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An intraoperative lumbar neurological force monitoring system with high-density flexible pressure sensor array①

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Abstract

In the surgery of lumbar disc herniation (LDH), the nerve root retractor is used to pull the nerve root to prevent damage. The traditional medical nerve root retractor cannot quantify the force on the nerve root. In order to improve the nerve root retractor, this paper proposes an intraoperative lumbar neurological force monitoring system. The core module of this system is the improved nerve root retractor equipped with the high density flexible pressure sensor array. The high density microneedle array and multiple pressure detection units are used in the pressure sensor to realise sensitive pressure monitoring in a narrow surgical operation area. The sensing area is 4 mm × 17 mm, including 6 detection units. The sensitivity of sensor is 67.30%/N in the range of 0 – 5 N. This system is used for in vitro animal experiments, which can continuously detect pressure.

Key words: nerve root retractor, flexible sensor, force monitoring, lumbar disc herniation (LDH) surgery

0 Introduction

Lumbar disc herniation (LDH) is a common clinical disease that seriously affects people's daily life and work. The causes of LDH are that the lumbar annulus fibrosus injury causes the nucleus pulposus to degenerating, bulging or protruding to where the annulus fibrosis tore[1]. LDH can lead to sciatic nerve or cauda equina nerve injury, lower limb numbness and sexual dysfunction, and in severe cases paralysis. Surgical treatment is widely used in patients with LDH. Surgical treatment can minimize soft tissue destruction and relieve patients' pain more quickly and effectively[2,3]. The nerve root retractor is a necessary instrument for the surgery of LDH such as marrow nuclear excising surgery and lumbar spinal fusion[4,5], whose role is to fully expose the field of vision during the surgery to remove the prominent nucleus pulposus or to implant the artificial nucleus pulposus and the lumbar interbody fusion cages in the intervertebral space to prevent serious damage to the nerve. The nerve root retractor must be used to periodically pull the nerve root to the opposite side of the surgery's operation area[6]. The nerve root operation area is only 1.5 cm × 2 cm, which is extremely narrow, so it is easy to damage the nerve root due to improper operation.

The force and time to pull the nerve root are important factors of the success of lumbar surgery. However, the traditional medical nerve root retractor cannot measure the force on the nerve root, so surgeons have to rely on their long-term accumulative experience to judge the nerve root tension and location to avoid injuring the nerve root in surgery, rather than referring to the accurately quantified force[7]. Insufficient or excessive pulling will effect on the operation of the surgery; insufficient pulling of the nerve root will not fully expose the surgical field of view which bring great difficulty in the surgery, while excessive pulling of the nerve root is easy to cause iatrogenic neurological injury[8], resulting in failed back surgery syndrome (FBSS). Moreover, the traditional nerve root retractor cannot dynamically monitor the damage of the nerve root in real time. Hence, during the surgery, the surgeons need to interrupt the surgery several times to monitor the degree of nerve root damage, resulting in long

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surgery time and low surgery efficiency. The traditional method for judging nerve root damage is to use tissue staining or stimulate the nerve root with stimulating electrodes and record the nerve root afferent signal and efferent signal with recording electrodes. Nerve electrophysiology testing cannot quantify the force on the nerve root. To improve traditional methods, the Vioptix company patented a nerve root retractor with oximeter to measure blood-oxygen saturation and compare it with the expected range to determine the nerve root state, so that appropriate adjustments can be made until the oxygen saturation pair returns to the desired range[9]. The patent can only make a simple judgment on the degree of nerve damage, but cannot quantify the nerve root force. Micro electromechanical system (MEMS) pressure sensors are widely used in medical instruments due to their small size, high sensitivity and good integration. Liu et al.[10] proposed a nerve root retractor with a pressure sensor by using an integrated MEMS silicon piezoresistive pressure sensor, where silicone rubber is used as the main packaging material. This pressure sensor can only perform a fixed direction pressure monitoring, which cannot fully and accurately reflect the specific force and limit the direction of use of the nerve root retractor. In general, the products and researches of nerve root retractors equipped with flexible pressure sensors are currently few.

