

Original Article

Effect of Neulen Ti plate on hinge side bone healing in unilateral open-door cervical expansion laminoplasty: a preliminary report on 26 cases with short follow-up

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Received September 3, 2015; Accepted December 17, 2015; Epub February 15, 2016; Published February 29, 2016

Abstract: This comparative study aimed to evaluate the effect of internal fixation with a Neulen Ti plate toward the hinge side bone healing (HSBH) in unilateral open-door laminoplasty for cervical expansion. A total of 56 patients underwent unilateral open-door cervical expansion laminoplasty to treat cervical stenosis, of whom 26 underwent Neulen Ti plate internal fixation (Neulen group) and 30 underwent traditional suspension fixation (suspension group). Axial computed tomography images taken 3 and 6 months after the operation were used to evaluate the status of HSBH. Three months after the operation, the HSBH rate in the Neulen group was 76.1%, while that in the suspension group was 55.9%, a difference that was statistically significant. Six months after the operation, the HSBH rate was 90.6% in the Neulen group and 88.3% in the suspension group, but the difference was not statistically significant. During the follow-up period, there was no Ti plate shift or closure phenomenon in the Neulen group, while 8.3% cases in the suspension group had a decreased open-door width. Use of the Neulen Ti plate effectively prevented the closure phenomenon and promoted HSBH; this resulted in spinal expansion that helped to achieve the stable state sooner.

Keywords: Unilateral open-door cervical expansion laminoplasty, neulen ti plate, bone healing, CT

Introduction

The incidence of cervical spinal canal stenosis gradually increases with age, and it can seriously affect the quality of life and life expectancy. The surgical methods for cervical spinal canal stenosis include anterior, posterior, and anterior-posterior combined spinal decompression. Posterior surgery has obvious advantages for the treatment of long-segmental cervical spinal canal stenosis. Since Hirabayashi et al [1] reported unilateral open-door cervical expansion laminoplasty (UODCEL) in the 1970s, this method has become the most effective surgical treatment for multi-segmental cervical spondylotic myelopathy (CSM), long-segmental cervical ossification of the posterior longitudinal ligament (OPLL), and developmental cervical stenosis [2].

Suture suspension is the traditional unilateral open-door lamina fixation method, while cutting, breaking, or extending the thread would

result in lamina rebound, and the closure phenomenon would also easily appear, resulting in re-opening failure and spinal re-stenosis [3]. If the hinge side bone (HSB) completely breaks when the lamina door opens, vertebral instability affects bone healing; therefore, lack of HSB healing is one of the reasons for closure [4, 5]. If the broken end of the lamina collapses toward the spinal canal, the spinal cord becomes compressed, resulting in surgical failure.

With the development of surgical techniques and instruments, open-door fixation methods are constantly improving; therefore, the identification of a reliable and effective vertebral fixation method has also become a clinical hotspot. Internal fixation with a micro Ti plate is a relatively new fixation method, and certain research reported that the application of Centerpiece Ti plate internal fixation could provide stable support, thus effectively preventing closure [6, 7]. The Neulen Ti plate (Neulen) (Changzhou Waston Medical Application Co., Ltd., Nanjing,

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Table 1. Diagnosis of two groups

	Neulen group	Suspension group
OPLL	12	14
CSM	14	16
Accompanied developmental cervical spinal canal stenosis	5	7



Figure 1. Neulen plates and screws.

Table 2. Definitions of Hinge Healing

	Ventral cortex		
		Bridged	Not bridged
Dorsal Cortex	Bridged	Healed	Not healed
	Not Bridged	Not healed	Not healed

The dorsal and ventral cortex is evaluated for the presence of bridging by either cancellous or cortical bone. The overall healing status of the hinge is determined by combining the status of the dorsal and ventral cortices according to the matrix. It can be considered healed only when both the ventral and dorsal cortices have been bridged.

China) is a new type of micro Ti plate that has started being used clinically in recent years. In this study, the observation, from the perspective of iconography, was performed for evaluating HSBH 3 and 6 months after the application of Neulen internal fixation in UODCEL to evaluate its structural stability for reconstructing the spinal canal.

