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Case Report

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Fluoroscopically Guided Interventional Transforaminal Needling for Lumbar Instability using a Specially Designed Needle Conjoining Epiduroscopic Evaluation: An Exploratory Study

Ahn K[1], Jhun HJ[2*], Park CW[1] and Kim JH[1]

Abstract

Objective: Spinal instability is a major cause of low back or radicular pain. We developed an interventional procedure to manage pain resulting from lumbar instability using a specially designed needle. This study describes the methodological approach and clinical application of the procedure.

Methods: A cadaveric study was conducted to develop an approach route for the needle. After developing an approach route, the technique was applied clinically to patients with lumbar instability (n = 15). The patients underwent epiduroscopy before undergoing the procedure to evaluate the epidural space findings related to lumbar instability. A specially designed curved Round Needle was inserted 8-12 cm lateral to the midline, one level above the target. The needle was advanced to the facet joint and moved forward and backward within a range of a few millimeters until smooth sliding was felt at the tip of the needle. It was advanced in a medial and caudal direction along the facet joint and superior articular process. When the needle accessed the interface between the posterior longitudinal ligament and annulus fibrosus in the lateral recess, below the inferior end plate, it was moved forward and backward within a range of a few millimeters again until smooth sliding was felt at the tip of the needle.

Results: After the patients underwent the intervention, outcome measures in this study (visual analog scale pain score, EQ-5D index, and self-rated improvement following intervention compared with initial state) improved significantly at the 2- and 6-month follow-up evaluations.

Conclusion: This study suggests that fluoroscopically guided interventional transforaminal needling has clinical significance in managing pain resulting from lumbar instability.

Keywords

Instability; Intervention; Lateral recess; Needle; Pain; Spine; Technique

Introduction

It has been estimated that 70-85% of all people experience back pain or sciatica at some time in their life [1]. Thus, the economic and public health burdens of back disorders are enormous [2].

The origins of back pain can be broadly classified as mechanical, neuropathic, or secondary to another cause. Most back pain is of mechanical origin, indicating that the source of the pain is in the spine or its supporting structures [3].

Damage to the restraining structures of the spine, such as the facet joint, intervertebral disc, ligaments, and muscles, results in abnormal movements of the spine, which lead to an altered equilibrium and thus instability [4]. Spinal instability has recently been recognized as a significant cause of morbidity associated with spinal mechanical dysfunction [5]. Pope and Panjabi [4] and Frymoyer and Selby [6] defined instability as a loss of motion segment stiffness, such that force application to that motion segment produces abnormally greater motion than that in a normal spine. It is thought to be a major cause of low back pain and is often an important factor in determining the surgical indication for spinal fusion with decompression [7]. Furthermore, instability is associated with and/or accompanied by pathological mechanisms of various spinal disorders, including spondylolisthesis [8], disc herniation [9,10], spinal stenosis [11,12], peridural fibrosis [13], and failed back surgery syndrome [14].

Typically, conservative treatments are used to manage lumbar instability, including exercise, physical therapy, medications, and epidural steroid injections [15,16]. Patients with segmental instability resulting in severe disability may consider undergoing lumbar spinal fusion surgery [17].

The effects of dry needling in the management of myofascial trigger points have been evaluated in randomized clinical trials and comprehensive reviews [18]. Furthermore, dry needling has been used in the management of various musculoskeletal disorders, including tennis elbow, patellar tendinosis, adhesive capsulitis of the shoulder, and spinal stenosis [19-21]. We developed an interventional procedure using a specially designed needle to manage pain resulting from lumbar instability. This study describes the methodological approach and clinical application of the procedure.

Methods

The lateral recess is bordered laterally by the pedicle, posteriorly by the superior articular process, and anteriorly by the posterior lateral surface of the vertebral body and adjacent intervertebral disc. At this level, the nerve root is covered by the root sleeve and is surrounded by cerebrospinal fluid. The lateral margin of the nerve root sleeve contacts the medial cortical bone of the pedicle, and the medial margin of the nerve root is surrounded by epidural fat tissue [22].

