

Smart syringe using actuator and force sensor for epidural anesthesia injection

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Abstract

The anesthesia process in the epidural space is quite difficult as it requires a high level of skill. Therefore, a medical accident occurs, and intensive training is required. In order to reduce these medical accidents, medical technology is being developed, which provides safe and accurate treatment services. This paper proposes a smart syringe design for safe and accurate anesthesia in the epidural space. The smart syringe is designed to measure the electrical sensing waveform by using a sensor instead of the sense of the hand during anesthesia and show the position of the needle through external monitoring. To design a smart syringe, a force sensor, actuator, and CPU were used, and a 3D printer was used to produce the outer shape. An animal test was conducted to evaluate the performance test of the smart syringe, and satisfactory results were obtained by measuring the needle insertion process of the smart syringe and the position of the needle through the animal experiment.

Keywords

Smart syringe, epidural space, actuator, force sensor, injection

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Introduction

In the epidural space anesthesia process to manage pain in the surgical procedure, accurate drug injection is very important. Incorrect drug injection can cause damage to the spinal cord, nerves, spinal cord, CSF leak, etc., and in severe cases, death.^{1,2} Therefore, epidural space anesthesia and pain treatment must have accuracy and high proficiency.

Automatic control medical technology for quantitative drug injection and accurate and safe syringe needle insertion is a trend that can reduce medical accidents. Automated systems for injecting drugs in syringes include electrostatic liquid pumps, thermopneumatic liquid pumps, piezoelectric liquid pumps, boiling liquid pumps, EHD liquid pumps, electrolysis liquid pumps, and micropumps.^{3–8} In this case, the electrostatic and piezoelectric driving methods are capable of high-speed response (ms).^{3–6} However, since the operating voltage (10 V/20 s) is very high,³ it is not suitable for the use of a vascular endoscope.

Thermo-pneumatic and boiling methods can operate at a voltage as low as 1 kV (30 s).⁴ However, they generate a lot of heat. Although the EHD method has a simple structure and is easy to manufacture, it is not suitable for drug

injection due to limiting factors such as viscosity and dielectric properties of the pumping fluid.^{7,8}

The electrolysis method uses gas pressure as a driving force source through an electrolysis reaction of an electrolyte.⁹ Therefore, since the electrolysis method uses a low

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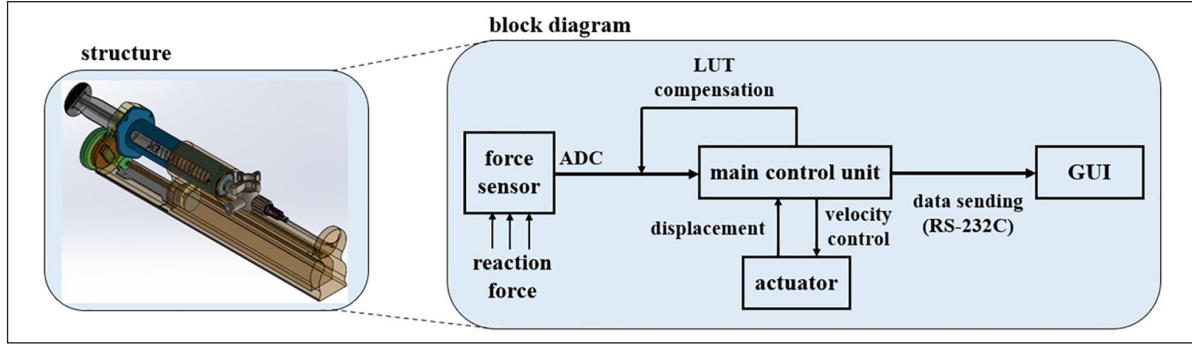


Figure 1. Components for the operation of the smart syringe.

voltage, a large displacement can be obtained and the flow rate control is easy, but the electrolysis method has a complicated structure and a slow response speed because it is repeatedly driven through a reverse reaction. The common characteristics of the automated drug injection system are that the semiconductor processing unit cost is high, bulky, and heavy, and it is not easy to use in a limited space in the medical field. An automated system for epidural space anesthesia should be inexpensive, small in volume, and easily portable. In addition, accurate drug injection must be possible, and the drug injection volume must be constant. An important element of drug injection for epidural space anesthesia is that the operator should feel the sensation at the fingertips through the tool.