Materials and methods

A total of 56 patients were enrolled between January 2010 and December 2012, and they underwent UODCEL for the treatment of cervical spinal canal stenosis. All patients were diagnosed on the basis of disease history, physical examination, X-ray, CT and MRI. 26 patients (15 men, 11 women; mean age, 62.3 years; range,

39-81 years) underwent Neulen internal fixation (Neulen group). The inclusion criteria for Neulen Ti plate: Patients have progressive limb sensation, movement or sphincter dysfunction. The X-ray shows a complicated developmental or degenerative cervical spinal canal stenosis; disc space narrowing and osteophytes. CT and MRI showed multi segment (≥ 3) cervical OPLL; multi segment (≥ 3) CSM; cervical flavum ligament thickening or calcification; developmental cervical spinal canal stenosis. Above factors lead to multi segment (≥ 3) spinal cord compression and cervical spinal canal stenosis. Exclusion criteria: Cervical lordosis disappeared or kyphosis; Cervical instability; Severe osteoporosis; Severe heart and lung disease; Could not afford the high cost. The other 30 patients (18 men, 12 women; average age, 60.5 years; range, 41-71 years) underwent traditional suspension fixation (suspension group). This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of Shandong University. Written informed consent was obtained from all participants.

All the above cases (**Table 1**) exhibited obvious cervical stenosis and spinal cord compression accompanied with disc space narrowing and osteophyte formation in the Luschka joints, and at the vertebral trailing edge. If the surgical indications were definite, we performed UODCEL at the C3-C6 or C7 lamina. Additionally, we recorded the Japanese Orthopaedic Association myelopathy score (JOA score) for each patient before and after surgery to assess the outcome of both operative options, as shown in [Table S1](#) and [Figure S1](#).

Characteristics of the Neulen Ti plate

The Neulen Ti plate, provided by XX, has two models (12-mm and 14-mm long), each of which has two nail holes on both ends of the plate (screw length, 6 mm and 8 mm, respectively). There is a blocking structure on the lamina end and lateral mass end, respectively; the blocking structure on the lamina end appeared as a curve, while the blocking structure on the lateral mass end appeared jagged, which was a good match for the lamina and the lateral mass (**Figure 1**). Neulen Ti plate is made of TA2. The hardness, Toughness and biocompatibility of Titanium are universally acknowledged.

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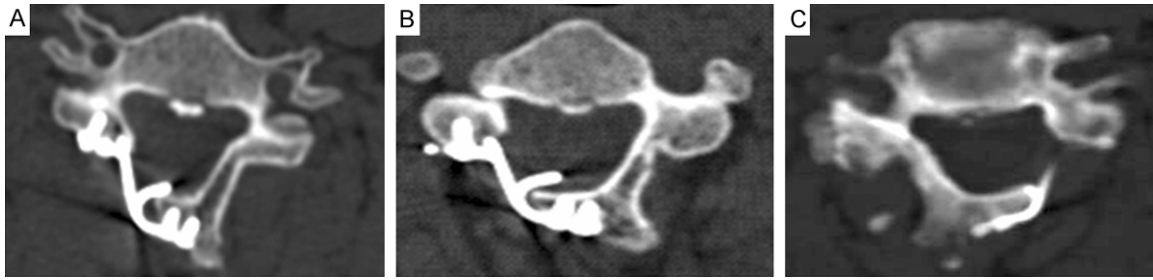


Figure 2. Laminoplasties with hinge healing. A. Both the dorsal and ventral cortices were bridged by cortical bone, and a callus was present. B. The ventral cortex had continuous cortical bone but the dorsal cortex was bridged by cancellous bone. C. Both the dorsal and ventral cortices were bridged by cancellous bone.