Pressure sensors can be classified into resistive[11,12], piezoelectric[13,14] and capacitive types according to their working principles. The capacitive pressure sensor has a good application prospect due to its high sensitivity, simple preparation process, small temperature coefficient, stable output, low power consumption, and good dynamic response[15]. Jang et al.[16] proposed a sensor based on silicon-based MEMS process, with aluminum as the electrode layer and silicon as the support structure, which is easy to hurt people. Lee et al.[17] proposed a capacitive pressure sensor array prepared by paper, Polydimethylsiloxane (PDMS) and graphene. However, due to the different Poisson's ratio and elastic modulus of paper, PDMS and graphene, large deformation will result in a short life of the sensor. Liang et al.[18] proposed a capacitive flexible pressure sensor but the sensor had only 4 sector-shaped measuring electrodes, for which the measuring electrodes are too few. This paper designs a sensor made of flexible materials such as PDMS and flexible printed circuit board (FPCB). PDMS can get a high tissue affinity because it is non-toxic, high chemical stability, and biocompatibility. Moreover, the flexibility and the Young's modulus of PDMS can be changed by adjusting the components. FPCB is selected to be flexible material considering its flexibility and high mechanical strength. Furthermore, even if the designed sensor is small, the density of the detection units is quite large.

In summary, the existing nerve root retractor used in lumbar spine surgery is not perfect, it cannot measure the force of pulling nerve root or it is limited on measurement accuracy. The intraoperative lumbar neurological force monitoring system will be researched in this paper, including the high-density flexible pressure sensor array and the intelligent nerve root retractor. It is of great significance to accurately measure the nerve root stress to avoid the FBSS and improve the success rate of surgery.

1 Design

As shown in Fig. 1, the main components of the intraoperative lumbar neurological force monitoring system are the high-density flexible pressure sensor array and the nerve root retractor. The nerve root retractor is used to pull the nerve root intraoperatively. The flexible pressure sensor is used to detect the pulling force on the soft nerve root in real time, and the multi-detection units of the sensor are used to finely quantify the force. The sensor is mounted on the head of the nerve root retractor, and the data processing FPCB of the sensor is assembled in the window of the improved nerve root retractor. The upper computer software displays the force value, the force time and the force curve of the nerve root in real time.

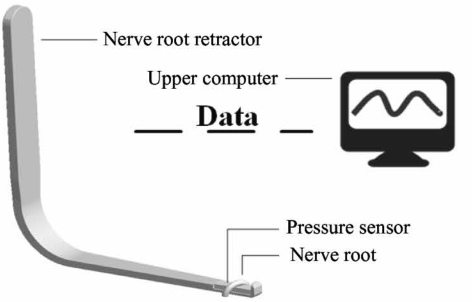


Fig. 1 The intraoperative lumbar neurological force monitoring system

1.1 The flexible pressure sensor array

As shown in Fig. 2, the flexible pressure sensor is composed of 4 functional layers: the protective layer, the sensing layer, the pressure-sensitive layer and the analysis layer. The sensor is of capacitive structure, wherein the sensing layer is upper electrode layer for sensing the pressure received by the sensor; the pressure-sensitive layer is a dielectric layer for transmitting the pressure received by the sensing layer; the analysis layer is a lower electrode layer for analyzing and calculating the pressure transmitted by the pressure-sensitive layer; the protective layer is a packaged layer enclosing the whole sensor for isolating the body fluid and protecting the sensor.