This study proposes a handheld type of intelligent automatic drug injection syringe system for accurate and safe drug injection in Epidural. This handheld type of automatic drug injection system is small in size, light in weight, and easy to carry. In addition, the characteristic of the system is to control the mechanical force with the amount of current using the actuator.

Design methods and operation process

The proposed smart syringe system is composed of force sensor (FSS010WNSX), ADC component, LUT compensation part, main control unit, actuator, GUI, velocity control part, and data sending unit as shown in Figure 1. From the figure, the data sending part is used for RF-232C (communications cable: MAX232), and the voltage and frequency of a CPU (arduino pro mini) is operated by 5 V and 16 MHz, respectively. The actuator is used for stepper motor driver (drv 8872). Then, the actuator is used to move the syringe forward or backward.

The simple structure of the spinal cord where epidural space anesthesia is performed is shown in Figure 2. From the figure, the structure of the spinal cord through which the nerves of the human body pass are covered by several muscular membranes such as skin, supraspinous ligament, interspinous ligament, ligamentum flavum, and dura mater. At this time, anesthetic drugs are injected into the epidural space (2 mm). Assuming that a smart syringe

developed for drug injection in the epidural space will be used, whenever the needle passes through the muscle membrane, the developed smart syringe cannot sense the human hand, so it detects the pressure against the resistance of each tissue and detects the external pressure. Through monitoring of the needle, the position (tissue) of the needle should be expressed in the form of a signal.

Smart syringe controls needle position and insertion using force sensor, linear actuator (load cell) and CPU as shown in Figure 2 and equations (1)–(3).^{9–11} At this time, when the needle of the smart syringe passes through the skin, the force sensor (pressure sensor, F_{ps}) senses the pressure (friction of force, F_{fr}) because of the high resistance to the density (m) of the epidermis, and then transmits the data to the CPU. The CPU transmits a control command signal (current) to the actuator.

$$F_T = mx = F_{AF} - F_{CF} - F_{fr} \quad @ \quad F_T : \text{total force} \quad (1)$$

$$\frac{dF_{af}}{dt} = \frac{\partial F_{fr}}{\partial x} \cdot \frac{dx}{dt} + \frac{\partial F_{CF}}{\partial x} \cdot \frac{dx}{dt} \quad (2)$$

$$\frac{dF_{af}}{dt} = C \cdot \left(\frac{\partial F_{fr}}{\partial x} + \frac{\partial F_{CF}}{\partial x} \right) \quad (3)$$

The actuator in which the current value is input outputs a mechanical force (applied force, F_{af}) so that the needle can penetrate the skin more strongly ($x \mu\text{m}$). Therefore, the variation value for force (cutting force, F_c) becomes the maximum value ($x = \text{constant } C$) to show the state that the needle is piercing the skin. When the needle passes through the skin, the supraspinous ligament has a low density and resistance, so the current value of the actuator is lowered, so the force that the needle penetrates ($x=0$) is weakened. Therefore, the needle easily passes through the supraspinous ligament, and the speed of needle passage ($x \mu\text{m}$) is low. When the needle meets the interspinous ligament, the high resistance causes the needle to pass strongly, generating a large amount of current in the actuator. At this time, the change in force shown in the graph becomes the maximum value. This phenomenon is repeated until the