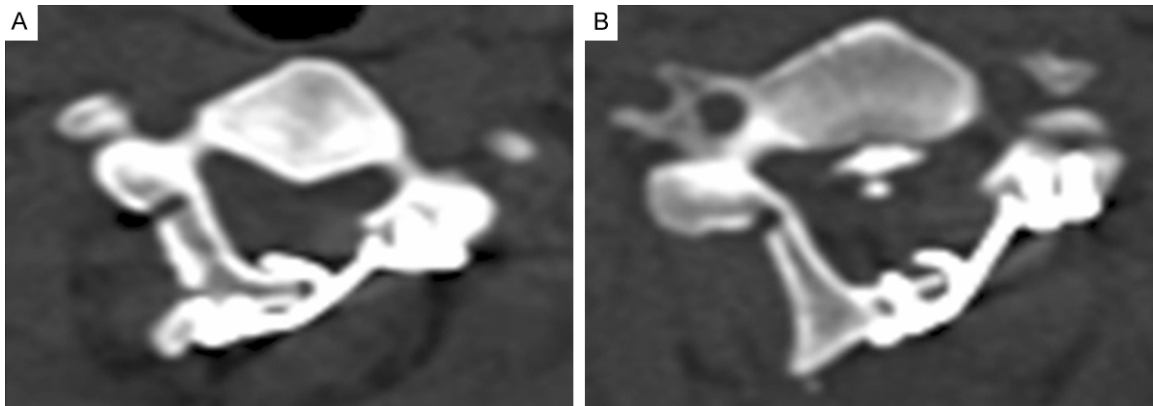


Figure 3. At postoperative 1 week, Axial CT scans exhibited that the ventral cortex displayed a continuous cortical line, while the dorsal cortex was empty.

Operative procedures

The patient was placed in the prone position after general anesthesia was administered; the standard posterior cervical incision was made to expose the C3-C7 lamina, spinous process, and lateral mass according to the narrowed segment (C3-C6 or C7). At the junction of the lateral mass and lamina, we used a spherical burr to completely remove the dorsal cortex of the bone and to thin the ventral cortex, but we left it continuous, which led to the formation of a U-shaped groove at the hinge side; another groove was milled through the whole lamina at the open-door side. We completely and slowly lifted the C3-C7 (or C6) lamina toward the hinge side to expand the narrowed vertebral canal, carefully separated the adhesions between the spinal dura mater and ligamenta flava or lamina, and carefully stopped the bleeding. A total of 26 patients were given support and fixation with the Neulen (Neulen group); in such cases, we placed the Neulen with the proper length into the open-door site, a burr (1.5 mm in diam-

eter) was used to drill into the lateral mass and lamina after the initial stabilization. We then fixed the plate by using 8- and 6-mm-long miniature screws. Sixteen patients received 5 plates each, 7 patients received 4 plates each, and 3 patients received 3 plates each. Each plate required 4 screws. Thirty patients received the traditional wire suspension fixation (suspension group). After the open-door procedure was completed, double 1th (0.400-0.499 mm, USP) wires were used to fix the lamina to the capsule of the facet joint on the hinge side. No bone graft was performed during the surgery, and the routine neurotrophic and dehydration drugs were administered after the surgery. One week after the surgery, the patient could walk with a collar. Professor Nie Lin did perform surgical procedure.

CT analysis

CT examinations of the surgical segments were performed pre- and postoperatively at 1 week, 3 months, and 6 months, and postoperative CT

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Table 3. Healing situations of HSLB in the Neulen group and the suspension group

Groups	Postoperative 3 months				Postoperative 6 months			
	Cases	Bone healing number	Healing rate	P	Cases	Bone healing number	Healing rate	P
Neulen	117	89	76.1%	0.035*	117	106	90.6%	0.152
Suspension	145	81	55.9%		145	128	88.3%	

* $P < 0.05$.

