Clinical Trial/Experimental Study

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# Safety and efficacy of cervical laminoplasty using a piezosurgery device compared with a high-speed drill

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**Abstract**

**Background:** Piezosurgery is a relatively new osteotomy technique using microvibrations of scalpels at ultrasonic frequencies to perform safe and effective osteotomies without damage to adjacent soft tissue, which is widely used in spinal, oral, and maxillofacial surgery. We hypothesized that such a device could also be useful in cervical laminoplasty. The purpose of this study was to compare the safety and efficacy of a piezosurgery device with those of a highspeed drill in cervical laminoplasty.

**Methods:** A prospectively randomized clinical study was designed. Forty-two consecutive patients were enrolled in the study. All patients underwent modified expansive open-door laminoplasty and were randomly divided into 2 groups according to the instrument for transection of the lamina, using high-speed drill (drill group) or piezosurgery device (piezosurgery group). The operation time, intraoperative blood loss, and postoperative drainage were recorded. Japanese Orthopedic Association (JOA) score and visual analogue scale (VAS) as clinical assessments were quantified.

**Results:** No significant difference was observed in the operation time between the 2 groups. In the piezosurgery group, there were less loss of the intraoperative blood and postoperative drainage compared with the drill group. However, clinical results (VAS and JOA scores) showed no significant difference between both groups during the all follow-up periods.

**Conclusion:** The piezosurgery is a useful instrument and at least as safe and efficacious as the conventional high-speed drill in cervical laminoplasty.

**Abbreviations:** CSM = cervical spondylotic myelopathy, JOA = Japanese Orthopedic Association, ODL = open-door laminoplasty, OPLL = ossification of the posterior longitudinal ligament, VAS = visual analogue scale.

**Keywords:** cervical laminoplasty, high-speed drill, piezosurgery, safety and efficacy, spinal decompression

## 1. Introduction

Cervical multilevel myelopathy is mainly caused by multisegment cervical spondylotic myelopathy (CSM), congenital cervical canal stenosis, or ossification of the posterior longitudinal ligament (OPLL).[1–5] Surgical treatment is indicated in severe and progressive cases or when nonoperation is ineffective. During the past decades, the expansive open-door laminoplasty (ODL) is considered an effective and safe method for decompressing multisegmental cervical lesions, and has been widely accepted in clinical practice.[6–10]

At present, in order to further improve the safety and effectiveness of decompression and stability of the spine, a variety of modifications and supplementary procedure were introduced, such as plate fixation, spacers, and plate fixation combined with bone struts and ceramic spacers. These were used in the laminoplasty to construct a complete laminar arch and avoid the secondary narrowing of the spinal canal and neurological deterioration over the long-term follow-up.[11–14]

Conventional cervical laminoplasty, however, had a high technical demand on using high-speed drills, which may cause spinal cord and nerve injury with inappropriate handling.[15,16] Piezosurgery is a relatively new osteotomy technique using microvibrations of scalpels at ultrasonic frequencies to perform safe and effective osteotomies. It can ensure a greater precision in cutting and increase safety, thanks to its characteristic of selective bone-cutting properties with preservation of adjacent soft-tissue structures.[17–19] Moreover, unlike other conventional drill, it does not produce high temperature during its use, which could result in a higher incidence of marginal osteonecrosis.[20] So far, piezoelectric bone surgery had been described in patients undergoing spinal, oral, and maxillofacial surgery, with good success.[21–24]

The aim of this study was to compare the safety and efficacy of piezosurgery devices with those of a conventional high-speed drill for the transection of the lateral laminae.

## 2. Material and method

### 2.1. Patient population

This prospective randomized controlled study was conducted between June 2012 and December 2014 in the Department of Spinal Surgery, Liaocheng People's Hospital, Shandong province, China. In this study, we enrolled 42 patients, who met the following inclusion criteria: age 18 to 75 years, primary diagnosis

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**Figure 1.** A cervical magnetic resonance imaging (MRI) of an illustrative case. Preoperative T2 sagittal MRI cervical spine demonstrating multilevel spondylosis with myelomalacia and compression both dorsally and ventrally.

