

Vibration Diagnostic Probe for Discogenic Pain Due to a Fissure in an Annulus Fibrosus

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Abstract: Discogenic pain is the most common cause of chronic low back pain, accounting for 39% of causes. One possible diagnostic method to determine the cause of discogenic pain is provocative discography. However, this method is not available to patients with severe fissures due to degenerative disc disease. In this paper, we present a diagnostic probe in which plastic optical fiber (POF), which is located in a hole in the flexible tube of the probe, can be steered to the vicinity of fissures in the annulus fibrosus. Then, a linear motor placed inside the grip generates a minute axial vibration of the POF tip, which irritates the tiny pain nerves located near fissures. The intensity of the pain thus generated is used as a guideline to determine the level of discogenic disease. The frequency and amplitude of the vibration discography ranged from 2.5 Hz to 5.7 Hz and 1.5 mm to 3.4 mm, respectively. The applicability of the designed probe was successfully confirmed by testing the modified intradiscal microprobe in an ex vivo animal experiment.

1 INTRODUCTION

The intervertebral disc (or disk) is the core structure of the vertebral column located between vertebral bodies, lending stability of the body. In the center of the disc lies a jelly-like structure, the nucleus pulposus, which is composed of collagen fibers and mucopolysaccharides. The nucleus pulposus is surrounded by strong, thick layers of the annulus which confines the nucleus pulposus in the center of the disc. On one hand, discs play a key role in absorbing the axial pressure load delivered from the trunk and head during movement of the body. On the other hand, discs are a common source of chronic low back pain.

The pathological process of a disc usually starts from the tearing of the annulus. As the lesion deteriorates, the tears enlarge and coalesce until they form a fissure in the annulus (internal disc derangement: IDD), or annulus ruptures at the site of herniation of disc materials (disc herniation). Subsequently, low back pain is generally known to be produced by the secretion of inflammatory cytokines around the fissure in IDD and by mechanical compression of the nerve root in disc herniation (Burke et al., 2002). Although disc

herniation has been well known to the public for some time, our understanding of the etiology of chronic back pain has changed during the last two decades. Major studies on chronic low back pain have shown that discogenic pain caused by IDD is estimated to range from 26 % to 39 %, whereas pain cause by disc herniation ranges from 2.8 % to 3.5 % (Schwarzer et al., 1995). Recent advances in high-resolution diagnostic imaging techniques, such as computed tomography (CT) and magnetic resonance imaging (MRI), facilitate the diagnosis of disc herniation. However, even modern imaging methods are not sufficient to discern the internal disc derangement.

Modern discography is a pain-provocative test which can reproduce each patient's unique pain. Despite controversy regarding the accuracy and specificity of discography, it is recognized as the only method of proving the diagnostic standard for discogenic pain. Discography is known to provoke pain by pressing onto nerve structures around the fissures through the injection of contrast media (Shin et al., 2009). However, intradiscal pressure cannot be increased to provoke pains because severely degenerated discs cannot entrap contrast medium inside the discs (Kim et al., 2009); (Adams et al.,

1986). Therefore, discography has practical limitations in patients with severely degenerated discs.

Meanwhile, vibration diagnostic method of discogenic pain was studied by stimulating lumbar spinous process (the bony part of the spine) from skin surface (Yrjama et al., 1994). The method, however, also couldn't diagnose patients with total annular rupture because they felt no pain during the bony vibration provocation.

In this paper, to overcome the weakness of conventional discography, we propose a novel intradiscal microprobe that delivers direct mechanical stimuli on the nerve endings around the fissure. The microprobe, capable of steering and vibrating, was realized for clinical trials, and its applicability was confirmed by ex vivo animal experiment.

2 CONFIGURATION

Fig. 1 shows the configuration of the proposed intradiscal microprobe used to diagnose discogenic pain. The intradiscal microprobe is composed of a polymer tube, a plastic optical fiber (POF), a steering lever, a steering wire, a grip, a linear motor and a motor controller. The polymer tube has two holes for insertion of the steering wire and the POF. The steering wire is inserted into one hole of the polymer tube, and then each end of the wire is fixed to the tip of the polymer tube and the lever. Thus, the lever bend the polymer tube in a counter clockwise direction as the lever is driven manually.