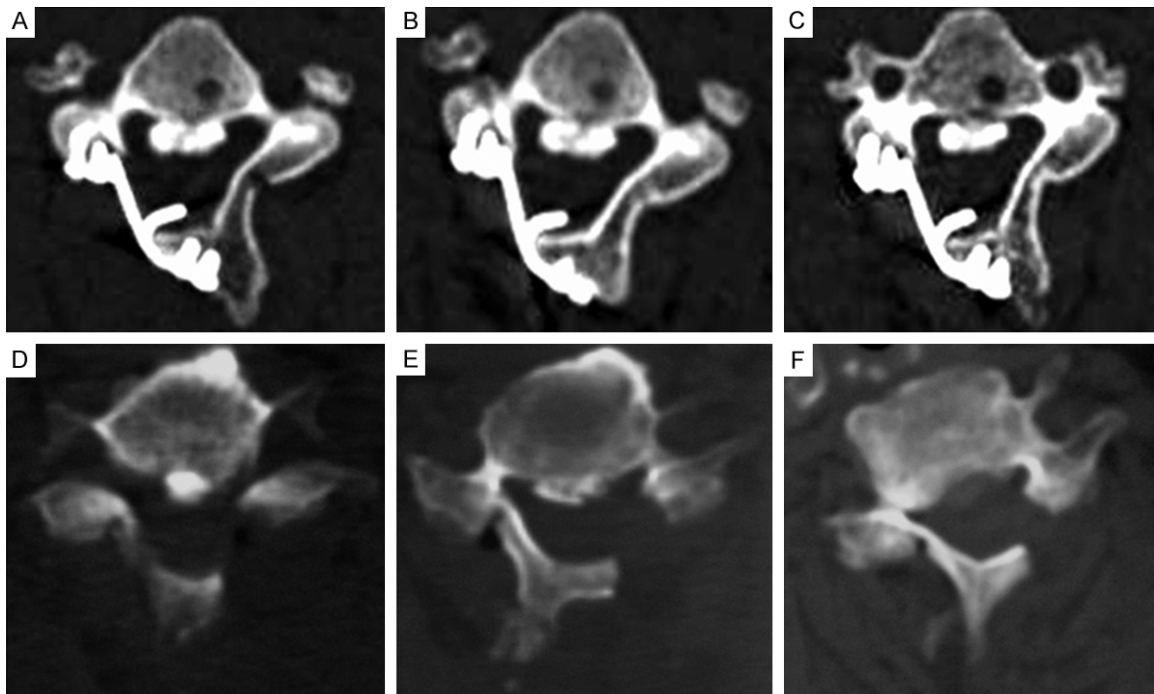


Figure 4. Male patient, 55 years old, CT scans were performed at 1week (A), 3 months (B) and 6 months (C) post-operatively. Axial CT scans at 6 months (C) demonstrated that hinge union and the canals were patent. The length of the screws was suitable. The plates were in position and there was no closure and screw backout. (D-F) were CT scans of 48 year-old male patient received traditional suspension fixation, performed at 1week (D), 3 months (E) and 6 months (F) postoperatively.

data were collected at the same time for analysis. Average sagittal diameter of the spinal canal was recorded. To assess the bone healing (Table S2 and Figure S2), the following judgment criteria of Rhee et al [5] were adopted (Table 2): when healed, the dorsal and ventral cortical parts were connected with the bone (including cortical and cancellous bone) (Figure 2); when unhealed, there was bone connection on the ventral side, but neither a cancellous bone nor a cortical bone connection in the dorsal part.

Statistical analysis

Quantitative data were presented as the mean \pm SD. Statistical analysis of data was performed

by SPSS 17.0 using a Student's t-test for two groups comparisons, or one-way ANOVA with a Dunnett's test in multiple comparisons of means. The P -values of < 0.05 (*) or < 0.01 (**) were considered statistically significant.

Results

Hinge healing versus time

The surgeries were all successful; there were no cases of accidental nail/plate fracture or the occurrence of complications such as nerve or spinal cord injury. The 1-week postoperative CT scan revealed that there was no bone growing on the hinge side. The most ventral parts of the lamina remained connected to the cortical

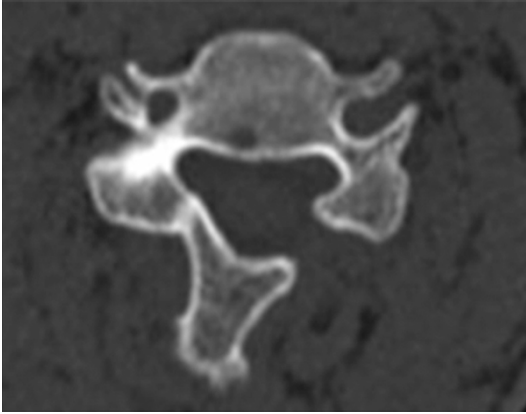


Figure 5. Axial CT scans at 6 months demonstrated that the level with no plates maintained the spinal expanded canal patent.

bone, while there was no cortical bone connection in the dorsal parts, which was the ideal state of the hinge side in laminoplasty. The ventral cortex was continuous (**Figure 3**) with few bilateral cortical fractures, while no collapse toward the inside of the spinal canal was observed. At 3 months postoperatively, a total of 117 segments (89 segmental hinge side bone) healed in the Neulen group (healing rate, 76.1%). In the 145 lamina of the suspension group, 81 segmental hinge side bones healed (healing rate, 55.9%); at 6 months postoperatively, the healing rate of the Neulen group was 90.6%, while that of the suspended group was 88.3% (**Table 3**).