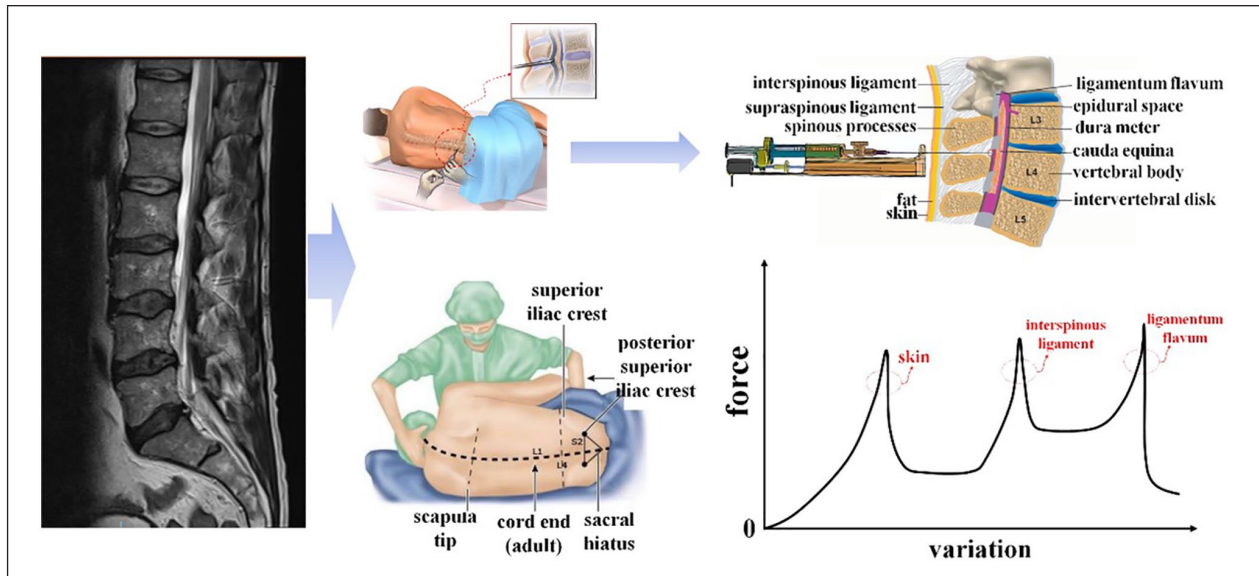


Figure 2. Smart syringe operation and anesthesia process.^{10–13}

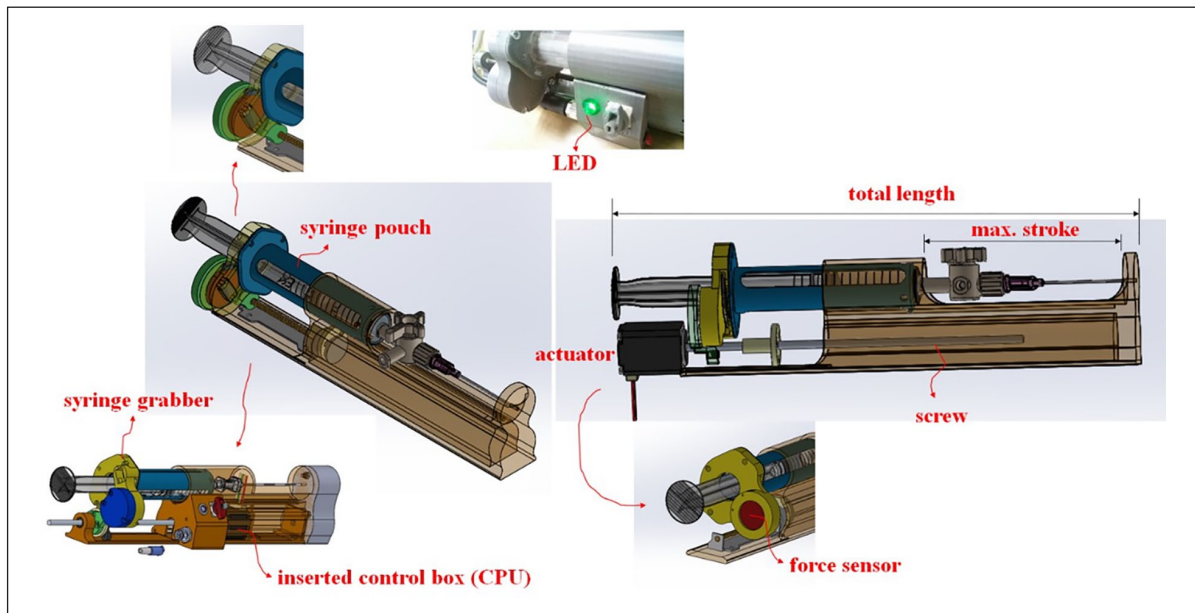


Figure 3. Design of a smart syringe.

ligamentum flavum. When the needle reaches the epidural space with low resistance, the force change is reduced to a minimum value, and the force sensor and actuator stop working. The smart syringe then starts injecting the drug into the epidural space.

Fabrication

The smart syringe was manufactured using a 3D layout tool as shown in Figure 3, and the size is 185 mm (total length) and 60 mm (maximum stroke). From the figure, the syringe is wrapped around the grabber and pouch, and the control box is

inserted into the instrument unit. The actuator and force sensor devices are connected to the outside of the smart syringe. The smart syringe is equipped with an LED indicator to notify the injection when injecting the drug. The syringe has a capacity of 10 cc and the needle size is 22 G (80 mm).