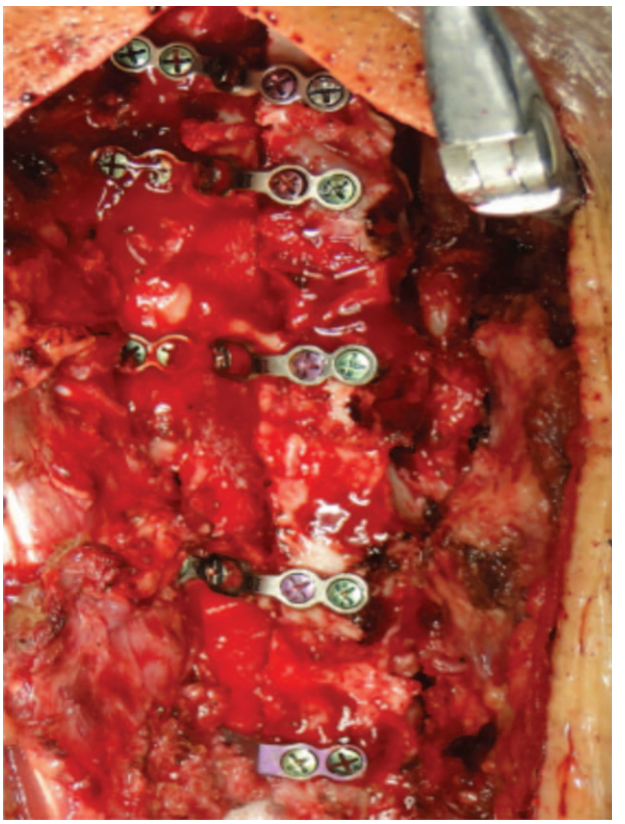

**Figure 2.** Intraoperative picture demonstrating laminae held open by specially designed plates during the open door laminoplasty technique.

of CSM, OPLL, and developmental canal stenosis, involving 3 or more levels, no cervical fracture and dislocations (Fig. 1). The exclusion criteria were as follow: dysfunction of coagulation, existence of segmental instability, local kyphosis, or major anterior pathology, a history of cervical spinal surgery, presence of myelopathy caused by spinal cord injuries, tumors, or infections.

The study was approved by the Ethics Committee of Liaocheng People's Hospital and all patients provided written informed consent. Patients were randomly divided into 2 groups on the basis of the admission date to undergo expansive ODL, either by piezosurgery devices (piezosurgery group) or by high speed drills (drill group) during the transection of the lateral lamina.

### 2.2. Surgical procedures

The surgery was performed as described by Chen et al[11] and Jiang et al.[25]

All procedures were carried out under controlled general anesthesia with endotracheal intubation. Following induction of general anesthesia, each patient was positioned prone in slightly flexion of neck in a Mayfield head fixator. The standard posterior midline approach was used to expose the lamina, spinous processes, and the medial facet joints from C3 to C7. The supraspinous and interspinous ligaments were cut between C2 and C3 and between C7 and T1. The spinous processes were then amputated. The opening side was made on the side with more symptoms by completely cutting the lamina off along the medial margin of the facet joints and only the dorsal cortex and the cancellous bone were removed on the hinge side. Trough preparation in the hinged and opening sides was performed respectively with high-speed drill (drill group) or piezosurgery device (piezosurgery group). A V-shaped bone trough was created at the junction of the lamina and the lateral mass. The lamina was opened carefully and the ligamentum flavum between the opening laminae and dura was removed. After elevating the open side of the lamina approximately 1 cm en bloc, prebent titanium plates were placed on each segment. Two screws in the lateral mass and 2 in the lamina were used to fix the plate tightly. Screws that were 8 or 6 mm in length were used for most patients (Fig. 2). A drainage tube was left in the wound.

### 2.3. Postoperative managements

Patients were routinely administered prophylactic antibiotics for 24 hours and encouraged to start out-of-bed activities with braces within 1 week postoperatively. The drainage rubber was pulled out from the wound at the 2nd day postoperatively. However, the postoperative protocol included immobilization in a hard collar for a minimum of 6 weeks. All patients received mechanical thomboprophylaxis. Following discharge from the hospital, all patients were clinically and radiologically assessed in the orthopedic outpatient clinic every 3 months (Figs. 3, 4).