The lateral recess has been reported to be a principal compression site in the lumbar spine [23]. According to our clinical experience in epiduroscopy in lumbar spinal disorders, including lumbar instability, epidural inflammation and fibrosis and obliteration of fatty tissue are usually found at the lateral recess (Figure 1A, 1B). Anatomically, the posterior longitudinal ligament (PLL) and outer

***Corresponding author:** Hyung-Joon Jhun, Seoul Madi Spine and Joint Clinic, 1426 Joongang-ro Ilsanseo-gu, Goyang, 10386, Republic of Korea, Tel: +82-31-911-8875; Fax: +82-31-914-8875; E-mail: oemdoc21@gmail.com

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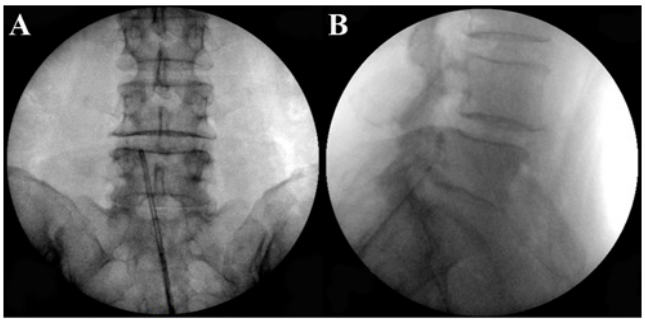

Figure 1: C-arm fluoroscopic images taken during an epiduroscopic evaluation of a patient with lumbar spondylolisthesis and instability and an anatomical illustration of the epidural space, **1A:** Anteroposterior C-arm fluoroscopic image taken when the epiduroscope was advanced to the lateral recess; **1B:** Lateral C-arm fluoroscopic image taken when the epiduroscope was advanced to the lateral recess.

layer of the annulus fibrosus (AF) interface in this space. The PLL is attached to intervertebral discs, hyaline cartilage end plates, and adjacent margins of vertebral bodies, and it is separated from the center of the vertebral bodies (Figure 1C, 1D) [24]. Considering the anatomy and biomechanics of the lumbar spine, we speculated that the interface between the PLL and AF in the lateral recess would be an important treatment point to manage pain resulting from lumbar instability.

Figure 2 shows the specially designed needle used in this study: a curved Round Needle (Hansung Precision, Siheung, Korea). The needle was 1.2 mm in diameter and 140 mm long. A yellow circular sticker was attached to the triangular handle to indicate the side of the curved tip (Figure 2A, 2B). It was streamlined, solid, and flexible, and had a blunt, round, curved tip (Figure 2C, 2D).

Cadaveric study

We designed a transforaminal procedure using the curved Round Needle to manage pain resulting from lumbar instability. A cadaveric study was conducted to develop an approach route for the needle.

Based on anatomical knowledge and needling experience in cadavers, we found that the needle should be inserted at one level above the target and advanced in a medial and caudal direction at a 30° angle towards the interface between the PLL and AF, below the inferior end plate.

Figure 3A shows that the Round Needle was advanced into the interface between the PLL and AF, below the inferior end plate. Figure 3B shows the needle after drawing aside the dura mater.

Patients

After developing the approach route for the needle, the technique was used clinically in patients with lumbar instability. In total, 15 patients (7 men, 8 women) with lumbar instability underwent fluoroscopically guided interventional transforaminal needling at a chronic pain management center in Korea.

A diagnosis of lumbar instability was made based on a comprehensive medical history, physical examination, and imaging studies. Medical histories included the subject's back 'giving out,' painful catching or locking, pain with transitional activities or sustained postures, and recurrent or chronic pain [25]. To detect instability, we primarily palpated the interspinous gap change during lumbar flexion and extension motion [26]. Additionally, physical examinations, such as the instability catch sign, painful catch sign, apprehension sign, and passive lumbar examination test, were also evaluated [27]. Imaging studies, including lumbar neutral radiographs, flexion and extension radiographs, CT, or MR, were evaluated to detect indirect and direct radiological findings of abnormal vertebral motion. They included the vacuum phenomenon, traction spur, translation of one vertebra over another, excessive angular movement of a motion segment, facet joint arthritis, traction osteophytes, and annular tears [7,28].

One patient had received back surgery previously (laminectomy and L5-S1 fixation) and experienced persistent pain after surgery. We diagnosed the condition of that patient as adjacent instability after an instrumented lumbar fusion, a type of "failed back surgery syndrome" [29]. No other patient had any history of back surgery.