Figure 4 shows the actually manufactured smart syringe, and the syringe was manufactured using 3D printing technology. Then, the weight of the syringe is 150 g. When the switch is pressed, the force center, actuator, and CPU are operated. At this time, when the force sensor detects tissue density and resistance and transmits it to the CPU, the CPU sends a control signal to the actuator. Therefore, the actuator

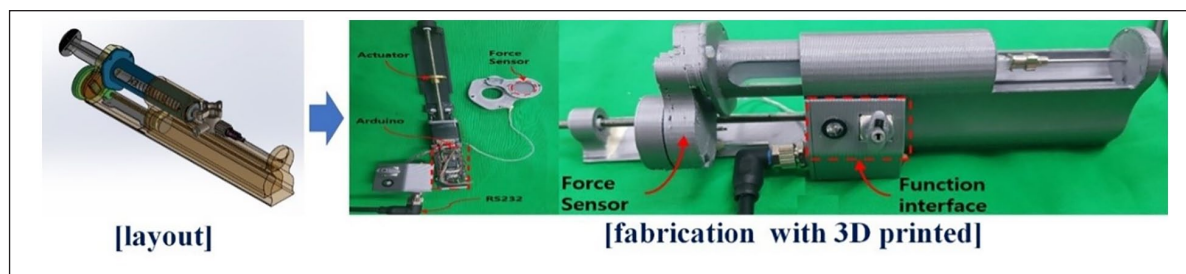


Figure 4. Fabrication of a smart syringe using 3D printer.