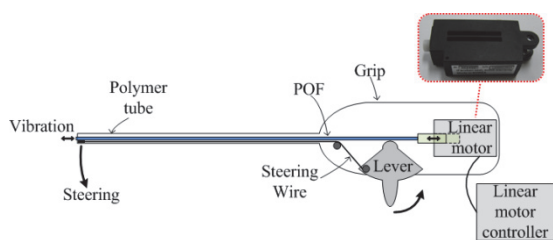


Figure 1: Diagram of the proposed intradiscal microprobe capable of steering and vibrational stimulus. The device is composed of a polymer tube, a plastic optical fiber (POF), a steering lever, a steering wire, a grip, a linear motor and a motor controller. The steering lever enables the tip of the polymer tube to be navigated within an annulus fibrosus. The linear motor and motor controller are used to generate axial vibration of the POF tip.

Meanwhile, the POF is inserted into the other hole of polymer tube and then connected with the moving part of the linear motor, which is located in

the grip of the microprobe. Also, the linear motor is linked to the motor controller which enables the reciprocation of the linear motor. Reciprocation leads to axial vibration of the POF tip which facilitates stimulation of the nerve endings around the fissure.

3 OPERATION PRINCIPLE

Fig. 2 shows how the POF, which is placed in the polymer tube of the intradiscal microprobe, approaches the annulus fibrosus. First, the polymer tube is introduced through a guide needle into the nucleus pulposus (jelly-like substance inside the disc). After that, the POF is steered to the vicinity of the fissure in the annulus fibrosus as the lever is pulled slowly. As shown in the inset of fig. 2, one end of the POF comes out from the polymer tube, facilitating navigation toward the fissure. The other end of the POF is connected to the movable part of the linear motor. The movable part moves back and forth to produce the alternating motion of the protruding POF tip which delivers a vibrational stimulus to nerve structures near the fissures. The frequency and amplitude of the vibrational stimulus can be changed according to two input variables of the linear motor. The variables are velocity and span, which can be regulated by the motor controller.

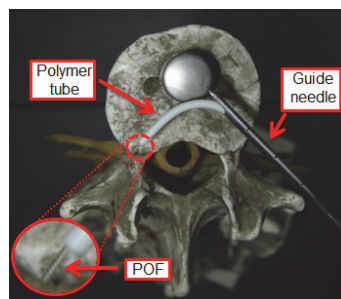


Figure 2: Photograph of the polymer tube steered towards the outer disc above a life-size human spine model. The inset is a magnified view of the protruding POF tip. A round metal plate is a fixture used to fasten the spine.

The vibration of the POF tip directly irritating the nerve endings will cause pain, the intensity of which is applicable as an effective indicator for the diagnosis of discogenic pain. In addition, unlike conventional discography, the proposed method is valid even for patients with severely degenerated discs where the nucleus pulposus has escaped from the annulus fibrosus.

4 FABRICATION

The intradiscal microprobe was fabricated by modification of commercial steerable catheter for drug injection. First, considering the size of the human intervertebral disc, the polymer tube length was designed to protrude 30 mm from the guide needle. Next, the linear motor (PoteNit, LSA-3024) was fixed inside the grip of the microprobe, and was electrically coupled to the motor controller outside of the grip. After that, one end of the wire (dia. 250 μm) was inserted into the smaller hole (dia. 300 μm) of the polymer tube (dia. 2000 μm), and was fixed at the tip of polymer tube. The other end was joined to the lever. Then, the moving part of the linear motor was connected with one end of the POF (dia. 500 μm). Finally, the fabrication of the microprobe was completed by the insertion of a POF into the larger hole (dia. 2000 μm) of the polymer tube.

Fig. 3 shows the process of steering the polymer tube tip that is inserted into the guide needle. The steering angle of the tube tip was about 10° when the steering lever was in the middle of the operating range as shown in fig. 3a. As the lever was fully pulled back, the tube tip became more bent in a counter clockwise direction as shown in figs. 3b and 3c. Meanwhile, the POF tip protruded further outwards as the steering angle of the tube increased, as shown in the insets of figs. 3a, 3b, and 3c. Consequently, the protruding POF tip could reach to the fissures more easily and more efficiently.

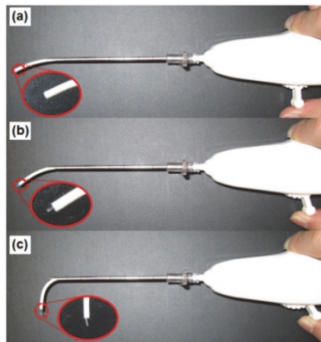


Figure 3: The steering process of the polymer tube tip of the fabricated intradiscal microprobe: (a) initial state, (b) the lever in the middle, and (c) the lever fully pulled. The steering angle of the tube tip ranges from 10° to 90° . The insets show that the POF tip protrudes from the polymer tube with bending of the polymer tube. The protruding length ranges from 0 mm to 2 mm.