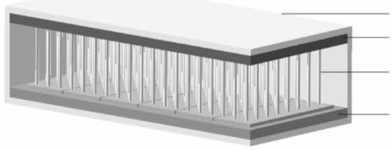
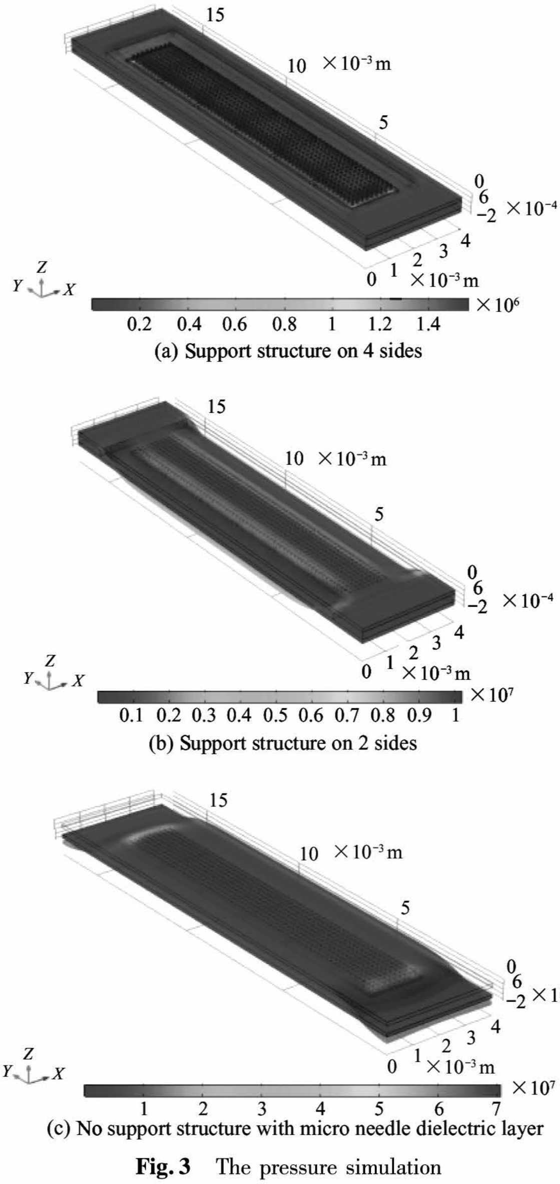


Fig. 2 The structure of the flexible pressure sensor

The sensing layer is made of conductive fabric with good electrical conductivity and flexibility, and is designed as a rectangular of 4 mm × 17 mm area.



(a) Support structure on 4 sides

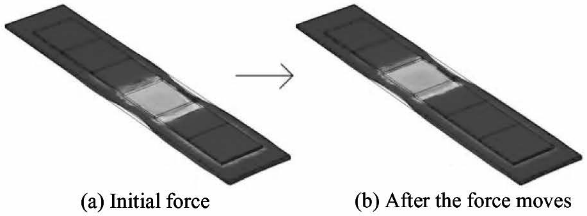
(b) Support structure on 2 sides

(c) No support structure with micro needle dielectric layer

Fig. 3 The pressure simulation

The pressure-sensitive layer determines the sensitivity of the sensor. The pressure-sensitive layer is made of PDMS and designed as a high density cylindrical micro-needle array. The height of the micro-needle is 280 μm and its radius is 25 μm and the density of micro-needle array is 2 500 dots/cm^2. The micro-needle array can quickly return to the initial state after the pressure is removed, which has stability. The micro-needle dielectric layer combines the advantages of the air dielectric layer and the PDMS block dielectric layer, and can keep both good sensitivity and long service life[19]. Through COMSOL multiphysics simulation, it can be seen that the maximum force of the microneedle array without the support structure is the largest, as shown in Fig. 3. Besides, adding the support structure around the microneedle array can make the force distribution more uniform and extend the service life of the sensor compared to the microneedle array without the support structure. Therefore, a micro-needle array with support structure is adopted in the design.

The analysis layer is made by the pad of the FPCB. The analysis layer has 6 detection units, and the area of each unit is 2 mm × 2 mm. The density of the detection units is about 9 dots/cm^2. By dividing the detection units into several regions, the main force receiving position on the sensor is obtained according to the proportion of the force applied on each detection units. With this structure, high data throughput is still ensured in a narrow area, and the multiple detection units can collect and integrate pressure information to obtain complete and comprehensive pressure information, as shown in Fig. 4.



(a) Initial force (b) After the force moves

Fig. 4 The main force position moves from (a) to (b)

The protective layer is prepared by PDMS and designed as a rectangular barrel box, as shown in Fig. 5. It plays a role of a package with excellent flexibility, sealing, anti-interference and biocompatibility to protect the sensor from damage and isolate it from body liquid.

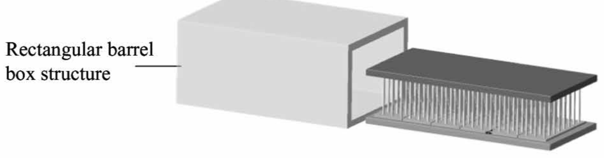


Fig. 5 The protective layer

1.2 Nerve root retractor

The nerve root retractor is made of 316L stainless steel, a kind of biomedical material, shaping like a letter "L", as shown in Fig. 6, including head, rod1, rod2 and handle, wherein the rod1 is an isosceles trapezoid; the rod2 is rectangular; the bending region of the rod1 and the rod2 is isosceles trapezoid and is a quarter circle.