Patients were provided with comprehensive information on the benefits and potential risks (such as infection, bleeding, and post-

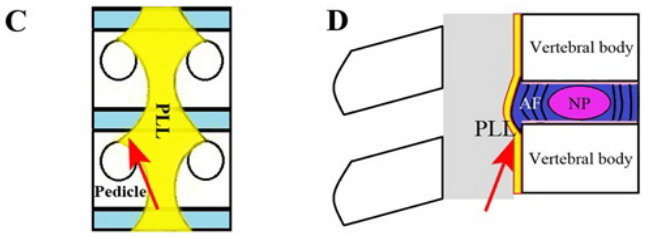

Figure 1C: Anatomical illustration of the anterior epidural space in the anteroposterior view. The red arrow indicates the interface between the posterior longitudinal ligament (PLL) and the annulus fibrosus (AF) in the lateral recess; **1D**: Anatomical illustration of the epidural space in the lateral view. The red arrow indicates the interface between the PLL and the AF. NP, nucleus pulposus.

Figure 2: The specially designed needle used in interventional transforaminal needling to manage lumbar instability, **2A:** The front of the curved Round Needle; **2B:** The back of the curved Round Needle.

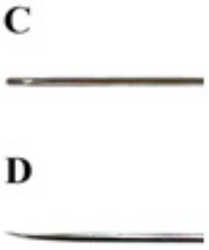

Figure 2C: Close-up of the tip from above; **2D:** Close-up of the tip from the side.

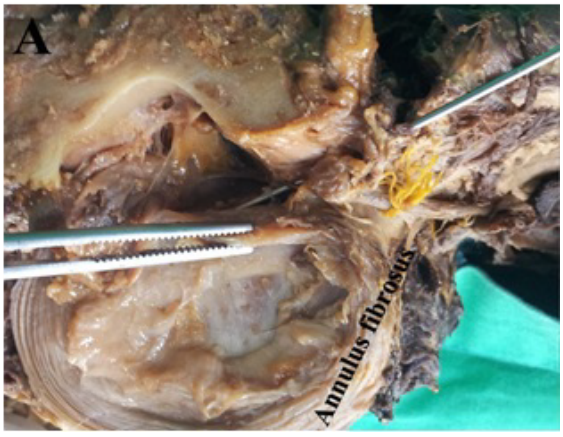

Figure 3: Cadaveric examination was used to develop the approach route to the interface between the posterior longitudinal ligament (PLL) and annulus fibrosus (AF) below the inferior end plate; **3A:** The curved Round Needle was advanced into the interface between the PLL and AF below the inferior end plate.

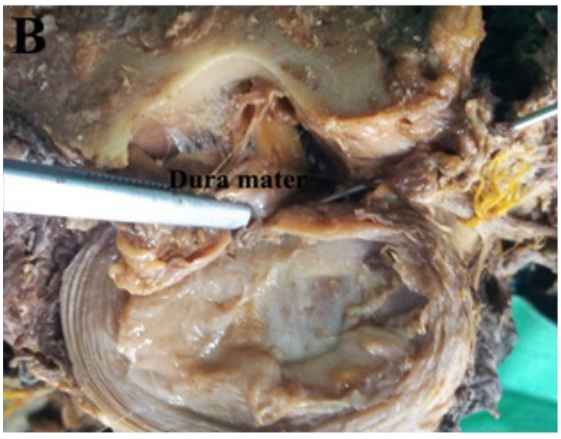

Figure 3B: The curved Round Needle was advanced into the interface between the PLL and AF below the inferior end plate and shown after drawing aside the dura mater.

needling soreness) of the intervention. They then provided written informed consent before treatment.

No separate informed consent was required because this study was a follow-up of patients who had previously undergone the intervention. The Institutional Review Board of CHA University approved the study protocol.

Procedure

All of the patients underwent epiduroscopy before undergoing the procedure to evaluate epidural space findings related to lumbar instability. The patients were placed on a table in the prone position. Remifentanil (Ultiva®) 1 mg was mixed with 50 mL normal saline and administered as an intravenous infusion in doses ranging from 0.1 to 0.5 μg/kg/min. This enabled the patients to communicate with the medical staff without pain during the procedure.

