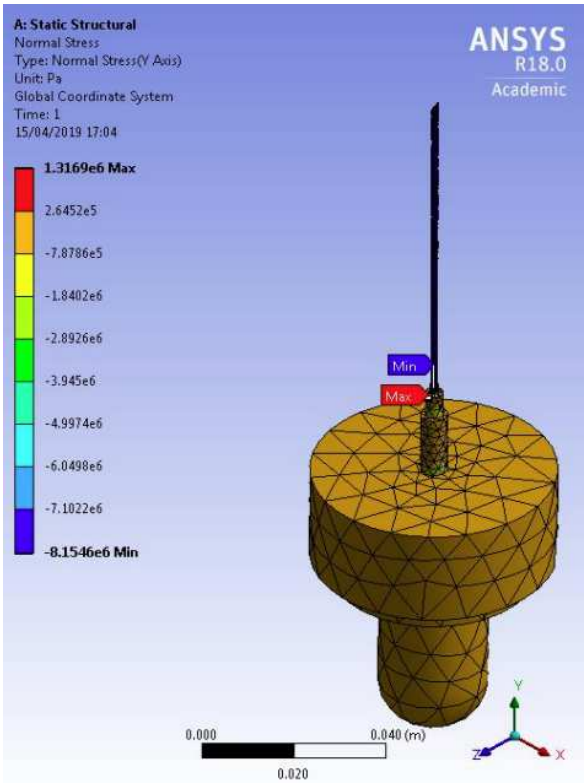

Fig. 6. The Finite Element Analysis of the tactile sensing device.

The quality of the PLA materials used in 3D printing the tactile sensor is good; however, the attachment of the sensor holder to the sensor lid could be improved because it is only held together by two glued springs. This allows the sensor lid to shake because the springs allow movement. In addition, when removing the needle device out of the tissue, the sensor lid must be held otherwise the springs could stretch too far and damage the device.

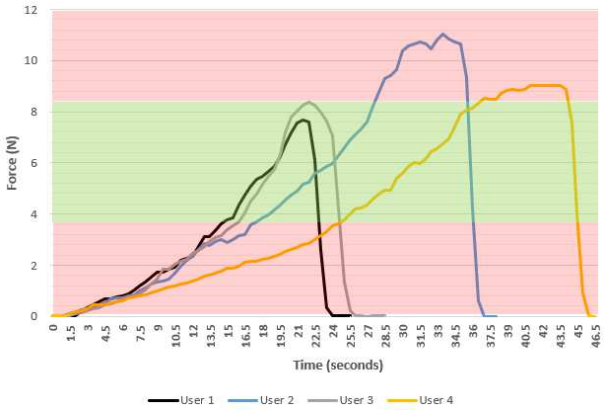

Fig. 7. Testing of the insertion of the tactile needle devise into the three layers of the spinal model by four users.

Four users placed the device into the testing model, and the force was plotted on a graph to determine the intra-observer reliability (Fig. 7). In order to rate and remark on the user-friendliness, the users also filled out an anonymous survey; the results are displayed in Table III. Upon studying the graphs, they find that because the graph patterns were so similar, each user received force outputs that were comparable to one another. The bone layer was where the most force was found; however, some users' maximum recorded forces were as high as 10.67 N and as low as 7.56 N. This varied depending on how quickly the user put the needle into the model; some users completed the test in 24 seconds, while others needed 36 seconds. This indicates that the device differs depending the technique of the user.

To guarantee that each operator uses the device consistently, a standard procedure would need to be established. Overall, user feedback was quite good, with the most common comment being how easy it is to use. Users felt that the LED system was a useful guide for them to find the right tissue. The device can only be operated in one direction, and the load cell did not always return to zero after usage, were some issues.

TABLE III. SURVEY OF THE INSERTION OF THE NEEDLE INTO THE SPINAL MODEL LAYERS BY THE FOUR USERS

User	Feedback	Grading (out of 10)
1	Very easy to use, LEDs are a good indicator	8
2	Doesn't always calibrate back to zero	7
3	Sensor is very sensitive and accurate, no issues with device	9
4	Easy to use, can only use in one direction (forward	8

The instrument can only take readings when going forward, towards the tissue. As a result, the instrument must be reinserted into the tissue to obtain correct readings, which is inefficient. A solution might be to use a load cell that measures both compression and tension, such as the DCE -

Compression & Tension load cell [13]. As a result, when the device is withdrawn from the tissue, the load cell detects the tissue's tension rather than compression. The attachment of the sensor holder and sensor lid is an issue since it is only attached by two springs, which reduces stability and causes the lid to wobble.

IV. CONCLUSION

Back pain is a common issue that affects many people. Current treatments, such as epidural injections, can provide relief but are not always accurate and safe. A new device using tactile feedback and LED guidance has been developed to help doctors identify target tissues more precisely. Testing on a spinal model showed promising results, with users finding the device easy to use. However, improvements are still needed to ensure consistent performance, such as adding the ability to measure tension and improving the device's stability. Overall, the new device has the potential to improve the accuracy and safety of epidural procedures, making it easier for medical professionals to identify and treat the right tissues. In the future, an animal spine will be used to calibrate and test the prototype.

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