The nerve root retractor is designed as a hollow structure for placing the sensor and the FPCB. The rod1 makes a 2 cm window to place the sensor. The outer surface of the sensor and the nerve root retractor's head are facing to the same direction. The exit of the signal transmission line is reserved at the handle.

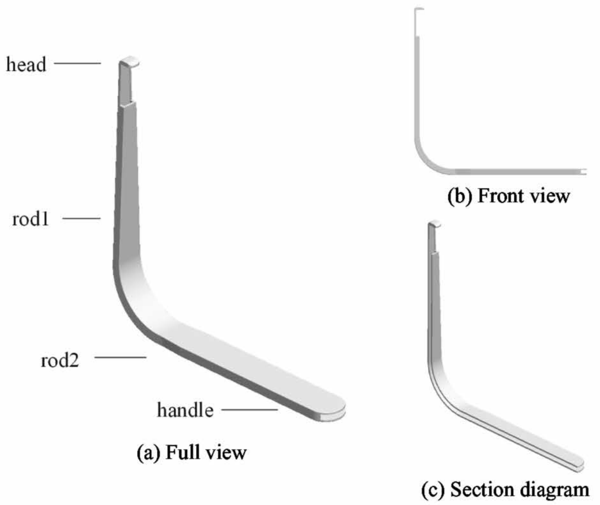


Fig. 6 The nerve root retractor

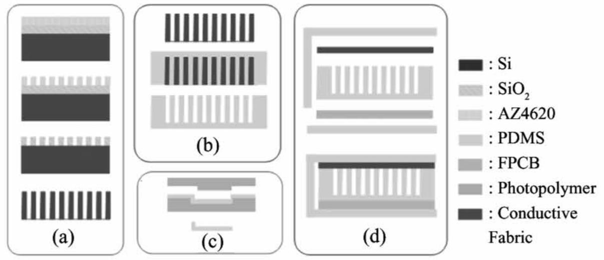
2 Fabrication

The intraoperative lumbar neurological force monitoring system is prepared by silicon-based MEMS preparation process, molding technology, and 3D printing technology.

2.1 The flexible pressure sensor array

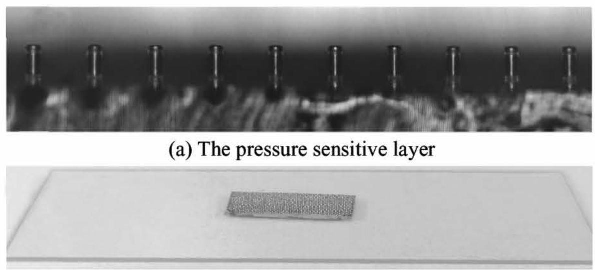
As shown in Fig. 7, they are the fabrication methods of sensor.

The flexible pressure sensor is prepared by the silicon-based MEMS preparation process and the molding technology. At first, the pressure-sensitive layer's mold is obtained by cleaning, oxidizing, photolithography, ICP and silanization of the silicon wafer. Then, the parylene is grown on the mold to facilitate removal of the micro-needle array. The ratio of PDMS basic component to the curing agent (Sylgard 184 A: B) is 20:1. PDMS is dropped on the mold, and then the mold spins coating at 600 rpm for 20 s. The PDMS-coated mold is vacuumed for 30 min to remove bubbles in the PDMS. After curing at 90 ℃ for 15 min, the pressure-sensitive layer is prepared, as shown in Fig. 8.



(a) Pressure-sensitive layer mold fabrication process; (b) Pressure-sensitive layer fabrication process; (c) Protective layer fabrication process; (d) Assembled sensor