An epiduroscope was inserted, as reported previously [30,31]. A pillow was placed under the abdomen to minimize lumbar lordosis. The patient's sacral hiatus was sterilized, and an 18-gauge Tuohy needle was inserted through the sacral hiatus under local anesthesia. The tip of the needle was confirmed to be within the epidural space by fluoroscopic imaging. A 0.8-mm guidewire was then inserted into the sacral epidural space through the Tuohy needle under fluoroscopic guidance, and a 4-mm (8.5-F) introducer (Myelotec, Roswell, GA, USA) with a dilator was advanced into the sacral epidural space over the guidewire using the Seldinger technique. A video-guided catheter (Myelotec) with a 1.2-mm endoscope (Myelotec) was inserted through the introducer after removal of both the dilator and the guidewire. The catheter with the endoscope was then advanced in the cephalic direction under fluoroscopic guidance. The location of the catheter was confirmed by fluoroscopic imaging. The epidural space was observed directly with the endoscope. Contrast medium was administered through the catheter into the epidural space, and epidural contrast flow was evaluated by fluoroscopic imaging.

After finishing the epiduroscopic evaluation, a curved Round Needle was inserted 8-12 cm lateral to the midline, one level above the target. A C-arm fluoroscope was positioned in the lateral view, and the needle was advanced in a medial and caudal direction at a 30° angle with the concave surface facing down (Figure 4A, 4B). After the needle had contacted the facet joint and entered the intervertebral foramen, it was moved forward and backward several times within a range of a few millimeters for easy handling of the needle. 1차 목표점

The needle was then turned so that the concave surface faced upward with respect to the facet joint (Figure 4C, D). It was then moved forward and backward within a range of a few millimeters until smooth sliding was felt at the tip of the needle. It was simultaneously advanced in a medial and caudal direction along the facet joint and superior articular process.

When the needle reached the cranial surface of the pedicle, approximately 1 mm above the superior portion of the vertebral body, it was pushed gently into the interface between the PLL and AF in the lateral recess, below the inferior end plate (Figure 4E, 4F, 4G, 4H).

Figure 5 shows C-arm fluoroscopic images of a woman with L4-5 spondylolisthesis and instability who underwent the procedure after an epiduroscopic evaluation. Figure 5A, 5B show a curved Round Needle advanced towards the inferior end plate in a medial and caudal direction. After the needle had passed the inferior end plate, it was advanced further, and then it contacted the cranial and medial surface of the pedicle and entered into the lateral recess (Figure 5C). When the needle accessed the interface between the PLL and AF, it appeared to be bent and overlapped with the pedicle in the lateral view (Figure 5D). It was moved forward and backward within a range of a few millimeters at the interface between the PLL and AF, below the inferior end plate. Needling continued until smooth sliding was felt at the tip of the needle.

After completion of the needling, epidurography was again performed through the catheter with an endoscope. We considered that reduced pressure in the epidural space when injecting contrast and improved epidural contrast flow after needling, compared with that before needling, indicated a successful treatment. After completion of the procedures, the patients were transferred to the ward and stayed at the hospital for 6 h.

Data Analysis

We selected three outcome measures to evaluate the effectiveness of the treatment: a self-rated pain score, EQ-5D, and self-rated improvement following the intervention. We asked the patients to rate

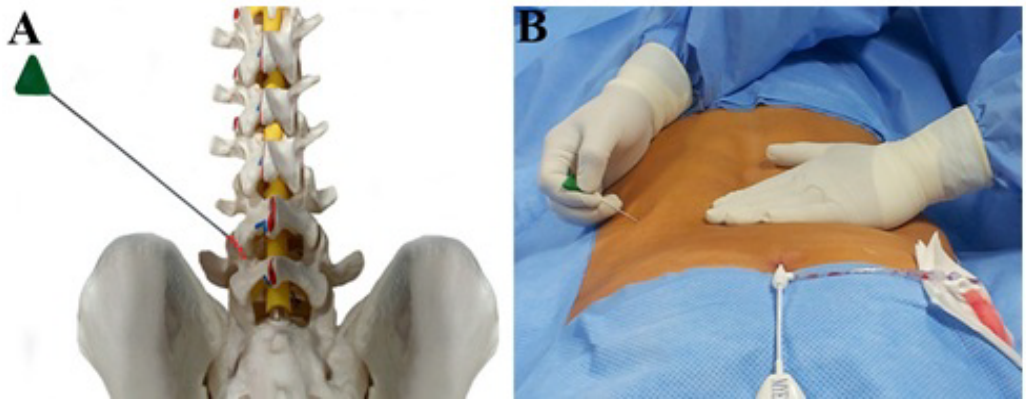

Figure 4: Fluoroscopically guided interventional transforaminal needling procedure using the curved Round Needle. **4A:** A curved Round Needle entered the left L4–L5 intervertebral foramen and contacted the facet joint with the concave surface facing down in a human skeleton model; **4B:** A curved Round Needle was inserted into a patient with the concave surface facing down as an epiduroscope was inserted.