### 2.4. Observation index

The operation time, intraoperative blood loss, and postoperative drainage were recorded. The postoperative drainage would be excluded when the celebrospinal fluid leakage or dural tear occurred. Functional outcome was assessed by Japanese

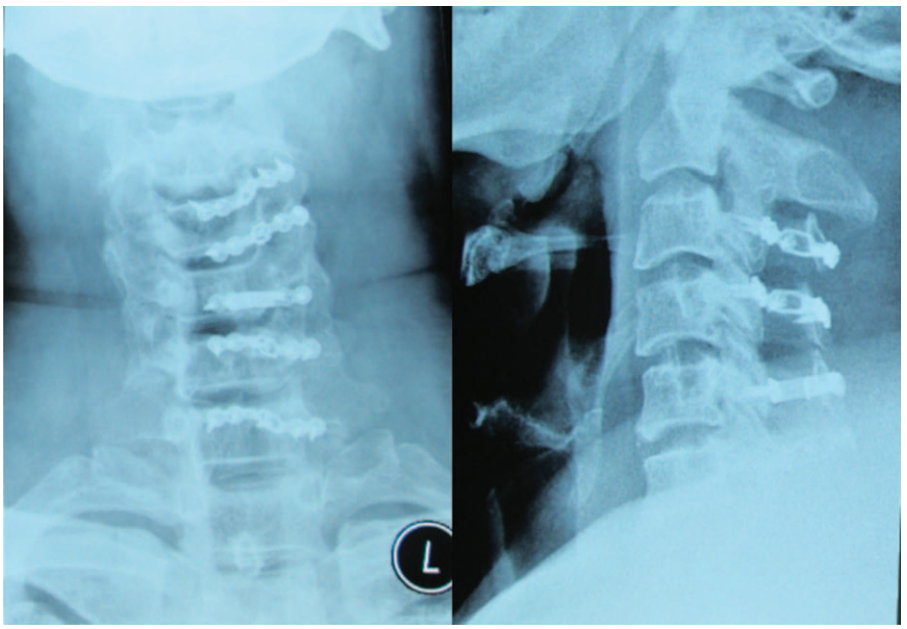

**Figure 3.** Postoperative anterior–posterior and lateral cervical spine radiograph following open door laminoplasty.

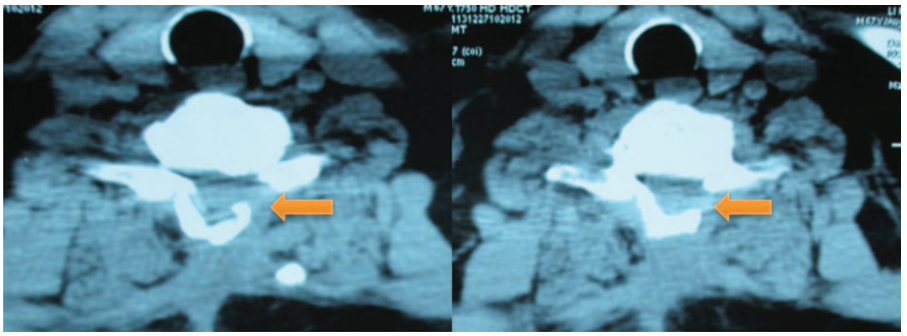

**Figure 4.** Postoperative axial computed tomography (CT) scan following open door laminoplasty; where the arrow () marks are the opening side, and the other is the hinged side.

Orthopedic Association (JOA) score. Neck pain was quantified using a visual analog scale (VAS). We collected the functional scores preoperatively and 1 week and 1 year postoperatively. We used computed tomography scans and MRI postoperatively to assess the bony fusion status and evaluate the status of decompression. All the data were reviewed by an independent observer with no involvement in their treatment.

### 2.5. Statistical analyses

Statistical analyses were performed using the SPSS statistical package, Windows V17.0 (SPSS, Chicago, IL). The 2-sample *t* test, Chi-square test, and ANOVA analysis were used for data analyses. Data were presented as the mean ± standard deviation. For all analyses, a $P$ value $<0.05$ was considered statistically significant.

## 3. Results

The study consisted of 42 consecutive patients, 31 male and 11 female, with a mean age of 56.5 years (range 37–72 years). After randomization, the piezosurgery group and drill group included 21 patients, respectively.

Baseline demographics and diagnosis in both groups are shown in Table 1. No significant differences were observed between the 2 groups.