Fig. 7 The fabrication methods



(b) The flexible pressure sensor

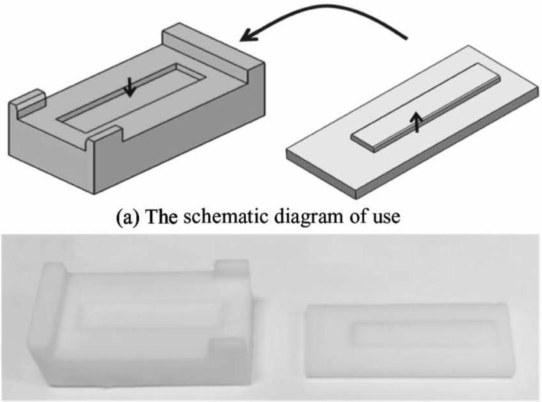
Fig. 8 Prepared sensor

The analysis layer is made by the pad of the FPCB. The FPCB also contains an AD7147, which converts capacitance to digital by sampling, quantization, digital filtering, environmental compensation, encoding, etc. The FPCB is 15.98 cm long and the narrowest is only 4 mm, as shown in Fig. 9. The 3 μm parylene is grown on the FPCB so that even if the human body fluid contacts the pad of the FPCB, short circuit and leakage will not occur.

The sensing layer, the pressure-sensitive layer and the analysis layer are bombarded with plasma stripping technology to increase the adhesion and activity of the surface, and then assembled to obtain a sensor structure.

Fig. 9 The FPCB assembled with sensor

The protective layer mold is prepared by 3D printing technology, and 3 μm parylene is grown on the protective layer mold to ensure removing PDMS easily. The PDMS is dropped into the mold, and then the upper mold presses on the lower mold, as shown in Fig. 10. The slope of the 2 columns protruding from the lower mold determines the thickness of the PDMS. After curing at 90 ℃ for 2 h, the protective layer is prepared.



(a) The schematic diagram of use

(b) The prepared lower mold (c) The prepared upper mold

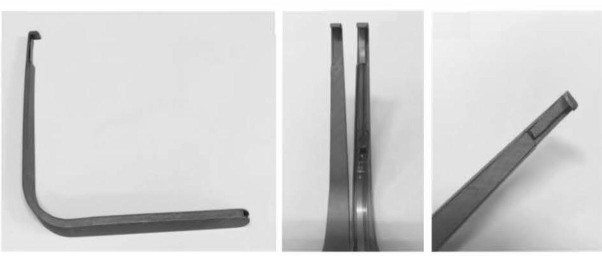
Fig. 10 The protective layer mold

2.2 The nerve root retractor

The nerve root retractor is prepared by metal 3D printing technology. 10 μm parylene is grown on the surface of the nerve root retractor equipped with the sensor as a signal isolation layer to isolate the interference between the biological signal and the sensor signal.

PDMS is dropped in the window of the rod1 of the nerve root retractor and cures at 90 ℃ for 15 min. Then, the plasma stripping technology is used to bombard the protective layer, the assembled sensor and the PDMS of the rod 1. The assembled sensor and the PDMS on the rod 1 are bonded, and the protective layer and the nerve root retractor are also bonded. Finally, 3 μm parylene is grown on the surface of the system.

Through a series of processing preparations above, the intraoperative lumbar neurological force monitoring system is obtained, as shown in Fig. 11.



(a) Full view (b) Section diagram (c) View of sensor

Fig. 11 The intraoperative neurological force monitoring

3 Measurement and discussion

Apply the pressure of 0 – 5 N (1 MPa) to the flexible pressure sensor with the weights. The initial value of the sensor output is 0.018 pF. Fig. 12 shows the *F-C* fitting curve, in which the result indicates that the sensitivity of the sensor is 67.30%/N in the pressure range of 0 – 5 N. Table 1 shows the static parameters of the sensor.

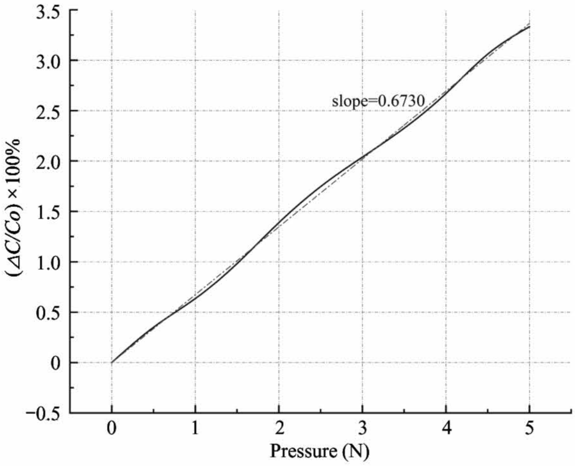


Fig. 12 The *F-C* fitting curve

Table 1 The static parameters of the sensor

Performance	Parameter
Area of the sensor	4 mm × 17 mm
Area of each detection units	4 mm^2
Range	0 – 5 N
Initial *C*	0.018 pF
Sensitivity	67.30%/N
Resolution	0.05 N
Nonlinearity error	1.52%
Repeatability error	2.12%
Aging error	2.78%