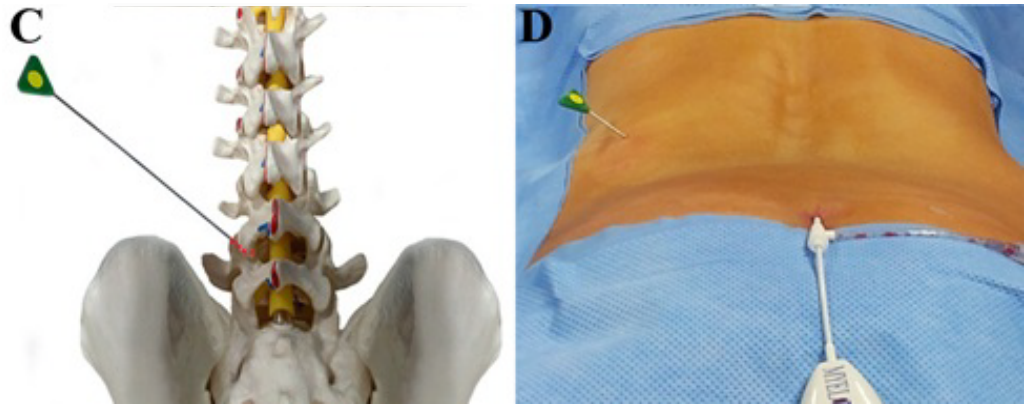

Figure 4C: The curved Round Needle contacted the facet joint and superior articular process, with the concave surface facing upwards in a human skeleton model. **4D:** A curved Round Needle was inserted into a patient, with the concave surface facing upwards as an epiduroscope was inserted.

their pain level using a visual analog scale (VAS) consisting of a 10-cm line, anchored at the two extremes. EQ-5D is a measure of health status developed by the EuroQol Group. It consists of five questions on mobility, self-care, pain, usual activities, and psychological status, with three possible answers for each (1 = no problem, 2 = moderate problem, and 3 = severe problem) [32]. A summary index with a maximum score of '1' (EQ-5D index) can be derived from these five dimensions by conversion using a score table. The maximum score of '1' indicates the best health state, in contrast to the scores of individual questions, where higher scores indicate more severe or frequent problems [33]. We also asked the patients to rate their improvement following the intervention compared with their initial state on a percentage scale at their follow-ups.

The outcome measures were evaluated three times in this study: before intervention and at 2 and 6 months after intervention. The self-rated pain score and EQ-5D were assessed before and at 2 and 6 months after treatment. Self-rated improvement was assessed at 2 and 6 months after treatment.

The Wilcoxon signed-rank test was used to evaluate the differences between pre- and post-interventional self-rated pain scores and EQ-5D indices. The null hypothesis of no improvement after treatment was tested to assess self-rated improvement following treatment.

Results

The average age of the patients was 43.9 ± 12.5 years (43.9 ± 10.0 for the men, 44.0 ± 15.0 for the women). The average duration of pain prior to the treatment was 22.1 ± 30.8 months (18.7 ± 20.2 for the men, 25.0±39.1 for the women). Epiduroscopic evaluation revealed that 13 (86.7%) patients had epidural adhesion, 12 (80.0%) had epidural inflammation, 8 (53.3) had nerve-root inflammation, and 1 (6.7%) had obliteration of fatty tissue. The most common treatment levels in these subjects were L4-5 and L5-S1, right (20.0%), and L4-5 and L5-S1, left (20.0%; Table 1).

The average VAS of the patients before intervention was 7.7 ± 1.7 points, and the average EQ-5D index was 0.58 ± 0.21 points. At 2 months after the intervention, the average VAS of the patients decreased, by 3.6 ± 2.7 points (p<0.01), the average EQ-5D index increased, by 0.18 ± 0.23 points (p<0.01), and the average self-rated improvement score following the intervention was 55.7 ± 35.4% (p<0.01). At 6 months after the intervention, the average VAS of the patients decreased, by 3.9 ± 3.0 points (p<0.01), the average EQ-5D index increased, by 0.19 ± 0.24 points (p<0.01), and the average self-rated improvement score following the intervention was 54.0 ± 43.0% (p<0.01; Table 2). No significant or fatal adverse effect was reported following the treatment.