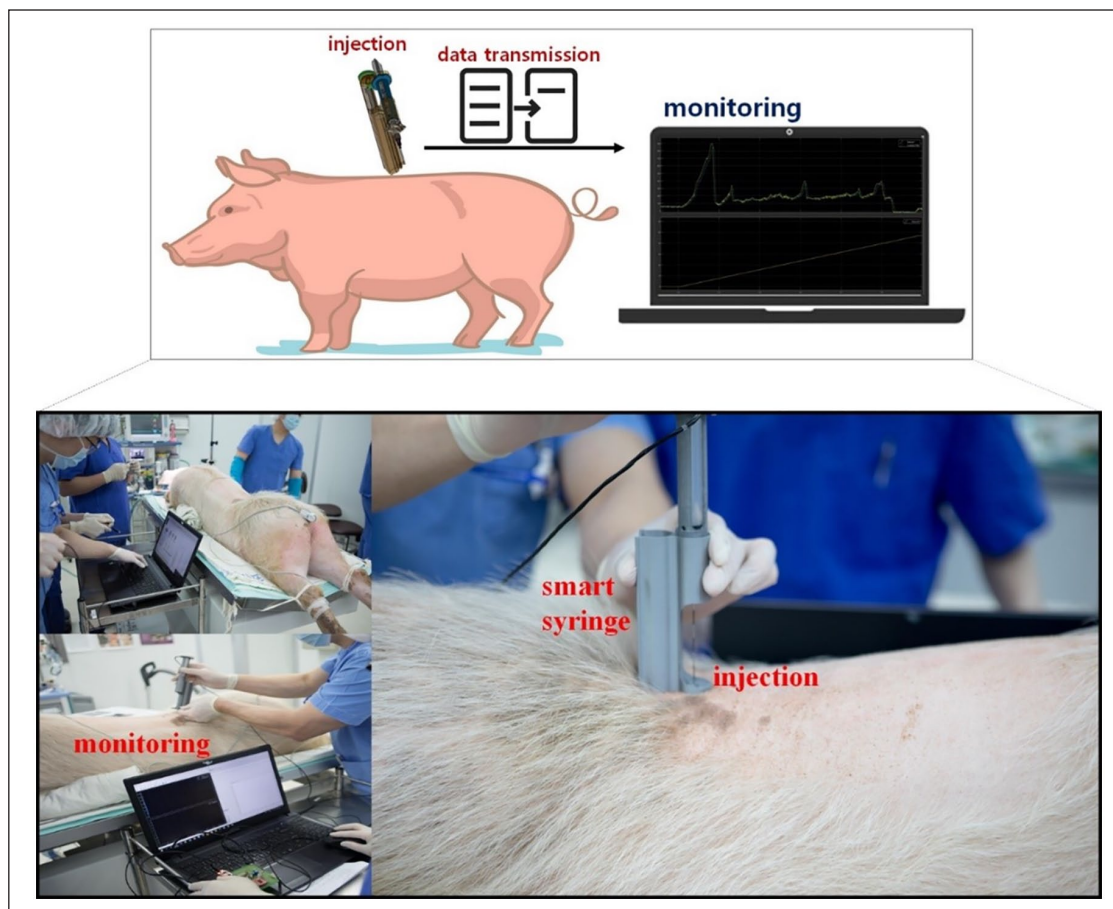


Figure 5. Large animal test (conventional pig).

obtains the current value for the control signal and converts it into a physical force value, and the actuator rotates the screw (2mm/s) to move the needle forward.

The voltage for operating the CPU, actuator and force sensor is 7.2mV, and the force sensor can detect force in the 0–5N range.

Animal test and measurement result

To evaluate the smart syringe performance, a large animal experiment was performed as shown in Figure 5. The animal was tested from the experimental animal center of

Osong Medical Innovation Foundation, KBIO (Osong Medical Innovation Foundation, KBIO).

We animal institutional review board (IRB) permission request to animal ethics commission (KBIO-IACUC-2019-021). In the animal test, the animal test is used for conventional-type pig (Farm) of male (1 ea) which weight is 60 kg.

The animal test results of the smart syringe are shown in Figure 6. When the needle passes through the skin, the pressure rises to the level of 191 gF and then stays at 200 gF ($\chi=0$). As the needle passes through the tissue and approaches the supraspinous ligament and interspinous ligament, the pressure