5 EXPERIMENTAL RESULTS

Fig. 4 shows the experiment set-up to evaluate the performance of the intradiscal microprobe. The axial reciprocation of the POF tip was expressed as a sine wave on an oscilloscope by using a microvibrometer (Nihon Kagaku Eng. MLD-211D) which was set to a horizontal scale of 50 ms/div and a vertical scale of 160 $\mu\text{m}/\text{div}$. The sine waves were recorded while the velocity and span, which are input variables of the device, were increased from 12 mm/s to 24 mm/s in increments of 6 mm/s and 2 mm to 3 mm increments of 0.5 mm, respectively. The frequency and amplitude of the sine wave were converted to those of the axial reciprocation of the POF tip using the scale. The minimum values of the measured frequency and amplitude were 2.5 Hz and 1.5 mm, respectively, and the corresponding maximum values were 5.7 Hz and 3.4 mm, respectively (fig. 5).

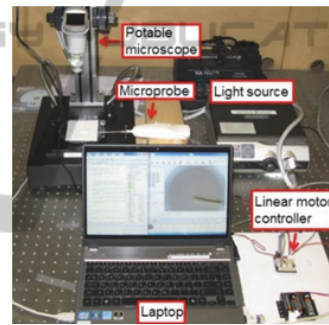


Figure 4: Photograph of the experiment set-up to evaluate the intradiscal microprobe for vibration discography.

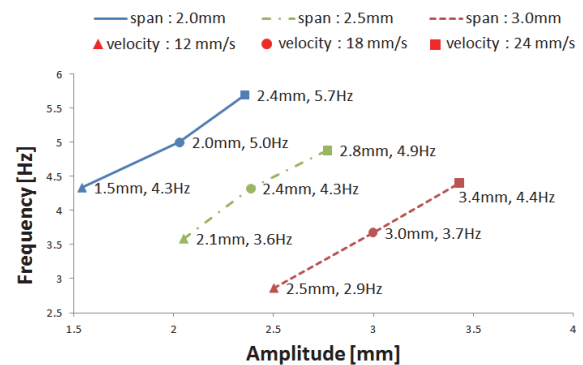


Figure 5: Measured vibration characteristics of the intradiscal microprobe.

The maximum frequency obtained with currently available micro-motor was 5.7 Hz which is smaller than 42 Hz to 50 Hz of the bony vibrator device (Yrjama et al., 1994). The vibration frequency of the

present intradiscal microprobe is thought to be high enough to provoke pains because the method directly irritates the nerve ending, not the bone.

In addition, the preliminary experiment to evaluate the ex vivo steering performance of the intradiscal microprobe was implemented using C-arm x-ray imaging. The experiment was carried out in a pig spinal cord, instead of the nucleus pulposus, because an x-ray image of the polymer tube would not be visible due to the opaque vertebrae located at top and bottom sides of the nucleus pulposus. Considering that the mechanical properties of the jelly-like spinal cord are similar to those of the nucleus pulposus, this preliminary experiment is thought to be able to provide meaningful data for subsequent ex vivo experiment.

Prior to the ex vivo experiment, we conducted a steering test of the polymer tube in air to compare with the steering performance in the ex vivo spinal cord. The protruding length of the polymer tube, from the guide needle, was decreased to 13 mm, because the diameter of the pig spinal cord prepared for the experiment was only 15 mm. The maximum steering angle of the 13 mm length of the protruding tube in air was measured to be 42°, which is about half that of the 30 mm protruding tube. The reduction in the steering angle is attributed to the shortening of the protruding tube length, which is easily predictable.

Fig. 6 is an ex vivo x-ray image (C-arm) which shows that the polymer tube was successfully guided to the outer rim of the pig spinal cord. The maximum steering angle in the spinal cord was measured as 40°, which is in good agreement to that in air. This indicates that there is a negligible difference in the steering angle in air and that in the spinal cord. Even in a case of the tube protruding 30 mm, we can infer that the steering angle and amplitude in clinical trials will be almost the same as the results obtained from experiments in air.

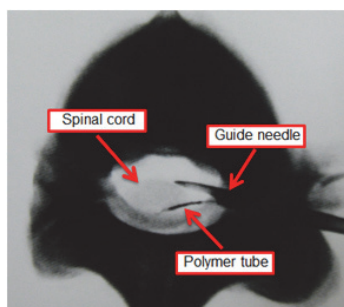


Figure 6: The C-arm picture of the polymer tube steered towards the outer rim of the pig spinal cord.

In a further study, we will carry out an in vitro vibration experiment using a model that has mechanical properties similar to those of the nucleus pulposus before clinical trials. Also, a high-performance linear motor will be used to achieve a wider range of vibration frequency and amplitude.

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