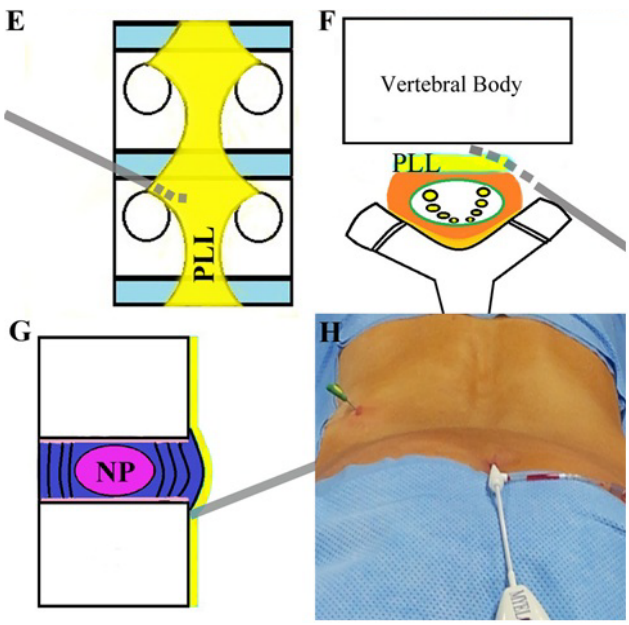

Figure 4E: The concept of transforaminal access of the curved Round Needle into the interface between the posterior longitudinal ligament (PLL) and annulus fibrosus (AF), below the inferior end plate, with the concave surface facing upwards is demonstrated using a schematic diagram in the coronal plane; **4F:** Introduction of the curved Round Needle into the interface between the PLL and vertebral body is demonstrated using a schematic diagram in the axial plane; **4G:** Introduction of the curved Round Needle into the interface between the PLL and AF below the inferior end plate is demonstrated using a schematic diagram in the sagittal plane. NP, nucleus pulposus; **4H:** A curved Round Needle accessed the interface between the PLL and AF in a patient, with the concave surface facing upwards as an epiduroscope was inserted.

Discussion

We conducted fluoroscopically guided interventional transforaminal needling using a specially designed curved Round Needle in 15 patients with lumbar instability. After the patients underwent the intervention, outcome measures in this study improved significantly. These results suggest that our procedure has clinical significance in managing pain resulting from lumbar instability.

Surgical treatment is indicated in patients with lumbar instability whose symptoms do not respond to a trial of conservative treatment or who have accompanying neurological symptoms. Fusion is the most commonly offered procedure and can be performed anteriorly, posteriorly, posterolaterally, or in combination. Patients treated with spinal fusion combined with instrumentation following posterior decompression generally have favorable outcomes [34]. However, surgery has drawbacks, including surgical morbidity, a risk of neural damage, and failed back surgery syndrome. Furthermore, not all patients are willing to undergoing surgical treatment. Therefore, we believe that our procedure has clinical importance as a new interventional procedure to manage pain resulting from lumbar instability.

In terms of the treatment mechanism, we consider that needling improves mobility of the dural sac and nerve roots, reduces neuronal hypersensitivity, and promotes the natural healing process, resulting in alleviation of the pain that results from lumbar instability.

In an animal study, vertebral instability and overuse caused peridural venous impairment, resulting in peridural fibrosis [13]. Epidural adhesion is an important cause of low back and lumbar radicular pain, especially after spinal surgery [35]. In the epiduroscopic evaluations, epidural adhesion was found in most (86.7%) of the patients in this study. We consider that dry needling using a 1.2-mm-diameter needle may release the adhesion of the dural sac and nerve roots from the surrounding tissue, thus improving the mobility of the dural sac and nerve roots and alleviating pain. 1차 목표점에서 그렇다는 말이겠지..