Laminoplasty complications

The postoperative follow-up CT scans revealed no plate shift or closure phenomenon in the Neulen group, although the segments that were not fixed with Neulen, did not show the closure phenomenon either; no cases were noted of screw breaking and compressing the spinal cord (**Figure 4**). In the suspension group, 12 lamina appeared with the closure phenomenon, showing an occurrence rate of 8.3%.

Among the 26 patients of the Neulen group, three segments showed the bilayer cortical fracture in the hinge side, but no drift or obvious instability was found among these 3 lamina segments after Neulen implantation. After the Neulen was fixed, it could effectively maintain the lamina position after the vertebral canal was expanded, and no other supplement-

ary fixation procedure was performed. At 6 months postoperatively, intermittent bone callus growth could be seen on the hinge sides of the fractured segments among all the above 3 cases, but they did not heal. The positions of the Neulen did not change and the screws did not need to be pulled out, indicating that the vertebral canal expansion was effectively maintained. In some cases fixed with 3 (C3, C5, and C7) or 4 Neulen, postoperative 6-month follow-up imaging revealed that the expansion state of the vertebral canal could be maintained without the occurrence of closure phenomenon (**Figure 5**). In the suspension group, 5 cases of double cortical fracture occurred on the hinge side and still had not healed 6 months later, but no cases of collapse toward the spinal canal occurred.

Discussion

The treatment modalities for cervical spinal canal stenosis include conservative and surgical methods. Posterior UODCEL is a safe and effective surgical procedure for the treatment of long segmental cervical spinal canal stenosis, which has a variety of causes. Compared with other posterior surgeries, UODCEL has many advantages including low incidences of postoperative kyphosis and cervical instability, maintenance of cervical vertebral activity, and reduced degeneration of the associated segments [8, 9]. Stability and good bone healing are the important factors contributing to maintenance of the lamina open-door status and prevention of further re-closure. Therefore, bone healing of the hinge side indicates stability and shape formation of the cervical vertebra [4, 10, 11].

After UODCEL, it is difficult to fix the lamina. The re-closure phenomenon occurs easily, so the fixation achieved with UODCEL continuously improves [4]. The traditional suture suspension has complications such as fixation failure, cervical restenosis, and intractable shaft pain, which greatly limits its clinical application [12-14]. Hosono et al [15] implanted coralline hydroxyapatite and ceramic devices beside the side of the open door; however, obtaining immediate postoperative stability was difficult, and the risk of re-closure was high. In this group, the incidence of vertebral rebound was 8.3%, and all cases occurred in the suspension

group, confirming the inferiority of non-rigid fixation.

With prolonged time, the grooves in the hinge side might heal. Bone healing could prevent the lamina rebound or closure, but it requires certain conditions. The appropriate amount of cancellous bone should be reserved in the groove, as thicker lamina can promote bone healing [5]. It should be emphasized that stable internal fixation is the important condition. Matsumoto et al [16] observed patients for 3 months after surgery and found that re-closure was mostly caused by lamina instability and that stronger fixation is critical to preventing the re-closure phenomenon, which occurred in 34% of the patients. Owing to the lack of stable internal fixation, muscle contraction, and neck activities, the opened lamina would be in micromotion status for a long time, which is not conducive to bone healing at the hinge side, thus leading to "closure". The Neulen Ti plate could provide early support to the opened lamina and help to fix it, preventing lamina overactivities after the open-door procedure and resulting in early bone healing. After healing of the hinge side, the expanded spinal canal could obtain stable support, which would prevent closure.

Many kinds of posterior Ti plates are gradually being used. In posterior cervical UODCEL, Rhee et al [5] applied a Centerpiece for the fixation, and he reported that 55% of the segments of hinge side bones healed within 3 months, while 77% of the segments healed 6 months later. To increase the fixation effects and reduce complications, Shaffrey et al [17] and Park et al [18] performed a bone graft on the open-door side, which had the disadvantage that the graft might fall into the spinal canal because of loose fixation or lack of healing, causing severe spinal cord compression. Wiedemayer et al [19] reported the surgical technique of reconstruction of the laminar roof using titanium miniplates with satisfying outcomes. Asgari et al [20] also reported that decompressive laminoplasty in multisegmental cervical spondylotic myelopathy using miniplates offered comparable neurological improvement.