### 3.1. Operation index

The mean operation time was 138.2 ± 26.6 and 125.8 ± 23.5 minutes in the piezosurgery and drill groups, respectively. No

**Table 1**

**Baseline demographics of the patient cohort.**

| Parameter | Piezosurgery group | Drill group |
|---|---|---|
| Number of patients | 21 | 21 |
| Age, years | 55.5 ± 9.7 (41–72) | 57.6 ± 11.0 (37–72) |
| Gender, males/females | 15/6 | 16/5 |
| Diagnosis | | |
| CSM | 10 | 10 |
| OPLL | 7 | 6 |
| CSS | 4 | 5 |

CCS = cervical canal stenosis, CSM = cervical spondylotic myelopathy, OPLL = ossification of the posterior longitudinal ligament.

**Table 2**

**The differences of operation time, intraoperative blood, and postoperative drainage loss.**

| Parameter | Piezosurgery group | Drill group | *P* |
|---|---|---|---|
| Operation time, minute | 138.2±26.6 | 125.8±23.5 | 0.117 |
| Intraoperative blood losses, mL | 272.9±87.2 | 357.4±129.9 | 0.018 |
| Postoperative drainage loss, mL | 127.9±28.6 | 153.2±29.5 | 0.011 |

significant difference of the operation time was observed between the 2 groups while that of piezosurgery group is longer ($P > 0.05$).

Intraoperative blood losses in the piezosurgery and drill groups were 272.9±87.2 and 357.4±129.9 mL, respectively. There was significant difference between 2 groups ($P < 0.05$) (Table 2), which indicated a lower blood loss with the use of piezosurgery.

When we recorded the postoperative drainage, 4 patients were excluded due to the dural tear, 2 in the drill group, and 2 in the piezosurgery group, respectively. The amount of postoperative drainage was 127.9±28.6 and 153.2±29.5 mL in the piezosurgery and drill groups, respectively. Statistical difference in the postoperative drainage was found between the 2 groups ($P < 0.05$).

### 3.2. Clinical outcomes

Preoperatively, average JOA scores were 8.9±1.7 and 8.5±2.1 points in the piezosurgery and drill groups, respectively, and these were significantly increased in 2 groups after surgery ($P < 0.05$). However, no statistical difference was observed in the JOA score at the follow-up periods between 2 groups ($P > 0.05$) (Table 3).

At 1 week and 1 year postoperatively, VAS scores in the 2 groups were obviously decreased compared to preoperation ($P < 0.05$). However, there was no significant difference between the piezosurgery and drill groups ($P > 0.05$), which revealed the similar change with JOA scores (Table 4).

### 3.3. Related complication

Each group experienced complications. However, the overall rates of complications were comparable (Table 5).

The overall rate of C5 paralysis was 7.1% (3 of 42 patients). C5 paralysis developed in 2 of 21 patients (9.5%) in the piezosurgery group compared with 1 of 21 (4.8%) in the drill group. There was no statistical difference in the incidence of C5 palsy between 2 groups ($P > 0.05$). All patients were completely recovered at 3 months postoperatively.

Two dural tears occurred respectively in the drill and piezosurgery group, and no significant difference was showed between 2 groups ($P > 0.05$).

No neurological deterioration, postoperative infection, and hardware failure occurred in 2 groups during the follow-up period. There was no clinical deterioration, permanent morbidity, or mortality in this study. We did not observe any spinal canal restenosis or secondary closure of the opened doors. Computed tomography scans revealed osseous fusion on the hinge side in all patients more than 6 months.

**Table 3**

**The change of visual analogue scale (VAS) in the pre- and postoperative period.**

| Group | Preop | 1 week postop | 1 year postop |
|---|---|---|---|
| Piezosurgery | 6.2±1.4 | 3.0±1.1 | 2.2±0.8 |
| Drill | 6.4±1.3 | 3.1±1.2 | 2.2±0.8 |
| *P* | 0.569 | 0.694 | 0.852 |

**Table 4**

**The change of Japanese Orthopedic Association (JOA) in the pre- and postoperative period.**

| Group | Preop | 1 week postop | 1 year postop |
|---|---|---|---|
| Piezosurgery | 8.9±1.7 | 11.1±1.7 | 13.3±1.4 |
| Drill | 8.5±2.1 | 11.3±1.9 | 13.7±1.7 |
| *P* | 0.569 | 0.737 | 0.493 |