The sinuvertebral nerve innervates intervertebral discs, the PLL, and the ventral surface of the dura mater. It has been implicated in low back and lumbar radicular pain because of its pathway and sympathetic component [36]. Dry needling has been used in the management of musculoskeletal disorders and has been shown to modulate sensory hypersensitivity [37]. Thus, needling into the anterior epidural space, PLL, and AF may reduce hypersensitivity of the sinuvertebral nerve. SVN 이 dry needling으로 좋아진다? 바늘의 강성이 부족하여 lamina쪽으로 붙을수가 없었으며 부득이 anterior 로 진행할 수 밖에 없는 수기적 제한점을 감추는 말임.. 차라리 접근점을 외측으로 하여 upper end plate 보다 caudal 진행하여 lamina에 붙는 것이 더 안정.

Needling produces minute wounds. These wounds generate a current of injury continuously for several days or weeks, which promotes the natural healing process in the spine, resulting in alleviation of the pain that results from lumbar instability.

Ahn et al. [20] reported a fluoroscopically guided transforaminal epidural dry needling technique using a specially designed flexed Round Needle to manage lumbar spinal stenosis. According to the study, the needle was introduced into the intervertebral foramen and advanced to a position between the facet joint and pedicle. However, the needle was not advanced further, beyond the pedicle, and needling 저자 방법상으로는 머들선단 부위에 anterior spinal artery있으므로 이곳에 접근함을 위험하다. 더구나 blind하게는..

Table 1: Clinical data of the patients.

	N	(%)
Gender		
Male	7	(46.7)
Female	8	(53.3)
Age (years)		
20 – 29	2	(13.3)
30 – 39	5	(33.3)
40 – 49	2	(13.3)
50 – 59	4	(26.7)
60 – 69	2	(13.3)
Pain duration (months)		
≤ 12	8	(53.3)
13 – 24	4	(26.7)
>24	3	(20.0)
Epiduroscopic finding		
Epidural adhesion	13	(86.7)
Epidural inflammation	12	(80.0)
Inflammation of nerve root	8	(53.3)
Obliteration of fatty tissue	1	(6.7)
Treatment level		
L3-4, L4-5 Left	1	(6.7)
L3-4, L4-5 Both	1	(6.7)
L4-5 Right	2	(13.3)
L4-5 Left	1	(6.7)
L4-5 Both	2	(13.3)
L4-5, L5-S1 Right	3	(20.0)
L4-5, L5-S1 Left	3	(20.0)
L4-5, L5-S1 Both	1	(6.7)
L5-S1 Left	1	(6.7)

Table 2: Treatment responses of the patients.

Outcome measure	Baseline	Two months after intervention		Six months after intervention	
	Average	*Average*	*P*	*Average*	*P*
VAS (points)	7.7 ± 1.7	4.1 ± 2.7	0.0002	3.8 ± 3.0	0.0010
EQ-5D index	0.58 ± 0.21	0.76 ± 0.18	0.0024	0.78 ± 0.18	0.0016
Self-rated improvement following treatment	-	55.7 ± 35.4	0.0002	54.0 ± 43.0	0.0010

VAS, visual analog scale pain score

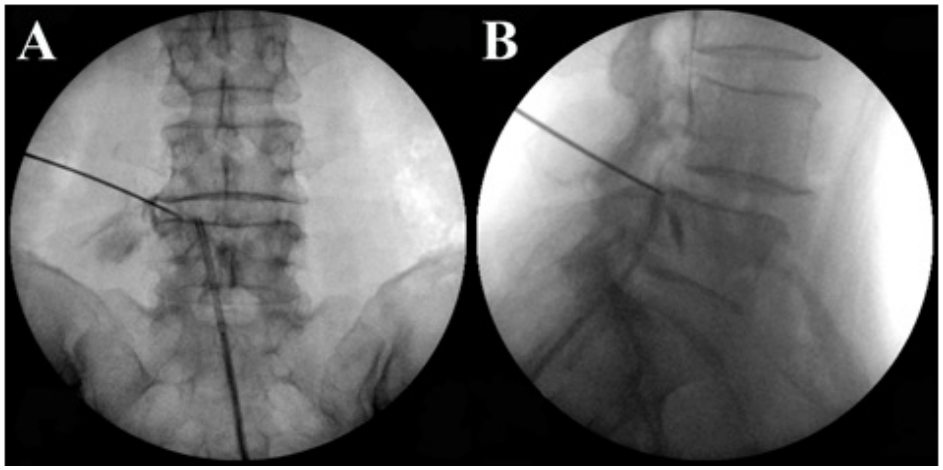

Figure 5: C-arm fluoroscopic images of a woman with L4-5 spondylolisthesis and instability who underwent fluoroscopically guided interventional transforaminal needling after an epiduroscopic evaluation. **5A:** Anteroposterior C-arm fluoroscopic image when a curved Round Needle was advanced towards the inferior end plate in a medial and caudal direction; **5B:** Lateral C-arm fluoroscopic image when the curved Round Needle was advanced towards the inferior end plate in a medial and caudal direction