The difference between the Neulen and Centerpiece lay in the fact that the lamina side blocking structure was curved, which can better fit the lamina end with maximum limitation. The blocking structure on the lateral mass side

was also longer, which made it convenient for the implantation. The blocking structure achieves immediate stability and firm support. In this study, the follow-up showed that the 3- and 6-month healing rates of the hinge side bone in the 26 patients who were treated with Neulen were higher than those reported by Rhee (55% and 77%, respectively). However, because the patients and surgical techniques differed, proving whether the difference was statistically significant requires future studies with larger numbers of cases and experiments that are more sophisticated.

During the surgery, the maximum possible part of the ventral cortex in the hinge side should be kept to form a V- or U-shaped groove. It would be difficult to avoid the occurrence of double cortex fracture in some segments, which would cause a floating lamina. The method to stabilize these segments and prevent the occurrence of spinal cord compression requires close attention. In this study, 3 segments of double cortex fracture in the Neulen group had not healed 6 months later, although the Neulen was still able to maintain the spinal canal expansion. Therefore, the support of the Ti plate combined with connection to the ligamenta flava also helped to avoid collapse of the lamina into the spinal canal and subsequent spinal cord compression. Even if the individual segment did not heal for a long period of time, the laminoplasty stability and lamina expansive status would not be affected because of the connection and support provided by the other healed segments.

C5 nerve root injury is a postoperative complication of UODCEL because the opening angle is too large and the spine drifts backward excessively [21]. Uematsu et al [22] emphasized that when the open-door degree was $> 68^\circ$, the incidence of C5 nerve root palsy increased significantly. In this study, the 12- and 14-mm-long Neulen Ti plates can limit the opening angle, thus avoiding C5 nerve root injury caused by the excessive open-door angle. In addition, plate fixation can avoid suture-induced damage to the muscle and small joint capsule as well as maintain the lamina stability. These factors might reduce the occurrence of axial pain.

The potential drawbacks of the Neulen include screw pullout and the plate breakage and displacement. Rhee et al [5] reported that 5 (2.3%)

of 217 segments demonstrated screw pullout after Centerpiece UOD laminoplasty but Ti plate shift, closure, and nerve damage did not occur. The posterior Ti plate would not cross the motion segment and not bear the load as the spinal fusion surgery, which would also help the hinge side healing. Despite the lack of screw fixation, the Neulen could maintain immediate stability by blocking structures on the lamina and lateral mass sides, thus reducing the screw load at a later stage and the probability of screw loosening and pullout. The screw lengths on the lateral mass were 6-12 mm, which was safe and could not only increase the fixation reliability but also prevent the occurrence of spinal cord compression. In this study, 6- and 8-mm screws were used in all 26 patients. Two screws were placed on each side to increase the fixation stability and reduce the load per screw. The spherical burr with a 1-mm diameter was selected to drill the holes and implant the screws, which successfully avoided excessively large nail holes and breakage.

Although healing rates of both the groups 6 months after the surgery were similar, there was a significant difference at 3 months post-operatively. This finding confirmed that the Neulen has a role in promoting bone healing of the hinge side. The postoperative CT film showed that Neulen fixation was safe and reliable.

Conclusions

Unilateral open-door cervical expansion laminoplasty is the most effective surgical treatment for multi-segmental cervical stenosis. Use of the Neulen achieved immediate and early-stage stability and promoted bone healing on the hinge side. Moreover, the installation was easy and safe. Using a spherical burr to mill the groove and drill the screw holes is a good choice. However, only a few cases were followed-up and the duration was short. The determination of whether the Neulen would break, screw pullout would occur, or the fractured lamina of the hinge side could achieve healing over time requires further study.

Acknowledgements

Lin Nie and Yong Hou performed the operations. Lin Nie conceived of the study, and Yong Hou participated in its design, Xin Pan and

Meng Si collected film and data, Jing-Kun Li performed the statistical analysis. Yong Hou and Ti-Xue Wang was involved in drafting the manuscript, Yong Hou revising it critically for important intellectual content. Lin Nie have given final approval of the version to be published. All authors read and approved the final manuscript.