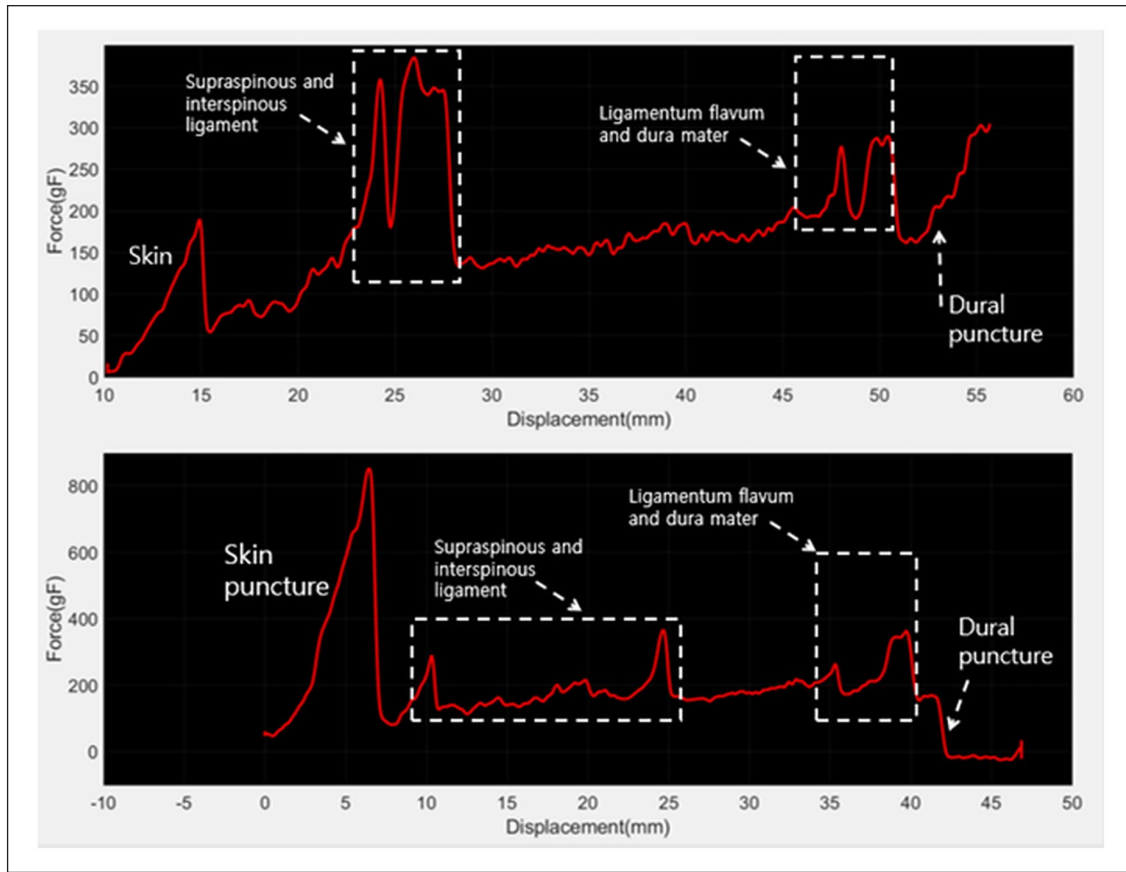


Figure 6. Measurement results for smart syringe using animal test.

obtained by the needle rises to 351 gF and then stays below 200 gF again. When the needle continues to pass through the tissue and reaches the ligamentum flavum and dura mater and dural puncture, the force values reach 280 and 290 gF, respectively, and then the force on the tissue drops to 200 gF or less, and the needle reach the epidural space. At this time, the smart syringe injects the drug when x of the epidural space is 0.

To verify the reliability of the developed system's performance, the system was subjected to three real-time experiments. Therefore, reliability and safety were good, and very good results were obtained. The accuracy of the results is more than 94%.

Discussion

The paper proposes a smart syringe for anesthesia in epidural space. For accurate and safe anesthesia in epidural space, we design a smart syringe system that can inject drugs using the correlation between force sensors and actuators and the reaction force against resistance of tissue density. Because this system is a highly sensitive local anesthetic, it requires high reliability in operation. Therefore, in order to increase reproducibility and accuracy in the process of animal experiments, it is essential to

repeat the experiment three or more times. This system is easy to use during anesthesia practice time and can be used in the clinical field of anesthesia process.^{14,15}

The developed system can detect the position of the needle by observing the measured waveform instead of the sensation obtained from the actual hand when the needle penetrates the tissue.

To be more specific, the developed smart syringe is not a robot that inserts needles automatically. The developed smart syringe is for an anesthesiologist to directly hold and administer injection treatment. The syringe system is therefore equipped with an auxiliary force-sensing sensor. So, it has a similar tactile feel to the existing injection treatment. Therefore, the injection treatment between TH2-TH13 and L2-L5 will not be much different from the existing injection treatment method because the anesthesiologist directly judges the needle and inserts it. It has the advantage and feature of being able to observe the flow and force sensing information for needle insertion through external monitoring.

In addition, the system should consider the injection process and injection location, as well as the reference of the developed smart syringe. Before using the smart syringe, you must first secure the epidural location for injecting the drug. After that, the smart syringe allows the needle to reach the

epidural space through the dura (interspinous ligament and dura mater) between the vertebrae for injection.^{16,17}

At this time, the needle of the smart syringe is inserted through the dura located between L2 and L5. The reason is that the space between the vertebrae between TH 3 and TH12 (upper vertebra) is narrow. Therefore, smart syringes are difficult to insert needles between the vertebrae. Therefore, needle insertion favors the lower vertebra with a wide dura space between the vertebrae. In particular, needle insertion is much favored between L3 and L4 or between L4 and L5.^{17,18}

In the process of anesthesia, it is practically difficult for older patients to insert the needle into the syringe because of the deformation of the vertebral bones. For this reason, when the needle is inserted, the injection drug is administered through fluoroscopy guided monitoring. Therefore, the developed smart syringe should also refer to injection drug injection through fluoroscopy guided for patients with deformed vertebrae.

This study tested the performance of a syringe developed through animal testing. After anesthesia, side effects that differ depending on the patient may include headache and back pain caused by the flow of cerebrospinal fluid during anesthesia, and accidental nausea and vomiting after surgery. Also, during anesthesia, temporary sequelae such as headache may occur due to the reason that the fine fibrous connective tissue between the brain and the dura is pulled. At this time, if the patient's blood is collected (10 cc) and injected into the epidural space of the anesthetized area, the effect of headache disappearing can be obtained. Considering these considerations, there is a need for supplementary research on safety/reliability for clinical trials and patients in a state that sufficiently considers side effects and sequelae of patients in the future. In addition, the future task of the system is to collect data according to individual differences such as race, body type, gender, and weight, and then clinical trials and medical device licensing processes are required.

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Declaration of conflicting interests

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