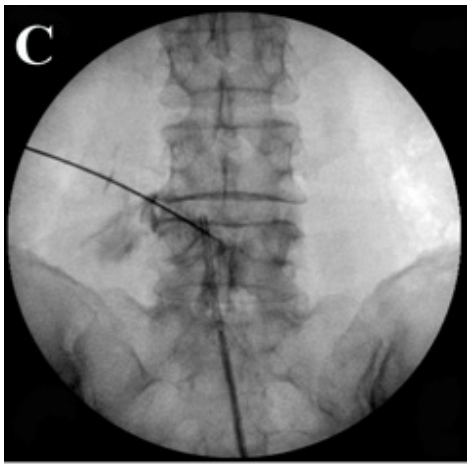

Figure 5C: Anteroposterior C-arm fluoroscopic image when the curved Round Needle was advanced into the lateral recess in a medial and caudal direction;

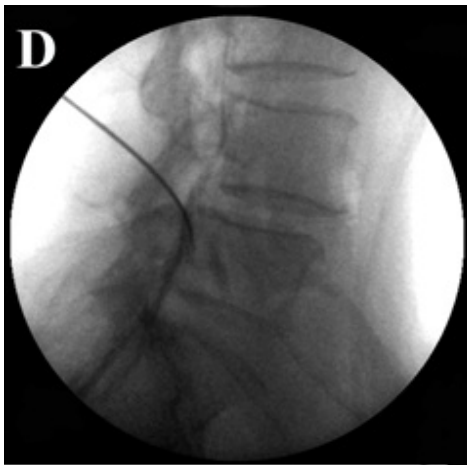

Figure 5D: Lateral C-arm fluoroscopic image when the curved Round Needle was advanced into the lateral recess.

내 입장:
lateral recess가 원인으로 생각된다면, 자입점 상방으로 하여 후방 lamina에 붙는 것을 시행해 볼 수 있다.

환자 pathophysiology에 따라 다르다. 빈도가 적은 foraminal narrowing이 원인이라면 이전 2010 적용가능하다. 그러나 lateral recess가 원인이라면 자입점을 상방으로 하여 시도할 수 있지만 강성부족을 anterior로 갈것이며 결국 저자 방법이 되어 위험하다.

was limited to within the foraminal zone. In this study, the curved Round Needle was advanced to the lateral recess and accessed the interface between the PLL and AF. Introduction of the needle into the lateral recess is an important technical advancement in this study compared with the technique reported previously.

Epiduroscopy has been used to find the source of pain and alleviate low back or leg pain. A bolus injection of saline was conducted for lysis of adhesion, and a steroid / local anesthetic solution was injected to alleviate a painful nerve root [30]. However, access to the lateral side of the epidural space is limited, and the injection of solutions is sometimes insufficient to manage lumbar spinal disorders. In this study, the principal treatment was conducted with a specially designed needle, and epiduroscopy was used to evaluate findings in the epidural space related to lumbar instability and to perform epidurography before and after needling.

We were careful to avoid complications, which were not observed in any of the patients while undergoing the intervention or during follow-up. To confirm the safety of our intervention, we used the intervention only after first assessing its safety in cadavers (Figure 3A). We believe that the streamlined shape, solid but flexible body, and

round, blunt tip of the specially designed needle minimize tissue damage. Additionally, the curved tip is useful in entering the intervertebral foramen with the concave surface facing down and in trimming target structures (i.e., the facet joint, superior articular process, and the interface between the PLL and AF) when the concave surface faces up.

Some limitations should be considered when interpreting these results. The design of this study, a case series and an exploratory study, poses a limitation, and further studies or randomized clinical trials are needed to evaluate the efficacy of our technique compared with other treatment methods for lumbar instability.

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Author Affiliation

[1]*Ahnkang Pain Free Hospital, CHA University, Seoul, Korea*

[2]*Seoul Madi Spine and Joint Clinic, Goyang, Korea*

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