Disclosure of conflict of interest

None.

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Table S1. JOA score in the Neulen group and the suspension group

Groups	JOA score			
	Pre-operation	1 week	3 months	6 months
Neulen	9.76 ± 2.43**	13.24 ± 1.53	14.13 ± 1.95	14.55 ± 2.87
Suspension	9.82 ± 1.97**	13.52 ± 2.48	13.82 ± 2.16	14.32 ± 1.92

**P < 0.01.

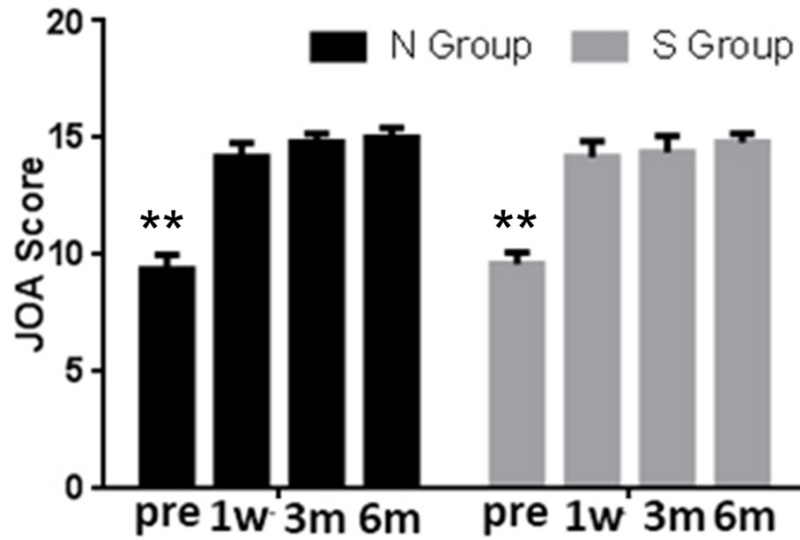


Figure S1. Cervical JOA score demonstrated significant neurological improvement after surgery. **P < 0.01.

Table S2. Sagittal diameters of the spinal canal in the Neulen group and the suspension group

Groups	Sagittal diameters of the spinal canal (mm)			
	Pre-operation	1 week	3 months	6 months
Neulen	13.76 ± 3.86**	18.53 ± 2.89	17.83 ± 2.77	17.35 ± 3.52
Suspension	12.32 ± 2.05**	19.42 ± 4.62	18.37 ± 1.16	18.02 ± 2.28

**P < 0.01.

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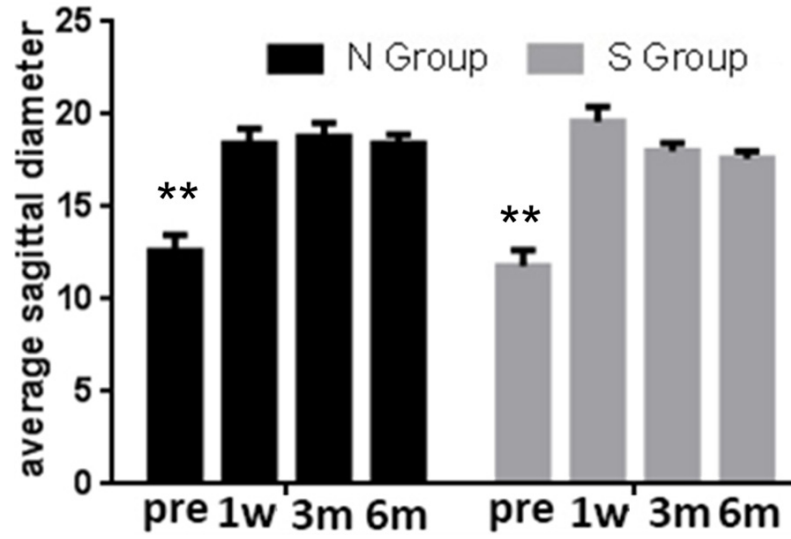


Figure S2. Average sagittal diameter of the spinal canal of N group was recorded pre- and postoperatively, the decompression of the technique appeared persistent. ** $P < 0.01$.