**Table 5**

**The rate of complications in 2 groups.**

| Group | C5 paralysis | Dura tear |
|---|---|---|
| Piezosurgery | 2/21 | 2/21 |
| Drill | 1/21 | 2/21 |
| *P* | >0.99 | >0.99 |

## 4. Discussion

Since the introduction of the laminoplasty by Hirabayashi et al[26] in 1976, cervical expansive ODL has become a popular treatment for patients with multilevel cervical compression myelopathy resulting from CSM and OPLL. As surgical techniques are continuously being improved and surgical devices become increasingly fine, the rate of good surgical efficacies continues to improve while surgical time, blood loss, and relevant complications decrease.[25,27,28]

In our study, all the patients underwent modified expansive ODL using 5 titanium miniplates and showed clear improvement after operation. The average JOA score was from 8.7±1.7 to 11.2±1.8, and VAS from 6.3±1.3 to 3.0±1.2, respectively, and there were significant differences observed after surgery.

In the current study, we recorded the operation time, intraoperative blood loss, and postoperative drainage of all patients and compared those of piezosurgery group with drill group. The intraoperative blood loss and postoperative drainage in the piezosurgery group were 272.9±87.2 and 127.9±28.6 mL, respectively, which were significantly lower than those of drill group (357.4±129.9 and 153.2±29.5 mL, respectively). The results indicated that using the piezosurgery could reduce the intraoperative and postoperative blood losses of cervical expansive ODL, which was due to the advantage of piezosurgery that avoids soft tissues injury and the air–water cavitation effect that assists in closing the smallest blood vessels and rinses away any blood from the larger vessels.[29]

Several previous studies on the oral and maxillofacial surgery had shown that the micrometric cutting action of piezosurgery required a longer surgical time compared with rotatory instruments use.[30–32] Our result also showed that the operation time of the piezosurgery group was a little longer than that of the drill group (138.2±26.6 vs 125.8±23.5 minutes); however, there was no statistical difference between 2 groups, which indicated that the use of piezosurgery would not significantly prolong the surgery and increase the risk of operation.

In this series, we also compared the clinical outcome and complications of 2 methods. The JOA scores in both groups were

from 8.9±1.7 and 8.5±2.1 to 11.1±1.7 and 11.3±1.9, respectively, and both of them significantly increased after surgery. The VAS score was also improved postoperatively. However, there were no statistical differences of them observed between 2 groups. The results indicated that the instrument for the lamniplasty would not affect the clinical outcome because the effect was determined by the decompression of spinal cord, not by the instruments for the transection of lamina.

The rate of complications was compared in both groups. The rate of C5 paralysis was comparable in 2 groups (2/21 in the piezosurgery group vs 1/21 in the drill group), which was similar to the previous reports, and no difference was observed. Narrower preoperative foramina and nerve root traction caused by excessive spinal cord drift after laminoplasty were the pathologic mechanisms of C5 palsy,[33,34] which could explain why no difference was found in the rate of C5 paralysis between both groups.

When it came to the dura tear, we would expect to fewer patients of dura tear and cerebrospinal fluid leak in the piezosurgery group; however, the rates of the dura tear in 2 groups (9.5% vs 9.5%) were comparable. We analyzed the main reasons were that the cervical canal was large enough to avoid the dural tear with conventional instrument, and the familiarity of the piezosurgery was inferior to that of high-speed drill.

High-speed drill is potentially injurious because of the production of excessively high temperatures during osseous drilling. Such temperatures can engender marginal osteonecrosis which ultimately impairs bone regeneration.[35–37] The result of this study showed that osseous fusion of the laminar arch was observed in every patient in the radiological follow-up of more than 6 months. However, we had not focused on the difference of osseous fusion rate and time of the laminar arch during the follow-up periods in both groups, which was 1 limitation of the current study.

Another shortcoming of this study includes the small patient population. Future studies, enrolling more patients and with more parameters such as fusion rate and time during the follow-up period, will be necessary to evaluate the safety and efficacy of piezosurgery devices with conventional high-speed drill.

In conclusion, the piezosurgery is a useful instrument and at least as safe and efficacious as the conventional high-speed drill, although our clinical valuation of the effectiveness of this technique was based on intraoperative and postoperative parameters. Thus, we recommend this device for application in various spinal surgery fields as a good substitute to high-speed drills or other instruments.

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