The in vitro animal experiments with sheep spine are performed using the proposed nerve root retractor equipped with a flexible pressure sensor, as shown in Fig. 13. First, the adult sheep spine is isolated from the body, and the incision is made in the middle of lumbosacral region. It is cut layer by layer and stripped off the paraspinal muscles on both sides of the periosteum so that the lamina can be removed and the nerve root can be exposed. The nerve root is pulled intermittently for several times and continuous pressure monitoring is performed.

At first, the nerve root retractor pulls the nerve to the midline of the spine, and then withdraws the retractor. Then, the nerve root is pulled again 0.5 mm above the midline of the spine to obtain the force diagram shown as Fig. 14. It can be seen from the figure that during the first pulling, the maximum force on the detection unit 1 is 2.12 N. The forces on the detection unit 2, 3, 4, 5, 6 are successively decreased. According to the proportion of the force on different detection units, it can be inferred that the detection unit 1 is the main force receiving position. During the second pulling, the maximum force of the detection unit 1 is 2.94 N. The experiment shows that the designed nerve root retractor equipped with a high-density flexible pressure sensor can monitor the nerve root's force in real time, provide ideas for other researchers, and help surgeons on surgical operation.

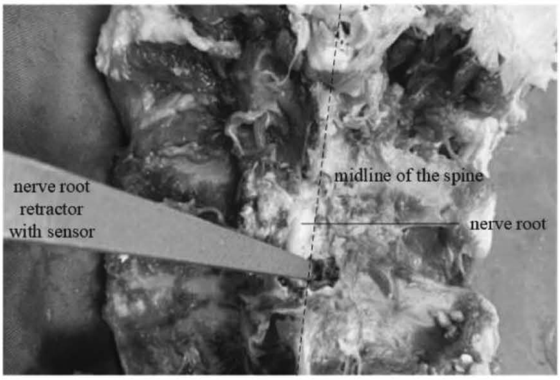


Fig. 13 The in vitro animal experiments in sheep

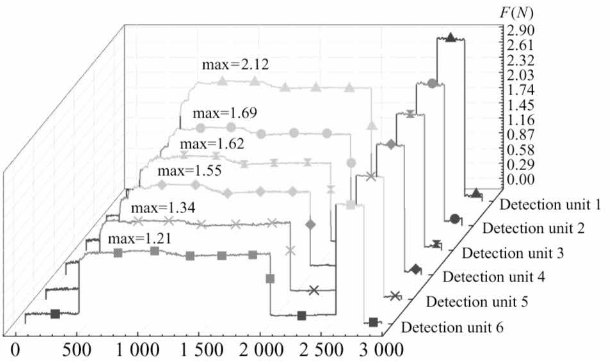


Fig. 14 The force diagram of each detection units

4 Conclusions

This paper proposes an intraoperative lumbar neurological force monitoring system consisting of high-density flexible pressure sensor array and nerve root retractor. The flexible pressure sensor array comprises 4 functional layers: the protective layer, the sensing layer, the pressure-sensitive layer and the analysis layer, where the sensor area is only 4 mm × 17 mm. The high-density micro-needle array provides high sensitivity and repeatability to the sensor, and the support structure around the micro-needle array prolongs the service life of the sensor. The density of micro-needle array is 2 500 dots/cm^2. The sensor has 6 detection units with each area of only 4 mm^2. The rectangular barrel box structure is the package that isolates the body fluid environment and protects the sensor. The sensitivity of the sensor is 67.30%/N in 0 – 5 N, which has high consistency and can judge the main force position. The nerve root retractor equipped with high-density flexible pressure sensor array is used for animal experiments. In experiments on the isolated sheep spine, the nerve root is pulled to the midline of the spine with max force of 2.12 N, and the max force of pulling the nerve root over the midline by 0.5 mm is 2.94 N. It can continuously and stably monitor the force of pulling the nerve root. It provides a new thinking for the pressure monitoring of pulling lumbar nerve root, which will help other researchers to further research.

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